How can quality of health care be safeguarded across the European Union?

Can Europeans be confident about the quality of care received in another EU country? **Helena Legido-Quigley and colleagues** discuss the various mechanisms at work across Europe to ensure quality and safety

The European Union (EU) is built on the concept of free movement of goods, services, people, and capital. Laws enacted to implement and protect these freedoms impact on the healthcare sector. For example, to facilitate professional mobility, qualifications obtained in one country are automatically recognised in others. Citizens can travel freely within Europe, reassured that they will have access to health care should an emergency arise.[1] The licensing of new drugs and medical devices is harmonised across Europe. But can Europe's citizens be confident that any care received in another EU country will be safe and of high quality?

We discuss why healthcare professionals and patients in the European Union should take an interest in this subject, and we describe the current status of some of the elements of a high quality health system, who is in charge, and how things might change.

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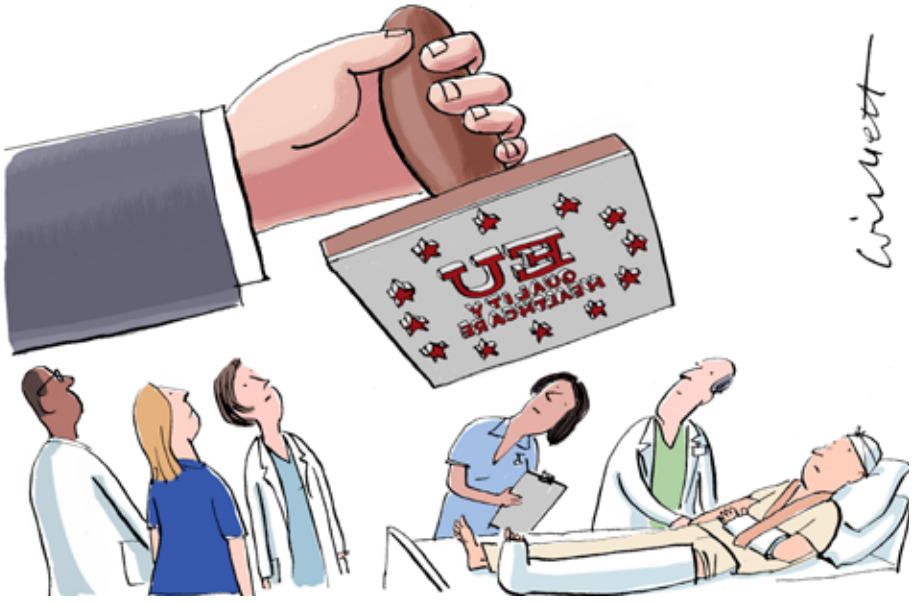
Why is this becoming an issue now?

In the EU, delivery of health care is a responsibility of individual countries. The assumption that health services provided according to national regulations in any EU country will be of adequate quality is confirmed by the European Court of Justice, which has applied the principle of mutual recognition in its rulings.[2] Yet within Europe the approach to quality in different countries varies, often for historical reasons, such as whether doctors have been state employees, subject to oversight of their work—or whether they view themselves as a liberal profession, demanding professional autonomy.[3] These differences are becoming increasingly important for two reasons.

Firstly, the number of health professionals moving within the EU is increasing rapidly.[4] These professionals need information on the structures and processes to promote quality that they will be encountering, and professional teams need to understand that newly joining members from abroad may have different experiences and expectations.

Secondly, it is still unusual for citizens of one country to obtain health care in another European country (it accounts for at most 1% of total health expenditure[5])—but in some places, and for some groups, this phenomenon is important. Visitors may need to be treated while travelling, and many people are now retiring to another country. Also, people may need to obtain services that are not available at home—for example, people living in border areas or in small countries that cannot offer highly specialised services, or where treatment is available more quickly or cheaply elsewhere.[6] Some healthcare providers and institutions now operate in more than one European country, and the liberalisation of healthcare insurance and provision in some countries is likely to accelerate this trend.



Elements of a high quality health system

Healthcare policy in the EU has, at its centre, a fundamental contradiction. Successive European treaties clearly state that health care is the responsibility of member states—but the delivery of health care involves people, goods, and services that are subject to European law.

Initiatives on the quality of health care can be divided into two broad categories. Some are top down, often in the form of legislation or regulations from governments and official bodies. Others are bottom up, initiated by health professionals and other providers.

Within Europe there is another dimension, the extent to which there is consistency or diversity among countries. Laws and regulations range from those at the European level, through those where some or all countries have adopted common solutions, to those where policies are entirely national. Bottom up initiatives often start in one setting but may be copied by

others and applied in several countries.

The diverse approaches to improving quality make it impossible to produce an ideal taxonomy of quality related initiatives. We have identified seven broad categories of initiatives that illustrate both the similarities and the diversity within European health systems.

Approval of drugs and medical devices

Approval of drugs is one of the few areas within health care where practice is harmonised within the EU.[7] Manufacturers can submit new products for approval centrally, to the European Agency for the Evaluation of Medicinal Products. Alternatively, they may seek approval by a national evaluation agency, which then circulates details to the relevant agencies in all other EU countries; if no objection is received, the product is approved for sale throughout the EU (principle of mutual recognition). Some products, such as those involving biotechnology, must be approved centrally; otherwise, the manufacturer can choose which route to use. The EU has also legislated to require that drugs are accompanied by detailed patient information leaflets.

Training of health professionals

The ability of a health professional trained in one country to work in another is based on mutual recognition. Successive EU legislation has set out minimum standards for training programmes. People completing such a programme are deemed to meet acceptable European standards. The system has been criticised, however, because the criteria for recognition relate almost exclusively to the length of study, with no consideration of the content, nor do they 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 recognised everywhere and those relating to specialties recognised in only a few countries, such as dermatovenerology. Qualifications in the second group can be used only in a country that recognises the specialty. EU law does not deal with revalidation, which is in place in some countries, such as the Netherlands, and is being introduced in others.[8]

Registration, licensing, and accreditation of facilities

Several countries have implemented their own systems to ensure that health facilities meet certain standards above and beyond those applicable to all public buildings (such as fire regulations). No Europe-wide system exists, although international initiatives have been used in some places (box 1). In countries such as Denmark, the Czech Republic, Italy, and Spain, individual hospitals or groups of hospitals have voluntarily sought accreditation from the Joint Commission International, and others have used models adapted from Canadian quality standards. Variants of the organisational audit, pioneered in the United Kingdom by the King's Fund,[9] have been adopted in Sweden and Finland.

In France, Finland, Germany, Denmark, Poland, Sweden, and the United Kingdom, some individual hospitals have sought certification by the International Organization for Standardization. The ISO 9000 standard covers areas such as record keeping and initiating action in response to emerging problems, but it is generic rather than specific to clinical quality. Hospitals in Finland, Luxemburg, the Netherlands, and Hungary, as well as in some regions of Spain and Italy, have adopted the self assessment framework developed by the European Foundation for Quality Management (EFQM), in some cases linked to national award schemes. As with ISO 9000, its content is not specific to the health sector.

Most countries have national accreditation bodies for laboratories, although procedures vary greatly. These national bodies are working together to develop common approaches.[10]

Patient safety

Both Luxembourg and the United Kingdom used their rotating presidency of the EU to make patient safety a priority.[11] The World Health Organization has created a World Alliance for Patient Safety, and the importance of patient safety has been endorsed by the Council of Europe.[12] A recent European study on patient safety found, however, that in 2005 only Denmark, Germany, Spain, the Netherlands, and the United Kingdom had established specific institutional structures to ensure patient safety; the systems implemented by Denmark

Box 1 | Examples of international quality initiatives

EFQM

The European Foundation for Quality Management (EFQM) provides a framework for self assessment that is used by facilities applying for the European Quality Award and corresponding national awards. EFQM was founded in 1988 by the presidents of 14 major European companies, with the endorsement of the European Commission. It seeks to stimulate and help organisations participate in improvement activities, leading to excellence in customer and employee satisfaction, and thus an impact on society and business performance.[23] It follows the Donabaedian structure-process-outcome principle and emphasises organisational development through self assessment. Two elements, "positioning and improving" and "self-assessment," are especially relevant to healthcare organisations.[24]

European Practice Assessment

The European Practice Assessment framework offers a means of assessing how well general practices are organised and managed.[25] It is based on five domains—infrastructure, staffing, information, finance, and quality and safety—with measures designed to facilitate international comparisons. It is in use in nine European countries.

ISO

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies covering industrial, economic, scientific, and technological sectors and provides standards against which organisations or bodies may be certificated by accredited auditors. The ISO 9000 series, used for assessing healthcare facilities, comprises five standards on quality management and quality assurance. Facilities wishing to be certified to ISO 9000 standards apply directly to a certification body and an audit is conducted by experts in ISO norms.[26] The international comparability of the ISO 9000 standard has been questioned.[27]

Joint Commission International

The Joint Commission International is the international arm of the US accreditation organisation launched as the Joint Commission on Accreditation of Hospitals in 1951 by the American Colleges of Physicians and Surgeons, the American Hospital Association, the American Medical Association, and the Canadian Medical Association. It accredits US healthcare organisations funded by the federal government and now offers a modified programme for healthcare organisations overseas.[28] Its assessments examine structures and processes in relation to access to and continuity of care, assessment and care processes, education and rights of individuals, management of information and human resources, quality leadership, infection control, collaborative integrated management, and management of facilities.

and the United Kingdom were judged as the most advanced (box 2).[13] Other countries had implemented elements such as national or regional incident reporting systems, requirements that facilities employ risk managers, and protection for whistleblowers, but their nature and scope varied greatly.

Clinical guidelines

Almost all countries have a variety of processes in place to develop or adapt clinical guidelines. These range from initiatives within individual facilities to national programmes that employ teams of analysts conducting systematic reviews. In 2001 the Council of Europe developed a set of recommendations for producing clinical guidelines.[14] Several European specialist associations, such as the European Association of Urology, have well established systems of guideline development. Also, the European research project AGREE and the Guidelines International Network, an international network for guidelines developing organisations, have contributed substantially to creating a consensus at European level on methods to develop guidelines and to assess their quality.[15 16] The progress made by individual countries varies considerably.

Box 2 | Patient safety initiatives

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 whistleblowing provision so that healthcare workers who report an adverse event cannot be subjected to investigation or disciplinary action by their employer, the health board, or the courts for doing so.

United Kingdom

The National Patient Safety Agency was established in 2001. It consists of a patient safety division, operating a national reporting and learning system that analyses information on adverse events and takes appropriate action, for example by issuing alerts; a national clinical assessment service, which provides confidential advice and support where the performance of doctors and dentists is giving cause for concern; and a national research ethics service. It also runs a series of confidential inquiries into suicide and homicide by people with mental illness; maternal and neonatal deaths; and perioperative deaths.

Box 3 | Dutch visitatie model

The visitatie system originated in the Netherlands in the late 1980s as a system of peer review owned and led by doctors, designed to assess the quality of care provided by groups of hospital based medical specialists.[17] The system is organised 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.[29]

Box 4 | Quality indicator initiatives

Denmark

The National Indicator Project measures the quality of care provided by hospitals for patients with six common conditions (lung cancer, schizophrenia, heart failure, hip fracture, stroke, and acute surgery for gastrointestinal bleeding). Information is extracted from medical records on severity of illness, treatment, and outcome.[30]

Germany

A national benchmarking system was established in 2001, with explicit criteria relating to over 30 diagnoses and procedures. The data cover about 20% of cases treated in Germany[31] and are published in annual quality reports.

United Kingdom

The performance of general practitioners is assessed with the quality and outcomes framework. This consists of about 140 measures developed through evidence and professional consensus. Most focus on clinical aspects, although organisational and patient focused elements are also present. The measures are combined to produce a "balanced score card."[32]

Peer review

A few countries have implemented peer review systems, such as the Dutch visitatie system (box 3) and clinical audit in the United Kingdom.[17] Local and regional examples elsewhere tend to reflect the presence of enthusiastic individual clinicians, and multidisciplinary audit seems to be relatively rare.

Quality indicators

Only a few countries have adopted quality indicators, and those that exist vary considerably. Notable examples include the systems in place in Denmark, Germany, Spain, and the United Kingdom (box 4). Quality indicator systems have been criticised for focusing on what is easily measured rather than what is important, and for being used in ways that encourage opportunistic behaviour, either by manipulating data or changing behaviour to achieve targets while compromising care.

Who is driving the process?

Except for drugs (where policy has been driven largely by industrial concerns), the EU itself has a limited role in quality of care. 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 doctors are self employed. Quality assurance activities seem to be more common where health professionals work in multidisciplinary teams, presumably because it is easier to organise peer review with colleagues than with competitors when practising singlehandedly.

Professional associations can also have 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. The nature and power of such associations vary considerably. 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 Denmark, the Netherlands, and the United Kingdom (where they have initiated a number of national audits), professional organisations have been active in a range of quality assurance activities.[18 19]

In countries where health care is funded through social insurance, insurance funds have established organisations to provide technical support for including quality in contracts with providers—for example, the National Institute for Sickness and Disability Insurance (RIZIV-INAMI) in Belgium. In Germany, the Federal Office for Quality Assurance (BQS) was established by the corporate actors to support the development and implementation of measures for external

quality assurance in hospitals.

International influences have been important, as exemplified by the adoption of the Joint Commission International's accreditation model. In countries such as Hungary, quality assurance associations arose through participation in collaborative projects funded by the EU, with Dutch teams being especially influential.[20] Approaches also vary within countries, reflecting differences between those where the health system is organised centrally and those where it is decentralised. Thus, the Spanish autonomous regions Catalunya and Andalucia have implemented systems to accredit hospitals, Aragon and Cantabria are applying the EFQM model, and Navarra has developed its own quality management programme.[21] Similarly, there is considerable diversity among Italian regions.

Conclusion

The quality of some of the elements of health care is coordinated at a European level, either by the creation of centralised systems, as with some drugs, or by harmonisation of standards, as with professional education. But other elements, such as the quality of healthcare systems, organisations, and clinical processes, are not coordinated. A few countries show little evidence of any concrete progress; in others, what exists is based on the work of a few individuals, with little impact on the majority of health professionals.

The delivery of health care is a national responsibility—but, in a Europe characterised by free movement, national governments and other stakeholders must take account of the wider European context in health policymaking and planning. Given the enormous diversity of health systems and clinical practices, and the absence of a clear treaty basis for action, Europe-wide legislation to mandate a single approach to quality of care is not a realistic possibility in the near future. Instead, the proposed directive on health services seems likely to leave the details of possible mechanisms to national governments.[22] In the medium term, however, it seems likely that more coordinated mechanisms will emerge, often informally, at a European level to assure the quality and safety of care for European citizens.

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Methods

This paper draws on evidence collected from two major projects funded by the Scientific Support to Policies component of the European Union Sixth Framework Research Programme. Europe for Patients (2004-7) sought to provide evidence that would maximise the benefits that can be achieved from enhanced patient mobility in Europe. It combines in-depth country case studies with crosscutting thematic analyses, including a detailed review of healthcare quality strategies in all 27 EU member states.

The second project is MARQuIS (Methods of Assessing Response to Quality Improvement Policies), which will help to assess the value of different quality strategies, and provide needed information both for countries when contracting for care for patients moving across borders and for individual hospitals when reviewing the design of their quality strategies.

SUMMARY POINTS

Quality of health care across Europe is increasingly important because of growing mobility of professionals and patients

The systems to ensure high quality care in European Union countries vary considerably

European citizens cannot be guaranteed that the care they will receive in another part of the EU is of high quality

Although health care is a responsibility for national governments, the EU has a role in encouraging and supporting progress

Professional associations and organisations of health providers can help bring about change

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