RESPONSE TO THE EUROPEAN COMMISSIONS PUBLIC CONSULTATION ON CROSS BORDER HEALTHCARE

by THE NHS TRUSTS ASSOCIATION

The NHS Trusts Association (NHSTA) is uniquely placed to respond to this consultation having sat, with our corporate legal member Weightmans, on the Department of Health Working Party known as Capacity, Plurality and Choice which was responsible for drawing up the Code of Best Practice to be used by Primary Care Trusts when sending patients for treatment abroad and when bringing in overseas medical teams to work in the British NHS.

We believe that certain protocols should be pre imminent in deciding whether or not one EU country will treat the patients of another. The first of which should be whether there is spare capacity in the healthcare structure of the receiving country or whether an influx of patients from other EU countries is going to disadvantage and compromise the needs of the indigenous patient population.

For the purposes of this consultation it is assumed that as far as the United Kingdom is concerned the majority of cross border treatment will involve the outflow of British NHS patients to other EU countries for treatment abroad.

From a clinical point of view, the benefits of sending patients abroad should be weighed against the potential increase in risk that may be precipitated by our requiring a patient to undertake air travel with the attendant risks of DVT etc. having only recently undergone major joint surgery. We are assuming here that a significant percentage of overseas treatment will be for such procedures as for example hip replacement, so our NHS Working Party (capacity plurality and choice) recommended a maximum flight time of no more than 2.5 hours.

Nonetheless, if it can be demonstrated that a British NHS patient is likely to receive treatment of a quality and standard at least equal to that which they would expect to receive from the British NHS and by sending them abroad, waiting lists may be reduced, thus hastening treatment for those patients who wish to go abroad and shortening the waiting time for those patients who wish to remain in the United Kingdom and wait for their treatment under the British NHS, then the cross border option should be available.

As far as accountability is concerned countries sending patients for cross border treatment (the submitting member should ensure that the consultant responsible for the patients treatment prepares a best practice regimen BPR), which is first agreed with the member country receiving the patient (the admitting member). Once the admitting member state has agreed the protocols in the BPR with the submitting members state a fee should be agreed for the procedure. The additional travelling costs should be met by the submitting member when convalescence is likely to be extended consideration should be given for paying the travelling costs of the spouse/partner. The travelling costs of at least additional person should be met automatically if the patient is likely to require assistance with their mobility when travelling.

The basis on which the submitting member will repay the admitting member state should be a matter for negotiation. Typically it may be agreed that there will be a block of treatments booked and the admitting member agrees with the submitting member to undertake X number of procedures for an overall cost to be agreed. Issues such as whether treatment costs are paid on block prior to procedures or post procedure would again be a matter for negotiation.

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NHS Trusts Associations Response to the European Commission's Public Consultation on Cross Border Healthcare

## Legal Aspects

The European Commission has asked for input into the discussion as to what degree, if at all, the European Commission should be active in European Union (EU) citizens' ability to access healthcare in other EU states.

There are a number of legal issues arising from this, and there is a question as to whether there is a need for legislation or regulations, or simply an Interpretive Communication from the European Commission, to address anticipated problems arising from possible conflicts or complications between existing regulations and case law.

The EU consultative document identifies four particular types of cross border healthcare:

- \* Use of healthcare services abroad, "patient mobility". This could be a foreign EU national who needs immediate medical attention, or a EU national whose home state has agreed to fund treatment for that national in another EU state, either on an individual basis or as a block contract.
- \* The permanent presence of service providers from one EU state , setting up a clinic or other medical establishment in another EU state.
- \* The temporary presence of EU national healthcare professionals working in another EU state
- \* The remote cross border provision of healthcare services. For example electronically by telemedicine.

In respect of the legal aspects of the proposals, the main areas that need to be considered are:

1 Regulation of the cross border flow of patients seeking medical services

Can the purchase of medical services ( utilising the healthcare budget of the EU citizen's home state), be treated by the EU citizen in the same way as the purchase of any other service from a provider within the European Union?

## 2 The Protection of Patients

With whom will the responsibility for adverse healthcare incidents lie, both in respect of compensation and investigation? Will it be the foreign provider of the healthcare, or the domestic commissioner of the healthcare?

# 3 Regulation

Who is responsible for the health care staff in a member state providing healthcare to citizens of another member state? Not only is it the question of legal responsibility for their actions and as to who the individual might sue if he or she were to suffer a medical mishap, but also the question as to who regulates and oversees the healthcare professionals? What will be the role of their employers and professional bodies?

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### 4 Tele Medicine

Clarification would be welcome in respect of the legal responsibility and regulation of the remote cross border provision of healthcare services

### 5 Transfer of data

With the actual and anticipated greater movement of patients going abroad to obtain healthcare, or their sensitive personal data being sent abroad to be diagnosed and interpreted, there is a need for secure systems for the transfer and storage of data.

## 1 Control on movement of patients between member states?

There is a clear tension between allowing patients to obtain medical services in any member state they wish i.e. treating healthcare as any other purchasable service, and allowing member states to regulate and plan their expenditure on healthcare.

There is a difference between an individual who wishes to purchase for themselves healthcare abroad (the legal relationship being between the individual and the healthcare provider), and an individual who wishes their home state to reimburse them, or directly pay the provider, for the provision of healthcare services abroad. With the recent UK case of Yvonne Watts, (16th May 2006 Case C-372/04)the European Court of Justice noted the tensions between allowing the freedom of EU residents to obtain health services from with in other EU states, especially if waiting lists in their home state are excessive, and the need for states to organise and plan their health and social care systems. This area needs to be clarified. The European Commission needs to indicate where it believes the balance should lie between freedom of movement of individuals with in the EU seeking medical services, and the European Commission's non-involvement in the provision of regulation of healthcare services and social services in each individual state. It is for those states to fund, budget and regulate the healthcare and social care services. Uncontrolled movement of patients, and healthcare professionals, across EU borders has the potential of causing great instability in the provision of healthcare services in member states. Some member states may then be faced with unsustainable demands for their services, adding to existing waiting lists etc. Conversely, other states may end up with expensive healthcare facilities that are underused and redundant healthcare professionals, if their citizens are using foreign health care providers, as opposed to domestic ones. Unless healthcare and social care services are planned centrally by the EU, then it is unclear what can be done to prevent such a situation occurring, if unrestricted cross border flow of healthcare is allowed. This issue needs to be clarified by the European Commission.

## 2 Protection of patients

English case law suggests that if an adverse healthcare incident were to occur abroad to a UK citizen, then the individual or the establishment providing the healthcare would be potentially liable, particularly if the incident was as a result of alleged negligence. This would be the case either if the patient was a casual visitor to that member state, or the healthcare provider in the member state was providing care under a contract with the patient's domestic health care commissioner. A definitive statement upon this would be welcome from the European Commission, also clarifying the legal position of the commissioner of the healthcare.

In addition to this, clarification would be helpful as to who would be responsible for investigating any such incidents e.g. if there is a need for an inquiry or inquest etc., especially if such incidents followed a pattern. This is in addition to any civil or criminal proceedings. The home state of the patient involved may wish to investigate through the inquest system, or any other inquiry system in existence, as may the state where the healthcare was provided. An inquiry panel may require the attendance of individuals based abroad to assist with the investigations. Clarity on the responsibilities and options available should be provided, especially in respect of quality, safety

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and complaints procedures. Such procedures could be complicated if the patient is receiving a series of treatments both at home and abroad. A coordinated approach for such situations, following guidance provided by the EC, would be helpful.

## 3 Regulation of healthcare staff

European wide systems have and are being established, for recognising and co-ordinating the various regulatory bodies of healthcare professionals, allowing those professionals to work within different member states, recognising the validity of training and qualifications obtained in other EU states.

Nevertheless, there will be a need to ensure that "rogue" doctors and other healthcare professionals, cannot simply move from one member state to another without the adverse incidents for which they are responsible for, being tracked and noted on an EU wide basis. There must be a facility for keeping track of these individuals ensuring if they need retraining that occurs, and there to be a system of "alert letters", similar to that used by the Department of Health in the UK. Foreign EU citizens must benefit from the clinical governance regime in the country in which they are receiving treatment.

# 4 Tele Medicine and the remote cross border provision of patient care

With the expansion of the use of email and the internet, it is anticipated that diagnostic and prescription services, amongst others, increasingly will be offered in one member state and delivered electronically to the health services or individual purchasers from another member state. Examples are tele medicine, remote diagnostic and prescription services, and remote pathology services, i.e. the lab results being interpreted in one state and sent to another. It may be fairly straightforward in that it is simply a contractual issue i.e. that the healthcare provider is solely responsible for this, not the home state commissioner. Difficulties can be envisaged in the incorrect interpretation of such results, which are then passed on to the health care commissioner, and acted upon to the detriment of the patient. As stated, well drawn contracts could well prevent any confusion about legal liabilities, but any guidance, regulations etc produced by the European Commission would be welcome in clarifying legal responsibilities and liabilities arising from such remote cross border provision of patient care.

## 5 Cross Border transfer of personal data

In order to ensure that healthcare providers have sufficient medical history as to the foreign patients' medical conditions, and also to allow the provision of cross border telemedicine, diagnostic and prescription services, there will be a need for personal sensitive data to be transferred abroad. Contractual obligations between the healthcare provider and commissioner should ensure that the former is adhering to EU directives (e.g. Data Protection Directive 95/46/EC) on data processing and in particular data security. Nevertheless, European Community clarification on this issue would be welcome, setting out as to what would be expected from member states and their organisations providing healthcare to citizens of other member states in respect of data security and transmission, particularly for the reassurance of the patient seeking healthcare abroad. There is a need for assurances that data will simply be used for the purpose for which it was provided, and no other, and as to who will have access to this data.

# Conclusion

As stated above, there is existing legislation, directives, regulations etc, and case law which cover many of these points. Nevertheless it is anticipated that these are not collected together and easily accessible as a whole. A document that drew together all the relevant case law, regulations, directives

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and legislation, and provided an overall interpretation, would assist in providing clarity for all those involved in this matter, and facilitate the provision of cross border health care.

The implications of cross border healthcare

With efficient and wider cross border healthcare the main beneficiaries appear to be the patients, who have widened choices and possibilities for integrated and continuous care. The EU also seems set to gain from this, as it fits in with their goal of securing free movement of goods and services. The result is likely to be mixed for insurers and providers. Pros include being able to use resources efficiently (due to mobility of patients and contracting possibilities with providers abroad). Cons include the threat of unfair competition and not being able to impose certain standards on foreign parties.

However the contingent most likely to bear the brunt of improved cross border healthcare appears to be the individual member states. In Implications of Recent Jurisprudence on the Coordination of Health Care Protection Systems, Palm et al. state "member states see the ECJ decision as encroaching on their prerogative of organising their protection and health systems in accordance with their own choices; most of the member states also feel that unrestricted access to health care abroad would endanger policies for containing health care expenditure, for allocating resources effectively and for public health".

This would seem to suggest that enlarged options for cross border healthcare, although highly beneficial for patients, would be a real no-no for member states. However, this is obviously dependant on the number of patients who exercise these options, and current research would appear to show that currently intentional mobility of patients is low, even in cross border regions (e.g. those living near to the Germany/ Austria border). It is estimated that less than 2% of the insured population in the AU opt for cross border care in other member states. Even with increased options for patients, the increase can be kept minimal through a variety of (national) authorisation procedures, whereby member states can (still) to a large extent determine the conditions for cross border care. Add this to issues of language and culture and cross border healthcare movements are likely to be limited within border regions.

This raises the question: which issues regarding cross border healthcare should be handled on a national level and which on a community (EU) level? Although in theory the EU's principle of free movement of goods, services, persons and free movement of establishment would be fully secured in a free market competitive framework with perfect information, this is very much an economic theory, which operates differently to the realities of the medical-care industry. Because of the differences within various healthcare markets and industries, for example health status and care load, a more diverse product or service is required. Because of this government involvement appears both essential and characteristic to cross border health care.

So a suitable degree of decentralisation needs to be reached away from the EU, or as Oates puts it (in Fiscal Federalism) "the optimal structure of the public sector in terms of assignment of decision-making responsibility for specified functions to representatives of the interests of proper geographical subsets of society". It can be assumed that this means each provision should be linked to that jurisdiction of which spatial range corresponds with actual use by citizens. This ties in with the question of how member states can ensure financial stability of their system. Tiebout, in a Pure Theory of Local Economics, points towards the best possible size of a state's resources for every pattern of community services (including healthcare). The optimum number is the number of residents for which services can be produced at the lowest average costs. Whilst some states below the optimum will seek to attract new residents, others will try the opposite. In relation to cross border healthcare, long waiting lists for e.g. hip replacements in one country can stimulate the use of services in neighbouring countries. The patient chooses the jurisdiction that best fits in with their preferences. The limitation of voluntary patients' movements within border areas, coupled with flexible procedures for cross border care movements within these areas, can operate as the main instruments to achieve this best possible size.

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The upshot of this is that whilst the role of the EU as a whole is important in cross border healthcare, it is important not to diminish the role of individual member states. National authorisation procedures, flexible national rulings on cross border care in cross border regions and regional arrangements between two member states are all instruments to achieve an efficient level of output and this optimal size in relation to resources. In any event the benefits for patients that take advantage of cross border healthcare is likely to outweigh the costs for individual member states.

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