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ASSURING THE QUALITY OF HEALTH CARE IN THE EUROPEAN UNION

A case for action

Helena Legido-Quigley
Martin McKee
Ellen Nolte
Irene A Glinos

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Assuring the quality of health care in the European Union

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List of abbreviations

AEZQ	Agency for Quality in Medicine (Germany)
AFSSAPS	Agency for the Safety of Health Products (France)
AIDS	Acquired immunodeficiency syndrome
ANAES	Agency for Accreditation and Evaluation of Health Care (France)
ANDEM	National Agency for the Development of Medical Evaluation (France)
BÄK	Federal Chamber of Physicians (Germany)
BIG	Individual Health Care Professions Act (the Netherlands)
BMA	British Medical Association
BMGFJ	Federal Ministry for Health and Women's Affairs (Austria)
BQS	Federal Office for Quality Assurance (Germany)
CAF	Common Assessment Framework (Finland)
CBO	Dutch Institute for Healthcare Improvement
CEPS	Economic Committee for Medical Products (France)
CIS	State Claims Agency (Republic of Ireland)
CME	Continuing medical education
CMT	Centre for Medical Technology Assessment (Linköping University, Sweden)
COLD	Chronic obstructive lung disease
CoPh	National College of Physicians (Romania)
CQI	Continuous quality improvement
CT	Computed tomography
CYS	Cyprus Organization for the Promotion of Quality
DACEHTA	Danish Centre for Health Technology Assessment
DGEC-SECM	Department for Medical Evaluation and Control (Belgium)
DHIF	District Health Insurance Fund (Romania)
DIHTA	Danish Institute for Health Technology Assessment
DIMDI	German Institute for Medical Documentation and Information
EA	European Co-operation for Accreditation
EC	European Commission

EFQM	European Foundation for Quality Management
EGQM	European Good Quality Management model
EHIC	European Health Insurance Card
EHIF	Estonian Health Insurance Fund
EIQA	Excellence Ireland Quality Authority
ELOT	Greek Standards Organization
EMEA	European Medicines Agency
EPA-PM	European Practice Assessment Practice Management framework
ESQH	European Society for Quality in Healthcare
EU	European Union
FAGG-AFMP	Federal Pharmaceuticals and Health Products Agency (Belgium)
FPS	Federal Public Service (Public Health, Food Chain Safety and Environment) (Belgium)
G-BA	Federal Joint Committee (Germany)
GMC	General Medical Council (England (United Kingdom))
GP	General practitioner
HAS	National Authority for Health (France)
HIQA	Health Information and Quality Authority (Republic of Ireland)
HKZ	Foundation for Harmonisation of Quality Review in Health Care and Welfare (Netherlands)
HOPE	Standing Committee of the Hospitals of the European Union
HSE	Health Service Executive (Republic of Ireland)
HTA	Health technology assessment
ICH	Irish Clearing House
IGZ	Health Care Inspectorate (Netherlands)
IHSAB	Irish Health Services Accreditation Board
IKAS	Institute for Quality and Accreditation in Health Care (Denmark)
ILAC	International Laboratory Accreditation Cooperation
IMC	Irish Medical Council
INFARMED	National Institute of Pharmaceuticals and Medicines (Portugal)
INSALUD	National Institute of Health (Spain)
IOM	Institute of Medicine (of the National Academies) (United States)
IQWiG	Institute for Quality and Efficiency (Germany)
ISO	International Organization for Standardization
ISQSH	Irish Society for Quality and Safety in Healthcare
ISQua	International Society for Quality in Health Care (Inc.) (Australia)
IT	Information technology
JCAHO	Joint Commission on Accreditation of Healthcare Organizations (United States)
KAKuG	Law on Health Care Institutions (Austria)
KBV	National Association of Statutory Health Insurance Physicians (Germany)
KCE	Health Care Knowledge Centre (Belgium)
KESY	Central Health Council (Greece)

KFOA	King's Fund Organizational Audit (United Kingdom)
KTQ	Cooperation for Transparency and Quality in Health Care (Germany)
KZI	Care Institutions Quality Act (Netherlands)
LOK-GLEM(s)	Local Medical Evaluation Groups (Belgium)
LQS	Regional Offices for Quality Assurance (Germany)
MHRA	Medicines and Healthcare Products Regulatory Agency (England (United Kingdom))
MRI	Magnetic resonance imaging
MRSA	Methicillin-resistant staphylococcus aureus
NAM	National Agency for Pharmaceutical Medicines (Finland)
NBHW	National Board of Health and Welfare (Sweden)
NCAS	National Clinical Assessment Service (England (United Kingdom))
NCCHTA	National Coordinating Centre for Health Technology Assessment (England (United Kingdom))
NCQA	National Centre for Quality Assessment in Health Care (Poland)
NHIF	National Health Insurance Fund (Bulgaria, Romania)
NHS	National Health Service (Greece, Norway, Portugal, Spain, England (United Kingdom))
NIA	National Insurance Administration (Norway)
NIAZ	Netherlands Institute for Accreditation of Hospitals
NICE	National Institute for Health and Clinical Excellence (England and Wales Department of Health)
NIP	National Indicator Project (Denmark)
NIVEL	Netherlands Institute for Health Services Research
NPSA	National Patient Safety Agency (England (United Kingdom))
NRES	National Research Ethics Service (England (United Kingdom))
NSAI	National Standards Authority of Ireland
NTPF	National Treatment Purchase Fund (Ireland)
NVZ	Dutch Hospital Association
NZa	Dutch Healthcare Authority
OECD	Organisation for Economic Co-operation and Development
RIZIV-INAMI	National Institute for Sickness and Disability Insurance (Belgium)
SACHI	State Agency for Compulsory Health Insurance (Latvia)
SALAR	Swedish Association of Local Authorities and Regions
SBU	Swedish Council on Technology Assessment in Health Care
SEMC	Standards of Efficient Medical Care (Czech Republic)
SGB	Social Code Book (Germany)
SGL	State General Laboratory (Cyprus)
SIQUAS VRQ	Italian Society for Quality Health Care
SMC	Supreme Medical Council (Bulgaria)
SPRI	Swedish Institute for Health Services Development
STAKES	National Research and Development Centre for Welfare and Health (Finland)
TEO	National Authority for Medico-Legal Affairs (Finland)

TQM	Total quality management
URML	Regional Medical Unions (France)
VAT	Value-added tax
WGBO	Medical Treatment Contracts Act (the Netherlands)
WHO	World Health Organization
WKCZ	Clients' Right of Complaint Act (the Netherlands)
WMCZ	Participation by Clients of Care Institutions Act (the Netherlands)
WTZi	Admission of Care Institutions Act (the Netherlands)
ZOM	*Zorg op Maat* project: experimental cross-border health care project in the Meuse-Rhine border region (Netherlands)

About the authors

Ms. Helena Legido-Quigley, Research Fellow in Public Health, London School of Hygiene & Tropical Medicine, London

Professor Martin McKee, Professor of European Public Health, London School of Hygiene & Tropical Medicine, and Research Director, European Observatory on Health Systems and Policies, London

Dr Ellen Nolte, Senior Lecturer in Public Health, London School of Hygiene & Tropical Medicine, and Senior Research Fellow, European Observatory on Health Systems and Policies, London

Ms. Irene A Glinos, Researcher, Observatoire Social Européen, Brussels, and University of Maastricht, Maastricht

Foreword I: The European experience

Kevin McCarthy
Public Health Research, European Commission

It gives me great pleasure to introduce and recommend this publication on *Assuring the quality of health care in the European Union*. It comes at an important time in the policy debate on health care and the role of the European Union (EU). Health systems and health policies across the EU are becoming more interconnected than ever. This is a result of many factors, including movement of patients and professionals (facilitated by rulings of the European Court of Justice), common public expectations across Europe, dissemination of new medical technologies and techniques through information technology (IT), and the enlargement of the EU. This increased interconnection raises many health policy issues, not least that of quality and access to health care and it is clear that the ability of European citizens to obtain health care of high quality throughout the EU is emerging as an important policy issue. The European Commission (EC) Directorate-General for Research is committed to research that informs policy and this published work is a clear example of how such research can feed into the policy process, such as the EC's deliberations on a Community framework for the application of patients' rights in cross-border health care. At the same time it is evident that the richness of European research is clearly illustrated by the array of contributors involved, and I would like to congratulate the authors on this achievement.

This publication grew out of the research carried out within the *Europe for Patients* project (2004–2007), one of the first to be supported under the Scientific Support to Policies Activity of the EU 6th Framework Programme for Research (FP6). *Europe for Patients* was an initiative to provide scientific underpinning and the evidence base needed by EU policy-makers to take concerted and coordinated action to allow Europe's citizens (or patients) to benefit from enhanced mobility in Europe.

The Scientific Support to Policies Activity under FP6 targeted research to serve the formulation and implementation of EU policies. The objective was to help to create over time a more efficient environment for policy research in the EU, providing policy actors throughout the EU with a facility to access relevant Community research, reinforcing the link between research and policy, making it stronger, more responsive and more coherent than before.

This approach has now become mainstream in the "Health Theme" under the EU 7th Framework Programme for Research (FP7, 2007–2013). The intention is that European public health research will aim to provide the necessary basis both for informed policy decisions on health systems and for more effective strategies of health promotion, disease prevention, diagnosis and therapy. These activities are part of the 3rd pillar of the Health Theme under the Specific Programme "Co-operation" of FP7 that is entitled "Optimizing the delivery of health care to European citizens". Loosely referred to as "public health research", this pillar will contribute to the policy debate at European level by seeking to provide the framework to develop new research methods and generate the necessary scientific basis to underpin informed policy decisions by Member States on health systems and on more effective and efficient evidence-based strategies of health promotion and disease prevention.

I believe this book will provide policy stakeholders throughout the EU with better insight and evidence for enhancing policy decisions – ultimately for the benefit of all European citizens. It should also demonstrate that first-class research leads to high-quality policies. EU research funding is ideally placed to serve the needs of policy-makers in this domain and I look forward to further results and policy contributions from such projects under the new direction provided for in FP7.

Foreword II: The United States' experience

Karen Davis
Commonwealth Fund, New York

Geographic variation in quality of health care: the United States' experience

In the last few years, increasing awareness of variations in the quality of health care across geographic areas has helped propel a quality improvement movement. This important book documents concerns with variations across European nations, analyses quality measurement, assurance, and improvement efforts in various European countries, and sets forth an agenda for ensuring that everyone has access to high-quality care regardless of where they live or travel.

Similar enquiries are ongoing in the United States. Four recent reports document extensive variation in quality and costs across states within the United States. State-by-state reports on quality by the Agency for Healthcare Research and Quality (AHRQ), along with the state scorecard on health system performance by the Commonwealth Fund Commission on a High Performance Health System, constitute a rich database to inform state and national health policy and stimulate further research and analysis of the determinants of, and interrelationships among, quality, health outcomes, access, cost, and equity dimensions of performance (AHRQ 2006; Cantor et al. 2007). A United Health state report card focusing on health outcomes and public health adds to this rich database (United Health Foundation 2007) and more recently, Martin and colleagues have documented broad variations in health expenditure across states (Martin et al. 2007).

Several conclusions from these recent studies stand out.

- Health care access, quality, costs and efficiency vary widely across the United States. The range of performance is often two- to threefold or greater on various key indicators.

- Leading states consistently out perform lagging states on multiple indicators and dimensions. The patterns indicate that federal and state policies and local and regional health systems make a difference.
- Across states, better access is closely associated with better quality. States with the highest rates of uninsured residents tend to score highest on measures of preventive and chronic disease care, as well as other quality indicators.
- There are significant opportunities to reduce costs as well as to improve access to and quality of care. Higher quality is not associated with greater spending across states (Davis and Schoen 2007).
- All states have significant room to improve. States can learn from best practices and policies that contribute to benchmark levels of health system performance.

In the United States, as in Europe, benchmarks set by leading geographic regions show there are broad opportunities to improve and achieve better and more affordable health care. With health costs rising faster than incomes and straining family, business, state and federal budgets, and with startling evidence of variable quality and inefficient care, all states and nations have much to gain from aiming higher.

Comparable databases on which to assess international variations in quality need considerable further development but important work is shedding insight into variations across countries. For 10 years, Commonwealth Fund international health policy surveys of the public, sicker adults and health care professionals have compared select aspects of health system performance in five to seven countries (Davis et al. 2007). Again, significant variations exist, although some systematic patterns persist. The United States, with its market-based health system and limited role for regulation of the health system systematically scores lowest among the countries compared, most recently including Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom, as well as the United States (Schoen et al. 2007).

An Organisation for Economic Co-operation and Development (OECD) international working group on health care quality is developing and expanding a database on comparable clinical quality indicators (Hussey et al. 2004). Important work by Nolte and McKee is expanding our understanding of variations in mortality amenable to medical care (Nolte and McKee 2003; Nolte and McKee 2008). All of these resources are an important foundation from which to promote greater understanding of promising strategies for meeting and raising benchmark standards of care.

In the United States, the quality improvement movement is being advanced by a growing acceptance of the need for transparency regarding quality and cost performance by health care providers, and the importance of accountability for results and proper stewardship of resources at national, regional, and local levels.

The quality improvement agenda starts with better data on benchmark levels of performance on key indicators, for example the level achieved by the top decile of hospitals, physicians, health care organizations or geographic areas. Knowing how one stands, who the top performers are and the best practices leading to peak performance are key to improvement. This requires greater openness, collaboration and resources devoted to improvement. The United States is watching the nations that have established organizations devoted to developing, synthesizing and disseminating comparative effectiveness information on prescription drugs, devices and procedures.

Activated, informed patients are also key to quality improvement, which can be facilitated with a philosophy of shared decision-making and access to information and tools to assist patients in this role. Similarly, an engaged and motivated professional commitment to high standards of quality and continuous quality improvement – through the actions of physicians and other health professionals and their professional societies – is crucial to success.

But all sectors of society will need to make quality improvement a priority to narrow variations and improve overall levels of performance. The United States lags markedly behind other countries because it has not committed sufficient resources to health information technology (Schoen et al. 2006). Other strategies that need to be part of a multifaceted approach to quality improvement include better technical assistance, changes in the organization and delivery of care, and at least in the United States context, financial incentives that reward better results. For other countries, a greater array of regulatory and other governmental strategies may also be effective.

Achieving a shared goal of a high-performance health system requires, most of all, a commitment to learning both from variations within countries and across nations. This book is an important starting point in identifying the array of strategies to measure, assure and improve quality across European countries. It needs to be followed by systematic mining of data on variations in performance, and research to better understand the multiple determinants of health outcomes, quality, access, equity and cost.

Contributors

Austria

Ms. Ursula Fronaschuetz, Department of Quality Management and Health Economics, Austrian Federal Ministry of Health and Women, the Ministry of Health, Austria

Dr Guido Offermanns, Assistant Professor at the University of Klagenfurt/ Austria, Faculty of Management and Economics, Department of Public, Non-Profit and Health Management, Austria

Dr Esther Thaler, Managing Director, ÖQMed – Austrian Society of Medical Quality Assurance and Quality Management LLC, Vienna, Austria

Belgium

Ms. Rita Baeten, Policy Analyst, European Social Observatory, Brussels, Belgium

Ms. Leen Meulenbergs, Advisor to the Minister of Health, Belgium

Mr Pascal Meeus, Ministry of Health, Belgium

Bulgaria

Dr Lidia Georgieva, Associate Professor, Senior Advisor Head of Health Risk Management, Marsh EOOD, Sofia, Bulgaria

Ms. Svetla Tsolova, Associate Research Fellow, Index Foundation, Sofia, Bulgaria

Cyprus

Dr Annita Anastassiadou, Coordinator, European Integration Sector, Ministry of Health Cyprus, Cyprus

Dr Mamas Theodorou, Associate Professor of Health Policy, Cyprus Open University, Cyprus

Czech Republic

Dr Aleš Bourek, Head of University Center for Healthcare Quality, Masaryk University Medical Faculty, Czech Republic

Ms. Lenka Grohova, International Department, Czech Medical Chamber, Czech Republic

Ms. Milena Kalvachova, Ministry of Health, Department of Health Care, Czech Republic

Denmark

Dr Jan Mainz, Professor, University of Southern Denmark, Hojbjerg, Demark

Dr Thomas Schiøler, Chief Project Officer, the Danish Healthcare Quality Assessment Programme, National Board of Health, Denmark

Ms. Gunilla Svensmark, Consultant, Danish Nurses' Organization, Denmark

Estonia

Mr Ain Aaviksoo, CEO, Director of Health Policy Program, PRAXIS Center for Policy Studies, Tallinn, Estonia

Dr Maris Jesse, Health Policy Analyst, PRAXIS Center for Policy Studies, Tallinn, Estonia

Finland

Dr Risto Pomoell, Ministerial Counsellor, Ministry of Social Affairs and Health, Finland

Dr Juha Teperi, National Research and Development Centre for Welfare and Health, Finland

France

Dr Charles Bruneau, Scientific Advisor, French National Authority for Health, La Plaine Saint-Denis, France

Mr Christophe Debout, President of the French Nurses Association ANFIIDE, France

Mr Pascal Garel, Chief Executive, HOPE, Brussels, Belgium

Germany

Professor Reinhard Busse, Professor and Director, Department of Health Care Management, Berlin University of Technology, and Associate Head of Research Policy, European Observatory on Health Systems and Policies, Berlin, Germany

Professor Dr Günter Ollenschläger, Director, Agency for Quality in Medicine, Berlin, Germany

Professor Doris Schiemann, Fachhochschule Osnabrück (University of Applied Sciences), Faculty of Business Management and Social Sciences, Osnabrück, Germany

Dr Susanne Weinbrenner, Research Officer, Department of Health Care Management, Berlin University of Technology, Berlin, Germany

Greece

Mr Nykos Polyzos, Associate Professor, Financial Management of Health and Welfare Units, Kalamata's Technical University (TEI), Greece

Hungary

Mr Zoltán Balogh, President of Association and Official Delegate, Hungarian Nursing Association, Hungary

Dr Eva Belicza, Senior Fellow at Health Services Management Training Centre, Semmelweis University, Budapest, Hungary

Dr Laszlo Gulácsi, Chair Professor, Health Economics Research Centre, Corvinus University, Budapest, Hungary

Republic of Ireland

Dr Ian Callanan, Head of Clinical Audit, St. Vincent's Healthcare Group, Dublin, Republic of Ireland

Dr Breeda Howley, Lecturer, UCD School of Nursing, Midwifery & Health Systems, Republic of Ireland

Dr Jim Kiely, Chief Medical Officer Department of Health and Children, Hawkins House, Republic of Ireland

Professor Miriam Wiley, Head of the Health Services Research and Information Division at the Economic and Social Research Institute, Republic of Ireland

Italy

Dr Luigi Bertinato, Director of International Health & Social Affairs Office, Veneto Region, Venice, Italy

Professor Piera Poletti, Director, CEREF, Padova, Italy

Professor Julita Sansoni, Director of Nursing Area, Department of Public Health, University of Rome "La Sapienza", Italy

Dr Simonetta Scaramagli, Medical Doctor, Local Health Unit 10, Veneto Region, Venice, Italy

Latvia

Mr Girts Brigis, Medical Academy of Latvia, Latvia

Lithuania

Dr Ramune Kalediene, Dean of the Faculty of Public Health, Kaunas University of Medicine, Lithuania

Dr Ramune Navickiene, State Inspectorate of Medical Audit by the Ministry of Health Care, Lithuania

Luxembourg

Ms. Marie-France Liefgen, Vice-president ANIL, Luxembourg

Dr Susanne Michel, Director Health Consulting, United Kingdom

Malta

Dr Natasha Azzopardi Muscat, Director General, Strategy and Sustainability, Ministry of Health, the Elderly and Community Care, Valletta, Malta

The Netherlands

Dr Cule Cucic, Programme Director, CBO Dutch Institute for Healthcare Improvement, Utrecht, the Netherlands

Mr Willem Kistemaker, CBO Dutch Institute for Healthcare Improvement, Utrecht, the Netherlands

Professor Niek Klazinga, Professor of Social Medicine, Academic Medical Centre, University of Amsterdam, Amsterdam, the Netherlands

Ms. Eveline Klein-Lankhorst, Research Assistant, London School of Hygiene and Tropical Medicine, London, United Kingdom

Mr Benno van Beek, Senior Advisor, Knowledge and Innovation Department, CBO Dutch Institute for Healthcare Improvement, Utrecht, the Netherlands

Poland

Ms. Basia Kutryba, ESQH President, National Center for Quality Assessment in Health Care, Krakow, Poland

Ms. Halina Wasikowska, National Centre for Quality Assessment in Health Care, Poland

Portugal

Dr Francisco Alpendurada, Medical Doctor, Royal Brompton Hospital, London, United Kingdom

Mr Antonio Manuel V. A. Silva, Director, International Affairs, Ordem dos Enfermeiros, Portugal

Dr Suzana Parente, Portuguese Society for Quality in Healthcare, Lisbon, Portugal

Romania

Dr Cassandra Butu, Public Health Expert, National School of Public Health, Romania

Dr Victor Olsavszky, Head of WHO Country Office, Romania

Dr Gabriela Scintee, Public Health Expert, Center for Health Policies and Services, Romania

Professor Dr Cristian Vladescu, Professor of Public Health, Timisoara Medical University, Romania

Slovakia

Dr Darina Sedlakova, Head of WHO Country Office, Slovakia

Slovenia

Dr Tit Albreht, Adviser to the Director, Institute of Public Health of the Republic of Slovenia, Ljubljana, Slovenia

Ms. Elizabeta Bobnar Najžer, Medical Chamber of Slovenia, Slovenia

Professor Dr Andrej Robida, Medical Faculty and Faculty for Health Sciences, University of Maribor, Slovenia

Ms. Eva Turk, Researcher, Institute of Public Health of the Republic of Slovenia, Ljubljana, Slovenia

Spain

Dr José Mª Amate, Head of Unit, Health Technology Assessment Agency Institute of Health Carlos III, Ministry of Health & Consumers Affairs, Spain

Ms. Isabel de la Mata, Health Counsellor, Spanish Permanent Representation to the EU, Spain

Dr Juan Garcia-Caballero, Preventive Medicine Services, Hospital La Paz, Madrid, Spain

Ms. Maria Lluch, Project Coordinator, London School of Economics and Political Science, London, United Kingdom

Professor Angel Otero, Department of Public Health, Autonomous Universty of Madrid, Spain

Dr Rosa Suñol Sala, Director, Avedis Donabedian Foundation, Barcelona, Spain

Sweden

Ms. Ewa Axelsson, Doctoral Candidate in Medical Law Faculty of Law, Uppsala University, Sweden

Dr Michael Bergstrom, Global Knowledge Explorer, Change Agent, Project Director, Swedish Association of Local Authorities and Regions, Stockholm, Sweden

Mr Karl-Henrik Lundell, Medical Director, Jönköping Health Care District, Vice President Swedish Forum for Quality in Health Care, Sweden

Ms. Anette Richardson, Adviser, Swedish Association of Health Professionals, Sweden

United Kingdom

Dr Jason Christopher, General Practitioner in Tower Hamlets, London, United Kingdom

Dr Helen Hogan, Research Fellow/Specialist Registrar Public Health, London School of Hygiene & Tropical Medicine, London, United Kingdom

Dr Lorelei Jones, Research Fellow, London School of Hygiene and Tropical Medicine, London, United Kingdom

Dr David Somekh, Vice President, European Society for Quality in Healthcare, Whitwell, United Kingdom

Mrs Maggie Somekh, Kingates Farm, Isle of Wight, United Kingdom

Professor Kieran Walshe, Professor of Health Policy and Management, University of Manchester, Manchester, United Kingdom

International

Professor Elias Mossialos, European Observatory on Health Systems and Policies (London hub), London School of Economics and Political Science, London, United Kingdom

Dr Josep Figueras, Director, European Observatory on Health Systems and Policies, Brussels, Belgium

Mr Willy Palm, Dissemination Development Officer, European Observatory on Health Systems and Policies, Brussels, Belgium

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1 Deceased

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Preface

The European Union (EU) is built on the concept of four freedoms: 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 European Commission (EC) safety 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).

The challenge now facing the EU'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 European Union citizens can be confident that any care they receive outside their own Member State will be safe and of high quality.

This book asks the question: can the citizens of the EU be assured of receiving high-quality care if they need health care beyond their national frontiers? It forms part of the *Europe for Patients* project, which was undertaken within the EU's 6th Framework Programme for Research (FP6).

The first part of the book is divided into three chapters. The first presents an overview of the concept, nature, methods and players involved in the assessment of quality of care, thus identifying the main issues surrounding quality of care and providing the conceptual basis for the rest of the book. The second focuses on those strategies for promoting quality of care that already exist within the EU as well as on those being considered for the future. It draws on a large amount of material, summarized in Chapter 4, which provides a description of the mechanisms to ensure quality of care in each EU Member State.

The third chapter presents the issues pertaining specifically to quality of care when care is delivered in a cross-border setting, that is, when patients travel to be treated outside their home country. The chapter is divided into four parts. Before entering the discussion on quality of care, it is necessary to explain what we understand by cross-border care and to introduce the different categories of mobile patients that we have identified. The first part of the chapter presents a taxonomy of five patient types that constitute a useful way to conceptualize patient mobility and to understand the motivations and arrangements by which people use health care services outside their home country. The second part focuses on quality of health care in cross-border settings from the *patient's perspective*, based on patient surveys and interviews that highlight the needs, expectations and satisfaction of those who have experienced cross-border care. The third part complements this by examining quality of cross-border care from a *functional perspective* to identify what mechanisms are in place to ensure quality of care and fluid communication between health professionals in projects that link providers, purchasers and health authorities on both sides of a border. This part is based on descriptions of projects in the literature and, where available, the opinions and experiences of involved stakeholders are presented. The final part presents an overview of the needs, in terms of assurance of quality, of each of the five patient types.

The fourth chapter collates brief descriptions of the systems to enhance quality of care that have been established in each of the EU's 27 Member States.

Finally, the fifth chapter introduces a 2-step logic which, if adopted by policy-makers, could ensure that patients receive high-quality health care when they are treated abroad. This chapter concludes that there is considerable variation between and within EU Member States in the approaches they have taken and the extent to which they have implemented programmes to ensure quality of care. However, while we have been able to assemble a number of descriptions of systems already in place, with very few exceptions there is a remarkable lack of evaluative research that can provide information on whether the systems that exist are effective, or even in many cases how widely implemented they are in practice.

Chapter 1

Quality of care: an overview

Quality of care: definitions

The literature on quality of care in health systems is very extensive and at the same time difficult to systematize. Depending on the disciplinary paradigm, quality can be understood in diverse ways, using different terms, labels and models. Where there seems to be agreement is that there is no consensus on how to define quality of care and that the lack of a common systematic framework is, to a considerable extent, due to the diversity in the language used to describe this concept (Blumenthal 1996; Brook, McGlynn and Cleary 1996; Saturno, Gascón and Parra 1997; Evans et al. 2001; Shaw and Kalo 2002; Suñol and Bañeres 2003). This chapter reviews the most frequently used definitions of quality of care that have been proposed so far and examines how quality can be assessed, using the available literature. An understanding of the core concepts, dimensions, measurement tools and the players involved in the decision-making processes is key to assessing quality assurance systems that exist within the European Union (EU).

Drawing on the seminal work of Avedis Donabedian, the first step in assessing the quality of care involves defining what is meant by quality (Donabedian 1988). Yet, as indicated above, there are many possible definitions. The choice of which one to adopt will to some extent depend on the level of analysis or specific context. Consequently, different definitions may be acceptable depending on their intended use, as well as the nature and scope of the responsibilities of the person who is defining them (Donabedian 1988). There is, however, a risk that failure to accept certain general principles within Europe will make

it much more difficult to define consistent frameworks for measurement. It is also important to recognize that the definitions of quality of care are constantly evolving. Initially, the definition and assessment of quality was within the purview of health professionals and health service researchers. However, there is a growing recognition that the preferences and views of patients, the public and other key players are also relevant (Brook, McGlynn and Cleary 1996; Shaw and Kalo 2002).

Table 1.1 provides an overview of the most frequently applied definitions of quality of care, as identified in the literature. These definitions demarcate the boundaries of quality, while a second set of definitions, presented below, more clearly distinguishes the various dimensions of the concept.

Table 1.1 *Definitions of quality of care*

Author/Organization	*Definition*
Donabedian (1980)	Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.
IOM (1990)	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.
Department of Health (UK) (1997)	Quality of care is: • doing the right things (what) • to the right people (to whom) • at the right time (when) • and doing things right first time.
Council of Europe (1998)	Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results, having regard to the current state of knowledge.
WHO (2000)	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.

Notes: IOM: Institute of Medicine; WHO: World Health Organization.

The definitions put forward by Avedis Donabedian and by the Institute of Medicine (IOM) have been particularly influential. Thus, Donabedian defined *quality* as "the ability to achieve desirable objectives using legitimate means", while *quality of care* was defined as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account

of the balance of expected gains and losses that attend the process of care in all its parts" (Donabedian 1980). He argued that before assessing quality of care it is necessary to define whether monetary cost should enter the definition of quality. He thus distinguished a "maximalist" specification from an "optimalist" specification of quality. The maximalist specification ignores monetary costs and defines the highest quality as the level that can be expected to achieve the greatest improvement in health. In contrast, in the optimalist specification of quality, very expensive interventions that do not achieve a great improvement in health would be avoided (Evans et al. 2001). Initially, Donabedian defined quality of care from a maximalist perspective, while later he opted for the concept of value, with quality defined as the maximum that is possible given the inputs that are available.

One other very influential definition of quality of care is that proposed by the IOM in the United States and which has been adopted by a range of (mostly American) organizations including the United States Department of Health and Human Services, the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance, as well as regulatory bodies such as the Health Care Financing Administration (now Centers for Medicare & Medicaid Services) (Edinger 2000). Already in 1974 the IOM had commented on quality assurance, stating that its "primary goal … should be to make health care more effective in bettering the health status and satisfaction of a population, within the resources which society and individuals have chosen to spend for that care". When reviewing this early work later, the IOM realized that "quality of care" had not been defined. It also acknowledged that the method of reviewing and assuring quality depended on how quality of care was defined (IOM 1990).

Therefore, in a 1990 report, the IOM authors reviewed over 100 definitions and parameters of quality of care according to the presence or absence of 18 dimensions (IOM 1990). Based on this review, the authors arrived at a definition of quality of care that considers 8 of the 18 dimensions identified. Consequently, quality of care was defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM 1990).

The definition:

- includes a measure of scale;
- encompasses a wide range of elements of care with reference to health services;
- identifies both individuals and populations as targets for quality assurance efforts;

- is goal oriented, making a distinction within the health care goals depending on whether they emanate from government, patients, administrators, health care practitioners or other participants in the health care system;
- recognizes the importance of outcomes without specifying for whom, thus allowing the possibility of differing perspectives on which values of quality are most important;
- highlights the importance of individual patients' and society's preferences and values and implies that the patients have been taken into account in health care decision- and policy-making;
- underlines the constraints placed on professional performance by the state of technical, medical and scientific knowledge, implying that the State is dynamic and that the health care provider is responsible for using the best knowledge base available.

It is important to note that compared to the definition developed by Donabedian, the IOM definition narrows the goal from improving total patient welfare to improving health outcomes (Evans et al. 2001). At the same time, it shifts the focus from patients to individuals and populations, hence allowing quality of care also to incorporate health promotion and disease prevention and not just cure and rehabilitation. It also adds "desired outcomes" to the definition so as to emphasize the need to consider the perspective of the recipients of services, and by highlighting that care should be "consistent with current professional knowledge" it implies that the standards of the service also need to be defined.

Dimensions of quality of care

As noted above, several authors and/or organizations have defined quality of care by describing the concept according to a set of dimensions (Table 1.2). The most frequently used dimensions include (in descending order of frequency): effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, patient responsiveness or patient-centredness, satisfaction, health improvement and continuity of care. These dimensions are, however, neither comprehensive nor mutually exclusive.

The dimensions of effectiveness and efficiency are included in all definitions of quality of care analysed here. Effectiveness refers to the extent to which the intervention in question produces the intended effects (Maxwell 1992; Witter and Ensor 1997). Efficiency, in contrast, refers to the extent to which objectives are achieved by minimizing the use of resources (WHO 2000). The goal is to maximize the output for a given input, or conversely to minimize the input for a given level of output, for example by comparing the unit cost associated

Table 1.2 *Dimensions of quality of care*

	Donabedian (1988)	*Maxwell (1992)*	*Department of Health (UK) (1997)*	*Council of Europe (1998)*	*IoM (2001)*	*JCAHO (2006)*
Effectiveness	X	X	X	X	X	X
Efficiency	X	X	X	X	X	X
Access	X	X	X	X		X
Safety	X			X	X	X
Equity	X	X	(X)		X	
Appropriateness	X	X		X		X
Timeliness			X		X	X
Acceptability		X		X		
Responsiveness		Respect Choice Information			Respect Patient-centredness	
Satisfaction			(X)	X		
Health improvement	X		X			
Continuity					X	
Other		Technical competence Relevance		Efficacy		Availability Prevention/ early detection

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

Notes: IOM: Institute of Medicine: JCAHO: Joint Commission on Accreditation of Healthcare Organizations.

with the intervention with the unit cost elsewhere for the same intervention or service (Maxwell 1992).

Access (to care) is also an important dimension in all definitions of quality of care considered in the literature, except for the one put forward by the IOM (IOM 2001). Access can, in very simple terms, be operationalized as the proportion of a given population in need of health services that can obtain them (WHO Regional Office for Europe 1998). It is important to note that access has been attributed different meanings by different authors (Saturno, Gascón and Parra 1997). However, the common concern is to quantify whether a health service or treatment is available to the person needing it, at the time it is needed.

Safety refers to the reduction of risk and forms an important component of several definitions. According to the IOM, patient safety is "freedom from accidental injury due to medical care, or medical errors", with medical error being defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim…[including] problems in practice, products, procedures, and systems" (Kohn, Corrigan and Donaldson 2000).

Patient safety has traditionally been considered as 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 concerning patient safety has developed in parallel to mainstream quality of health care initiatives. It is therefore important to reiterate that patient safety forms a dimension of quality of health care.

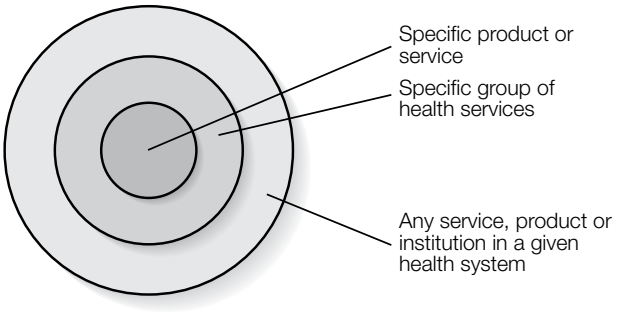
Equity, as a separate, if related, dimension is also included in some classifications. This is different from, but often confused with, equality. Equity implies considerations of fairness so that, in some circumstances, individuals will receive more care than others to reflect differences in their ability to benefit or in their particular needs.

The next sets of dimensions 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 (receiving treatment within a reasonable time frame); acceptability (how humanely and considerately the treatment is delivered); responsiveness to patients or patient-centredness (consideration of individual patients' and society's preferences and values); satisfaction (how the treatment and the improvement in the patient's health meets her/his expectations); and continuity of care (the connectedness between stages along the patient pathway). As will be seen later, continuity of care is regarded as the most important concern by those patients who are receiving care abroad.

An overriding dimension mentioned specifically by Maxwell is that of relevance (Maxwell 1992). It refers to the optimal overall pattern and balance of services that could be achieved, taking into account the needs and wants of the population as a whole. The Council of Europe also includes two notions that are not included by the other definitions considered here, namely those of efficacy and assessment. Efficacy constitutes for the individuals in a defined population the probable benefit of a given medical technique for a specific medical problem, in ideal circumstances, and as such is a rather more limited element of effectiveness. Assessment refers to the degree to which effective health care has been implemented and achieved and results have been attained (Council of Europe 1998).

The choice of dimensions to measure quality of care is critical as it will influence the health care policies adopted. Thus, (Shaw and Kalo 2002) underline the key challenge for every country to recognize these diverse but legitimate expectations and to reconcile them in a responsive and balanced health system.

Figure 1.1 *Levels of analysis in the concept of quality*



Source: Adapted from Saturno, Gascón and Parra 1997.

Levels of quality of care

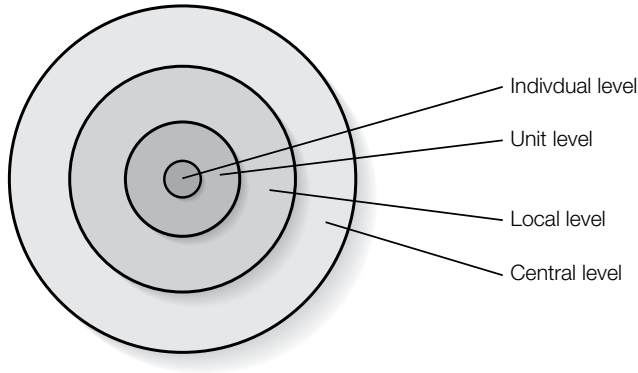
There are different levels at which quality of care can be addressed. Here we present four possible approaches to classifying levels of quality of care, ranging from broad concepts to Donabedian's thorough and comprehensive analysis, and concluding with a framework that looks at different levels of regulation as applied to patient safety.

Saturno and colleagues distinguish three levels of quality that relate to the delivery of care (Figure 1.1) (Saturno, Gascón and Parra 1997). The first level refers to a *general concept of quality* and is applicable to any service, product or institution in the health system. The second level is applicable to a *specific group of services*, while the third level refers to a *specific product or service* that is provided in health institutions.

The Council of Europe (1997) proposed an approach that takes account of the different administrative and organizational tiers of the health care system, emphasizing the need to improve the quality of care at each level of service delivery (Figure 1.2), including: central (country, district); local (hospital, local or regional organization for home care, collaboration practices, etc.); unit (practice team, hospital unit); and individual level (individual health care provider).

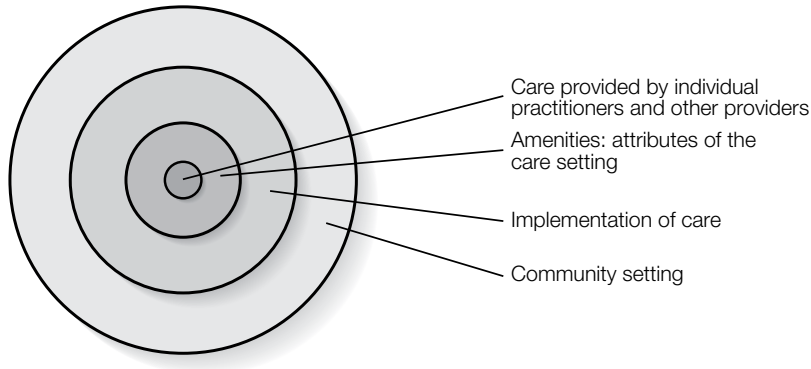
The approach proposed by Donabedian considers four levels at which quality may be assessed (Figure 1.3). It takes account of the actors involved in the process of care (providers, patients, communities) as well as the setting in which health care takes place. This classification not only distinguishes different levels of quality but also identifies specific elements that define quality at that level. At the core he places the care provided by practitioners and other providers. These are further defined by two elements of performance: technical performance and the management of interpersonal relationships. The former depends on

Figure 1.2 *Organizational levels of quality improvement in health care*



Source: Adapted from Council of Europe 1997.

Figure 1.3 *Levels at which quality may be assessed*

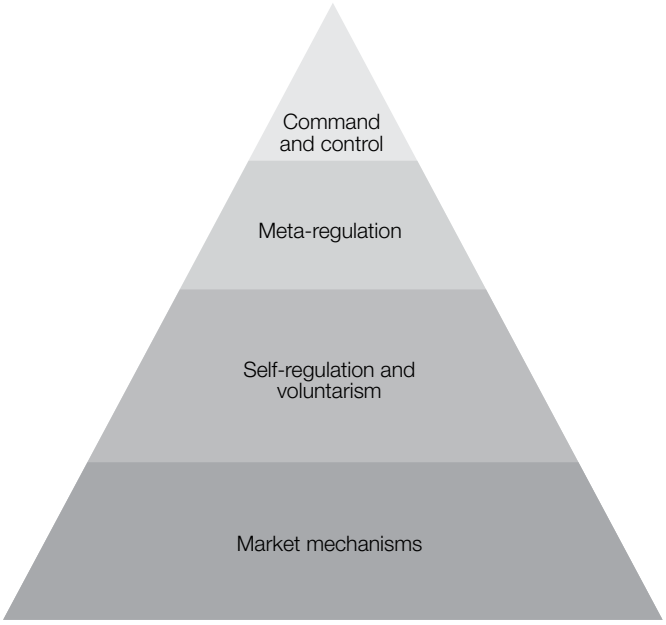


Source: Adapted from Donabedian 1988.

the knowledge and judgement used in arriving at the appropriate strategies of care and on the skills needed to implement those strategies. It is assessed in comparison with best practice. The second element relates to the way in which technical care is implemented and on which its success depends, an element that is often ignored in assessments of quality of care.

The second level involves the amenities of care, focusing on the desirable attributes of the settings in which care is provided. The third level refers to the actual implementation of care, responsibility for which is shared between the provider and the patient. The final level refers to the care received by the community as a whole and considers issues of social distribution of levels of quality. Thus, according to Donabedian, the definition of quality becomes either narrower or more expansive, depending on how the concept of health and related responsibilities are being defined (Donabedian 1988).

Figure 1.4 *Regulatory pyramid and health care safety and quality mechanisms*



Source: Adapted from Braithwaite, Healy and Dwan 2005.

A different approach was taken by Braithwaite, Healy and Dwan (2005), who proposed a framework for analysis that is based on regulation, its different levels and its applicability to patient safety. Their main argument derives from the concept of responsive regulation "which maintains that regulators are more likely to succeed by using mechanisms that are responsive to the context, conduct, and culture of those being regulated". Escalating sanctions can be invoked "that is, soft words before hard words, and carrots before sticks" (Braithwaite, Healy and Dwan 2005). The authors illustrate the concept by means of a regulatory pyramid that stretches from regulation to market mechanisms, with examples relating to patient safety across the spectrum (Figure 1.4). The base of the pyramid is formed by market mechanisms (e.g. payments to incentivize quality), followed by voluntarism (e.g. clinical protocols), self-regulation (e.g. industry standards) and meta-regulation (e.g. compulsory incident reporting), with command and control at the apex of the pyramid (e.g. criminal penalties).

Assessing quality of care

The preceding sections have presented a range of systematic approaches to defining and classifying quality of care. Yet, the various concepts and models say little about how actually to assess quality. Donabedian pioneered this work by proposing that we can measure the quality of health care by evaluating its

structure, processes and *outcomes* as adapted from the concept of input–process–output in industrial manufacturing (Shaw and Kalo 2002). He argued that "good structure increases the likelihood of good process, and good process increases the likelihood of good outcome" (Donabedian 1988).

Donabedian defined *structure* (or *input*) as the *attributes of the settings* in which care occurs and the *resources* needed for health care. This would include material resources (facilities, capital, equipment, drugs, etc.), intellectual resources (medical knowledge, information systems) and human resources (health care professionals). *Process* denotes the *use of resources* in terms of what is done in giving and receiving care. This can be classified into patient-related processes (intervention rates, referral rates, etc.) and organizational aspects (supply with drugs, management of waiting lists, payment of health care staff, collection of funds, etc.). *Outcomes* describe the *effects of health care* on the health status of patients and populations and comprise final outcomes such as mortality, morbidity, disability or quality of life, as well as intermediate outcomes, for instance, blood pressure, body weight, personal well-being, functional ability, coping ability, improved knowledge and others.

However, Donabedian also argued that before assessing quality one must decide (Donabedian 1988):

- whether to adopt a maximal or optimal specification of quality;
- how health and our responsibility for it is to be defined;
- whether the assessment is to involve the performance of practitioners only or also to include that of patients and the health care system; and
- whether the amenities and the management of the interpersonal process between patient and provider are to be included in addition to technical care.

Shaw and Kalo (2002) have explored Donabedian's approach further and identified the dimensions of quality of care that correspond to each category (Table 1.3). Donabedian's approach to describing and evaluating the quality of care has been accepted widely and is possibly one of the very few points of consensus in the field of quality of care. In reality, however, it appears that the three components are rarely analysed in a comprehensive manner. Traditionally, efforts to assess quality were founded on structural measures of health care, such as recognition of professional qualifications and experience, approval of drugs and medical devices, and radiation dosage reduction. More recently, the focus has shifted towards developing measures of process and outcome.

Table 1.3 *Dimensions in the assessment of quality of care*

	Dimension of quality of care
Structure (Input)	How resources are allocated in terms of time, place and responsiveness to the needs of populations *(access)* Fairness in sharing costs and benefits *(equity)*
Process	How the resources are applied *(stewardship)* Use of time and resources *(efficiency)* Avoidance of waste *(economy)* Reduction of risk *(safety)* Evidence-based practice *(appropriateness)* Patient-focused care *(continuity)* Public/patient information *(choice, transparency, accountability)*
Outcome	Population health *(health improvement)* Clinical outcome *(effectiveness)* Meeting expectations of public and workforce *(cost–benefit)*

Source: Shaw and Kale, 2002.

However, there is a long-standing debate in the literature about the relative merits of process and outcome measures. Brook and colleagues (2000) argue that process data often provide a more sensitive measure of quality than outcome data, since a poor outcome does not necessarily result from a failure in the provision of care (Brook, McGlynn and Shekelle 2000). In addtion, physicians usually define quality of care in terms of process (Brook, McGlynn and Cleary 1996). Outcomes are more generally perceived as poor measures of quality of care as they are only partially attributable to health services and may be more strongly influenced by other factors such as nutrition, environment, lifestyle or socioeconomic circumstances. Thus, outcomes of patients receiving the same treatment reflect to some extent patient characteristics rather than factors under the control of health care providers. Also, the interval between an intervention and its ultimate outcome may be lengthy and it may be difficult to attribute many outcomes of interest to the provision of particular services.

Similarly, Wareham and colleagues (2001) noted that "[m]easuring the outcome of care would intuitively appear to be the final arbiter, but outcomes are not necessarily the best measures of quality". This is because outcomes do not capture all elements of performance but only permit an inference about the quality of the processes and structures of care (Wareham, Pencheon and Melzer 2001). Also, echoing Brook, McGlynn and Shekelle (2000), the authors contend that poor outcomes do not always imply poor quality of care. Furthermore, outcomes can be difficult and costly to measure and their measurement is subject to statistical uncertainty.

This issue is further highlighted by Mant and Hicks (1995) who, taking the example of thrombolysis for myocardial infarction, showed that it would take

many years to detect a difference in outcome between two hospitals offering the treatment to very different proportions of patients, yet a measure of process (uptake of the intervention) would identify the difference rapidly (Mant and Hicks 1995). At the same time, Mant (2001) noted that outcome measures are attractive as they are important in their own right, whereas a process measure by itself is usually of little intrinsic interest to those receiving the intervention. Also, it can be argued that outcome measures capture the sum of "all aspects of the processes of care and not simply those that are measurable or measured" (Mant 2001).

A rarely discussed issue is whether an "optimal" assessment of quality of care is being pursued or whether the cost of assessment is considered in the equation. Ideally, any system of assessment would include elements of structure, process and outcome as they examine different aspects of the care provided in health systems while using process and outcome measures on their own may be misleading.

Conceptual framework

This book addresses the question of whether patients moving within the European Union can be assured that they will obtain high-quality care. To do so we begin by developing a conceptual framework to enable systematic assessment of existing quality of care strategies in the EU. The framework is described in more detail below, with the findings of the actual analysis presented in detail in Chapter 2 of this book. Chapter 3 seeks to present the issues pertaining to quality of care when care is delivered in a cross-border setting, that is, when patients travel to be treated outside their home country. Finally, Chapter 4 describes the policies to promote quality of care in each EU Member State, based on the approach to analysing the policy process as developed by Walt and Gilson, which distinguishes the context within which policies are being made, the actual process of policy development and the key actors involved in that process (Walt and Gilson 1994). Where possible the conceptual framework outlined below has been applied, which includes health system, organizational and clinical quality assessment schemes. Based on the evidence compiled here, Chapter 5 concludes the volume, proposing steps that policy-makers at both national and European levels should undertake to ensure that citizens of Europe crossing national borders can be assured of receiving high-quality care.

The brief review presented in the preceding sections illustrates that there are many different perspectives on health care quality. For the purposes of this book we chose as a starting point the definition developed by the IOM detailed

previously, since it has probably the widest currency in both policy and academic literature (Lohr 1990):

> 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.

It is important to recognize that this definition emerged within a United States paradigm from which the notion of "access" was excluded. In contrast, the European context requires stressing 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.

As for the dimensions of quality of care, we select those that appear to be most relevant for policy development: effectiveness, acceptability, appropriateness, satisfaction, and patient or care experience. While, as noted above, "patient safety" is considered to be an integral element of quality, because it is developing a separate existence in some places, we also include those initiatives that focus on it.

In line with work by Øvretveit (2001), we distinguish levels at which policy development takes place: the health system (or macro) level, the organizational (meso) level and the clinical (micro) level. Thus, policies operating at the health system level include national legislation and regulation, patient safety, registration and licensing of pharmaceuticals and medical devices, health technology assessment (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 (Øvretveit 2001; Øvretveit and Gustafson 2002). However, organizational quality assessment schemes are directed at the evaluation of organizations providing care and cover a wide variety of mechanisms, which can be separated into compulsory and voluntary. Voluntary mechanisms are normally carried out by professional organizations while those that are compulsory are often carried out by governments or agencies acting on their behalf. Clinical quality assessment schemes involve, amongst other factor, 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).

Chapter 2 applies this framework to examine, in detail, quality of care strategies that have been adopted in the EU Member States.

Chapter 2

Quality of care strategies in the European Union

Introduction

There is a wide range of national and international organizations addressing issues of quality of care and these have influenced the development of regional, national and international quality of care strategies across Europe. Among the most influential are the United States-based JCAHO and the IOM, as well as the International Society for Quality in Health Care (ISQua). At European level, influential bodies include the European Society for Quality in Healthcare (ESQH), the Council of Europe and the World Health Organization (WHO) Regional Office for Europe. In addition, the Cochrane Collaboration has played a major part in ensuring availability of the evidence on which quality care is based, including a considerable volume of work on the effectiveness of strategies for changing clinical practice.

In 1995 the Council of Europe established a committee of experts to examine the issue of quality in health care, with a subsequent report developing recommendations on "Dimensions of Quality Improvement Systems" (Council of Europe 1998). This provided a framework to compare the activities being undertaken in different countries. In 1998, health ministers agreed to collaborate on quality in the health sector; and the Austrian Federal Ministry of Health and Women's Affairs published a summary of quality policies in EU Member States, followed by a similar summary of policies in the then candidate countries in 2001. In May 2000, the EU adopted a new health policy, taking 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 and Kalo 2002).

In 2008, the European Commission envisages certain non-legislative proposals relevant to quality of health care. The main initiatives planned are (European Commission 2007):

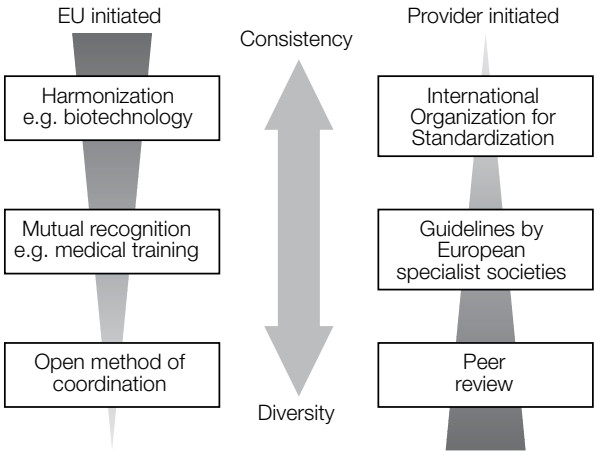
- a Communication and Council Recommendation on Patient Safety and Quality of Health Services (November 2008);
- a Green Paper on Health Professionals in Europe and launch of a High Level Reflection Process on Health Professionals in Europe (4th Quarter 2008);
- a proposal for improving patient safety by prevention and control of health care-associated infections (December 2008).

The two primary objectives of the initiative on Patient Safety and Quality of Health Services are (European Commission 2007):

- to support Member States in ensuring the highest possible levels of patient safety throughout EU health systems by providing necessary and relevant practical and legal tools and mechanisms for the Member States, as well as the key stakeholders, to take appropriate actions to improve safety and quality of care; and
- to improve EU citizens' confidence that they have sufficient information available on the safety of EU health systems.

It is important to note that the development of policies on quality of health care within the EU has been complicated by, on the one hand, the clear statement in successive European treaties that health care is the responsibility of Member States, yet, on the other hand, the fact that health care delivery involves people, goods and services whose characteristics are regulated at European level. As a consequence, and as we will see below, there is a wide legislative spectrum from those areas that are addressed exclusively at European level through to areas where some or all countries have adopted common solutions, to those where arrangements are entirely local matters. The same is true of initiatives developed by health care providers, ranging from purely local approaches to those that have been adopted across many countries (Figure 2.1). A detailed description of the approaches to promotion of quality of health care adopted by individual countries is contained in Chapter 4.

Figure 2.1 *A conceptual model of strategies for health care quality in Europe*



Health systems quality assessment

The following paragraphs summarize those strategies for promoting quality of care already in existence within the EU.

Legislation and policies on quality of care

There is considerable variation between and within European Union Member States in the approaches each has adopted and the extent to which legislative measures to ensure quality of care have been implemented. To some extent, this variation reflects the prevailing view in each country about whether health care quality is a legitimate matter for legislation or for other measures such as voluntary agreements. This is a question that is unresolved and which will almost certainly be determined by specific national circumstances; the absence of legislation should not necessarily be seen as a weakness. A closer look at what has been done by the various Member States does, however, reveal some commonalities. Three broad categories emerge. The first category consists of those Member States that do not have any legislation on quality of care, or national policies on quality. The second category includes those countries that have only recently either enacted legislation or implemented policies relating to quality of care. The third category includes those 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. The first includes those that have had systems in place for a considerable period that are now firmly embedded and where major reform is not envisaged. The second includes those where there is also a long tradition of activities to promote quality of

care but where major reforms are envisaged or are in progress due to perceived limitations of the existing systems.

The first category includes Bulgaria, Cyprus, Estonia, Greece, Hungary, Malta, Luxembourg, Latvia, Poland, Portugal, Romania and Slovakia. Although these countries have some initiatives in place, these are not systematically applied at national level. For example, various efforts have taken place in Greece since the mid-1990s to initiate quality of care activities. In 1996 and in 2001, the then ministers of health established National Committees for Quality on Health Care, while a facility for a proposed Institute of Quality and Accreditation in Health Care Services has been built. The 2001 Committee produced, in 2002, an in-depth report that recommended ways to enhance quality of care. However, with changes of government, as well as a lack of financial support, few of the proposed activities have taken place.

In Estonia, the establishment of a quality assurance system was first identified as a priority during the Estonian Health Care Project (1995–1998), funded by the World Bank and the Government of the Netherlands (World Bank 2001). The project included development of a policy on quality of health care. A report was presented to the Estonian Government for approval but was later rejected due to a lack of clarity about funding of the measures proposed. Following its rejection, a quality working group was initiated by the Ministry of Social Affairs and the Central Sickness Fund (Estonian Health Insurance Fund since 2000), together with the Medical and Nursing Associations (Shaw and Kalo 2002). Although the proposal was not approved, Estonian health care institutions have used it as a basis for quality-related activities (Kaarna and Kalda 2005). The first official mention of quality of health care was in the Health Services Organization Act of 2001. The Act required the Minister of Social Affairs to set standards for accessibility and quality of health services. It also established minimum standards for health care professionals and health care providers (Kaarna and Kalda 2005).

In Hungary, it was in the early 1990s when quality assurance first became a priority for the Government, leading to the enactment of several government resolutions, decrees and orders related to quality (Gulácsi 2001). The first regulation was the Law on Health Care (1997), which provided a legal basis for internal and external quality management systems. The Law stated that each health care organization was required to establish an internal system and it also defined some minimum quality standards and set out in detail the rights of patients. However, at the time of writing, Hungary has not yet developed a specific policy on quality of health care. It has been reported that policy-makers were more interested in quality of health care during the 1990s than in the new

millennium. A survey carried out in 107 hospitals clearly shows that the level of quality-related activity was lower in 2005 than in 2000 (Gulácsi 2006).

In Luxembourg, the first developments establishing a framework for quality in health service delivery took place in 1998. The Law on hospital establishments (28 August 1998, published 18 September 1998) was changed to integrate the option that hospitals are given 2% of their annual hospital budget on the condition and achievement of defined quality measures. However, participation of hospitals in this endeavour was on a voluntary basis.

In Bulgaria, the Health Act passed in 2004 referred to a few quality improvement strategies. The Act set out standards for different medical specialties, outlined the responsibilities of the 28 regional health centres and the Ministry of Health in controlling the competencies of medical specialists and monitoring the quality of care, and included a process for patient complaints and appeals (Avdeeva and Georgieva 2007). The process of health care reform is widely accepted to have been difficult. Several years after the initial reform, many problems persist. Quality of care remains one of the most significant challenges facing the health care system, and it has been especially difficult to improve quality in rural areas.

In Cyprus, one element of current reforms initiated by the Ministry of Health involves the introduction of a system of quality assurance, which will seek to identify areas for improvement, formulate guidelines for best practice and evaluate the delivery of care. The Ministry of Health has established a quality assurance committee, the National Committee for Quality Assurance and Risk Management, which includes representatives from all branches of the Ministry of Health. It envisages a process whereby all hospitals in Cyprus would be accredited with an international body, and has developed an action plan to strengthen quality assurance in all health facilities. The Ministry of Health supports quality initiatives through its funding of the Committee but there is a consensus that its achievements have been limited.

In Romania, quality of care is not regulated by a specific act, but Law 95/2006 includes some references to quality of care in each sector of the health care system, for instance, hospitals, laboratories, primary care facilities, etc. For instance, the Law specifies that hospitals need to be accredited based on standards that are to be elaborated by the Ministry of Public Health.

Turning to the second category, that is, countries that have recently adopted quality of care laws and related measures, we find that several of the new Member States, namely the Czech Republic, Lithuania and Slovenia, as well as the Republic of Ireland, fall into this category. In some cases, the accession process has acted as a stimulus to develop these policies.

In 2000 the Government of the Czech Republic adopted a National Quality Policy in Decree No. 458. This defined a package of methods designed to improve quality of products, services and activities. The main objectives of the Decree included: development of a national accreditation system; assurance of quality in public services; standardization; staff training and retraining; and creating a system of quality assurance.

Measures related to quality of care in Lithuania include a system of licensing (based on the International Organization for Standardization (ISO) ISO 9000 standard) for health care and pharmaceutical organizations (introduced in 1995); provision for medical audit in health facilities, since 1998; a system of accreditation of health care institutions, dating from 1999, and a Health Care Quality Assurance Programme, proposed in 2004. This programme, based on a concept developed two years earlier, seeks to direct health care more clearly towards the needs of patients and the public; to improve quality and safety; and to develop health care quality management. However, the majority of measures envisaged have not been implemented due to lack of funds.

In the Republic of Ireland, in the late 1990s, three major reports into health services were published, leading to a major review of the organization and delivery of care. This process culminated in 2001 with the publication of a national health strategy, "Quality and fairness, a system for you". This strategy recommended a radical reorganization of the health services in the Republic of Ireland, proposing the abolition of the 11 regional health boards and their replacement by a centralized, unified health authority (the Health Service Executive (HSE)) that would deliver primary, secondary and continuing care. In tandem with this new authority an equivalent oversight body was proposed to regulate the standard health care services delivered by the HSE. This authority, the Health Information and Quality Authority (HIQA) was established on an interim basis in March 2005. Its role is to ensure the delivery of high-quality services based on evidence of best practice, to design and monitor standards of care provision, to conduct HTAs and to advise on and regulate elements of health care information processes. In initial discussions, it was envisaged that it would also incorporate the Irish Health Services Accreditation Board (IHSAB) and the National Cancer Registry.

In Slovenia, quality has risen higher on the health policy agenda following proposals for health care reforms in 2003. The current emphasis is on connecting the elements already in place and adding the missing links, so as to create a framework for sustained quality improvement (DRMED 2007). This is being operationalized by means of an expert committee within the Ministry of Health and the appointment of a national coordinator for quality in general practice. However, it is reported that neither have received adequate financial

support. At the time of writing, new legislation on quality and safety is being prepared. The Ministry of Health supports the creation of a national institution for quality and safety in health care, with mandatory reporting by health care providers. However, the approaches proposed by the Ministry have not so far been well received by health professionals, with support concentrated among those already actively involved in quality-related activities.

Finally, the third category consists of countries with a well-established tradition of quality of care legislation and related measures. As noted above, these can be further divided into those that have had policies in place for some time and are anticipating only minor reforms – France, Finland, Germany, Italy, Spain and Sweden – and those that have a long tradition of quality strategies but are going through major reforms to reorganize their systems (Austria, Belgium, the Netherlands, the United Kingdom/England and Denmark).

Quality assurance activities in Finland started in the early 1980s, when professional groups became engaged in different quality assurance projects, and these expanded during the 1990s. In 1994 a National Policy on Quality for Health Care was approved. One year later the first National Recommendation on Quality Management was published. In 1998 a quality strategy was proposed for public services and in 1999 recommendations on Quality Management for Health Services provided and purchased by municipalities was introduced (Outinen 2003).

In France, growing concern about the quality of care emerged in the 1980s and early 1990s following a series of incidents exposing undesirable practices in health care services. As a result, the Government embarked on a series of reforms which saw the creation in 1990 of the National Agency for the Development of Medical Evaluation (ANDEM) and the Hospital Act No. 91-748 of 31 July 1991, in which assessment of care became mandatory (de Pouvourville 1997). Other initiatives comprise dissemination of practice guidelines, lengthening general practice training periods, the development of medical information systems and piloting networks of health care providers to improve coordination and continuity of care. These were (partly) formalized in the context of the 1996 "Juppé reform" of the French health care system that also established the Agency for Accreditation and Evaluation of Health Care (ANAES), which replaced ANDEM (Sandier, Paris and Polton 2004). In October 2004, the role of ANAES was subsumed under the newly created National Authority for Health (HAS) that also resumes the roles of the Commission on Transparency and the Economic Committee for Medical Products (CEPS) (created in 1999), among others (Haute Autorité en Santé).

In Germany, systematic quality assurance programmes addressing selected topics were introduced for the first time in the mid-1970s at regional level by the State Chambers of Physicians (Birkner 1998; Ollenschläger, Marshall and Qureshi 2004). At national level, professional self-regulation, with monitoring of technical safety and hygiene, was, until the end of the 1980s, regarded as sufficient to ensure quality of health care (Busse and Riesberg 2004). In the mid-1990s, "quality in health care" became a priority topic both in professional self-administration and health policy at state level – focussing on the use of quality management programmes, clinical guidelines, and quality indicators (Helou, Schwartz and Ollenschläger 2002). Subsequently, it became more prominent in the national policy debate (Allen and Riemer Hommel 2006) and quality requirements for in- and outpatient care have progressively been transformed from a voluntary activity to a legal obligation, and, from 2000, successive measures to improve the quality of care were introduced.

In Sweden, the Health and Medical Services Act (1982:763) explicitly stipulates that quality of health care shall be guaranteed and systematically and continuously developed. The Act is primarily directed at health care providers. It does not confer any explicit rights on patients to receive good-quality health care, but it sets out obligations for providers to deliver health care of high quality. In the 1980s, quality assurance activities started in Sweden and the first National Strategy on Quality was developed in 1990, initiated by the Government. In 1994 the National Board of Health and Welfare issued a further set of regulations on quality assurance, subsequently revised in 1997 and in 2005. These regulations state that all health services in Sweden must include a system for continuous, target-oriented quality improvement.

Spain and Italy represent examples of countries where, although quality improvement is mostly promoted by the national Ministry of Health, regional governments have responsibility for introducing and implementing policies on quality of health care. Thus, in Spain responsibility for health care has been devolved to the 17 Autonomous Regions since 2002, leading to 17 different policies on quality of care. For example, Catalunya, Andalucia and Madrid have implemented accreditation of hospitals; Aragon and Cantabria are using the European Foundation for Quality Management model (EFQM); and Navarra is implementing its own quality management programme (Comite Editorial RCA 2004). In Italy, the national Government provides general guidelines but regional governments are entirely responsible for quality of the care provided in their territories. As a result, there are essentially 20 regional health care systems with marked differences in strategies on quality. There are, however, three principle sources of national guidance on quality, derived from the National Reform Act passed in 1992. These refer to accreditation, quality assurance and

citizens' rights. Based on this legal framework, the regions approve their own regulations.

Austria, Belgium, the Netherlands, the United Kingdom/England and Denmark have introduced highly regulated strategies to ensure quality of care, with polices characterized by a "top-down" approach. In Austria, a key step in the process of promoting quality was the amendment of the Law on Health Care Institutions (KAKuG) in 1993, which established a legal framework for the implementation of quality assurance in hospitals (Hofmarcher and Rack 2001). Further reforms were introduced in 2005, including the Law on the Quality of Health Care Services, which sets out the responsibilities for quality of care by the different actors. The objective of the 2005 health care system reform involves promoting closer cooperation of the inpatient (hospital) and outpatient sectors (hospital clinics, doctors in private practice).

In 1993, the Danish Ministry of Health and the Danish National Board of Health introduced a National Strategy for Quality Improvement in Health Care, based on the principle of "bottom-up" quality improvement. Between 1993 and 2000, a wide range of initiatives were introduced within the framework of this strategy, although these were largely local, ad hoc and informal activities. In 2003 the Danish Ministry of Health and the National Board of Health developed a 3-year National Strategy for Quality Improvement that consciously sought to overcome the problems encountered with the previous strategy. This specified that quality improvement should be related to clinical pathways and should use set standards and indicators. That same year, as part of the new strategy, a Danish Health Care Quality Assessment Programme was proposed.

In the Netherlands it is predicted that, following recent reforms, health care delivery will change considerably over the next decade. The health care reforms have resulted in an increase in market competition and a decrease in government control. It can be envisaged that some care providers will focus on specific markets, whilst others will focus on enhanced quality. Two laws define the framework for individual providers and care institutions: the Individual Health Care Professions Act (BIG, *Wet op de beroepen in de individuele gezondheidszorg*) enacted in 1993 and the Care Institutions Quality Act (KZI, *Kwaliteitswet Zorginstellingen*) passed in 1996. Legislation stipulates that the primary responsibility for quality lies with health care providers and professionals (Dutch Department of Health 2005). An evaluation of the Health Care Quality Law carried out in 2002 showed that little progress had been made by health care institutions towards implementing a structured quality system. Following recommendations made in late 2002, the Minister of Health announced specific measures to make quality management compulsory. This

envisaged a move from a supporting role to a more controlling position (den Exter et al. 2004).

In Belgium, after years of maintaining a predominant focus on cost-containment, assessment of quality of care is now gaining more attention. Whereas the traditional way of assuring quality was through specific licensing standards, mainly for health care institutions, the responsible authorities have more recently been seeking to strengthen quality assurance by means of accreditation of care providers, peer review and audit. Several laws, such as the Hospital Act and the Health Insurance Act, incorporate quality improvement initiatives.

Patient safety

In the last 20 years, the issue of patient safety has become recognized increasingly as a key element of overall quality. 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 (Leape et al. 1991), which showed that adverse events occurred in 3.7% of hospitalizations and that 27.6% of the adverse events could be attributed to errors.

The second, and most influential study published to date, was carried out by the IOM in 2000, entitled *To err is human: building a safer health system*. This study estimated 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 that for those who died each year from motor vehicle accidents (43 458), breast cancer (42 297) or AIDS (16 516) (Kohn, Corrigan and Donaldson 2000). This report received worldwide attention. The following year the English National Health Service (NHS) published the pioneering report, *An organisation with a memory*, which estimated that about 10% of admissions to NHS hospitals were associated with adverse events causing harm to patients, affecting more than 850 000 patients a year (Department of Health 2000).

Both the Luxembourg and British Presidencies of the EU in 2005 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 (Council of Europe 2006).

The High Level Group on Health Services and Medical Care, a committee set up for taking forward the Communication COM (2004) 301 of 20 April 2004 on patient mobility, 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 actions proposed by WHO's Global Alliance for Patient Safety (see Box 2.1) (Bertinato, 2005).

Box 2.1 *Action areas of WHO's Global World Alliance for Patient Safety (2004)*

Global Patient Safety Challenge: focusing throughout 2005–2006 on the challenge of health care-related infection.

Patients for Patient Safety: involving patient organizations and individuals in the work of the Alliance.

Taxonomy for Patient Safety: ensuring consistency in the concepts, principles, norms and terminology used in patient safety work.

Research for Patient Safety: developing a rapid assessment tool for use in developing countries and undertaking global prevalence studies on adverse effects.

Solutions for Patient Safety: promoting existing interventions and coordinating activity internationally to ensure new solutions are delivered.

Reporting and Learning: generating best practice guidelines for existing and new reporting systems, and facilitating early learning from the information available.

Source: World Alliance for Patient Safety 2004.

Despite its growing visibility on the policy agenda, patient safety has not yet been translated into tangible action in all Member States. 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 (Department of Health 2000).

A recent European study on patient safety found that in 2005 only Denmark, Germany, Spain, the Netherlands and the United Kingdom had established specific institutional structures to ensure patient safety; with the systems implemented by Denmark and the United Kingdom being judged as the most advanced (Somekh 2007) (Box 2.2). Other countries had implemented various elements, such as national or regional incident reporting systems, requirements that facilities employ risk managers, and protection for "whistleblowers", but there was great variation in both the nature and scope of these elements. Inevitably the degrees of investment both financially and in institutional engagement will vary and will to some extent mirror the overall development of health care services in the country concerned.

However, as with quality of health care, 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 being developed in the United States and Australia at the time of writing (Emslie, Knox and Pickstone 2003).

Box 2.2 *Patient safety initiatives in Denmark and the United Kingdom*

Denmark

A confidential, non-punitive, but mandatory system for reporting adverse medical events was established in 2004. Hospitals are required to report medical errors and adverse events to a national database managed by the National Board of Health. The scheme focuses on learning from experience so as to prevent recurrence of adverse events and has a protective whistle-blowing provision, so that any health care worker who reports an adverse event cannot be subjected to investigation or disciplinary action by their employer, the Board of Health or by the courts for doing so.

United Kingdom

The National Patient Safety Agency was established in 2001 comprising a Patient Safety Division and operating a National Reporting and Learning System that analyses information on adverse events and takes appropriate action, for example by issuing alerts. The Agency also operates a National Clinical Assessment Service, which provides confidential advice and support where the performance of doctors and dentists is giving rise to concerns, and a National Research Ethics Service. It also runs a series of Confidential Enquiries into suicides and violent deaths by people with mental illness, maternal and neonatal deaths, and peri-operative deaths.

Approval of pharmaceuticals and medical devices

Systems for approval of pharmaceuticals are universal within the EU and are subject to the provisions of EC directives (Permanand and Mossialos 2001). Pharmaceuticals can be approved either by the European Medicines Agency (EMEA) or by a Member State. Medical devices are regulated by three EC 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 (e.g. training, registration, certification and revalidation).

There are also function-specific inspectorates for public health and safety (e.g. fire, radiation and infection) in many EU Member States (Shaw and Kalo 2002). Licensing of health care institutions is widespread within the EU, although safety and organizational standards vary between EU Member States and within Member States (e.g. Italy). Requirements for professional registration and licensing are set out in EC directives on free movement of professions. There are, however, ongoing discussions in several Member States about the effectiveness of professional registration (see "Training of professionals").

Training of professionals

There are many differences in the ways 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 safe to practise throughout the EU. The system has been criticized because the criteria for recognition relate almost exclusively to the length of study, with no consideration of the content. They also do not take account of the growing use of competency-based approaches in professional education. Specialist qualifications are of two types: those relating to specialties, such as surgery, that are recognized everywhere, and those relating to specialties recognized in only a few countries, such as dermatovenerology. Individuals in the second group can only use their qualification in a country that recognizes that specialty. This approach, codified in 1997 Directives 77/452 and 77/453, is clearly inconsistent with moves in some Member States to require evidence of continuing capability in order 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). The Netherlands already has a system of regular revalidation, in which physicians have to demonstrate continuing competence regularly in order to practise. The United Kingdom and the Republic of Ireland are in the process of developing a similar system. In the United Kingdom this will be the responsibility of the General Medical Council (GMC), which maintains the medical register. The British model is likely to be a summative assessment which is expected to comprise an assessment of skills in addition to information collected at doctors' annual appraisals. There is, however, no provision in EU legislation to address the issue of revalidation, which could in theory pose a barrier to mobility (Merkur et al. (in press)).

Training in quality of care

Training in methods used to ensure quality of care is not the norm in the EU although it does take place in some countries. In France, 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. The scale of these activities is difficult to assess, as many take place as part of routine continuing professional development. The Austrian Association for Quality Assurance has initiated training programmes on quality and is the accreditation body for ISO 9000 activities. In Belgium, the Flemish community has introduced a training programme for doctors and nurses linked

to a care evaluation programme through the Flemish Institute for Integral Quality in Health Care. In Cyprus, a training programme for GPs on medical audit has been developed, but its coverage is quite limited. The Luxembourg Hospital Association organizes training in quality (HOPE 1996), and in Poland the National Centre for Quality Assurance in Health Care organizes several training courses on methods and tools for quality assurance. In Slovenia, the Association of General Practitioners has established a working group on quality improvement, and in Spain a training programme has been initiated as a collaboration between the National Institute of Health (INSALUD) and the National School of Public Health. The Irish Society for Quality and Safety in Healthcare (ISQSH) provides courses on quality in health care, and in France, ANAES is the lead agency for training on quality (Lefebvre 2004). In Sweden and Norway the integration of knowledge improvement into health professional education is well established, taking place in the Universities of Oslo, Linköping and Jönköping.

Health technology assessment

HTA is a comprehensive, systematic assessment of the conditions for and the consequences of using health technology. HTA includes assessments of four main elements: the technology, the patient, the organization and the economics (DACEHTA 2007).

It is difficult to assess how widespread HTA is within the EU, as countries define HTA in different ways. Notwithstanding this challenge, four categories have been identified, varying from those countries where HTA has not been developed extensively to those where HTA is now being implemented. The first category where almost no HTA developments have taken place include Bulgaria, the Czech Republic, Estonia, Greece, the Republic of Ireland, Latvia, Luxembourg, Malta, Portugal, Romania, Slovakia and Slovenia. The small size of some of these countries means that it can be appropriate to draw on assessments undertaken elsewhere, especially given the shortage of health service researchers in Europe.

The second category includes countries that have started some initiatives but where policy itself remains poorly defined. This category includes countries such as Poland, where an HTA group has been created at the National Centre for Quality Assurance in Health Care. In Hungary, HTA is regulated by the Government, although it is reported not to be widely used in the Hungarian health care system. In Lithuania the State Health Care Accreditation Agency at the Ministry of Health is responsible for approval of health care technologies. In Cyprus, HTA is carried out by permanent technical committees, but it is not clear what definition of HTA is being used.

The third category is composed of countries with some organized initiatives, although the extent to which these initiatives are implemented is often unclear. In France, the French Agency for the Safety of Health Products (AFSSAPS) is expected to provide a focus for systematic evaluations (Sandier, Paris and Polton 2004). In Germany, HTA has received a boost from the establishment of an Institute for Quality and Efficiency in 2004. In Belgium, a health care knowledge centre was established in 2003, which has HTA as one of its key priorities (KCE 2007). In Austria, HTA activities are not yet well established, although institutes for technology assessment have recently been established.

The fourth category includes those countries that have well-established HTA programmes. The Danish Institute for Health Technology was established in 1997 and works in partnership with a range of stakeholders, and in Finland an independent public agency was created to coordinate HTA in 1995. In Spain responsibility is devolved to the regions. The Basque Country and Catalonia were the first regions to introduce technology assessment and evaluation bodies in 1982 and 1984 respectively. In Sweden, the Centre for Medical Technology Assessment (CMT) at Linköping University was established in 1984 following an agreement between Linköping University and the County Council of Östergötland (the local health care provider). In the Netherlands, HTA has expanded steadily since the early 1990s, and the Health Council is responsible for adopting new technology. Italy has no national agency responsible for HTA. However, many organizations are active in this field: in 2007 the Italian Society for HTA was established, and other centres working on HTA include the Centre for the Assessment of Biomedical Equipment, located in Trieste; the regional Centre for Technology Assessment and Quality Improvement in Health Care, in the Veneto region, which assesses individual technologies; and the HTA Centre at the Cattolica University in Rome.

Finally, in the United Kingdom, the National Coordinating Centre for HTA coordinates the HTA programme on behalf of the Department of Health's Research and Development Division. The purpose of the programme is to ensure that high-quality research information on the cost, effectiveness and broader impact of health technologies is produced in the most effective way for those who use, manage and provide care within the NHS (NIHR Health Technology Assessment Programme 2007).

Organizational quality assessment

The mechanisms used to carry out external assessment of organizations differ from those at the health system level and vary widely. The first important distinction is whether these mechanisms are compulsory or voluntary. Those

which are voluntary are normally carried out by professional organizations and those which are regulatory by government or by agencies acting on its behalf. There are differences between external review programmes driven by professionals (collegial) and those by government (regulatory). Collegial activities are often developmental, focusing on education, self-development, ensuring professional accountability and fostering cooperative relationships. Regulatory approaches tend to be more judgemental, based on aspects that can be counted, such as timely response to complaints and adverse events and compliance with standards (Shaw and Kalo 2002).

External systems for improving the organization and delivery of health services are often characterized by explicit, valid standards, by structured assessment processes and by complementary mechanisms for implementing improvement (Shaw 2000a). The systems presented in this chapter are those which were identified by a research project (Heaton 2000) funded by the EC that explored peer review techniques. This project identified four different models within the EU. These were two industrial models that have been applied to health care (the ISO and the EFQM model and two models developed within health care (Accreditation and Peer Review or Visitatie) (Shaw 2000a). 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.

Some of the different entities involved in organizational quality assessment are detailed here.

The International Organization for Standardization (ISO)

The ISO model provides standards against which organizations or bodies may be certificated by accredited auditors (ExPeRT 1998). It has its origins in defence engineering and manufacturing industries. ISO is a worldwide federation of national standards bodies covering industrial, economic, scientific and technological sectors. The ISO 9000 series is used for the assessment of health care facilities. ISO 9000 standards comprise a set of five individual but related international standards on quality management and quality assurance. Health care facilities wishing to be certified to ISO 9000 standards apply directly to a certification body. The audit is executed by experts in ISO norms, which means that this is not a form of peer review. Although this model has become increasingly popular in the EU, it has also received much criticism. The ISO model does not take account of the impact of health services on population health or clinical results (Heaton 2000; Klazinga 2000). A guide for the use of ISO 9004 in improving performance of health services has recently been published (British Standards Institution, 2007).

We could find no reports of the ISO system being used in the health sector in Estonia, Latvia, Luxembourg, Malta or Portugal. In the Czech Republic, introduction of the ISO standards to the public health system is in the planning stages, although some voluntary activities using ISO norms are being performed in health care facilities. In Greece, many private hospitals and diagnostic centres have been certified by private accreditation bodies using ISO criteria or similar. This approach is also increasingly taking place in some public hospitals, although there is no requirement to do so.

In Belgium, some organizations providing technical, administrative and management services to health care institutions have been certified. In Austria, France, Germany and Sweden, some hospitals have undertaken the ISO 9000 process but, apart from a few enthusiasts, it has not become popular and it is widely seen as inappropriate for health services. In Cyprus, the main hospitals in the private sector have introduced ISO systems. In the United Kingdom, many health care providers voluntarily participate in external assessments (for example accreditation programmes, ISO 9000, Charter Mark) in addition to internal quality improvement initiatives and other forms of inspection. In Denmark a few hospitals have undertaken the ISO procedures, with some laboratories adopting its standards, and in Poland, more than 50 hospitals have gained ISO accreditation. In Bulgaria, some hospitals have introduced ISO standards, whilst in the Republic of Ireland several facilities have recently succeeded in achieving ISO standards in the area of health care. In Finland, ISO standards have been used to inform other quality assurance programmes, and a survey by the Hungarian Ministry of Health from 2004 reported that 76 hospitals in the country were seeking the ISO 9000 standards. In Spain, the statutory quality assurance scheme is based on the ISO standards but the extent of implementation is variable.

Finally, in the Netherlands since 1994, the Foundation for Harmonisation of Quality Review in Health Care and Welfare (HKZ), which includes providers, insurers and patients' associations, has been established to translate, develop and approve ISO-based certification for health care organizations. A number of specific schemes have been developed covering areas such as homes for the elderly, mental health care, community care, pharmacies, ambulances and some aspects of hospital care. If there is a HKZ standard, it takes precedence over the original ISO one. The HKZ has, however, achieved limited penetration of the acute hospital sector.

Accreditation

Accreditation has its origins in 1917 when it was initiated by the American Association of Surgeons, which joined with the American College of Physicians, the American Hospital Association, the American Medical Association and the Canadian Medical Association in 1951 to create the Joint Commission on Accreditation of Hospitals. It accredits United States health care organizations obtaining funding from the federal Government and now, through its international arm, the Joint Commission International, offers a modified programme for health care organizations overseas.

Accreditation is a procedure that seeks to obtain public and peer recognition of the quality of an establishment. It also serves to incentivize establishments to attain agreed standards (Council of Europe 1998). In accreditation, emphasis is often put on specific performance indicators, such as hospital infection rates (Klazinga 2000). It should, however, be noted that the concept of accreditation has at least three different meanings, which is why the term can sometimes be rather confusing. These relate to accreditation of health professionals, health care delivery programmes and facilities (Shaw and Kalo 2002).

Accreditation is primarily relevant where there is a choice of provider and a desire to have an alternative to government control of external quality assurance (Klazinga 2000). In this respect there is a difference between accreditation, certification and licensing. In general, licensing is obligatory, by inspectors, using minimal standards of structure and inputs. Accreditation, which was often voluntary in Europe in the past, is increasingly being funded or managed by governments (Shaw and Kalo 2002).

Shaw and Kalo (2002) have analysed the diverse quality mechanisms that exist. They contend that there is little evidence that regulatory systems have led to sustained improvements in quality, but also that internal mechanisms of organizational and personal development on their own have often also failed. The main conclusion to emerge is the importance of a collaborative balance between voluntary, independent peer review by health professionals (such as clinical audit) as a means of enhancing quality, and a broad framework of statutory, governmental control (such as licensing, registration and inspection) that can ensure compliance with basic standards.

As previously mentioned, accreditation 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 to contract with. Consequently, this approach is of only limited applicability in much of Europe, except potentially in relation to health professionals, although this role is largely covered by professional registration systems. Notwithstanding the

limited scope for a direct transfer of this model, some versions of this approach are being explored (Shaw and Kalo 2002).

In particular, in several countries some hospitals have been encouraged 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 Slovakian 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, a contract between the National Accreditation Body and the Ministry of Health led to the creation of two accreditation committees. In Lithuania, the State Service of Accrediting for Health Care Activities at the Ministry of Health 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). The Danish Government launched a national quality assessment and accreditation programme in 2006. Two regions have sought accreditation with foreign programmes, the Joint Commission International (United States) and Health Quality Service (United Kingdom). Formal certification and accreditation is provided by the Danish and European Quality Awards, which follow the same criteria for Total Quality Management (TQM) as the European Quality Award. Portugal has examined the concept of accreditation and several proposals have been made but it has not been considered appropriate to adopt it.

Other countries have established programmes that are either voluntary or compulsory (Italy, United Kingdom, Spain and Finland). In Finland a health care accreditation programme was introduced in 1993. After exploring the different strategies available, the programme chosen was based on the King's Fund Organizational Audit (KFOA) from the United Kingdom. In France, every public and private hospital must be accredited in accordance with nationally defined norms and standards. These standards are developed by a national agency, the HAS, whereas in Italy, accreditation is performed by regional governments. Several voluntary programmes exist in the United Kingdom, with the KFOA being the most widely known (Shaw 2000), although many of these programmes have become less widely used in the face of the many governmental initiatives that have emerged since the late 1990s. In Spain, the only existing system is in Catalonia, which differs from the other regions in terms of its many private hospitals. The Catalan Hospital Accreditation Programme was established in 1981 and the Health Department of the *Generalitat de Catalunya* (regional government of Catalonia) acts as the accrediting body in Catalonia (Bohigas 1998).

European Foundation for Quality Management

The EFQM model is a framework for self-assessment, used by facilities applying for external review in order to achieve the European Quality Award or other national awards. It was founded in 1988 by the presidents of 14 major European companies, with the endorsement of the EC. The main aims of the EFQM are to stimulate and assist organizations throughout Europe to participate in improvement activities, leading ultimately to excellence in customer and employee satisfaction, and to result in changes to society and business (Klazinga 2000). The EFQM model, instead of aiming at the implementation of international norms as the ISO scheme does, promotes quality management. The EFQM follows the Donabedian structure–process–outcome principle and underlines organizational development through self-assessment (Heaton 2000). Blomberg notes that the self-assessment process allows the organization to discern clearly its strengths and areas in which improvements can be made, and culminates in planned actions for improvement, the progress of which is then monitored (Blomberg 1998). The model has had considerable influence, as it has also been adapted in some countries to form the basis of national awards (Heaton 2000). The model is not, however, widely used in the health sector. The Flemish Centre for Quality Care in Belgium 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 (Vernero, Favaretti and Poletti 2004). In Finland, the EFQM and Common Assessment Framework (CAF) criteria are used.

In Luxembourg, between 2003 and 2006, a quality management programme was introduced, based on EFQM. Again, the programme is focused on delivery of health services in hospitals. Initially, hospitals were rewarded when they implemented the EFQM model. They were evaluated externally but were also asked to submit a self-evaluation report. From 2005 to 2006 a quality premium that had been payable to hospitals adopting the EFQM was supplemented with additional payments against extended criteria.

Finally, in Spain, 12 of the 17 Autonomous Regions use the EFQM model. Some have used it for many years, while others have just started.

European Practice Assessment Practice Management

The European Practice Assessment Practice Management (EPA-PM) framework arose from work by the TOPAS-EUROPE Association and the Bertelsmann Foundation. It offers a means of assessing how well general practices are

organized and managed and is designed to facilitate international comparisons (Engels et al. 2005). The EPA-PM is based around a conceptual framework for practice management with five domains: infrastructure, staffing, information, finance, and quality and safety. These indicators were derived from existing ones and from published research before being subject to a review process involving six national expert panels. The resulting instrument was piloted in 273 practices across 9 European countries.

EPA-PM is used extensively in primary care in Germany and Switzerland and has informed the accreditation system in the Netherlands. It has been used on a smaller scale in Belgium, Denmark and Slovenia.

In practice, a trained facilitator conducts the EPA-PM process during a site visit to each practice. This is a formative process encouraging staff to conduct self-assessments, to reflect on their strengths and weaknesses and to identify scope for quality improvement. This is supplemented by questionnaires for specific staff members and patients. Individual practice feedback is given on the same day. This method of reporting allows practices to compare their performance with that of others and to observe how their performance changes over time.

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 and Lohr 1992). Many countries within the EU are showing great interest in developing and implementing clinical guidelines. This is an area where cooperation and sharing of information is yielding considerable benefits, as shown 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. 2004), and the Guidelines International Network G-I-N, a Scottish Charity coordinating the activities of national guideline agencies worldwide (Ollenschläger, Marshall and Qureshi 2004).

However, there is considerable diversity in the extent to which EU Member States have established systems to develop and implement guidelines. Countries beginning to introduce guidelines include: Austria, Cyprus, Greece, Latvia, Poland and Romania, while others have long-established systems of guidelines of various types in place, such as Belgium, Bulgaria, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, the Republic of Ireland, Italy, the Netherlands, Norway, Slovenia, Spain, Sweden and the United Kingdom (Guidelines International Network 2007).

In the Czech Republic, the National Board for Medical Standards evaluates the current state of medical guidelines and converts them into standards of effective medical care (Gulácsi, Nizankowsky and Bourek 2000/2001). In Denmark, the Good Medical Department Program has developed clinical standards and indicators for the entire continuum of care for in- and outpatients. The Finnish Medical Society has been producing electronic guidelines for primary care since 1988. Its guideline collection is reported to be used by nearly 100% of Finnish physicians, and is viewed as the most important single source of medical information in Finland (Kunnamo 2005). In France, ANAES, now the HAS, has published approximately 30 recommendations on clinical practice.

In Germany, the Scientific Medical Societies and the Physicians' Self-Governing Bodies have been issuing clinical practice guidelines since the mid-1990s. In 2002 a National Disease Management Programme was established based on clinical guidelines (Ollenschläger and Kopp 2007).

In Spain, the Catalan Agency for HTA has begun preparing clinical guidelines and teaches methods of guideline development. Consensus guidelines figure prominently in the Catalonian health care reform. In 1996 alone, the technology assessment agency in Madrid disseminated over 10 000 copies of clinical guidelines and technology assessments (Woolf, Grol and Hutchinson 1999). The Dutch College of General Practitioners has produced clinical guidelines since 1987, and it has issued more than 70 sets of clinical guidelines at a rate of 8–10 topics per year (Woolf, Grol and Hutchinson 1999). The Department of Health in England and Wales has created the National Institute for Health and Clinical Excellence (NICE) to ensure that authoritative national guidance on the latest drugs and technologies is available for all health professionals. An associated development is the publication of National Service Frameworks, which sets out the care that people in certain categories (e.g. patients with cancer or diabetes or children) should expect, spanning prevention, treatment and rehabilitation.

Quality indicators

Quality indicators are gaining importance in many EU Member States. However, there are still many challenges facing those involved in indicator development. Only a handful of 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. For six frequently occurring conditions (lung cancer, schizophrenia, heart failure, hip fracture, stroke and acute surgery for gastrointestinal bleeding), information is collected from the patients' medical records about treatment, severity of the illness and outcomes (NIP 2006).

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 are already collected. In Italy, a set of indicators has been identified, such as epidemiological measures, use of resources and waiting times.

In Germany, in 2001, a national system for medical performance measurement was set up to provide the 2 200 German hospitals with quality measurement tools which can be used for medical benchmarking purposes. The system is focused on quality goals for medicine and nursing which have been defined by expert groups for more than 30 diagnoses and procedures. Every year results and comments are published in quality reports based on hospital data collected during annual national surveys. The national data represent approximately 20% of the case volume in Germany (BQ 2007).

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 (i.e. Diabcare). The Swedish health services also benefit from the ongoing efforts to improve clinical performance and outcomes represented by some 60 national health care quality registers, each containing data on health care outcomes and treatment for a large number of categories of illnesses. These registers serve as a knowledge base for continuous improvement. The Nordic Council has supported a Working Group on National Quality Indicators among the Nordic Countries and has also linked its work to the Health Care Quality Indicators Project by the OECD (OECD 2007). In the United Kingdom, the Healthcare Commission produces performance ratings for NHS Trusts in England, reflecting the priorities of the Department of Health.

Peer review

The Peer Review or Visitation model has been defined as a "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 1998). This model has been developed most extensively by the Dutch medical associations (Box 2.3). A key condition for the success of visitations is a climate of trust. Visitation demands a self-critical and learning attitude from physicians. At the same time, visitators are asked to assist those being visited, by giving them feedback on their performance and diagnosing the department's opportunities for improvement. The visitation programmes are organized and administered by peers (ExPeRT 1998). In the United Kingdom, an annual appraisal based on peer review is in the process of becoming a pre-requisite for remaining licensed to practise medicine (Heaton 2000) and physicians have

Box 2.3 *The Dutch visitatie model*

The visitatie system originated in the Netherlands in the late 1980s as a doctor-led and -owned system of peer review designed to assess the quality of care provided by groups of hospital-based medical specialists (Lombarts and Klazinga 2001). The system is organized with specialist groupings and involves visits by a group of peers every 3–5 years. The findings are documented in confidential reports that contain recommendations for improvement. Responsibility for implementing the recommendations lies with the specialists who are visited but some specialist societies offer support from management consultants (Lombarts, Klazinga and Redekop 2005).

been required to undertake audits and other forms of peer review since the early 1990s.

In Belgium, since the end of the 1990s, hospitals have 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, professionals have adopted peer review during the 1990s in order to create impetus for continued quality improvement. In Malta, there are plans to expand existing peer review activities, and in Poland, professional involvement in quality of care includes the development of consensus on standards and involvement in peer review. In Slovenia it is mandatory to engage in peer review in hospitals, but there is no monitoring of the extent to which this takes place.

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 popular satisfaction with health services, although the results have been inconsistent in successive waves. In Spain, a contract between INSALUD and each hospital sets out quality objectives. Evidence of achievement of these objectives comes, in part, from surveys of patient satisfaction as well as claims and complaints. The Department of Health in England has established a National Survey of Patient and User Experience, involving a rolling programme of large-scale surveys of patient experience in different parts of the NHS. In Austria, consumer surveys are reported to be in the process of development, while the Estonian Health Insurance Fund carries out regular satisfaction surveys. In Hungary a computerized nationwide patient satisfaction survey is being established (Gulácsi 2003). A patient satisfaction survey conducted in Cyprus revealed that patients were less satisfied with services provided in 2002 than in 1996, and

that they were more dissatisfied with the public sector than the private sector. In the Republic of Ireland, surveys in 2000 and 2002 of patient perception of the quality of care received during hospitalization (Dunne et al. 2002) found that patients were satisfied with the level of care they received, with levels varying between 88.9% and 95.7% in 2000 and 92.9% in 2002. In Poland, a public opinion survey reported high levels of discontent with the reformed system: 62% of the public believed that the reformed system was worse than the old system, 70% believed that the public sector does not work properly and 57% did not believe that the changes had led to an improvement. The Slovak Association of Hospitals conducted a survey in the mid-1990s that revealed low awareness of patients' rights, leading to the drafting of a "Charter for Patients' Rights". A further survey, conducted in 1999, again showed poor awareness. In April 2001 the Charter was adopted by the Slovakian Government. In Slovenia a postal survey among patients revealed that health care reform was seen as having improved health care quality, in particular the ability to select a family doctor and the level of satisfaction with family doctors. In Romania, the Centre for Health Policies and Services initiated in 1999 a series of studies regarding the health status of the Romanian population and the way in which health services respond to health needs of the population. Five studies are available at the time of writing: two public and three among physicians. These studies also investigated patients' opinions about quality of care. The 2006 public study reveals that the quality of medical services provided in Romanian hospitals is perceived as "good" or "very good" by approximately one third of the respondents. In addition, approximately 30% of the population considers that medical services in the country are of "average" quality and one quarter assesses the services as being of "poor" or "very poor" quality (CPSS 2007).

Chapter 3

Patients, quality of care and cross-border care in the European Union

Introduction

This chapter seeks to present the issues pertaining to quality of care when care is delivered *in a cross-border setting*, that is, when patients travel to be treated outside their home country.

The chapter is divided into three parts. Before entering the discussion on quality of care it is necessary to explain what we understand by *cross-border care* and to introduce the different categories of mobile patients we have identified. The first part of the chapter will therefore present five patient types which constitute a useful way to conceptualize cross-border care and to understand the motives for which and the arrangements through which people use health care services outside their home country. Following on from this, the second part focuses on quality of health care in cross-border settings from the *patient perspective* and will be based on patient surveys and interviews to highlight the needs, expectations and satisfaction of those who have experienced cross-border care. The third and final part complements the second by examining quality of cross-border care from a *functional perspective* to see what mechanisms are in place to ensure quality of care and fluid communication between health professionals in projects involving providers, purchasers, and health authorities from both sides of a border. This latter part will be based on descriptions of projects in the literature and where available, on the opinions and experiences of stakeholders involved.

Methodology

Sources

The chapter draws 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 EU (Glinos and Baeten 2006). 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 taking 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 input for this chapter. As studies reporting on patient experiences do not abound, it is even more challenging to obtain studies which address users of cross-border care. In total, eight such studies have been examined for the chapter. In addition to the surveys and interviews, the literature review also extensively covers reports and studies describing cross-border arrangements and their functioning; where information on quality assurance mechanisms in cross-border settings is available, this material has been included in the chapter.

Limitations

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. Reports and documentation are of varying quality, data are often unreliable or unrepresentative and in any case incomparable between projects and between countries. Furthermore, the nature of some types of patient mobility based on institutionalized cooperation between stakeholders, often with the involvement of public authorities, means that more has been written on these projects. Formalized structures of patient mobility may thus be overrepresented in the literature in comparison to patient mobility, which is initiated by individual patients who are mostly treated in commercial settings when they go abroad. The lack of written material does not, however, make this latter group less important.

Another limitation is the geographical representativeness of documentation. As will become clear to the reader, most sources of information stem from countries of "heartland" Europe, i.e. the Benelux countries, France and Germany, Scandinavia, the British Isles and to some extent from eastern European countries; much less is available on countries of the Mediterranean.

The lack of evidence can signal that no patient mobility takes place in some regions, or that nothing has been written on it if it does take place, or that it is very difficult to get hold of such information.

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 and which we have already described, there is only very limited information on why some patients choose to travel – or not to.

I: The users of cross-border health care: mobile patients

The policy response to the issue of patient mobility has, to a considerable extent, been shaped by the circumstances of those patients who have gone to the European Court of Justice because they believed that their right to obtain treatment abroad was being infringed. However, in reality, the vast majority of health care is obtained from providers located in the same country with individuals often unwilling to travel significant distances, even in their own country. Yet distance is not the only discouraging factor; people will generally be even more reluctant to seek care abroad where they may face language, administrative and financial barriers (such as travel time and costs). The desire to be treated near to home is apparent in the protests that typically greet attempts to close hospitals. Indeed, one can generally assume that patients want to be treated as close to home as possible, by providers speaking their own language, surrounded by their relatives in a system with which they are familiar. However, in some circumstances patients are willing to use cross-border health care – either because they happen to be outside their country at the moment the need for medical assistance arises, or because cross-border health care offers some advantages in comparison with care available at home. Through research as part of the *Europe for Patients* project, five sub-types of *mobile patients* have been identified, which fall into two broad categories (Box 3.1).

Box 3.1 *Typology of mobile patients*

Patients who are abroad when in need of health care

- Temporary visitors abroad
- Long-term residents abroad

Patients who go abroad for the purpose of obtaining health care

- People living in border regions
- People sent abroad by their home systems
- People who go abroad on their own initiative to seek treatment

The distinction detailed here is important, as patients will have different needs and expectations depending on whether they happen to be abroad when they fall ill or whether they go to another country deliberately to seek health care. The latter case implies the patient making a conscious choice and it could be argued that the aspect of patient expectations is more prevalent when considering "deliberate" patient mobility.

Each of the five patient types will be examined in turn to see what features characterize them as patients and what arrangements, practical as well as financial, make it possible for them to obtain health care in another EU Member State.

Temporary visitors abroad

People who are abroad for a short period, such as tourists, mainly need emergency assistance or treatment for chronic conditions when abroad; if further treatment is necessary they usually return home.

Recent years have seen a surge in the volume of tourism in Europe. Factors such as increases in real incomes, reductions in the cost of travelling as well as growing numbers of retired people have contributed to making year-round travel abroad a reality for many people whose parents might never have left their own town or even village. These are the individuals for whom the E111 scheme was developed, subsequently replaced by the European Health Insurance Card (EHIC), enabling them to obtain care abroad in the event of an emergency. The mechanism has its legal basis in the Regulation 1408/71 which entitles European citizens to treatment which becomes medically necessary during their stay in another Member State. There are, however, certain circumstances in which the mechanism does not work as intended.

In parts of Europe there are very large seasonal influxes of tourists. An example is the camping sites in the Veneto Region of Italy where the population in some areas may be swollen by several thousand people every summer. This has required the Veneto public authorities to put in place extensive infrastructure to absorb the upsurge in demand, for example by setting up additional medical centres in proximity to large camping sites during the summer months. In other parts of Europe, where authorities have been less willing (or less able) to respond to seasonal changes, facilities may come under severe pressure at certain peak periods of the year.

Other problems may arise when some providers are unwilling to accept an individual's EHIC, instead demanding that they pay out of pocket for the care provided (and potentially obtain reimbursement using their travel insurance if they have it). In some places, there are highly developed networks, often involving taxi drivers who divert patients away from public facilities and redirect them to private providers. Patients are especially vulnerable to such practices if they have an acute or painful medical problem, if they do not speak the language of the country and/or are ignorant about how the health care system works. A study of German tourists abroad revealed the access problems tourists may face: 40% of those treated in Austria and only 18% of those treated in Spain were successful in using their E111s as intended when they fell ill (Agasi 2002).

On the other hand, there are situations in which individuals receive treatment without having to produce their EHIC. While this does not pose problems to patients, it does have important implications for local providers. An illustration of this is the many Spanish hospitals where care is provided to tourists but details from the E111 are not recorded because there is no incentive for the hospital to do so. When information is collected and transferred to the central authorities (as the E111 procedure foresaw), any reimbursement from the patient's funding institution in the home country is retained at the central government level and not passed back to the hospital. Finally, as with any documentation, people forget to apply for an EHIC before travelling, they leave it at home, or lose it.

Although the EHIC is at the time of writing simply a card containing basic details of the bearer, there are ongoing discussions about combining it with national smart cards that might act as a form of electronic patient record. There are, however, many unresolved issues. These include the medium of data storage, with some countries using magnetic strips on their cards (e.g. Spain and Portugal) while others use microchips (e.g. Germany, France, Lombardy Region in Italy, and Austria). Yet even if this could be resolved, there are many other issues to be addressed, such as compatibility of data content, data format, readability, encryption and security.

Long-term residents retiring to other countries

A second group of people requiring care when abroad is the growing number of people retiring to another country. These people will have very different health care needs compared to tourists, precisely because they settle down in another country over the *long term*. Although such retirement-related movements have existed for many years (an example might be Irish people returning to the Republic of Ireland after spending their working life in England), the numbers involved and the destinations being chosen have changed greatly. There are now thousands of people from northern Europe who are retiring to southern Europe. Typical destinations include Spain, Portugal, France, Italy and Greece but less significant and yet rapidly increasing flows have also started towards Croatia, Bulgaria and Turkey. They are mostly concentrated in certain regions of these countries such as the areas around Malaga, Alicante or the Balearic Islands in Spain, Provence and Côte d'Azur in France and the Algarve in Portugal. Their rights are also based on Regulation 1408/71, which established a series of mechanisms by which individuals can obtain health care in another Member State.

These new population groups are giving rise to several issues. One is that of age-related dependency. Traditionally, social care for vulnerable elderly people in southern Europe has been based on family support. Yet, the new population of elderly settlers have left their children and social networks behind and may face severe problems if in need of home-based or long-term care. Because of capacity constraints, elderly foreign residents (despite their rights) are rarely high on the priority list. In contrast, residential care services for the elderly in northern Europe tend to be better developed and often fall within the publicly funded system.

In addition to concerns over access to in-kind care services, it is reported that some long-term residents are concerned about being disadvantaged because of the less generous social benefits in the Member State to which they are moving. For example, pensioners in the United Kingdom have supplementary benefits such as winter heating allowances, disability allowances and care allowances that are not available in some other Member States. Language barriers are another concern reported by key informants. Together these factors can create problems for newcomers in countries with different linguistic and cultural traditions from their home country. Hospitals in Spain, which is a common destination for retirees from northern Europe, are becoming aware of the need to assist non-Spanish speakers and are beginning to include language skills as a criterion for hiring new staff.

In addition, difficult situations may arise in the event that one partner passes away. Given the difference in life expectancy between men and women, it is most often women who become widowed. If the surviving partner is unable to drive and has limited language skills, the situation may become particularly dire as she(/he) risks becoming very isolated.

A problem of administrative nature is that some newcomers do not transfer their social rights to the new country of residence as they are afraid of losing the option of returning to their home country should they come to need important treatment. In general, these patients do not mind using the health care facilities of the new country for simple matters such as GP consultations but are likely to prefer to return to the home system which they feel familiar with for more serious conditions requiring hospitalizations. As large numbers of long-term residents opt not to regularize their situation, they form part of the "floating population" (Rosenmoller and Lluch 2006). There is no clear provision for these groups as they are not officially regsitered, which becomes particularly problematic for patients with chronic diseases.

People living in border regions

A glimpse at a map of Europe reveals the numerous borders on the old continent. Borders do not just separate countries they can also be the point where cross-border communities meet. In countless parts of Europe, border regions are vibrant areas of exchanges, interchanges and cross-border movements, where crossing the border is an intrinsic part of people's lives and where cross-border cooperation in the field of health care has been going on for many years, sometimes decades. Patients willingly cross the border to obtain care from a provider they feel comfortable with and who might speak the same dialect as they do; insurance funds seek to make agreements with providers "on the other side" to allow access for their affiliated members; and local hospitals might welcome the influx of (not-so) foreign patients as this extends their catchment populations.

To ease the cross-border flows of patients, of payments and of information, structural arrangements have in many cases been set up by cooperating partners on each side of the border. These partners usually include funding institutions (e.g. a health insurer), health providers (individual or institutional) and/or public authorities (e.g. a local health authority). The cooperation arrangements can take various forms: direct contracts between sickness funds and providers such as those concluded between Dutch insurers and Belgian hospitals; collaboration agreements between providers such as the long-standing links between the academic hospitals of Aachen (Germany) and Maastricht (the Netherlands);

or indeed, cooperation based on shared health care facilities which may involve joint financing (e.g. the Danish local authority of Southern Jutland co-financing a radiotherapy unit in the German St Franziscus Hospital in Flensburg) and sometimes even common management (as in the planned cross-border hospital to be built on the Spanish-French border in the Pyrenees).

It is important to note that patients who use health care services in border regions often do not to perceive "the other side" as foreign but rather as part of their homeland. In some regions, the cross-border communities share a common history, culture, language or dialect, and traditions – which may all contribute to a feeling of shared identity. If so, people might well feel more attached to the neighbouring region on "the other side" than to the State whose authority they actually fall under.

The cross-border care used by populations in border regions can span the entire range from emergency services organized across the frontier, consulting a doctor in ambulatory care, or accessing highly specialized hospital care. As distances generally are relatively short it becomes possible in some cases to benefit from complementarity between providers as in the case across the French–Belgian border where Belgian patients can access the infectious disease department of Tourcoing Hospital (FR) while French patients can go to Mouscron Hospital (B) for dialysis.

The practical and financial arrangements which make it possible for patients to use cross-border facilities are as a general rule either based on direct cross-border contracting or on a relaxation of the Regulation 1408/71 procedure so that border region populations are not required to ask for prior authorization from their funding institution but can freely access care across the border. Relaxed access schemes usually cover a precise range of services which will be specified in the agreements between cooperating partners.

People sent abroad by their home systems

If people in border regions go abroad for health care because they feel closer to it, other population groups do so because the health care they need is not available in their home system. Availability of care, or the lack of it, should be considered both in terms of the quantity of services and in terms of the type of services available. Some health care systems suffer from (structural) undercapacity, which might result in lengthy waiting times for patients and waiting lists for certain treatments. In other systems, decision-makers might choose not to provide the entire array of medical services, which are technically possible, based on calculations that population numbers are too small to economically justify investments in highly specialized care facilities. In either

case, public health authorities might decide to set up schemes allowing their nationals to go abroad for certain types of treatments which cannot be obtained at home or at least not in due time. Such national programmes have been set up in recent years in England, Norway, the Republic of Ireland and Denmark[1] in the face of long waiting lists in the public systems, while Malta has a long-established cooperation programme with the United Kingdom through which patients with rare or severe conditions requiring advanced treatment have been sent to selected British hospitals since the 1970s.

Such national schemes for cross-border care present several advantages to patients. First, patients are being guided through the entire process as all medical, logistic and travel aspects of cross-border care are organized for them: transport arrangements such as airplane tickets are booked; hospital rooms are reserved; and medical appointments, including pre- and post-treatment consultations, the actual treatment (e.g. an operation) and if necessary rehabilitation, are organized for the patients. Second, public authorities generally go to great lengths to check the medical expertise and quality standards of the foreign providers to which they send their patients and they have strict requirements on quality, safety and hygiene.

On the other hand, however, where cross-border care involves travelling considerable distances, patients may feel isolated if they are unaccompanied, especially if the illness is serious. Furthermore, the journey back home after surgery can, in some cases, prove very unpleasant.

The treatments for which patients go abroad under such schemes can vary considerably but will generally involve significant surgery. English patients have been going to France, Germany and Belgium for hip and knee replacements as well as cardiac surgery; Norwegian patients have been going for conditions relating to the muscular, skeletal or circulatory system; while Maltese patients are sent to the United Kingdom for treatments such as transplants.

People who seek treatment abroad on their own initiative

The least documented, least studied and perhaps the most heterogeneous group of mobile patients is those who decide to look for treatment or medical assistance in another country on their own initiative. They have various reasons for doing so. The flows of patients going to eastern Europe for cheap dental treatment are just one example; others include people travelling to obtain aesthetic surgery, fertility treatments, abortions or even euthanasia. What most of these medical services have in common is that they do not form part of the benefits package

1 It should be noted that in the cases of Ireland and Denmark, patient flows have been going mostly to the private sectors within each of the two countries; only few patients have gone abroad – in the case of Irish patients to the United Kingdom and in the case of Danish patients to Germany and Sweden.

of the public system from which the patient comes, sometimes because the services are outlawed, as is the case with abortion and/or euthanasia in some EU Member States. What then motives people to travel for these services is that they are either cheaper (often the case with dental care and plastic surgery), more readily available (due to waiting lists at home for fertility treatments or cardiac surgery) or simply not illegal and therefore safer and easier to access abroad.

People who travel abroad for these types of medical care can do so through their private health or travel insurance, or they might pay out of pocket. The sources of information through which people learn about the options for "faster access" or "cheaper care" reflect the private nature of this type of patient mobility. Potential patients generally find information about cross-border health care from the Internet, the press, from brokers acting as middlemen or from their private insurer.

Patients going abroad on their own initiative are likely to circulate in networks of commercial health actors, potentially giving them fewer guarantees that the quality standards that apply to providers in the public sector will be adhered to. It is widely recognized that patients do not have the necessary knowledge to assess the quality and appropriateness of care they receive, which is why the public system has a role in ensuring standards for quality and safety in the health care sector. Concern about the lack of quality guarantees when people are treated by commercial providers outside the public system is further accentuated when patients go to a country where they do not speak the language and where they are unfamiliar with the health care system. This makes it particularly difficult for them to check whether the provider is qualified and accredited.

In addition, the fact that patients receive treatments outside the public system also implies that these patient flows are less well reported; statistical evidence is virtually impossible to obtain; and surveys of these patients hardly exist. What we know about this patient group is generally anecdotal material and press cuttings. In contrast, patients who go abroad through national schemes or in the setting of cross-border cooperation projects are widely documented as public authorities often are required to report on their initiatives and even to carry out patient surveys and assessments.

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

In this section patients' experiences with cross-border health care are presented. The focus of the analysis will be on the various dimensions of quality of care.

The section will not categorize the findings according to the five patient types but instead follow the broad topics which emerge in the surveys and interviews. This approach appears more relevant as it highlights patients' concerns. Furthermore, it avoids imbalances as questions in surveys are often not comparable and as there is less abundant evidence on some patient groups. The final part of the chapter will instead conclude by summarizing the needs of each of the five patient groups.

Defining the scope of quality in cross-border care

Due to the particularities of care delivered in cross-border settings, the notion of "quality of care" has been widened to include aspects intrinsic to cross-border health care, such as:

- travelling time, effort and comfort;
- geographical displacement and emotional costs associated with it;
- perception of the foreign providers (doctors and medical staff) – feeling of confidence, trust and of being in safe hands;
- linguistic/sociocultural problems or misunderstandings.

Sources and references

The sources that are used adhere to 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, and over which time period. In terms of content, all the studies 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, have not been included. The surveys and interviews on which we have based the analysis are explained in the following subsections.

Surveys carried out in border regions

A patient survey carried out in the Belgian component (Boffin and Baeten 2005) of the *Europe for Patients* research project involved questionnaires being sent 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 is concentrated in the border regions with Belgium. After drawing a random sample of 1195 adult members of CZ and OZ recorded as having cross-border contracted care in the second part of 2004, it was possible to obtain sufficient details to

send out 1120 questionnaires in February 2005. 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 Health Care Management) (Grunwald and Smit 1999) during the *Zorg op Maat* (ZOM) project in which Dutch inhabitants benefited from easier access (through a relaxed version of E112 called E112+) to German and Belgian health care facilities, including specialist care, in the Meuse-Rhine Euregio. The first questionnaire asked Dutch patients, who had received their E112+ form in 1997, about their opinion on information concerning the project, and 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 conducted with local Dutch doctors. A total of 458 patients took part in the first survey and 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 and Fransen 2003). Access to the hospital, which is located approximately 15 km away 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; 95 patients sent back their questionnaires (a response rate of 82%), of which 81 had received ambulatory care and 14 patients had been hospitalized.

Interviews were carried out in 2002 with 11 Dutch patients who received orthopaedic surgery in the Belgian hospital Ziekenhuis Oost Limburg (approximately 25 km away from the border) (Engels 2003). Orthopaedic patients were chosen because the survey focused on problems with cross-border after-care. In total, 33 patients were contacted. One third of 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 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", for which the Norwegian 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 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. A total of 3419 replied to the questionnaire (a response rate of 71%). The Norwegian study also offers some comparisons with data from 1996 and 1998 when patients treated at local hospitals in Norway were surveyed.

A patient survey was undertaken during the English NHS pilot project in which patients waiting for orthopaedic and ophthalmologic surgery were sent to France and Germany 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 used with 26 English patients treated in two German hospitals in Essen and in Cologne in early 2001 (Birch and Boxberg 2004), 24 of whom went through the NHS pilot project (described above) and 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 to November 1999 by the German sickness fund *Techniker Krankenkasse* among members who had submitted a request for reimbursement following a stay abroad during 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 (a response rate of 35.7%).

Methodological limitations of the findings

While the overall assessment of cross-border care by mobile patients is generally positive, several methodological cautions should be mentioned, as described here.

Lack of reference groups. As most of the surveys do not use reference groups, we cannot compare the satisfaction rates and experiences of people treated abroad with people who were treated in their home system. Only the Norwegian study offers an approximate comparison.

The Hawthorne effect. Actors might alter their behaviour when they know they are being observed. This applies to patients as well as providers. As one

English NHS patient noted: "the doctors were very, very good to the point that I felt they only wanted good reports back to the United Kingdom".

Medical versus nonmedical. People might be more explicit and critical about nonmedical aspects of care (food, friendliness of staff, cleanliness) as they are able to evaluate these better than medical or technical aspects. Such satisfaction or dissatisfaction rates do not, however, say much about the quality of treatments.

Gratitude. Cross-border patients might naturally be inclined to feel grateful to the foreign providers and the foreign health care system which, in a sense, have "rescued" them. This might be particularly true for patients who have been on waiting lists for extended periods and for whom treatment abroad brings enormous relief. According to the surveys, some English NHS patients had been waiting for almost two years, while the mean amount of time since patients were put on an inpatient waiting list was 260 days. Data on Norwegian NHS patients showed that 52% had been waiting for treatment for under one year, 20% between one and two years and 12% between two and three years. Dutch CZ patients going to Belgium for bariatric or abdominal surgery had been waiting for almost 18 months.

Selection bias. As mentioned earlier, the surveys we have examined concentrate on patients who receive *institutionally arranged cross-border care*, that is care which is organized by the institution, such as an NHS body or sickness fund, which funds the treatment abroad. The institution which finances and organizes the practical, medical and travel aspects of the cross-border care may also carry out patient surveys in connection with it. Sound and solid data on the experiences of people who are abroad at the time at which they need care (e.g. tourists) and of those who themselves manage the cross-border care arrangements (e.g. for dental or cosmetic surgery) are virtually impossible to obtain. Only anecdotal evidence from newspapers and magazines exists on this latter type of patients; yet the lack of "scientific" data and of patient surveys directed at these cross-border care users does not imply that the issues they are concerned with are less significant; in fact, quite the contrary. It is precisely patients who go abroad on their own initiative through commercial arrangements who might be most vulnerable in terms of the quality of care they receive.

Results and findings

The main finding of the surveys is the high levels of satisfaction with the overall cross-border experience expressed by a majority of respondents, independently of where they come from and of where they travel to. However, there are differences in the needs and experiences of patients with serious conditions

travelling long distances and patients travelling in border regions. Problems that seem to be encountered most often by cross-border patients involve the travelling itself and financial issues, as well as the emotional costs associated with the distance from home, access procedures, long processess and continuity of care.

Access, distance and travel

Patients have different experiences and different needs regarding access to cross-border care depending on their medical situation, physical condition and geographical location. People living closer to the cross-border provider (i.e. mostly people in border regions) are more likely to be concerned about access mechanisms and administrative procedures, while people who travel from further away (and who generally go through national schemes that arrange the practical aspects on their behalf) are more worried about the ease and comfort of the travelling, the costs and the fact that the distance is an obstacle for relatives to visit them (explored in more detail later).

Patients going frequently for cross-border care express most concern over access procedures. Border-region patients use cross-border facilities because they are within reach, and travelling times and distances are shorter both for the patient and for relatives. Also, these people are less likely to perceive the border as an obstacle because they are used to commuting back and forth for activities relating to work, leisure and shopping.

In the border region where the ZOM survey was carried out, over half the respondents found that there was room for simplification of the complex procedures, the multitude of institutions involved, as well as the difficulty of and delays in obtaining authorizations to go abroad (Grunwald and Smit, 1999). This is not surprising as patients had approximately five different stages to go through with different institutions, and with the possibility of delays in between each stage. On the other hand, 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 patients' Dutch GPs.

For patients having to travel longer distances, the trip home can be difficult and painful, especially after surgery. This was mentioned as the most negative aspect of cross-border treatment by a majority of Norwegian patients (53%) (HELTEF 2003). In comparison, only 17% of patients had a negative experience of the outbound journey, while 53% had a positive experience. The median travelling time was six hours from the patient leaving her/his home until they reached the foreign hospital. The maximum travelling time reported by one patient was

96 hours. The survey did not ask respondents about the duration of the return trip.

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 journey back. Of those who did not have anyone with them, some did express a need to be accompanied. A total of 11% of respondents had felt the need for an accompanying person during the journey out, 18% during the stay in the hospital and 38% during the journey home. There were notable differences between the replies of men and women on these questions, as almost half of female respondents had missed having an accompanying person on the trip home, while less than a quarter of male respondents had felt this way (HELTEF 2003).

Among English NHS patients travelling to France and Germany during the pilot project, the "journey home" was also rated somewhat less positively than the outbound journey: 93% of patients sent to France and 88% of patients sent to Germany said that the outward journey was quite or very satisfactory, while the respective satisfaction rates for the travel home were some 10 points lower, at 84% and 77%. Furthermore, when asked how the travel arrangements could be improved, respondents' answers indicated a need for more comfort and ease – more comfortable vehicles (e.g. more legroom), less walking on the platforms, reduced waiting and travelling time (some patients had been travelling for up to 15 hours on the journey home), priority for patients at stations, and reservation of seats. These appear reasonable requests from people who mostly travelled abroad to obtain surgery for hip and knee replacements (Lowson et al. 2002).

German patients who were abroad at the time they needed cross-border care reported problems with the E111 form, as approximately 40% of patients treated in Spain, France and Italy had to pay the foreign provider themselves, despite having the correct form (Techniker-Krankenkasse 2001).

Costs

The costs related to receiving treatment abroad are closely related to the profile of the patients concerned and to issues of access and distance. When considering possible costs of cross-border care to the patient one should bear in mind that these can be both financial and nonfinancial.

There appears to be a correlation between the seriousness of patients' medical conditions and the financial and psychological costs that the patient and relatives incur with cross-border care. The more serious the condition, the longer the stay in hospital is likely to be and the greater the need for support

from an accompanying relative. One can easily imagine how feelings of homesickness, loneliness and anxiety become all the more acute when patients suffering from serious and sometimes painful conditions are far from home for extended periods. At the same time, financial costs also increase with distance, as relatives have further to travel. The situation becomes even more sensitive when it involves a child to be treated abroad.

Patients from Malta who have to travel due to a lack of highly specialized treatments at home may be hospitalized abroad for serious conditions requiring repeated interventions, or for longer periods (e.g. for bone marrow transplants). If several trips are necessary, cross-border care becomes even more costly for patient and relatives. The Maltese treatment abroad scheme pays for airline tickets, subject to means testing, but anyone accompanying the patient has to pay for their own travel and accommodation (Muscat 2004; Muscat et al. 2006). As the experience of Malta shows, expenses related to transport and lodging of relatives is one of the main concerns for patients and their families. Maltese patients are usually sent to hospitals located in London where accommodation prices are especially high.

As an anecdotal illustration of the emotional costs of cross-border care and the link with the severity of the medical condition, the testimony of a Swedish cardiac patient is also indicative. Having undergone bypass surgery in Denmark due to long waiting lists in Sweden, the patient stressed in an interview after the treatment that he had been overwhelmed by the complexity of the operation and the time it took to recover, and underlined how important it was to have the support of a relative (Ingels 2001).

The overall cross-border experience

A consistent finding from patient surveys is the high level of satisfaction with cross-border care. In some cases, it appears that people are even more content with the care they obtain abroad compared to that which they would (expect to) receive in the home system.

This is illustrated by the results of the ZOM survey. Respondents (from the Netherlands) were asked to give the reason(s) why they had crossed the border (to Belgium and Germany) for health care. While faster access to care emerged as the most common motivation (for almost 90% of respondents), a series of other reasons related to the *quality* and the *content* of care also scored very high. For 78% of respondents, care abroad was considered more thorough/complete, while 72% felt that treatment was different compared to that in the Netherlands. Three concrete examples given in the study are orthopaedic after-care, where physiotherapy is included in the package in Germany; oncology, where more

alternative therapies are available in Germany; and ophthalmology, where German doctors are quicker to make use of laser treatments. A total of 70% of respondents also identified faster results and good after-care as arguments for using cross-border care. What makes the findings all the more noteworthy is that over 50% of respondents had already had a previous experience with cross-border care, indicating that people know what to expect when they cross the border *and* that they do so precisely because they feel that the type and quality of care on the other side of the border suits their needs and expectations best. It can therefore be suggested that the patients in the border region weigh up the alternatives and base their decision on a comparison between facilities and services at home and abroad (Brouwer et al. 2003).

On the whole, cross-border patients in the ZOM surveys were pleased with the care they received in Belgium and Germany, as 67% declared themselves to be "very satisfied" and 23% to be "satisfied".

The survey on Norwegian cross-border patients produced similar results. When questioned about the overall experience of having been a patient in the treatment abroad programme, 71% of participants answered "very positive", 24% said 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 majority (68%) answered that they were "entirely satisfied" by giving the score 10 out of 10. Another 13% of respondents gave the overall care 9/10 and 7.5% gave it 8/10. The Norwegian study also provides an interesting comparison with a survey carried out approximately five years earlier (1996/1998), when patients treated in local hospitals in Norway were asked exactly the same question. In that survey, 34% of patients answered they were "entirely satisfied" (10/10), while 30% gave the score 9/10 and 16% gave 8/10 (HELTEF 2003). Comparisons of other aspects of hospital treatment also showed notable differences in satisfaction rates: in the 1996/1998 surveys, less than one third of respondents had been "very positive" when asked about their impression of the organization of the hospital, unexpected delays, and the attention given by doctors. In contrast, over two thirds of cross-border patients had been "very positive" about these issues. Less than 50% of patients treated in Norway gave a "very positive" assessment of whether they felt that one doctor had been responsible for them and of what they thought of the doctors' competencies, while the vast majority of patients treated abroad (approximately 80%) answered "very positively" to these questions (HELTEF 2003).

The high levels of satisfaction were also confirmed in the survey of English NHS patients who had been sent to Germany and France. Patients were asked to assess the entire experience of their treatment overseas, from first contact

to the after-care received in England. Almost 80% of both samples were "very satisfied" with their experience. No patients ranked their treatment as "very unsatisfactory" and only three patients that were sent to France found the encounter "quite unsatisfactory".

Hospital staff

Helpfulness, competence and professionalism of medical and nursing staff are also aspects of cross-border care which are highly valued in almost all studies. Patients in border regions even state that they go to the neighbouring region because they feel that doctors are better and/or more patient oriented. In no survey did patients have concerns about the competence of health professionals.

In the *Europe for Patients* survey, Dutch patients were asked to give their main reason for travelling to Belgium (Boffin and Baeten 2005). For patients affiliated with the OZ sickness fund, the main reason for going across the border was the reputation of the physician (mean: 4.06) and in second place came 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).

Among patients surveyed in the ZOM project, the patient–provider relationship was a key motivation for travelling (Grunwald and Smit 1999). Five aspects of this relationship were addressed (being taken seriously, not being treated as a number, complaints being better understood, being listened to and being better informed about one's illness) and all reported very positively by Dutch respondents.

Interestingly, in the survey carried out among German patients being treated at the Dutch University Hospital, St Radboud, the highest degree of satisfaction was recorded concerning relations with doctors (Witt and Fransen 2003). Both ambulatory and inpatient patients evaluated doctors' competence and care very positively – and higher than their evaluation of overall quality of care.

Among Norwegian waiting-list patients treated abroad, experiences with the hospital staff were also very positive (HELTEF 2003). Asked whether patients felt that nurses had made enough time for the patient, had been caring and whether the patient had confidence in the nursing staff's competences, between 75% and 80% of respondents answered positively. The two latter questions were also asked regarding the doctors treating them: 63% of Norwegian patients felt that doctors had been caring and 81% had complete confidence in their competence. Strikingly, when the same questions were put five years earlier to Norwegian patients treated locally, satisfaction rates were considerably lower.

Among English NHS patients, satisfaction with medical staff was also very high, with 96% of patients treated in France and 98% of patients treated in Germany reporting hospital staff as "quite" or "very courteous" (Lowson et al. 2002).

Information

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

Some English patients (15% of those going to Germany and 8% of those going to France) stated that they would have liked more information on certain aspects, such as items they should bring, food, hospital procedures, details of the operation, post-operative guidance, arrangements for laundry and details of the journey. Some also suggested that they could have been given a phrase book (Lowson et al. 2002).

Dutch patients going to Belgium were generally positive or very positive about the information they had on matters such as the reputation of the hospital, conditions of reimbursement and the procedures in Belgian hospitals, but would have liked more information on possible extra costs related to the cross-border treatment (Boffin and Baeten 2005). This is not surprising, as out-of-pocket contributions for hospitalization are normal in Belgium but non-existent in the Netherlands.

Of the 11 Dutch patients interviewed after undergoing orthopaedic surgery in Belgium, 5 said they would have wanted more information from their insurer on cross-border care before going abroad. There were also 3 patients who experienced problems with admission to Dutch health care institutions because of fears that they might be bringing infections (methicillin-resistant staphylococcus aureus, MRSA) with them from Belgian hospitals; these patients would also have liked to be better informed on the differences in infection control policies between Belgium and the Netherlands (Engels 2003b).

Continuity of care

Safe, well-defined patient pathways with no gaps between the different phases of care are especially important in cross-border contexts where continuity of care to a great extent depends on the willingness of health professionals to cooperate

with each other.[2] The cross-border transfer of information on patients is an essential prerequisite for the safety of the entire care experience, from referral to full recovery. In the surveys reviewed, some patients experienced reluctance on the part of their referring physician to send a referral letter or to transfer their personal files. There is also evidence from other studies of doctors refusing to cooperate with physicians to which "their" patients are referred. Even when there is full cooperation, the process may be complicated by differences in clinical practice and terminology.

Given the central role played by doctors, the following analysis of patient surveys will look both at questions on continuity of care and at questions about patients' experiences of how their home-based doctors and hospitals reacted towards the option of sending patients abroad. This is especially important as the patient's usual doctor will provide care *before and after* cross-border treatment. In several cases patients have complained about difficulties in accessing providers at home. Two English patients complained that their NHS surgeon refused to see them upon their return (HELTEF 2003). Some Norwegian patients seeking after-care from their GP reported negatively on how they were received, and more reported problems when visiting hospital doctors and emergency departments. However, these views were relatively infrequent, as 70% believed they were well received by their GP and 60% of those accessing a hospital or polyclinic also reported a positive experience.

This diversity is also apparent in relation to access to the cross-border programme. A total of 18% of Norwegian patients took the initiative to be sent abroad by asking at their local hospital whether they could take part in the overseas scheme. Of these patients, 47% expressed that their wish to go abroad was received with a positive attitude from the Norwegian hospital, 29% said that their request was received in an acceptable way, while a quarter (24%) reported that they were dealt with in a negative manner and 7% in a "very negative" way (HELTEF 2003).

It should be noted that the treatment abroad project led to heated debates in Norway and considerable media attention, with arguments centred on the outflow of funding from the national system and the risk of infectious diseases from patients treated abroad returning home. This might go some way towards explaining some of the less cooperative attitudes experienced by patients among some health care providers.

The interviews with the 11 Dutch patients that 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

2 Cross-border cooperation between doctors is further examined in the next section on cross-border mechanisms.

specialists were positive towards the possibility of cross-border care, others were far less supportive. Some GPs refused to write referral letters and/or give patients their personal medical file. In one case a specialist explicitly asked the patient not to tell other Dutch specialists that he had mentioned the possibility of cross-border care to the patient.

As the patients selected for the survey received orthopaedic treatment and were elderly, they all needed some after-care. A total of 8 of the 11 respondents had to arrange for after-care themselves (i.e. a spouse or a child did so for them), which is different from usual Dutch practice where the treating hospital contacts organizations (such as rehabilitation or home care) that provide post-treatment care. When back in the Netherlands, there were some problems due to differences in the prescription of medication and infection control policies (Engels 2003b). As mentioned earlier, three patients had difficulties accessing Dutch care institutions after treatment in Belgium due to fears of contamination with MRSA. One patient had to stay longer in the Belgian hospital because there was no space available to be admitted in a Dutch care institution. These patient experiences identify a certain segmentation of the care path as patients face difficulties in going from one phase of care to the next.

The interviews with the 24 English patients treated in Germany also reveal a somewhat mixed picture of the quality of follow-up care in the United Kingdom. Six patients rated it as "excellent", three as "good" and five as "satisfactory", while additional comments provided by some patients indicated that they were not treated appropriately. Two patients did not need follow-up care. Yet, 10 patients rated after-care as "unsatisfactory", among which four patients did not receive any after-care at all, with one complaining during the interview that her/his knee condition was as bad as it had been prior to operation. Two patients additionally complained that their "NHS surgeon refused to see them upon their return from Germany" (Birch and Boxberg 2004). Some patients also mentioned the contrast between the high quality of German after-care, such as physiotherapy, and the inappropriate treatment they had received when back in the United Kingdom (Birch and Boxberg 2004).

The aspects which were rated most negatively in the *Europe for Patients* survey were also related to patients' experiences once discharged from hospital (Boffin and Baeten 2005). Almost half of the respondents left the Belgian hospital where they were treated with a prescription for pharmaceuticals, yet obtaining the prescribed drugs in their home country (the Netherlands) was rated less positively compared to other aspects of care. The availability and reimbursement of medical devices were also perceived to be suboptimal by the small proportion of patients (14%) who needed them. Last, but not least, the 10% of respondents

who needed home care found that transfer of information to their home care organization was not always optimal.

The hospital environment

Several questionnaires also examined patients' opinions of the comfort and ambience of the foreign hospitals at which they had been treated.

The survey of English NHS patients included several such questions (Lowson et al. 2002). When asked about the comfort of hospital rooms, all patients treated in France reported being "quite" or "very satisfied" (100%) compared to 90% among those who had been to Germany. A larger gap emerged on the question regarding the culinary aspects of the hospital stay: 80% of English NHS patients in France described the food as "quite" or "very pleasant", compared to 49% of patients in Germany. On the other hand, language problems were experienced as less pressing an issue in Germany than in France, as 24% of patients treated in the French hospitals had faced difficulties in communicating in English compared to just 8% at the German hospitals. Patients treated in Germany also noted how helpful the so-called Europals (nonmedical staff employed to escort and assist patients with translation and other issues) had been.

Respondents were also asked to mention which other things could have improved the hospital experience. A series of suggestions were made, including access to English newspapers, television or radio, better catering, the presence of an interpreter; and a common room where English patients could socialize with each other (Lowson et al. 2002).

An interview with the director of La Louviere Hospital in Lille, where English NHS patients were treated, gives some additional insight into the hospital environment. The hospital director explains how the hospital had made special provisions for receiving English patients by adding three extra British channels to its satellite television, offering English newspapers daily, translating all documents for patients into English and by having bilingual care personnel including physiotherapists, nurses and assistants. An Anglican priest also visited the French hospital regularly and local people of English origin had offered to volunteer and visit any English patients that might be feeling neglected (Quille 2002).

Dutch patients treated in Belgian hospitals were asked in the *Europe for Patients* survey to assess service aspects of the hospital stay. Waiting time for room assignment, quietness, cleanliness of rooms, privacy of rooms and meals all scored over 4 on a 5-point scale (5 being the highest) (Boffin and Baeten 2005).

III: Mechanisms for ensuring quality of care and communication between providers

The following section looks at mechanisms for selecting patients to be treated abroad, selecting providers to treat the mobile patients and facilitating communication across borders. A series of projects from across Europe are examined in turn, starting with cross-border care in border regions, followed by national schemes to send patients abroad and finishing with illustrations of patients who arrange medical treatment abroad on their own initiative.

Before doing so, it is important to highlight once again that the material used for this part of the chapter generally amounts to "grey literature", i.e. material from the Internet and the press. Dental and cosmetic interventions are not the only forms of cross-border care which patients arranged on their own initiative. We know that British patients go to clinics in India (India Health Tour 2007) and Thailand (Business Week 2007) for open heart surgery and other serious operations, that recent legislation on sperm and egg donor anonymity in Britain have given rise to an outflow of British couples heading to Spain (where laws encourage donations) for fertility treatment, and that women from countries where abortions are outlawed go to countries where abortion is legal. Yet, these patient flows are poorly documented and when they have been studied, the quality of care is rarely, if ever, described.

Cooperation in border regions

Sweden–Denmark: Cross-border cooperation in the Øresund Region

Patient mobility between Sweden and Denmark forms part of wider regional integration efforts, encouraged by the opening, in July 2000, of the Øresund Bridge connecting the two regions that were previously separated by a narrow water channel (the Sound) (Øresundskomiteen and ØresundDirect 2003). Cross-border workers have been commuting across the channel for many years so that coordination of health care services is an essential element of mobility. It is estimated that approximately 9000 people commute daily between the two regions for work. Joint projects have adopted a "bottom-up" approach, giving prominent roles to local stakeholders. This also reflects devolution of many health services to the county level in both countries.

The focus of the Øresund Committee, which oversees the programme, has been on developing links between health professionals and provider organizations, emphasizing (Øresundskomiteen and ØresundDirect 2003):

> … raising and ensuring the quality of health care and strengthening research by exchanging experience, through joint education and 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.

Collaboration has not, however, always been easy. This is illustrated by the proposal to develop a Joint Unit for Breast and Endocrine Surgery, linking the University Hospital in Lund and Copenhagen University Hospital. It sought to develop exchange of clinical staff and shared research projects, all with the goal of establishing a "centre of excellence". This was seen as important because neither department was considered large enough on its own to have a critical mass of expertise for rare diseases. However, the centre of excellence did not materialize. Danish and Swedish stakeholders expressed the view that "things take time" and that success requires the project to mature. Understaffing at the Copenhagen hospital meant that the project lacked clear anchorage on the Danish side. However, staff from both centres continue to support the idea of a joint centre, not least due to the prospect of stiff competition from other hospitals in Scandinavia and Germany.

Belgium–the Netherlands: Cross-border contracting and absence of mechanisms to ensure continuity of care

A large study in 2003 examined how continuity of care could be assured for patients going from the Netherlands to Belgium for hospital care and returning to the Netherlands for after-care (Engels 2003a; Engels 2003b).

Dutch insurers faced with several thousand people waiting for treatment and a legal obligation to ensure their affiliates have access to health care have seen cross-border contracts with Belgian providers as a partial solution to waiting lists in the Netherlands. Yet, for patients this means that the care pathway becomes a cross-border chain with several stages. A typical patient pathway is as detailed 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 GP (or specialist) for a referral letter.
- Consultation with Belgian specialist who assesses the need for tests and hospitalization.
- If required, preoperative tests, imaging, etc. are carried out (even if these have already been carried out in the Netherlands).
- Preoperative laboratory and other results will be discussed either with the Belgian specialist or the home-based local GP.

- If after-care is necessary following discharge, it will be provided in the Netherlands. The Belgian specialist and/or a clinical nurse will prepare 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 in the process are apparent. There is no oral communication between the Belgian specialist and the Dutch GP during hospitalization or after-care. On the other hand, there is a multiplication of superfluous medical procedures (and therefore costs) when Belgian doctors disregard tests already carried out in the Netherlands. Also, going back and forth 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 infection control strategies between the two countries. From interviews with 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 each other, which lead to uncertainty about responsibilities along the chain of care. Furthermore, there was a conflict of interest between regional Dutch providers and insurers as to who should coordinate the process; the one who directs patient flows to some extent also controls financial flows. Usually, medical providers arrange patient pathways among themselves, but insurers – as financers – also want to play an active role in coordinating health care, not least across a border.

These problems become particularly important in the light of figures on Dutch patients who go abroad for medical treatment; an estimated 30 000 people received care abroad in 2002, up 50% from 2001. As the use of cross-border care increases, so will the demand for after-care and the necessity to develop clear patient pathways. The report concludes that despite Dutch insurers offering the possibility to their members to be treated in Belgium, the elements of cross-border care are not yet sufficiently connected to speak of a "borderless care chain"(Engels 2003a).

The Netherlands–Belgium/Germany: Cross-border deployment of emergency services in five Euregios and the associated technical and administrative difficulties

A 2000 study of emergency care on the Netherlands' borders with Belgium and Germany (Post and Stal 2000) sought to identify "opportunities and impediments […] in the area of cross-border urgent medical assistance at administrative, judicial, operational and equipment employable level and

which solutions may be submitted to tackle existing bottlenecks" (Post and Stal 2000). As the research covered a large geographical area, the border regions were divided into five entities according to existing Euregio structures, that is: Scheldemond, Meuse-Rhine, Rhine-Waal, Rijn-Ems-Ijssel and Ems-Dollard (Post and Stal 2000). Several existing treaties and agreements provide for cooperation in urgent medical assistance between public authorities at national, regional and local levels.

Based on a series of interviews with people involved in cross-border emergency care at all levels (medical, operational, administrative, political), numerous bottlenecks of different types have been identified, all of which were mentioned by Dutch stakeholders.

Differences in the regulation of ambulances had to be resolved as these are considerable between the countries (in Belgium all ambulances must comply with Belgian regulations, whereas in the Netherlands non-registered cross-border ambulances are exempted from Dutch legislation) (Post and Stal 2000). There are differences in the qualifications and competences of ambulance staff. Whereas Belgian and German ambulance personnel are trained to give Basic Life Support, 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 Dutch regulations reserve for a qualified doctor or ambulance-nurse. In contrast, Dutch emergency staff may only provide Basic Life Support in Belgium and Germany – they can only employ their more advanced skills under the supervision of a Belgian or German doctor. These differences also impact on the admission of patients into hospital as emergency department staff have to take into consideration that a patient's condition might differ according to whether they are brought in by Dutch, Belgian or German ambulance crews. Problems also arise with the admission of patients into hospitals: according to Belgian law, accident victims can only be admitted to hospitals that have an approved emergency service. This means that Belgian patients may only be admitted to the St Franciscus Hospital in Roosendaal as no other Dutch hospital in the border region has an emergency department recognized by the Belgian authorities.

Strict rules apply for the deployment of medical vehicles on national territories; it is very difficult for a Belgian emergency communication room to call for the assistance of a Dutch ambulance because of the Belgian deployment processes. Conversely, German or Belgian ambulances are only allowed to cross the border with the consent of a Dutch emergency communication room. Such problems can impede the efficiency, and hence the quality, potentially life-saving emergency services and can affect how these are delivered to patients (Post and Stal 2000).

National schemes for sending patients abroad

Denmark: Direct contracting with foreign hospitals

In July 2002, legislation on "Extended Free Choice of Hospitals" gave Danish patients the right to be treated in private clinics in Denmark or at foreign hospitals, providing that (Amtsrådsforeningen 2004):

- 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 which can make individual agreements with private or foreign providers;
- providers wishing to deliver health care under the extended free choice of hospitals scheme must present documentation regarding the treatment offered, including their experience, professional qualifications, on-call facilities, equipment standards, principles of treatment, waiting times and patient rights.

Some 130 agreements have been concluded with privat Danish clinics and 13 with foreign hospitals (all private), of which 10 are in Germany and 3 in Sweden. This prevalence of Danish providers is reflected in the patient flows which occurred between 1 July 2002 and 31 December 2003 (Amtsrådsforeningen 2004).

In total, 26 093 patients were treated under the extended free choice of hospitals scheme of which only 344 (1.3%) were treated in German and Swedish hospitals. Most cases involve orthopaedic or cataract surgery.

Unlike the situation with Danish public providers, the National Board of Health does not inspect the private hospitals or monitor the quality of treatments they provide. However, 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 include several provisions on quality. The contracting hospital must adhere to the standards listed here.

- A responsible doctor must be designated to ensure that medical practices carried out at the hospital are performed in accordance with good practice standards and with applicable legislation.
- Patient files are to be kept in accordance with the rules defined by the National Board of Health.
- The patient must be informed during the entire care process (diagnostics and treatment) about their illness, tests, treatment, risks and side-effects, and no treatment is to be carried out without informed consent from the patient, as set out in the Danish Law on Patients' Rights.

A survey carried out in 2003–2004 examined what stakeholders thought of this scheme. Questionnaires were sent to the 15 participating public hospitals (all replied) and to the 153 private and foreign contracting hospitals (of which 97 replied; a response rate of 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 by which Danish public providers are bound. Public hospital directors considered that this could be achieved by obliging the private or foreign clinics to submit clinical data to the national patient register or by ensuring that they treat a minimum number of patients per year. The private and foreign clinics had mixed feelings on 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 proposed the following additional obligations: a minimum volume number of patients per year; participation in clinical databases; stricter requirements on hygiene; and requirements on the handling of instruments (Amtsrådsforeningen 2004).

Norway: Medical Treatment Abroad project

A 3-year "Medical Treatment Abroad Project" was established in Norway in January 2001 for patients waiting for elective surgery. The aim was to reduce waiting lists; the Norwegian Parliament had previously granted one billion Norwegian kroner (€122 million) for the purchase of care abroad (Nesse 2001). Over the first two years of the project, 10 000 treatments had been carried out abroad.

The top three destination countries were Sweden (48% of patients), Denmark (33%) and Germany (17%). The remaining patients went to France, Finland, Spain, England or Austria. Of the 55 foreign hospitals which had an agreement with the Norwegian health authorities, the top three were the private Hamlet Hospital in Denmark, which received approximately 33% of Norwegian patients, and two in Sweden (Axess Elisabeth Hospital in Uppsala and Dalsland Hospital, which is about half way between Gothenburg and Oslo, with respectively 13% and 12% of patients).

To select which foreign hospitals could be used, the Norwegian National Insurance Administration (NIA) contacted approximately 20 hospitals that had expressed interest in receiving patients. The enquiry outlined services sought and quality standards. Norwegian experts examined the offers received from foreign hospitals in terms of medical profile (medical quality, infection and complication rates), prices and legal aspects. Next, negotiations were launched, each hospital in question was inspected and by late 2001 approximately 15

contracts were concluded with hospitals in Sweden, Denmark, Germany and France. In addition to the above-mentioned selection criteria, aspects such as similarity in the approach to and traditions of health care were also taken into account, favouring other Scandinavian countries (Nesse 2001).

For patients, the first step in the procedure involved those on waiting lists being offered the possibility to go abroad by their local hospital. If the patient accepted the offer she/he would go to the local hospital for evaluation. The local hospital would then send a request for referral for overseas treatment to the NIA, which would in turn send a request to the contracted foreign hospital. The patient would then receive a concrete offer from the NIA and the transport would be organized. From the moment when 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 sent patients abroad for treatment since independence (Muscat 2004). Considerations such as the likely number of patients, start-up costs and availability of the required expertise all influence the choice of health authorities on whether to provide particular services or to send patients abroad. A bilateral agreement was signed 30 years ago between Malta and the United Kingdom to allow the referral of Maltese patients for specialized hospital treatments. This agreement has been very successful, partly due to the excellent links between health care professionals and the absence of linguistic barriers. 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, must not be available in Malta nor be experimental, and must be evidence based. Once authorization 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). Protocols have been developed for referral of patients to foreign centres of excellence, with clearly defined procedures for the preparation and transfer of patients according to their situation (e.g. intensive, highly dependent or unconscious patients) (Muscat et al. 2006).

England–Belgium: the London Patient Choice Project

Between May 2003 and September 2004, approximately 600 patients on English NHS waiting lists were treated in Belgian hospitals as part of the "London Patient Choice Project" (Glinos, Boffin and Baeten 2005). Four NHS London Hospital Trusts and the NHS Lead Commissioner, acting as a middleman,

concluded direct contracts with five Belgian hospitals which would treat the waiting-list patients. The four London Trusts that agreed to take part in the scheme were:

- University Hospital Lewisham (South-East London)
- Bromley Hospitals NHS Trust (South-East London)
- Barnet and Chase Farm Hospitals NHS Trust
- Barking, Havering and Redbridge Hospitals Trust.

The contracts were limited to 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 and legal aspects were all meticulously included in the very detailed contracts. A total of 15 annexes spelled out all aspects of the treatment:

- prices
- general legal terms
- patient consent form
- treatment route and application of contract
- patient referral letter
- clinical and nonclinical 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 (staff who accompanied patients to facilitate the process)
- description of clinical procedures and performance standards
- control of hospital infection
- 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. The contracts with the Belgian hospitals were based on experiences from an earlier pilot project when patients were sent to France and Germany in 2001. The role of the Euro-PALs is particularly relevant: these are nonmedical, multilingual

staff that escorted and assisted patients through the entire cross-border process. Part of their function was to facilitate communication between doctors, patients and their families. The Euro-PAL service received very positive endorsement by English patients.

Despite the initial expectation that the scheme would continue for years, with contracts extending to March 2007, the contracts with the Belgian hospitals were terminated prematurely (June 2005) and the patient flow stopped after just 18 months. There are several possible explanations. First, the budget for the London Patient Choice project may have run out (a possibility given the very short duration of many British initiatives for this reason). Second, it is known that the project faced considerable resistance from British doctors. The third and most likely explanation is that the project had achieved its aim of demonstrating to the British media that the Government was "doing something" to address the problem of waiting lists.

Republic of Ireland–Northern Ireland/United Kingdom: the National Treatment Purchase Fund (NTPF 2007)

Established in 2002 to tackle waiting lists for treatments in Irish public hospitals, the National Treatment Purchase Fund (NTPF) was initially aimed at adults who had waited at least for one year or children who had waited over six months, although in some cases waiting times were reduced to three months for adults and children. Care provided under the scheme incurs no additional charges and it is reported that more than 36 000 patients have gained faster access to treatment as a result.

The NTPF arranges and purchases care mainly in private hospitals within the Republic of Ireland and the United Kingdom, in particular Northern Ireland. Patients who qualify can be referred either by their health board, hospital, specialist or GP. Travel arrangements are covered by the scheme, including provision for an accompanying person if the patient goes to the United Kingdom. Liaison officers have been appointed at all participating hospitals, to act as the first contact point for patients, explaining how the NTPF works and transferring patients' medical files. Follow-up care is managed by the patient's GP but, if necessary, the NTPF will arrange for outpatient consultations with the specialist who operated on the patient. Participating hospitals are assessed according to quality standards.

People who go abroad on their own initiative to seek treatment

A growing number of people seem willing to go abroad for treatment because they can obtain services at lower cost. People travel from the old to the new

Member States in their thousands to obtain medical services that are often excluded from national benefits packages. This raises the question of what guarantees, if any, such individuals have when they are treated by foreign providers working in the private, commercial sector. Another characteristic of this sort of patient mobility is the frequent involvement of commercial middlemen, bringing potential patients and providers together. Dental care and cosmetic surgery are prime areas for so-called "medical tourism".

The Danish dental broker

OuchMyTooth.com is a Danish agent specializing in advice to patients seeking dental care in Poland, Hungary, the Czech Republic, Turkey, Spain, England, Germany and Sweden. It promotes its services on its web sites, the first of which was launched in 2001 in Danish, with an English version following in June 2005. The company states that, when selecting which dental clinics to include, it carries out on-site visits and only accepts those that fulfil its "quality requirements".[3] Providers must:

- speak Danish or English
- guarantee their work for two years
- maintain quality standards similar to those in Danish clinics
- have a "high standard of hygiene"
- only allow qualified maxillo-facial surgeons to carry out implants
- be insured
- be patient-oriented and friendly
- be qualified dentists (including the manager or owner of the clinic).

While these "quality requirements" might attract new clients to go abroad for dental care, it is unclear what exactly some of the requirements entail. The wording is vague and subject to interpretation and it is not obvious whether these requirements actually give patients any increased guarantees in terms of quality.

Dental care in Hungary

A comparable company is the similarly evocative "Smiles Savers Hungary" which directs British patients seeking dental care to Hungary. With the promise of "selecting the best", the company web site enumerates a long list of criteria against which dentists and clinics are said to be assessed to suit the needs of a British clientele. These include: that most of the staff at clinics have good

3 Presented in the order that they appear on the company web site.

knowledge of English; that all dentists are "fully qualified" and affiliated to international dental organizations; that all lead practitioners have more than 10 years' experience; that the majority of services are provided on site or very close by; that clinics use the "latest technology throughout" and can offer specialized care such as "periodontology, orthodontology and implantology"; that staff can work during weekends and offer out-of-hours services; that clinics give minimum guarantees for their works (in terms of years); that they charge fair prices; and that they "offer free transportation from the airport and for every visit to and from the clinic" (Similes Savers 2007). The web site also presents a breakdown of the tariffs patients can expect to pay in Hungary, the prices they would have to pay in the United Kingdom and the "average savings" which they will make by receiving dental care in Hungary. The company even goes so far as to give an explanation for why Hungarian tariffs are so much lower: "Perhaps the biggest factor that influences prices are the sheer numbers of highly qualified dentists competing in the same market. The end result is escalating quality and plummeting prices." (Smiles Savers 2007)

While patient-friendly web sites may well appear reassuring about the quality of treatments and the competences of foreign providers, it remains questionable to what extent such selection criteria are effective and guarantees are valid, or whether these merely amount to good marketing tools.

An interesting perspective on these trends of "dental tourism" comes from the director of the National Institute for Stomatology in Budapest. He stated that he was certain of the high quality of the education and training that Hungarian dentists receive, but admitted that the scope for increasing their income rapidly by treating foreign patients could entail lowering the quality of care (Cojean 2005). This potential risk has been stressed, and often exaggerated, by dentists and dental associations in the older EU Member States. While sometimes amounting to campaigns of denigration, some concerns appear to be legitimate. Representatives of French dental organizations, while stressing that a protectionist approach within the EU would be wrong, expressed concerns about legal responsibility in the event of problems.

Europe–Tunisia: Patient mobility for aesthetic surgery

As with patient flows from western to eastern European Member States for dental care, French, Swiss, British and Belgian patients are also motivated by large price differences to go to Tunisia – "the new El Dorado for plastic surgery" (Meeus 2005). As in Poland and Hungary, transport, luxury hotels and the medical treatments are arranged for the patients before they arrive, with the help of brokers such as "Cosmetica Travel" and "Estetika Tour". This form of medical tourism has Tunisian Government support; foreign patients are exempt

from the usual 10% value-added tax (VAT) on medical charges. Published prices seem to be about half of what would be charged in European Union Member States.

An article in a Belgian magazine described how patients had to fill in a detailed medical questionnaire before being accepted at a clinic in Soukra; their general health condition was assessed and they had long discussions with the treating surgeon. However, there were no pre-operation consultations, no time for reflection and no follow-up.

Such considerations highlight once more the vulnerable position these patients are likely to find themselves in, both in terms of being able to assess the quality of treatments they receive and in terms of receiving adequate medical and nonmedical support before and after treatment. Furthermore, if a patient has to return to the foreign hospital or provider due to post-operative complications, what seemed a "deal" can soon become an expensive and unpleasant experience.

Chapter 4

Policies to promote quality of care in European Union Member States

Introduction

The remainder of this book attempts to provide an overview of policies designed to improve the quality of care provided to Europe's citizens. Each set of country-specific policies will be described in turn, highlighting the key actors and processes that are important in each State. We do not pretend that the outcome of our mapping exercise achieves perfection; our aim has been to present our findings in as complete a way as possible. The descriptions reflect the fact that for some countries we have been able to collect ample information, while for others material has been scarce and difficult to obtain. Even gathering the most basic descriptions of policies that are in place has involved a great deal of effort, complicated by the fact that policies are fragmented and inconsistent in many countries. Lines of accountability, to the extent that they can be discerned at all, are often blurred. Responsibilities often overlap, while elsewhere clear gaps emerge. Accounts by different informants are, at times, mutually contradictory, making it almost impossible to be sure about the situation that really is in place. Organizations are created and abolished and they merge and break up, often for no apparent reason. It can be extremely difficult to determine whether participation in activities is voluntary or compulsory and, if the latter, whether any enforcement action is ever taken.

It is important to note that what we describe are in almost all cases *de jure* situations. From our observations, it is all too clear that often these bear almost no relationship to the de facto situation. In only a very few countries have there been any serious evaluations of the systems in place. For example,

official documents describing how payments might be linked to quality make no mention of the almost ubiquitous informal payments that we know really determine the quality of care that is provided in some Member States. Such documents also fail to convey the images presented to us by investigative journalists, who in many Member States are the only people who have really described quality of care, especially in areas that often lie beyond the gaze of officials, such as mental health. Yet, in many cases, it has proven impossible to obtain any actual documentation on whether the processes that are meant to be taking place actually do so – an obvious prerequisite to any evaluation. On the other hand, a few countries clearly do have very extensive, well-thought out policies that do make a difference and which, over recent decades, have been associated with what is now a deeply embedded acceptance by those providing care of the need not only to do one's best but also to be able to confirm to oneself and to others that one has succeeded.

This work was undertaken within the framework of the European Commission research project, *Europe for Patients*. It asked the question of whether a European citizen travelling to another Member State can be assured that the care they receive is of high quality. We do not doubt that in many cases the care that they will receive will be of an excellent standard. However, in most Member States, they face considerable difficulty in obtaining reassurance that the health professionals treating them have the requisite skills, that the facilities and the treatments are safe, or that there is any mechanism to monitor their outcomes. This situation is simply not satisfactory.

What follows can only be regarded as a tentative first step. We have tried, as far as possible, to resolve any inconsistencies in the accounts we have received, but some remain. We hope that readers who identify errors, omissions and inconsistencies will let the authors know so that if we undertake this task again it will be even more accurate.

Methodology

The assessment of quality of care strategies in EU Member States is based on three complementary sources: *Health Systems in Transition* reports by the European Observatory on Health Systems and Policies, a review of the published and grey literature, 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 the time of writing and the World Wide Web (Google search engine). References cited in documents identified by this search were obtained and related journals hand-searched to uncover further related articles. The review concentrated on literature

published in peer reviewed journals, papers presented at conferences and unpublished reports. The ExPeRT project (1998) (ExPeRT 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. In addition, the authors reviewed reports recommended by the relevant experts of each Member State.

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, and 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), the Netherlands (1), Poland (1), Portugal (1), Slovakia (1), Slovenia (2), Spain (2), Sweden (2), and the United Kingdom (2).

A second stage of the research consisted of sending the document to external reviewers identified as experts in quality of health care in their own Member State. Where possible the experts chosen were not involved in the first stage of the research. In this second stage Bulgaria and Romania were also included, which previously had not been since at that time they were Accession States. A total of 51 reviewers participated in this process: Austria (2), Belgium (4), Czech Republic (1), Denmark (1), Estonia (1), France (2), Germany (2), Greece (1), Italy (4), Ireland (2), Malta (1), Spain (3), Sweden (2), United Kingdom (3), Finland (1), Poland (1), the Netherlands (3), Lithuania (1), Slovenia (2), Romania (3), Latvia (1), Hungary (2), Luxembourg (1), Portugal (3), Bulgaria (2), Cyprus (1), Slovakia (1).

Thus, a total of 83 experts participated in the compilation of the quality of health care reports of all 27 Member States (including reviewers, second reviewers and those who filled in the questionnaire).

Austria

Context

A key step in the process of promoting quality in Austria was the amendment of the Law on Health Care Institutions (KAKuG) in 1993, which established a legal framework for the implementation of quality assurance in hospitals (Hofmarcher and Rack 2001). The amendment identified three elements of quality. The first relates to the technical aspects of health care, such as effectiveness of interventions. The second relates to issues of humanity of care, including interpersonal skills of health professionals and adherence to patient rights. The third includes issues of cost–effectiveness (HOPE 1996). Further reforms were introduced in 2005, including the Law on the Quality of Health Care Services, which sets out the responsibilities of different actors for quality of care.

Austria is a federal State, with responsibility for health care divided between the federal Government and the provinces (the *Bundesländer* (*Länder*) and the capital city, the *Hauptstadt*, Wien (Vienna)). In 1996, the Federation and the *Länder* reached an agreement on health system reform which, although it had been preceded by many earlier steps, finally achieved a fundamental breakthrough with a directional change in the system's development. The initial step was concluded via an agreement in accordance with article 15a of the Federal Constitution Act between the Federation and all nine *Länder* and took place between 1997 and 2000. The second stage of health care reform took place from 2001 to 2004. The Health Care Reform Act of 2005 set out a basis for sustainable financing of the health care system. It created State Health Agencies in each *Land* to replace the former state funds for financing inpatient care services. They consist of a minimum of representatives of the federal State, social health insurance (in equal shares) and the federal Government. In parallel, it created State Health Platforms, bringing together representatives of the medical associations, patients, cities and municipalities and legal representatives of public and private non-profit-making hospitals. A clear objective was to improve quality and to achieve more transparency in the fragmented system. The themes of quality and management across care interfaces are elaborated in the articles of the Agreement According to Art. 15a of the Federal Constitution Act on the Organization and Financing of the Health Care System (2005–2008).

The Act provides for the development and implementation of nationwide standardized specifications for health services. It affects all sectors, including public and private hospitals and outpatient care, as well as all health professionals. The new Law stipulates that regular quality reporting is to be developed, with

reports written on all sectors and professions according to uniform nationwide methods. The Act also provides for the creation of incentive measures to ensure quality in public health services. In addition, it established a Federal Institute for Quality in the Health Care System to support the Austrian Federal Ministry for Health and Women's Affairs (BMGFJ) in the development of quality (Hofmarcher and Rack 2006).

Actors

Governmental

The BMGFJ reports a growing awareness of the need for quality strategies. It identifies as obstacles constraints on budgets, limited methodological expertise, lack of time and concerns about transparency. Within the Ministry, the Department of Quality Management and Health Economics has sought to engage a variety of partners in large-scale projects to facilitate adoption of quality-related initiatives. These have included (BMGFJ 2006):

- dissemination of knowledge;
- introduction of regulations that would be binding;
- incentives (such as awards for quality);
- improving information available to patients and health professionals (e.g. production of the first Austrian quality report and work on indicators);
- sanctions to be considered as a matter of last resort.

The Federal Institute for Quality, established following the 2005 reform, is charged with supporting the implementation of the Law on the Quality of Health Care Services. It is expected to develop expert advisory groups and build on existing quality activities. In this way, it will be able to use as much knowledge and experience as possible in its work, and ensure the necessary level of acceptance. The systematic involvement of patients is also planned. Its tasks include (Hofmarcher and Rack 2006):

- participation in drawing up general specifications and principles for the development of standards in the fields of structural, process and outcome quality, and the analysis of improvement including a priority concept and a recognition procedure for the documentation on quality reporting and for quality reporting itself, for contributory measures, incentive mechanisms and supervision;
- monitoring, recommending and drawing up obligatory quality standards to be issued by the Minister of Health and Women (federal quality directives) or recommended as guidance (federal quality guidelines);

- compilation of an annual quality report;
- the implementation of and/or participation in promotional measures and introduction of incentive measures;
- the implementation of, or participation in, monitoring compliance with the regulations of this law and the regulations or other guidelines issued on the basis of this law.

Nongovernmental

In 2003 the umbrella organization of the Sickness Funds (*Hauptverband der Sozialversicherungsträger*) created a special department for evidence-based health care.

There are two organizations undertaking HTA, the Institute for Technology Assessment, and the recently created Ludwig Boltzmann Institute. In 1997 Austria launched a plan for investment in high technology (*Großgeräteplan*), agreed between the federal Government and the *Länder*. A facility wishing to purchase certain technological equipment must satisfy criteria of quality, equity and cost–effectiveness. In the area of transplantation there is an office (ÖBIGTransplant) that disseminates information within Austria.

The Austrian Association for Quality Assurance undertakes training on quality and is the accreditation body for ISO 9000 activities. According to the ExPeRT project (1998), there has been an unwillingness to use the ISO 9000 standards because of the problems in applying them to a complex clinical organization (ExPeRT 1998). There is no accreditation system for hospitals in Austria. There are a small number of initiatives on EFQM, but they are not widespread. The Federal Ministry of Health reports that it is developing surveys of the public and patients, as well as statistical indicators.

Registration of physicians is undertaken by the Austrian Medical Chamber (*Oesterreichische Aerztekammer*) in cooperation with its counterparts in each Länd, in conformity with EU legislation. Current developments focus on harmonizing training and credit transfer (Hofmarcher and Rack 2001). The Austrian Medical Chamber established a limited company in 2004, the Austrian Society for Medical Quality Assurance and Quality Managemen, LLC, whose responsibility is the definition of quality criteria for medical licensing.

Process

During the 1990s, quality assurance was seen as a matter for individual hospitals and health professionals, with government assuming responsibility only for creation of the requisite conditions that would permit quality care to be delivered (ExPeRT 1998). As part of its facilitative role, the Federal Ministry of

Health published guidance on the development of quality assurance, although the content was purely advisory (ExPeRT 1998). Since 1997, a series of 4-yearly agreements between the federal and *Land* governments and the Sickness Funds have emphasized the importance of strategies to enhance quality.

A few Austrian hospitals have participated in international initiatives. One hospital has been accredited by the United States Joint Commission International, another is certified by the German Cooperation for Transparency and Quality in Health Care (KTQ, *Kooperation für Transparenz und Qualität im Gesundheitswesen*), while others are employing the ISO approach (Offermanns 2007).

In 2000, a government statement set out a clear definition of quality standards and requested the development of a basic information system that would enable nationwide comparisons of performance in the secondary and primary care sectors (Hofmarcher and Rack 2001).

The Federal Government has, however, also 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 and performance of health professionals, patients' rights and quality management in hospitals. In addition, there has been official support for many voluntary quality-related projects. A process of defining mandatory structural quality criteria for various specialties has also been initiated.

In addition, the Federal Government has supported and financed a multitude of quality-related projects in recent years, including those addressing the interface between different levels of care, quality reporting, patient orientation, rational antibiotic prescribing, optimizing the use of blood components, hygiene, quality assurance in microbiological diagnosis, patient safety and the avoidance of adverse events.

The new laws stipulate that regular quality reporting should be developed, involving standardized reports covering all sectors and professions. On the one hand, this instrument is designed to ensure transparency for the public, but at the same time it also introduces a method for the systematic improvement of quality work.

Belgium

After years of emphasizing cost-containment and cost–effectiveness, assessment of quality of care is now gaining more attention in Belgium. Whereas the traditional approach to assuring quality was through specific licensing standards for health care institutions, the responsible authorities have more recently sought to strengthen quality assurance by means of accreditation of care providers, peer review and audit. Several laws, such as the Hospital Act and the Health Insurance Act, incorporate quality improvement initiatives.

In 2003, the Government devised a policy to make providers more accountable, based upon the following principles:

- quality promotion, by encouraging good medical practice based on guidelines and feedback to physicians that will allow them to relate their medical practice to that of other physicians;
- preventing and, if necessary, using sanctions in the event of divergence from good medical practice, as well as enforcing adherence to existing stipulations within the compulsory health insurance system.

Examples of other relevant legislation in the field of inpatient care involve patient safety and the creation of a balanced score card for hospitals, which takes into account medical and nonmedical indicators. Through benchmarking, hospitals are stimulated to improve the quality of the care they provide.

Actors

Three sets of actors have a legal responsibility to promote quality standards in Belgium. The first is the Federal Public Service (FPS) for Public Health, Food Chain Safety and Environment, which regulates access to the market for pharmaceutical products, health professionals, and health care institutions. The second is the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) which is responsible for setting reimbursement criteria. The third, reflecting the highly devolved nature of the Belgian federal system, comprises the governments of the three communities (French-, Flemish- and German-speaking communities), which not only implement federal licensing norms but also have the power to impose more stringent quality regimes than those set out at Federal level.

The FPS has oversight of regulatory matters related to market access of pharmaceutical products and the distribution of pharmaceuticals. It implements EC Directives, once they have been incorporated into national legislation and manages a system of pharmacovigilance, in which providers are obliged to notify suspected side-effects of drugs. In 2007, it established a Federal Pharmaceuticals

and Health Products Agency (FAGG-AFMP) to ensure the quality, safety and effectiveness of pharmaceuticals for humans and animals.

The FPS is also responsible for the Hospital Act, which includes licensing norms for hospitals. The National Board of Hospital Facilities has an advisory role in relation to this legislation, and the Minister has final responsibility for this. The legislation also includes norms on the installation of complex medical equipment in health facilities. The final approval for the opening of a hospital service or installing major capital equipment lies with the Minister of the community within which the facility is situated, based on nationally established norms. If a hospital fails to meet the criteria, the RIZIV-INAMI can refuse to reimburse treatment provided by the equipment in question and the hospital can be penalized by a reduction in its tariffs.

The FPS is, in the first place, responsible for ensuring quality in terms of the structural aspects of care, while the RIZIV-INAMI monitors and evaluates medical practice on the basis of quality criteria. Since 1999, Colleges of Physicians have been established within the FPS to receive annual reports on quality from the medical director of each hospital, as well as to promote good medical practice.

The Department for Medical Control of the RIZIV-INAMI was reformed in 2003 to tackle concerns about divergence from good medical practice. As a result of reforms introduced to make health care providers more individually accountable, the Department for Medical Control became the Department for Medical Evaluation and Control (DGEC-SECM) and received two new assignments, as follows:

- monitoring reimbursement of medical care to detect and prevent misuse;
- providing information to health care providers, such as recommendations on good medical practice and indicators of overconsumption.

The RIZIV-INAMI also oversees continuing education of physicians, employing an accreditation system and peer review. A system of voluntary accreditation for physicians and dentists was introduced in 1995, with the following objectives:

- promotion of quality, cost-conscious care and efficient relationships between physicians;
- exchange of patient data to prevent duplication of effort;
- ongoing training of physicians to promote quality of care.

In 2002, this gave rise to a National Council for Quality Promotion, comprising representatives of physicians, universities, scientific medical associations, sickness funds and the Minister of Social Affairs and Public Health. It is

responsible for managing the system of peer review, making recommendations for good medical practice and supplying feedback to physicians.

Local Medical Evaluation Groups (LOK-GLEMs) were established on a voluntary basis in 1996. These are groups of 8–25 physicians from a single specialty who establish criteria for accreditation, based on agreed specialty-specific guidance and review of prescribing and treatment profiles.

An evaluation in 2003 reported that the accreditation process had improved both the quality and uptake of continuing training. It concluded that physicians had become more aware of their roles in relation to ethics, economics and quality, with evidence that medical practice had improved with greater peer review, better knowledge and more interdisciplinary discussions (Heyrman, Lemye and Moens 2003).

HTA is performed by technical councils reporting to the RIZIV-INAMI. A Health Care Knowledge Centre (KCE) was created in 2003. It carries out research and provides policy advice on HTA.

As already mentioned, the communities can also play an important role in developing strategies for quality of care and can require providers to go beyond national standards. In 1997, the Flemish Community created its own framework to improve quality of care in health care institutions. Each health care institution in Flanders must implement a quality manual and accompanying implementation plan. Every care institution is expected to set up improvement schemes and to evaluate them periodically. The indicators of practice identified by the regional government are:

- clinical performance, including in-hospital mortality, unplanned readmissions, obstetric care, average length of stay, day care and transfusion reactions;
- operational performance defined as ongoing monitoring and improvement of the general organization;
- satisfaction of patients;
- satisfaction of employees.

These measures led to a new dynamic within Flemish health care institutions. Perceptions of quality became more structured and the institutions started to create mechanisms to monitor results. A dialogue developed among care institutions and the Government, giving rise to a "bottom-up" movement to strengthen quality assurance (Valepyn 2005).

Process

The FPS requires hospitals to comply with certain norms before being authorized to offer a service and to maintain their authorization (inspection controls). There are mainly "input" norms, such as:

- infrastructure (architectural standards, performance criteria for medical apparatus);
- staff (minimum staff numbers and qualifications required to offer different services);
- functional norms (such as record keeping);
- organizational norms (such as governance of medical and nursing activities, hospital hygiene);
- minimum capacity of the institution and the facilities required for each service.

Additionally, at the end of the 1990s, it required hospitals to comply with some "process" norms, such as registration of medical and nursing activity; participation in internal and external peer review processes; and internal audit and multidisciplinary patient reporting. Some specific initiatives have also been launched, mainly based on voluntary (financial) incentives. These include programmes to prevent hospital infections and bedsores and to improve perinatal care.

The system of accreditation is concerned primarily with aspects of safety, hygiene, quality and continuity of care. In recent years, hospital planning and accreditation are moving away from a view of the hospital as a single entity towards seeing it in terms of its various medical and supportive services. Since 1999, the regulation and accreditation of medical hospital services and functions have gradually been replaced by the accreditation of "care programmes".

In addition to basic standards that guarantee a minimal level of quality for inpatient care, the Hospital Act contains several measures to promote quality of care, such as requirements for the organization of medical and nursing activity; description of the tasks of the medical manager; an obligation to maintain personal medical records; the tasks of the Medical Council; and the establishment of specialized committees.

Hospital hygiene is attracting renewed interest, with efforts to strengthen links between medical microbiologists and infection control nurses. Additional measures are being put in place to improve staff compliance with hygienic practices and to increase registration of cases of MRSA and clostridium difficile.

Special attention has been given to hand hygiene and antibiotic committees are being established in hospitals.

Increased interest in clinical pathways, especially for certain diseases such as diabetes and renal failure, is seen as offering a way to foster quality of care through greater integration of care.

Belgium has a number of information systems in place that collect hospital activity. They include a Clinical Minimum Data Set, a Nursing Minimum Data Set, a Psychiatric Minimum Data Set, a Financial Minimum Data Set and a Mobile Urgency Group Data Set (Roger France and Mertens 2001). In 2007, an integrated system for data collection is planned combining the Clinical Minimum Data Set, the Nursing Minimum Data Set and the Mobile Urgency Group Data Set. Data are also collected from GPs, offering some scope to monitor adherence to guidelines and standards.

In recent years, a number of pilot projects have been developed that focus on patient safety within hospitals. They include the introduction of incident reporting systems and the development of patient safety indicators derived from the Clinical Minimum Data Set. In 2007, committees for quality and patient safety are planned in hospitals, each supported by a coordinator who will follow up reported incidents on the basis of a "no shame, no blame" approach.

Entry to a health profession is regulated by the Practice of Health Care Professions Act. There are three steps. First, a licence, valid indefinitely, is required from the FPS. Licences can be withdrawn in the event of malpractice. In addition, however, before practising medicine, a physician must register with the Order of Physicians. Finally, if the physician seeks reimbursement from the statutory insurance system, s/he must notify the RIZIV-INAMI. The regulation of health professionals incorporates ethical obligations (confidentiality, continuity of care) and sets out the scope of activities for each profession.

In 2002 the Act on Patients' Rights (22 August 2002) came into force. This guarantees patients the right to:

- quality treatment according to prevailing medical standards
- free choice of health professional
- information
- give informed consent
- an individual patient file
- consult the patient file
- privacy protection

- complaint mediation
- a representative.

As elsewhere, implementation of policies on quality has been complex, with the FPS identifying, as the main barriers, a lack of direction, burn-out of professionals and limited financial resources.

Bulgaria

Background

In the 1990s, the Bulgarian Government instituted three key changes: introducing compulsory health insurance, reorganizing primary health care and rationalizing outpatient and inpatient facilities (Georgieva, Salchev et al. 2007). The process of health care reform is widely accepted to have been difficult. Several years after the initial reform, many problems remained. In 2004 the Ministry of Health formulated a number of objectives for further reform related to quality of care, including (Salchev 2004):

- ensuring high quality
- overcoming the existing geographical and quality unbalances
- introducing new technologies and innovations
- increasing staff qualifications.

Quality of care remains one of the most significant challenges facing the health care system in Bulgaria. It has been especially difficult to improve quality in rural areas.

The Health Act passed in 2004 referred to a number of quality improvement strategies. The Act set out standards for different medical specialties, it outlined the responsibilities of 28 regional health centres and the Ministry of Health in addressing the competence of medical specialists and monitoring quality of care, and it included a process for patient complaints and appeals (Avdeeva and Georgieva 2007).

In 2006 the Ministry of Health developed a National Health Care Strategy for 2007–2012 (a new version was then elaborated in 2007), which highlights nine strategic goals for future health care reform. Two relate to quality: the need to provide high-quality health services and the need to optimize primary care (Georgieva et al. 2007).

Actors

Health policy in Bulgaria seeks to ensure the necessary conditions for improving the health status of the population. According to the Constitution of the Republic of Bulgaria, the formulation of health policy takes place at state and municipal levels, as well as at the level of health care establishments (Popov 1997).

The quality of medical services in Bulgaria is monitored by the Ministry of Health, the National Health Insurance Fund (NHIF), the Bulgarian Medical

Association and the Union of Dentists (Avdeeva and Georgieva 2007). The scope of the Ministry of Health includes private health care establishments, with respect to which it drafts guidelines and regulations, and accredits facilities. In the pharmaceutical sector the Ministry has established an Executive Agency on Pharmaceuticals, which registers pharmaceuticals and regulates the pharmaceutical market (Georgieva et al. 2007).

Municipalities are of considerable importance. In compliance with the Local Self-government and Administration Act (1991) "the municipality is the main administrative and territorial unit, within which self-governing is performed" (article 1). The municipalities own the health facilities situated on their territory, with the exception of hospitals with national roles.

Professional training is regulated centrally, by a Supreme Medical Council (SMC). The SMC also proposes criteria for assessing the quality of diagnostic and preventive activities (Georgieva et al. 2007).

The NHIF was established in 1999. It has the right to specify clinical pathways, as well as prescribing guidelines and regulatory standards (Georgieva et al. 2007). An annex to the National Framework Contract, negotiated annually by the NHIF and the Bulgarian Medical Association, contains a list of specific quality indicators for primary and secondary health care.

Professional organizations are responsible for continuing education and training and professional standards (Georgieva et al. 2007). Their roles and functions are defined in article 5 of the Physicians' and Dentists' Professional Associations Act (1998) and include creating guidelines for good medical practice and control of their implementation.

In recent years, the legislative framework has allowed for more active involvement of civil society in health policy development. Citizens' organizations can be involved in health policy at national or local levels. The amendment of the Health Insurance Act (article 7 (2)) envisages participation of a representative of citizens' organizations (1 person) in the management board of the NHIF.

Process

The National Framework Contract sets out the regulatory regime for health care providers. Reimbursement of health facilities is based on standardized clinical pathways. The Framework Contract forms the basis for medical and financial auditing by NHIF inspectors. There have, however, been difficulties in recruiting sufficient auditors (Georgieva et al. 2007). Furthermore, according to Avdeeva and Georgieva (2007), selective contracting between both public and private sector providers and the NHIF, which has recently been introduced, is not

actually applied in practice, so the potential to facilitate quality improvements has not been fully realized.

Linkages between primary and hospital care are found to be problematic, impairing quality and accessibility to care (Tsolova and Balabanova 2007).

The 2004 Health Act established a register of health professionals, to be maintained by the Ministry of Health, linked to professional standards (Georgieva et al. 2007).

Health care facilities are accredited by the Ministry of Health. Its Accreditation Council drafts standards, regulations and indicators for accreditation. The process of accreditation in Bulgaria started in 2003, although the legislation was passed in 2000 and updated in 2003 (Bulgarian Ministry of Health 2000; Bulgarian Ministry of Health 2003). The process has two stages: self-assessment by hospitals and external assessment by the Ministry of Health. Facilities are awarded between one and five stars; the gradings are published on the Ministry of Health's web site. The first accreditation is valid for a period of 1–5 years depending on the evaluation score obtained, with facilities receiving a low score having to repeat the process sooner (Balabanova, Tsolova and Delcheva 2005).

In Bulgaria accreditation is a mechanism for quality assurance and is considered by stakeholders as one of the main components of independent quality assessment. Although health establishments must be accredited to enter into contracts with the NHIF, the number of stars does not influence payments. There are no sanctions or benefits arising from accreditation. Some hospitals have introduced ISO standards (Avdeeva and Georgieva 2007).

Key stakeholders consider the introduction of an accreditation process to be a positive aspect of the reform. As part of the process of accreditation, health establishments are evaluated with respect to their structure, diagnostic and care process, staff qualification and quality of services. Some critics argue that the process of accreditation is hampered by a lack of clear and precise guidelines which can differentiate hospitals with respect to their capacity to perform particular types of services. Results from the study performed by Balabanova, Tsolova and Delcheva (2005) show that key stakeholders prefer voluntary rather than imposed accreditation, with accreditation being performed by an agency independent of the Ministry of Health, and believe that there should be benefits for high-performing health care establishments (Balabanova, Tsolova and Delcheva 2005).

Although there is no explicit strategy on patient safety, hospital managers have started to use surveys to gather feedback from patients. Complaint procedures are being established gradually at the level of health facilities as a way to monitor quality and address shortcomings (Tsolova and Balabanova 2007).

There is no specific law on patients' rights but existing normative documents regulate the following basic rights, which include rights relating to quality of care: right to information and informed consent; right to safety; right to choice of medical-care provider; right of complaint; right to autonomy and to choose one's physician and health institution, etc. (Georgieva et al. 2007). However, in reality, many people are unable to exercise their right to choose a health facility due to financial barriers. Therefore, free choice is unlikely to enhance significantly the quality of care received by the majority of the population. Moreover, the lack of comparative data on quality of care in different hospitals poses an obstacle to the exercise of free and informed choice (Balabanova, Tsolova and Delcheva 2005).

There is a proposal to extend licensing to specialized medical services, to establish an independent quality agency, and to empower patients to report problems. These measures remain under discussion at the time of writing.

Cyprus

Context

The Cypriot health care system is undergoing a major reform, in part as a consequence of surveys revealing growing levels of dissatisfaction in both the private and (especially) public sectors (Golna et al. 2004).

Part of the reforms being initiated by the Ministry of Health involves the introduction of a system of quality assurance. This will seek to identify areas for improvement, formulate guidelines for best practice, and evaluate the delivery of care.

Actors

The Ministry of Health has established a quality assurance committee, the National Committee for Quality Assurance and Risk Management, which includes representatives from all branches of the Ministry. It envisages a process whereby all hospitals in Cyprus would be accredited by an international body and has developed an Action Plan to strengthen quality assurance in all health facilities. Its stated objectives include:

- establishment of national policy frameworks;
- monitoring the provision of health care in all hospitals across Cyprus;
- ensuring that hospitals operate in line with international and local legislation;
- monitoring the development of quality and risk management systems within the new Nicosia General Hospital and other hospitals across Cyprus;
- facilitating the communication of effective quality and risk management systems across Cyprus;
- keeping the Minister of Health and all other relevant bodies informed of quality and risk management developments in hospitals in Cyprus;
- encouraging the development of communication networks among hospitals in Cyprus.

Since 2006, the Ministry of Health has also been participating in the European HTA project (EUnetHTA), with the aim of institutionalizing HTA in Cyprus.

The creation of the National Committee for Quality Assurance and Risk Management has been followed by the establishment of similar committees at district hospitals and health centres. Training programmes in quality assurance

and risk management were initiated in May 2004 and the National Committee is exploring how to implement a nationwide system of peer review. In 2004, pilot surveys to assess patient satisfaction were conducted at Nicosia General Hospital and it is envisaged that the National Committee will undertake regular surveys in other hospitals in the future.

The Medical Devices Competent Authority, established in 2004, is responsible for approving medical devices to be entered into the market, along with market surveillance and running the Medical Devices Vigilance System. The Medical Devices Competent Authority is part of the Department of Medical and Public Health services of the Ministry of Health.

The National Infection Control Committee's mission is to coordinate and support hospital infection control committees, which are charged with aspects of surveillance, prevention and control of infection in hospitals.

The State General Laboratory (SGL), a department of the Ministry of Health, has been accredited as a reference laboratory. It is responsible for ensuring the chemical and microbiological safety of foods and industrial products. A total of 16 of its 21 specialized laboratories are accredited as complying with ISO 17025 standards.

Health professionals have to be registered with the competent authorities (professional councils for doctors, dentists, pharmacists, nurses and midwives) if they are to be granted a licence to practise. Paramedical professions are also regulated (i.e. psychologists, dieticians, pharmacists, speech therapists, chiropractors, physiotherapists, beauticians, dental technicians, medical representatives, opticians). Relevant legislation has been amended in line with EU legislation.

During the year 2007 a Nursing Department was established within the new Technological University of Cyprus. However, Cyprus has no medical, dental or pharmacy school. For this reason, doctors, dentists and pharmacists are trained abroad (mainly in Greek and British universities).

Process

According to the Standardization, Accreditation and Technical Notification Law (L.156(I)/2002), the Cyprus Organization for the Promotion of Quality (CYS) is the sole national body responsible for accreditation activities in compliance with relevant international standards and has been operating since 2004. The main focus so far has been on laboratories. Accreditation activities began in the mid-1990s with a number of training and awareness activities. The CYS is a Full Member of the European co-operation for Accreditation (EA) and an

Associate Member of the International Laboratory Accreditation Cooperation (ILAC).

Since 2004, progress has been made towards the accreditation of government hospitals, beginning with the Nicosia General Hospital. Changes have been made in the management of the hospital, as well as in the introduction of standards, protocols and training in all areas of the hospital. In the private sector the main hospitals have introduced ISO systems.

A Patients' Rights Law, including elements addressing patient safety, was enacted in January 2005.

A Health Monitoring Unit, established within the Ministry of Health, has been charged with the task of collecting relevant data to support policy-making, strategic planning, monitoring and regulation of the health care system.

The Ministry of Health has, however, identified some barriers to the implementation of quality strategies.

- Motivating health care professionals to become involved in developing guidelines can be problematic.
- Audits are sometimes considered to create excessive workload.
- The absence of a national health insurance system, with the consequent fragmentation of the system, makes progress difficult.

Czech Republic

Context

In 2000 the Government of the Czech Republic adopted a National Quality Policy in the form of Decree No. 458. This defined a package of methods designed to improve quality of products, services and activities. The main objectives of the decree included: the development of a national accreditation system; assurance of quality in public services; standardization; staff training and retraining; and creating a system of quality assurance.

In the same year the Ministry of Health founded the Czech Republic Quality Council to coordinate the health-related elements of the National Quality Policy. The Council brings together government departments, professional associations and trade unions, and nongovernmental organizations. The Council is charged with providing a basis for monitoring quality and effectiveness of health care in the context of a programme of accreditation of health care facilities. It has an extremely ambitious programme (Box 4.1).

Box 4.1 *Functions of the Czech Republic Centre for Health Care Quality*

- This is a centre for laboratory accreditation, authorization and certification programmes. It will undertake quality assessment in laboratories and workplaces, operating as part of the National Institute of Public Health in Prague. (For more information, visit www.szu.cz/cekz).
- QMS: This envisages the creation of a virtual working environment, including collection and management of documents and data, a dictionary of health care quality terminology, directory of personnel and organizations, and access to IT tools. It functions as a "technology platform" but its use at the time of writing is limited due to recent changes at the Ministry of Health (see www.med.muni.cz/cekz).
- Measurement/HTA/Standardization.
- Introduction of the EFQM and ISO 9004:2000 into the public health system.
- Accreditation and certification in health care – this will be a voluntary model, based on mutual assistance, drawing on foreign experience.
- Cooperation with patients' associations and health-related special interest groups.
- International cooperation.
- Research and development.

Notes: QMS: Quality Management Server; IT: information technology; HTA: Health technology assessment; EFQM: European Foundation for Quality Management; ISO: International Organization for Standardization.

Actors

The Ministry of Health is responsible for registration of medical facilities. Reference laboratories are subject to a national system of authorization managed by the National Institute of Public Health. Regional Governing Bodies, which own most health facilities, are playing an increasing role in quality assurance. New legislation on sickness funds is also anticipated, which should also provide these organizations with a role.

Licensing of professionals and facilities is undertaken by the Czech Medical Chamber. It is envisaged that this will be changed in forthcoming legislation, with a transfer of responsibilities to the Ministry of Health or to regional bodies, but the precise direction remains unclear at the time of writing. In 1998 the Joint Commission for Accreditation of the Czech Republic was established. This is a voluntary programme, based on the principles set out by the ISQua. A few facilities have submitted themselves to the Joint Commission International.

Process

It is reported that quality improvement activities are, on the whole, well received by health professionals, with an increasing number of projects being carried out each year. In 2005, 53 proposals for Healthcare Quality Improvement Projects had been submitted to the Ministry of Health. However, it is also reported that some health professionals perceive barriers to implementation. These include the formality of some processes, a lack of research on outcome indicators, the existence of a legislative "vacuum" with regard to quality management strategies, along with constant policy changes. The Healthcare Quality Improvement Projects were put on hold for 2006.

Other quality of care initiatives include the development of clinical guidelines, peer review (in radiology), EFQM (for some facilities), consumer surveys (albeit very limited) and creation of statistical indicators. The ISO system is widely used for "quality management of document flow" in health care facilities. Some voluntary activities involve ISO norms. All activities are "bottom-up" and carried out on a voluntary basis.

There is very limited HTA activity and no designated national agency for HTA. Close links between Czech health professionals are the product of multinational activity. Standardization efforts are not coordinated by the Ministry of Health but in all areas of health care "Standards of Efficient Medical Care" (SEMC) have been produced (currently published in printed form by Dashofer Publishing House).[1] Probably the strongest driving force in relation to health

1 More information and SEMCs produced during grants in the year 1998 and 2003 are available on the MediQuali web site (www.mediquali.cz/std/iga98/index.html, accessed November 2005).

care indicators and measurement is enabled through cooperation with a health care information systems company, STAPRO.

Some activities in "quality developed" health care organizations relate to the implementation of clinical pathways. (A good example of these efforts may be found at www.homolka.cz/en/, accessed November 2005.)

Great progress has been achieved in research and development, especially in oncology (with the highest achieved level of electronic data collection and interpretation for use in decision-making).[2]

The Czech Republic University Center for Healthcare Quality of Masaryk University seeks to cooperate with patients' associations and health-related special-interest groups, dealing with public relations and media and involving seminars, training, conferences and education. However, no progress in this domain was reported during 2007.

One area in which the Czech Republic University Center for Healthcare Quality has been very active is in promoting international cooperation. The 11th European Forum on Quality Improvement in Health Care was held in Prague in 2006.

These quality initiatives have taken place against a background of health system reform, involving privatization of primary health care and the removal of restrictions on access to specialists. This has been reported as being viewed positively by many people, although there are also concerns that equity and integrated delivery of health care have remained largely neglected (Holcik 2000).

2 There are several consolidated and active programmes. For a more detailed description please refer to the Institute of Biostatistics and Analyses web site (www.iba.muni.cz/index-en.php), where many are described (SVOD: System for Visualisation of Oncology Data; MaSc: Mammography screening, etc.).

Denmark

Context

In 1993, the Danish Ministry of Health and the Danish National Board of Health introduced a National Strategy for Quality Improvement in Health Care, based on the principle of "bottom-up" quality improvement. Between 1993 and 2000, a wide range of initiatives were introduced within the framework of this strategy, although these were largely local, ad hoc and informal activities.

Between 2000 and 2002 a range of nationwide quality improvement projects were initiated. These included (Mainz 2004):

- Danish National Indicator Project
- Good Medical Department
- Nationwide Patient Satisfaction Surveys
- National Clinical Guidelines Project on hospital care.

These projects were initiated as part of a collaboration between the Ministry of Health, the National Board of Health, the County Council Association (now entitled the Danish Regions), professional organizations and medico-scientific societies (Mainz and Nordentoft 2002).

In 2003 the Danish Ministry of Health and the National Board of Health developed a 3-year National Strategy for Quality Improvement that consciously sought to overcome the problems encountered with the previous strategy. This specified that quality improvement should be related to clinical pathways and should use standards and indicators.

That same year, as part of the new strategy, a Danish Health Care Quality Assessment Programme was proposed. This was implemented the following year, based on a policy paper agreed between the Ministry of Health, the National Board of Health and the Danish Regions, with implementation led by a newly created Institute for Quality and Accreditation in Health Care (IKAS).

In 2006–2007 the development of standards and indicators proceeded, with 36 themes divided among generic, disease-specific and organizational components. After a process of revision it is expected that these standards will be implemented during 2008 and be used as a basis for accreditation in 2009.

Actors

As indicated above, quality improvement initiatives in Denmark have developed

from the involvement of a loose coalition comprising the Ministry of Health, the National Board of Health, the Danish Regions and professional organizations.

Responsibility for the delivery of health care in Denmark is largely decentralized to regional authorities. However, the Ministry of Health has a substantial role in regulating health care. Its main responsibilities in relation to quality of care include: providing organizational guidelines for the health sector; providing health and health care-related information; promoting quality; dealing with patient complaints and maintaining patients' rights (Vallgårda, Krasnik and Vrangbaek 2001). The Ministry of Health works in collaboration with regional authorities and professional groups. Through this collaboration, it has sponsored a programme of evidence-based guidelines, although only 10 major clinical guidelines are so far in place.

As mentioned above, the IKAS was created in 2005 to implement and manage the Danish Health Care Assessment Programme. Cooperation between the IKAS and the Health Quality Service (a British company formerly known as the King's Fund Organisational Audit) was established to develop standards, recruit and train surveyors, and design the overall process of accreditation.

The Ministry of Health and the National Board of Health are jointly responsible for defining the content of postgraduate specialist medical training. In recent years, concerns have been voiced about the quality of clinical training and the National Board of Health has created an inspection system, including a national peer review programme for postgraduate medical education.

The Danish Medicines Agency is responsible for regulation of pharmaceuticals and medical devices, approval of new products, deciding which pharmaceuticals should be reimbursed, and the licensing of companies that produce or distribute pharmaceuticals (Vallgårda, Krasnik and Vrangbaek 2001). In addition, the Institute for Rational Pharmacotherapy provides guidance on the rational use of pharmaceuticals, assessing effectiveness and cost–effectiveness. However, marketing approval does not take explicit account of need or cost–effectiveness (Vallgårda, Krasnik and Vrangbaek 2001).

In 1997, the Danish Centre for Health Technology Assessment (DACEHTA) (former Danish Institute for Health Technology (DIHTA)) was established to perform HTA in partnership with a range of stakeholders. Most assessments are contracted out, although DACEHTA also carries out some in-house work (Vallgårda, Krasnik and Vrangbaek 2001).

The Danish College of General Practice, together with medical colleges in other specialties, produces practice guidelines distinct from those of the Ministry of Health (Vallgårda, Krasnik and Vrangbaek 2001). These clinical guidelines mainly focus on General Practice Care.

Process

The Danish Health Care Quality Assessment Programme (the Quality Programme) is a joint programme intended to support continuous quality improvement (CQI) of the Danish health care service as a whole. The programme has taken its inspiration from the United States (accreditation), Canada (self-assessment), Scotland (disease-specific policies), France (mandatory government programme), Australia (indicator associated accreditation), Ontario (performance indicators) and the United States Institute for Healthcare Improvement's "break-through series", among many other initiatives.

The Quality Programme originated from the Economy Agreements for 2002 and 2003, resulting in the establishment of a Steering Committee consisting of the Danish Regions, the Copenhagen Hospital Cooperation, the Ministry of Health and the National Board of Health. The activities of the Quality Programme include (Borgwardt 2006):

- formulating joint standards;
- making tools available to highlight and improve quality (indicators, evaluation tools, analyses tools, benchmarking and feedback, etc.);
- performing external assessment of quality improvement measures through dialogue and counselling (external evaluation);
- promoting CQI (accreditation).

At the time of writing, only 2 counties (out of 16 – including 2 municipalities) are accredited by international accreditation programmes. These two groups of regional public hospitals have been accredited by the Joint Commission International (six Copenhagen hospitals) and by Health Quality Service (five hospitals in Southern Jutland). From 2009 these regions will join the Danish accreditation scheme and will follow the Quality Programme.

Formal accreditation of facilities is provided by the Danish and European Quality Awards. There are some alternatives to accreditation such as external audit ISO 9001-9002, used by a few hospitals and 9004:2 for laboratories. Few laboratories have been accredited in relation to ISO standards.

A total of approximately 45 national disease-specific or specialist-specific registers (clinical databases), which can yield performance indicators, have been developed by professional scientific societies since the early 1980s.

As described in the earlier section on context, some quality improvement projects were already in place before the introduction of the Quality Plan (the National Indicator Project (NIP); the Good Medical Department; National Clinical Databases; Secretariat for Clinical Guidelines; Patient Safety and Risk

Management; and Nationwide Patient Satisfaction Studies). Three of the most successful projects are described here.

The NIP measures the quality of care provided by hospitals to groups of patients with specific medical conditions (Mainz 2004). For nine frequently occurring conditions (lung cancer, schizophrenia, heart failure, hip fracture, stroke, acute surgery for gastrointestinal bleeding, chronic obstructive lung disease (COLD), birth and diabetes) information is collected from the patients' medical records with respect to treatment and severity of illness, and results are compared with other patients treated for the same conditions. The objective is to identify aspects of care that need to be improved. It is mandatory to report data related to all patients treated at all clinical departments in Denmark to the NIP. Data are available at departmental level on a publicly accessible web site (Mainz 2004).

A confidential, non-punitive, but mandatory system for reporting adverse medical events has existed since 2004 as part of the Patient Safety Act. Participation is compulsory and focuses on prevention of recurrence and learning from experience. Hospitals are now required to report medical errors and adverse events to a national database under the auspices of the National Board of Health. Additionally, a national strategy on public release of quality of care information has been implemented, linked to a star-rating system for hospitals.

A number of laws have been passed in Denmark regulating patients' rights and the possibility of registering complaints and receiving compensation. Patients have a right to see their own medical records free of charge, and doctors or other medically trained personnel are obliged to interpret case records if the patient so wishes. A complaints system has also been established regarding professional treatment in the health service. The Patients' Complaints Board is an impartial public authority which may express criticism of the medical staff or submit particularly serious cases to the public prosecutor with a view to legal action. Additionally, national patient satisfaction surveys are carried out every second year and some regions undertake their own local or regional patient satisfaction surveys.

Health professionals have reported some reluctance to implement quality of care strategies. The main areas of dissatisfaction are:

- reluctance to having to conform to standards set by others
- dislike of having to give up professional autonomy
- dislike of being required to report data
- mistrust of the methods being used – questioning the "scientific" approach

- dislike of the amount of administrative work required
- scepticism about the clinical value of accreditation and star-rating.

In general, however, quality is well embedded in the Danish health system.

Estonia

Context

The establishment of a quality assurance system was identified as a priority for the first time during the Estonian Health Care Project (1995–1998) funded by the World Bank and the Government of the Netherlands (World Bank 2001). The project included development of a policy on quality of health care. The document was presented to the Estonian Government for approval but was later rejected due to a lack of clarity about funding of the measures proposed. Following its rejection, a quality working group was initiated by the Ministry of Social Affairs and the Central Sickness Fund (named the Estonian Health Insurance Fund (EHIF) since 2000), together with the relevant Medical and Nursing associations (Shaw and Kalo 2002). Even though the proposal was not approved, Estonian health care institutions have used it as a basis for quality-related activities (Kaarna and Kalda 2005).

The first official mention of the quality of health care was in the Health Services Organisation Act of 2001. It required the Minister of Social Affairs to set standards for accessibility and quality of health services. It also established minimum standards for health care professionals and health care providers (Kaarna and Kalda 2005).

Actors

Key actors include the Ministry of Social Affairs, charged with ensuring the availability, quality and safety of health services and medicinal products. The Health Care Department, one of the three departments within the Ministry of Social Affairs in 2007, plans and implements healthcare policy (Kaarna and Kalda 2005). However, according to Kaarna and Kalda (2005), the Ministry is not actually engaged in quality assurance, having delegated the role, even though, formally, it is part of its mandate.

The Health Care Board is a government agency which supervises aspects of the health care system on behalf of the State (Kaarna and Kalda 2005). Its functions include:

- issuing activity licences for providers of specialized medical care, emergency medical care and nursing care;
- registration of health care professionals and health care providers;
- supervision of compliance with quality requirements;
- coordination of activities organized by the competency board of health care professionals.

The Health Care Board has also established an expert committee that reviews complaints from patients or their representatives and provides expert appraisal on the quality of health services (Kaarna and Kalda 2005).

The State Agency of Medicines is responsible for the registration and quality control of pharmaceuticals, for regulation of pharmaceutical trade (including imports and marketing) and to oversee sales. It also has some responsibility for the registration of medical technology.

The EHIF has an obligation to monitor the use of health insurance resources, including establishment of quality criteria for services for which it pays (Kaarna and Kalda 2005).

County governors are responsible for the provision of general medical care in their counties and are required to monitor its quality. However, mechanisms to do so have not yet been established and the role has decreased (Kaarna and Kalda 2005).

Educational institutions train health care professionals in compliance with EU provisions. The curricula of prospective physicians and nurses include quality assurance, taught within courses on health care management. Similar courses are now included within postgraduate training schemes (Kaarna and Kalda 2005).

In 2002, responsibility for professional accreditation was transferred from the Government to professional associations that is on a voluntary basis and currently introduced by many associations. The Estonian Medical Association has introduced a certification programme for medical specialists. To improve quality some professional societies have developed guidelines for treatment and prevention of certain diseases.

The Health Services Organisation Act requires health care providers to establish a quality management system. However, as Kaarna and Kalda note, at least in 2005, few facilities had established systematic activities.

Process

Management information systems that will support quality assurance are progressively being put in place. However, there are no generally accepted quality indicators, except for those included in a system for paying bonuses to family doctors (described in more detail later).

There are a number of informal systems in place in many hospitals. In some cases, participation is encouraged by the use of financial incentives and quality awards. Three out of 19 hospitals providing acute in-patient care took part

in the Estonian Quality Award contest during 2003–2004. Since 2005 many hospitals integrated quality assurance into their mission statements.

In addition, WHO and the EHIF initiated a project in 2005 whereby a group of six hospitals developed, on a voluntary basis, a quality assessment system based on the WHO PATH methodology. By 2006 most of the hospitals had unified annual patient satisfaction surveys. On the other hand, as already noted, many facilities do not undertake any systematic quality assurance activity and there is no evidence to assess to what extent the data obtained in quality assessments are actually used (Põlluste, Habicht et al. 2006).

In the late 1990s, the EHIF began to assess the quality of the treatment it paid for and, since 2002, periodic checks have been made in areas such as internal medicine, surgery, intensive care, obstetrics and gynaecology.

The EHIF also coordinates the development of clinical guidelines by professional associations of specialist doctors. The clinical guidelines are coordinated by the special commission that invites the development of guidelines and approves them. Where these have financial implications the EHIF carries out clinical audits among providers.

The EHIF carries out patient surveys to assess the accessibility of primary care. A 2006 survey found that 99% of patients with acute problems were able to access their family doctor on the same day, and that 99% of patients with chronic conditions could see their family doctor within three days. A survey carried out in 2003 showed that 88% of patients who had visited their family doctor were satisfied with the service. Satisfaction had risen by 11% since 1999 and by 14% since 2001. However, the system of partial gatekeeping is reported to be not yet well accepted by the population (Jesse et al. 2004).

Another study carried out in 2002 sought to assess among managers the perception of the quality of care provided. More than 500 people completed the survey. Of the total of the sample, 27.8% evaluated the quality of health services as "good" and 62.7% as "satisfactory". When asked about the quality of different health services, the answers ranged considerably. Dental care was considered to be of "good" or "very good" quality by 51% of respondents and specialized outpatient care was evaluated as "good" or "very good" by 41.2% of the respondents. The quality of primary health care services was evaluated as "good" by less than one third of the managers, and the quality of rehabilitation services was evaluated as "good" by 25.6% and "satisfactory" by 33.1% of respondents. The poorest evaluation was of the quality of nursing and social care services, with 36.3% and 50.3% of respondents, respectively, evaluating the quality of these services as "bad" or "very bad" (Põlluste et al. 2002).

Family physicians can apply for bonus payment if they meet performance standards for vaccination coverage, monitoring of certain chronic diseases and pregnancy, and performing simple surgical procedures. The policy was launched in 2005 and first payments were due in 2007, based on performance in 2006 (Aaviksoo 2005).

Perceived barriers to the further development of quality assurance include an inadequate legislative basis, weak financial incentives, and lack of coordination. The most commonly mentioned problem is lack of coordination, as no single public institution has assumed overall responsibility for quality of health care. The EHIF is taking a lead role, but providers are very cautiously joining the purchaser-led (and controlled) quality assurance model (PATH, mentioned earlier). Hospitals and family physicians have identified an urgent need to implement some sort of quality assurance system and both parties are taking active steps to do so.

Finland

Context

Quality assurance activities in Finland started in the early 1980s, when professional groups became engaged in different quality assurance projects, which expanded during the 1990s. In 1994 a National Policy on Quality for Health Care was approved. One year later the first National Recommendation on Quality Management was published. In 1998 a quality strategy was proposed for public services and in 1999 Recommendations on Quality Management for Health Services provided and purchased by municipalities were introduced (Outinen 2003).

Actors

The Ministry of Social Affairs and Health defines policy on health care at national level. The Ministry also leads international cooperation on quality assurance and indicator development in health care. The main approaches taken by the Ministry to promote quality of care are:

- creation of a system to monitor quality in health and social care (in cooperation with the National Research and Development Centre for Welfare and Health (STAKES));
- establishment of nationwide registers and quality indicators;
- introduction of patient safety indicators;
- international cooperation on indicator development.

These approaches are reported as being accepted increasingly by health professionals, although cultural barriers are still perceived to exist. In 2005 nationwide guidelines for treatment of 193 non-acute diseases were established.

The National Authority for Medico-Legal Affairs (TEO) is responsible for licensing, registration and monitoring of health care staff and, in part, health care organizations. It also undertakes disciplinary procedures against health care staff.

The National Agency for Pharmaceutical Medicines (NAM) grants permission for products to enter the market, although manufacturers can also use the integrated European authorization system (Järvelin 2002). This institution also provides national guidance on the use of medical equipment, including hygiene routines. Implant registers are also maintained by the NAM. The Accreditation

Service implements a number of international certification schemes (SFS-Inspecta for ISO 2000, Qualisan for laboratories).

Efeko (a newly formed training organization and management consultancy), responsible for the Social and Health Quality Service, is in the process of developing an accreditation system. At the time of writing it offers a quality stamp of approval following an audit by health and social care experts from public and private organizations.

FinOHTA, an independent public assessment agency, was established in 1995 to coordinate HTA (FinOHTA 2005), including dissemination of assessments conducted outside Finland. It is credited with raising awareness of HTA among health professionals (Järvelin 2002).

The Finnish Medical Society, Duodecim, is producing evidence-based guidelines for health care. These guidelines are widely used at the time of writing, and in their electronic form are considered to be the most important single source of medical information in Finland (Kunnamo 2005).

The Association of Finnish Local and Regional Authorities supports the towns and municipalities to strengthen quality of care and has developed a self-assessment tool. In addition, there are several private actors within the health care field engaged in evaluation, development, certification and accreditation of health care organizations.

Process

A health care accreditation programme was introduced in 1993. Health care providers were pivotal in the introduction of this programme because they wanted to include quality measures in their contracts. After exploring the different strategies available, the programme selected in the end was based on the United Kingdom's KFOA. At the time of writing the Finnish health care accreditation programme covers all health care and social services. Standards and criteria have been produced and published for public and private acute hospitals, health centres, psychiatric care, private physician practices, rehabilitation centres, occupational health care, nursing homes and the entire social sector.

In addition, the EFQM and the CAF criteria are used as assessment tools. Health care organizations regularly participate in the annual Finnish Quality Award competition. There are also specific certification and accreditation systems both for clinical and pathological laboratories. Peer reviews, audits and benchmarking activities are undertaken by health professionals on voluntary basis.

By 2005 the Social and Health Quality Service had audited 88 organizations (22 large public or private hospitals or health centres). A total of 59 had applied and been granted a quality recognition (15 large hospitals or health centres). In addition, 44 organizations had begun quality improvement initiatives using Social and Health Quality Service criteria.

National guidelines on quality assurance in social welfare and health care were published in 1995 and 1999. The principles underlying the guidelines were the promotion of patient-oriented services; the incorporation of quality assurance as part of daily activities; and the use of knowledge as the basis for monitoring, measuring and evaluating activities in social welfare and health care (Järvelin 2002).

On 1 March 1993 the Finnish Act on Patients' Rights entered into force and this was the first law of its kind in Europe. This Law mainly concerns the patient's right to information, informed consent to treatment, the right to see any relevant medical documents, and the right to autonomy (Järvelin 2002). In 1996 a review of its implementation found that practical mechanisms open to patients to claim their rights were well established, but active participation and access to information needed to be improved. There are also various patients' associations active in discussions on health policy.

Patient satisfaction surveys are widespread. STAKES provides a scheme with nationwide patient satisfaction questionnaires for six different fields within health care services. The TEO has a standing committee for patient complaints and treatment hazards (HOPE 1996).

In summary, a commitment to quality is now well established within the Finnish health system.

France

Context

Growing concern about the quality of care in France emerged in the 1980s and early 1990s, following a series of incidents exposing undesirable practice in health care services. These included the 1992 publication of a report by the National Sickness Fund revealing substantial levels of over- and misuse of medical services by practitioners (de Pouvourville 1997) and, more prominently perhaps, serious safety concerns surrounding a blood transfusion scandal in the 1980s which resulted in the infection with HIV of an estimated 4000 to 6000 people receiving contaminated blood products (Steffen 1999). As a result, the Government embarked on a series of reforms which saw the creation of the ANDEM in 1990 and the 1991 Hospital Act (No. 91-748, 31 July 1991), through which assessment of care became mandatory (de Pouvourville 1997). Other initiatives include dissemination of practice guidelines, lengthening general practice training periods, the development of medical information systems and piloting networks of health care providers to improve coordination and continuity of care. These were (partly) formalized in the context of the 1996 "Juppé reform" of the French health care system that also established the ANAES, which replaced ANDEM (Sandier, Paris and Potton 2004). In October 2004, the role of ANAES was subsumed under the newly created HAS that also incorporates the roles of the Commission on Transparency and the CEPS (created in 1999), along with others (Haute Autorité en Santé).

Actors

Key actors include the Ministry of Health, which promotes quality strategies at various levels of the health care system through professional regulation, norms and standards setting, accreditation procedures and competency assessment.

The HAS is an independent scientific public authority aiming, among other things, to promote good practice within the French health care system (Bellanger, Cherilova and Paris 2005). Specific objectives include, among others, the development and dissemination of clinical practice guidelines; HTA; evaluation of professional practice of physicians; development and implementation of hospital accreditation procedures; and certification of medical IT, such as web sites or prescription software. The HAS acts in response to requests from the Ministry of Health, the health insurance funds and the medical unions.

Evaluation of pharmaceuticals is the responsibility of the AFSSAPS, established in 1998 (Bellanger, Cherilova and Paris 2005). It has regulatory functions, involving oversight of the market authorization process for pharmaceuticals,

and is also responsible for market monitoring regarding pharmaceuticals and medical devices.

Sickness funds have a role in evaluating the quality of care in hospitals through their own medical inspectors, their representation in Regional Hospital Boards (ARH) and their involvement in the development and implementation of regional strategic health plans.

Regional Medical Unions (URML), established in 1993 and comprising general practitioners and specialists, aim to support physicians by evaluating professional standards of practice, disseminating guidelines and facilitating evaluations undertaken in physicians' surgeries (Or 2002).

Process

Accreditation of (public and private) hospitals (recently renamed as certification) was made mandatory in 1996 as a means to "ensure continuous quality and safety improvement of health care" (Daucourt and Michel 2003). The accreditation procedure is an external evaluation of the quality and safety of health care provided within each health care institution. It is carried out by the HAS, following an accreditation manual originally developed by ANAES, according to which facilities are evaluated in the areas of patients' rights and patient care, management and organization for the patient's benefit, and quality and prevention. Each section contains a set of standards and criteria to be met by the facility, a total of over 80 standards and approximately 300 criteria (Daucourt and Michel 2003). The procedure involves a period of self-assessment, a visit from experts and exchanges with the HAS. The resulting report is examined by the Accreditation Commission, within the HAS but independent from the accreditation department which grants the actual accreditation award, taking account of the level of improvement required. By mid-2006 all 3000 health care organizations had completed the process, with approximately 30% receiving accreditation with (major) reservations because of departure from the required standards (HAS 2005).

In addition, hospitals are required to establish quality steering committees. The committee is then responsible for monitoring statutory standards of care set by the Ministry of Health, as well as evaluating performance; promoting a culture of CQI within departments; implementing quality improvement plans; assuring the accreditation standards and preparing accreditation visits by experts; and assessing professional practice.

In the ambulatory sector, a formal voluntary programme of external evaluation of quality of care provided by physicians, based on self-evaluation, was introduced by law in 1999, with the URML taking the bulk of responsibility

for this process (Or 2002). Since 2005, this programme was adapted to be integrated into the new requirement of a mandatory external practice appraisal for all physicians every five years. In another programme, officially launched in July 2006, physicians who have a higher risk practice may volunteer to participate in an accreditation programme where they report "near misses" to their professional societies and integrate corrective actions into their practice in exchange for a reduction in insurance premium payments.

By the end of 2005, 2557 health care organizations (86% of the total) had completed their accreditation procedure and 2156 accreditation reports had been posted on the HAS web site. The second version of the accreditation manual was introduced in 2005 and was used by 97 health care organizations taking part in a second round of the accreditation procedure. The 97 accreditation visits identified 1015 CQI initiatives in medical practice. However, preliminary results would seem to suggest that fewer health care organizations achieve unconditional accreditation with the second version of the manual, which focuses on the extent to which criteria are met, compared to the first version, which was more concerned with whether the health care organization was engaged in CQI.

As noted above, the HAS is also responsible for issuing clinical practice guidelines. Its predecessor, ANAES, had published approximately 30 recommendations on clinical practice relating to the diagnosis, treatment and supervision of certain conditions (Sandier, Paris and Potton 2004). Mandatory practice guidelines were introduced in by law in 1993. These are recommendations on good practice, mainly involving pharmaceutical prescriptions and, to a lesser extent, the prescription or provision of medical treatment (Durand-Zaleski, Colin and Blum-Boisgard 1997). Initially, doctors who failed to adhere to these guidelines faced the threat of financial penalty, although the system of penalties was rarely used and was eventually abolished in 1999 (Durieux 2000; Sandier, Paris and Potton 2004). Available evidence suggests, however, that the most relevant guidelines had led to substantial changes in doctors' prescribing behaviour (Or 2002).

The HAS is also responsible for HTA, which includes the evidence-based assessment of commonly used technologies in health care, as well as rapid assessment of emerging or fast-developing technologies and emerging public health issues. Reports produced as a result of these activities have, however, no formal status and their impact on decision-making in health (care) policy is uncertain (Orvain, Xerri and Matillon 2004).

As mentioned earlier, an external evaluation of the quality of care given by individual physicians has been a legal obligation for every French physician since

July 2005. This external evaluation must be repeated every five years. Bodies authorized by the HAS validate the process. Continuing medical education (CME) is mandatory and contributes to the evaluation process described earlier. There are plans to extend the external practice evaluation programme to other health care professionals.

Germany

Context

In Germany, systematic quality assurance programmes addressing selected topics were introduced for the first time in the mid-1970s at regional level by the State Chambers of Physicians (Birkner 1998; Ollenschläger, Marshall and Qureshi 2004). At national level, professional self-regulation, with monitoring of technical safety and hygiene, were, until the end of the 1980s, regarded as sufficient to ensure quality of health care (Busse and Riesberg 2004). In the mid-1990s, "quality in health care" became a priority topic both in professional self-administration and health policy at state level, focusing on the use of quality management programmes, clinical guidelines and quality indicators (Helou, Schwartz and Ollenschläger 2002). Since then, quality of health care has been a priority in national policy (Allen and Riemer Hommel 2006) and quality requirements for in- and outpatient care were codified in the Social Code Book (SGB, *Sozialgesetzbuch*), the regulatory framework for the German social health insurance system. Beginning with the 1989 Health Care Reform Act, which made quality assurance measures a mandatory element in contracts between hospitals and sickness funds, quality assurance in hospitals and, more recently, in the ambulatory sector has progressively been transformed from a voluntary activity to a legal obligation. This was, in part, prompted by a report in 2000/2001 by the Advisory Council for Concerted Action in Health Care, revealing considerable shortcomings in the quality of health care in the German system, documented by inappropriate provision of services for those with chronic conditions (Deutscher Bundestag 2001). From 2000, successive measures to improve quality of care included:

- a legal obligation on the part of hospitals and the ambulatory sector to engage in external quality assurance and internal quality management;
- definition of minimum service volumes for selected elective services;
- introduction of structured disease management programmes;
- establishment of the Federal Joint Committee (G-BA, *Gemeinsamer Bundesausschuss*) and the Institute for Quality and Efficiency (IQWiG, *Institut fur Qualitat und Wirtschaftlichkeit im Gesundheitswesen*) in 2004;
- publication of external quality reports on hospitals (Geraedts, Schwartze and Molzahn 2007).

Actors

The federal Ministry of Health promotes quality strategies at various levels of

the health care system by determining the legislative framework as set out in the SGB.

The G-BA is the highest decision-making body in the self-governing health care system and is responsible, among other items, for defining quality standards for ambulatory, inpatient and intersectoral health care services (Busse and Riesberg 2004). The G-BA also issues directives on health care provision in each health care sector. The committee subsumes the tasks of several (former) committees and working groups at the federal level that had been involved with the promotion and implementation of quality assurance systems in the statutory health insurance system, such as the former Coordinating Committee, involving the German Hospital Federation and the sickness funds (introduced in 2000), and the former Working Group Quality Assurance (1993).

The IQWiG was established in 2004 to support the G-BA. The Institute is independent of government and funded through the social health insurance system; its legally defined tasks include the compilation of scientific reports, opinions and statements on the quality and efficiency of services provided under the mandatory social health insurance system; recommendations on disease management programmes; evaluation of evidence-based guidelines for epidemiologically important diseases; and the provision of patient-information on quality of health care and others.

The Federal Office for Quality Assurance (BQS, *Bundesgeschäftsstelle Qualitätssicherung*), established in 2001, supports the contracting partners in the statutory system in the development and implementation of measures for external quality assurance in hospitals as stipulated in the SGB.

The regional Chambers of Physicians (*Ärztekammern*) are responsible for postgraduate accreditation and continuing education, and for setting professional standards. Their activities are coordinated at federal level by the Federal Chamber of Physicians (BÄK, *Bundesärztekammer*), which has also been issuing guidelines and recommendations for decades on specific topics and procedures, such as ethics in health care, ambulatory surgery, medical imaging and transplantation (Ollenschläger, Marshall and Qureshi 2004). In 1995, the BÄK, together with the National Association of Statutory Health Insurance Physicians (KBV, *Kassenärztliche Bundesvereinigung*) founded the German Agency for Quality in Medicine (AEZQ, *Ärztliches Zentrum für Qualität in der Medizin*), charged with initiating and analysing project work in the field of quality assurance on behalf of the self-governing bodies of the German health care system, cooperating with national and international partners (AEZQ 2005). Specifically, the AEZQ organizes the National Disease Management Guidelines Programme (Ollenschläger, Marshall and Qureshi

2004), the German Physicians' and Self-Help-Groups' Joint Clearinghouse for Patient Information (Sanger et al. 2002; Allen and Riemer Hommel 2006) and the Physicians' Patient Safety Programme (Thomeczek and Ollenschläger 2006; AEZQ 2007).

Process

As noted earlier, since the year 2000, hospitals are legally required to have internal quality systems and to implement external quality assurance mechanisms as set out in their contracts with sickness funds (Busse and Riesberg 2004). The external system involves the documentation of quality indicators, a process supported by Regional Offices for Quality Assurance (LQS, *Landesgeschäftsstelle für Qualitätssicherung*). Data are compiled and analysed at national level by the BQS and the findings are fed back in the form of reports and recommendations to individual hospitals and made publicly available in a comprehensive format through the publication of an annual quality report (BQS 2005). For example, the 2004 report covered a total of 19 areas, including gynaecology, obstetrics, hip and knee replacement, prevention of pressure ulcers (nursing), cardiac revascularization and breast surgery. These were assessed by means of a total of 212 quality indicators, linked to specified numerical targets (BQS 2005). Hospitals identified as underperforming are required to explain the situation and, if deemed necessary, take appropriate action to improve performance. Also, hospitals that fail to document data required by law will face financial penalties (Döbler and Mohr 2004).

In addition, since 2005, legislation requires hospitals to publish standardized quality reports biennially (Gemeinsamer Bundesausschuss 2005b). These include structure and process data on the hospital, such as number of beds, staffing, levels, volume of services provided, and medical equipment, as well as documentation on the internal quality management system in place. By September 2005, just over 1900 hospitals (98% of all hospitals required to do so) had published a quality report. The reports are accessible online, enabling the public to search for information on quality by hospital and/or location, although direct comparison is not possible. While providing comprehensive information, reports have been criticized for not including outcomes data (Tuffs 2005).

From 2000 onwards, hospitals have also been encouraged to participate in certification procedures established in a joint initiative involving associations of sickness funds and various hospital organizations. There are two major certification systems, both combining self-assessment (following a standard protocol) and external assessment (visitation), based on the EFQM and

European quality award system, the so-called "Cum Cert" for confessional hospitals and the KTQ (Busse and Riesberg 2004).

As in the hospital sector, providers of care in the ambulatory sector covered by social health insurance are legally required to implement internal quality management systems, adhering to regulations establishing minimum standards that were put in place in 2006 (Gemeinsamer Bundesausschuss 2005a). Selected specialist services provided in the ambulatory setting, such as invasive procedures and medical imaging, require certification of providers, who also have to hold a licence to practise as specialist (Busse and Riesberg 2004). To qualify for certification, facilities have to meet minimum technical standards and providers need to demonstrate that they have obtained additional training (defined as the number of supervised cases undertaken). Maintaining eligibility for reimbursement requires recertification. (Re)certification criteria are defined by the KBV and form part of the contractual arrangements between sickness funds and regional physicians' associations.

The importance of evidence-based guidelines and patient information as basic tools for quality promotion in health care has been stressed by the physicians' self-governing organizations (BÄK, KBV, AEZQ) and scientific associations since the mid-1990s (Ollenschläger, Marshall and Qureshi 2004). Against this background, nationwide guidelines (Ollenschläger, Marshall and Qureshi 2004) and patient information programmes (Sanger, Nickel et al. 2002; Allen and Riemer Hommel 2006) were established, based upon international standards (Council of Europe 2001; Ollenschläger, Marshall and Qureshi 2004). Among these, national disease management guidelines (AEZQ 2007) are implemented nationwide by means of certified CME programmes (Vollmar et al. 2006) and interlinked with the social health insurance system's national disease management programme for chronic care (Ollenschläger, Marshall and Qureshi 2004).

More recently, the KBV and BÄK initiated a national critical incident reporting system (CIRSMedical.DE) permitting health professionals to report, voluntarily and anonymously, (near) medical errors, involving an Internet-based reporting system set up in April 2005 and complementing other initiatives set up by several stakeholders in Germany (Tuffs 2005). It is as yet unclear, however, whether and how these and related initiatives will help in identifying and minimizing risks.

The regulation and control of health technologies in Germany has not in the past been a major issue, but with recent health care reforms, HTA has become an increasingly important feature of health care decision-making. It is now taken into account when defining the package of health services covered under

the statutory system by the G-BA (Busse and Riesberg 2004). The IQWiG commissions assessments and makes recommendations for the inclusion into or exclusion of technologies from the benefits covered under the social health insurance system, although it does not have any decision-making powers. An HTA database has been established at the German Institute for Medical Documentation and Information (DIMDI, *Deutsches Institut für Medizinische Dokumentation und Information*) to support decision-making by the G-BA and others. However, the overall approach towards regulating innovations and using evidence to inform decision-making still appears to be somewhat inconsistent, especially due to the coexistence of two competing approaches to health quality policy. The first are "bottom-up" programmes, which have been introduced or endorsed mainly by physicians' self-governing and scientific associations (e.g. professional training in quality management and evidence-based medicine (Bundesärztekammer and KBV 2003; Bundesärztekammer and DNEbM 2005; Bundesärztekammer, AWMF et al. 2007), voluntary certification of health institutions (AEZQ 2006), or disease management guidelines (Ollenschläger, Marshall and Qureshi 2004). The second are mandatory quality control programmes imposed on health care providers by the SGB. It remains to be seen whether recent initiatives such as the establishment of the IQWiG or the disease management guideline programme will have a noticeable impact.

Greece

Context

Various efforts have taken place in Greece since the early 1990s to initiate quality of care activities. In 1996 and in 2001, the then Ministers of Health established National Committees for Quality on Health Care, while a facility for a planned Institute of Quality and Accreditation in Health Care Services has been built. The 2001 Committee produced an in-depth report that recommended ways to enhance quality of care. However, changes of government and a lack of financial support have meant that few of the proposed activities have taken place. Nevertheless, the topic remains on the policy agenda.

Actors

Quality of care is the responsibility of the chief executive and the medical directors of each health care facility. There are a number of organizations involved in quality initiatives. The ExPeRT project (1998) reported that the Greek Standards Organization (ELOT) had an active quality certification department and their team may play a key role in any project aiming to produce national standards for accreditation of health care services (ExPeRT 1998). However, various other (mainly hospital-based) initiatives have been undertaken in collaboration with private companies, such as that in the Onasis Cardio-surgery Center, which was fully certified by the end of 2004, as well as in other smaller units.

Legislation enacted in 1994 established a postgraduate education department within the Ministry of Health, in collaboration with the Central Health Council, to organize continuing education programmes. Continuing education is also the responsibility of hospitals and of scientific medical societies (WHO 1996). Many activities are undertaken, largely on an opportunistic basis, but there are no educational criteria against which to judge them.

Medical graduates do not need to have completed specialized training in order to practise in ambulatory care settings (although most have), but they must serve for a year in rural health care settings (this requirement is soon to be phased out). The curriculum in the seven medical schools comprises mainly hospital-oriented training, and, with the exception of the University of Crete, contains little that is related to primary health care, public health or family medicine (WHO 1996). Since the 2002 reform, all doctors in the public sector are required to be revalidated by the relevant medical councils in their region (the directors) or their hospital (all others). However, it is not clear whether this process has proven to be effective. Poor performance is mainly dealt with

by the medical associations (there are no lay members in the decision-making process).

During the 1990s, a National Committee on Patients' Rights was established within the Ministry of Health, working in collaboration with similar committees in each hospital. These committees examine many cases brought to their attention each year but they have yet to report publicly on the outcome of their deliberations. Recently it was announced that a "Health Ombudsman" post would be established. The law dealing with medical bioethics has recently been revised (Council of Europe Convention on Human Rights and Biomedicine, incorporated into Greek national legislation by law 2619/1998).

The National Organization for Medicines (EOF) is responsible for the regulation and supervision of the pharmaceutical sector. Its main responsibilities include: approving and licensing all pharmaceuticals on the market (other than those authorized through the EMEA process); ensuring good manufacturing practice; and hosting the committee responsible for making recommendations for including medicines in the reimbursement list (the main criterion being the daily treatment cost, which does not take into account overall costs, either direct or indirect).

Pharmaceutical pricing is the responsibility of the Ministry of Trade; the process is not linked to reimbursement decisions or to any evidence of cost–effectiveness analysis. It is, however, recommended that pharmaceutical companies should include cost–effectiveness analyses with their applications for the licensing of any new pharmaceuticals.

In 2001 the Greek health service underwent a process of regionalization, giving rise to structures that, since 2005, have been designated as Regional Health Administrations. These are responsible for NHS hospitals and health centres on their territory. So far, their focus has been on budgetary control, human resource development, infrastructure maintenance, and supplies. Laws established in 2001 and 2005 required every regional health authority and every NHS hospital to set up a Quality Department, although few hospitals have done so. The Health Insurance Funds, as partial funders of care, are responsible for monitoring health care quality, which they can do through administrative reporting on compliance with contracts and patient surveys. The private sector, which absorbs over 45% of health care expenditure, employs over 50% of doctors and manages over 30% of hospital beds, has not yet been obliged to implement policies on quality except for basic structural provisions concerning building installations and qualifications of staff. Private health providers are, however, required to be licensed, which involves an inspection by the district medical officer and an assessment of hygiene standards. Many private hospitals

and diagnostic centres have been certified by private accreditation bodies according to ISO criteria or similar. This approach is also increasingly taking place in some public hospitals, although there is no requirement to do so.

Process

There are no formal systems for HTA in Greece. Recently EKEVYL (as a branch of EOF) has started to play such a role. Policies to improve cost-effective use of pharmaceuticals do not exist but have recently been proposed by the Ministry of Health, reflecting concerns that Greece has one of the highest rates of pharmaceutical consumption in the EU. Health care facilities in Greece are not evaluated by any "accrediting" organization and there are no official organizational or quality standards (ExPeRT 1998). However, since 1990 DEPANOM (a public company responsible for building and refurbishing public hospitals, health centres and other facilities) has adopted international technical standards in terms of areas such as catering facilities, elevators, etc. Biomedical devices have to follow European and international guidelines, and to this end the standards produced by EKEVYL comply with ISO 9000 standards.

Many hospitals have begun to develop their own quality assurance programmes, although these are far from being widely established. The 2002 reform established a department responsible for quality issues in every regional health authority. Each public hospital now has an office for dealing with patients and their relatives (so-called Office on Communication with the Citizens). In collaboration with the National School of Public Health and some universities, many hospitals carry out periodic or ongoing assessments of patient and staff satisfaction.

Since 2002, most hospitals have implemented programmes of continuing professional education. A contract to establish processes for quality and accreditation has recently been signed by ELOT and the Central Health Council (KESY).

A department within the Ministry of Health tracks utilization and financial indicators relating to each hospital and other health facilities. However, the proposed "Health Map" based on these data has yet to be compiled or published.

Public hospitals have little incentive to review their organizational structure because resources (including staff) are allocated on the basis of hospital beds (not outputs or activities). This creates perverse incentives to inflate the numbers of hospital beds, and to ignore less productive or even unnecessary clinics (Polyzos 2002). It is compulsory for all hospitals to have their equipment certified to ISO 9000 standards (ExPeRT 1998).

Initiatives to audit hospital laboratories have been under way for several years in cooperation with external companies.

The ExPeRT project identified a number of individual projects that have not been rolled out across the whole country. For example, the Institute of Biomedical Technology, in collaboration with professional associations and other groups, has generated standards and guidelines. The Greek Association of Medical Physicists and the Greek Association of Biomedical Technology have developed quality control protocols for medical equipment. Other projects have piloted the development of quality indicators, evaluation of quality of care in tertiary hospitals and the development of educational seminars on quality of care. There have also been some activities focusing on evaluation of primary health care, using patient reports.

In the absence of specified quality indicators, surveys on patient satisfaction at the individual hospital level (typically obtaining high scores) and national surveys on popular views of the NHS (often yielding low values) are the main sources of data on health care quality. Waiting lists are also a major issue in Greece, because large metropolitan hospitals are overutilized, while district hospitals are underutilized.

A comprehensive approach to quality has not yet been fully established in the Greek NHS. Governmental bodies assess infrastructure, and regional authorities assess personnel and financial management procedures, but none evaluate the process of care delivery. Beyond the national responsibilities of the Ministry of Health, medical and other health professional associations either at national level or at the level of individual specialties have not formulated guidelines on evidence-based clinical practices. Thus, quality remains critically dependent on the motivation of the individual health professional. There is, however, some evidence that attitudes are changing.

Hungary

Context

Quality assurance first became a priority for the Hungarian Government in the early 1990s, leading to the enactment of several government resolutions, decrees and orders related to quality (Gulácsi 2001).

The main regulation was the Law on Health Care (1997), which provided a legal basis for internal and external quality management systems. The Law stated that each health care organization was required to establish an internal system and it also defined some minimum quality standards and set out in detail the rights of patients. These quality standards related mainly to structure, including staffing levels. There is no requirement to establish internal quality assurance systems and there is no provision for quality indicators, nor any specification of external assessment methods to be used. Under this Law, once a health care organization could show that it meets the minimum standards, it would be granted permission to operate. However, in practice, even now most organizations continue to operate under a temporary permit.

Since 1997, however, there has been little legislative activity. It is reported that policy-makers were more interested in quality of health care during the 1990s than in the new millennium. A survey carried out in 107 hospitals clearly shows that the level of quality-related activity was lower in 2005 than in 2000 (Gulácsi et al. 2006).

In 2007 the system of health care financing was restructured. It is intended that the current single insurance fund will be split into multiple funds and a new supervisory organization has been established. The Health Insurance Supervisory Authority has been given an explicit responsibility to monitor and improve the quality of care provided by health care organizations and paid for by the proposed new funds. However, the mechanisms by which it will do this have yet to be decided, although the Authority is, at the time of writing, engaged in a process of developing and testing possible approaches.

Actors

The Ministry of Health created a Quality Assurance Department in 1992, responsible for producing and continuously updating guidelines on a range of topics, such as the management of hypertension. It works in close collaboration with professional bodies and the guidelines are published on the Ministry's web site. Other activities being supported by the Ministry of Health include:

- implementation of quality management systems (ISO) in health care;

- development of service-specific operational standards;
- development of performance indicators;
- development of evidence-based directives;
- the "Hospital of the Year" scheme, which rewards hospitals that have performed well on quality improvement and assurance activities.

The existing single payer, the Health Insurance Fund, has a formal responsibility to monitor health care quality. In practice, it concentrates on administrative functions, although it also takes a considerable interest in the quantity and quality of health care delivered. The Fund has established a quality indicator programme, using data from its own administrative database. The results are fed back to individual providers, who can see where they lie in terms of the distribution of all providers, but the published results do not allow identification of individual units. The goal of the programme is to incentivize quality improvement activities. The measures chosen are, as far as possible, evidence based, internationally validated process and outcome indicators (Belicza and Feher 2004).

The National Centre for Healthcare Audit and Inspection launched a clinical audit programme in 2005. It seeks to support the development of clinical audit by facilitating data feedback, working closely with providers. The programme is still under development and its impact on quality is as yet unclear.

The Hungarian Hospital Association has been active in the field of quality of care since the 1990s. It participated in an evaluation of the applicability of accreditation standards of the Joint Commission International. In 1993 the Association established its own Quality Control Committee to assist with developments in this field. However, accreditation of health services has not been introduced in Hungary. In 2006 an adverse event reporting system was launched by the Hospital Association, in close collaboration with the Health Services Management Training Centre at Semmelweis University. It has adapted the WHO draft guidelines for adverse event reporting and learning systems. The programme aims to identify and reduce hazards as a means of enhancing patient safety in hospitals.

HTA is regulated by the Government, but is not being widely used within the Hungarian health care system. Two agencies have been created: a governmental HTA agency and the Unit of Health Economics and Health Technology Assessment within the Department of Public Policy and Management at the Corvinus University, Budapest.

Health care providers must obtain a licence to practise from the National Public Health and Medical Officers Service, which maintains a register of authorized

providers. Before issuing a licence to the provider, medical officers should inspect the facilities and ascertain whether they meet minimal building and hygienic requirements, as well as staffing and material standards. In practice, this rarely occurs, so a temporary licence is issued.

Process

While in 1992 the concept of quality assurance was largely unknown in Hungarian hospitals, by the year 2000 most had a director of quality assurance, a coordinator, a quality assurance committee or at least one physician or nurse whose working time was partly or fully devoted to quality assurance. In 2007, more than half of Hungarian hospitals had some kind of certificated quality assurance system in place. Most often these involve the ISO 9000 quality system and other operational standards. Certification is generally voluntary but, in certain circumstances, can be required.

In 2001 the Ministry of Health published a Handbook of Hospital Care Operational Standards, which has subsequently been updated regularly. This covers areas such as:

- admission and discharge of patients
- arrangements for medical assessment
- enforcement of patients' rights
- quality improvement
- leadership
- human resources management
- safety of equipment and facilities.

During recent years, standards have also been developed and published for other services, such as outpatient care, home care and primary care. Adherence to these standards is assessed within the largely voluntary certification systems.

Republic of Ireland

Context

In the late 1990s, three major reports into the Irish Health Services were published, leading to a major review of the organization and delivery of care. This process culminated in 2001 with the publication of a national health strategy, "Quality and Fairness, a system for you". This strategy recommended a radical reorganization of the health services in the Republic of Ireland, proposing the abolition of the eleven regional health boards and their replacement by a centralized, unified health authority (the Health Service Executive or HSE) that would organize and deliver primary, secondary, continuing and community care. In tandem with this new authority an equivalent oversight body was proposed to regulate the standard health care services delivered by the HSE. This authority, the Health Information and Quality Authority (HIQA) was established on an interim basis in March 2005. Its role is to ensure the delivery of high-quality services based on evidence of best practice, to design and monitor standards of care provision, to carry out HTA activities and to advise on and regulate elements of health care information processes. In the initial discussions, it was envisaged that it would incorporate the IHSAB and the National Cancer Registry.

The HIQA's legislative basis was enacted in April 2007 and the Authority itself (as opposed to the interim HIQA) has been operational since 14 May 2007. The National Cancer Registry remains as a stand-alone body; the accreditation section is subsumed by the HIQA, as is the Social Services Inspectorate.

Actors

Governmental

It is envisaged at the time of writing that the Department of Health and Children, the HSE and the HIQA will be equal partners in the strategic development, organization and delivery, and monitoring of health care services (see Box 4.2 for more detail on key elements of the Irish reform programme).

The Department of Health and Children, in its new role, is responsible for strategy and overall coordination of the health and social services in the Republic of Ireland. It retains responsibility for some functions, such as health surveillance, health promotion and public–private partnership arrangements, but the financial responsibility for service delivery has been devolved to the HSE.

Box 4.2 *Key elements of the Irish reform programme*

- Rationalization: A major rationalization of existing health service agencies seeks to reduce fragmentation. This includes the abolition of the existing health board/ authority structures and the creation of a single health care delivery body.
- Reorganization: The reorganization of the Department of Health and Children, to ensure improved policy development and oversight, with devolvement of delivery to the HSE and quality and regulation monitoring to HIQA.
- Executive: The establishment of an HSE which will be the first ever body charged with managing the health service as a single national entity. The executive is to contain:
  - National Hospitals Office
  - Primary, Community and Continuing Care Directorate.
- Information and Quality: The establishment of an HIQA to ensure that quality of care is promoted throughout the system.
- Modernization: The modernization of supporting processes (service planning; management reporting, etc.) so that they are brought in line with recognized international best practice.
- Governance: The strengthening of governance and accountability across the system.
- Focus: The programme's priority focus is improved patient care, better value for taxpayers' money and improved health care management.

Notes: HSE: Health Service Executive; HIQA: Health Information and Quality Authority.

The transition from the regional boards, responsible for both hospital and community care, to the HSE has led to the division of these responsibilities into acute care and primary, continuing and community care.

The HIQA has the following functions:

- promoting quality improvement and quality assurance programmes and implementing a system of accreditation within the health service, as well as implementing minimum standards and supporting organizations in achieving accredited status;
- carrying out health information functions, particularly the assessment of major developments in IT and the setting of standards for the development of information systems;

- incorporating the office of the Social Services Inspectorate to monitor nursing homes, pre-schools, intellectual disability services and other institutions;
- undertaking HTA activities.

The HIQA has also assumed responsibility for the former ISHAB, which was established using secondary legislation on 1 May 2002, and was launched on 3 October 2002. It has based its approach on standards validated by the ISQua. Initially the focus of the scheme was on acute services, with plans to expand to other fields of health care in due course. To date 80% of all acute care hospitals have volunteered to participate in the scheme. The existing system is being changed to a 2-tier system in which all health care organizations must undergo a licensing process, to ensure that they meet a minimum standard, with an optional accreditation scheme for those organizations striving for excellence.

The Irish Medicines Board (IMB) is responsible for ensuring the quality, safety and efficacy of pharmaceuticals, within the European framework for medicines evaluation. Before a medicinal product can be authorized for use, an application must be made to the IMB and this must contain all the necessary data supporting its quality, safety and efficacy. The IMB carries out the following services within the Republic of Ireland (IMB 2007):

- licensing of medicinal products for human use
- licensing of veterinary products
- licensing of wholesalers of human medicines
- licensing of manufacturers of human and veterinary medicines
- pharmacovigilance and pharmaceuticals safety monitoring
- clinical trial licensing
- inspection of wholesale and manufacturing sites.

The National Standards Authority of Ireland (NSAI) publishes national standards and provides a comprehensive product certification service. The certification service operates in accordance with the EN 45000 series of European Standards, and the global ISO conformity assessment procedures. Several facilities have recently succeeded in achieving ISO 9002 in the area of health care (ExPeRT 1998).

Insurance cover for medical errors is the responsibility of a statutory State Claims Agency (CIS). There is little evidence of any risk management approach in its activities and, in essence, it functions as a claims management agency.

Nongovernmental statutory bodies

The Irish Medical Council (IMC), a nongovernmental professional body, accredits hospitals for the training of doctors. It is also responsible (under the new Medical Practitioners Act) for a new system of revalidation, which doctors will participate in on a rolling basis. Revalidation will involve demonstration of CME, regular audits of their practice and undergoing peer review assessments.

Postgraduate training and supervision is delegated by the IMC to the Royal Colleges or Irish Colleges, such as the Royal College of Surgeons, of Physicians or the Irish College of General Practitioners. The Irish Royal Colleges predate the independence of Ireland and have close links with corresponding colleges in the United Kingdom. There are also Irish Colleges (such as in general practice) that play a significant role in medical education. All such Colleges have established joint committees on higher medical training and have implemented and supported systems of clinical audit. These work closely with the IMC for accreditation purposes and in the training of medical professionals in the Republic of Ireland. The Colleges inspect health care organizations to determine their suitability for postgraduate training.

Although the training standards and practice of medicine in the Republic of Ireland are highly regarded, medical practitioners are largely independent of the State and of local control. Clinical guidelines are voluntarily adopted and observed. Professional regulation is undertaken by the IMC. The Colleges have developed practice guidelines but adoption is variable and sanctions rarely, if ever, applied. Recent examples of poor practice have had national repercussions, leading to the revision of the Medical Practitioners Act, which establishes a lay majority on the IMC.

An Bord Altranais (the Irish Nursing Board) accredits hospitals for nursing education as well as supervising the nursing curriculum. At the time of writing it is working on a scheme to register nurse prescribers.

It should be noted that the Republic of Ireland has separate regulatory bodies for doctors, nurses, pharmacists (and an increasing number of other health professionals), and trade unions or organizations representing the employment interests of these groups. This is similar to the situation in the United Kingdom but contrasts with that of other EU countries where such functions are often combined within a single organization.

A newly established Health Professionals Council will oversee the regulation and development of allied health care professionals such as occupational therapists, speech and language therapists and dietetic professionals.

Nongovernmental, voluntary and commercial

The ISQSH is a non-profit-making network organization established for health care personnel to exchange lessons on CQI. It has just under 1000 members and provides a wide range of courses on quality in health care. It is also involved in projects such as a National Patient Perception Survey (11 000 patients in acute care), a smaller survey on patient satisfaction with accident and emergency services, the development of a national framework to support the development of customer care, and the establishment of National Quality in Healthcare Awards and Healthdata (ISQSH 2005). It hosts a national conference annually with a competition for the best CQI project. In 2006 a total of 70 projects entered the competition.

The Irish Clearing House (ICH) is a repository for projects on clinical outcomes and effectiveness studies undertaken on health services in the Republic of Ireland. The objectives of ICH are (ICH 2005):

- to develop and promote approaches to health outcomes assessment within routine health and social care practice;
- to encourage a shift from process to outcome measurement, and the use of patient-centred and clinically relevant outcomes criteria;
- to support the use of process information and existing data sources where it is not yet feasible to measure outcomes directly;
- to raise awareness of key issues in health outcome measurement, in particular the issue of attribution;
- to promote the role of health outcomes within decision-making in health and social care;
- to collate and disseminate Irish health outcomes research information.

Some other commercial agencies have significant roles in health care quality improvement and certification. An example is the Excellence Ireland Quality Authority (EIQA), which certifies many private hospitals.

Process

The approach to quality assurance has been influenced by revelations of a series of incidents exposing undesirable practice in a hospital in Drogheda. A total of 188 peripartum hysterectomies were carried out at Our Lady of Lourdes hospital between 1975 and 1998, a figure described in the inquiry as "truly shocking". The rate of caesarean hysterectomies was 1 for every 37 caesarean sections, compared with approximately 1 in 250 for similar institutions. As a result the Government undertook an inquiry that concluded:

- support systems must be in place to conduct regular and obligatory audit;
- there must be mandatory continuing professional development and skills assessment at all levels of health care, along with recognition that procedures should change in accordance with evidence-based research, hospital managers should have more authority and training should have more medical input.

At the time of writing, two national hygiene audits of acute hospitals have taken place, using consistent methods, to facilitate comparison. The audits represented a "spot check" of standards observed on the day of the visit rather than what was happening over a period of time. However, they provided an indication of issues that may need addressing on a hospital-wide basis. When the results from both audits were compared it was clear that significant work had been carried out at hospital and national levels. Almost every hospital had increased its overall score since the first audit, with some of the most significant improvements being shown by those hospitals that recorded "poor" scores in the first audit.

Some of the results include:

- 32 hospitals were in the "good" category in the second audit, compared to 5 in the first audit;
- 19 hospitals were in the "fair" category compared to 23 in the first audit;
- only two hospitals were categorized as "poor" in the second audit, compared to 26 in the first audit; furthermore, these two hospitals were both only 1% short of achieving the "fair" categorization.

Patient safety issues are also coming to the fore within Irish health care but at a slow pace. Voluntary organizations such as the ISQSH have led the field in disseminating information on this issue. HIQA has a statutory duty to advance the agenda on patient safety and to this end has already formed close links with international networks. Adverse incidents surrounding medication can be (and are to be) reported to the IMB, which collates the information and in some recent cases has acted with significant speed to remove medication (Nemiseludine) from the market.

Research undertaken in 2002 assessed patients' perception of the quality of care they received during their stays in Irish hospitals. Respondents were asked to rate their satisfaction with several aspects of their care during their hospital stay in 2000 and overall quality of care in 2002 and in 2005. In general, patients were satisfied with the level of care they received, with levels varying from 88.9–95.7% in 2000 to 92.9% in 2002. This was the first nationwide study of this type to take place in the acute hospital sector. An exercise conducted by the ISQSH, in conjunction with the Health Services National Partnership

Forum, based on these findings, identified a number of possible improvements in the hospitals surveyed. As a result of feedback from patients, a wide range of initiatives were launched, including the creation of patient information booklets and leaflets, improved waiting-list management and facilitation of communication training for frontline staff. The most significant booklet launch was named "Let's talk…" with over 250 000 copies distributed across the system.

Within primary care there have been many successful initiatives, including the expansion of the postgraduate research centre of the Irish College of General Practitioners, a diploma course by distance learning and a national quality prize. Current projects include the creation of a quality indicators database (with funding of €450 000) and benchmarking of sentinel practices. The College is also part of the Europe-wide EQUIP network.

HTA activities have, for the most part, been confined to assessments of the cost–effectiveness of medication prior to it being listed on the national formulary for reimbursement (e.g. sindalafil). This work has been carried out for the Department of Health and Children by the National Centre for Pharmacoeconomics, a state-subsidized centre of excellence based in one of the teaching hospitals. In future, work of this nature may be undertaken by the HIQA but is likely to be contracted out for some time.

As a direct result of the centralization of the delivery of care, many local and national initiatives that traverse the boundaries of primary and secondary care have been introduced. Examples include the management of national and local waiting lists through a statutory referral agency that purchases treatment slots for those waiting over three months for operations, IT projects, and systems to manage delayed discharges within the acute care sector.

Italy

Context

To understand the Italian health care system it is necessary to recognize the impact that decentralization has had. The health care system in Italy is moving towards the conclusion of a process of devolution to the Regions. The National Health Plan constitutes the framework within which the Regions implement their own health policies. The national Government provides general guidelines but regional governments are entirely responsible for quality of the care provided in their territories.

As a result, there are essentially 21 regional health care systems with marked differences in quality strategies. There are, however, three principle sources of national guidance on quality, derived from the National Reform Act passed in 1992. These refer to accreditation, quality assurance and citizens' rights. Based on this legal framework, the Regions approve their own regulations. In 1993, the legislative Decree No. 502/1993 on the development of health management in local health units (the territorial divisions within the Regions) was passed.

The National Health Care Plan for the period 2003–2005 established the principle that quality of care was to be assured. The subsequent 2006–2008 Health Care Plan introduced the concepts of clinical governance and quality improvement. Here, quality improvement is understood as a system approach that involves patients, professionals and providers.

More recently, in 2006, the Ministry agreed the "Pact for Health and Wealth" with regional representatives, which includes the development of a national programme for systematic quality improvement. At the time of writing, the programme has been written and has undergone a public consultation. The programme included five areas for development: patients' and citizens' involvement; appropriateness; efficacy; patient safety; and health system development. It is expected to be approved in 2008.

Actors

Governmental

As noted earlier, the Ministry of Health provides national guidelines, while regional health departments oversee the delivery of health services and set the legislative framework within which providers operate, monitoring their performance with regard to quality, appropriateness and efficiency of service delivery (Donatini, Rico et al. 2001).

In the mid-1990s, guidance on clinical pathways was developed by the Ministry of Health, working with the National Institute of Health and with input from other stakeholders such as the Italian Medical Federation of Scientific Societies (Law No. 662 of 23 December 1996, article 1). Other initiatives introduced at this time included the implementation and routine monitoring of clinical guidelines and outcome measurement. In 2004, following a ministerial decree, the Ministry of Health introduced a National System for Clinical Guidelines.

In 2004, the Ministry of Health summarized its approach to quality of health care in an OECD ministerial meeting that took place in Paris. It stated that Italy pursues the improvement of quality of care through the increasing application of the principle of clinical governance (Italian Ministry of Health 2004).

Another important actor in quality improvement is the Agency for the Regional Health Care System (*Agenzia per i Servizi Sanitari Regionali*), a public institution established in 1995 that aims to support Regions pursuing innovative organizational models.

Italy has no national agency responsible for HTA. However, many organizations are active in this field. In 2007 the Italian Society for HTA was established. Other centres working on HTA include:

- the Centre for the Assessment of Biomedical Equipment, located in Trieste, which was established by the Ministry of Health to monitor the dissemination of major health technologies and to collect data on technical characteristics and purchase prices of equipment;
- the regional Centre for Technology Assessment and Quality Improvement in Health Care, in the Veneto Region, which assesses individual technologies; and
- the HTA Centre at Cattolica University in Rome.

Nongovernmental

The Italian Society for Quality Health Care (SIQUAS VRQ, *Società Italiana per la Qualità dell'Assistenza Sanitaria*) has developed a programme for voluntary accreditation of emergency departments, and has published an accreditation manual. Those who participate in the activities of the Society can develop standards in their specialist area of interest. In 2005, SIQUAS VRQ presented at its national conference a set of recommendations on patient safety, stakeholders partnerships, indicators, external quality evaluation, clinical pathways and education. SIQUAS VRQ has also created an observatory of best practice (www.osservatoriosanita.it) developed in conjunction with other

institutions and charged with collecting information and experiences in the area of quality improvement.

Scientific societies are also very active in promoting quality improvement. As mentioned earlier, the Italian Medical Federation of Medico-Scientific Societies (*Federazione Italiana Delle Società Medico-Scientifiche*) in particular is actively involved in promoting national quality initiatives. Nearly all specialist societies carry out their own activities in this field.

Process

Within the Italian health care system, two concepts of accreditation coexist. The first is institutional, with regional governments authorizing public sector entities to operate and private entities to receive public funds, if accredited. A National Accreditation Act, approved on 15 January 1997, outlines the standards. The other concept relates to accreditation carried out by an independent agency which assesses quality of services. This is performed on a voluntary basis. This can be referred to as "voluntary accreditation" or "accreditation of excellence".

The Accreditation Act covers subjects such as: mission; polices and objectives; human resource management and training; technical resources utilization; quality management; procedures and guidelines; quality of infrastructure; and information systems. The Act requires that each facility has a quality improvement office and that all diagnostic laboratories have an internal and external quality control system. It requires guidelines for common procedures to be reviewed every three years, and the appointment of an individual responsible for quality. In practice, the way in which accreditation is implemented varies among Regions, but ultimately processes adhere to standards set out in the Act. The Regions that have made most progress with accreditation include Piemonte and Lombardy, which use ISO 9000 standards, and Liguria, Emilia-Romagna, Marche, Toscana, Veneto and Puglia, which have introduced a model adapted from the Joint Commission International and the Canadian Council for Quality Standards. The system in the Marche Region is adapted from the criteria established by the ALPHA Council of ISQua. The system of Trentino uses the Joint Commission International model, along with the EFQM Excellence Model application system. Additionally, in 2002 seven Italian health care organizations have implemented a benchmarking project based on the EFQM model (Vernero, Favaretti and Poletti 2004).

Quality indicators were introduced in Italy in the mid-1990s. Two Decrees "Contents and utilization of quality and efficiency indicators" and "Indicators to evaluate quality requirements related to humanization, personalization of care, information right and prevention", set out a comprehensive set of

indicators. Many Regions implemented them, using the results as a starting point to discuss quality improvement. In 2001, a new set of indicators was introduced, focusing on areas such as use of resources and waiting times.

A focus on patients has been emphasized since the mid-1990s when the Charter of Public Health Care Services was published (Decree of the President of the Council of Ministers, published 31 May 1995). In 2003, a review of the charter's implementation was carried out in nine Regions. It provided evidence that citizens' rights were embedded in the health system in the northern Regions (Piemonte, Liguria, Lombardia, Veneto, Friuli, Trento and Bolzano Länder, Emilia-Romagna, Toscana, Marche) but there was less evidence that this was the case in the southern part of the country. In 2004, a nationwide survey by the Ministry of Health was more positive but it recognized that there was a need for better cooperation between regional governments and patients' representatives and involvement by both parties in the evaluation process.

In 2003 a National Expert Group for Patient Safety was established at the National Ministry of Health. A national survey on clinical risk management in hospitals was carried out and a first manual for professionals was released. A national voluntary sentinel events reporting system was implemented and its first report has recently been released.

In January 2007, a patient safety programme was initiated. It is based at the Ministry of Health and linked to the National Agency of the Regions and regional clinical risk management offices. The system monitors sentinel events, promotes education, and publishes recommendations and tools to support professionals and providers. That same year, the Ministerial Safety Group distributed a patient safety e-learning course through the Federation of Colleges of Nursing and Physicians.

A survey conducted by the National Institute of Statistics in March 2007 reported that 60% of citizens evaluate the quality of health care positively, and this percentage rises to 80% in some Regions (ISTAT 2007).

The 2008 Italian Budget Law included a draft bill on quality of health services and health protection in the National Health System. This foresees the establishment of a national evaluation system for medical treatment.

Latvia

Latvia inherited an extensive health infrastructure from the Soviet Union but one that had suffered from underinvestment for several decades. It also inherited the Soviet model of health care that was hierarchical, rejected much scientific evidence, and paid little attention to patients' rights. Although much has been done to overcome these problems, Latvia now faces other difficulties. It is one of the poorer countries in the EU and is losing skilled health professionals who seek higher earnings in other Member States.

Actors

Municipal authorities, which own most health care facilities, have very limited capacity to undertake quality assurance activities. Consequently, by default, the organization with the greatest potential role in terms of quality is the State Agency for Compulsory Health Insurance (SACHI), responsible for contracting with service providers. It has been developing quality indicators to help evaluate delivery of care.

In addition, the State Agency of Health Statistics and Medical Technology inspects facilities and certifies institutions in terms of hygienic conditions and staffing levels. Most hospitals have quality assurance activities of various sorts, with growing use of evidence-based guidelines. However, there is a widespread view that many aspects of quality of care can only be tackled effectively once the health system infrastructure is improved.

The Health Inspectorate deals with patients' complaints.

The State Agency of Medicines is responsible for registering and controlling the quality of pharmaceuticals, implementing a law passed in 1993.

It is reported that the medical profession in Latvia has a positive attitude to implementing quality assurance activities, although some managers are concerned about the additional costs of implementing them.

Process

There is no specific legislation on quality of care but some laws do include references to quality. The 1997 Law on Medicine regulates relations between medical professionals and service users, asserting patients' rights to treatment. The Primary and Secondary Health Care Development Strategy (1999) specifies the importance of accessibility, equity and quality of care (WHO 2001).

A system of certification of facilities was initiated in 1997. As with other former communist countries acceding to the EU in 2004, there have been considerable

changes in the training of health professionals. In 2005 a new system for paying primary care doctors was introduced, which, while based mainly on capitation, included an element driven by quality measures, which typically accounts for 15% of total funding.

Lithuania

Context

Measures related to quality of care in Lithuania include a system of licensing (based on the ISO 9000 standards) for health care and pharmaceutical organizations (introduced in 1995); provision for medical audit in health facilities, since 1998; a system of accreditation of health care institutions, dating from 1999, and a Health Care Quality Assurance Programme, proposed in 2004.

This programme, based on a concept developed two years earlier, seeks to direct health care more clearly towards the needs of patients and the public; to improve quality and safety; and to develop health care quality management (Box 4.3). However, the majority of measures envisaged have not yet been implemented due to a lack of funds.

Actors

The Ministry of Health is responsible for licensing health care staff, funding the continuing education of health professionals, licensing public and private institutions and creating mechanisms for the accreditation of health care institutions. It discharges this responsibility through its State Service of Accrediting for Health Care Activities.

A State Medical Audit Inspectorate is responsible for establishing medical standards and implementing a system of quality control.

The State Sickness Fund at the Ministry of Health is responsible for monitoring the quality of services that it finances.

All three bodies are empowered to order the closure of an institution.

Process

As mentioned earlier, in 2007 the National Audit Office of Lithuania reported that there was no functioning quality assurance system covering the health care system as a whole. It noted the absence of quality indicators and a lack of evaluations by municipalities, who own most primary and secondary care facilities. It described a situation in which facilities are paid for services provided, irrespective of quality (National Audit Office of Lithuania 2007). The Implementation Audit also found that the Ministry of Health only allocated 5% of the required funds to implement the Quality Assurance Programme up to June 2007 (National Audit Office of Lithuania 2007). Subsequently, additional funding has been received, allowing planned activities to be implemented.

Box 4.3 *Lithuanian Health Quality Assurance Programme 2005–2010*

I. To orient health care towards the needs of patients and the public:

- to provide patient-centred health care services, responsive to the needs, values and preferences of the patient and public;
- to empower and strengthen the patient's and his/her family's participation in the health care process;
- to enhance patient organizations' role in tackling health care issues.

II. To improve quality and safety of health care services provided to patients:

- to identify priority areas in health care quality improvement
- to ensure accessibility and timeliness of health care services
- to increase safety in health care services
- to increase equity of health care services
- to increase clinical effectiveness of health care services
- to increase cost-efficiency of health care services
- to ensure continuity and coordination of health care services.

III. To improve health care quality management:

- to strengthen administrative capacities of health care human resources in health care quality management;
- to promote evidence-based (HTA) health care development;
- to enhance science and practice unity – national and international cooperation in health care quality management;
- to create and implement an information system for health care quality management needs;
- to develop and improve external and internal health care quality assurance systems;
- to ensure rational use of health care resources.

Note: HTA: Health technology assessment.

There are, however, a number of local initiatives in place. Provisions for a Quality Management System in hospitals were approved by the Ministry of Health in 1998. A study published in 2006 found that the system was operating successfully in one third of small local hospitals, but was more commonly featured in the larger hospitals (Buciuniene, Malciankina and Zigmas 2006).

The same study identified a lack of financial resources, information and training as barriers to implementation of quality assurance. Success was facilitated by managerial engagement and investment in training (Buciuniene, Malciankina and Zigmas 2006).

The Lithuanian Law on Patients' Rights establishes a patient's right to choose a doctor, nurse or health provider; to obtain information on diagnosis, treatment and prognosis; to complain where necessary; and to claim compensation for damage to their health. A survey of medical staff and patients at the four Kaunas city health care units was carried out in 2002 to assess awareness of the provisions of the Law among medical staff and patients (Ducinskiene et al. 2006). The suvey found that physicians were in general well-informed about patients' rights but do not always respect them. The research team suggested that this may reflect a lack of assertiveness among patients (Ducinskiene et al. 2006).

Luxembourg

Context

The level and implementation of measures relating to quality in health services is determined by the organization of health service delivery. Factors that influence the implementation of quality measures in Luxembourg are:

- patient safety and safety of employees in the health system;
- the liberal status of hospital physicians (hospital physicians are not employed on a contractual basis with hospitals);
- patient satisfaction;
- health system financing.

The first developments establishing a framework for quality measures in health service delivery took place in 1998. The Law of 28 August 1988 on Hospital Establishments was changed to integrate the option that hospitals are given 2% of their annual hospital budget on the condition and achievement of defined quality measures. However, participation of hospitals was on a voluntary basis. The implementation and evaluation of the quality measures are carried out in a common initiative between the National Association of Hospitals and the National Sickness Fund, but in cooperation with individual hospitals.

Hospitals were asked to develop programmes in four predefined areas targeted at the improvement of quality of services and service delivery processes:

- reduction of nosocomial infections
- improvement of patient records
- improvement of pain treatment
- improvement of technical quality of mammographies.

In 2002, the National Sickness Fund and the National Association of Hospitals evaluated the programme. They found that all hospitals had participated and had established quality coordinators and that a culture of quality had been established, together with a process of continuous improvement of quality. At the same time, the evaluation found several aspects that required further attention, such as certain targets that were rather ambitious and led to insufficient implementation and a lack of achievement of targets. It also identified a risk of undesired competition between hospitals and that the implementation of measures was not uniform across hospitals, leading to many different practices.

In 2003–2006, an initial programme of organized quality management was introduced, based on EFQM. This allowed a stronger focus on quality achievements in processes, rather than pure outcomes. Again the programme is focused on delivery of health services in hospitals. With the implementation of EFQM, a strengthening of the evaluation also took place. Initially hospitals were rewarded when they implemented the EFQM model. They were externally evaluated but were also asked to submit a self-evaluation report. From 2005/2006 onwards the premium given to the hospitals was further aligned to not only reward the actual implementation of EFQM, but also to reward performance against predefined criteria, resulting in a 2-tier quality reward process.

A strong principle in Luxembourg is to discourage competition between hospitals based on the achievement of quality targets, and to foster an approach, based on the needs of individual hospitals, that is geared more towards establishing and achieving quality targets. This is manifested by the fact that there are no comparative, publicly available reports on quality performance. Some consequences of the incremental and non-competitive process are:

- patients are not well informed of which hospitals achieve quality targets and where quality is lacking, and can therefore not push for better quality;
- this is a very long process;
- there is a lack of incentives to improve (apart from budget incentives);
- "watering down" the rationale for improvement, which usually is based on either patient demand, safety or pressure from "competitors" (other hospitals) can be a problem.

Actors

The Ministry of Health is ultimately responsible for Luxembourg's health care system, advised by a number of national organizations, such as the Luxembourg Hospitals Association (Rosch 1998).

Luxembourg imports all pharmaceutical products. The Directorate of Health's Division of Pharmacy maintains a comprehensive list of pharmaceuticals approved for use in Luxembourg. The Ministry of Health authorizes the entry of new pharmaceuticals, following advice from the Directorate of Health's Division of Pharmacy. The Government publishes a list of costly, specialized medical equipment that cannot be purchased by hospitals without special authorization from the Ministry of Health. In early 1999 this list specified 31 categories of health care technology (WHO 1999).

The Luxembourg Hospitals Association organizes continuing education on quality, which it defines as "a set of characteristics of a hospital service which endows it with the ability to satisfy expressed or implicit needs whilst meeting an approved level of excellence" (HOPE 1996).

To practise in Luxembourg, physicians simply need approval of their (foreign) diploma by the Ministry of Health (if awarded in an EU Member State) or by the Ministry of Education (if awarded in other countries) and an authorization from the Ministry of Health. A licence to practise in Luxembourg means automatic access to remuneration by the compulsory health insurance system. There is no full university medical degree in Luxembourg, and most medical students receive their training in Belgium, France or Germany.

The Medical College and the Superior Council of Certain Health Professions are disciplinary bodies responsible for monitoring clinical quality. A surveillance committee, set up by the Ministry of Social Security, monitors abuse of the social security system (WHO 1999).

The health care system is based on the principle of a high level of responsibility and autonomy for physicians. One method of increasing quality, therefore, is to raise awareness among clinicians about quality. There are different initiatives, training courses and information programmes available to physicians in the ambulatory and hospital sectors. The effectiveness of these programmes in terms of how they contribute to the strengthening of quality has not been evaluated at the time of writing.

Process

Recent years have seen the development of a major programme of public investment in hospital developments, including construction, renovation and modernization projects. The aims of these investments are 2-fold: greater quality and cost savings, based on concentration of services (European Commission 2005).

Between 2003 and 2005, hospitals were required to initiate EFQM models of quality management. Participation was voluntary but those hospitals that did so attracted financial benefits if they achieved a good evaluation. From 2006, the Ministry of Health has been expanding the EFQM model. This has resulted in broad acceptance by health professionals, perhaps because there are financial incentives to participate. Hospitals are guided by criteria that are validated by a commission in charge of evaluating the programme (*commission paritaire*).

The increase in availability of very expensive pharmaceutical treatments put constraints on the National Sickness Fund. In the past Luxembourg's National

Sickness Fund was in a position to reimburse at least 65% of all medicines. With the increase in the availability of costly treatments, increased patient demand for treatments and demographic changes, the Government realized that assessments of efficacy and cost–effectiveness might be necessary in order to still be able to make high-quality medications available to all patients, excluding some on the basis of efficacy or cost–effectiveness. In previous years, Luxembourg has been known to have a very high level of health technologies (in particular in diagnosis by means of CT and/or magnetic resonance imaging (MRI)) available to patients. However, interest has grown in recent years in assessing the need, costs and utility of major investments in hospitals and as a consequence, the Ministry of Health has requested to develop HTA analysis, looking at the major drivers for investment and to inform investment decisions.

Malta

Context

There is a growing emphasis on quality in Malta, with initiatives in areas of education, regulation and quality service charters. However, a comprehensive quality strategy has yet to be introduced. The main activities to date have focused on registration and licensing of private medical clinics, homes for the elderly and specialist clinics.

Actors

The Ministry of Health is being restructured with a clear split between the responsibilities for licensing and standards of all (public and private) care providers on the one hand and, on the other, responsibility for service delivery. Quality standards will be promulgated at national level through the Directorate for Public Health Regulation, while the Directorate for Health Care Services will be responsible for ensuring quality and clinical governance in public hospitals, primary care centres and public homes for the elderly. The following components constitute the proposed quality strategy:

- quality assurance – setting and monitoring of standards through a specific department for licensing and services standards;
- development of a legislative framework through a new Health Care Act;
- establishment of an appropriate infrastructure;
- strengthening the culture of clinical audit and clinical practice guidelines;
- risk management and patient safety.

Pharmaceutical products are registered in accordance with the EU legislation on quality, safety and efficacy of medicines. The Medicines Authority licenses pharmacies, requiring a qualified pharmacist to be in attendance at all times (WHO 1999). The Malta Standards Authority is responsible for implementing EU legislation in the area of medical devices. This has been incorporated under a General Product Safety Act. There is no Maltese HTA agency, but the Ministry of Health, the Elderly and Community Care is presently establishing an HTA function.

An integrated health information system is being rolled out at the time of writing and this will eventually be based on electronic health records.

Laboratories also participate in quality assurance programmes, and doctors, nurses and allied health care professionals participate in CME.

Process

Specific quality systems exist in certain areas, such as processing and manufacturing of blood and blood components and in diagnostic pathology laboratories. Private hospitals, clinics and homes for the elderly are obliged to fulfil basic statutory requirements in order to be licensed by the Ministry of Health, the Elderly and Community Care, but licensing does not require a quality assurance system to be in place.

Malta's proposed quality strategy was identified as a key part of its most recent Biennial Collaborative Agreement with WHO. Quality assurance is mostly carried out at the level of the individual clinical provider and the only formal scheme is the "quality assurance initiative". As part of this scheme, consultants and senior registrars employed in the public health sector are invited (the scheme is voluntary) to submit quality improvement projects on an annual basis. These projects are evaluated and adjudicated by an elected committee of their peers and those that are considered to fulfil the requirements for a successful project lead to a monetary award for the individual clinician.

Systematic audit and peer review are at a rudimentary stage at the time of writing, but are increasingly being adopted by physicians. Clinical guidelines are widespread, although information systems and quality indicators are poorly developed. Benchmarking was introduced in association with the Standing Committee of the Hospitals of the European Union (HOPE), but has not yet been implemented. Some hospital departments have developed their own systems of quality assurance, based on the concept of evidence-based medicine, such as the cardiology department in St Luke's Hospital (Puringer, Abbuhl and Dezsy 2001).

It is too early to comment on acceptance by health professionals of the proposed quality strategy. Barriers to the implementation of quality of care strategies include the lack of a vocal consumer voice promoting change, as well as limited human resources.

The Netherlands

Context

The health care reforms that have been implemented in the Dutch health care system since the mid-1990s have resulted in an increase in market competition and a decrease in government control. There has been a shift in decision-making power from the Government to the market through the introduction of financial incentives for all stakeholders and deregulation of planning and tariffs, which in turn is expected to lead to greater competition between health care providers and between health insurers. In the quality field, however, the Government still retains responsibility for quality control and defines the cover to be provided by the standard insurance policy.

Two laws define the framework for individual providers and care institutions: the Individual Health Care Professions Act (BIG), enacted in 1993 and the Care Institutions Quality Act (KZI), passed in 1996. Legislation stipulates that primary responsibility for quality lies with health care providers and professionals (Dutch Department of Health 2005).

The BIG regulates the provision of care by professionals. It lists titles of six health care professions that are protected by law and treatments that can be applied only by licensed professionals. It enforces mechanisms such as revalidation, disciplinary processes and peer review and makes professional bodies responsible for the training and conduct of their members. The Law thus enforces self-regulation within certain boundaries (den Exter et al. 2004).

The Care Institutions Quality Act (Quality Act) makes a functioning quality system mandatory for all health care institutions. The Act enforces various initiatives for internal quality system development and for external reporting and evaluation. This act no longer seeks to regulate in minute detail how parties involved in health care should interact, but instead gives greater responsibility to providers, patients and insurers (Dutch Ministry of Health 1999).

The Quality Act applies to all care, regardless of which facility or institution is delivering the care. Only independent professionals such as GPs and dentists fall outside the scope of the Act. With the passage of the Act, existing legal requirements for quality assurance have been integrated into the new legislation. The Quality Act establishes four requirements that all providers of care must fulfil (Dutch Ministry of Health 1999), detailed here. Institutions must:

- provide "responsible care", i.e. care that is characterized as being of a good level, effective, suitable, patient oriented and geared to the real needs of the patient;

- make clear what they are doing to achieve and maintain this "responsible care";
- systematically protect and improve the quality of care they provide (as much as possible);
- publish both an annual report detailing the quality control policies they have applied, and reports on the quality of care they have delivered.

An evaluation carried out in 2002 of the Health Care Quality Law showed that little progress had been made by health care institutions towards implementing a structured quality system. Following recommendations in late 2002, the Minister of Health announced specific measures to make quality management compulsory. From this point in time, the policy on quality of care presented by the Government would alter its focus, moving from the initial supporting role to a more controlling position (den Exter et al. 2004).

Within the aforementioned health care reforms, the new Admission of Care Institutions Act (WTZi, *Wet Toelating Zorginstellingen*) establishes the entitlement to provide care to insured patients. The Act states that the entry of new providers is regulated by central Government and both hospitals and "Independent Treatment Centers" are licensed by the Government. The licensing system includes working agreements to ensure adequate availability and quality of care. However, these agreements do not have legislative foundations and moreover, government involvement in determining the capacity and other requirements for buildings used in the provision of health care services is to decrease. The WTZi aims to control health care institutions by creating the conditions for good entrepreneurship, rather than imposing building regulations.

It is predicted that, following recent reforms, Dutch health care delivery will change over the next decade. It is envisaged that some of the care providers will focus on specific markets, while others will focus on enhanced quality. It is argued that competition can lead to higher quality of health care. On the other hand, introduction of market forces and financial reforms creates pressures on quality as providers seek to reduce costs. It has also been reported that the focus of the contract negotiations between hospitals and the major insurers is already shifting towards the "content" of care provision. Health insurers have introduced sets of quality criteria, such as the acceptable percentage of complications further to treatment for specific conditions. Current indications suggest that performance indicators already play a key role in the negotiations, alongside price and volume, and that quality is an important aspect of the health insurer's decision-making process.

Actors

The Dutch Government, as already mentioned, 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 the care provider and patient, and the enforced hospitalization of people unable to give their informed consent. Beyond issuing rules and regulations, the Dutch Government also pursues the goal of quality improvement by financial and technical assistance to researchers, professional societies and care institutions (Dutch Department of Health 2005).

Dutch government policy relating to pharmaceuticals is implemented by the Dutch Ministry of Health, Welfare and Sport. The Ministry supervises and controls the quality, preparation, distribution and supply of pharmaceuticals.

The Health Care Inspectorate (IGZ) is the institution responsible for ensuring that regulations are adhered to (den Exter et al. 2004), but does not comment on their structure or assess their impact on quality of care. It also investigates incidents and complaints in care facilities, and assesses compliance of providers with safety regulations. It may launch, on its own initiative or directed by the Minister of Health, so-called thematic reviews to describe quality problems in particular sectors of the health care system (Dutch Department of Health 2005). In addition, the Ministry of Health, Welfare and Sport has asked the IGZ to use its knowledge and expertise to support care providers, insurers and patients to develop sensible standards and indicators as quickly as possible (Dutch Ministry of Health 2007).

Health care insurers are responsible for buying care of adequate quality. They can stipulate requirements concerning quality of care when concluding agreements. However, for collective preventive care and for social care, the municipalities bear the responsibility and set out the quality requirements (Dutch Ministry of Health 2007).

As mentioned earlier, the medical profession and care institutions play an important role in the implementation of policies related to quality of care. Professional health care providers bear the responsibility for setting up and monitoring their own quality systems. The IGZ supervises this process.

The Dutch Healthcare Authority (NZa), established in 2006, is the supervisory body for all health care markets in the Netherlands. The organization supervises both health care providers and insurers. One of the aims of the NZa is "to promote quality by setting those market conditions that encourage quality and innovation in health care" (NZa 2007).

The Netherlands Institute for Accreditation of Hospitals (NIAZ) operationalizes accreditation. In the Dutch context, accreditation is understood as a voluntary test of institutional competence against defined standards and has a history dating back to 1989. Following the first pilot tested in eight hospitals, based on the Canadian model, it is now a national programme covering approximately 50% of beds with the recommendation of the Dutch Hospital Association (NVZ) to have all general hospitals accredited. In addition, the programme has been recognized by the IGZ as a quality system.

Dutch medical scientific associations are the initiators of the development and implementation of visiting programmes (Visitatie programme) for their members. Visiting programmes are organized and administered by peers as a structured external evaluation exercise. One of the most important conditions for the practice of visits to succeed is a climate of trust and mutual willingness among professionals. Visits also demand a self-critical and learning attitude. At the same time, visitors are asked to serve their peers being surveyed by giving them feedback on their performance and identifying the department's opportunities for improvement. The Visitatie programme appears to be closest to actual clinical performance in terms of structure and process as well as outcome (Klazinga 2000). This model, which was initiated in the Netherlands, has reached other EU Member States such as Finland, Sweden and the United Kingdom. Participation in visitation programmes is required for recertification of all medical specialties.

Since 1994, the Foundation for Harmonisation of Quality Review in Health Care and Welfare (HKZ) has been set up by all parties in the system (providers, insurers and patients) to translate, develop and approve ISO-based certification for health care organizations. A number of specific schemes have been developed, using their own model, and they cover areas like homes for the elderly, mental health care, community care, pharmacies, ambulances and some aspects of hospital care. If there is an HKZ scheme, ISO certification for health care has to be carried out based on that, rather than on the original ISO norm. This approach has different levels of penetration within the health sector, and its use is limited, especially in acute hospital care.

It has been reported that the Dutch health care system has absorbed and adapted the phenomena "accreditation" (Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) and "certification" (ISO) in a way that is consistent with its structure and culture (ExPeRT 1998).

The Health Council is responsible for adopting new HTA activities. The evaluation process of technology follows these stages (den Exter et al. 2004):

- identifying technologies in need of assessment

- collecting data necessary to conduct the evaluation
- synthesizing relevant clinical outcomes and cost data
- disseminating findings to decision-makers
- taking necessary action.

The Dutch College of General Practitioners introduced clinical guidelines in 1987, and since then it has issued more than 70 at a rate of approximately 8–10 topics a year (Woolf, Grol and Hutchinson 1999). According to Woolf and colleagues (1999) more than 80% of Dutch family doctors are aware of clinical guidelines within a few months of publication, with over 70% adherence to them.

The Dutch Institute for Healthcare Improvement (CBO), which was founded in 1979 by the Dutch Association of Medical Specialists and by the Dutch Association of Chief Medical Officers as an independent, non-profit-making foundation, also advises and supports expert groups delegated by Royal Colleges and other involved actors in the development of guidelines. These guidelines are problem oriented, multidisciplinary and evidence-based. The first guideline (on blood transfusion) was developed in 1982. At the time of writing, 100 guidelines have been published and 35 more are in progress (CBO 2007).

The Netherlands Institute for Health Services Research (NIVEL), among other health services research activities, produces surveys in several forms for various specific areas (e.g. mental health care) under the aegis of client-oriented care and employing QUOTE-instruments. Besides QUOTE, translations of the United States CAPS questionnaires are used within pay-for-performance projects and for international comparison. National data are also collected by the Central Office for Statistics. Surveys in mental health care are being carried out by the Trimbos Institute of Mental Health and Addiction. CAPS have also been developed by Miletus, a foundation that has been set up by four major insurance companies.

Many organizations have introduced Information Systems. For example, nongovernmental organizations and WHO collaborating centres (e.g. NIVEL), dedicated institutions (PRISMANT), academic affiliates (e.g. Vumc-EMCOG) and the IGZ have all introduced Information Systems. These data are being used for yearly planning according to New Public Management principles, for mid-term and long-term scenario planning. A framework for performance indicators was installed in 2003. There are also professional Information Systems for registration of complications, hospital infections (CBO/RIVM) and others.

Process

The Better Faster ("Sneller Beter") Programme was launched in 2003 by the Ministry of Health, Welfare and Sport, the NVZ, the Order of Medical Specialists and Patient Organizations to improve quality of health care. The idea behind the programme was to introduce changes in the system by working with a group of organizations, in order to help health institutions to improve their performance, starting with hospital and primary care. The Better Faster Programme comprises three core activities (den Exter et al. 2004):

- benchmarking in primary care for all GPs and 10 pilot hospitals;
- introduction of indicators for safer and better care;
- a programme based on quality, innovation and efficiency, with priority on patient safety and patient-centred delivery of care.

As already mentioned, at the same time a standardized quality reporting requirement for hospitals was introduced. The IGZ carried out inspections, but only hospitals could publish the necessary data. Insurance companies could request data, but it is still not clear whether they can also publish them. Reporting to the IGZ is thus obligatory, but publication of results is not. As a result, in June 2007 agreements were made on the gradual introduction of publication (transparency) of data for hospitals by 2011. In addition, a change in the inspection process for hospitals is to accompany the reporting requirements, with this having started in 2005. The IGZ is to conduct a 2-step inspection process, starting with a questionnaire on governance, patient safety policies and care patterns. The information from those questionnaires, combined with a review of the hospital's performance according to the above-mentioned quality indicators is to identify potential problem areas and guide a targeted survey of the hospital (Dutch Department of Health 2005).

According to the Dutch Minister of Health in his letter to Parliament of 6 July 2007, quality of health care must be measurable and visible. The Minister has made indicator development a priority of his remit. In 2007, the institutions in the sector of nursing care and home care were expected to give an account of care performance provided on the basis of the justified care indicators. The area of disabilities is to follow one year later. In mental health and addiction care, the first set of indicators was defined at the end of 2006. Further indicators are to be developed at a later stage (Dutch Ministry of Health 2007).

In relation to GPs and dental care, administrative arrangements concerning how to make quality visible and measurable are still being prepared. Thus, supervision of prevention on the basis of indicators is to take place in 2008, and the first results for rehabilitation are to appear on the web site dedicated to

health care consumer information (www.kies.beter.nl) in 2009 (Dutch Ministry of Health 2007).

In the field of patient safety, the report *Accidental harm in Dutch hospitals*, published in April 2007, has had an immense impact in the country. The report is based on a retrospective patient record study carried out in Dutch hospitals. Patient records of randomly selected admissions of patients discharged in 2004 and admissions of patients who died in the hospital in 2004 were reviewed in a 3-stage review process by nurses and physicians between August 2005 and October 2006 (Zegers et al. 2007). The results show that there were adverse events in 5.7% of hospital admissions. This means that 30 000 patients suffer preventable harm during treatment every year. The study estimated that there were potentially 1735 avoidable deaths in 2004 (NIVEL 2007).

As a result of the publication of this report, the Ministry of Health proposed an Action plan to reduce avoidable deaths and avoidable injury within five years. In the hospital sector, it proposed halving avoidable injury over this period. The programme is being developed in close consultation with other key actors. The initiatives for improvement for the hospital sector were presented at the IGZ conference on 12 June 2007 (Dutch Ministry of Health 2007).

In the hospital sector, national organizations of care providers and hospitals have set up an ambitious programme to reduce avoidable care in hospitals. As a result, a certified safety management system is to be required in hospitals from 2008. The sector has set out a standard for this and institutions will have to implement the standard from now on. The IGZ is supervising the process and will, where necessary, ensure enforcement of and compliance with the required standard (Dutch Ministry of Health 2007).

Finally, basic patient rights are protected by law in the Netherlands. The 1995 Medical Treatment Contracts Act (WGBO, *Wet op de geneeskundige behandelovereenkomst*) defines requirements for informed consent, privacy protection and liability. The 1995 Clients' Right of Complaint Act (WKCZ, *Wet klachtrecht clienten zorgsector*) requires care providers to have accessible complaints procedures in place and the 1996 Participation by Clients of Care Institutions Act (WMCZ, *Wet medezeggenschap clienten zorgsector*) mandates client councils which can step in on institutional policy decisions. While these laws do not specify detailed requirements, they contain an evaluation clause that calls for regular assessments of their implementation. Additionally, through the PGO Fund (a foundation for patients, disabled people and the elderly), the Government encourages patient, disabled and parent organizations to support the individual (Dutch Ministry of Health 2007).

Poland

Context

The process of health care reform in Poland is widely accepted to have been difficult. Commentators describe unacceptable variations in performance, high levels of patient dissatisfaction, long waiting times for some services and large regional variations in the provision of health facilities.

Public discontent is high even after the huge changes the system has experienced. Some of the reasons for this discontent are: insufficient information about the rules on how the new system works; difficulties in accessing specialized services; increasing patient participation in the costs of health care (costs of medicines); and weak enforcement of patients' rights (Puringer, Abbuhl and Dezsy 2001).

The National Centre for Quality Assessment in Health Care (NCQA) was established by statute in 1994. The Ministry of Health supports quality initiatives through its funding of the NCQA, but there is a consensus that its achievements have been limited. Since April 2006, the NCQA is also the WHO Collaborating Centre for Development of Quality and Safety in Health Systems.

In 1997 the Comprehensive Health Insurance Act came into force. This provides the current legal basis for the health care system. Quality does feature in the act, although the provisions are not very specific (e.g. there should be "comprehensive training for primary health care") (Puringer, Abbuhl and Dezsy 2001).

Actors

The NCQA and the Polish Society for Quality Promotion in Health Care are the key actors in the field of quality in health care. The NCQA has a range of tasks, the core ones including:

- accreditation of health care organizations (based on the United States Joint Commission International model);
- monitoring of quality indicators and conducting patient satisfaction surveys;
- dissemination of knowledge on patient safety among health care professionals;
- training in TQM, quality improvement, and patient safety;
- advising the Ministry of Health on scientific, technical and policy issues relating to quality and patient safety;

- providing quality assessment for highly specialized clinical procedures in invasive paediatric cardiology, immunology, radiotherapy and transplantation facilities.

The NCQA provides assessment criteria and evaluation of the Polish Quality Award "TERAZ POLSKA" for the hospitals and primary care organizations and participates in the European Network of Quality Institutes (MARQuIS 2007).

Process

According to Nabialczyk (1997), the first attempt to raise awareness of the concept of quality assurance among Polish health professionals was in the early 1990s, when some hospitals participated in a survey on quality-related activities. This project was instrumental in the development of the National Society for Quality Promotion in Health Care (1993) and, a year later, in the creation of the NCQA. By 1994, quality improvement programmes had been initiated in three Polish hospitals (Warsaw, Krakow, Radom) in association with the Vlaams Institute for Quality in Belgium (Nabialczyk 1997).

The Polish National Programme of Accreditation was initiated in 1998, based on the United States Joint Commission model. It covers hospitals, primary health care, ambulatory health care and psychiatric care. The Joint Commission assisted the NCQA with the development of accreditation standards, procedures, and implementation of survey processes. The process was inclusive, with the participation of (among others) the Polish Chamber of Physicians, the Polish Chamber of Nurses and Midwives, the Polish Hospitals Association, the Association of Healthcare Managers, the Polish Association of Hospital Managers and the Polish Society for Quality Promotion in Healthcare. Accreditation is a voluntary process, although it is seen as facilitating better terms in contracts with insurance funds.

Many hospitals have established quality improvement committees and teams to facilitate the process, and any have also applied for ISO accreditation.

Patient safety is emerging as a key issue within the national accreditation programme, although it has not been widely and explicitly articulated in the accreditation manuals. However, the revised edition of accreditation standards for hospitals, planned to be published at the beginning of 2008, does focus directly on safe delivery of care and reporting of adverse events.

The establishment of national quality indicators is still at a preliminary stage. However, it is important to note that 40 Polish hospitals participate in the PATH project – the first initiative on such a scale to collect indicators not

for administrative or reimbursement reasons but for improvement of hospital performance.

Formal self-assessment is not yet well developed, although there are many informal systems in place to develop clinical guidelines, as well as investment in the necessary information systems.

Some hospitals and clinics are conducting their own satisfaction surveys, aimed at analysing patients' expectations and identifying areas that need to be improved. However, the methodologies and contents vary, precluding comparison. In 2003 the NCQA implemented Package Satisfaction (PASAT), an Internet-based tool to collect patient's views, ultimately with a view to benchmarking, although it is still in an early stage of development.

Commentators identify several obstacles to greater implementation of quality strategies in Poland. These include the lack of a national quality policy, lack of clear leadership, lack of adequate financial support and incentives, limited motivation of health professionals and lack of training in quality and safety for health care leaders, managers and professionals (Puringer, Abbuhl and Dezsy 2001).

Portugal

Context

The issue of quality emerged on the health policy agenda in Portugal after 1999. A range of policies have been implemented since then and are now being consolidated, although participation in many quality assurance programmes remains voluntary and is not yet a condition of the contracts with providers that were initiated in 2004.

Actors

The Ministry of Health is responsible for promoting quality strategies at various levels of the health care system through professional regulation, norms and standards setting, accreditation procedures and competency assessment.

As a result of major reforms in the structure of the Ministry of Health in 2006, the National Health Quality Institute (*Instituto da Qualidade em Saúde*), which was the primary entity responsible for quality of care, has been abolished and its responsibilities have been integrated into the General Department of Health (*Direcção Geral de Saúde*) and the newly created Central Administration of Health (*Administração Central do Sistema de Saúde*). The former is now responsible for clinical quality, whereas the latter is responsible for managerial quality in the health care system (Law by Decree 212/2006).

The Ministry of Health has to approve the purchase by hospitals of the most sophisticated items of equipment (Bentes, Matias Dias et al. 2004), although there is no formal HTA programme. An institute to undertake HTA was proposed in 2000 but has not been further developed.

Responsibility for certification of specialist training for physicians is shared between the Ministry of Health and the Portuguese Medical Association, with specialist status awarded after completion of an approved training programme and an assessment of skills (Bentes, Matias Dias et al. 2004).

The National Institute of Pharmaceuticals and Medicines (INFARMED) was established in 1993. Since 1994, its remit has been widened to cover not only pharmaceuticals, but also medical equipment and other medical products. INFARMED is responsible for approving all drugs to be reimbursed by the NHS and for setting co-payment levels. Recently, INFARMED has introduced the principle of cost–effectiveness into its assessment procedures for new pharmaceuticals, based on guidelines issued in 1999 (Bentes, Matias Dias et al. 2004). The National Pharmacovigilance Centre, part of INFARMED, was

established in 1992 to monitor drug safety. A Quick Alert System collates reports of untoward events.

Process

There is an active debate about how to take the quality agenda forward. In particular, there has been some interest in the accreditation of hospitals, with proposals to establish a public accreditation body. However, the question of what to do in case a public hospital should fail to be accredited has yet to be resolved, with commentators highlighting the near impossibility of closing a public hospital, although failure to act would undermine the accreditation system. Private hospitals have also been slow to show any interest in accreditation.

In 2005, the Ministry of Health announced that it would implement an accreditation system that would be compulsory for public hospitals and be based on international associations, such as the King's Fund Health Quality Service. However, progress has been slow.

Some clinical departments undertake quality assurance activities, but these have not been widely taken up. Guidelines have been issued by a number of professional associations (physicians, pharmacists and nurses, operating room assistants), but there has been little interest so far in measures to address patient safety.

Private health facilities are subject to licensing following inspection, but this is only mandatory for those performing invasive procedures. Some private and public health care organizations, such as pathology laboratories, blood departments, and hospital and community pharmacies have undergone the ISO certification process.

Despite considerable effort in new management plans and actions to improve quality within the health care system, the lack of consistent and reliable data addressing this issue makes it difficult to assess the efficacy of current strategies and to implement new strategies.

Romania

Context

The Romanian health care system is undergoing a process of rapid transformation, with new legislation perceived by many practitioners as being somewhat complex. As a consequence, there is often lack of clarity about who in practice has the authority to implement change (Vladescu, Radulescu and Olsavsky 2000).

Key health policies established in 2000 and revised in December 2001 formally sought to:

- improve hospital performance and increase accessibility to hospital services;
- increase access to high-quality, effective and safe pharmaceuticals;
- improve health financing and assuring system sustainability;
- improve health status of mothers, children and the family.

Quality of care is not regulated by any specific legislation, although Law 95/2006 on reforming the health field establishes that the Ministry of Public Health and the National Health Insurance Fund (NHIF) are responsible for establishing quality criteria for care provided to insured people (Romanian Ministry of Public Health 2007). It further includes some references to quality of care in sectors of the health care system such as hospitals, laboratories and primary care facilities. For instance, it specifies that hospitals need to be accredited based on standards elaborated by the Ministry of Public Health.

More recently, the Romanian Government Programme 2005–2008 explicitly addresses the issue of quality of care, with one stated aim being to increase the quality of life through improving the quality and the security of health care. Stated strategies to meet this and related aims include:

- encouraging competition within the health sector;
- removing the "preponderantly coercive and punitive measures aimed at medical staff" and creating an "administrative and legal framework to stimulate and reward [staff] for adherence to contracted objectives and quality indicators".

Improving the institutional framework is seen as an essential step towards better quality of health care. Within this context, the Ministry of Public Health initiated the drafting of a regulation on quality of care and health care quality management that is expected to be subject to public debate in 2008.

Actors

The Romanian health care system was transformed from being almost entirely state owned, managed by the Ministry of Public Health through 41 district health directorates and the Bucharest Health Directorate, to one where relationships among a much greater number of actors are considerably more complex. To a large extent the Government of Romania continues to operate as a centralized command and control system. This focuses political power at the top levels in the ministerial hierarchy. In the case of the Ministry of Public Health, the Minister and senior officials have either initiated reforms or taken on board those suggested by the World Bank and others. The Ministry of Public Health maintains responsibility for developing national health policy and for dealing with public health issues; at local level the Ministry of Health acts through the District Public Health Authorities. The Ministry of Public Health plays a major role in the decision-making process in health policy; almost all the major health policy documents have been initiated at this level.

The NHIF sets the rules for the functioning of the social health insurance system and coordinates the 42 District Health Insurance Funds (DHIFs). The NHIF negotiates the framework contract, which has established, together with accompanying norms, the benefits package to which insurees are entitled. The NHIF also decides on the distribution of funds between districts. It has the right to issue regulations (rules, norms and standards) that are binding for DHIFs.

Legislation was passed in 1995 to establish the College of Physicians (CoPh), although the body only began to function in 1997. All doctors must register with the CoPh, which regulates the medical profession, including oversight of training and accreditation. The role of the CoPh in health policy has considerably decreased over time, from being involved in negotiating the framework contract that forms the basis for all individual contracts between DHIFs and providers before the year 2000, to a mere consultative role in the majority of health policy decisions. It is noteworthy that, although the medical profession is not politically strong in an organizational sense, individuals are important in their links with Parliament (approximately 50 Members of Parliament were or are medical professionals, including the President and Vice President of the Health Commission), as well as with political parties, and particularly through their occupancy of important positions within the Ministry of Public Health hierarchy.

The Order of Nurses and Midwives is the most recently established professional association based on Law 307/2004. Nurses and midwives must be registered with the Order prior to being permitted to practise their profession. So far, both

professional bodies have focused much of their attention on harmonization with EU requirements on professional training in the run up to Romania's accession to the EU in 2007.

Process

Elements of quality can be found in different regulations, as indicated earlier, but in the absence of a dedicated quality assurance framework it is difficult for authorities systematically to evaluate and assess the quality of care. However, several relevant commissions and committees are working in coordination with the Ministry of Public Health. These include the Hospital Accreditation Commission, which is organized at national level, while the primary/ambulatory care providers are accredited locally (at district level).

The insured population is entitled to receive a basic benefits package that includes health services, pharmaceuticals and medical devices. The benefits package and the conditions for service delivery are set out in the framework contract elaborated by the NHIF, agreed by the Ministry of Public Health and approved by the Government every year. Patients' rights are protected by the Law on Patients' Rights issued in 2003. The current legislation also assures free choice of provider for the patient, patient participation in decision-making, patient safety and compensation measures.

The implementation of the framework contract is monitored at both National Health Insurance House and District Health Insurance Houses levels by designated units. These institutions also undertake periodic checks of providers to ensure compliance with contract provisions (in terms of both volume and quality). The framework contract establishes sanctions for contraventions by both the District Health Insurance Houses and the service provider. The same rules of contracting apply to both public and private providers. In practice, the focus of these activities is on financial aspects and the volume of services provided rather than on quality aspects.

The CoPh is involved in quality evaluation but mainly regarding alleged failures involving physicians. Untoward incidents involving hospitals and primary care providers lead the Ministry of Public Health to conduct investigations.

The Ministry of Public Health approves the installation of high-technology equipment in public hospitals. Technology has to be registered with the Ministry of Public Health but registration only requires evidence of safety and effectiveness, without a review of cost–effectiveness. At the time of writing, HTA is in an embryonic state in Romania. In 1998, a collaboration was set up between the University of Medicine, Bucharest and Alberta Heritage Foundation for Medical Research (Edmonton, Canada). Several activities were

carried out, such as seminars with health professionals and decision-makers, a web site hosted by the CoPh (www.cmb.ro/hta/), and the introduction of a training course on basic aspects of HTA in continuous education for doctors. A survey of mid-level decision-makers revealed a high level of interest in HTA (75%), with only 63% declaring any knowledge about HTA and its concepts, while 10% had never heard about it (Moga, Corabian and Harstall 2003). As a follow up, in November 2002 the Ministry of Public Health, the NHIF and the CoPh signed a memorandum to establish an HTA programme. To date no further steps have been taken.

Professional liability by health service providers is regulated by the Law on Health Reform (95/2006). This Law stipulates that all providers in both the public and private systems must have professional liability insurance. Guilt or innocence is established by the Commission for Malpractice Monitoring, which comprises representatives of the NHIF, professional associations and a medico-legal expert.

The establishment of treatment guidelines is regarded as a necessity by all professional bodies and was initiated by the CoPh in 1999 but has not been widely implemented. In 2003, the process was relaunched with the publication of a methodology for developing clinical guidelines, supported by WHO. The Family Doctors Association has already produced four guidelines and more are expected to emerge. The Ministry of Public Health, the NHIF and the CoPh are in the process of institutionalizing a system for the production of guidelines.

Slovakia

Context

In its Manifesto published in 2006, the Slovak Government states that quality of health care for all citizens and patient safety are priorities and proposes the following measures:

- to support the creation of conditions for transparent competition of health care providers;
- to support the creation of contractual relationships between health insurance companies and health care providers according to the criteria of efficiency and quality of health care provided;
- to support the introduction of quality systems and efficiency in all areas of health care provision, compliant with EU regulation;
- to implement the development of the health care education system that will ensure an adequate number of high-quality professionals for all health care activities;
- to set forth by law the number of so-called end-hospitals, providing the most specialized health services at the highest level.

Since 2005, the Ministry of Health has been assessing the quality of health care providers (predominantly hospitals) against a set of indicators, linked to financial incentives to provide care of better quality. A similar approach has been adopted by health insurance funds that have periodically created a ranking of health care providers (both out- and inpatient) against a set of indicators. These indicators have been criticized by providers, however, because they do not take into account different working conditions, urban and rural differences, and social and economic circumstances of patients.

Actors

Since the introduction of the first quality assessment models at the end of 1990s, there have been negotiations on how to move forward between the Ministry of Health, the Slovak Medical Chamber, the Slovak Medical Association, and representatives of other professional organizations.

A fundamental reform of the health system began in 2004 with a set of health reform acts, known as the "reform puzzle", as the new six health laws were inseparably bound together. Pursuant to them, the Ministry of Health is responsible for issuing regulations on minimum standards for staff and technical equipment; the process and content of postgraduate training; education of

health professionals; and the scope of health services covered by the basic benefits package and contractual conditions for the health insurance funds. A new body, the Health Care Surveillance Authority, was created in 2005 to supervise health insurance funds (system of purchasing health services for their insurers) and providers (to ensure provision of quality, safe and timely health care).

In 1999, the Ministry of Health established the first Centre for Quality and Accreditation in Health Care, an advisory body charged with preparing a system of health care accreditation. The resulting Slovak National Accreditation System was meant to accredit all health care providers. This process was halted following the election of a new government in 2002, which argued that the health care sector was not ready for accreditation. Moreover, it had never been clear what "accreditation" would really mean in practice.

At the time of writing, the main approaches taken by the Ministry of Health to promote quality are:

- to develop and implement a system of quality indicators;
- to create a mechanism for a complaints system, linked to effective sanctions;
- to develop a mechanism to withdraw providers' licences and to issue regulations and guidelines.

The Ministry of Health is also responsible for registration of health professionals. The Act on Health Occupations, adopted in 2002, in compliance with EU law, established the requirements for practising as a pharmacist, physician, dentist, nurse or midwife. This Act was later supplemented by regulations on undergraduate and postgraduate training of health professionals.

Medical products, testing and registration of pharmaceuticals and the approval process for medical devices are regulated under Act No. 140/1998 on Drugs and Medical Devices. The Act has been amended on several occasions, the last being in 2006. The system is now in full compliance with EC Directive 89/105/EEC and uses objective and evidence-based criteria.

It is reported that professionals accept what the Law stipulates, but in reality some provisions are either not implemented, require investments that have not been made, or are simply ignored as professionals continue with their traditional modes of practice.

Process

In reform Act No. 578/2004, the Ministry of Health imposed on health care providers a duty to implement a quality assurance system by 1 April 2008.

The Ministry of Health intends to review this Act, reflecting the current situation.

In April 2007, the Ministry of Health published in its bulletin a Methodological Instruction No. 20406/2007 for the collection of quality indicators to assess the provision of health care. The Ministry of Health has asked leading representatives of the professional associations and its own senior experts to put forward a proposal for new appropriate quality indicators to be published as a legally binding Ordinance of the Government of the Slovak Republic in 2008.

At the time of writing, some activities are carried out, for example, accreditation of laboratories, and implementing ISO systems or the EFQM Excellence model application system, but these are not undertaken in a systematic fashion. There have been many clinical guidelines adopted, but uptake remains patchy. Quality systems are, however, routinely applied in laboratory practice. Additionally, most health care facilities have implemented some quality management systems according to ISO 9000 standards.

Since the late 1990s there have been several initiatives to promote patients' rights. In the mid-1990s, the Slovak Association of Hospitals assessed awareness of patients' rights among the public. The findings showed low awareness among those being interviewed. Subsequently a "Charter for the Hospitalized Patient" was drafted, but not implemented.

In 2001 the Government approved a Charter of Patient Rights. It was elaborated by a group of experts appointed by the Ministry of Health in collaboration with Dutch experts. Later, its content, together with elements from the European Charter of Patients' Rights was incorporated in the 2004 health reform acts. However, public awareness has lagged behind the legislative change.

Slovakia has recently considered establishing an information system to support a Patient Safety Strategy. Its implementation is supervised by the Health Care Surveillance Authority.

Despite several government initiatives in recent years, including the adoption of the necessary legislative framework, systematic approaches to quality of care are still at a basic stage of development in Slovakia.

There are no evaluations of the extent to which quality of health care initiatives are being implemented. Slovakian commentators report that, in reality, there is little cooperation between professional associations and the Ministry of Health in relation to quality of care.

Slovenia

Context

Quality has risen higher on the health policy agenda in Slovenia following proposals for health care reforms in 2003. The emphasis at the time of writing is on connecting the elements already in place and adding the missing links, so as to create a framework for sustained quality improvement (DRMED 2007). This is being operationalized by means of an expert committee within the Ministry of Health and the appointment of a National Coordinator for Quality in General Practice. Unfortunately, experts in the field have reported that neither of the above has received adequate financial support.

The recent developments build on a 2001 report on "The quality of the health care system in the Republic of Slovenia" (Kersnik 2001). This set out a series of ideas for achieving quality of care, although some key concepts, such as TQM, CQI and patient safety were not included. It was followed by a report informing the 2003 reform that included a proposal to introduce quality of care strategies, this time including TQM, CQI, self-assessment and accreditation. Discussions with managers of health facilities and with health professionals took place but little action followed. Following a change of the Minister of Health, the proposals were not implemented.

The 5th priority goal of the National Health Care Programme – Health for all by 2004 – also identified a need to introduce integrated quality development. It envisaged that a system of integrated health care would be developed spanning all levels of health care, but this never materialized.

At the time of writing, new legislation on quality and safety is being prepared. The Ministry of Health supports the creation of a national institution for quality and safety in health care, with mandatory reporting by health care providers. However, the approaches proposed by the Ministry have not so far been well received by health professionals, with support concentrated among those already actively involved in quality activities.

Actors

Governmental

In 2003 the Ministry published the *Slovene handbook on clinical guidelines* and distributed it to clinical guideline groups, with national guidelines being developed in the same year. Further guidelines have been developed since then, mainly by the Slovenian Medical Association, but many are not in line with recommendations in the Handbook. The Department for Quality in Health

Care was established at the Ministry of Health in 2004. It has become the main promoter of quality and safety in health care organizations, acting through a number of working groups. The National Commission for Healthcare-Associated Infection has also been established by the Ministry of Health.

The National Policy for the Development of Quality in Healthcare has also been published (Robida 2006) by the Department for Quality in Health Care. Its purpose is to encourage health care providers, managers of health care organizations, health care insurance companies, educational health care organizations, health care professionals, patients and other stakeholders to improve quality of care and patient safety. The National Institute for Quality in Health Care was also proposed, with the main tasks of coordinating domains of CQI such as clinical guidelines and pathways, standards and indicators development, training and research, and accreditation of health care providers.

The Department for Quality in Health Care is also working on the formulation of clinical indicators for primary, secondary and tertiary health care. At the time of writing, six indicators are to be reported to the Ministry of Health: falls, decubitus ulcers, waiting time for CT scans, waiting for hospital discharge after treatment, percentage of unplanned readmissions (same hospital within seven days due to the same illness), and presence of MRSA infection.

The Department for Quality in Health Care has organized national conferences on clinical indicators, clinical pathways, clinical culture and patient safety. In collaboration with WHO, a pilot study on Health Promoting Standards for hospitals was conducted and one hospital is involved in the PATH project.

Slovenia has no national agency responsible for HTA. At the time of writing, advice to the Government is provided by the Health Council, an expert group that considers proposed innovations. Its work is also informed by a number of national specialty groups.

Nongovernmental

The Medical Chamber of Slovenia has established a programme of clinical indicators for 35 specialties in partnership with the Ministry of Health and the Health Insurance Institute of Slovenia. In 1999 a pilot project on clinical indicators was conducted and in 2002 all hospitals and GPs were asked to provide regular data to generate clinical indicators. However, because the programme is voluntary, the response has been poor.

Within the Association of General Practitioners, a working group on quality improvement activities has been established. The activities include: promotion of a quality improvement philosophy; development of methods and tools; participation in the National Committee for Quality in Health Care; participation

in "Electronic Quality Information for Patients" (EQUIP); development of guidelines; development of quality indicators for general practice; and assistance with self-assessment activities. However, only approximately 10% of GPs are reporting on the indicators agreed.

In order to practise, doctors are required to obtain a licence, which they must renew every seven years. However, participation in quality improvement activities does not form part of the licensing process, although the concept of quality has been introduced into the curriculum for vocational training of family doctors and a new postgraduate course on quality and safety in nursing is being established in 2007.

Health care providers do seem to be aware of the need for CQI, although they are often reluctant to engage fully in the process. There is a widely held view that better quality will emerge automatically should greater funding and more health care workers be made available.

Process

Generic standards for hospitals, a self-assessment programme, and an accreditation programme have been published by the Ministry of Health. However, lack of governmental support and strong opposition by providers has prevented the implementation of accreditation to date. With guidance from the Department for Quality in Health Care, clinical pathways were developed and implemented in four public hospitals. In 2004, approximately 15% of cases were covered by clinical pathways (Hindle and Yazbeck 2005), a figure that has since increased. A survey conducted in 2006 showed that half of hospitals were using clinical pathways (Yazbeck and Robida 2006). The development and implementation of clinical pathways are to be promoted further by a publication on "Methodological recommendations for clinical pathways development" (Yazbeck and Robida 2006).

Requirements regarding structures, processes, business, efficacy, continuing professional development and clinical indicators, as described earlier, were approved in the hospital agreement acts for the years 2006 and 2007. In 2007, hospitals were required to introduce several additional quality and safety improvements addressing patient safety leadership, morbidity and mortality meetings, internal audits, and management of clinical documentation. In addition, each hospital is now required to have a quality committee. These bodies meet on a regular basis to develop quality assurance strategies within the hospital. The committees are also responsible for mandatory reporting of nationally agreed data on clinical and nonclinical performance.

A Law on Patients' Rights is under discussion in Parliament and was expected to be adopted by the end of 2007. It includes a dispute settlement procedure, managed by a commission for complaints that seeks to solve disputes faster and more efficiently.

Patient safety activities remain in an embryonic phase, although policy is being developed. A national system of voluntary reporting of sentinel events does exist, but it is rarely used by health professionals.

Perceived barriers to more rapid implementation of quality of care strategies include lack of coordination and, at local level, shortage of funds. Managers also report a sense of being overburdened with routine problems and the economic survival of their organization and are thus unable to see the need for quality improvement (Puringer, Abbuhl and Dezsy 2001).

In 2006 a national survey on patients' experiences was carried out among hospital patients. It focused on timeliness; doctor/nurse–patient communication; patient information and participation in decisions; pain relief; and hospital environment and nutrition. Patients were generally positive about their experiences. Patient satisfaction with family practice has also been found to be relatively high compared to other European countries. However, there remains a recognition that there is still much to be done, in particular to reduce waiting times and improve communication skills (Kersnik 2000).

Spain

Context

The General Health Law of 1986 states that assessment of the quality of health care should be a continuous process, involving all health personnel and services within the Spanish NHS. Responsibility for health care in Spain has been devolved to the 17 Autonomous Regions since 2002 (with some regions achieving autonomy much earlier), giving rise to 17 different policies on quality of care. For example, Catalunya, Andalucia and Madrid have implemented accreditation of hospitals; Aragón and Cantabria are using the EGQM model; whilse Navarra is implementing its own Quality Management Programme (Comite Editorial RCA 2004).

Notwithstanding the process of devolution, the Ministry of Health and Consumer Affairs in Madrid has continued to play a role in developing guidance, advised by scientific societies working in the health field. This culminated in 2006 with the publication of the Quality Plan for the Spanish NHS. The aim of the plan is to design strategies to guarantee the maximum quality of care for all citizens. The plan clearly states that these strategies need to be supplementary to those carried out by the authorities in the different Autonomous Regions.

The guiding principles of the National Quality Plan are (Spanish Ministry of Health and Consumer Affairs 2006):

- focus on patient and user needs;
- orientation towards health protection, health promotion and prevention;
- concern about encouraging fairness for all;
- determination to encourage clinical excellence;
- interest in promoting assessment of technologies and procedures based on the best available evidence;
- capability to expand the use of new technologies;
- capability to plan human resources far enough in advance;
- transparency for all those involved;
- ability to assess the outcome of actions.

In addition to these objectives, the Quality Plan envisages the introduction of quality awards as one element of stimulating good practice.

In order to achieve these objectives, the Ministry of Health and Consumer Affairs envisages collaboration with the Autonomous Regions, scientific societies, research institutes and patients.

The Quality Plan has received core funding of €50 million per year and, with additional resources from other sources, it was expected to spend approximately €270 million in 2006–2007.

Actors

The key actors taking responsibility for quality of health care are the 17 Regional Health Services, while the national Ministry of Health and Consumer Affairs adopts only a supportive role. The main responsibility of the Ministry of Health and Consumer Affairs is ensuring equity, equality and the cohesion of the system (Law 18/23). In 2006, with the publication of the National Quality Plan, the Ministry of Health and Consumer Affairs also established objectives for quality of health care in Spain.

According to Martinez-Garcia (2006), the Regional Health Services mostly agree with the measures proposed by the central Government in the National Quality Plan, but they would have liked more involvement in its elaboration. The author stresses that some health authorities raised concerns about who will finance the measures proposed in the Quality Plan, while questioning the wisdom of proposing measures before undertaking a situational analysis of what already exists (Martinez-Garcia 2006).

Associations of health professionals also agree in general with the measures included in the National Quality Plan. Many health professionals have, in association with Autonomous Communities and patients' associations, been involved in the process of designing most of the strategies included in the Quality Plan (Patients' Safety, Cancer, Cardiopathy, Diabetes, Mental Health, Palliative Care, Maternal and Child Health, Nutrition and Physical Activity) and they will also participate in the 2-year evaluation process.

Within each Regional Health Service there is an authority responsible for the regional quality programmes. Likewise, in public hospitals and in primary health care there is an officer within the managerial structure responsible for the quality of health care.

Scientific and professional organizations at regional and national levels are playing a greater role in developing clinical guidelines and recommendations for improving quality of care. These organizations receive funding from regional and national authorities.

Pharmaceutical policy is based on the Medicines Act of 2006. The Ministry of Health and Consumer Affairs is responsible for: regulation and authorization of clinical trials; issuing marketing authorizations for pharmaceuticals; licensing pharmaceutical laboratories; and regulating the quality and manufacture of pharmaceutical products.

The Ministry of Education is responsible for undergraduate training of health care staff. Postgraduate training of medical specialists and GPs is conducted within a postgraduate training system that involves a residency period of between four and five years in designated centres.

In coordination with the Ministry of Health and Consumer Affairs, specialist accreditation is undertaken by a series of national commissions, comprised of representatives from the Ministry of Education and the Ministry of Health and Consumer Affairs, scientific societies, university teachers, health professionals, residents and medical colleges (WHO 2000).

The Departments of Health in each Autonomous Region, in association with professional organizations and medical associations, regulate continuing professional development. The Ministry of Health and Consumer Affairs has introduced a programme of accreditation for continued training of health professionals.

Process

Each Regional Health Service approves a quality programme that contains explicitly stated objectives linked to indicators to be collected by public health care institutions, including both hospitals and primary health care centres. These indicators are reported on each year. The National Quality Plan seeks agreement on a common set of indicators to be used in all Autonomous Regions.

Private health care institutions in Spain require a certificate of accreditation from the relevant regional authority in order to be allowed to function. This accreditation is not needed in public institutions, although some Autonomous Regions promote specific programmes of accreditation and certification (Catalunya and Andalucia).

Most of the Regional Health Services have agreed to promote the EFQM model of accreditation. In addition, many health services have also applied the ISO model.

The national Ministry of Health and Consumer Affairs has placed safety very high on the agenda. One of the eight strategies of the National Quality Plan involves "improving the safety of patients for whom care is provided at National Health System health care centres". The objectives of the strategy include (Spanish Ministry of Health and Consumer Affairs 2006):

- promotion and development of a patient safety culture, known to professionals at all levels of health care;
- design and establishment of systems for reporting on patient safety-related incidents: incident reporting systems are not aimed at identifying and penalizing health care personnel involved in the incident, but rather at learning from the mistakes made and preventing them from being repeated;
- implementation of agreements with the Autonomous Regions which will promote and assess safe practices in eight specific areas;
- assurance of implementation and proper use of informed consent forms, as well as full compliance with the wishes of the patient;
- reinforcement of quality systems for transfusion centres and services;
- carrying out measures to improve the quality of care provided by the National Transplant Organization.

The following examples illustrate some of the measures being developed to increase patient safety in several of the Autonomous Regions (Martinez-Garcia 2006). In Cantabria a new protocol to reduce infections and clinical errors in hospitals has been implemented. It also considers the safety of health professionals and visitors to the patient. In Catalunya, health professionals are allowed to report online anonymous information on errors in the utilization of pharmaceuticals (Martinez-Garcia 2006).

In terms of the regional level, Suñol (2006) analyses the data published by the Ministry of Health and Consumer Affairs on quality of health care strategies in the Autonomous Regions. A total of 12 out of the 17 Autonomous Regions had introduced a Quality Plan as part of their strategic objectives. The same number of Autonomous Regions focus on the EFQM model. However, the author stresses that there are Autonomous Regions with a long tradition of enacting this model (e.g. Basque Country), while other Autonomous Regions have only just started implementing it. Seven regions report implementing their own systems of accreditation, while other regions implement an international system (Joint Commission International). A total of 14 Autonomous Regions report patient satisfaction surveys covering areas such as primary health care, hospitals and emergencies, amongst others. Finally, 12 regions provide information on patient safety, and five have developed their own Patient Safety Plan, while the rest follow advice provided by the Ministry of Health and Consumer Affairs on the implementation of patient safety strategies (Suñol 2006).

At the end of 2006, the Ministry of Health and Consumer Affairs promoted a voluntary agreement in favour of "clean hands" policies in health care centres, with support from 140 scientific societies.

Key informants interviewed for the present study report that while there are many successes, barriers to a broader implementation of quality strategies in Spain include:

- a weak culture of quality and safety among health professionals and managers;
- inadequate academic training on quality and safety;
- limited dissemination of best practice.

Sweden

Context

In Sweden, the Health and Medical Services Act (1982:763) explicitly stipulates that quality of health care shall be guaranteed and systematically and continuously developed. The Act is primarily directed at health care providers. It does not confer any explicit rights on patients to receive good health care, but it sets out obligations for providers to deliver health care of high quality.

During the 1980s quality assurance activities began in Sweden with the first National Strategy on Quality being initiated by the Government in 1990.

In 1994, the National Board of Health and Welfare (NBHW) issued a further set of regulations on quality assurance, subsequently revised in 1997 and in 2005 (SOSFS 2005:12). These regulations state that all health services in Sweden must include a system for continuous, target-oriented quality improvement. The new regulations embody a new approach to quality improvement, emphasizing monitoring, systemic improvement measures and technical quality, while also focusing on the patient's experience.

Actors

Governmental

The Ministry of Health promotes quality strategies through laws and regulations at national level. These are reported to be widely accepted by health care professionals.

The Medical Products Agency (MPA, *Läkemedelsverket*) is the Swedish national authority responsible for regulation and surveillance of the development, manufacturing and sale of pharmaceuticals and other medicinal products. According to the MPA, Sweden has bought its legislation into line with EU safety requirements concerning testing, certification and labelling of medical devices (Swedish Medical Products Agency 2007).

According to the pharmaceutical legislation (*Läkemedelslag* 1992:859) a pharmaceutical or medicinal product should be of good quality and suited for its purpose. There are very strict provisions and guidelines issued by the MPA concerning, for example, quality control and quality assurance in the clinical testing of pharmaceuticals.

Concerning medical devices, there are demands on quality assurance, surveillance and supervision in the Swedish Medical Devices Act (1993:584), provisions from the MPA and provisions from the NBHW. The Blood Security

Act (2006:496) and provisions from the NBHW contain demands on quality control and supervision of blood and blood components.

The NBHW produces status reports and monitors and evaluates the effects of health care reforms. In the quality field it has a broad range of responsibilities (NBHW 2007), detailed here.

- It collaborates with the Swedish Association of Local Authorities and Regions in developing national quality indicators in health and social care. Health care professionals are responsible for reporting information needed to generate these indicators to the NBHW.
- It develops standards to support those working to raise quality and improve safety and efficiency.
- It issues regulations (mandatory rules) and general advice (strong recommendations) in relation to health services, communicable disease prevention and control, environmental health and social services.
- It draws up national guidelines for care and treatment. These provide support for prioritizing the allocation of resources.
- It carries out supervisory work. Under Swedish law a care provider has to report all cases in which, in the course of receiving treatment, a patient suffers, or is exposed to risk of, serious injury or illness.
- It carries out inspections on its own initiative. The focus is usually on quality and patient safety in health care processes, and in particular on the care provider's quality system and self-assessment. When there is found to be negligence it can ask the Medical Responsibility Board to impose disciplinary sanctions. Under certain circumstances the NBHW has a legal duty to report to the Medical Responsibility Board.

The Medical Responsibility Board is the institution that receives complaints against health care professionals. Patients can complain directly to the Board, which investigates whether the accused individual has been negligent or has given substandard care. The Board can give health care providers a reprimand, a warning, or revoke their licence to practise.

The Swedish Institute for Health Services Development (SPRI) operated an Organizational Audit Programme employing both self-assessment and external assessment. By the late 1990s only approximately 20% of Swedish hospitals were participating and the SPRI was consequently closed down.

The Swedish Council on Technology Assessment in Health Care (SBU) has a mandate from the Swedish Government to assess health care technology from medical, economic, ethical and social standpoints. Although their reports are

widely distributed, it has been suggested that more work needs to be done to achieve implementation of their recommendations.

The CMT at Linköping University, established in 1984, also carries out HTA. The Centre, which is affiliated to the Department of Health and Welfare, conducts methodological development, disseminates research findings, and assesses medical, social, economic and ethical consequences of technology.

Nongovernmental

The county administrative boards are responsible for operational supervision of their facilities, while the NBHW has an overall national responsibility.

The Swedish Association of Local Authorities and Regions (SALAR) – the membership organization for all municipalities, counties and regions -- provides cooperative support for quality improvement and has identified models, methods and tools from abroad and adapted them to the Swedish situation since 1996. These activities also contributed to the development of several very successful local quality improvement projects (for example Memeologen and Qulturum).

Health care organizations within some counties use a Quality System Assessment Framework based on the United States Malcolm Baldridge framework. The health care version is called Quality Development and Leadership. It is similar to EFQM. This framework has also been used for the Swedish Health Care Quality Awards provided by the SALAR.

Health care providers use various tools to comply with the requirements set up by law. One example is that providers are required to audit their own activities continuously. According to the Act on Professional Activity in Health Services and certain provisions in the recommendations from the NBHW, health professionals have legal obligations to report adverse events and "near misses" to their superiors. These must be reviewed at the level of the facility and, if deemed to be severe, must be reported to the NBHW.

Accreditation is very common in technical support departments and laboratories but is rarely found in clinical services.

Process

The SALAR and the NBHW support the development and use of National Quality Registries. In 2005, approximately 60 registers were in existence, each containing data on health care outcomes and treatment for particular categories of illnesses. They serve as a knowledge base for CQI and allow for research and benchmarking. In addition to their applications at the local level, the registries are being used to a greater extent in more general planning and management and

are increasingly transparent. The registries have been developed and managed by the professional groups that use them. Three competence centres for quality registries have been created to support new registries. The potential application of these registers becomes wider as increasingly more registries begin to move beyond medical data to include patient-perceived quality and quality of life. "Transparent Comparisons" comparing over 50 health care indicators have been published since 2006. The results in these reports reveal substantial variations between county councils, leading to demands for quality improvement from the leadership of the county councils.

Similarly, long-term efforts to raise awareness of patient safety are under way. The aim is to develop a safety culture which will increase acceptance of the fact that it is often failures of the system as a whole which lie behind patient injuries. The Swedish self-reporting system for medical errors focuses on serious injuries caused by treatment in the health care sector. The first law was introduced in 1937 (*lex Maria*, focusing on disciplinary action and assigning responsibility for reporting patient injuries to both the NBHW and the police). It has its origins in an incident that occurred at the Maria Hospital in Stockholm (Ödegård 1999), where four patients died following injections of mercuric oxicyanide instead of a local anaesthetic. The Law focused on disciplinary action, although in subsequent amendments it has been adapted to take a preventive approach (Ödegård 1999). The laws related to safety are being revised at the time of writing.

During the late 1980s all of the then available programmes for internal self-assessment and external audit were surveyed. They included the JCAHO; the Canadian Council on Health Services Accreditation; the Australian Council on Healthcare Standards and the United Kingdom KFOA. After piloting several models in different health care locations, the models developed by the King's Fund and the Canadian accreditation system were chosen as the prototype for the SPRI Organizational Audit Programme. There are over 60 trained health surveyors in Sweden at the time of writing. The SPRI developed a list of explicit criteria for becoming a surveyor, including personal qualifications, formal qualifications, reputation within the profession and ability to accept regulations.

Medical and clinical audit processes had already been developed in 1990 and are still being used by the Swedish Medical Society. Their main purpose is to support learning.

The international and European ISO standards for quality systems have been implemented in several areas of Swedish health care, such as internal medicine and surgery, laboratories, nursing homes and dental practices.

Almost all biochemical laboratories in Sweden have applied the European Standard (EN 45001) and have been, or are on their way to being, formally accredited by the Swedish accreditation body (SWEDAC).

Initiatives by the SALAR, together with professional organizations and universities, have been taking place since 1996 to promote the integration of quality into health professional education at all levels. Sweden is also an active contributor to European activities in this area (such as initiatives by the ESQH). Recent regulations in Sweden require quality to be incorporated into undergraduate education and medical specialist licensing. However, it is proving challenging to identify sufficient training staff.

The recently established Medical Management Centre at the Karolinska Institute undertakes research on quality improvement and patient safety. The VinnVard Initiative was launched in spring 2007 by Vinnova and the Vardal Foundation to fund health services research and quality improvement activities.

A commitment to quality improvement is increasingly embedded within the Swedish health system.

The United Kingdom

Context

To understand the delivery of health care in the United Kingdom it is necessary to understand its unusual governmental structure. It consists of four separate countries (England, Scotland, Northern Ireland, and Wales). Elected administrations have been created in Northern Ireland, Scotland and Wales, each of which has responsibilities for certain areas including many aspects of health care, although the precise powers that have been devolved vary. There is no comparable elected administration in England, so that policies affecting England are determined by the Government of the United Kingdom, which includes politicians from all four countries. To understand this section, it is also necessary to be aware of some of the specific terminology that is unique to the United Kingdom. A Primary Care Trust is an organization responsible for purchasing health care for residents of a defined geographical area, often co-terminous with one or more local government bodies. A Provider Trust is either a hospital (or group thereof) or an organization providing community health services. A Foundation Trust (only existing in England) is a health care provider (hospital or community) that has a greater degree of financial autonomy from the Department of Health.

As a consequence, the organization of health care is rapidly diverging, a process that is likely to accelerate following elections in Scotland and Wales in 2007 that, for the first time, placed different political parties in power in the four countries that make up the United Kingdom.

In England, the Department of Health, like other ministries responsible for public services, is engaged in a rapid process of "modernization", by which a swift succession of often disconnected reforms have been implemented over recent years with the promise of even faster change in the future. The pace of change is such that anything written about the English NHS is likely to be out of date as soon as it is printed – a factor that must be taken into account by the reader, who will also note in the following paragraphs the speed with which organizations are merged, reorganized or renamed.

In contrast, in Scotland, health policy is characterized by a more incremental development with a clearly defined direction. Policies in Wales are also more incremental, while in Northern Ireland the situation is still unclear at the time of writing, as the devolved government has delayed publication of its new health policy. The remainder of this section will describe the situation in England, except where otherwise stated.

Actors

Governmental

In the report *Delivering the NHS Plan 2002* the Department of Health proposed the formation of a Commission for Healthcare Audit and Inspection (known as the Healthcare Commission). This body was to replace the Commission for Health Improvement, although it was essentially a continuation of it. The Healthcare Commission was to continue to monitor the quality of health care organizations through an updated assessment process which aims to reduce regulatory burden while giving the public a more accurate picture of performance. It continues to award controversial annual performance ratings to health facilities. The inspection process and annual performance ratings are in part to draw on how Trusts perform against a new set of national standards the Government published in 2004 (National Standards, Local Action: health and social care standards and planning framework 2005/2006, 2007–2008). These standards cover seven key areas including safety; clinical and cost–effectiveness; governance; patient focus; accessible and responsive care; care environment; and amenities and public health. Each area includes what the Healthcare Commission considers that health care organizations should be achieving now, known as core standards, and what they should be aiming for in the future, known as developmental standards. It has been reported that these have helped Trusts to focus their efforts towards improvement, even though the standards themselves require further work.

The Healthcare Commission has also taken over the role of the former National Care Standards Commission, which had a remit to inspect private and voluntary social care services. It undertakes some work for the Audit Commission (a statutory body that assesses value for money and undertakes financial audit of public services) relating to efficiency, effectiveness and economy of health care.

Another organization, the National Patient Safety Agency (NPSA) is charged with collecting information on adverse incidents and "near misses", with the aim of initiating preventative measures. The NPSA's remit also includes work to build safety into hospital design; cleanliness (a major political issue in the United Kingdom following concerns about failing standards and hospital-acquired infection widely believed to be linked to the widespread use of low-wage contract staff); food safety (transferred from NHS Estates); ensuring research is carried out safely, through its responsibility for the Central Office for Research Ethics Committees (now the National Research Ethics Service (NRES)); and supporting local health care providers that have concerns about the performance of individual doctors and dentists, through its responsibility for the National Clinical Assessment Service (NCAS), formerly known as the

National Clinical Assessment Authority. The NPSA also manages the contracts with the three confidential enquiries into maternal, perinatal and post-operative deaths.

NICE was created to produce evidence-based clinical guidelines and HTAs. In 2005 it was merged with the Health Development Agency (responsible for health promotion activities) to form the National Institute for Health and Clinical Excellence (although still abbreviated to NICE). NICE guidance is based upon an appraisal process that seeks and considers evidence derived from an independent assessment and from information obtained through consultations. Surveys have shown that the rate of implementation of NICE guidelines across the country varies. According to NICE, "managing the application of this guidance is proving to be a substantial challenge" (NICE 2007).

A concern among providers is the failure to link resources to the implementation of guidelines, although NICE guidance also informs a series of National Service Frameworks (explained in more detail later), which should, at least in theory, inform resource allocation. However, the guidance is widely viewed as having improved uptake of effective care and decreased ineffective care.

The Healthcare Commission, NICE and the NPSA represent the chief regulatory agencies that the Department of Health charges at the time of writing with the task of supporting quality improvement across the NHS in England. One commentator has argued that the purpose of regulatory bodies such as these is to put distance between politicians and difficult decisions to be made, so that responsibility is shifted to the regulator. However, ministers retain overall responsibility for these decisions (Walshe 2002).

The National Coordinating Centre for Health Technology Assessment (NCCHTA), which is part of the Wessex Institute for Health Research and Development at the University of Southampton, coordinates the HTA programme on behalf of the Department of Health's Research and Development Division. Every year the HTA programme and its advisory panels, supported by the NCCHTA, decide which of the many suggestions received from the NHS and its users should become research priorities. The HTA Programme works closely with NICE, commissioning review groups to carry out independent assessments on behalf of NICE (NIHR Health Technology Assessment Programme 2007). A similar body, responsible for service delivery and organization, based at the London School of Hygiene and Tropical Medicine, coordinates a programme of research on models of care.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is an Executive Agency of the Department of Health, responsible for protecting and

promoting public health and patient safety by ensuring that pharmaceuticals, health care products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness and are used safely. Its Licensing Division is responsible for the evaluation of the quality, safety and efficacy of all new medicinal products to be authorized for use in the United Kingdom (MHRA 2007).

On average, two National Service Frameworks per year were published by the Department of Health after their inception, although none have been published since 2005. The programme so far covers:

- mental health (1999)
- coronary heart disease (March 2000)
- cancer (September 2000)
- older people (March 2001)
- diabetes (December 2001)
- children's services (September 2004)
- long-term conditions (March 2005)
- renal services (March 2005).

National Service Frameworks have had a significant influence on the strategic development of services across England and have helped to identify areas of poor service as well as good practice that others can learn from. In particular, they have sought to minimize the inequity of the "postcode lottery", where access to services (e.g. coronary artery bypass surgery) depended on the patient's health district of residence.

The NHS Plan, which provides the basis for current policy, significantly strengthened the existing mechanism to allow the public input into how health services are run. Patient Advice and Liaison Services were established in every Provider Trust and Primary Care Trust in April 2002, to provide information to patients, their carers and their families to help them through the system and resolve any immediate problems and complaints. Patients' Forums were also established in every hospital and Primary Care Trust to represent the views of patients and users of services provided, although they remain purely consultative. Together, they replaced Community Health Councils, which had statutory powers in relation to approval of service reconfigurations. A Commission for Patient and Public Involvement has been created, with the stated aim of promoting involvement of the public in the decision-making process. While in theory these reforms could improve the quality of care received by patients, there is little evidence that they have been effective. In practice, managerial

actions are driven almost exclusively by the pursuit of the large number of centrally imposed targets relating to service delivery and, especially, financial performance, many of which have given rise to gaming and other forms of opportunistic behaviour by providers.

Nongovernmental

The following bodies are active throughout the United Kingdom NHS. The GMC is the medical profession's regulatory body. It was established by the 1858 Medical Act to protect patients from unlicensed and underperforming practitioners. The GMC maintains a medical register and will oversee the proposed process of revalidation – the requirement for doctors to demonstrate on a regular basis that they continue to be fit to practise – once its format is agreed and it is introduced. Revalidation is a summative assessment which is likely to comprise an assessment in addition to information collected at doctors' annual appraisals. Unlike revalidation, appraisals are a formative process which encourage doctors to identify and reflect on the quality of their care and submit professional development plans for improvement. Appraisals require all doctors to collect and present annually and confidentially to an independent doctor, data on their performance as individual clinicians. In addition to clinical data (e.g. child immunization rates), evidence on the quality of clinicians' relationships with patients and staff, continued professional development, probity, health, and practice management are presented where possible. Revalidation will be a prerequisite to continue to practise in the United Kingdom.

The GMC investigates problematic doctors and, if necessary, can remove them from the register. It is also responsible for setting standards for medical education and training. Specialist training and continuing professional development are the responsibility of the Royal Colleges. They are responsible for the examinations that doctors must pass as part of the process of achieving specialist status. The Royal College of General Practitioners fulfils a similar role for general practice. The Royal Colleges have played a major role in the development of clinical standards and led the introduction of medical (and subsequently clinical) audit in the 1990s.

Process

Governmental

A new contract with GPs explicitly links payment to quality improvement through a Quality and Outcomes Framework. The Framework is designed to raise organizational and clinical standards in primary care. Practices are awarded

quality payments on the basis of their achievement on a quality and outcome framework scorecard.

Practices are assessed on the basis of their performance in four domains. Each domain contains a range of areas described by key indicators. The four domains are detailed here.

- Clinical: coronary heart disease, stroke or transient ischaemic attacks, hypertension, diabetes, chronic obstructive airways disease, epilepsy, cancer, mental health, hypothyroidism and asthma.
- Organizational standards: records and information about patients, education and training, practice management and medicines management.
- Patient experience: use of accredited questionnaires to gain patient views and make appropriate improvements, 10-minute appointments.
- Additional services (with defined quality standards): cervical screening, child health surveillance, maternity services and contraceptive services.

The Quality and Outcomes Framework has been credited with improving the quality of care in general practices that were previously lagging behind and ensuring a greater degree of conformity. However, the Framework is extremely mechanistic and it has been criticized for concentrating efforts on what can be measured, rather than less tangible things such as communication with patients. The centrally driven agenda may come at the cost of patient-centredness. With only 7–10 minutes per consultation, family doctors become more eager to meet these directives than to explore and be led by the concerns of the patient. It is widely reported that there is a tendency to pay less attention to problems that have not attracted quality payments.

The purchasers, the Primary Care Trusts, are also able to contract with practices to deliver specific enhanced services tailored to the needs of the local community, such as clinics for refugees and asylum seekers. The Primary Care Trust can specify the quality standards it expects for such a service. In 2006, however, there was a major reorganization of Primary Care Trusts in many parts of England, a process that has impaired the ability of these organizations to function effectively during the transition.

Clinical teams working in hospitals have been required to participate in quality assurance programmes since the early 1990s, with many specialists developing their own stand-alone data collection systems to overcome the known inadequacies of the existing information systems. The results of audits form a core element in the annual appraisals that all doctors must undergo.

Nongovernmental

The ExPeRT project (1998) was set up to exchange practical experience of external peer review systems in health services within the EU, including the United Kingdom. Shaw (2000b) differentiated between three types of programmes in the United Kingdom: those offering organization-wide assessment (e.g. hospital accreditation programmes); those catering for speciality areas within organizations (e.g. accreditation and development of health records programmes); and those assessing organizations dedicated to specialty areas of health care (e.g. autism services accreditation programme). The programmes that were included in this research were: the Hospital Accreditation Programme, which examines the future of small hospitals; the KFOA, which is the most widely known external peer review system in the United Kingdom; Health Services Accreditation, which assesses specific areas of health care and their supporting services; Trent Accreditation Scheme, which assesses community hospitals and other services in the Trent Region; and the Wessex Institute for Health Research and Development of the University of Southampton, which designed a tool for a total organizational audit, a peer review with a matching hospital and an accreditation scheme (ExPeRT 1998).

Numerous initiatives have been developed by professional societies and other groups, such as registers to monitor outcomes of patients undergoing selected procedures, or laboratory quality assurance programmes, as well as many more local initiatives led by individual clinicians.

Assessment

The United Kingdom, and England in particular, has seen the creation and, in many cases, rapid reorganization of what can seem like a bewildering array of organizations that have some responsibility for health care quality. This is on top of the myriad of activities undertaken by professional bodies and individual clinical teams. It is apparent that the process of ensuring quality has improved almost beyond recognition since the mid-1980s. However, some concerns remain, as set out by the British Medical Association (BMA), detailed here.

- A lack of "ownership" of strategies by health professionals. In some cases the implementation of strategies has involved bullying of staff by managers with a subsequent adverse impact on morale.
- Legitimate concerns about clinical guidelines, for example the shifting nature of the evidence base.
- Insufficient resources and failure to pilot initiatives.
- Workforce shortages and shortages of beds, especially in community care.

To set the BMA's comments in context, one has to recognize that the quality strategy that was set out in the seminal paper *The NHS: a first class service*, which introduced the concept of clinical governance in 1998 (linking quality to resources and replacing earlier policies promoting audit), was implemented across the NHS in only seven years. This was an attempt to create a TQM system within NHS organizations in a remarkably short time.

There is no evidence to suggest that, at least in England, the rapid pace of change is about to diminish. Although a great deal of what has been achieved has been led by individual health professionals and their associations, the English Department of Health, like other government departments such as those dealing with education, has favoured policies that diminish the role of professional values and accountability and replace them with a combination of central planning and regulation (for example, the widespread use of very detailed targets) and market mechanisms (based on what is termed "patient choice"). Choice is a central element of the United Kingdom's ideology, based on the view that individuals place a high value on the ability to choose which public service provider they will use – a view that is, unfortunately, not borne out by evidence that instead consistently shows a desire for uniformly good services so that people do not have to choose somewhere far away.

The BMA comments that, while many professionals share the Department of Health's commitment to transparency, accountability and responsiveness in health care, there remains resistance to excessive management control. It has also expressed concern about the extent to which market mechanisms will improve the quality of care patients receive and, in particular, about the pre-eminence in government policy of the concept of "choice", rather than other goals such as equity. Nonetheless, professional organizations have collaborated with the Department of Health in the development of quality initiatives and in some cases, for example confidential enquiries and vocational training in general practice, professional initiatives have led reform.

Several writers contend that a continuing problem in the NHS is the failure to value staff (Cooke and Chitty 2004; Finlayson 2002). The Government's approach is seen as failing to address the relationship between staff morale and clinical outcomes, through its lack of emphasis on some of the key issues which influence organizational culture, such as the quality of the working environment and availability of resources. Given the day-to-day pressures that health care professionals are under, they argue that a developmental approach to quality improvement would seem more appropriate than a punitive one.

Chapter 5
Conclusions

This book has shown that mechanisms to promote quality of care vary extensively within the EU. The EU itself has a very limited role in quality of care, except in terms of pharmaceutical care, where policy has been driven largely by industry concerns. In other areas, the situation reflects fundamental differences in health systems and the interests and influence of the various stakeholders. Governments are, at least in theory, able to play a greater role where they employ health professionals directly, as with hospital doctors in countries with national health services. Government involvement is often less where physicians are self-employed and where they view themselves as a liberal profession, demanding professional autonomy (Kaprio 1978).

Quality assurance activities seem to be more common where health professionals work in multidisciplinary teams, presumably because it is easier to organize peer review with colleagues than with competitors when practising single-handedly. Professional associations can also play an important role. In general, these associations work in three broad areas: negotiating on behalf of their members, tackling unprofessional behaviour and actively enhancing professional standards. In some countries, such as the United Kingdom and the Republic of Ireland, these roles are undertaken by different bodies but elsewhere these may be combined. Moreover, the nature and power of such associations varies considerably. Clearly, a key factor is the priority that associations give to enhancing professional standards, which may be minimal if their efforts are focused on financial negotiations. In some countries, such as Denmark (Vallgårda, Krasnik and Vranbaek 2001), the Netherlands (Woolf, Grol and

Hutchinson 1999) and the United Kingdom (where they have initiated a number of national audits), professional bodies have been active in a range of quality assurance activities.

In countries where health care is funded through social insurance, insurance funds have established organizations to provide technical support to facilitate the inclusion of quality in contracts with providers, for example the RIZIV-INAMI in Belgium. In Germany, the BQS was established by corporate actors to support the development and implementation of measures for external quality assurance in hospitals.

International influences have been important, exemplified by the adoption of the Joint Commission International's accreditation model. In countries such as Hungary, quality assurance associations arose as a result of participating in EU-funded collaborative projects, with Dutch teams being especially influential (Gulácsi 2001).

Approaches also vary within countries, reflecting differences between those where the health system is organized centrally and those where it is decentralized. Thus, the Spanish Autonomous Regions Catalunya and Andalucia have implemented systems to accredit hospitals, while Aragon and Cantabria are applying the EFQM model and Navarra has developed its own Quality Management Programme (Comite Editorial RCA 2004). Similarly, there is considerable diversity among the Italian Regions.

Meeting the needs of Europe's citizens

This book addresses the major challenge facing the EU's legislators of how to fully align two goals: that goods and services provided across borders are of appropriate quality, and that freedom for people to move is not constrained, by ensuring that they can obtain health care when outside their home country. Consequently, the question that needs to be answered is this: how can the citizens of Europe be assured that they will receive high-quality care if they need health care beyond their national frontiers?

It is clear that while the quality of some of the elements of health care is carefully controlled at a European level, either by the creation of centralized systems, as with some pharmaceuticals, or by harmonization of standards, as with professional education, many others are not, such as the quality of health care systems, organizations and clinical processes. In a few countries, there is very little evidence of any concrete progress and, in others, what exists is based on the work of a few individuals, with little impact on the majority of health professionals.

This section proposes two steps that must be taken by European policy-makers if high-quality care is to be guaranteed. It takes account of both the clear statement in the Treaties that health care is a matter reserved for Member States and also the current legal uncertainty arising from successive rulings by the European Court of Justice on cross-border care. It also notes that the proposed new Directive on Health Services seems likely to leave the details of possible mechanisms to national governments (McKee and Belcher (in press)), but opens the door to exchange of ideas and the adoption, on a voluntary basis, of common solutions.

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. While the detail of these policies is a matter for governments and those acting on their behalf in Member States, it is clear that they should promote care that is effective, acceptable, appropriate to the patient's needs and patient centred.

If this is to happen, appropriate policies should be in place at all levels. Some are already in place, such as regulation of pharmaceuticals. Others are in place in some Member States but not in all. They include, at the level of the overall health system, mechanisms to ensure the quality of the other main inputs to the system, such as technology (HTA) and the work force (training and continuing education of health professionals). At a clinical level they include methods to enhance the processes and outcomes of care, such as the creation and implementation of practice guidelines, monitoring systems (quality indicators, patient surveys) and quality assurance systems (clinical governance arrangements and audit processes).

It is certainly not necessary that governments of Member States should undertake all these roles and, indeed, there is considerable evidence to suggest that it would be better if they did not. There is great scope to exchange experience on the many voluntary mechanisms used by organizations 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 (9000).

While recognizing the many limitations in the information gathered for this book, 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. As noted above, there are some universal or quasi-universal elements, especially those related

to safety of pharmaceuticals. In other areas, however, such as the quality of clinical care, there is great diversity. 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 to which they can be put. This is often a consequence of differences in the interpretation of European data protection legislation, placing the right of the individual to maintain anonymity above the right of society to receive safe and effective health care.

Measures to improve patient safety are central to ensuring quality overall. Within Europe, patient safety is only slowly being prioritized; only a few countries, such as Denmark and the United Kingdom, have formal structures and systems in place.

Second step: ensuring quality of cross-border care

The second step in assuring care of high quality for those crossing borders relates specifically to the process of cross-border care and to the type of cross-border care being considered. While all patients ought to be reassured that the key elements of a high-quality system are in place, the importance of continuity of care will be different for a young person developing an acute, but self-limiting disease while on holiday, to an elderly person falling ill with a complication of a chronic disease after having retired and settled down in another Member State.

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 research undertaken so far.

People who use facilities serving border regions

Patients receiving care in a border region may worry most about the cross-border pathway and continuity of care. Although most patients seem to be positive about their experience, it is clear that there are some bottlenecks that could jeopardize quality. Communication between professionals can be poor during hospitalization or during after-care and there may be multiplication of superfluous medical procedures (and costs) when doctors disregard tests already carried out. Also, transfering back and forth between doctors and different care institutions is likely to be unpleasant and confusing for the patient (Boffin and Baeten 2005). Lack of knowledge about specialists and differences between countries in infection control policies can also pose a problem (Engels 2003).

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. A second approach is where the main focus of the collaboration is on improved quality of care. A third approach involves collaboration for sharing best practice.

People sent abroad by their home systems

There are two situations in which purchasers establish procedures to allow patients to go abroad for care. One is where payers facilitate or arrange treatment abroad to overcome a shortage of domestic provision. The second situation arises where a small country makes an explicit decision to obtain highly specialized services abroad because its population is insufficient to justify providing them domestically. In most of these situations, quality requirements are stated in the contract agreements. We have identified different levels of detail and requirements in the specifications regarding quality of the services provided. They range from the excessively bureaucratic to those that contain few details because they are based on long-standing relationships with high levels of mutual trust. 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.

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

A growing number of people are willing to go abroad for economic reasons. Price levels in Europe differ considerably, with patient flows reflecting these differences. People travel from the older to the newer EU Member States in their thousands to obtain medical services, many of which are excluded from national benefits packages. Dental care and cosmetic surgery are prime examples of so-called medical tourism. The question is 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 and are thus not bound by quality requirements applicable in the public sector. Another characteristic of this sort of patient mobility is the frequent involvement of commercial middlemen who act as brokers between potential patients and providers. In many cases the main source of information on quality of health care is provided by a web site created by intermediary organizations. While patient-friendly web sites may well provide reassurance about the quality of treatments and the competences of foreign providers, they remain largely unregulated (except where they are hosted in countries with effective systems to uphold advertising standards) and the information provided can be seen as potentially misleading.

Long-term residents

Although there is a long tradition of people retiring to other countries within Europe, in the past 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 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 and home care when moving to countries where 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. This is clearly an area requiring further attention by those involved, to develop effective working arrangements that reflect the local context.

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 probability of seeking care may be low the absolute numbers of tourists falling ill and in need of 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 that are necessary within countries in order to respond to the increasing ethnic heterogeneity of Europe (Legido-Quigley et al. 2007). It needs to be stressed that, even when these systems are in place, if facilities are understaffed this can jeopardize the quality of the services provided.

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 (Legido-Quigley, McKee 2006).

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

One lesson to emerge from the experience so far is the importance of involving health professionals. Health professionals can adopt one of two distinctive attitudes towards cross-border care. Where initiatives are imposed from above, and where they fail to take account of the views of health professionals (for example, when used to challenge what is perceived as underperforming staff), those health professionals have been reluctant to become involved. In contrast, those projects that were initiated and driven by health professionals have often had considerable success and have enhanced quality of care. Unfortunately, in many cases, the former are more common than the latter.

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 systems. 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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Europe's citizens are on the move. In unprecedented numbers they are travelling across borders, their passage eased by the removal of national frontiers, the adoption of a common currency, and the growth of low cost air travel. People have always travelled within Europe for work and leisure, although never before with the current intensity; some even commute weekly between, for example, Poland and the United Kingdom. Now, however, they are travelling for many other reasons, including the quest for key services such as health care.

Whatever the reason for travelling, one question they may ask is "if I fall ill, will the health care I receive be of a high standard?". Until now, they could only go on trust. Surely each country had put in place systems that would ensure that the care provided on its territory was safe, effective, and humane? But they had no way of knowing whether this was the case.

This book now examines, for the first time, the systems that have been put in place in all of the European Union's 27 Member States. The picture it paints is mixed. Some have well developed systems, setting standards based on the best available evidence, monitoring the care provided, and taking action where it falls short. Others need to overcome significant obstacles.

The European Union has only limited ability to take action on health care but if free movement of Europe's citizens is to become a reality, an essential measure would be to ensure that appropriate systems are in place to ensure high quality care, even if the approaches taken will vary according to local circumstances. This requires a dialogue between those responsible for funding and providing health care in Europe. This book contributes to this important process.

The authors

Ms Helena Legido-Quigley is a Research Fellow in Public Health, London School of Hygiene & Tropical Medicine, United Kingdom.

Professor Martin McKee is Professor of European Public Health, London School of Hygiene & Tropical Medicine, and Research Director, European Observatory on Health Systems and Policies.

Dr Ellen Nolte is Senior Lecturer, London School of Hygiene & Tropical Medicine, and Senior Research Fellow, European Observatory on Health Systems and Policies.

Ms Irene A Glinos is a researcher at the Observatoire Social Européen, Brussels, and the University of Maastricht, Maastricht, the Netherlands.

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