Royal College of Physicians
Setting higher medical standards

COMMUNICATION FROM THE EUROPEAN COMMISSION

Consultation regarding Community action on health services

Response from the Royal College of Physicians, London (RCP)[1]

1) What is the current impact of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

In absolute terms, the number of people whose care is paid for in another European country is still very low. It has been estimated that public expenditure on cross-border care represents at most 1% of total expenditure. An unknown number also pays for their own care or obtains care that is later reimbursed from travel insurance policies, although again the total numbers are likely to be low in relation to the overall volume of healthcare delivered in Europe. Yet these considerations underestimate its importance. Patient flows are extremely unevenly distributed so that in some places, in some circumstances, and for some people, the implications can be considerable. Here we consider five broad categories of patient mobility.

Temporary visitors abroad

The growth of budget airlines, combined with rising incomes has fuelled an explosion in tourism within Europe. Year-round travel abroad is now a reality for many people whose parents might never have left their own country. The E111 scheme (now superseded by the European Health Insurance Card (EHIC)) should provide access to care in the event of an emergency, including when this is an exacerbation of pre-existing illness. Yet problems remain. Firstly, despite an extensive advertising campaign, we understand that patients and the public at large in the UK are still generally unaware that the E111 has been replaced by the EHIC and the fact that it entitles access to non-urgent treatment of existing conditions is also not common knowledge. Secondly, some parts of Europe experience enormous seasonal influxes of tourists, potentially increasing the local population several times over. Although most tourists are healthy, there are high levels of some problems, such as those associated with alcohol. These can easily swamp the local delivery system. Furthermore, in some areas, it can be difficult for tourists to access providers that will accept the EHIC and, worse, there are some well-established networks of taxi-drivers and guides who divert tourists to private facilities in return for gratuities. Tourism within Europe can be expected to continue on its upward trend for the foreseeable future. ▷

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Long-term residents retiring to other countries

There is a long tradition of people retiring to other countries within Europe, although this often involved people returning to the country of their birth, as with Irish people who had spent their working life in England. The numbers involved, and the destinations being chosen, are now very different, as many people from northern Europe retire to southern Europe, in particular to Spain, Portugal, Italy and Greece, although also to countries in the process of accession to the European Union, such as Croatia and Bulgaria.

Traditionally, social care for elderly people in southern Europe has been undertaken by families but these new residents will usually have left their family networks behind. The situation becomes more complicated when one partner dies, especially if this is the one who drove the car and spoke the local language. Returning home to receive care is not straightforward as most will have transferred their entitlement to their new country of residence and so will require authorisation from their local health payer.

There is, in addition, a 'floating population' of 'false tourists' who live in another country for more than three months of the year, but without regularising their situation as they are required to do. The bureaucracy involved in transferring their entitlements back and forward can be extremely daunting.

This category of patient mobility can be expected to increase considerably as Europe's population ages. This development poses considerable challenges, in terms of accessibility and financial sustainability, in many of the affected regions. There is a clear need to simplify the procedures that such individuals must undertake as, at present, they can pose obstacles to accessing timely and effective care.

People in border regions

Europe's borders often traverse sparsely populated areas, dividing communities that share common languages and cultures. In some cases, borders divide towns and villages. The principle of territoriality has often led to a duplication of healthcare facilities in these areas but there are now increasing examples in which people living on either side of a border can access care in each others' countries with, in some cases, health facilities shared across borders. Such initiatives can enhance access and quality of care for people in sparsely populated border areas. Invariably there are practical problems to overcome, ranging from the incompatibility of sirens on emergency vehicles to different payment mechanisms. Much can, however, be learned from successful experiences such as those of the Euregio Meuse-Rhine.

People sent abroad by their home systems

We have identified two situations in which purchasers establish procedures to allow patients to go abroad for treatments that are not easily available at home. One is where authorities offer treatment abroad to overcome a shortage of domestic provision, sometimes coupled with guarantees that patients waiting more than a specified period in the public system can demand treatment by domestic private providers or providers abroad. An example is Norway's Medical Treatment Abroad Project. Typically, these projects include large volumes of patients but are limited in time as health authorities try to build domestic capacity. In some cases, this approach is intended primarily as a means of challenging what are seen as unresponsive domestic providers. These are typically attended by much publicity but involve few patients. They are exemplified by the English Department of Health's short-lived projects that sent patients to Belgium, France and Germany. The second situation arises where a small country, such as Malta or Cyprus, makes an explicit decision not to offer highly specialised services because its population is insufficient to justify them.

Surveys indicate that most patients involved in such schemes are positive about them, although a frequent concern relates to post-operative management, with patients often unsure about their ability to manage with the level of support available. There are also many normally minor, administrative problems. A consistent finding is that success is linked to active involvement by all stakeholders, in particular referring physicians. Where it is used as a threat to domestic providers, health professionals have been unwilling to co-operate, with

adverse consequences for continuity of care. In general, however, such schemes offer benefits to both patients and health systems, increasing access and quality while not undermining financial sustainability.

However, there are potential implications concerning equity which need to be borne in mind with greater awareness of the entitlement to treatment funded by the NHS in the UK but delivered in other Member States. Patients lower down a UK waiting list, as defined by clinical need, may be able overtake other patients depending on their willingness to be treated outside the UK. Moreover, under current UK rules, the restrictions on obtaining care within the UK in regions where there maybe shorter waiting times contrasts with rights to EU treatment where there is 'undue delay' at home. This is clearly an issue for the NHS in the four parts of the UK to address rather than the EU, but we feel it is important to flag it up at this stage.

People who go abroad on their own initiative

Despite their prominence in cases brought before the European Court of Justice, patients travelling abroad specifically to obtain treatment are relatively few and, in most cases, the treatments are on the margins of what is funded by their healthcare system. Examples include stays at spas, cosmetic surgery and dental treatment. While it is important to take account of such patients, they create few issues in terms of quality, accessibility, or financial sustainability and it is important that the issues arising in relation to this small group of patients does not dominate the agenda at the expense of the other categories of patient mobility.

2) What specific legal clarification and what practical information is required by whom to enable safe high quality and efficient cross-border healthcare?

The College has identified five major areas requiring clarification:

- The NHS in the UK, as with health systems in some other Member States, views its system of referral and gatekeeping as important in ensuring that patients can make informed decisions about the care they receive, an issue of growing importance as health professionals in primary care assume greater responsibility for helping patients with complex and often multiple disorders to navigate the health system. While respecting the right of other Member States to employ direct access to specialists, we believe that this encourages waste and duplication, without achieving health gain. We contend that mechanisms should be established that will not undermine gatekeeping systems in countries that use them.
- At present there are two mechanisms by which care abroad can be paid for, Regulation 1408/71 and that established in the Kohll/Decker cases. Which applies in which circumstance must be resolved. The College understands the competing arguments for these two approaches. If a patient is not reimbursed in full, then it could be viewed as a barrier to patient mobility. If a patient is reimbursed in full and goes to a more expensive system, this will have adverse consequences for the home system. We believe that the current system is largely satisfactory but does require some clarification. In other words, patients temporarily abroad when they become ill, or experience an exacerbation of their condition, should be funded on the basis of 1408/71. This should also apply where their payer sends them abroad because of an explicit decision not to provide certain care at home, as is the case with the smaller Member States. The problem arises where patients demand the right to travel abroad because of undue delay. Here, however, we believe that the appropriate solution may necessitate a clearer understanding of the concept of 'undue delay' rather than a change to the funding system. From the patient's points of view in particular, 'undue delay' remains a grey area. We believe that it is not realistic to establish a EU wide definition that would be workable. Instead we propose that Member States should be required to establish a robust mechanism whereby the concept of 'undue delay' could be operationalised in the context of their own circumstances. There will inevitably be differences between Member States, which can then be

the legitimate subject of debate, but given the rapidly changing nature of healthcare, as well as the different health system contexts, we see no realistic alternative.

- The College believes that there are a number of issues related to patient safety that require clarification. These are discussed below.
- The College is concerned about the mechanisms to ensure that patients are adequately informed about the options open to them in relation to mobility options.
- Systems of capital financing vary among Member States. In some countries, major capital investments are funded by grants from national governments so that they are excluded from charges for care. In others, healthcare providers must recoup the cost of capital. As a consequence, the cost of care varies substantially, even when other inputs are similar. If healthcare was considered a service, this could be considered a form of unlawful state subsidy. As healthcare is not (in most cases) a service under the Treaty this does not apply but it does introduce serious distortions into the market that need to be resolved.

3) Which issues (eg clinical oversight, financial responsibility) should be the responsibility of which country? Are these different for the different kinds of cross-border healthcare?

This is a second order question, the answer to which will depend on decisions in many of the areas discussed in the consultation. However, two broad distinctions can be made in the type of cross-border healthcare and the responsibilities that may flow from them. Firstly, where healthcare abroad is organised by a UK commissioning body then the body, acting as an agent for the patient, should be responsible for issues such as those above and for informing the patient accordingly. Secondly, where a patient arranges independently for treatment in another Member State then the principle of 'caveat emptor' should normally apply, perhaps by extending the notion of consent to treatment to include awareness of the consequences of care in areas such as legal redress etc.

4a) Who should be responsible for ensuring safety in the case of cross-border healthcare?

The relevant principle, enshrined in many aspects of Community law, is that of mutual recognition. It is assumed that national authorities will put in place systems that will ensure that the care provided by health professionals and in health facilities established on their territory comply with standards that allow patients to be reassured that they will be treated safely. There is one exception, where on grounds of economies of scale, a Europe-wide system of quality assurance has been established. This is the EMEA system of authorising pharmaceuticals. It is, of course, complementary to national schemes. It is difficult to envisage how a system of ensuring the quality of care in health facilities or by health professionals across the EU might operate at European Union level. Similarly, it is difficult to envisage how, in practice, authorities in one Member State could undertake inspections in other ones, with the exception of certain trans-frontier projects where there are substantial patient flows, thus justifying the investment in common procedures.

The crucial question is whether each Member State does indeed have a system for ensuring that the quality of care, and thus the safety of patients, is assured in its healthcare provision. The College believes that adequate systems are not in place in all Member States. There are no agreed European minimum standards in relation to many aspects of healthcare delivery. Where they do exist, as in the case of professional regulation, they are extremely basic and provide no meaningful reassurance that an individual has obtained the requisite experience or is up to date with current knowledge and the current lack of requirement for language skills poses potential dangers for patient safety. One difficulty is that medical knowledge is rapidly evolving and

systems must have sufficient flexibility to adapt to this changing situation. The College believes that professional associations could play an important role in the development of shared standards of care that would enhance patient safety, building on a number of successful experiences by individual specialities.

A second difficulty is that the systems of professional and facility regulation vary widely among Member States and it will be impossible to impose a single model. Instead, the College believes that the professional associations working with regulatory authorities, governments, and payers, could engage in discussions that would establish the principles that each system would apply, adapting them to its individual circumstances.

4b) If patients suffer harm, how should redress for patients be ensured?

This is an extremely complex issue so, in an attempt to simplify it, we assume a situation in which a patient travels abroad to receive care, which leads to a claim for compensation due to alleged medical malpractice. It is assumed that the patient has returned to his/her home country. It is impossible to consider in detail all the possible permutations of national law in relation to tort, so general principles of cross-border contract law will be considered.

A patient travelling abroad enters into a contract with a foreign provider, giving rise to reciprocal and interdependent obligations between the two parties. The question then arises as to which law the contract is under the jurisdiction of. Clearly, a case heard in the territory where the provider is established could give an advantage to the provider while one heard in the territory in which the patient lives could give the advantage to him or her.

The decision is regulated by the 1980 Rome Convention, to which all EU Member States adhere, and which establishes that the law to be applied will address, among other things, "the consequences of breach, including the assessment of damages" of the contract.

Article 3 of the Rome Convention establishes the principle of 'party autonomy', allowing the parties the freedom to choose which law is to be used to consider their contract. Where the parties are unable to agree, a situation that may not be uncommon in these circumstances, Article 4(1) states that the contract shall be governed by the law of the country with which it is most closely connected. Article 4(2) clarifies this point by stating that this shall be the country where 'the party who is to effect the performance which is characteristic of the contract [...][has his] principal place of business'. Thus, where the parties fail to agree otherwise, any legal action will be before the courts of the country in which the healthcare provider is established. Although the Rome Convention does include some provisions that enable consumers who have obtained a service from another country to seek redress in their home country, this does not apply where they have travelled abroad to receive the service.

While Directive 2005/36/EC provides for the exchange of information between professional regulatory authorities in relation to malpractice, the principles set out in the Rome Convention have the additional advantage that there is likely to be a better-established system of communication between the legal and professional regulatory systems in the same country, so facilitating any action beyond that of awarding compensation. The College believes that a departure from these general principles of contract law would not be justifiable in the case of claims for compensation for medical error.

As well as clarifying legal aspects, the College believes that the European Commission should promote the availability of practical assistance to patients seeking legal redress in terms of requiring each Member State to establish and publicise information points in each Member States, with signposting to relevant national bodies and organisations.

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5) What action is needed to ensure that treating patients from other Member States is compatible with the provision of balanced medical and hospital services accessible to all?

This is a complex issue although at present the level of patients flows in and out of the UK are not large enough to have significant financial implications. However, should that change, as a result for example of future EU enlargement, it will almost certainly require specific legislation permitting health authorities to take actions that balance the right to free movement with the assurance of sustainability of services. In certain circumstances, there may be scope for targeted use of EU structural funds to support the provision of a balanced infrastructure.

6) Are there further issues to be addressed in the specific context of health services regarding movement of health professionals or the establishment of healthcare providers not already addressed by Community legislation?

The consultation document raises the question of clarity in relation to ethical issues. Some Member States take very different views on some difficult subjects in areas like assisted reproduction and abortion. The College accepts that these decisions reflect national values and believes that they are rightly an issue for individual Member States.

One issue that has sometimes proven difficult is the nationality of children born in a shared obstetric unit where this is across the border from where the parents live. The authorities in France and Spain have overcome this in the case of their shared hospital by allowing such children to have joint citizenship but this has proved an obstacle to development of shared facilities in the divided town of Valka (Latvia)/Valga (Estonia).

7) Are there other areas where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States suggest in order to facilitate cross-border healthcare?

One specific issue identified in UK discussions is the impact that inward patient flows might have on the private treatment of UK based patients. If Foundation Trusts continue to form the basis of secondary care provision, a substantial increase in patients from other EU Member States may require an increase in, or removal of, the statutory cap on the number of private patients that can be treated. Otherwise, EU patients will either not receive treatment or at the expense of UK citizens seeking private healthcare.

8) In what ways should European action help support the health systems of Member States and the different actors within them? Are there areas not identified above?

One of the most important areas where European action is needed is in the production of information. Activity statistics from providers, such as those supplied by national authorities to OECD and reproduced by WHO, are well recognised to be deeply flawed, not least because, in increasingly pluralistic systems, they fail to capture the full range of providers. The solution identified in the USA, where the problem is even greater, is to conduct regular population-based surveys of the experience of the public in their interactions with health services. Examples include the National Hospital Ambulatory Medical Care Survey in the US and the National Patient Survey Programme in England, which is overseen by the Healthcare Commission. Although the Eurobarometer series does, from time to time, include questions on health services, the samples are far too small for meaningful analysis.

The College supports the proposal to establish networks of centres of excellence. These could build on a number of informal arrangements that already exist in relation to rare diseases. It will, however, be important to ensure that adequate funding is provided to ensure that such networks can operate effectively. Here there are many lessons that can be learned from the imperfect, fragmented, and uncertain systems of supporting the many very successful networks that have been established with EU support in the area of communicable disease control.

The College also agrees that it is important to have evidence that can support policy and notes that the rich diversity of health and health policy within Europe offers many opportunities for shared learning. We are, however, puzzled by the suggestion concerning an observatory, given that a successful one already exists, bringing together universities, international agencies, and governments of Member States, and with which the Commission already works closely. The College considers that there is no case for establishing a parallel institution but rather that it should continue to work with and support the existing European Observatory on Health Systems and Policies.

The College strongly supports the Commission's intention to develop a sound methodology to undertake health systems impact assessment. Had such methods been established previously, some of the current problems might possibly have been avoided.

9) What tools would be appropriate to tackle the different issues related to health services at EU level? Which issues should be addressed through Community action and which through non-legislative means?

A package that comprises both legally binding measures and incentives could be envisaged to address the various issues. Firstly, a primary legislative framework will be required as a basis for progress and to help guide the European Court of Justice in future rulings. However, the College believes that a great deal can be achieved through 'softer' less formal measures such as the open method of co-ordination and by the provision of support for networks that can agree common procedures and standards.

The lessons of successful regional cooperation in healthcare, in border regions such as Rhine Meuse, demonstrate the value of encouraging local initiatives alongside EU level actions. Existing regional programmes and initiatives, including the structural funds, should be better harnessed for healthcare.

As mentioned earlier, information provision is of crucial importance. The College believes that the European Commission's Patient Information initiative, led by DG Enterprise, should be extended to cover health service issues alongside the current focus on medicinal products.

As well as specific measures such as those mentioned above, a broader statement of principles is required to reconcile internal market principles such as free movement with wider health and social objectives. The College believes that the 'common values and principles' of solidarity, access, equity and universality agreed by the Council of Ministers in June 2006 should be enshrined in any future legal framework to guide action on health services.