European Community action on health services:
A Memorandum to the European Commission DG SANCO on UK views

Contents

	Executive Summary	Page 2
1.	Introduction	Page 8
2.	Health services in the Member States and the scope for EU action	Page 9
3.	The specific consultation questions	Page 11
4.	Issues for Member States where health policy is devolved internally	Page 19
5.	The formation of European policy on health services	Page 19
6.	Pressures for change	Page 20

EXECUTIVE SUMMARY

Introduction

1. This memorandum from the Nuffield Trust offers a commentary on the European Commission's consultation, launched in September 2006, on possible community action on health services. This response is informed by the Trust's recent research programmes and by a series of discussions with representatives from a wide range of organisations across the health services of the four countries of the UK.

Health services in the Member States and the scope for EU action

2. It should be noted that, important though mobility impacts may be, they are only one of a variety of forces impinging on Member States' health systems and, in the view of many, not the most important one. ***Any policy outcome from the Commission's current initiative on health services can only be a partial response to a nexus of issues, problems and challenges.***

3. Health status, and health systems, increasingly are being affected not only by decisions taken by those responsible for health policy, but by policies, priorities and initiatives taken in other areas of government, such as trade and industry, economic development, education and labour law.

4. The very significant diversity among the health services of the 27 Member States poses a major challenge to any European Union initiative in health services. ***This should limit the EU's aspirations for introducing any legal instruments.***

5. Member States' health services are shaped by the differing national cultures and traditions, and organised and financed in different ways. Differences extend to ways that particular conditions are treated and managed, with no consensus necessarily existing on what is best practice. The structures of the professional workforces, their specialisms, the way they practice, the demarcation between different specialties or grades, and the ways professionals are regulated, varies widely.

6. ***The Commission does not always appear to appreciate sufficiently the substantial and deep-rooted differences between Member States' health systems, and the constraints these impose on potential EU-level actions.***

7. There are at least four important dimensions of diversity that need to be reflected in any European aspirations for a role in health services. They are the differing conception of illness; the basis for providing health care services; the nature of professional work; and the structure and regulation of health professions.

8. ***There is concern that what may appear at first as a 'clarification' exercise may evolve over time into a less acceptable legal intervention that the European Court may interpret in such a way as to infringe the subsidiarity principle.***

9. ***There is support for the explication of the arrangements applying when the citizen of one EU country are treated in another.*** There is doubt, however, that enshrining the values and principles in a legal framework will necessarily deliver the desired legal certainty.

10. ***Any attempt to use the outcome of the consultation to change current arrangements by instituting common healthcare entitlements across the EU would be both extremely difficult and, in many quarters, strongly resisted.***

The current impact of cross-border healthcare and how this might evolve

11. Cross-border healthcare currently is having little impact in the UK, although there are certain localities where the issues may have a greater impact. Should the volume of cross-border activity increase, the range of concerns that could arise includes cost pressures; equity; and quality of treatment.

12. Individual patients are expected increasingly to drive change in health systems by exercising the right to elect for treatment outside their home country. This will increase the pressure for the provision and operation of health services to be treated as market activities. ***Any such trend could lead to greater inequalities in 'home' health systems, or otherwise distort timely access to needed healthcare provision.***

What legal clarification and information are required to enable safe, high-quality and efficient cross-border care?

13. At present, often both EU citizens and purchasing and providing organisations are unsure about entitlements. ***If the EU consultation did no more than produce a clarification of these entitlements then it would be worthwhile.***

14. There are two separate routes for patients seeking treatment in another EU country, depending on whether the treatment is organised by a commissioning body or by the patient, to which different considerations apply. ***It would be helpful to clarify each of these in terms of entitlements; control arrangements; aftercare; and liability.***

What issues should be the responsibility of the authorities of which country?

15. A patient contemplating treatment in another EU country should be aware of the financial support to which he or she is entitled; the competence of the provider who will undertake the treatment; the nature of the patient experience; arrangements for after-care; and means for seeking redress if problems arise.

16. Where patients' treatment in another country is being arranged by a 'commissioning body', that body has a responsibility to inform the patient on all these matters. Where a patient makes his or her own arrangements, the principle of 'caveat emptor' normally should apply. ***The meaning of consent to treatment might be widened so that provider bodies ensure that patients are aware of the potential consequences of being treated in another country.***

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

17. ***When arrangements for patients to be treated abroad are made by commissioning bodies, those bodies should be responsible for safety and redress issues. For patients making their own arrangements, the responsibility must lie with the provider organisation.***

What 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?

18. Should numbers seeking cross-border healthcare rise significantly, arrangements for financial compensation by "receiving" countries would be appropriate. ***Without this, the capacity of these services to meet the needs of the resident populations of the countries concerned might be impaired.***

Are there further issues to be addressed regarding movement of health professionals or establishment of healthcare providers?

19. For the majority of those consulted by the Nuffield Trust, issues arising from professional mobility are currently of much greater concern than those arising from patient mobility. The two principal concerns are about competence and language skills.

20. At present, EU arrangements mean that national regulatory bodies can address neither the issue of the *current* competence nor that of the language skills of health professionals from other EU states. ***There are strongly felt opinions that these matters need urgent action at EU level.***

21. ***Such action should include empowering the competent authority in the host state with the legal ability to:***
    - ***require registration when a healthcare professional has moved to another Member State to provide services;***
    - ***test the language competence of all health professionals where their first language is not that of the Member State in which they seek registration.***
    - ***impose a legal duty on regulators to exchange regulatory and disciplinary information and to act on it, in the interests of patient and public safety.***

Are there other issues where legal certainty should also be improved in the context of each specific health or social protection system?

22. The issues identified where legal certainty should be improved fall into four main categories, how the process of patient mobility can be organised and controlled; the risk management implications; the supporting information requirements and systems needed; and issues of governance, accountability and regulation.
23. The fundamental assumptions supporting mobility should be that:
    - Health care systems can only be held responsible within national borders.
    - Patients must understand that if they go abroad for treatment there will be risks.

- If the 'home' health system limits legal exposure, patients cannot sue it if they go abroad for treatment and things go wrong. The host system must accept responsibility

24. The interests of *all* patients must be considered as mobility increases, and in this respect the requirement for prior authorisation of treatment abroad is a protection. ***The EU must confirm the legality of the requirement for prior authorisation of treatment abroad.***

25. ***There must be confirmation that terms of redress of the provider state applies to treatment where individual patients exercise their rights to mobility. Commissioners or purchasers in the patient's home country cannot provide quality control or redress in such circumstances.***

26. ***The EU should clarify the application to health services of ECJ case law, which always supersedes any directive.***

What tools would be appropriate to tackle the different issues related to health services at EU level?

27. Without significant 'technical' knowledge about the operation of Community law and Community institutions, people find it difficult to decide between the use of legislative and non-legislative action. Two proposals for positive action by the EU are identified, and a further two areas cited where the general view is that it would be better if the EU did not involve itself. However, specific guidance on the relative merits of legislative or non-legislative action is not identified.

28. The first intervention, discussed in paragraphs 19-21 above, is addressed at enabling member countries' healthcare regulatory bodies better to address the issues of professional competence and language skills.

29. The second proposal is for action by the EU to improve its assessment of the impacts on health of EU initiatives in other fields, such as employment and competition policies. The recent introduction of health impact assessment methodology is welcomed but more needs to be done to improve its application.

30. While identifying the recommendations reported above, ***the Nuffield Trust's discussions have revealed virtually no support for the establishment of EU-level regulatory and provider assessment organisations or machinery.*** The most that would be acceptable would be a 'regulator of regulators' role, limited to setting standards to which member countries' regulatory and provider assessment bodies should aspire, and monitoring their achievement of these. Similarly, any EU locus in standard setting should be limited.

31. ***While patient mobility will bring requirements for the transfer of patient information across borders, this should not be used as an argument for the introduction of a European electronic health record.*** When particular patients exercise rights to mobility, the specific health records that apply to the proposed intervention should be transferred.

Issues for Member States where health policy is devolved internally

32. The United Kingdom is one of a number of Member States where responsibility for health policy, and the organisation and management of health and social services, is devolved wholly or partially from the national government.

33. In such countries, there will be concern lest actions at European level prejudice the key principle of subsidiarity, and constrain choice in the way local services are secured, provided and accessed. ***Issues arising from internal differences within a Member State in policy and organisation of health services should be for the particular Member State to determine. Any action by the EU on health services must reinforce the principle of subsidiarity.***

The formation of European policy on health services

34. Given the complexity and the inter-relatedness of all the issues, there is a concern about the timescale of the consultation, which is shorter than in many other cases, and also disrupted by the recent holiday season.

35. So daunting is it to unpick all the relevant issues raised by the consultation that the Trust 's evidence indicates that some organizations have abandoned hope of responding in the timescale required. And there are other organisations which may be unaware of the consultation or its full implications.

Pressures for change

36. Issues of patient choice and patient wishes are expected increasingly to drive the health systems of the Member States. Although much of the drive is likely to come from "information rich, choice rich" health service consumers, the pressures will be hard to resist whatever is the impact on resources, choice and availability for the wider population.

37. To date, ECJ judgements in a small number of cases concerning health care have created turbulence far beyond the numbers involved. There is support for the consultation's focus on the need to "improve clarity to ensure a more general and effective application of freedoms to receive and provide health services". While greater clarity is needed about what people are entitled to, some doubt whether the proposed initiatives will produce such clarity.

38. As well as single market legislation, labour market regulation and regulations impacting on the qualification, regulation and mobility of professionals also have very significant impacts on health systems. Addressing these needs a wide perspective, looking at general competition law and the market in health services.

39. One effect of patient mobility proposals may be reduced access for other patients. The EU needs to protect those who might otherwise be the losers from an increase in mobility. One important way of doing this is to sanction the building in by Member States of safeguards which they can operated, and which will be respected by the European Court of Justice.

40. ***In the UK there is strong support for the Commission's assertion that policy development should result from political consensus, and not solely from case law.*** While the current consultation focuses on health services, the rights to an adequate public health system are not as clear as the rights of access to health services, and consequently the amount of public protection varies. ***The EU should work to support the improvement of public health systems across all Member States.***

41. ***There is widespread welcome for the Commission's statement that it is not its intention to bring about the harmonisation of national health or social security systems.***

42. Because of the potential long-term significance of the European Union adopting a role in the area of health services, and the potential for unexpected consequences from policy change, it is particularly important that those running health services are fully engaged throughout the process of developing EU policy on health services.

European Community action on health services:

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1. Introduction

1.1 In September 2006, the European Commission announced a period of consultation on possible community action on health services.

1.2 The Nuffield Trust aims to improve the health of the people of the UK, to improve the quality of healthcare and to improve the quality of health policy. Recently, the Trust has been examining through a series of seminars, visits and other initiatives the growing importance, and impact, on health policy of the European Union.

1.3 In the four countries of the United Kingdom the health systems continue to espouse the original principles articulated by Bevan in 1947. However, there are significant, and growing, differences in the way the different systems are organized, regulated and governed

1.4 Health status, and health systems, increasingly are being affected not only by decisions taken by those responsible for health policy, but by policies, priorities and initiatives taken in other areas of government, such as trade and industry, economic development, education and labour law.

1.5 The European Commission's consultation addresses a highly important but complex and inter-related set of issues. The Trust has produced this contribution to the Commission's consultation, to:

- ensure that the consultation is informed by the perspectives of all the key policy areas (including health, education, research, trade and industry, etc.) necessary to provide a comprehensive assessment of the different proposals.
- identify and illuminate those issues, if any, on which there may be differences of view

1.6 As the Trust took steps to gather information and opinion on the impact of the European Union on the UK's national health services, it became clear that one side-effect of its actions was that they raised awareness of the consultation, and of the possible significance of the eventual outcomes. Neither the consultation nor the possible outcomes were as well-known across the different health communities as they might have been.

1.7 The Trust sought to involve, inter alia:
- Health service providers, from primary, secondary and tertiary care, including (from England) Foundation Trusts and third sector providers
- 'Commissioners' of health services
- Patients' representatives
- Regulators
- Bodies responsible for medical, nursing and related education and training

- Trade, industry and economic development bodies, including those involved with labour law and workforce issues
- The Health Departments of all the UK's Devolved Administrations.

1.8 The Trust wishes to express its thanks to all those who contributed to these different activities, and to the valuable insights they provided. These have informed the drafting of this paper, but the Trust is solely responsible for the analysis, interpretation and conclusions contained herein. It also accepts responsibility for any errors of fact or omissions.

1.9 The Commission's paper identifies four categories of cross-border healthcare, of which patient mobility is only one, all of which are intended to be covered by the consultation. The Trust's experience in the different discussions in which it has engaged suggests that it is likely that the issue of patient mobility will dominate most responses, important thought the other manifestations of mobility are.

1.10 However, mobility issues are only one of a variety of forces impinging on Member States' health systems and, in the view of many, not the most important one. ***Therefore any policy outcome from the Commission's initiative can only be a partial response to a nexus of issues, problems and challenges.***

1.11 The Commission's consultation is structured around nine questions. These questions are addressed below, following which some observations about the potential wider and longer-term developments wider issues are made.

2. Health services in the Member States and the scope for EU action

2.1 The evidence offered during the Trust's consultations points clearly to the very significant diversity among the health services of the 27 Member States. ***This diversity poses a major challenge to any European Union initiative in health services, and should limit the EU's aspirations for introducing any legal instruments.***

2.2 It is not just that Member States' health services are shaped by the differing national cultures and traditions, and organised and financed in different ways. The expert clinicians and specialists consulted stressed that the way particular conditions are treated and managed varies widely across Europe, with no consensus necessarily existing on what is best practice. Further, the structures of the professional workforces, their specialisms, the way they practice, the demarcation between different specialties or grades, and the ways professionals are regulated, varies widely.

2.3 There are at least four important dimensions of diversity which need to be reflected in any European aspirations for a role in health services. They are:

- **The conception of illness**.
  What are perceived as health problems in some countries and routinely treated as such, for example low blood pressure, are not regarded as problems in others and no treatment

is offered. And what constitutes some health problems, and how they are best treated, also differs across countries. An example here is mental ill health, where the UK is much more oriented to treatment in the community than some other Member States.

- **The basis for providing health care services**.

  Services in some EU countries are insurance based, while in others are provided as public services funded from general taxation. Even within countries there can be substantial variations in how services are organised. For example, in the UK, services in England are moving to a more commercial basis, with explicit pricing policies and the notion of contestability, whereas in Wales this trend is being resisted and the traditional public service model is being retained. Further, there are variations in patient entitlements even within apparently uniform systems. For example, in England a commissioning body in one area might pay for a specific form of treatment, while a similar body elsewhere might not. This effectively gives patients within the country different entitlements.

  All these differences needed to be taken into account when trying to make any EU-wide policy statements on healthcare and, especially, citizens' entitlements to healthcare.

- **The nature of professional work**.

  There are major differences in professional practice in EU countries. For example:
    - in the UK, patients with cancer are treated by oncologists or other consultants specialising in cancer treatment. In some EU countries there is less specialisation and many senior doctors treat some patients with cancer as part of their practices;
    - some clinical procedures which are undertaken in the UK by non medical professional staff (under the auspices of a consultant) are, in other countries, always undertaken by senior medical staff.

- **The structure and regulation of health professions**.

  There are differences between countries, especially in respect of the professions allied to medicine. In the UK, for example, non medically qualified chiropractors are allowed to practice, but not, it is believed, in France.

2.4 ***Those consulted by the Trust have strongly expressed the view that the Commission does not always sufficiently appreciate the substantial and deep-rooted differences between Member States' health systems, and the constraints these impose on potential EU-level actions.*** There are also some who are unclear of the Commission's objectives in seeking to involve itself directly in health service matters. They ask if the consultation is intended to lead to an intervention that will clarify the complexity of existing arrangements which relate to patients from one EU country being treated in another, or whether it is seen as a vehicle to assist in changing those arrangements.

2.5 The development over time of the EU's role in public health and, now, healthcare, is noted. Some people view this positively, as 'logical incrementalism'. Others, drawing on past experience, are wary of the emergent nature of policy-related issues, and caution against

'mission creep'. They are concerned lest, a little further down the track, they may find themselves in a place they never imagined, coping with problems they did not expect.

2.6 ***There is understandable concern that what may appear at first as a 'clarification' exercise may evolve over time into a less acceptable legal intervention which the Court may interpret in such a way as to infringe the subsidiarity principle.***

2.7 The Commission's Common Values and Principles paper states:

> *"We believe there is particular value in any appropriate initiative on health services ensuring clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and in enshrining these values and principles in a legal framework in order to ensure legal certainty."*

There is general support for the first part of this statement, the explication of the arrangements applying when the citizen of one EU country are treated in another. There is doubt, however, that enshrining the values and principles in a legal framework will necessarily deliver the desired legal certainty.

2.8 ***Any attempt to use the outcome of the consultation to change current arrangements by instituting common healthcare entitlements across the EU would be both difficult and, in some quarters, strongly resisted.***

2.9 These general remarks form the background to the following discussion of the nine questions of the Consultation document.

3. The specific consultation questions

Consultation 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?

3.1 At present there is relatively little data readily available on patient mobility in Europe. The evidence suggests that currently cross-border healthcare is having relatively little impact in the UK. Commissioning bodies have paid for some patients to be treated in other countries, usually for conditions where waiting times in the UK have been long. Additionally, some patients are making their own arrangements and seeking re-imbursement from the NHS. Numbers in both categories currently are small (a few hundred cases per year) and recently have actually been falling as waiting lists decrease.

3.2 Similarly, there is little indication at present that large numbers of people are coming to the UK for elective procedures from other EU countries. This situation could change as new countries with less developed healthcare systems join the Community.

3.3 It is recognised, however, that there are certain 'hot spots' where patient mobility is a much more significant concern, for example where significant numbers of citizens retire, or spend

significant parts of the year, abroad. These people require access to the local health services, and the added demand creates problems for the providers concerned. Similar pressures arise in locations which are popular tourist destinations.

3.4 The limited size of current cross-border healthcare in the UK as a whole nevertheless masks localities where the issues may have a greater impact, for example the south east of England (patients travelling across the Channel) , and the areas of Northern Ireland bordering the Irish Republic. It is believed that the EU has some as yet unpublished research studies on these and similar cross-border flows in other countries. It would inform discussion if these studies could be made available.

3.5 If the extent of cross-border healthcare increases a range of concerns are identified. These include:

- **Costs**

3.6 If patients are entirely free to choose to receive elective healthcare in other EU countries, with the home country meeting the costs, it could generate significant cost pressures. At present, waiting times are the most obvious manifestation of rationing, and the ability to "beat the queue" by going to another country for quicker treatment could mean either pressure for more resources, or a reduction in resources to home providers as money has to be withdrawn to meet the costs of treatment in other countries.

3.7 Costs could rise in two further ways. First (and depending on where responsibility is laid) from any cost of putting right any overseas treatment that has gone wrong, and of compensating patients concerned. Second, by any attempt to give patients being treated abroad a right to support costs, such as transport. If any such entitlement is established on an EU-wide basis, and the home health services have to meet part of the travel costs of any patient being treated in another EU country, it would represent an additional and possibly significant extra cost to the services.

- **Equity**

3.8 The ability of patients to secure treatment abroad has implications for equity as well as cost. Effectively, patients placed lower down a waiting list for reasons of clinical priority who are willing to be treated abroad might not only get treatment more quickly than those higher up the list who prefer to be treated at home, but - depending on the financing arrangements - might even delay the treatment of those patients.

- **Quality of treatment**

3.9 A patient being treated in one EU country but normally resident in another might well need aftercare, which is most realistically given by a local provider in his or her home country. In principle this would not be too difficult to arrange, but in practice there are likely to be delays, e.g. in the home country provider service receiving discharge notes in the appropriate language, which could be detrimental to the patient's care.

3.10 Looking to the future, the Trust's consultation identified expectations that individual patients will increasingly seek to drive change in health systems, by exercising the right to elect

for treatment outside their home country. If they do so, this will increase the pressure for the provision and operation of health services to be treated as market activities. ***As detailed above, there is concern that any such trend could lead to greater inequalities in 'home' health systems, or otherwise distort timely access to needed healthcare provision.***

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

3.11 EU judicial cases have demonstrated the lack of clarity within EU countries about citizens' existing entitlements to healthcare. At present not only are citizens often unsure about their entitlements, but purchasing and providing organisations too are sometimes unclear, for example about from whom and how they can claim re-imbursement. ***If the EU consultation did no more than force a clarification of these entitlements then it would be worthwhile.***

3.12 There are two separate routes for patients seeking treatment in another EU country. In some cases a commissioning body will arrange the treatment. In others a patient will make his or her own arrangements and then seek re-imbursement from the commissioning body. Different considerations apply to these two circumstances. ***It would be helpful to clarify each of these in terms of entitlements; control arrangements; aftercare; and liability:***

- **Entitlements**

3.13 What are the entitlements of citizens to be treated in other EU countries? For example, to what costs are patients seeking treatment in other EU countries entitled? To the extent that such treatment can be initiated without the consent of a commissioning authority, on what basis (home country costs or costs in the EU country providing the treatment) does the home authority have to pay?

3.14 An important consideration is whether any EU policy would respect a home government's "gate-keeper" role as regards entitlement to specific services, e.g. its ability to determine that specific forms of service should not be made available, or to devolve such decisions to commissioning bodies to decide in the light of local circumstances and priorities, thus effectively allowing variations in entitlements.

- **Control arrangements**

3.15 Do a citizen's entitlements transcend another EU country's control arrangements? For example, under current UK legislation there is a cap on the number of private patients that NHS Foundation Trusts can treat. The body established to regulate such Trusts will require them to comply with this limit. If patients from other EU countries seek treatment at UK Foundation Trusts in sufficient numbers that the Trusts reached the private patient cap, could further patients' entitlement to seek treatment in the UK be limited by the existing UK legislation?

- **Aftercare**

3.16 Who is responsible for aftercare – the provider who treats a patient or the relevant

provider in the patient's normal residence?

- **Liability**

3.17 Who is responsible for compensating the patient if things go wrong – the provider (or provider's health care system) or the relevant UK commissioner? Does the latter's potential duty to the patient include checking that the provider is competent to undertake the procedure.

3.18 It is important that any EU action on health services produces clarity and certainty in the answers to such questions.

Consultation question 3: What issues (e.g. clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for different kinds of cross-border healthcare?

3.19 A patient contemplating treatment in another EU country needs to know about a range of issues before deciding to go ahead with such treatment. The issues include

- the financial support to which he or she is entitled;
- the competence of the provider who will undertake the treatment;
- the nature of the patient experience, which differs between countries, with for example more expected of relatives in some than others;
- arrangements for after-care; and
- means for seeking redress if problems arise.

3.20 For patients whose treatment in another country is being arranged by a commissioning body, that body has a responsibility to inform the patient on all these matters.

3.21 Where a patient makes his or her own arrangements, often without any involvement on the part of the local commissioning body, the principle of 'caveat emptor' normally should apply. ***The meaning of consent to treatment should be widened, so that provider bodies ensure that, when agreeing to treatment, patients are aware of the consequences of being treated in another country in terms of matters such as aftercare and the seeking of redress if problems arise .***

3.22 Specifically in terms of cost, where a patient is being treated in another EU country through arrangements made by a commissioning body or other authority in his or her normal country of residence, the principle should be that the commissioning body should be responsible for costs up to the level of those applying in the country of residence. Where a patient makes his or her own arrangements and seeks re-imbursement, any responsibility on the commissioning body's part should be limited to the costs applying in the country where the treatment is provided.

Consultation 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?

3.23 ***In the case of patients whose arrangements to be treated abroad are made by***

commissioning bodies, those bodies should be responsible for safety and redress issues.

3.24 ***For patients making their own arrangements, the responsibility must lie with the provider organisation.***

Consultation 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)?

3.25 Several points relevant to this Question have been considered above, namely the right of a country to determine the form of health services to which its citizens are entitled, including devolving decisions on provision in a way that means there could be different entitlements in different parts of the country.

3.26 At present, it seems that the numbers of EU citizens exercising their rights to mobility to access healthcare are not large enough to raise nationally significant financial issues. Should this change, for example as a result of further countries joining the EU, arrangements for financial compensation by "receiving" countries would be appropriate. ***Without this, the capacity of these services to meet the needs of the resident populations of the countries concerned might be impaired.***

Consultation 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?

3.27 The Trust's consultation clearly indicates that issues arising from professional mobility are currently of much greater concern than those arising from patient mobility. They are considered to have very considerable implications for the quality of care and patient safety. The issues are seen as of great significance for the operation of health services in general. Issues arising from professional mobility have been addressed in detail by the Alliance of UK Health Regulators on Europe in its response to the Commission's consultation. The evidence collected by the Nuffield Trust is entirely consistent with this submission.

3.28 There are two principal concerns, about competence and language skills. The competence of doctors and other professional staff trained in many other EU countries is likely to be of a standard broadly comparable to that of UK trained staff, though this is not necessarily true of all Member States. Even where professionals are trained in those countries where this is the case, there are differences in approach which are reflected in training. However, it is about language skills that current concern appears to be greatest, since these may cause the greater potential hazard to patient safety.

3. 39 In order to provide high quality and safe care, healthcare professionals must be able to communicate effectively with their patients and with other members of the healthcare team. Without adequate language competence there can be misunderstandings in discussions with patients or professional colleagues, misreading of notes, etc. Therefore, healthcare

professionals are required them to be proficient in the language or languages of the country in which they are working.

3.30 Currently, EC law enables European regulators only to be satisfied about an individual's professional qualifications before he/she is registered and able to take up practice in a host state. They are not permitted to satisfy themselves about the individual's language proficiency. In effect this means that the present EU arrangements leave national regulatory bodies unable to address either the issue of the *current* competence or the language skills of health professionals from other EU states.

3.31 On language competence in particular, it is sometimes thought that this can be addressed by employers. While it is true that employing authorities can take account of language competence, this ignores the fact that many healthcare professionals and workers are independent practitioners. It is considered vital that healthcare regulators across Europe should be able to establish at the point of registration that a professional has the level of language proficiency necessary to practice safely. ***European legislation must be amended to allow this.***

3.32 Since healthcare professionals must have good communication skills in order to practice safely and effectively, they must be required to be proficient in the language or languages of the country in which they work. This means that the relevant authorities should have the legal ability to test the language competence of all health professionals where their first language is not that of the Member State in which they seek registration. The language competence issue is relevant to the provision of healthcare generally, not only to cross-border care. ***There are strongly felt opinions that the matter needs urgent action at EU level.***

3.33 One issue which does relate specifically to patient mobility across borders is that of the regulatory regimes which should apply for doctors and other health professionals involved. In some particular locations, depending on local geography and travel/communications factors, there can be circumstances in which patients choose to access health services across a border rather than use their domestic service, which might actually be provided further from their place of residence.

3.34 Local arrangements may be developed to deal with the regulatory regimes that should apply in particular circumstances of cross-border patient mobility. Without such local arrangements, the situation might arise where practitioners will be required to accept dual accountability to different national medical bodies. This could introduce varying, or even conflicting, requirements. Therefore, the over-riding principle which must apply is that all healthcare professionals must be registered with the competent authority for the country in which they practice.

Consultation 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 to facilitate cross-border healthcare?

3.35 This consultation question raises a large number of issues for consideration. In the Nuffield Trust's discussion, the issues identified fell into four main categories, relating to:
- How the process of patient mobility could be organised and controlled
- The risk management implications of patient mobility
- The information requirements and systems to support patient mobility
- Issues of governance, accountability and regulation

3.36 It is suggested that there are a number of fundamental assumptions:
- Health care systems can only be held responsible within national borders.
- Patients must understand that if they go abroad for treatment there will be risks.
- If the 'home' health system limits legal exposure, patients cannot sue it if they go abroad for treatment and things go wrong. In such situations, the host system must accept responsibility

3.37 Some key principles are suggested. These include:
- The interests of *all* patients must be considered as mobility increases, and in this respect prior authorisation for treatment abroad is a protection.
- ***The EU must confirm the legality of the requirement for prior authorisation of treatment abroad.***
- ***There must be confirmation that terms of redress of the provider state applies to treatment where individual patients exercise their rights to mobility. Commissioners or purchasers in the patient's home country cannot provide quality control and redress in such circumstances*** (although they can if overseas treatment is provided as part of contracts entered into by purchasers.)
- The EU should impose duties of information disclosure/sharing on national regulators.
- ***The EU should clarify the application of ECJ case law, which always supersedes any directive.***

Consultation 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?

3.38 This question was considered to be too general to be address in a consultation focused purely on patient mobility. Several of the issues discussed in response to other questions also apply to health services more generally. The comments above about the competence and language skills of healthcare professionals from one EU country working in others are thought to be especially important.

Consultation 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?

3.39 Those involved in the Nuffield Trust's consultation found this a particularly hard question to which to respond, particularly since deciding between legislative and non-legislative action was considered to require rather more 'technical' knowledge about the operation of Community

Law and Community institutions than many people felt they possessed. Thus, while the Trust's communication resulted in the identification of two ideas for positive action by the EU, and a further two areas where the general view is that it would be better if the EU did not involve itself, specific guidance on the relative merits of legislative or non-legislative action was not identified.

3.40 The first intervention that received support is one addressed at enabling member countries' healthcare regulatory bodies better to address the issues of professional competence and language skills (see above).

3.41 The second area of support would be action by the EU to improve its assessment of the impacts on health of EU initiatives in other fields, such as employment and competition policies. The recent introduction of health impact assessment methodology is welcomed but more needs to be done to improve its application.

3.42 Two further areas were identified in which some believe the Commission will argue for a role, but where any proposed role is viewed with considerable caution. These are roles in relation to healthcare regulatory bodies and provider assessment.

3.43 It is recognised that some may argue for the establishment of EU-level regulatory and provider assessment bodies. ***The views the Trust received indicate virtually no support for the establishment of such bodies, and considerable concern about the prospect.*** There is support for the application across Europe of some common principles regarding safe and high quality healthcare. In particular, fundamental principles of standards and ethics (such as consent and patient confidentiality) should be embedded in national standards and codes of practice. ***But the idea of establishing a common ethical framework across the EU is believed to be unworkable, not least because it is important for member states to have the flexibility to take different decisions about the care they provide, and how they provide it, based on local cultural values and circumstances.***

3.44 There are considerable concerns about the costs and bureaucracy involved in any Community level regulatory and/or provider assessing machinery, and the majority appear to consider it better if the EU does not get involved at all. At the very most, all that would be acceptable would be a restricted 'regulator of regulators' role for the EU, limited to setting the standards to which member countries' regulatory and provider assessment bodies should aspire, and monitoring the achievement of such standards.

3.45 It is accepted that patient mobility will bring requirements for the transfer of patient information across borders. ***It is strongly argued that patient mobility should not be used as a justification for the development of a European electronic health record.*** Any such requirement would not only be formidably complex in terms of technology and systems, but inordinately expensive and would impose an unacceptable burden on the already stretched budgets of Member States. If particular patients want to exercise rights to mobility, the answer should be to transfer the specific health records that apply to the proposed intervention.

4. Issues for Member States where health policy is devolved internally

4.1 The United Kingdom is one of a number of Member States where responsibility for health policy, and the organisation and management of health and social services, is devolved wholly or partially from the national government. Political devolution now means that the responsibility for health policy, and the organisation and management of health and social services, is devolved from Westminster. The devolved administrations in Northern Ireland, Scotland and Wales now have responsibility for these policy areas.

4.2 Currently, all the national health systems within the UK continue to espouse the original principles of the National Health Service, first articulated in 1947. However, there are significant and growing differences in the ways in which the different national systems are organised, regulated and governed.

4.3 In countries which such internal devolution of responsibility for health services, there will be concern lest actions at European level prejudice the key principle of subsidiarity, and constrain choice in the way local services are secured, provided and accessed. ***Issues arising from internal differences within a Member State in policy and organisation of health services should be for the particular Member State to determine. Any action by the EU on health services must reinforce the principle of subsidiarity.***

5. The formation of European policy on health services

5.1 The Commission's consultation paper identifies four kinds of cross-border healthcare, all of which are intended to be covered by the current consultation, namely cross-border provision of services; use of services abroad -referred to as 'patient mobility'; permanent presence of a service provider; and temporary presence of persons (mobility of health professionals).

5.2 Despite this intention, the questions posed in the consultation document appear not to address all of these categories equally. If the Trust's experience is typical, it is likely that responses will focus largely on issues of patients moving abroad to receive services, which is normally termed 'patient mobility'. However, as discussed above, some of the questions raise issues which apply to health services more widely.

5.3 Both at national and European level, it is not only Health Departments/Directorates that are concerned with the issues raised by the consultation. Some of the categories of mobility will be the concern of government departments or EC Directorates dealing with matters of trade and industry, education etc. It is important that, at both national and European level, there is 'joined up' consideration of the issues raised by the consultation involving all the relevant arms of government, and all the key stakeholders. It is also particularly important that those running health services are engaged fully in formulating the appropriate responses.

5.4 Given the complexity and the inter-relatedness of all the issues, there is a concern about the timescale of the consultation, which is shorter than in many other cases, and also disrupted by the holiday season. It is not clear to many of those the Trust consulted why the time allowed for the consultation is so short, especially given the complex nature of the issues raised. So daunting is it to unpick all the relevant issues that the Trust believes that some organizations have in effect abandoned hope of responding in the timescale required. And there are other organisations which were unaware of the consultation or its implications.

5.5 Because of the potential long-term significance of the European Union adopting a role in the area of health services, and the potential for unexpected consequences from policy change, it is particularly important that those running health services are fully engaged throughout the process of developing EU policy on health services.

6. Pressures for change

6.1 The Trust heard many opinions to the effect that patient choice and patient wishes would increasingly drive the health systems of the Member States to respond. Although much of the drive is likely to come from "information rich, choice rich" health service consumers, the pressures will be hard to resist whatever is the impact on resources, choice and availability for the wider population.

6.2 The Nuffield Trust's exercise has identified a number of positive aspects of the European role in health services, which any response should note. However, the series of judgements by the ECJ, and the growing body of case law it is creating, do create problems for the providers of health services. The ECJ judges, in applying single market principles to the cases before them, are not necessarily aware of all the impacts of their decisions on the health systems concerned.

6.3 To date, ECJ judgements in a small number of cases concerning health care have created turbulence far beyond the numbers involved. There is support for the consultation's focus on the need to "improve clarity to ensure a more general and effective application of freedoms to receive and provide health services". While greater clarity is needed about what people are entitled to, some doubt whether the proposed initiatives will produce such clarity.

6.4 It is further noted that Single Market legislation is not the only cause of difficulty the EU generates for those responsible for health services and health systems. Labour market regulation, such as the European Working Time Directive, and regulations impacting on the qualification, regulation and mobility of professionals also have very significant impacts. Therefore, while the consultation document may give an opportunity to resolve some of the issues, it is argued that its view based simply on ECJ case law is too narrow. It needs a wider perspective, looking at general competition law and the market in health services.

6.5 This having been said, it is argued that mobility issues do need EU solidarity. One of the main priorities in discussing mobility is to protect those who might be the real losers. One way of doing this is to view any proposals through an "inequalities lens". One effect of

patient mobility proposals may be reduced access for other patients. The EU needs to protect those who might otherwise be the losers from an increase in mobility. One important way of doing this is to sanction the building in by Member States of safeguards which they can operated, and which will be respected by the European Court of Justice.

6.4 Where the 'narrow' issue of patient mobility issue is concerned, the key areas include how:

- the processes are managed
- risk is managed, both by individuals and by health systems
- information is provided to support patient mobility
- issues of governance, accountability and regulation are handled
- the likely financial impacts can be controlled.

The preceding paragraphs outline the suggestions on how these and other points can be addressed.

6.5 ***In the UK there is strong support for the Commission's assertion that policy development should result from political consensus, and not solely from case law.*** While the current consultation focuses on health services, the rights to an adequate public health system are not as clear as the rights of access to health services, and consequently the amount of public protection varies. A potential benefit of the EU lies in its ability to support the improvement of public health. ***The EU should work to support the improvement of public health systems across all Member States.***

6.6 If there is concern about the nature of some of the decisions already made by the Court, there is also concern that the current proposals may not be able to "wind the clock back". Some question the possible effectiveness of any Community action in bringing about the stated objectives of providing legal clarity.

6.7 Any move by the European Union to give itself a locus in the provision of health services is bound to be controversial. It is recognised that the Commission's consultation paper explicitly states that it is not its intention to bring about the harmonisation of national health or social security systems. ***There is widespread welcome for this statement by the Commission.***

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