

Title: EU Directive on Patients' Rights in Cross-border Healthcare IA No: 6013 Lead department or agency: Department of Health Other departments or agencies:	Impact Assessment (IA)		
	Date: 16/11/2012		
	Stage: Consultation		
	Source of intervention: EU		
	Type of measure: Primary legislation		
Contact for enquiries: Rob Dickman 0207 210 5439 Rob.Dickman@dh.gsi.gov.uk			
Summary: Intervention and Options			RPC Opinion: Awaiting Scrutiny

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, One-Out?	Measure qualifies as
£7.0m	£0	£0	No	NA

What is the problem under consideration? Why is government intervention necessary?

On 24 April 2011, Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, came into force. Member States are responsible for ensuring that their national legislation is consistent with European law. Where it is not, they must amend existing provisions, and introduce new law as necessary.

The Government is obliged to transpose the Directive's requirements into national law by 25 October 2013.

What are the policy objectives and the intended effects?

Transposition aims to ensure the application in UK law and policy of the legally binding provisions of the Directive:

- Clarification of established case law on patients' right to access health care elsewhere in the EEA;
- Setting out the grounds on which patients can claim reimbursement, from their home health system, for the costs related to such care;
- Equal application of patients' rights for all EU citizens;
- Improved information and better clarity on the rules that apply.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing: no transposition of the directive - this is option would mean the UK was non-compliant with EU legislation. Therefore this option is not viable as it could lead to diplomatic harm, legal action and significant financial penalties.

Option 2: "Intelligent copy-out" transposition of the directive - tranpose the directive in to UK legislation using "copy out" where appropriate, but ensuring that legislation is applicable and relevant domestically. Pure copy out is not possible due to the directive being open for domestic specification and clarification.

Transposition of the driective involves ensuring that rights and duties are clearly set out and enforceable. As such, many of the Directive's provisions do not to lend themselves to non-regulatory solutions.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: Month/Year						
Does implementation go beyond minimum EU requirements?			No			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		Micro No	< 20 No	Small No	Medium No	Large No
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)			Traded: unknown		Non-traded: unknown	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: Anna Soubry Date: 05 February 2013

Summary: Analysis & Evidence

Policy Option 1

Description: No transposition of the directive

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 0

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

Other key non-monetised costs by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	0	0	0

Description and scale of key monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

Other key non-monetised benefits by 'main affected groups'

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline.

Key assumptions/sensitivities/risks

Discount rate (%) N/A

In line with impact assessment guidance the do nothing option has zero costs and benefits as impacts are assessed as marginal changes against the do nothing baseline. The do nothing option would mean that England, thus the UK would be non-compliant with EU legislation which could cause diplomatic harm and lead to legal action and significant financial penalties.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:	In scope of OIOO?	Measure qualifies as
Costs: 0	No	NA
Benefits: 0		
Net: 0		

Summary: Analysis & Evidence

Policy Option 2

Description: "Intelligent Copy Out" transposition of the directive

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£1.6m	High: Optional	Best Estimate: £7.0m

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£0.5m	£0.3m	£3.4m

Description and scale of key monetised costs by 'main affected groups'

The main direct costs are the set up costs for a National Contact Point as well as the costs of operating cross-border health care functions at a centralised level. At this stage it is not clear exactly what form these functions will take, nor how they will operate. The costs provided are indicative estimates only and are likely to be cautious. We seek to refine these estimates through the consultation period. These costs will be born by DH/NHS.

Other key non-monetised costs by 'main affected groups'

It is unclear to what extent the transposition of this Directive will lead to an increase in patients utilising their cross border rights. There may be costs to patients and society of reduction in health for some, and health inequalities. There may also to be costs to providers (both NHS, private & third sector) if there is reduction in demand for domestic provision in particular treatments or localities. In addition, patients utilising cross border care may incur private costs e.g travel.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate	£0	£1.2m	£10.3m

Description and scale of key monetised benefits by 'main affected groups'

It is expected that there will be a cost saving as the administration of cross border health is centralised. This will reduce administrative burden on local commissioners while, at the same time, a critical mass of expertise and economies of scale are exploited, which will generate overall savings to the NHS. The assumed current costs of administration are based on early assumptions and limited evidence. We will seek to refine our estimates over the consultation period.

Other key non-monetised benefits by 'main affected groups'

Transposition reduces the risk of EU infraction procedures and thus fines and diplomatic harm will be avoided (benefit's UK government and society; could be significant but unquantified as per RPC guidance) as will some litigation (benefits NHS). The transposition of this EU directive may lead to an increase in patients utilising their cross border rights, thus, there may be health gains from more timely and cheaper treatments for some patients (benefit to patients and society).

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
<p>Limited evidence in this area. The impact on the uptake of cross border health care is unknown and depends on exogenous factors and implementation. Non-monetised impacts may be large. Quantified NPV is based on early estimates and is driven by the cost difference of current admin vs. proposed NHSCB admin. The lower bound NPV (above) is based on no cost savings being realised; could be due to higher costs (of NHSCB admin) and/or lower benefits (current admin not as costly as thought).</p>		

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0	Benefits: £0	Net: £0	No	NA

Evidence Base (for summary sheets)

This is a consultation-stage impact assessment setting out how England should transpose EU Directive 2011/24/EU. This Directive puts obligations on member states to make existing cross border healthcare rights clearer and more accessible. Therefore, this is not an impact assessment of patients' rights to cross-border healthcare as this Directive and its transposition do not grant any new rights, nor does it extend eligibility. We have impact assessed the obligations of the Directive itself rather than the wider (patients) rights that the Directive covers. The impacts assessed are also outside the scope of One In, One Out policy as discussed in paras 114-118.

Introduction

1. European Union (EU) citizens may seek publicly funded healthcare in an EU Member State other than their country of residence. They do so as tourists who require urgent care or when living and working abroad, but also by travelling especially to receive care.
2. When receiving health care in another EU Member State, EU citizens can access public funding through distinct routes:
 - A revised Regulation (EC 883/2004) about the transferability of social security rights, known as the S2 route (formerly E112);
 - A parallel route resulting from the relaxation on restrictions to the provision of services across EU borders, set out in Article 56 of the Lisbon Treaty (Treaty of the Functioning of the European Union - TFEU). This route is now formalised by Directive 2011/24 EU.
3. Rulings by the European Court of Justice (ECJ) have defined what Article 56 means for patients and the availability of health services. They have established that EU citizens enjoy the fundamental right to access healthcare in another Member State - and therefore have the right to be reimbursed for the costs of receiving a treatment in another Member State to which they would have been entitled in their domestic health system.
4. Based on these ECJ rulings, the Department of Health (DH) has recently introduced legally binding regulations for Primary Care Trusts (PCTs), setting out their obligations relating to cross-border healthcare. However, both domestically and in Europe, the rules for receiving cross-border healthcare and for reimbursement of costs are not always clear or easy to understand and the case law established over the years by the ECJ has further clouded the issue. This is why the European Commission developed a proposal for a legal instrument which would co-ordinate, codify and simplify the established case law and provide clarity for patients as to their rights for access to cross-border health care under the Treaty.
5. The EU Commission, the Parliament and the European Council formally adopted Directive 2011/24/EU on the application of patients' rights in cross-border health care on 28 February 2011. Member States now have a period of 30 months to transpose the Directive's requirements into their national laws (transposition deadline is October 2013).

Directive obligations

6. The Directive does not establish any new patient entitlements, but clarifies what has already been confirmed in European case law and puts binding requirements on all Member States. Notably, the Directive sets out duties on the patient's home Member State to reimburse the cost of healthcare received in another Member State if the patient would have been entitled to that treatment domestically. It also sets out duties for Member States to ensure that patients are provided with information about cross-border healthcare services and their right to these services.
7. In summary, the Directive places legally binding obligations on Member States in the following areas:

- Set up a National Contact Point (NCP) which will provide information to patients, commissioners and other interested parties (both domestic and foreign);
 - Ensure existence of transparent, objective and non-discriminatory systems for timely reimbursement and prior authorisation¹ of cross-border health care;
 - Arrangements for incoming patients, including clarity about professional indemnity;
9. The Directive also sets out various cooperation arrangements between Member States, for example regarding eHealth, health technology assessment and European reference networks. These measures are not mandatory and do not require implementing legislation as part of the Directive transposition. Where proposals are brought forward in the future, these will be the subject of separate consultation and assessment(s) of impact.
10. In detail, the binding obligations resulting from this Directive are as follows:

Setting up an NCP

11. The Directive requires Member States to set up National Contact Points (NCPs) whose role it is to provide information, in appropriate formats, to prospective cross-border patients and facilitate the exchange of information with NCPs in other Member States (and on request, the Commission)
12. Member States must ensure that NCPs provide citizens with information about their rights and entitlements including conditions for the reimbursement of treatments received in another Member State as well as information on the rules of appeal and redress and health professionals' right to practice. NCPs must also consult with patient organisations, other NCPs, providers and health commissioners/insurers as appropriate.

Establish transparent administrative systems for reimbursement and prior authorisation

13. Under the Directive, patients may access any healthcare service (provided privately or publicly) in another Member State that is the same as or equivalent to a service that would have been provided to the patient under the patient's home healthcare system. The patient then has a right to claim reimbursement up to the amount that the treatment would cost had the patient obtained that treatment from their home system - or the actual amount where this is lower.
14. Again, it should be noted that the 'home' state retains responsibility for deciding what healthcare it will fund, so the Directive is not a way for citizens to gain entitlement to treatments that would not normally be available under their home health service.
15. The Directive sets out the general principles that apply to the reimbursement of eligible costs to cross-border patients:
- systems and procedures must be easily accessible
 - information on entitlements must be made publicly available to citizens
 - application and decision-making processes must be objective, transparent, non-discriminatory with reasonable time limits
 - decisions on access to cross-border healthcare and reimbursement must be properly reasoned, subject on case-by-case basis to review and capable of being challenged by judicial proceedings.
16. In some cases, Member states can require prior authorisation before a patient accesses treatment in another Member State. Patients would then need to ask a designated point in their health system for authorisation before going to received treatment in another Member State. Where a patient fails to do so, they might not be reimbursed for their treatment cost (although Member States might grant retrospective authorisation in such cases).

¹ Under the Directive, Member states can require patients to ask for authorisation before accessing treatment in another Member State. For details of this provision see below.

17. Treatments may be subject to prior authorisation where the services provided require significant levels of planning and manpower and either involve overnight accommodation in hospital of at least one night or require the use of highly specialised and cost intensive medical infrastructure or medical equipment, such as PET-CT scans. Prior authorisation may also be applied to treatments that present a particular risk for the patient or the population or treatment provided by a healthcare provider that in a particular case would give rise to serious and specific concerns about the quality or safety of care. The categories of treatments subjected to prior authorisation must be notified to the Commission by individual Member States.

Arrangements for incoming patients

18. The Directive requires Member States to ensure that healthcare providers give incoming patients information on:

- treatment options
- their availability, quality and safety
- pricing
- licensing arrangements for the healthcare provider
- their indemnity/insurance liability cover.

19. Patients must also be informed of complaints procedures and processes for seeking redress where there is negligence or dissatisfaction. Their privacy must be protected, particularly in respect of processing data and they should be given a written or electronic record of the treatment that has been provided to them.

14. The Directive also applies the principle of non-discrimination based on nationality (e.g., same prices must be applied to EU patients and domestic patients). However, the Member State of treatment is not required to provide treatment to anyone where this would undermine the treatment of home patients.

15. A full list of the Directive's obligations is set out at Annex A

Policy Options

16. This section presents the potential options for transposing into UK law the above obligations insofar as they relate to the NHS in England. The UK devolved administrations (including Gibraltar) are responsible for the transposition of the Directive in the other parts of the UK. There will be separate impact assessments alongside their transposition proposals as appropriate.

17. Independently of the proposed transposition measures, DH is engaged in policies regarding professional liability insurance and the recognition of prescriptions from other Member States. These policies will ensure that the health system in England meets Directive requirements as set out in Art 4(2) and Art 11 of the Directive. Therefore, *no additional* transposition measures regarding these obligations are considered for this IA. The costs and benefits of the Department's policies regarding professional liability and prescription recognition are out of scope for this impact assessment and will instead be assessed in impact assessments accompanying the relevant policy proposals.

Option 1 - Do Nothing Option: Do not transpose the Directive

18. To do nothing would mean that the Government does not take any measures to transpose the Directive, so effectively this would maintain the status quo. This would mean that the UK would be in breach of European law, for instance, by not fulfilling the Directive obligation to have a National Contact Point for cross-border care.

19. In addition, experience has shown that the existing provisions are insufficient to meet the Directive's requirements of objective, transparent, non-discriminatory and timely decisions on prior authorisation and reimbursement. Currently, the responsibility to meet these requirements lies mainly with PCTs who struggle to do so despite existing regulations. Without further

legislative measures, decision making by the NHS would lack certainty and patients would not be able to access fully their rights.

20. Failure to transpose adequately the Directive would be contrary to European law. This would lead to infraction proceedings before the European Court of Justice (ECJ) resulting in substantial fines against the UK (a minimum of €11m – equivalent to about £9.2m - plus periodic payments until the breach is remedied). It is not possible to predict the level of payments before any ECJ ruling as it will depend on the Courts assessment of the severity of the breach (among other aspects).

Option 2 – Transpose the Directive in a way that meets Member State obligations (so-called “intelligent copy out”)

21. This is the preferred option: it transposes the Directive into national law using “copy out” where appropriate, but ensures that legislation is appropriate in the domestic context because strict copy out would not provide the level of certainty required. In fulfilling the obligations arising from the Directive, Government faces a number of policy choices. This option brings together the preferred options for each of these policy choices.
22. The measures proposed under this option fall into three main categories:

- Establish a centralised system to deal with the reimbursement of patient costs and consideration of prior authorisation of cross-border health care within the NHS Commissioning Board (NHSCB);
- Set up a National Contact Point which will provide information to patients, commissioners and other interested parties (both domestic and foreign);
- Establish arrangements for incoming patients.

Establish a centralised system to deal with reimbursement of patient costs and prior authorisation of cross-border health care in the NHS Commissioning Board

23. As noted above, under the Directive, patients can access treatments in other EU Member States and Member States are required to ensure patients are reimbursed for such treatments (where they would have been entitled to them domestically) in a transparent, objective and non-discriminatory way.
24. In England, the mechanisms by which requests for cross-border healthcare are currently dealt with operate at local level by Primary Care Trusts (PCTs). However, evidence that the decision-making that takes place at a local level on enquiries or applications relating to cross-border healthcare falls well short of the obligations set out in the Directive.
25. PCTs have not performed well in advising patients and managing cross-border requirements. For example, in a study by the University of York, only around 50% of PCT respondents were able to describe the Directive and only 10% of these in any detail.² Similarly, in a mystery shopping exercise as part of the same study, it was found that PCTs often just passed patients around the organisation without offering helpful or accurate advice. This reflects the fact that individual PCTs deal with only a small caseload of cross-border healthcare requests, which in turn makes cross-border healthcare of low priority and makes it difficult to acquire the expertise needed to deal efficiently and transparently with patient requests (e.g. knowledge of European law, rules and procedures, ability to translate and analyse foreign receipts etc).
26. Following the Health and Social Care Act 2012, decision-making on cross-border healthcare will fall under the remit of Clinical Commissioning Groups (CCGs). CCGs will be smaller in size and more numerous than the current configuration of PCTs. They would therefore find it even more difficult to guarantee transparent and equitable decision-making. Thus, under the do-nothing option, the UK would be at serious risk of not meeting the Directive’s obligations.

² Cross Border Healthcare and Patient Mobility: Data and Evidence Gathering, York Health Economics Consortium, 2010

27. For these reasons, the preferred option is to centralise decision-making on cross-border healthcare within the NHS Commissioning Board (NHSCB). The NHSCB would be able to generate and maintain the necessary expertise to deal with patient requests in an appropriate way, thus fulfilling the Directive's requirements.
28. This means that the NHSCB will take on the following responsibilities, the majority of which are currently delivered by PCTs:
- Receiving patient applications for reimbursement under the Directive and making payments;
 - Deciding whether a particular treatment requires prior authorisation;
 - Granting or refusal of prior authorisation;
 - Publicising information on rights, entitlements and reimbursement principles, including which services patients will be reimbursed for;
 - Calculating reimbursement levels and informing patients about this;
 - In some circumstances making payment directly to overseas providers on behalf of the patient following treatment (where this is in the patient's best interest);
 - Dealing with appeals & reviews;
 - Data collection;
 - Reconciling bills

Set up a National Contact Point

29. As noted above, Article 6 of the Directive requires Member States to establish NCPs. Essentially patient information and liaison bodies, NCPs will ensure that domestic and foreign patients, going to another Member State or EEA patients coming to the UK respectively, have access to all relevant information needed to access cross-border healthcare, i.e. information about:
- a. Information about whom to approach for treatment advice
 - b. Standards and guidelines on quality and safety (in UK and EU legislation);
 - c. Provisions for the supervision and assessment of health care professionals;
 - d. Information on which health providers are subject to such standards and any restriction on practice;
 - e. Information on hospital accessibility for persons with a disability.
 - f. Complaints procedures;
 - g. Mechanisms for seeking remedies under the legislation of the Member State of treatment;
 - h. Prices for treatments.
30. A number of options how the NCP functions could be arranged, and where they could sit, have been considered. A single UK NCP was considered but deemed infeasible given the individual needs of each devolved administration (DA). As a result, each UK territory will set up and run its own national contact point. It was then considered whether the NCP should be an independent organisation or placed with an existing Arm's Length Body or government organisation.
31. The NCP as new independent organisation or Arm's Length Body (ALB) was discounted because it would be disproportionate given the scale of the role, and infeasible given financial constraints. This proposition is based on the notion that it would be more expensive to set up a new, independent body – with its own governance structure and on-costs - than it is to add the NCP function to an existing body.
32. The role of the NCP has few synergies with existing ALBs or the Department of Health; however, there are close links between the work of the NCP and the cross-border functions the NHSCB will take on, as outlined above. Thus, the NHSCB is thought to be best placed to deliver the functions of a NCP, and that is what is proposed.
33. We also considered the possibility of an independent organisation possibly in the third sector carrying out this function. However, that would duplicate expertise that the NHSCB will have to have in any event in carrying out functions for the Secretary of State. In our view, greater cost effectiveness and critical mass of knowledge and skill would be achieved by carrying out this function centrally within the NHS.

Arrangements for incoming patients

34. As noted above, healthcare providers must not discriminate against patients from another Member State – however, providers are not obliged to provide or prioritise care for non-resident EU citizens where this would negatively affect the treatment of domestic citizens with similar levels of need. Measures must be limited to what is necessary and proportionate and must not be a means of arbitrary discrimination.
35. Providers must also apply the same scale of fees to patients from another Member State as they charge to domestic patients and they must provide information to help a patient make an informed choice, including on prices and clear invoices. Member States should also ensure that systems of professional liability insurance or similar are in place for healthcare providers.
36. Although these requirements will be present on the face of the implementing regulations, no specific actions are proposed in this area as the obligations relating to incoming patients either reflect good practice in accordance with the NHS Constitution or are being considered by DH as part of a separate policy on professional indemnity as mentioned above.

Alternative Options

Transpose the Directive based on “copy out”

37. The simplest way to transpose a directive is to “copy out”, i.e. to lay the text of the directive, word for word, into UK law. It is government policy to “copy out” EU Directives *as far as possible*. However, there are provisions in the present Directive which require further clarification to reflect the domestic system. For example, the Directive stipulates the need for Member States to introduce a National Contact Point (NCP), but does not make any provisions for the location and structure of that organisation.
38. In addition, some of the Directive’s articles and terminology require additional clarification to be applicable to the English health system and domestic legislation. “Copy out” would in many cases generate an ambiguous legal situation with no clarity for users and policy makers alike and may therefore increase the risk of incorrect implementation.
39. This option is not viable and thus is not formally assessed.

Non-regulatory options

40. The Directive seeks to clarify case law precedents established over a number of years by the European Court of Justice, as well as the rights of patients and duties on the Member State. It will be necessary to ensure that these rights and duties are clearly set out and enforceable. The Directive represents EU law which Member States are required to transpose within their own legal systems. Such legally binding obligations do not lend themselves to non-regulatory solutions.

Costs & benefits

38. This section assesses the impacts of Option 2 (the preferred option) over Option 1 (“do nothing”). It is important to note, first of all, that there is very little evidence to inform this assessment. For example, at this early stage, any assessments of the administrative costs associated with the proposals can only be tentative until further policy development has taken place.
39. In addition, there is no central data on NHS patients who currently go abroad for treatment and then claim reimbursement from the NHS. There is little concrete research evidence of the demand or use of cross-border health services, even in the most up-to-date academic literature.³

³ Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows. (forthcoming) Early view available: [http://onlineibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9515/earlyview](http://onlineibrary.wiley.com/journal/10.1111/(ISSN)1467-9515/earlyview)

It is difficult to assess the impact of the proposed transposition measures on the uptake of overseas healthcare and reimbursement. We will use the consultation period to gather more information where possible and strongly encourage responses to that end. What DH are aware of anecdotally and from the number of requests received from PCTs and patients for advice about rights to cross-border healthcare is that more patients are asking about the possibility of using those rights since the publication of the Directive.

40. The impacts of the proposed transposition measures are considered under three headings:

- The UK will avoid the political and financial costs associated with non-compliance with an EU directive.
- The proposed measures will change the administration of cross-border healthcare. This will result in implementation costs, but also generate efficiency savings.
- The proposed measures create incentives for an increased uptake in cross-border health care by NHS patients – leading to social costs and patient benefits.

Avoidance of non-compliance

41. The transposition measures proposed under this option will mean that the UK will be compliant with Directive 2011/24/EU. As a result, the UK will avoid political and financial costs associated with non-compliance with any EU Directive.

Cost savings: avoided diplomatic harm

42. The UK has been very closely involved in the development of the Directive. Non-compliance would weaken significantly the UK's position within the EU, notably in view of future negotiations in this or other (related) areas, such as the work being taken forward on the cooperation arrangements at Chapter IV of the Directive. Timely compliance prevents such diplomatic harm. This cannot be quantified, but may be substantial.

Risk reduction: avoided penalties

43. As noted above, any EU Directive represents a legal obligation on Member State governments. Where the European Commission suspects that EU legislation has not been effectively implemented, Member States risk legal action and corresponding financial penalties (collectively known as "infraction" proceedings).

44. The risk and potential size of infraction penalties cannot be quantified as it will depend on the assessment, by the ECJ, of the severity of the breach (among other aspects). It will also depend on transposition in the devolved administrations. It is also impossible to precisely predict when they would be incurred as this will depend, partially, on cases being brought to the attention of the European Commission.

45. Reflecting these uncertainties and following central government guidance, we treat the potential reduction in infraction fines as a reduction in risk, but not a quantifiable benefit. Note however, for illustrative purposes, that, at the very least, in case of non-compliance, the European Commission could impose a one-off penalty fine of €11m per infraction (ca. £9.2m).

Cost savings: avoided litigation costs

46. As noted earlier, the Directive does not create any new entitlements to cross-border healthcare, however, it obliges Member States to ensure clarity of procedures and easy access to information about patient entitlements and reimbursement levels.

47. Currently, Primary Care Trusts in England deal with requests for cross-border healthcare. In the future, a higher number of Clinical Commissioning Groups (CCGs) would fulfil these tasks. Without central guidance, there may be ambiguity in how local commissioners interpret the law. For example, commissioners could wrongly refuse reimbursement or prior authorisation to patients who are entitled to it. Alternatively, a commissioner may be right in denying

reimbursement or prior authorisation, but lack of clarity may encourage the patient to question the decision. In both cases, the patient may take their case to the courts and potentially onwards to the ECJ, resulting in litigation costs to the UK.

48. Under the preferred option, the Department of Health remains responsible for setting the policy, legal framework and setting guidance/directions for the NHSCB when it carries out the Secretary of State's functions. Decision making about cross-border healthcare will sit within a central unit at the NHSCB, which will develop the expertise to manage requests for cross-border healthcare appropriately. The proposed measures aim to ensure compliance with EU law and would reduce the relative likelihood of legal challenges.

49. It is difficult to estimate nor reliably quantify the overall impact of this as the likelihood of litigation will depend on individual cases and the amount of cross-border health care, which will depend on any increased uptake in cross-border health care resulting from the transposition measures taken, (which will be discussed later on). However, the UK has in the past been involved in ECJ cases relating to cross-border healthcare entitlements, where defence costs were significant in relation to a relatively inexpensive treatment cost of between £3-4000.

Changes to the administration of cross-border health care

Costs: setting up and operating a NCP

50. The costs associated with the setting up and running of the National Contact Point for England include:

- Transitional costs of setting up the organisation
- Maintaining manpower, infrastructure, IT, liaison costs in order to be able to
 - collate all necessary information (in appropriate formats) about treatments, providers, regulators, costs etc; people able to liaise with foreign NCPs
 - set up website etc
 - provide more direct assistance to patients
 - raise awareness of own existence
 - build links with DA NCPs and Commission

51. It is very difficult, at this early stage and in the absence of better information on potential demand, to make any presumption about what costs the NCP for England would precisely face going forward. Overall costings and resource implications will need to be considered alongside wider NHSCB EU functions, in the round.

52. However, for purpose of illustration, consider that DH estimates the set-up cost of NHS Choices, the UK's largest health website, to have been £500,000 with an annual operative cost of about £20m. This is for the provision of a website of nearly 100,000 pages with 14m visits per month. It cannot be predicted how many pages the NCP web presence will contain. However, it would seem that even 100 pages is an overestimate – suggesting that the costs of the NCP web presence may be around 0.1 % of NHS Choices' cost, i.e. **£20k pa**.

53. Setting up the NCP will, however, generate some additional transition costs, e.g. in terms operational structures or providing information about the NCP's existence to essential stakeholders. As a broad, initial estimate, it is, however, expected that they will not exceed the set-up costs of NHS Choices, i.e. **£500,000 one-off**.

54. Similarly, the operational costs of the NCP will be more than 0.1% of NHS Choices (or £20,000) as work will include not only the maintenance of the web presence, but also, for instance, direct information sharing with patients (e.g. on the phone). As noted above, the details of the operation of the NCP have not been decided upon and, crucially, it will fall upon the NHSCB to determine how it can fulfil its tasks in the most cost-efficient way. It is not clear to what degree the NCP will require additional staffing on top of what is required to maintain the website, nor what their pay or conditions would be.

55. For illustration purposes, we estimate that the NCP may require a staff level of about 2 to 4. Assuming an average employer paybill per FTE of around £30k⁴ and staff overhead multiplier of around 1.3⁵ gives an cost of around £40k per FTE and thus potential running costs of around **£120k pa** (between £80k and £160k pa). This is a broad illustration and should not be seen as reflecting any decision on actual staffing or pay levels which will be for the NHSCB to decide in time. We will use the consultation period to gather more information where possible and strongly encourage responses to that end.

Cost savings: centralised administration of cross-border health care

56. Cross-border healthcare imposes overhead costs on the NHS not occurring where patients receive care in the UK. This is because reimbursement of cross-border healthcare involves additional administrative work such as:

- Dealing with enquiries and applications;
- Consideration of prior authorisation and calculating reimbursement;
- Understanding/translation of foreign receipts;
- Determining applicable tariffs as foreign providers do not operate in the NHS tariff framework;
- Notifying decisions;
- Dealing with appeals and reviews.

57. Under the do nothing option in a reformed NHS, this will fall on around 230 CCGs (previously 151 PCTs). The obvious disadvantage of such a decentralised system is the one that exists now – that is, most commissioners gain little experience with cross-border issues, dealing with at most a handful of cases per year. Under the preferred option, a central unit at the NHSCB would take on this role.

58. There is no central data on the time and effort spend by PCTs on dealing with requests for cross-border treatments. However, anecdotal evidence suggests that even PCTs with experience in this area do not employ more than one fifth of a full-time equivalent staff member on dealing with these requests. Even if this were true for every PCT, it would suggest a total staff requirement of around 30 FTEs to deal with planned cross border health care. Although this maybe an upper bound for PCTs, as CCGs represent further decentralisation the staff requirement may be higher. Therefore, 30 FTEs is a starting assumption. Thus, we estimate that the overall effort devoted across all PCTs and thus soon to be CCGs could be around **£1.2m per year** (30 full-time equivalent staff members at employer paybill per FTE of around £30k⁶ and staff overhead multiplier of around 1.3⁷ gives a cost of around £40k per FTE). This is a broad estimate of an unknown cost. A large proportion of this effort could be saved when responsibilities are centralised in the NHSCB, as we expect that a critical mass of expertise and economies of scale can be exploited.

59. The NHSCB would be likely to face some costs local commissioners do not face. For example, where a patient received a treatment abroad for which there is no NHS tariff, the NHSCB would need to liaise with the responsible CCG to identify the proper level of reimbursement. In addition, as described earlier, the Directive requires Member States to ensure transparency with regard to prior authorisation requirements and availability of treatments. As a result, the NHSCB will need to define:

- an appropriate list of treatments requiring prior authorisation (based on policy set by DH)
- a list of treatments not generally available on the NHS; (In discussion with DH and CCGs)
- the level of reimbursement a patient should receive.

⁴ An estimate based on DH analysis of average staff costs for admin and clerical staff in NHS non-provider functions

⁵ Better Regulation Executive assumption

⁶ An estimate based on DH analysis of average staff costs for admin and clerical staff in NHS non-provider functions

⁷ Better Regulation Executive assumption

60. In addition, the NHSCB will need to advise patients to consult their CCG about their entitlements and/or directly ask the CCG in question where patients have not had any agreement with them before going abroad. Protocols will be needed to ensure effective and timely liaison between CCGs and the NHSCB. This reflects the fact that gatekeeping and establishment of patient entitlements to NHS services are based on the decisions of local commissioners and will, in the main, remain at CCG level in the reformed NHS. Prospective cross-border patients will therefore need to be advised to check with their local gatekeeper as to what they are and are not entitled to.
61. Despite these small additional costs, it is thought that a central unit would, over time, develop specialised knowledge on the rules and procedures governing cross-border healthcare as well as practical expertise - such as the ability to understand or translate foreign receipts and apply the correct reimbursement tariffs. We assume that the NHSCB will not need more than 5 FTEs to carry out these activities, which would be a cost of around **£200k** per year (employer paybill per FTE of around £30k⁸ and staff overhead multiplier of around 1.3⁹ gives an cost of around £40k per FTE). This could mean a net saving to the NHS of around **£1m per year**. This is a broad estimate of an unknown potential saving. If the current process is less costly than estimated (in para 58), or if the new NHS Commissioning Board process is more costly than estimated here, the savings will be lower and could potentially be nil.
62. These calculations are broad estimates ~~purely illustrative in nature~~. For a final assessment, data on current expenditure at local level needs to be generated which is not currently available. In addition, any expenditure and staffing at the NHSCB is purely indicative as no decision about any detailed provisions has been made and is for the NHSCB to decide. The numbers above should not be taken to indicate any decision about funding and/or staffing. We will use the consultation period to gather more information where possible and strongly encourage responses to that end.
63. In addition to the above, patients using cross border health care may realise cost savings. A more centralised administration system should reduce the search and organisation costs for patients. The process will be more transparent and this should benefit patients.

Potential increase in the uptake in cross-border healthcare

64. This Directive does not create any new entitlements to patients, so does not expand the market for cross-border healthcare. However, the transposition measures proposed under the preferred option will clarify procedures and provide patients with easier access to information about their entitlements to cross-border healthcare. Overall, it is envisaged that cross-border healthcare will become a more transparent, accessible and certain process for patients. As a result, the uptake of cross-border healthcare, under existing entitlements, will probably increase over time. This will result in costs and benefits.

Potential for an increased uptake

65. It is difficult to assess the likely extent of any increase in the uptake of cross-border healthcare due to the transposition of the Directive. The current baseline level of uptake of cross-border healthcare and the demand drivers are unclear. We believe that that it is highly likely that current administrative practice by the NHS discourages patients from seeking to exercise these rights but there may be other factors that will not change once the Directive is transposed which may also have an impact. There is no central data on NHS reimbursed treatments and even in academic literature the scale and cost of the UK cross border health travel and the motivations for patients is unknown and under-researched.¹⁰ A future benefit of the Directive is the requirement for Member States to collect detailed information about demand and the NHSCB will be doing this for DH.

⁸ An estimate based on DH analysis of average staff costs for admin and clerical staff in NHS non-provider functions

⁹ Better Regulation Executive assumption

¹⁰ Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows. (forthcoming) Early view available: [http://onlineibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9515/earlyview](http://onlineibrary.wiley.com/journal/10.1111/(ISSN)1467-9515/earlyview)

66. Medical tourism website Treatment Abroad estimates that in 2009 about 60,000 UK patients specifically travelled abroad for self-funded treatment. Some of these patients may be entitled to reimbursement by the NHS and clarification of rules and processes may encourage them to claim it. However, without detailed knowledge of the treatments received abroad, it is impossible to estimate what proportion of patients could claim reimbursement. In addition, the above figure of 60,000 has only limited relevance as it includes treatments outside the EU (even though destinations within the EU are most popular).¹¹
67. We may expect the cross border care demand to be higher now and in the future, as UK citizens have grown more mobile and accustomed to travel. In particular, it should be considered that the accession of Eastern European countries to the European Union has led to a growing familiarity of these countries (who are providing potentially high quality and relatively low cost treatments).
68. In the study by the University of York in 2010, 62% of respondents said they might consider planned healthcare elsewhere in the EU.¹² A survey for the European Commission reports this figure at 54% with major reasons for travel being access to (specialist) care, waiting times and perceived quality issues.¹³ In addition, NHS patients from another EU country may actually prefer treatment in their home country, for instance, to be closer to friends and family.
69. Despite this, DH is not aware of any evidence of an actual increased use of cross-border health care entitlements. This is supported by a recent academic literature noting that UK citizens' increased willingness to travel long distances to receive treatment overseas is contradicted by findings that UK patients rarely travel outside their local health community.¹⁴
70. There is limited evidence on why patients' *stated* willingness to consider cross-border healthcare does not translate into a higher uptake of cross-border healthcare, and in particular whether the current administration system is a significant issue. By extension, it is difficult to assess how the proposed measures may affect the uptake of cross-border care. However, the following needs to be considered:
- Patients are currently poorly informed about their entitlements – any additional provision of clear and transparent information is likely to increase the uptake of cross-border care;
 - Patients mainly travel to avoid (perceived) problems with the local provision of services;
 - However, generally, patients prefer to receive care as close to home as possible.

Better-informed patients may travel more often

71. Currently, many patients are unlikely to be well informed of their entitlements. This may prevent them from going abroad. For example, the European Commission has found that 25% of citizens across different EU member states (including the UK) are not aware of their right to receive care in another Member State.¹⁵
72. The NHSCB and NCP will find it easier to provide information to patients and there are clear obligations within the Directive requiring them to do so. Therefore, patients will find it easier to understand these rights and may upon implementation of the proposed measures, should they wish to do so. As patients become better informed of their rights they may be better able to make decisions about cross-border healthcare. Therefore, they may be more likely to avoid (perceived) problems with the local provision such as waiting lists and restricted access to services (i.e. where the local provision may not be comprehensive, for example, NHS dentistry).

¹¹ Treatment Abroad 2010, Pollard, Keith 2010: Medical tourism: Key facts , email correspondence with Treatment Abroad

¹² Cross Border Healthcare and Patient Mobility: Data and Evidence Gathering, York Health Economics Consortium, 2010

¹³ Gallup 2007, Flash Eurobarometer 210 – Cross-border health services in the EU suggests that 3% of UK respondents had received health care in another EU member state over the course of the preceding year.

¹⁴ Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows. (forthcoming) Early view available: [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9515/earlyview](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1467-9515/earlyview)

¹⁵ Commission of the European Communities 2008: Impact Assessment, page 12; Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, page 12;

http://ec.europa.eu/health/ph_overview/co_operation/healthcare/docs/impact_assessment_en.pdf

73. In addition, it should be noted that cross-border healthcare is sometimes facilitated by third parties ranging from commercial “facilitators” coordinating patients’ trips to websites offering information and marketing content.¹⁶ As the proposed transposition measures increase certainty in the way requests for reimbursement are dealt with by the NHS, they will arguably make it easier for third parties to promote cross-border travel for NHS treatment. This, in turn, may well increase patient’s access to information and therefore likelihood of travel.

Patients may travel to avoid issues with local provision

74. Even perfectly well informed patients will only travel if they see any benefit in doing so. Given that the NHS provides healthcare free at the point of need to everybody who is ordinarily resident in England, there would appear to be little reason for patients to travel abroad to receive treatment to which they are entitled to under the NHS. However, patients may do so for several reasons:

- (perceived) **higher quality** (e.g. higher success rates in IVF)
- difficulties in accessing specialist care in the UK because of **limited supply** (e.g. dentistry, access to donor eggs in IVF¹⁷)
- **waiting times**

75. In the York study, 50% of those patients who were willing to go abroad said that increased waiting times would be a major push factor. In this context, it should be noted that the NHSCB will have limited powers to refuse prior authorisation. For some treatments it may be possible to refuse prior authorisation for treatments where they can be provided by the NHS without “undue delay”, which the ECJ defines as a waiting time that *“exceeds the period which is acceptable in the light of an objective medical assessment”* (i.e. regardless of any national waiting time targets). However, the use of this provision has to be proportionate and is likely to be subject to appeal and challenge if used as a blanket restriction on patient rights.

76. Notably, for some treatments for which patients are most likely to wait on the NHS there is already an existing cross-border market. For instance, according to 2009/10 Hospital Episode Statistics, in that year, over 20,000 patient had an average inpatient wait of more than 15 weeks for hip and knee replacements and some 25,000 patients waited for a similar period for various eye procedures. Literature suggests these treatment types as typical examples of non-life threatening cross-border treatments.¹⁸

77. There are NHS treatment areas where supply in general is limited. For example, in some areas of the country access to NHS dentistry can be difficult. Some patients currently pay privately for their dental treatments despite them being available, in principle, on the NHS. In 2006, it was estimated that around 3m people would like, but could not access, NHS dental care¹⁹. The proposed measures would clarify that these patients are entitled to reimbursement for these treatments if received in another EEA country under the terms of the Directive. This may be attractive to many patients. Indeed, latest estimates²⁰ suggest that over 40,000 dental patients already travel for treatment, a number that might increase given additional clarification (note though that the current figure includes many purely cosmetic treatments not available on the NHS, so not available for cross-border reimbursement).

78. There may also be very specialist treatments with constrained NHS access such as for patients with very rare conditions; the incentive to travel for care may be high in these cases. However, if the treatment is not considered generally available to patients they may not receive authorisation

¹⁶ Cormany, Dan and Baloglu, Seyhmus 2011: Medical travel facilitator websites: An exploratory study of web page contents and services offered to the prospective medical tourist.

¹⁷ For an overview of the reasons for which patients travel for IVF see Culley et al 2011: Transnational Reproduction: An exploratory study of UK residents who travel abroad for fertility treatment – Summary Report, page 10; http://www.rcn.org.uk/_data/assets/pdf_file/0005/420296/TRANSREP_summary_report_FINAL_June_2011.pdf

¹⁸ Cormany, D. 2010, Hospitality and destination marketing’s role in medical tourism: a call for research, *International Journal of Behavioural and Healthcare Research* 2 (1), pages 38–58;

¹⁹ DH Dental Policy Team 2006

²⁰ Travelling for health: The potential for medical tourism - Economist Intelligence Unit, 2011

for cross-border treatment and therefore will not be entitled to reimbursement. On the other hand, if it is a treatment for which a critical mass is required to ensure domestic provision to remain viable, then it may be possible in certain circumstances to limit patient outflows under the Directive.

79. There is always the risk that patients receive treatments abroad which they would not receive under the NHS and then claim reimbursement. In principle, this should not be a problem as the Directive clearly states that patients' entitlements are not different in the cross-border context, and it is proposed that as NHS entitlements are defined at the local level by CCGs, the NHSCB will work with CCGs to understand the NHS entitlements for each person in each locality. In addition, it is proposed that the NHSCB will maintain a list of treatments that are not generally available under the NHS to clarify things further. Still, there is always a risk that this list misses some specialised and/or very new treatments, thus potentially making them available for reimbursement even if the NHS usually does not commission it.
80. Overall, however, this is unlikely to affect many patients. In addition, these treatments would likely be subject to prior authorisation and patients would be informed about their entitlement or not to the treatment through this process. However, in some individual cases, patients may have a strong interest to receive treatment abroad and then seek reimbursement by retrospective prior authorisation. Such cases, while rare, may be expensive.

Patients generally prefer to receive care close to home

81. It is clear from the above that, in some circumstances, patients might want to look for treatment in another EU Member State. However, as noted above, DH is not aware of any increased use of cross-border healthcare entitlements and academic literature points to a gap between patients' stated willingness to travel and the actual uptake of cross-border healthcare. It appears that, while there sometimes are good reasons to go abroad, there are equally good reasons for patients to seek treatment close to home. Despite the clarifications of patients' rights within the Directive and the proposed measures, the choice of going abroad for treatment is not a simple one.
82. The assumption in the Directive is that patients will need to pay for their treatment in advance and only later are they reimbursed. For more complex/costly treatments and/or low-income patients, this may be prohibitive. However, the Directive does allow other solutions and so the NHSCB may agree to make payment directly to overseas providers on behalf of the patient following treatment – in effect acting as a third party – should that be in the patient's best interests.
83. In addition, as is highlighted in the York report, there is a lot for an individual patient to consider before they take the decision to seek healthcare in another EU country – for example, a different language & culture, different professional and safety standards and outcome indicators, accommodation, travel and subsistence costs, assurance on care pathway(s), avenues to obtain appropriate redress etc. The patient would need to do their own due diligence to assure themselves that the financial and other considerations associated with cross-border healthcare outweigh staying within their own health system. In addition, the “contingencies of specific clinical conditions” such as fatigue, pain and travel risks may be strong deterrent to cross-border travel.²¹
84. These deterrents will affect individuals differently and patients' mobility will vary. For example, most of the above deterrents would apply less stringently to NHS patients who have family ties (or any other link) to another EU country. Those most in need of healthcare (the frail and very sick), are likely to find the deterrents above more prohibitive - at the same time, the care for these patients will be prioritised on the NHS and the incentives to travel may be lower. The deterrents will also be more prohibitive for those who need complex or risky procedures.

²¹ Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows. (forthcoming) Early view available: [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9515/earlyview](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1467-9515/earlyview)

85. In the medium term, the transposition of the Directive is not expected to result in a significantly increased uptake of cross-border healthcare. However, in certain situations, the disadvantages of cross-border healthcare will be less relevant:

- **Patients with links to another EU country:** these patients are familiar with the language, culture and health system of another country to which they are likely to travel on a regular basis. Therefore, the reasons preventing other patients from going abroad might be less of a hindrance to them. Crucially, for some treatments, they might indeed prefer treatment in their country of origin, i.e. closer to friends and family. Note, however, that there is neither data nor academic literature supporting this suggestion.
- **Low risk/cost treatments/treatments not subject to prior authorisation:** many of the concerns about dealing with a foreign health system in a foreign language will be much less relevant for ambulatory/out-patient treatments, treatments with little risk of complications or treatments for less severe conditions. Similarly, pain and fatigue are likely to be less of a deterrent to travel for many low severity conditions. In some cases, patients could even consider some ambulatory/out-patient treatment as part of their holidays abroad – potentially even as part of holiday package pre-arranged via a third party provider. This may be particularly relevant to dentistry.

86. Given the above, a clarified and centralised administration system may lead to an increase in the uptake of certain types of cross-border healthcare. This might be true for treatments that are low risk, not subject to prior authorisation and exhibit a degree of variation in local entitlements within the NHS (e.g. dentistry – where, for example, treatments in Poland, Hungary or Malta are widely marketed²²). We will use the consultation period to gather more information on this where possible and strongly encourage responses to that end.

87. Note also that demand for cross-border healthcare may well fluctuate with difficult-to-predict external factors such as changes in the exchange rate. A stronger Pound will make it easier for patients to go abroad, seek accommodation there and, crucially, pre-pay their treatments.

Health impacts of an increased uptake of cross-border healthcare

88. The overall social impact of any change in the uptake of cross-border healthcare is considered below.

89. Firstly, when a patient travels abroad to receive treatment, they will do so because they expect a health benefit from this choice. This benefit can come from a perceived higher quality of treatment or specialist treatment, or by the avoidance of waiting times. Thus, cross-border healthcare may improve overall social health outcomes where patients receive higher quality treatment at the same price or treatments of the same quality as NHS treatments but at a lower price²³ (allowing, in effect, the NHS to generate more health benefits for the same amount of money). Indeed, price comparisons reveal that some treatments may be substantially cheaper in some other EU member states: for instance, hip replacements in Bulgaria cost 65% less than on the NHS.²⁴

90. However, alongside this there will be impacts on equality and planning. Cross-border care is funded from the same fixed budget as all NHS treatment, and thus for any NHS care, domestic or not, when one person utilises treatment another potentially forgoes it at that time. As commissioners aim to maximise health benefits, this is usually dealt with by domestic provision being prioritised according to need. However, access to cross border care can change this as those who are mobile enough (financially and physically) can potentially access treatment in advance of when they would domestically and effectively queue jump. Patients who travel abroad

²² Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows (forthcoming) Early view available: [http://onlinelibrary.wiley.com/journal/10.1111/\(ISSN\)1467-9515/earlyview](http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1467-9515/earlyview); see also <http://www.vitaleurope.co.uk> for one of many anecdotal examples of a provider of dentistry services in Hungary.

²³ Reimbursement of the costs of overseas treatment is limited to the equivalent NHS cost of that treatment. While there is some risk that the NHS CB could determine the wrong level of reimbursement this is not expected on average and less of a risk than under the current process.

²⁴ Price comparison by Treatment Abroad (2008) cited by: Lunt, Neil T., Mannion, Russel and Exworthy, Mark 2012: A Framework for Exploring the Policy Implications of UK Medical Tourism and International Patient Flows.

are, all other things being equal, likely to belong to higher socio-economic groups (e.g. more likely to be aware of their entitlements, more likely to have the financial, language and other resources to make use of their entitlements)²⁵. Crucially, in some instances, by going abroad and claiming reimbursement, some patients may simply avoid paying for private treatment domestically (see paragraphs 103 and 109 for further discussion on this). Note also that patients will not go abroad if their condition prevents them from doing so. In addition, as noted above, patients are most likely to travel for less severe treatments and/or ambulatory treatments. The frail, severely sick or elderly are all less likely to travel abroad for treatment. As a result, the health gain forgone may outweigh the health gain of the travelling individual. In addition, it is assumed that a greater societal value is placed on those more in need and less well off, therefore the net health effect is likely to be negative from a societal point of view.

91. As an illustrative example, consider a hypothetical scenario in which an individual whose income puts them in the 5th income quintile claims £100 for a dental treatment which they have received abroad. In the absence of cross-border entitlements, they may well have received this treatment domestically as a private treatment. The financial benefit to the patient is £100. However, as the patient in question is in the highest income quintile, they are thought to gain proportionally less pleasure from that £100. Using the weights proposed by the Treasury Green Book, it is estimated that the social value of their financial gain is £50.²⁶ At the same time, because of reimbursements to cross-border patients, domestic treatments are delayed or restricted. Thus, for each £100 reimbursed to a high income patient, society's net loss is worth £50.
92. Overall, then, in the absence of detailed estimates about the number and kind of treatments demanded in a cross-border setting and by whom, it is difficult to assess – on an aggregate level – what will be the social net value of the health impact of any potential increase in the uptake of cross-border care.

Non-health impacts of an increased uptake of cross-border healthcare

93. On top of the net health impact described above, any uptake of cross-border healthcare creates costs that would not occur if treatment was received domestically:
- Additional NHS administration costs for cross-border health care (described in the section about setting up a central unit at the NHSCB above)
 - Patient travel, subsistence and insurance costs
 - Environmental impacts
94. Patients will travel because – to them – the benefits of doing so outweigh the cost of travelling. However, because those benefits are accounted for separately, so too need the costs. An estimate that travel arrangements will cost the patient between £200 and £250 seems sensible.²⁷ While there will be patients paying substantially more (e.g. because they prefer not to take the cheapest option available or because they do not travel alone²⁸), others will have lower costs. Indeed, some patients may have zero costs if they link the treatment with a planned trip abroad. These costs will, in general, be borne by the patients.
95. The Directive allows Member State authorities to consider the reimbursement of other related costs – for example, accommodation and travel costs, or extra costs which persons with

²⁵ A finding supported by a patient survey by York university: Cross Border Healthcare and Patient Mobility: Data and Evidence Gathering, York Health Economics Consortium, 2010

²⁶ The underlying idea is that the marginal utility of £1 decreases, the more £1 an individual has. Thus, high income persons are thought to benefit less from an additional £1, than those on low income. See HM Treasury's Green Book for the details of this central government practice in cost-benefit analysis: http://www.hm-treasury.gov.uk/d/green_book_complete.pdf

²⁷ Flight costs were estimated to be between £80 and £110 using the flight comparison website www.skyscanner.net (consulted on 9th February 2012) for flights to major EU destinations including all capitals of EU countries and cities belonging to the 30 largest in the EU by official population. Return flight dates entered were approximately 3 and 10 weeks away from the search date, for Sunday outward flights and Monday evening or night returns, i.e. March 4 – 5 2012, and April 22 - 23 2012 respectively. To this, one needs to add transport costs to and from the airport estimated at about £30 at either end (using www.nationalrail.co.uk/ for the UK end). The resulting costs of up to £170 are for patients within easy reach of an airport and using budget transport options. Therefore, the estimate is updated to £200 - £250.

²⁸ Those accompanying the patient can spend more than twice as much as the patient on hotels and tourism activities, according to NaRanong, A. and NaRanong, V. 2011: The effects of medical tourism: Thailand's experience, *Bulletin of the World Health Organization*, 89 (5), p336ff

disabilities might incur when receiving cross-border healthcare, such as an accompanying carer. This should be considered in accordance with national legislation and on the condition that there is sufficient documentation setting out these costs

96. The NHS does provide financial assistance on transport costs to low-income patients in England, via the means tested Healthcare Travel Cost Scheme (HTCS). Currently, this is estimated to cover less than 20% of the population in England, though if higher socio-economic groups are more likely to take up cross-border care, then the rate of patients entitled to assistance under the HTCS would be lower for cross-border healthcare than across the population as a whole. In addition, there is no entitlement to accommodation, nor subsistence costs.
97. In addition, where third-party providers such as travel facilitators are involved, costs for their efforts will be borne, either directly or indirectly, by the patient.
98. Finally, patients will need to travel to receive treatment and this, as such, may be felt to have disadvantages (time lost on travel, genuine dislike of travel and discomfort when travelling while sick). Conversely, travelling may also be seen as preferable by individuals – for example, there might be a genuine preference for travel, the ability to combine treatment with holiday, better recovery in nicer surroundings etc. However, without detailed knowledge of who travels and under what circumstances, it is impossible to assess whether the benefits of travelling will outweigh the dis-benefits. As noted earlier, we will use the consultation period to gather more information where possible and strongly encourage responses to that end.

Impacts on the domestic healthcare market of an increased uptake of cross-border healthcare

99. Making entitlements to cross-border healthcare clearer and more accessible to citizens essentially increases the effective healthcare market for UK residents, and increases the competition domestic providers face.
100. This could reduce demand for domestic services. Where patients choose to access treatment elsewhere in Europe, domestic providers (and the UK exchequer) would lose fee (and tax) income, while a non-UK provider (and their exchequer) would gain.
101. This would affect domestic NHS providers as some NHS services may see a reduction in demand, which could adversely effect NHS income and consequently the provision of services if a critical mass is required to make them viable. However, the Directive allows Member States to limit cross-border healthcare approvals if this presents a risk to their own healthcare provision. For example, where highly specialised, low volume departments would be threatened by even a small downturn in patient numbers. Such a move would have to be supported by clear objective evidence justifying the restriction.
102. It would also affect private domestic providers as demand for reimbursed cross-border healthcare may displace demand for private domestic healthcare. In some instances, those who have been using domestic private providers for NHS entitled treatments will be able to go abroad and claim reimbursement, so some patients may simply avoid paying for private treatment domestically (e.g. dentistry).
103. Domestic providers could offset the above impact if they respond to the increase in competition by improving the quality of the services they provide. Although this may cost providers, it will benefit patients and society.
104. In addition, domestic providers may also be able to offset any reduction in demand by attracting patients and income from other non-UK member states. The extent to which this occurs will depend on how other Member States transpose the Directive and clarify the entitlement for their population.
105. It is not possible to quantify the above impacts as they will depend on the decisions made on a case-by-case basis, are dependent on whatever levels of future demand are seen in cross-border healthcare, and which treatments/services are affected. However, given the discussion

above, it is not expected that the transposition of the Directive will lead to a substantial increase in the uptake of cross-border healthcare in general across the board, although there may be some areas of treatments and thus providers where the impact may be more significant e.g. dentistry.

Conclusion

Table 1: Intelligent copy out transposition: estimated NPV

£'000s	0	1	2	3	4	5	6	7	8	9	Total
	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22	2022/23	
Costs											
National Contact Point set up costs	500										500
National Contact Point operating costs (web + staff costs)	70	140	140	140	140	140	140	140	140	140	1330
Centralised NHS CB cross-border function administration costs	200	200	200	200	200	200	200	200	200	200	2000
Social cost of reduced demand for domestic provision	UNQUANTIFIED										
Social cost of cross border health care (e.g.health inequalities)	UNQUANTIFIED										
Private costs of cross border health care (e.g. travel costs)	UNQUANTIFIED										
Benefits											
Avoided diplomatic harm	UNQUANTIFIED, RISK REDUCTION										
Avoided infraction penalties	UNQUANTIFIED, RISK REDUCTION										
Avoided litigation costs	UNQUANTIFIED										
Saved NHS PCT/CCG cross-border function administration costs	1200	1200	1200	1200	1200	1200	1200	1200	1200	1200	12000
Social benefit of cross border health care (e.g. health gains)	UNQUANTIFIED										
Net benefit (undiscounted)	430	860	860	860	860	860	860	860	860	860	8,170
Discount rate	0.000	0.035	0.071	0.109	0.148	0.188	0.229	0.272	0.317	0.363	
NPV	430	831	803	776	749	724	700	676	653	631	6,973

106. This impact assessment has used the best information available, building on the evidence used in the partial impact assessment prepared for public consultation in 2008 as well as information from a variety of other sources as appropriate. These included an Impact Assessment on the Directive by the European Commission, a DH-commissioned study on cross-border healthcare undertaken by the University of York over 2009/10, academic literature including most up-to-date literature reviews as well as evidence from the medical tourism and travel industries and other stakeholders.

107. Table 1 above brings all the discussed impacts together and demonstrates that over 10 years the quantified net present value of the preferred option is around **£7.0m**. Due to a lack of information, there is much uncertainty in this estimate. This margin is driven mainly by the assumed potential cost savings of centralising the administration of cross-border care in the NHSCB. There is uncertainty around how much the current process costs at the PCT/CCG level, and uncertainty about how the centralised function will be organised in the NHSCB. If administration costs remained the same and no savings were realised there would be net present cost of £1.6m over 10 years.

108. The present impact assessment has provided an initial estimate of the costs of establishing a National Contact Point (£500k one-off and £1.3m over ten years) and the administrative cost savings associated with the proposed centralisation of cross-border healthcare functions (£10m over ten years). However, while key issues regarding the practical implementation of the Directive are yet to be decided (and could significantly alter the cost estimates), it should also be noted that some of the cost of this is already in the system within PCT allocations. The NHS Commissioning Board will need to consider how to organise the following tasks:

- How to ensure that patients (both incoming and outgoing) can access accurate information on their entitlements to healthcare;
- Decisions around how the process of prior authorisation will work in practice;
- How the cost of cross-border healthcare will be calculated (in particular for those procedures which are not subject to NHS tariff and where foreign receipts require decoding/translation);
- How the UK national contact points will operate.

109. In addition, it has not been possible to quantify a number of key impacts which will affect whether the transposition yields value for money or not. Many impacts of the proposed transposition

measures remain difficult to assess and additional information and evidence is sought from respondents to the accompanying consultation.

110. However, it is important to note that the reduction in the risk of being non-compliant is substantial. This includes the unquantified risk of diplomatic harm, but also the reduction in the risk of facing infraction procedures. The potential costs of infraction fines (at least £9.2m one-off) is much higher than any of the quantified costs and benefits.
111. Finally, it has been argued that the proposed measures, in ensuring the UK meets the obligations from the Directive, will increase transparency and ease of access to cross-border healthcare. This is expected to have some positive impact on the uptake of cross-border healthcare, but it is impossible to estimate the size of this impact. Indeed, in developing this impact assessment, we have found that there is very limited information available on potential impacts as very few patients choose to travel for treatment at the present time - and where they do, we know very little about their reasons, nor the types of treatment they receive.
112. Without this information, it is not possible to reliably estimate the expected scope of uptake of cross-border health care under the Directive and the degree to which this will be influenced by the proposed transposition measures. Further, without any detailed knowledge of who will take up cross-border healthcare and for what treatments at what price, it is not possible to assess whether patients going abroad increases overall social welfare (though earlier treatment at lower prices) or reduces social welfare (due to distributional concerns and the additional on-costs of cross-border healthcare).
113. In closing, it should be noted that any impacts identified in this assessment are contingent upon a wide range of risks the impact of which will be examined throughout the further development of the policy. The main identified risks include:
 - Involvement of commercial third parties promoting cross-border healthcare;
 - Patients accessing treatments usually not commissioned by the NHS (where the proposed negative list of treatments not available on the NHS includes loopholes);
 - Clear and transparent reimbursement mechanisms encouraging patients to claim reimbursement for treatments which they would have paid for privately otherwise (notably dentistry, but also other treatments such as IVF; also: EU citizens who are residents in the UK and therefore entitled to NHS care);
 - Problems in the provision of NHS services, such as waiting times, would encourage more people to go abroad
 - Equity considerations where patients with sufficient financial resources and who are not to frail to travel avoid waiting lists;
 - Exogenous factors such as fluctuations in exchange rates affecting uptake and costs of cross-border healthcare.

One-In One-Out

114. As per central guidance, EU Directives, Regulations, Decisions are out of scope of OIOO, as long as the transposition does not go beyond the minimum requirements.
115. As discussed, this IA assesses the impact of transposing EU Directive 2011/24/EU not the impacts of the directive itself. For instance, patients' rights to accessing cross-border healthcare result directly from the Directive and, indeed, the Treaty. These patient rights (and the consequential impacts of them being granted) are not contingent on any domestic transposition and are not affected by the proposed measures.
116. Transposition of this EU directive, in scope of this IA, mainly involves changes to the administration of cross border healthcare, e.g. involving the setting up and running of a National Contact Point. These administration changes, and any resulting costs and cost savings, affect the NHS and DH only, and do not go beyond what is necessary to meet the minimum requirements of the Directive.

117. As discussed in the main body of the IA, transposition of the directive may lead to an increase in uptake of cross border health by NHS patients. This may have implications for private sector providers where patients who may have used these providers to avoid NHS provision, may now be more aware of the option to go abroad and have this treatment reimbursed; a potential loss of business for domestic private providers. However, private providers may benefit from the transposition of the directive if it increases the number of incoming patients. Patient decisions will be made on an individual, case-by-case basis and are dependent on whatever levels of future demand are seen in cross-border healthcare. As discussed in the main body of the IA we are unable to estimate the numbers that may be involved.
118. There may be impacts on business of some elements of the transposition around Article 4 of the directive. However, as discussed impacts associated with policy around this article are out of scope of this IA and are being assessed separately.

Duty to Review

119. The UK implementing regulations will be reviewed 5 years after they come into force, this is a Ministerial requirement. Therefore, the expected review date will be 25 October 2018.

Small/Micro Business Assessment

It is clear that small businesses face particular challenges in their business operations. These include lack of specialist business skills, low cash flows, small asset bases and they are often expected to cope with the same levels of paperwork and regulatory obligations as larger companies. These characteristics impact upon their ability to comply with legislative requirements, in terms of the time, skills and resources required to implement changes.

As discussed above in paragraphs 103-109 and 118-122, although the patient mobility rights in the Directive itself may be a source of more significant impact on SME healthcare providers, the transposition measures are not. However, as a consequence of the transposition there may be an increase in uptake of cross-border care. This is likely to have costs (reduced domestic demand) and benefits (increased non-UK demand) to SME providers; however, these are dependent on whatever levels of future demand and patient decisions will be made on an individual, case-by-case basis. As a result it is not possible to estimate the likely net effect.

Within the Directive, the transposition around Article 4 requirements would seem to be the most relevant to SME healthcare providers in particular and certain expectations and requirements flow from this. Many of the Directive's provisions represent binding obligations on Member States (and in turn providers) and do not lend themselves to non-regulatory solutions. It will be necessary to ensure that these rights and duties are clearly set out and enforceable.

Currently, no legislative measures are deemed necessary to transpose Article 4, and thus as discussed policy proposals around this are outside scope of this impact assessment. However, we would welcome views on the possible impacts of Article 4 on small healthcare providers; this should be communicated via the consultation on this policy area that will happen in due course.

Competition Assessment

Transposition of the directive may increase the uptake of cross-border health care and thus may increase competition amongst UK and EU healthcare providers. Indeed, it may give providers a larger pool of potential patients over whom they can compete since they have the potential to attract patients from other Member States as well as domestic patients. This may have costs and benefits for domestic providers:

Domestic private providers may face increased competition from EU providers, from whom treatment may be reimbursed. This may result in a reduction in income streams.

On the other hand, while the cost of NHS care is in many cases higher than in other countries, domestic providers with spare capacity have an opportunity to attract patients from other Member States. This may be particularly true for domestic providers of highly specialised care and those who have an international reputation in particular specialisms. Being able to compete internationally helps diversify the income streams of domestic providers. With the removal of the private patient income cap, this may particularly be the case, given the ambitions outlined at Article 13 of the Directive, for NHS trusts with specialist expertise in the diagnosis and treatment of rare diseases.

In addition to the impact on domestic providers, the potential increase in competition could improve the quality of, and access to, provision of services for UK patients.

As explained in the main body of the impact assessment, there is no evidence to support that the proposed measures will lead to a substantial increase in the overall in- and/or outflow of patients. Therefore, it is not possible to understand the likely net impact of the transposition on competition.

We would welcome views on the possible impacts of competition aspects on healthcare providers.

Environmental Impact

This is difficult to judge and, as is noted throughout this impact assessment, much will depend on what level of future demand is seen in the development of cross-border healthcare as a legitimate choice for EU citizens in accessing health services and how the increase in clarity and transparency brought about by this policy will impact this.

As discussed, it is also the case that the current scale of patient mobility is thought to be very low, based on anecdotal evidence and research. Accordingly, any increase from this low baseline is not expected to be significant.

This policy may increase the demand for cross-border healthcare so it is likely that more people will travel to other Member States and so there will be some environmental impact as a result. However, as discussed, it is not possible to estimate the change in demand, although it is not expected that this will be large in general. In addition, the environmental impact should be further limited as increased demand may not lead to a net increase in travel if people access care abroad as part of usual trips or holidays. In addition, most of the associated will likely be short haul within Europe.

In the context of the millions of people who are being treated by the NHS, we expect the numbers who seek healthcare in another Member State will remain as a very small proportion of overall demand.

Health Impact Assessment

We believe that the only impact this proposed Directive is likely to have is on the potential demand for some health services, although we do not believe this to be significant. The impacts of this are discussed within the main text of the Impact Assessment. Therefore, we believe no separate health impact assessment is needed.

DIRECTIVE OBLIGATIONS

Setting up an NCP

- Ensure patients receive information from designated National Contact Points (NCPs) (article 4 and 6 of the Directive);
- Mechanisms in place to provide patients with information about rights and entitlements including conditions for reimbursement, appeal and redress (article 5);
- Duty of mutual assistance and cooperation including cooperation on standards and guidelines and exchange of information especially between NCPs (article 10);
- Ensure information on right to practice of health professionals contained in national or local registers is available on request to authorities of other Member States for the purposes of cross border healthcare (article 10).
- Provide the Commission with assistance and all necessary information for carrying out assessments and preparing (post-transposition) reports (Art 20).

Establish transparent administrative systems for reimbursement and prior authorisation

- Ensure treatment provided in accordance with standard and guidelines on safety and quality laid down in legislation and Union legislation (article 4);
- Require national authorities to reimburse the costs of cross border healthcare (article 5);
- Provide for the same medical follow up as available as if the medical care had been provided on its territory (Art 5).
- Require transparent mechanisms for calculating costs to be reimbursed (Art. 7);
- Member States may impose eligibility criteria (Art. 7);
- Member States may only impose prior authorisation in accordance with Art.8. (Art. 7)
- Healthcare subject to prior authorisation is limited to categories set out in Art.8(2);
- Member States must notify the Commission of categories of healthcare under Art.8(2)(a);
- Member States must grant prior authorisation where there is undue delay (Art 8);
- Member States may only refuse prior authorisation in the 4 circumstances set out in Art.8.
- Member States must ensure administrative procedures for reimbursement of costs are based on objective, non-discriminatory criteria (Art 9);
- Procedures must be easily accessible and publicly available “at the appropriate level” and capable of ensuring that requests are dealt with objectively (article 9);
- Member States must set reasonable time limits to decide patients’ requests, taking into account specific medical condition and urgency of individual cases. Time limits must be made public in advance (Art 9);
- Member States must ensure decisions on access to cross-border healthcare and reimbursement are properly reasoned, subject on case by case basis to review and capable of being challenged by judicial proceedings (Art 9);

Arrangements for incoming patients

- Ensure healthcare providers provide relevant information to help individual patients exercise choice, in particular on treatment options, quality and safety standards, clear invoices and price information, registration and insurance cover for clinicians and providers and that they apply the same scale of fees (Art 4);
- Ensure transparent complaints procedure and redress (Art 4);
- Privacy of patients and individuals must be respected (Art 4);
- Patients entitled to copy of record of medical treatment (Art 4).