Consultation of the Commission regarding Community action on health services

HOPE answers
Final version

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HOPE is the acronym of the *European Hospital and Healthcare Federation*, an international non-profit organisation, created in 1966. HOPE includes national associations of public and private hospital and where those do not exist, owners of hospitals. Today HOPE is made up of organisations coming from 26 Member States of the European Union and Switzerland as observer member.

The main mission of HOPE is: "to promote improvements in the health of citizens throughout the countries of the European Union and a uniformly high standard of hospital care throughout the EU and to foster efficiency, effectiveness and humanity in the organization and operation of hospital services and of the health systems within which they function."[1]

For this reason and following a long tradition of EU interest, the consultation has then been widely debated within HOPE. Most of its members have also organised their own consultations internally and even some provided their own answers directly to the Commission.

HOPE answers and comments are then based on this diversity of perspectives. They were at the same time nourished by various reports, surveys seminar and conferences organised directly by HOPE or in collaboration. HOPE has indeed been involved in recent years in EU-co-financed projects dealing with one aspect or another of the issues covered by the consultation: Marquis, Euregio, Europhamili, Manahealth, Health Basket, Health Access and Europe4Patients, etc.

Cross-border and HOPE

Patients as well as professional mobility have for a long time been at the core of HOPE activities. This interest is embedded in its principles and is visible in its various activities. One of HOPE objectives is to promote exchange, twinning programmes and training within the EU and elsewhere in the world. HOPE is for example: running since 1982 a yearly exchange programme for hospital professionals involved in management; organising other professional exchanges; supporting various hospital topic-oriented networks and recently created hubs involving individual hospitals.

[1] Constitution, HOPE, the European Hospital and Healthcare Federation, AISBL, June 2005

More specifically, since the late 90s, HOPE has also been working on healthcare cooperation in border regions, looking not at the "market" side but at the co-operative aspects: identifying obstacles, ways to overcome them, exchanging best practices, etc. This was related also to other HOPE studies, such as on organ donation and transplantation, on organization of emergency care, on disaster medicine, on quality, etc. In all cases, the idea was to tackle similar issues linked with a common EU perspective but from different angles.

Cross-border definition

Defining cross border healthcare as it is done in the consultation ("cross-border provision of services, use of services abroad, permanent presence of a service provider, temporary presence of persons/professionals") is certainly an interesting way of presenting the picture. It should however be completed: first to capture important aspects from a hospital and healthcare services perspective; then to cover all aspects related to it.

For example, cross-border provision of services (exemplified by the use of telemedicine services, remote diagnosis and prescription, laboratory services) can be the result of cooperation and be part of a complementarity strategy, of an efficient use of resources by collaboration of partners. On the opposite it can be simple act of purchasing, and even a way to bypass national or regional planning leading simply to over-consumption. Concerning the permanent presence of a provider there is a major difference whether this provider is working with public/collective funding or not. Temporary presence of professionals has a different meaning if the professional is salaried or not.

Parts of the issue seem not to be covered; it is at least ambiguous in some cases. Use of services abroad cannot be limited to "a patient moving to a healthcare provider in another Member State for treatment." This is rather restrictive. It seems to exclude the person (who can be or not a chronic patient) who becomes ill in a foreign country. Concerning the permanent presence of a service provider, it is not clear whether this covers for example a hospital purchased by a foreign (or multinational) company or if this only concerns companies coming or not with foreign teams. HOPE included in its answers and comments all professional mobility, considering a professional as a healthcare provider.

The consultation gives the impression that patients are considered as uniform and theoretical consumers. HOPE comments and answers tried to capture the situations in their diversity. Again the situations to which the patient are confronted vary whether there is admission or outpatient care, emergency or elective care, somatic or mental health care, if the patient is chronic or not, etc. In the survey on the priorities for using care abroad/delivering care to non-residents the Marquis project[2] shows major differences between planned and unplanned care. Another way to view this issue is to distinguish three cases:

[2] www.marquis.be

people travel and get sick; chronic patients travel and get sick; people are sick and travel to find care abroad. For a receiving hospital there are already quite different perspectives.

Cross-border and ECJ rulings

Without denying their importance in the debate, one cannot reduce cross-border issues to what was raised by the European Court of Justice (ECJ) rulings[3].

As already argued during the debates around the Commission's proposal for a directive on services in the internal market, the distinction hospital/non hospital used by the ECJ and subsequently in the proposal is not relevant. There is first of all a semantic reason, which is that this does not cover the same scope in all countries. The second aspect is even more important: healthcare is now widely recognised as a process involving different actors in various episodes of care (health as well as social care). This holistic view has oriented reorganisation in the healthcare sector with various methods, clinical pathways, seamless care, disease management, etc.

The ECJ rulings should not hide three facts.

Coordination of social protection is a formidable instrument that has benefited to patient as well as to hospital and healthcare services by structuring the mobility.

Border regions have already developed cooperation activities, in a complementary perspective and not a competitive one. Hospitals did not wait the ECJ rulings to work in what is defined in the consultation as crossborder care[4] and to find solutions as already exemplified in "Hospital co-operation in border regions in Europe" published in 2003 and in the subsequent Luxembourg conference "Free movement and cross-border cooperation in Europe: the role of hospitals & practical experiences in hospitals."

Various legal instruments facilitated the mobility of professionals and have also considerably improved the transparency and quality of this mobility. [5]

At the same time the ECJ court rulings have already changed the picture with a more or less direct impact.

Since the 1998 rulings and the 2001 ones, interesting changes happened, certainly influenced by the ECJ rulings. Waiting time has been reduced dramatically in some countries. Some purchasers had deliberate actions to

[3] The court did not establish new principles as written on page 3 of the consultation document. It did so in the past, but in the present case it just used existing principles.
[4] Hospital co-operation in border regions in Europe, A report carried out by the HOPE Working Party on Cross-border Co-operation - June 2003
[5] Directive 2005/36/EC on the recognition of professional qualifications

reduce waiting list and waiting time: setting time limits, organising new channels of care in the country or abroad, improving organisation of waiting lists[6], etc.

Finally the ECJ rulings had a positive influence driving Member States and the Commission to set up the High Level Group, which already showed interesting results, in particular when involving stakeholders.

General perspective

Those issues should be also viewed in a broader perspective and the consultation opens the door for a wider discussion, as does the discussion document on operational aspects of the Health Strategy. [7]

There is growing convergence in healthcare systems because of common issues. Ageing is usually given as an example, but ageing healthcare workforce, change of diseases and of culture are also major underestimated issues. The rapid homogenisation of care guidelines, based increasingly on European multinational clinical research will and has already greatly facilitated the convergence of specialised medical practice.

At the same time, systems are deeply rooted for good reasons in their history and are products of political choices at national, regional and even local level.

[6] http://www.hope.be/07publi/07newpublics/HOPE%20WAITING%20LIST%20WORKING%20PARTY%20REPORT.pdf
[7] http://ec.europa.eu/health/ph_overview/strategy/health_strategy_en.htm

Question 1: what is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

To rephrase the question, is there a positive or negative impact and in any case was it marginal or significant?

Most of the attention is driven to the use of services abroad and on a certain lack of information. There are enough qualitative information and evidence today concerning the level, type and motivation of patients seeking care abroad. The interesting question is why there seems to be grey zones of quantitative information. Before asking for more collection of data at central level, it would be necessary to work on the comparability of data and on defining why this data is needed.

From a hospital point of view, there are various reasons why hospitals do not code information that would be useful to give a picture differentiating cross border patients, for example by use of EU forms. There is usually no incentive to do so: it might not be considered as a determinant factor for the care given to the patient, it might concern only a limited number of patients, and it might not provide any financial incentive. In some cases the absence of figures is a sign of subsidiarity within the country that arrangements have been found in border regions without the intervention of the central purchasing structure.

At the same time, figures concerning the temporary and permanent mobility of healthcare professionals are crucially lacking. The available figures do not give an appropriate indication of what is happening at local and regional level and for each medical or nursing specialty. This last point is all the more important since some specialities are structuring elements of healthcare supply: for example the lack of radiologists has a major impact on diagnostic activities then on general safety.

Since the definition of cross-border healthcare includes cross-border provision of services, use of services abroad, permanent presence of a service provider, temporary presence of persons/professionals, the answers and comments will differentiate them.

ACCESSIBILITY

Has healthcare been more accessible for some patients and was it significant or not? Was it then less accessible or not for others?

Cross-border provision of services certainly improved accessibility. Is it significant or not?

As shown in HOPE report[8] (first of its kind but updated and upgraded with several EU-financed project such as EUREGIO[9]), border regions are giving various examples of best practices in the use of new information technologies, telemedicine services, remote diagnosis and prescription, laboratory services, etc. As long as this is not a way for one side of the border to avoid responsibility of financing care where it is needed, this has usually only positive impact on accessibility.

There are clearly more to come, in particular in border regions. This will develop if the cooperation spirit that characterizes those activities is not deterred by artificial competition or rigid rules.

Outside border regions, there have been also some developments and certainly more to come, in particular with market oriented initiatives that go farther than the EU borders. Using those services outside the EU means using human resources usually in developing countries. Using human resources for foreign affluent purchasers is also driving human resources.

In both cases there are then practical, and even ethical questions as well as a potential risk for reducing accessibility in EU member states if resources, and in particular human resources, are driven for those activities.

Use of services abroad has historically increased accessibility thanks to regulation 1408/71. The E111 and now the European Health Insurance Card have facilitated access to care in urgent situation. They might have reduce accessibility in tourist regions for local population but most of those regions have adapted their supply. The other E forms made also accessible treatments that were not available in the country of the patient. This concerned and still concerns for example countries at an earlier stage of development of a treatment or with a size of population that does not necessitate a full range of facilities. It has also been used for other reasons; continuity of care, presence of the family in the receiving country, etc. As shown in the Mapping Exercise of the High Level Group on health care

[8] Hospital co-operation in border regions in Europe, A report carried out by the HOPE Working Party on Cross-border Co-operation, with the support of the European Commission - June 2003, 88 p

[9] http://ec.europa.eu/health/ph_projects/2003/action1/action1_2003_23_en.htm

services[10] the number of patients is limited, even very limited. When used to reduce waiting list, this has been usually for a limited time as shown in the results of the Health Access project.

It is difficult on the other side to say that patients with E forms have reduced the accessibility in the countries where patients were coming from. It could be said at least that it could have prevented to use those resources to develop care in the country, but again as the flows were limited; this has certainly not been the case.

But the picture is changing, if it has improved access for some patients using care abroad, there is evidence that for some receiving countries it has been and still is limiting the access of the population to some treatment by driving human resources. Dentists are not more available in some European regions or at least for preventive activity or even children dental care. Some districts have 30 time less dentists than the EU average, some have 3 times less nurses than the EU average.

Whether there will be more accessibility thanks to cross-border will depend on choices that will be made following the present consultation.

Identifying six access hurdles (proportion of population covered with health insurance, cost sharing arrangements, geographical barriers, organisational barriers, utilization of accessible services and benefit package), the Health Access project concludes that the evolution of the content of the health insurance benefit package can be a driving force. The growing explicitness of services covered may make benefit packages more diverse, and therefore create access problems which patients may wish to overcome through accessing health care abroad.

In some countries with apparent spare capacities, providers might be tempted to position themselves and market their activities. There is however a constraint, which is that prices do not always reflect costs and that EU patients should not be discriminated. If for example every hospital in a given country has by law, to respect a given and fixed but average price, this averaged, fixed price may not be not sufficient to cover real costs.

Since around 90% of hospital care financial resources have public/collective sources (and that a significant part of the 10% remaining is complementary coverage), there will be not significant shift, if purchasers do not intend to do major changes. This may not be the same in ambulatory care if the ECJ rulings are fully implemented: resources are progressively less public/collective giving space for patient who can afford travelling to shop around.

[10] http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/high_level_wg_003_en.pdf

Concerning the permanent presence of a service provider, two situations should be differentiated:

- the provider is providing services within the benefit package of the country, and it presence might have been facilitated by a purchaser of care. This certainly resolved particular situations.
- the provider is not providing services within the benefit package, and drives private health resources. This may create inequalities but there is nothing specific to cross-border.

If they increased access, both situations may reduce accessibility in the country where those providers originate from.

Mobility of healthcare professionals was not significant in the past. With the exception of Irish doctors and nurses moving to the UK in the 70s and 80s, healthcare was considered as a sector were the migration rate was estimated as half of all sectors average. Even when countries with a lower income entered in the EU in the 80s, this did not create significant flows of healthcare professionals.

What is new with the 2004 enlargement and the 2007 is that the Gross Domestic Product (GDP) of most of those new member states is well below the EU average and that the share of their GDP devoted to health is usually under the EU average and even in one case half of the EU average. The cause/consequence of this is that there are no decent financial resources to pay healthcare professionals and huge differences with some EU-15 salaries.

Healthcare professional mobility starts then to create significant access problem in the regions where those professionals are coming from creating a negative impact in their country of origin

For the same reason, but with less impact, ***temporary presence of persons/professionals*** increases access in one country but may reduce or jeopardize the access in another.

The different types of provision have not significantly improved accessibility in quantitative term. It has however been significant for individual patients and patients residents of some border regions.

Whether this rather balanced situation will still exist in the future, will depend mostly on incentive for providers and decisions of purchasers.

QUALITY

Does cross-border care improve quality of care?

Quality of care delivered to patients who benefit from one of those form of cross-border care, cannot be separated from the quality of care for the other patients in the receiving country or in the country of origin of the mobile patient or professional.

The first question concerns the definition of quality. The challenge of quality is founded on the basic principle of reducing the number of errors. Various research[11] and reports[12] carried out demonstrate that the concepts and principles relating to quality management in health care differ from one country and culture to another. The same is true concerning the tools used to improve quality.

Health care has some specific features when compared to other organisations. Examples of this are the very complex organisations with a very wide range of knowledge, intensive expertise and often the very complex processes relating to individual patients. This creates an even bigger challenge for management and leadership.

For patient mobility the question is then what are the risks to patient safety. It is clear that since there are several initiatives to improve care inside structured purchasing, the main issue is regarding now the patient deciding deliberately to go abroad on an individual basis.

There is anyway some progress made in agreeing on key indicators.

One way to look at it might be from the angle of adverse events. Using for example one set of indicators of adverse events (here the Canadian ones[13]), it is obvious that some are certainly more relevant than others in the context of cross-border: unplanned admission, hospital-acquired infection or sepsis, dissatisfaction with care documented in the medical record, inappropriate discharge to home.

[11] www.marquis.be

[12] Quality of Health Care and Hospital Activities, HOPE, September 2000

[13] The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada CMAJ, May 25, 2004; 170 (11)

Another way is to follow the work done on performance indicators by WHO-Europe, used in the Marquis project. The WHO PATH Performance Assessment Tool for quality improvement in Hospitals project[14] as identified five elements to take into account: patient centeredness, responsive governance, staff orientation, clinical effectiveness, safety and efficiency.

Two elements should be looked at precisely. They both characterise the main quality issues of crossborder care: information (to, from and on patient) and continuity of care.

Is quality of care improved by ***cross-border provision of services?***

Since by definition those activities are supposed to fill up a gap, they have certainly improved quality of diagnostic for example. But at the same time quality could be at risk in the field of communication between professionals, and communication with the patient.

Is quality of care improved by the ***use of services abroad?***

One aspect of the question is to know whether choices made to use services abroad were based on quality indicators. There are limited examples, but some anyway when patients assume that they would get better quality outside the country. But since there is limited information on this, the most important is to see where quality could be at risk in cross-border.

To come back to the WHO PATH criterias, patient centeredness is obviously a major element in our discussion. This concept includes: patient perception/satisfaction survey; interpersonal aspects; client orientation: information and empowerment. Patient satisfaction is a quality indicator very much influenced by cultural factors, but also by the perception patients have of their own system, as Marquis project showed.

Communication is the main and most common requirement for patient safety and centeredness. When asked, patients consider the face to face contact with professionals as the main source of information[15]. This gives to language barriers a major role in jeopardizing communication. This language problem should not be underestimated. This is anyway not specific to patient crossing border. Some hospitals succeed in alleviating part but not this entire problem. Exemples of best practices were given as part of the Migrant Friendly Hospital project[16]

[14] http://www.euro.who.int/hosmgt/20060714_1?PrinterFriendly=1&

[15] http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/working_group_en.htm#1

[16] http://www.mfh-eu.net/public/files/experiences_results_tools/spc_training/SPC_evalreport/SPC_Eval_Report.pdf

There is then a direct link between information and the second major aspect, which is continuity of care.

Discharge procedure for crossborder patients is the weakest element of use of treatment abroad. Information requirement may not be satisfied, social support services are missing, medication differ in terms of type and dosage between countries, discharge timing depend on transport arrangement and organisation of follow up care may be more difficult to achieve. Finally, there are cultural differences with regard the ability and willingness to collaborate in the care process that may reduce the quality.

The problem of continuity of care becomes particularly acute with new ways of treating patient, shortening significantly for example the length of stay, giving then an increased importance to the environment before and after treatment. This is all the more true with the growing number of chronic patients and even patients with multiple chronic diseases.[17]

It is obviously more complex to provide good outcomes with mobile patients, as it is already with patients that do not move. For hospitals the main difference is the situation: emergency vs. elective. There is a major difference between the emergent and non emergent situation. What is important in any case is to distinguish the different situation in which patients are: emergency or not, which means a better capacity to organize the continuity of care. Preparedness for care that is not needed is costly and drives down efficiency.

Is quality of care improved by ***permanent presence of a service provider?***

Again looking at information to patients, the language and cultural barriers can be seen as a major issue.

Then, whether the provider is delivering services within the benefit package or not, there is an issue of continuity of care and communication with other healthcare providers in the country.

Finally, the issue of quality of the providers is raised in particular if this activity is not covered by a licensing system.

Is quality of care improved by ***temporary presence of persons/professionals?***

The same goes for temporary presence of persons/professionals. But it can be worse on both sides, in the country where the professional is temporarily working and in the country from he/she comes from. It can jeopardize quality in the case of professionals working on a week-end in a foreign country and the rest of the week at home.

[17] http://www.who.int/chp/chronic_disease_report/contents/en/index.html

FINANCIAL SUSTAINABILITY

Information available shows a limited financial impact at national level because limited to small outpatient activities. But it does not give indications of impacts at local and regional level. Again in some tourist areas there has been a strong financial impact for institutions delivering urgent care.

This limited financial impact today should not be a reason to underestimate the risk for financial sustainability. It can first be significant at local or regional level either in border regions where there are no natural barriers or when there is an important price difference for human resources or care.

Patient mobility has been considered by the European Court of Justice as a risk to the financial balance of social protection systems. This was considered as a reason for restrictions to freedom. But financial sustainability should also be viewed in the context of sustainability of the healthcare system, a major cohesion factor and it should not only be viewed in terms of number of patients as the Court does

As solidarity between Member states is very limited in the social protection sphere, there are no real mechanisms to avoid that healthcare resources are driven from poorer to richer countries. More than ever the national averages given should be carefully handled.

The consultation document states that the key to sustainability of healthcare systems is therefore the control of costs (certainly meaning expenses) that have increased more than GDP. It is important to remind that this trend is not bad in itself. In some cases, it was even deliberately decided. It should remain the case in several countries with appalling resources in health, focusing on excess of beds is useless.

It is worth reminding that healthcare is a structuring factor of cohesion (see Commission document, *The Contribution of Health to the Economy of the EU*[18] or HOPE publication *Health as a Growth Factor*[19]).

[18] http://ec.europa.eu/health/ph_overview/Documents/health_economy_en.pdf
[19] http://www.hope.be/07publi/fr_tot.htm

the financing system for Belgian hospitals, there is no link between the price of the care and the costs:

How will this evolve, what conclusions does it bring and what effects in the future?

Cross-border healthcare did not significantly improve accessibility but could reduce it in some regions and even countries.

Cross-border healthcare does not automatically improve quality.

Cross-border healthcare did not threaten financial sustainability but could in the future even threaten healthcare system sustainability.

This will depend of course of the decision taken following this consultation but also of the advancement of various other works of the High level group, of the initiatives concerning e-health or patient information for example.

This topic will certainly benefit from an impact study. But unlike the impact study[20] on the proposal of Directive on services which was too general to be of any use for the healthcare sector and then for the present consultation, it should consider health outcomes as first element to study and not first the fall of prices, rise of output, creation of new jobs, intensification of trade is consultation if not it would have been useful to mention it.

Where do we need more figures at this stage, considering the investment this would mean?

Precise figures are missing concerning professional mobility.

For patient mobility the most important will also be the most difficult to get: use of healthcare services by patients with their own resources and even with private insurances and not only within the EU. Some of this care could endanger the patient and there is limited information available.

[20] Economic Assessment of the Barriers to the Internal Market for Services, Final report, January 2005, Copenhagen Economics

Question 2: what specific legal clarification and what practical information are required by whom (e.g.: authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

What is efficiency?

The challenge for hospital and healthcare providers is to turn inputs and outputs to health improvements outcomes, knowing that health services are only one of the inputs with time, education, housing, diet, environment and others.

Apart from avoiding unnecessary care (supply-driven demand), two issues have been identified as specific indicators for crossborder care: patient centredness and continuity of care.

The question is then to define if legal clarification and practical information can significantly improve safety and quality.

Cross-border provision of services will certainly benefit from legal clarification. There are still open questions regarding data protection and quality standards. In some border regions it already started and the issues are so specific that the best option is bi-lateral agreements.

Use of services abroad

Legal clarification

As already mentioned hospitals need legal clarification on this confusing distinction hospital vs. non hospital care. Leaving individual patients decide to market for their health can jeopardise at least continuity of care.

The other question relates to the "medically acceptable time limit considering their condition". Receiving patient outside the authorisation procedure creates uncertainty in hospitals.

Practical information

That patients get information on cross-border care is also important for hospitals and healthcare services. It should help patients not being misled by wrong assumption and clarify potential risks. This should obviously be adapted to patients considering various factors such as health literacy. So that cross-border will not be a new way to create or increase inequalities.

Mapping exercise of the High Level Group on Health Care services 2006 shows that a single contact point for patients that seek information on access to health care across border should be adapted to the situation of each member states to

take into account the character of the system: decentralized, insurance based, etc.

Lack of information among patients about the different models supplying health care and the subsequent uncertainty for the patients has certainly provided an obstacle to cross border healthcare. But is it more important to have information in general on good quality care in the country or on what exists outside, whatever its quality is?

The understanding of good patient information is extremely culture-dependent, much more than medical practice in itself. Mental health patients and the elderly are particularly vulnerable to information gaps.

Question 3: which issues (eg: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

The guidelines procedure on how to organise a cross border healthcare, produced by the High Level Group, dealing with equity issues gives most of the answers needed.[21]

The legal system of the receiving country should apply. This should be the core principle driving all answers. At the same time the authorities of the receiving country should be responsible of clinical oversight. For other issues this will vary of course depending on the type of care, on the type of purchaser and on the relation established with providers.

Cross-border provision of services

In that case, delivery of service is provided from the territory of a country (that might not be an EU Member State) into the territory of another, without patients crossing borders. Two risks at least for patients are identified: that this would be a way for the provider to avoid regulation within the country of the patient; that this service would be provided to the patient directly to the patient without the intermediary of a healthcare provider. Again it is the responsibility of the authorities of the country where the patient is treated to prevent those risks.

Use of services abroad

Here the patient is treated in a foreign country. Again whether the patient is moving to a healthcare provider in another Member State for treatment as part of a structured plan or is a direct purchaser of care, the authorities of the country in which the patient is treated should be responsible of clinical oversight.

Concerning permanent or temporary presence of a service provider

[21] http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/highlevel_2005_017_en.pdf

Whether this permanent presence is a treatment in the benefit package or outside, the authorities of the country in which the patient is treated should be responsible of clinical oversight. This should not be a way to reintroduce the country of origin principle, excluded from the directive on services.

Question 4: who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

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

The responsibility lies in the Member State where patients are treated. Which level of authority is concerned (national or regional) should depend on the way the healthcare system is organised.

Concerning ***cross-border provision of services*** the question of responsibility for patient safety should be regarded in the agreement between the parties.

For ***use of services abroad*** by agreements between a purchaser in one country anad provider(s) in other countries the question of responsibility for patient safety should be regarded in the agreement between the parties. There are however possible grey zones when patients are left to themselves to get care, in particular outside the EU.

If the patient makes the choice to have health care in the other country where the provider has no agreement with the home country, the responsibility for patient safety lies in the country where the patient is treated.

The definition of safety as well as ways to improve it have quite recently been boosted with the work of the High Level Group and the various activities promoted by stakeholders. It will certainly develop in the coming future. Outside this context the idea of a European accreditation system as been expressed.

Accreditation[22] is only one of the models of external assessment. There are at least five other models of external assessment in use in Europe: ISO, the International Organization for Standardization; Peer review; The Malcolm Baldrige model for quality management: know in Europe by the European Foundation for Quality Management (EFQM); Registration and licensing. Some countries have more or less recently adopted and adapted various systems of external assessment.

[22] Accreditation is usually a voluntary program, sponsored by a non-governmental agency (NGO), in which trained external peer reviewers evaluate a health care organization's compliance with pre-established performance standards. Accreditation addresses organizational, rather than individual practitioner, capability or performance. Unlike licensure, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards, rather than adherence to minimal standards intended to assure public safety

The example of another continent shows the advantages of different systems. It is also reminded that the accreditation system is contrary to a top down approach and that its success depends on appropriation by institutions and professionals at national and/or regional level.

Exchange of best practices between the different models of external assessment and organization dealing with it at national or regional level will certainly be beneficial for the general quality of care. Whether a unique system would be appropriate to improve cross-border care lacks evidence.

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

The legal system of the country where patients are treated should apply.

More generally, EU hospitals and healthcare services would like to avoid the artificial level of litigation of the United States[23]. As already mentioned, initiatives have started on a European level to work on patient safety. HOPE recently adopted a firm position on the starting point of safety improvement: a fair reporting system.

Question 5: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

What could reduce the access for all patients?

As already mentioned, driving financial resources and human resources out of the country can also reduce access in the country.

But driving resources, and in particular human resources, for the benefit of foreign patients can indeed jeopardize access. There are concerns in touristic regions but not only there. It starts to be significant in countries were professionals are scarce, in particular for some specialties.

The first action should be to avoid creating incentives for artificial flows of patients by informing the patients as already mentioned. It is not so much to prevent massive flows of patients than to prevent flows in the most complex cases.

Although it is more difficult to control emergency than for elective care, there are ways to tackle the issue of balancing the resources in touristic regions.

[23] http://www.hope.be/07publi/07newpublics/HOPE%20MALPRACTICE%20REPORT%20APRIL%202004.pdf

This leads anyway to link activity and costs. This put pressure on hospitals to identify their costs but this did not wait cross-border, but is indeed part of new ways of financing hospitals and healthcare.[24]

[24] HOPE DRG report, January 2007

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

There are further issues linked to the contradiction between different principles: high level of care and free movement, free movement and cohesion. Some cannot be addressed by Community legislation as it stands.

Community legislation assumes that mobility is good in itself; but it can jeopardize cohesion as shown before. To quote the Council of Europe recommendation Rec (2006)11 on Transborder mobility of professionals: "the international mobility of health professionals can have both winning and losing stakeholders – both in host and home countries."

And although they have health as a priority, structural funds do not seem to be driven to seriously alleviate health inequalities.

Question 7: are there other issues 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 – such as healthcare providers and social security institutions – suggest in order facilitating cross-border healthcare?

The second question assumes that cross-border healthcare is good in itself and should be developed. Considering that any cross-border care is good in itself is based on "pure-and-perfect-market" assumption in a sector where asymmetry of information is a well known fact. One party to a transaction has more or better information than the other party. Informed choices in this context are very complex. It is already visible within some regions and countries.

Facilitate cross-border healthcare is not the goal of hospital and healthcare services and certainly not of healthcare systems. Their main goal is first to provide high-quality care. Cross-border care is then one way by which services are delivered. It might certainly be one of the tools to reach this high-quality care, but with many conditions. But it can also be a negative sign that something goes wrong in a health care system.

In border regions, for cross-border provision of services and use of services abroad, legal certainty should be improved for several issues but this has already started to be done on bi-lateral partnership.

For other cross-border provision of services and use of services abroad, the HLG has good starting basis.

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

European networks of centres of reference

Centres of reference were originally identified as *centres of excellence* and taken as a way to describe one particular aspect of patient mobility. The paper on Centres of Reference/Excellence for the Conference organized by the Spanish presidency in Menorca 31 May – 1 June 2002 mentions "the concept of European *Centres of Reference* is taken here to be synonymous with the concept of *Centres of Excellence* as discussed before in the context of the development of an internal European market in health."

But it really started with a May 2000 report by the Association Internationale de la Mutualite (AIM) entitled "Implications of recent jurisprudence on the co-ordination of health care protection systems." It noted that the "principle of territoriality" is not sufficient to guarantee population access to health care facilities, explaining that "sparsely-populated countries may have insufficient levels of population to support an adequate and sufficient healthcare infrastructure", and citing Luxembourg as an example.

HOPE is quoted in this report as saying that "possible incentives will have to be devised for which the European Union, staying within its role under subsidiarity could, for example, promote European centres of excellence (the results of intra-European cooperation (not always evident) between hospitals concerning rare or very complicated diseases, or diseases which are too expensive to be treated within one particular country."

After limited discussion in the High Level Process of reflection on patient mobility, the work really started in 2005 in the High Level Group (HLG) on health services and medical care working party on centre of reference. This working group has been publishing its results in the reports of the HLG.

The difficulty of defining this challenging concept is certainly rooted in the fact that there no clear answer to the question of the real goals. Is it to increase patient choice by removing borders? Is it to improve quality of care (and then to reduce patient choice) by limiting the centres? Is it aiming at creating an international division of labour in the hospital field in order to reduce costs? Is it a way to take into account differences in countries' size or in countries' wealth?

The pilot projects on rare diseases that will be financed by the Commission will be interesting to follow as well as the criteria on which they will be tested.

Realising the potential of health innovation

Health Technology Assessment on a European basis has also a strong potential and has already started. This is also important in the context of the Lisbon strategy. It should be linked also to European evidence-based clinical guidelines that are rapidly becoming a rule through the actions of the European specialty societies.

A shared evidence base for policy-making

There is indeed a great potential in this field. Developing the already existing collaboration with other major actors, WHO Europe (including the Observatory) Council of Europe and the OECD should be the main driving element.

Health systems impact assessment

Hospitals and healthcare are also supportive of this development as mechanism of information on EU influence on hospital and services healthcare of other policies are missing, due to the lack of integration of health issues. This would not only be helpful for new EU members.

Are there areas not identified above?

Structural funds are an area that should also be integrated in the discussion.

Finally, it seems important considering solidarity which is slowly moving out of the window, when there is another raising issue: the illegal non EU migrants and how to cover their healthcare.

Question 9: what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means?

Concerning the cross-border issues, since there is already a legal instrument, recently actualised Regulation 883/2004, the question is to know why it would not be possible to handle this in the regulation. There are however grey zones outside the coordination of social protection mechanisms where patients are at risk.

Concerning other healthcare services issues, those questions cannot be separated from three others: what legal certainty for services of general economic interest? Which specifics of social services of general interest? Should health and social services be dealt with together or separately?

Whatever solutions taken what should drive any Community legislation is efficiency.

This means first of all to take into account political efficiency. The '*principe de subsidiarité*' first appeared in a Commission paper submitted to a report on institutional reform in 1975, a time when Community confidence was at low ebb. The intention, to quote Jacques Delors, 'is not to give birth to a centralising superstate'. Subsidiarity means that powers or tasks should rest with the lower-level sub-units of that order unless allocating them to a higher-level central unit would ensure higher comparative efficiency or effectiveness in achieving them. Subsidiarity is then not a principle to protect itself but a way towards efficiency.

In the healthcare sector the subsidiarity principle has two sides. First the hospital and healthcare sector is structured around decentralisation. A vast majority of Member states have now decentralised care at the regional or local level. At the same time, hospital autonomy is the fast growing model that put subsidiarity at healthcare institution level.

Efficiency means also involving the stakeholders that will have at the end to implement decisions taken. There were serious contradictions in the process of the design in complete opacity of the Services Directive, when all stakeholders had participated few months before to the Services of General Interest consultation. This should not happen again and the present consultation gives a positive sign. This means that a clear articulation is needed with any initiative on Social Services of General Interest, where healthcare has obviously its place. It is not possible to handle this separately with an ageing population that will increase the need of coordination between all social and health activities. This will also facilitate avoiding mis-communication (false assumption given by ambitious communication strategies), while benefiting to all patients.