

# Quality and Safety in Healthcare in Europe: A Growing Challenge for Policymakers

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The quality and safety of healthcare are growing areas of concern and policy attention for governments and other stakeholders across the member states of the European Union (EU). In many states the quality and safety of healthcare have been the focus of legislative attention and health system reform in the last decade. At a national level, these reforms have been driven by factors like awareness of the costs and consequences of medical error and iatrogenic disease<sup>1,2</sup>, rising public expectations of service quality<sup>3</sup>, and changing notions of professional and public accountability<sup>4,5</sup>. Interest in quality and safety at a transnational and international level has developed largely because the flow of patients, health professionals, and health services across the border has increased and is likely to grow further. The free market provisions of European law, enforced through a succession of judgements in the European Court of Justice, have made it difficult or even impossible for any one state to control and regulate its healthcare system in isolation<sup>6</sup>.

People in Europe can now go outside their countries of citizenship to use health services with the costs met as if they had been treated at home. Whether as tourists, expatriate workers, retirees, migrants, or to access health services not available in their own country, these patients clearly need the same statutory

and regulatory protection against poor quality healthcare as they would have at home<sup>7</sup>. Furthermore, healthcare professionals can now work freely outside the country where they trained and first registered. The professional regulatory arrangements now have to deal with healthcare professionals with differing training, language skills, and clinical competences and track their performance as they move from country to country<sup>8</sup>.

Outside of the movement of doctors and patients across European borders, healthcare inventions such as pharmaceuticals and medical devices are now, in effect, regulated and approved at a European level, and their licensing is coordinated across all member states through a system of mutual recognition<sup>9</sup>. Additionally, the liberalisation of constraints on service provisions and the opening up of markets is likely to lead to the creation of healthcare provider organizations, especially those in the for-profit sector, who operate across a number of countries – for example running hospitals, primary care services or clinics in several states. There are no current arrangements for the regulation and oversight of such multinational entities. Paradoxically, healthcare remains largely outside the terms of the European treaties on which the European Union is based and is explicitly a responsibility of individual member

states, yet the consequences of the European free market are likely to lead to growing convergence in health policy, funding and provision<sup>10</sup>.

In that context, this paper explores how the member states of the European Union have developed national policies for quality and safety in healthcare, examines what can be learned to date from their experiences in implementing policy at a national level, and discusses the future prospects for the development of quality and safety systems at a European level. We draw on research undertaken for the European Commission, as part of the MARQUIS project, including a focused survey of sixty-eight expert informants across twenty-four of the twenty-five countries of the European Union at the time of the survey in 2005 (since then two states have joined the EU and there are now twenty-seven member nations), which examined their reports on the development, progress and impact of quality improvement in healthcare. More details of the MARQUIS project and its research reports are available from its website at [www.marquis.be](http://www.marquis.be).

First we examine how and why member states have developed quality improvement policies and strategies in their healthcare systems and the nature and content of those policies and strategies. Then we explore the uptake of quality improvement processes and systems in healthcare organizations, including what systems exist, and how their implementation and progress are monitored and evaluated. We try to draw from this some early lessons about the progress of quality improvement in healthcare organizations, the achievements to date, and the important facilitators of or barriers to progress which

have been identified. Finally, we discuss the impact of quality improvement policies and strategies on health services and the quality of healthcare and consider what measures could be taken which would accelerate the progress of quality improvement in healthcare, across all member states, while recognising that the current position of member states varies considerably.

### **Background**

For well over a decade, the need for quality improvement systems and structures in healthcare has been a concern for national policymakers in many European countries, and the importance of international learning and interchange and commonality of interest in this area has been identified<sup>11</sup>. In the last ten years, the World Health Organization (WHO) Regional Office for Europe, the Council of Europe, and the European Commission have all established groups, gathered information, published reports and made some recommendations relating to quality improvement in healthcare. For example, the Council of Europe established an expert committee in 1995 which made recommendations to health ministers<sup>12</sup>. WHO has commissioned or produced a number of reports collating information on quality systems in healthcare and offering guidance or recommendations to national policymakers on how to develop strategies for healthcare quality improvement<sup>13</sup>. The European Commission has undertaken surveys of health ministries in both the longer established member states of the European Union and the more recent accession states<sup>14 15</sup>.

Interest and policy attention in this

area has accelerated in recent years. This rise in interest is largely due to the new challenges created by free movement of healthcare users, services, providers, and institutions. For example, what would happen when a patient from one country was treated in another country and suffered a negligent adverse event – how would they secure compensation or redress, which legal system would deal with the case, which healthcare system would provide remedial or ongoing healthcare? How can a patient from one country be sure that a dentist, doctor, or nurse trained elsewhere in the European Union, perhaps in a member state with a very different healthcare system, will have the same competencies, skills, and knowledge as a professional from their own country? How does a professional regulator like the UK's General Medical Council keep track both of British-registered doctors working across the twenty-seven EU member states and of doctors from all those countries who come to work in the UK, and how do we ensure that professionals who are not fit to practice do not escape oversight by moving from one country to another? These are not abstract issues for policy debate, but real and practical challenges which now face healthcare policymakers and institutions across the European Union.

### **How and Why National Quality Policies and Strategies Have Developed**

In most member states, the last decade has seen the development of a range of initiatives concerned with assuring and improving quality in healthcare. The main impetus for these developments has been national in nature – pressure

from government, the healthcare professions, the media, and the public for example. International factors (such as comparisons with other countries or the activities of international organizations and agencies like the European Commission, the World Health Organization, or the International Society for Quality in Health Care) have been less important. In some countries these initiatives have taken place at a national level. Where the health system is organised at a subnational or regional level, however, (for example in Spain, Italy and the UK), we find there is often some regional variation in those countries in the way quality is evaluated and in quality improvement priorities and resourcing.

Governments – directly or indirectly – have played a central role in the development of healthcare quality improvement. Most countries in the European Union now have some official government policy documents which set out the government's approach to healthcare quality issues, including:

- **Legal Requirement.** In most countries there is some formal, legislative requirement for healthcare organizations to have systems for quality improvement in place. Generally, these legal requirements are relatively recent and were introduced in the last five to ten years, and they often apply to some healthcare providers or parts of the healthcare system but not others (for example, to hospital services and public service providers in particular, but less commonly to non-acute care and to private and for-profit healthcare providers). We find that these legal requirements have been important incentives to support progress in developing qual-

ity improvement.

- **Policy Content.** Again, most member states have produced national government policy documents on this subject, which often establish a framework for developing quality improvement policies, set some quality standards, and provide guidance and some support for implementation. These policy documents have had a significant functional and symbolic purpose – both setting out the direction and detail of policy, and making it clear to key stakeholders that government sees the quality of healthcare as a policy priority.
- **Policy Priorities.** Common government priorities for quality improvement include improving patient safety, securing greater patient involvement, developing quality systems and structures, and putting in place arrangements for evaluating quality systems in healthcare organizations.

There are a number of areas where respondents to our survey suggest governments could do more to support and drive healthcare quality improvement. Suggestions include attaching stronger political leadership and strategic importance to the issue, putting incentives in place for organizations to engage in quality improvement, providing resources for quality improvement systems, and supporting training for health professionals and others in quality improvement.

### **The Uptake of Quality Improvement in Healthcare Organisations in Europe**

It has already been noted that in some countries quality improvement

systems or processes are now mandated, though in large measure the implementation of healthcare quality improvement remains a voluntary undertaking for most healthcare organizations. We find that although there is a clear commitment to quality improvement at the policy level in most member states, there is a considerable gap in turning policies into action at the level of healthcare organizations.

The quality improvement systems most commonly in place in healthcare organizations are those which are historically been a part of the organizational infrastructure of healthcare systems, such as infection control committees, laboratory quality improvement programs, and clinical equipment maintenance programs. In contrast, organizations are less likely to have in place organised programs of quality improvement projects, systems for auditing and following up such projects, and dedicated resources to support quality improvement in the organization. Even in member states where policies for quality improvement are well established, our respondents indicated that many healthcare organizations lack the fundamental components of an effective quality improvement function such as a quality improvement plan, an organised program of quality improvement projects, dedicated resources for quality improvement, and systems for the audit and follow-up of quality improvement projects across departments and services.

There are some systems in place to monitor or evaluate the progress of quality improvement in healthcare organizations, internally and externally. Systems for organizational accreditation, licensing and certification, and

cross-organizational audits or quality improvement projects at a regional or national level provide some information on the progress of quality improvement. But shared access to such information is far from easy or straightforward for stakeholders such as provider associations, healthcare funders, or patient groups. Information about the quality of healthcare is not routinely collected or provided across national boundaries.

### **The Progress of Quality Improvement in Europe to Date. Early Lessons**

The early achievements of quality improvement policies and strategies are described by respondents as mainly occurring at a structural and systems level. Efforts have been concentrated on developing nationally coordinated arrangements for meeting quality standards and for improving patient safety. Important achievements include establishing national policies, legislative requirements, national quality improvement associations, accreditation programs, and other quality improvement infrastructure. Further research is needed to assess the extent to which these reported achievements at the policy level are having an impact on the quality of healthcare at organizational level.

Key factors reported as being important to the progress of quality improvement include strong professional involvement and commitment; the provision of professional training and education in quality improvement; the existence of a legal requirement or mandatory direction to healthcare organizations to undertake quality improvement; and the provision of a necessary infrastructure to support quality im-

provement activities (including staff, resources, leadership arrangements and planning and monitoring systems).

Important barriers to the progress of quality improvement identified by respondents include a lack of funding and support at an organizational level, an absence of clear political, managerial and clinical leadership commitment to quality improvement, the absence of incentives, either for individuals or for organizations, to become involved in quality improvement and to make it a priority, the existence of powerful cultural and professional barriers to quality improvement, and the lack of training and support for clinical professionals in quality improvement.

### **The Impact of Quality Improvement Policies and Strategies in Europe**

Our survey suggests that quality improvement policies and strategies are having a marked though variable impact on the quality of care and patient outcomes in Europe. In particular, the introduction of clinical guidelines, performance indicators, and patient feedback mechanisms is perceived as having the greatest impact on improving services. Accreditation systems, quality management strategies, and patient safety systems are perceived as having slightly less impact on improving services. However, across a host of measures we find significant associations between the existence of quality improvement systems and processes and respondents' ratings of both the progress of quality improvement and of the quality of healthcare.

The views from our respondents suggest that the impact of quality improvement strategies can be generally

enhanced by setting specific goals and targets for organizations, by expanding sources of support and guidance, and by providing access to professional education and training in quality improvement and leadership. Within organizations the right infrastructure seems to be important. The infrastructure requires having a quality improvement plan and dedicated resources, regular reviews of organizational and staff performance, a program of quality projects and an auditing process, good data collection systems, clear lines of responsibility, and well-maintained equipment.

### **Moving Forward: What Would Accelerate Progress?**

The research suggests there are a number of areas in which action could be taken to accelerate the progress of quality improvement policies and strategies in healthcare, and to maximise their impact on the quality of healthcare. Important opportunities include:

- At a system level, providing clear and consistent leadership and strategic planning, which prioritises quality improvement. This can be achieved through strong policy documents and legal and regulatory instruments which set the context in which healthcare organizations operate.
- At an organizational level, setting clear performance targets for organizations and services and putting in place a quality improvement infrastructure, including training and development for clinical professionals, dedicated resources to support improvement, and necessary information systems.
- At a professional level, taking steps to change professional attitudes to

quality improvement and to remove professional barriers which may impede change and improvement – in part through providing effective training programs for healthcare professionals

- At a patient level, increasing opportunities for patient involvement, providing information to patients and the public on the quality of care in forms which they can access and use, and making healthcare organizations and professionals more accountable to patients individually and collectively.

### **Discussion. The Future for Quality and Safety in Europe**

This paper provides a comparative overview of the development of policies and strategies for quality improvement in healthcare across the EU, and the findings may have significant implications for future policy and research.

Policy related to healthcare systems, funding, and provision are primarily determined at a national level in EU member states. This national focus is reflected in the development of policies and strategies related to quality improvement. National level impetuses such as public concern, media interest, and professional associations have been predominantly responsible for governments instituting healthcare reforms. While the experience of other countries has clearly been of some value and influence in shaping reforms in many member states, until the creation of the High Level Group on Health Services and Medical Care<sup>16</sup> there has not been an explicit attempt to link or coordinate policy in this area or to promote cooperation and learning between countries.

International impetuses such as the flow of patients and healthcare services and professionals across national borders and the activities of international agencies or organizations have not been as important as influences in this area to date, though their importance is certainly growing.

Nationally initiated reforms already demonstrate some degree of policy convergence, in that the policies put in place by governments show some immediate similarities. Some similar systems include widespread adoption of legal or statutory requirements for healthcare organizations to put quality improvement systems in place, the development of specific mechanisms such as accreditation programs, and the recent policy priority accorded to patient safety in many member states. But such convergence is unlikely to result in coordinated quality improvement systems or comparable and interchangeable quality standards, unless it is more deliberately encouraged and managed. An important challenge for the European Commission and for member states is the extent to which they wish to speed up convergence or leave it to evolve more slowly. If there is a case for accelerating convergence, there are a range of policy tools and instruments available to the European Commission. It could seek to promote collaboration through funding programs of work, using the "open method" of coordination, or it could use more legislative approaches, such as the creation of an EU directive. The latter course is more likely to bring about accelerated convergence, but is also more likely to meet with resistance from national governments and other interest groups keen to protect subsidiarity and national control over healthcare provi-

sion.

Among the EU member states, the rate of progress in healthcare quality improvement varies considerably. In broad terms, we can identify three groups of countries – the "well established" who have been active in this area at a governmental level for five or more years and have relatively well established quality improvement policies in place; the "recent adopters" who have generally established policies and strategies in the last five years and who are still developing their approaches; and the "slow starters" who may have made some moves in the area of quality improvement but who lack a coherent program of government policy in this area. There is undoubtedly an opportunity for member states from these different groups to work together to transfer learning and to benefit from experience elsewhere. Such actions would probably both promote the overall rate of progress in healthcare quality improvement across the EU, and support the process of convergence referred to above.

It should however be borne in mind that even in countries where quality improvement is "well established", the rate of policy development may exceed the pace of implementation in healthcare organizations. Many healthcare organizations, even in the more advanced member states, still lack fundamental systems and processes for healthcare quality improvement. Our survey suggests that while governmental action to establish policies and strategies for healthcare quality improvement may be necessary, this may not be sufficient in itself to drive implementation throughout the healthcare system.

Finally, our survey provides some limited evidence that quality improve-

ment policies and strategies are having at least a moderate impact on the quality of care and on patient outcomes. It points to some of the actions at a policy and system level which seem to be associated with this progress. While this data must be interpreted with caution, it supports the contention that investing in quality improvement policies and strategies is worthwhile and provides policymakers and other stakeholders with some important indications of “what works”.

### **Conclusions**

The European Commission undertook a consultation on the scope for community action on the future development of health services and health policy in 2006. It outlined the development of proposals and legislation in this area to date, and the rulings of the European Court of Justice (ECJ) in this area, and sought feedback from stakeholders on how the Commission should deal with issues like the nature and volume of cross-border healthcare, areas of legal uncertainty arising from ECJ rulings, areas where European level support might be needed, and what policy instruments should be used by the Commission in this area<sup>17</sup>. Responses to the consultation confirmed that the quality and safety of patient care was a key concern for many stakeholders. Proposals advanced include the development of common guidelines for dealing with issues like patient safety, the creation of European level sets of quality and safety indicators, and the development of common standards and rules for the regulation, inspection, or accreditation of healthcare providers.

Such proposals represent, in some

eyes, a further erosion of member states' primary responsibility for health services within their own jurisdiction and a progressive and unwelcome transfer of power from member states to the EU and to the Commission. This is sensitive and difficult territory, and it was not surprising that when the European Commission's Directorate General for Health and Consumer Affairs brought forward a draft directive on health services in 2007, its publication was first delayed and then shelved amid extensive opposition both within the European Commission, from the European Parliament, and from some member states. It has yet to be published, though the debate continues. However, in the longer term, it seems inevitable that greater convergence in European health systems will result, and that policy in areas like quality and safety will increasingly be shaped at a European level. 🏛️

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