Cross-border healthcare in Europe: clarifying patients’ rights

The adoption of a new directive on cross-border healthcare in the European Union could bring clarity for patients, health professionals, and policy makers, as well as raise the awareness of how healthcare differs between EU member states, say Helena Legido-Quigley and colleagues.

A proposal for a directive on patients’ rights in cross-border healthcare—defined as healthcare provided or prescribed in a member state other than that of affiliation—has been approved by the European Parliament and will be formally adopted by the Council of Health Ministers in February. The Directive on the Application of Patients’ Rights in Cross-Border Healthcare (http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/COM_en.pdf) could provide greater clarity on the rules governing patients travelling abroad to receive treatment. Moreover it could affect individual member states’ national health systems.

We should be concerned about how this issue is addressed. First, European citizens show a growing interest in travelling abroad to receive treatment. A recent survey in all member states found that 53% overall expressed a willingness to establish a clear legal framework within the European Union (EU). This finding was supported by surveys among German patients enrolled with a nationwide health insurance fund. In 2003 only 7% had obtained non-urgent treatment in another EU country, but by 2008 the proportion had increased to 40%. Second, any solution may have implications for how domestic health systems are run. In this paper we describe who is affected by the directive, review its proposals, and discuss its most contentious issues and examine its potential implications for patients, health professionals, and policy makers.

Who is affected by the directive

Mobile patients include temporary visitors abroad, people living in border regions, people sent abroad by their home systems, those seeking treatment on their own initiative, and those retiring to other countries. The directive covers all patients travelling abroad to receive treatment in another member state, except those currently covered by existing social security legislation (such as tourists, pensioners and cross-border workers). This would include, for example, someone seeking a specialist consultation elsewhere in the EU, who would be reimbursed to the amount that it would cost in their home country. Additionally, all patients treated abroad will benefit, directly or indirectly, from the directive’s provision of information on treatment abroad and the establishment of national contact points to provide it.

The content of the proposal and its legislative process

In July 2008 the European Commission first adopted the proposal for a directive on the application of patients rights in cross-border healthcare. It sought to establish a clear legal framework within the European Union by resolving ambiguities about the mechanisms involved in providing such care and establishing systems in which member states can cooperate to resolve outstanding issues.

The right to healthcare in another EU member state was established in 1971, with the regulations updated most recently in 2004 and implemented in May 2010. The scope of the legislation was limited to people in need of treatment while temporarily abroad and those receiving advance authorisation from their own health payer. However, a series of rulings by the European Court of Justice has expanded these provisions, progressively escalating the range of care that can be obtained without seeking advance authorisation—but with the specifics of rulings on individual, and often quite unusual, cases leaving several areas unclear.

The directive is intended to resolve these issues, providing clarity for patients, healthcare professionals, and policy makers.

The directive applies to all healthcare provision that patients are entitled to at home, regardless of how it is organised, financed, and delivered. It gives EU citizens the right to obtain from abroad any care not requiring a hospital stay without advance authorisation. However, where inpatient care or certain specialised investigations are involved, member states may create a system of prior authorisation to enable them to manage patient flows and avoid threats to the financial and operational sustainability of their health systems. In both cases, patients will only be entitled to reimbursement under this directive up to what would have been paid for if the care was provided at home. National contact points will be established to provide patients with information on rights and procedures. The directive also makes provision for mutual recognition of prescriptions written abroad and establishes a system of European Reference Networks for highly specialised care, as well as enhanced cooperation on e-health and on health technology assessment.

The progress of this directive has been arduous (see box 3 on bmj.com for timeline). European legislation is proposed by the European Commission for agreement by the Council of Ministers (representing national governments) and the European Parliament. After an extensive consultation process, the commission’s Directorate General for health and consumers finally published its proposals on 2 July 2008. A compromise between the Parliament and the Council was reached in December 2010.

Challenges to ensuring quality and safety, benefits, and information needs

We focus on three issues that have proved most challenging in creating a legal framework for cross-border care: quality, benefits, and information needs.
Assuring quality and safety

The directive reaffirms that member states retain responsibility for providing safe and high quality care on their territory and that cross border healthcare should be provided according to their own standards of quality and safety. This requires, first, that effective mechanisms for quality of care exist in each country. At a system level these include mechanisms to ensure the quality of drugs (registration and licensing), technologies including devices and medical procedures (health technology assessment), and the workforce (training and continuing education of health professionals). At a clinical level they include the creation and implementation of practice guidelines, monitoring systems, and quality assurance systems. Second, member states will have to address issues that are specific to cross-border care, in particular where follow-up visits are needed. At present, approaches to healthcare quality and patient safety vary widely in their nature, scope, and coverage and the existing Europe-wide initiatives are largely driven by voluntary professional groupings. 

Benefits

Even though health professionals in different countries read the same medical literature, management of similar conditions still varies considerably between (and even within) countries. These variations are apparent in the mix of staff involved (such as whether a task is performed by a doctor or a nurse), the extent of investigation, and the mode and setting of treatment. This creates considerable scope for confusion when a payer is asked to reimburse a package of care that may be quite different from what they expected—if the greatly varying classifications used even allow for such a comparison. For example, someone with an acute stroke may be treated much more aggressively in one country than in another.

Information needs

One of the most important provisions of the directive is the supply of good information for cross-border patients on the care they receive—information that will benefit not only those who seek healthcare abroad but also those who choose to remain in their own country. The national contact points will have to provide information on healthcare providers, including assessment, registration status, and restrictions on practice, patients’ rights, procedures for reimbursement, and complaint and redress mechanisms. Each healthcare provider must supply patients with information on availability, quality, and safety of care, clear invoices, and information on prices. This process will ultimately increase the transparency of healthcare systems and is likely to stimulate the improvement of care. However, it will pose many challenges, especially in decentralised health systems—including the reorganised NHS, where it will create substantial additional responsibilities for the proposed general practice commissioning consortiums. Another important aspect relates to communication between providers. This is addressed through provisions on e-health and by giving patients the right to access their medical record in both their home state and where they receive treatment.

Controversial issues

The most controversial issue, ever since healthcare was first discussed at European level, has been the principle of subsidiarity. Proposals have been judged by politicians in terms of the extent to which they interfered with the right of member states to organise and deliver their own system of healthcare, as set out in article 168 of the Lisbon Treaty. In part this reflects the origins of the legislation in policies on advancing the internal market rather than improving health. From an internal market perspective, healthcare is a service like any other and Europe’s citizens should be able to use it as they wish, subject to the constraints of national systems.
able to obtain it freely from anywhere within the EU. National governments, concerned about costs of treatment abroad and the sustainability of their domestic health systems, have taken a different view. They have also been concerned about exacerbating inequalities, because the proposal is likely to disproportionately benefit wealthy and well informed patients.

The most controversial issues during the negotiations between the council and parliament have been: prior authorisation, prepayment, treatment of rare diseases, the definition of quality and safety standards, and e-health.

Governments, through the Council of Ministers, have sought to develop criteria that increase their scope to refuse prior authorisation. For example, although they have tried to limit the scope of the commission to gather information on quality of care in other countries, they have also argued that concerns about the quality of care elsewhere should be grounds for refusal. The parliament and the commission, on the other hand, have argued that the council’s proposed criteria, which were non-exhaustive, were so vague as to increase legal uncertainty. Although the parliament was, in principle, against any prior authorisation, it accepted it as long as the criteria for refusal are objective and limited.

The European Parliament also differed from the council on payment, proposing that the home country should have paid in advance rather than to another member state for treatment and that concerns about the quality and safety of care provided to another member state for treatment and that expected to receive reimbursement for the cost of treatment because of “undue delay” at home, defined by their clinical condition rather than potentially arbitrary targets, may travel to another member state for treatment and expect to receive reimbursement for the cost of treatment. These areas could prove difficult for member states to administer, although the ease of accessing it, the volume of cross-border care in Europe will increase, not least due to growing body of case law for which applicability to a particular case is often uncertain. It will also extend the opportunities to obtain care abroad, although the extent to which it succeeds will only become clear once experience has been gathered of how the directive works in practice. European reference networks will be of particular interest to patients with rare diseases, offering them access to specialised care that might not have been possible otherwise, although the ease of accessing it remains uncertain.

Remaining controversies
Most problems have been resolved during the negotiations, but certain areas are likely to remain unresolved. First, some issues have been left out of the current version of the directive\textsuperscript{19} such as e-health services and standards of quality, which will not be addressed at EU level. Measures on these and issues such as rare diseases will be left to cooperation among member states, with the directive simply pointing to the possibilities offered by regulation (EC) no 883/2004 for referral of patients for diagnosis and treatments which are not available in the home member state.\textsuperscript{31}

Other areas could generate confusion when implemented—for example, the process of prior authorisation; the mechanisms for calculating costs of cross-border healthcare for each member state; and what is included in the reimbursement of a treatment. These areas could prove difficult for member states from an administrative point of view (particularly establishing the cost of treatment). Moreover some of the concepts included in the directive (such as what is a medically justifiable time limit) could be difficult to define in practice and thus give rise to different interpretations. Ultimately, the directive could introduce inequalities if there are differences in how member states decide to reimburse the costs of cross-border healthcare, with some only providing the minimum requested and others deciding to reimburse related costs, such as accommodation, travel costs, or extra costs incurred by people with disabilities.

What does the directive mean for patients, health professionals and policy makers? The benefits for patients
The volume of cross-border care in Europe will probably continue to increase, not least due to greater awareness among patients and those advising them. The current situation is far from satisfactory and a framework that brings greater clarity to an often confusing situation is clearly welcomed. In particular, the directive codifies and clarifies a growing body of case law for which applicability to a particular case is often uncertain. It will also extend the opportunities to obtain care abroad, although the extent to which it succeeds will only become clear once experience has been gathered of how the directive works in practice. European reference networks will be of particular interest to patients with rare diseases, offering them access to specialised care that might not have been possible otherwise, although the ease of accessing it remains uncertain.

Implications for policy makers
Policy makers will also benefit from the greater certainty about legal and financial aspects of cross-border care.\textsuperscript{31} The directive will offer them new options to address common problems such as waiting lists, underused facilities, and the ability to manage rare diseases. It should lead to improved mechanisms for sharing data, improving quality of care, greater compatibility of patient records, and the ability to prescribe across borders.\textsuperscript{21 35}

Implications for healthcare providers and professionals
Healthcare providers will need to understand much better the diversity of treatment pathways that exist in Europe for common conditions, as well as becoming familiar with regulations, enti-
tlements, and mechanisms for redress and compensation. The directive will provide a solid legal basis for greater co-operation across borders (including e-health solutions), which will be of particular value in sparsely populated areas.

**Conclusion**

That the organisation of cross-border care in Europe creates many problems has long been agreed, but achieving a solution has been difficult. Whether the directive offers such a solution remains to be seen. A tension persists between the Council of Ministers, which tends to see itself as a guardian of national health systems, and the European Parliament, which tends to see itself as the voice of Europe’s citizens (and potential patients), although many different views are held within both. The directive was approved in the European Parliament by an overwhelming majority on 19 January. The council will adopt it formally in February and the legislation will enter into force by the spring. Member states will have 30 months to transpose it into national law, so it should therefore become fully effective by 2013. This directive will at least bring a degree of clarity to this often confusing landscape but its success or failure will only become apparent once it is clear how it has been implemented.

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