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Analysis Health Systems Perspectives

Cross-border healthcare in the European Union: clarifying patients' rights

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

This paper is part of an occasional series prepared in conjunction with the European Observatory on Health Systems and Policies (www.healthobservatory.eu)

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—is currently being discussed by the European Parliament and the Council of Health Ministers.¹ 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 resolved. First, European citizens show a growing interest in travelling abroad to receive treatment.^{2 3} A recent survey in all member states found that 53% overall expressed a willingness to seek treatment in another country of the European Union (EU).² 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%.² 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 the current

proposals,¹ and review the process that has given rise to the draft directive. We 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 countries⁴ (box 1). The proposal 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).⁵ 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.

Box 1 Types of patients moving within Europe⁴

Temporary visitors abroad

Travellers abroad who fall ill in another member state are entitled to medical treatment in the country they are visiting on presentation of a European Health Insurance Card (which replaced the E111 form). An example is the large seasonal influx of tourists to the Veneto region (Italy), where the local health authority had to create special health services to cater for the tourist season.⁶

People retiring to other countries

Many older people from northern Europe retire to southern Europe. They include many British pensioners retiring to Spain who register with the Spanish system and are then treated the same way as Spanish citizens (using the E121 form).⁷

People in border regions

Most cross-border healthcare takes place in border regions where collaborations have served to rationalise services, as many borders traverse sparsely populated areas, dividing communities that share common languages and cultures. One of the oldest collaborations in Europe is that in the Euregio Meuse-Rhine region, dating from 1976, where three countries (Holland, Germany, and Belgium), with three national legal systems and four different cultures, collaborate in more than 15 cross-border healthcare projects.⁸

People sent abroad by their home systems

In some cases purchasers establish procedures to allow patients to go abroad for healthcare. This normally happens to respond to waiting lists, overcome a shortage of domestic provision, or to obtain highly specialised services, particularly in smaller member states where the populations are insufficient to justify local provision. For example, a bilateral agreement between Malta and the UK allows Maltese patients to obtain specialised hospital treatment in London.⁹

People going abroad on their own initiative

These people typically travel abroad to receive healthcare that is cheaper (such as spas, cosmetic surgery, and dental treatment), faster, or considered to be of better quality than in their home country. Patients may also seek interventions that are prohibited at home, such as abortions or fertility treatment, with the term “fertility tourism” coined to describe travelling to countries where donor anonymity is guaranteed for sperm and egg donations.¹⁰

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 health care.¹¹ 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 co-operate to resolve outstanding issues.

The right to healthcare in another EU member state was established in 1971,¹² with the regulations updated most recently in 2004⁵ and implemented in May 2010.¹³ 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.⁶ However, a series of rulings by the European Court of Justice^{14 15 16 17 18 19} 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 (box 2). The directive is intended to resolve these issues, providing clarity for patients, healthcare professionals, and policy makers.

Box 2 Examples of the role of European Court rulings

Kohll and Decker (1998)¹⁴—Two citizens from Luxemburg, Mr Kohll and Mr Decker, requested reimbursement for orthodontic treatment and the purchase of spectacles acquired in Germany and Belgium, respectively. The European Court considered that Luxemburg's statutory health insurance rules had created an impediment to the free movement of goods and services and established that individuals could obtain certain goods and medical services provided outside hospital and be reimbursed by their health funder without prior authorisation.²⁰

The Watts Case (2006)¹⁸—In 2002, Yvonne Watts, a 72 year old living in the UK, was diagnosed with osteoarthritis. Facing a one year wait for hip replacement at her local NHS hospital, and being refused treatment abroad, she decided, on her own initiative, to seek treatment in France.¹⁰ The European Court confirmed that patients facing “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 because of “undue delay”.¹⁸

European Commission versus French Republic (2010)¹⁹— French insurers required anyone going abroad for diagnosis or treatment that needed “major medical equipment” to seek prior authorisation if they were to be reimbursed. The European Court confirmed that prior authorisation was justified given the risk to the health system in terms of cost and distribution of major capital investments. ²¹

The proposed 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 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 co-operation on e-health and on health technology assessment.¹¹

The progress of this directive has been arduous (box 3). 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. At the time of writing it seems that a compromise will be reached, so that a final text can be adopted by the European Parliament on 19 January 2011 and by the Council of Ministers in February 2011.

Box 3 Timing of the legislative process

1971-1972: Council regulations 1408/71 and 574/72 on the coordination of social security systems

1998-2010: European Court of Justice cases on patient mobility^{14 15 16 17 18 19}

2003: High level process of reflection on patient mobility and healthcare developments in the EU²²

2004: High level group on health services and medical care²³

2006: Removal of health services from the directive on services in the internal market

2006: Council conclusions on common values and principles in EU health systems²⁴

2006-07: Public consultation on community action on health services

2008: European Commission proposal for a directive on the application of patients' rights in cross-border healthcare¹¹

2009: European Parliament's first reading²⁵

May 2010: Implementation of the revised social security coordination framework (EC regulation 883/2004¹² and regulation 987/2009)

June 2010: Council of EU ministers reach a common position²⁶

Nov 2010: European Parliament's report, second reading²⁷

Dec 2010: Informal trilogue negotiations to reach a final joint text

Jan 2011: European Parliament plenary sitting, second reading

Challenges to ensuring quality and safety, efficiency, 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.^{9 28} 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.²⁹ 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.³⁰

Information needs

One of the most important provisions of the proposed 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.²¹ 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 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 by a referring doctor 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 citizens having to pay upfront. One potential mechanism, rejected by the council, was the creation of a voucher system. Instead it was agreed that member states must at least ensure that patients are reimbursed as rapidly as possible unless they can opt for alternative mechanisms that already exist under social security legislation (regulation (EC) no 883/2004). Another point of disagreement related to Europeans affected by rare diseases, which some estimates suggest may apply to as many as 25 million individuals.³¹ The parliament argued that affected patients should have been entitled unconditionally to obtain healthcare abroad (including medicines) without any form of previous authorisation and be reimbursed even if the treatment in question was not among the benefits of their home system—a view contested by the council.

The commission and the parliament wanted to impose on member states the obligation to define clear quality and safety standards. The council opposed this, proposing as a compromise provisions to encourage member states to do so, including the possibility of refusing prior authorisation in cases of serious and concrete concerns about the quality of care in another member state.

Finally, on e-health, the council has challenged provisions that would allow the commission to promote interoperability, an action not well received by either the commission or parliament.

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 directive¹ 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.³²

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 needed. In particular, the proposed directive intends to codify and clarify 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 a final agreement is reached between the Council of Ministers and the parliament, and following experience 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.^{33 34} 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.^{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, entitlements, and mechanisms for redress and compensation.³³ 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 a solution has been difficult to achieve. 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. If agreement on the directive is reached this month it will at least bring a degree of clarity to this often confusing landscape. If not, the parties concerned will have to discuss it further, because the issues will not go away.

Notes

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Footnotes

- Contributors: HL-Q, IP, CK, and MM drafted the article. All authors revised subsequent drafts. MM is guarantor. All authors have worked in EU funded projects on patient mobility and cross-border healthcare and have published extensively on this subject. This article arose from discussions with EU decision makers, including participation in workshops and other meetings on this topic. HL-Q, MM, MW, and WP contributed to the commission's impact assessment of an earlier draft of the directive. The main sources of information were the official documents of the European Institutions.
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