Response to the EU Communication 'Consultation regarding Community Action on Health Services'

1. Introduction

The London NHS welcomed the Commission's decision to exclude health services from the scope of the Services Directive. Our main concerns were two-fold. First that health services, and health professionals providing services on a permanent or temporary basis, should continue to be regulated by the country in which the services were provided. Second, member states should be able to manage and regulate their own healthcare systems for the benefit of patients in general.

We support the view that health services have a general interest aim and rely on universality and solidarity. Patients are not ordinary consumers, but are often vulnerable and have to rely on expert opinion, given within a relationship of trust.

Our main issues of concern in developing any further EU action on health services are:

- Issues to do with **patient safety** particularly embedding the principle that it is the country where the treatment is provided that must regulate health service provision and professionals and ensuring a minimum level of regulation of health services in each member state.
- Making sure that patients who travel for treatment have sufficient **information** to make informed choices and know how service quality is ensured and services regulated, including what to do if things go wrong.
- Making sure that authorisation is retained for services where access in the patient's home country is via referral by a clinician. This includes some non-hospital services. We want therefore to ensure that there are **more adequate definitions** than the current 'hospital' and 'non-hospital care'
- **Legal certainty** should be provided in relation to the areas outlined in section 5. and should be limited to these areas:
- The **sustainability** of healthcare systems must be safeguarded

2. Patient safety

(a) The country in which the healthcare is provided must regulate the healthcare provider

Every Member State should have systems in place to ensure the quality of the healthcare provided within its borders.
Such systems must be **established at national level**, in order to ensure good quality of information, and to avoid an unacceptable bureaucratic and financial burden.

Healthcare professionals must be regulated in the country where the service is provided:

- Each member state should have a designated regulator of healthcare professionals
- All healthcare professionals working **for any length of time** in another member state must be registered with the relevant regulator in the host member state
- The relevant regulator must provide information on registration and fitness to practise of individual clinical practitioners working in other member states

- Fitness to practise must include adequate knowledge of the language in which the healthcare professional is expected to practise.
- High quality training of healthcare professionals is essential in ensuring patient safety: including post-graduate training for doctors.

Each member state should have an inspectorate of healthcare providers

- Ensuring the quality of healthcare provided within the member state's borders

Each member state should have a mechanism for setting standards

- Promoting use of evidence-based practice, and assessing clinical and cost effectiveness of procedures and treatments, in the context of the member state's population needs and financial constraints.

(b) Information for patients about the risks and implications of traveling for treatment

Traveling for treatment carries additional risks (see Appendix).

Patients need to be aware of these risks and be sufficiently informed. Such risks must be articulated and made available to the patient.

(c) Information for patients about service providers

Providers of healthcare services, who are willing to treat patients from other countries, must provide information which will enable patients to make an informed choice. (The types of information are provided in the Appendix).

3. Sustainability including financial sustainability

In order to safeguard the sustainability of healthcare services, the following are required as a minimum:

(a) Home healthcare systems must be able to determine what health services its citizens are entitled to and to reflect resources, practice, cultural and ethical views of the home state, to set its own priorities and manage its services accordingly.

(b) Providers must be able to retain the right to refuse treatment of patients from other member states if the provider does not have excess capacity to treat additional patients. This to ensure that patient mobility does not disadvantage patients who do not wish, or are unable, to travel for treatment. It will also ensure that service providers are able to continue to set their own priorities without the risk that these are distorted by a requirement to treat overseas patients.

(c) Patient mobility should be cost neutral. That is, the cost of treatment in another member state should not cost the home healthcare system or social security system more than it would cost if they were treated at home.

At present there are two different rules governing the reimbursement of costs, which is confusing:

- Regulation 1408/71 or E112 (reimbursement of the full costs of the treatment abroad

- Article 49 (reimbursement of costs to the level of what the treatment would have cost in the home country or actual costs if these were less)

Article 49 could become the single legal basis on which patients travel abroad for treatment, with 1408/71 applied in exceptional circumstances.

(d) Prior authorization should not only be for hospital treatment (see 5. below) but for all services which in the home healthcare system are subject to referral by a medical practitioner.

4. Hospital and non-hospital care and prior authorisation

European Court of Justice (ECJ) case law states that a system of prior authorisation is justified for hospital care on planning and financial grounds. The ECJ has stated that it has not yet seen evidence to support the requirement for prior authorisation for non-hospital care.

The terms 'hospital' and 'non-hospital' care are not defined in the consultation document. The division between these types of care and the absence of any need to seek prior authorisation for non-hospital care is unhelpful and could **compromise patient safety**.

Treatment that is performed in hospital and outside hospital varies from country to country and changes over time with advances in medical science.

The **principle of clinical necessity** should be established to prevent patients having unwarranted and inappropriate investigations and treatments. For example dental treatment: the clinical necessity of which is difficult to establish after the treatment has been completed.

The principle of clinical necessity exists within the English National Health Service (NHS) and is made operational by the requirement that a patient can only receive certain treatments if referred by a medical practitioner.

Non-hospital care:

- Requires similar levels of planning as hospital services – for example Magnetic Resonance Imaging (MRI), Computerised Tomography (CT) scans.
- Can be at least as expensive as hospital care
- Can be as complex and carry similar levels of risks to hospital care
- Requires similar information for patients on the quality and outcomes of procedures as care provided in hospitals so that patients can make an informed choice.

For reasons of patient safety, the planning of healthcare services, including prioritisation and allocation of resources within a cash limited system, prior authorisation should be required for all healthcare services for which, in the home healthcare system, a referral by a clinician is required.

Examples of non-hospital care where prior authorisation should be capable of being required:

- Surgery provided on a day-case basis: operations which used to require overnight stays in hospital on a day case basis, without the requirement for an overnight

stay. The number of these procedures is increasing (and is different country-by-country).
- Angiography and other invasive investigations
- Ionising radiation procedures e.g. CT scans

- Treatment programmes (eg chemotherapy) provided in the patient's own home by specialist staff

5. Legal certainty

The EU has recognized the special nature of health services by removing them from the Services Directive and by the Council of Ministers' statement on Common Values and Principles. These should either be enshrined in any future legal document related to Social Services of General Interest (from which at present health services are excluded), or within any proposed legal instrument concerning health services.

In addition, patients and healthcare commissioners and providers require legal certainty in the following areas:

- The member states are responsible for defining what healthcare services and treatments are available to their citizens
- Patients' entitlements to receive health care services in other countries and to be reimbursed for them, as outlined in current case law
- The country where treatment is provided must regulate the provider – whether the provider is temporary or permanent and whether it concerns an institution or individual healthcare professional. The regulator must share information on registration and fitness to practice.
- The need for clarity of:
    - The responsibility for the patient's care at any one time (this could be enabled by a written agreement between the patient, the provider and the home healthcare system)
    - The package of care to be provided, the follow-up and the need for patients to take out additional travel insurance
- The patient will be treated in the host country in accordance with the host country's regulatory system and standards of care. Consequently, any redress would be within the regulatory system and against the standards of care in the host country.
- Prior authorization must be applied to all care which in the home member state is subject to referral by a medical practitioner
- Regulatory bodies' ability to assess and address competency, language and cultural issues of foreign healthcare professionals working within the respective member states

6. Additional areas for improved co-operation between member states

There are a number of areas where it might be beneficial to improve the co-operation between member states which could be encouraged through non-legal methods open to the Commission, including:

- Impact assessments of EU policies' effect on healthcare systems

- The exchange and networking of healthcare specialists and facilitation of sharing evidence-based practice

7. No further action at EU level

NHS London **does not want to see action in** the following areas:

- The current definition of 'undue delay' is sufficient
  ('an objective medical assessment of the patient's medical condition, the history and probable course of his illness, the degree of pain he is in and/or the natire of his disability at the time when the request for authorization was made or renewed (Watts, 119))

- To create an EU healthcare record as this would be costly, complex and may compromise patient confidentiality. It is sufficient if the home healthcare system shares the individual patient's health record with the provider in the host country.

- To create common entitlement across the EU for all its citizens. Entitlement to healthcare must continue to reflect member states' healthcare needs, their cultural and ethical aspects, and their priorities of service provision within the resources available.

8. Cross-border provision of services (telemedicine, remote services etc).

Services can be distinguished between those provided by a healthcare professional who is present in person (and can therefore be required to register with the appropriate regulator in the respective member state), and services provided remotely by electronic ways[1].

The location, identity and authenticity of the provider of electronic health services cannot be easily identified during remote transactions.

The Commission should therefore facilitate the development of mechanisms (such as 'labeling' of e-health services, providing protection against false or malicious statements), and international agreements on supervision and safeguards, to ensure patient and professional protection.

[1] Prof M Rigby, Preliminary observations on the Consultation on Health Services

Appendix 1

Information on risks and implications

- Investigations may need to be repeated and results from diagnostic tests reviewed
- Lack of common language: medical jargon, different classification of diseases and disease stages, nomenclature, names for medication etc
- Communication with the patient's doctors in his/her home country
- Differences in clinical practice eg cancer surgery being performed by a general surgeon (compared with specialist surgeon within a multi-disciplinary team approach)
- Differences in procedures making follow-up in the home country more difficult (e.g. if a different procedure or prosthesis is used, medical staff in the home country may not feel competent to carry out the follow-up)
- Communication: between the provider and the patient; medical notes; diagnostic results and discharge information
- Transport of samples / information / X ray films etc

General information for patients about service providers

It is suggested that this should include:

- How the healthcare system is regulated and inspected, with names and contact details of the regulator and inspectorate
- To whom are clinicians accountable, appraisal process etc
- The processes in place to ensure good quality of care / clinical governance arrangements
- The process for redress, complaints procedure, ombudsman etc.

Specific information to include:

- Outcomes, mortality rates
- Complication rates/ hospital acquired infections etc
- What is included/excluded from the package of care purchased
- What happens if complications occur when the patient is in the host country, and after his return to the home healthcare system.

Patient information and issues that should be addressed through the prior authorisation system

- Different healthcare system and implications
- Outcome data
- Clinical governance arrangements, regulation, and inspection
- Language
- Insurance for repatriation
- Responsibility and mechanisms for redress, complaints procedure in the host country
- Administrative processes to be put in place (contract etc)
- An opportunity to ask questions
- Agreement on reimbursement of costs, and for which parts the patient would need to take out additional insurance

NHS London EU Unit
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