Title:	Impact Assessment (IA)
Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation **IA No:** 3018 **Lead department or agency:** Department of Health **Other departments or agencies:**	**Date:** 03/04/2012 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation

Summary: Intervention and Options

RPC Opinion: GREEN

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**
-£13.680m	-£3.154m	£0.324m	No	NA

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

Despite rapid advances in transplantation medicine and increased use of human organs for transplantation, there is a shortage of organs available for transplantation across the European Union (EU). Member States decided in July 2010 to adopt the Organ Directive which must be transposed into UK law by 27 August 2012. The Directive seeks to improve the quality and safety of organs for transplantation, enhance the efficiency and accessibility of transplantation systems and increase organ availability across the EU. It requires the UK to set up a new licensing regime for the authorisation of procurement and transplantation activities and ensure procedures for traceability and serious adverse events / reactions.

What are the policy objectives and the intended effects?

The policy objectives are to implement in full the Directive's requirements by 27 August 2012. In doing so, officials have sought to minimise the costs and burdens involved in setting up a new licensing regime (by the appointment of a single UK-wide competent authority and, in relation to the licensing of procurement activities, focusing on the licensing of approximately 40 retrieval teams rather than require every donating Trust to have a licence). We have taken the opportunity to strengthen the UK's procedures in relation to the traceability of donors and organs and likewise standardise the reporting of serious adverse events and reactions, which in turn will lead to improved quality and safety for organs in the future.

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

Two options were considered, though the second option has two sub-options:

0. Do nothing - this is the existing baseline but would risk incurring infraction proceedings against the UK.

1. Implementation of the Directive's requirements by UK implementing regulations. Non - regulatory options are not a viable option as the authorisation requirements of the Directive require the UK to set up a new licensing regime for the procurement and transplantation of organs. Our proposed approach, amended post consultation, seeks to minimise costs and burdens by having a single UK-wide Competent Authority to license procurement and transplantation activities and, in terms of procurement, licensing retrieval teams operating out of a transplant centre. This avoids the need for each donating Trust to obtain a licence for procurement. Sub options, which we do not intend to pursue, are to have four Competent Authorities for each UK Health Administration and to licence every donating Trust.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 07/2017

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** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible SELECT SIGNATORY: D.K Date: 17/5/2012

Summary: Analysis & Evidence

Policy Option 1

Description: Full implementation of the Organ Directive

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -13.680

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	1.720		£1.431m	**£13.680m**

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

Introduction of Serious Adverse Events and Reactions IT reporting system (central costs); pre-implementation phase staff & IT costs for developing required systems and procedures at transplant centres and post-implementation monitoring costs (central costs; costs to NHS and private sector); partner engagement costs (central costs); training (costs to NHS); licensing costs for transplantation centres (costs to NHS and private sector); record-keeping requirements (costs to NHS and private sector)

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

None

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'

None

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

Greater consistency in the reporting of serious adverse events and reactions (SAE/Rs), which may lead to greater opportunity for sharing lessons learnt, and a possible small increase in safety for transplants. Consultation responses have indicated that it near impossible to quantify this benefit.

Key assumptions/sensitivities/risks | **Discount rate (%)** 3.5

Costs have been estimated using information from experts in the field.
There are currently 30 NHS and 10 private transplantation centres who carry out transplantation and procurement activities. None of these are small or micro businesses. These numbers could go up or down.
Should Option 1 not be implemented, there would be a risk under Option 0 (do nothing) of incurring infraction costs for the UK, estimated at £10-11m.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.337	**Benefits:** 0	**Net:** -0.337	No	NA

Evidence Base (for summary sheets)

What is the problem under consideration?

Introduction

1. The Organ Directive came into force on 26 August 2010 and the UK, along with other Member States, is required to fully implement it by 27 August 2012. The goal of the Directive is to set minimum standards for the quality and safety of organs intended for human transplantation. The Directive sets out the legal framework for the quality and safety of organs in the European Union and it requires the appointment of a competent authority (or authorities) in every Member State. The competent authority is responsible for ensuring compliance with EU quality and safety standards which include establishing a traceability system for human organs, a reporting system for serious adverse events and reactions (SAE/R) and ensuring that the data collection on specific organ characteristics is standardised. The Directive will primarily impact on the public sector, both centrally and on the NHS. The impact on the private sector is limited to 10 private transplant centres, none of which are small or micro businesses.

Background

2. DH officials have been involved throughout negotiations on this Directive. During 2008, the UK was invited to be part of the technical working group considering the text of a draft Directive. The draft Directive itself was published in December 2008 and formal negotiations started in February 2009 under the Czech Presidency. The final compromise text was published in May 2010 (see list of references), and the Directive came into force on 26/08/2010. Transposition must be completed by 27/08/2012.

3. The UK has been supportive of this Directive as we are keen to raise the profile of organ donation throughout the EU and build on existing partnerships to identify appropriate strategies and strengthen donation frameworks to enable more people to benefit from a transplant. However, DH officials have sought to influence the Presidency and the Commission to ensure that this Directive is not overly burdensome as this might prove to be a disincentive to organ donation and transplantation. In particular, DH officials have sought to ensure that the competent authority and authorisation requirements in this Directive do not impose an unnecessary burden on hospitals in the UK.

4. Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ donation has a very high potential of saving lives and increasing the quality of life for patients. It is also cost effective. The Organ Donation Taskforce reported 'The most obvious and significant economic benefits are shown by an analysis of the costs of renal replacement therapy – dialysis – compared with the costs of kidney transplantation. Current indicative costs suggest an average annual cost for dialysis of £23,177, compared with an initial cost of £42,025 for a transplant followed by annual maintenance costs of £6,500.'[3] This potential can only be realised, however, when a sufficient number of organs is available for transplantation, when there are adequate quality and safety measures in place to reduce the risks of diseases being transmitted, and when processes are organised efficiently and are accessible to all those who are in need.

5. The number of organ donations and transplantations has grown steadily across the EU and thousands of lives are saved every year through this medical procedure. Organ transplantation is now the most cost-effective treatment for end-stage renal failure. For end-stage failure of organs such as the liver, lung and heart, it is the only available treatment.

6. For more detail of the Directive, and the Impact Assessment carried out by EC staff, see http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/oc_organs_en.htm

Problem description

7. The UK is required to fully implement the Organ Directive by 27 August 2012. The UK already has an advanced donation and transplantation programme and NHS Blood and Transplant (NHSBT) already carries out many of the activities that the Directive requires. We also have a consent system in place for organs which is overseen by the Human Tissue Authority (HTA). However, unlike for tissues and cells where the HTA is the Competent Authority, the UK does not currently have a licensing regime in place specifically for the procurement and transplantation of organs: currently, donating hospitals and transplantation centres have registrations for general healthcare activities with the Care Quality Commission (CQC) or equivalent.

8. Despite the best efforts of policy and legal officials during the negotiations process, the wording of the Directive does not allow us to rely on the existing general regulation of healthcare activities, such as the Care Quality Commission's registration of hospitals in England, to comply with the Directive's specific authorisation requirements for procurement organisations and transplantation centres. The UK is therefore required to appoint a Competent Authority to oversee compliance with the Directive's requirements and to set up a new licensing regime to comply with the authorisation requirements in the Organ Directive. In transposing this requirement in the Directive, we have decided to focus on licensable activities and to require organisations undertaking such activities to apply for a licence covering those activities. Where organisations undertake both procurement and transplantation activities, it is the intention that such organisations will only need to complete one application form and will be issued with one licence detailing the licensed activities they may undertake.

9. In transposing the Directive's requirements into UK law, officials have sought to minimise the burdens inevitably incurred by the setting up of a new licensing regime. In particular, we have sought to avoid having to licence each and every donating hospital as this would have been a serious disincentive to donation in the UK. Instead, we will only licence the 40 or so NHS and private hospitals procuring and transplanting organs. Following consultation from 26 October to 21 December 2011, when we invited more than 400 individuals and institutions to comment, we have amended our approach to make it more light-touch and reduce costs and burdens still further: operating procedures (eg on serious adverse events/reactions reporting) will now be developed at the national level in the form of templates which can then be used / adapted by procurement organisations and transplantation centres locally. This will help reduce burdens on these organisations. In addition, HTA will no longer develop training standards for staff working in the donation – transplantation chain: instead, existing training requirements will be used, as suggested by consultees, thus helping to contain costs. Similarly, HTA will no longer specify theatre operating standards and building requirements as standards exist currently and will continue to be adhered to by procurement organisations and transplantation centres.

10. The Directive does however give us the opportunity, via UK implementing regulations, to tighten up our procedures in relation to the reporting of serious adverse events and reactions (SAE/R).

Why is it necessary to consider further intervention?

11. Organ transplantation is a potentially life saving treatment, which nevertheless involves substantial risks to the patients. These risks emanate from the quality and matching characteristics of the organ as well as the medical treatment received. The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. Transplantation can also lead to the transmission of different types of cancers. In addition, the quality and safety of organs can be at risk due to organ damage during the procurement process. To reduce these risks, most transplantation systems apply quality and safety procedures throughout the complex donation process.

12. Currently, there are wide variations in quality and safety requirements between Member States; the UK is generally ahead of many of its EU counterparts, but there is still potential for improvement, and an increase in donation rates. A national approach could not ensure a minimum standard of quality and safety for the organs that are exchanged between EU countries each year. Member States therefore agreed that a Directive is needed to ensure a high level of health protection throughout the EU by establishing common standards of quality and safety of human organs intended for transplantation.

13. The UK now has to implement the Organ Directive's requirements into UK law by 27 August 2012.

What are the policy objectives and the intended effects?

14. The Organ Directive aims to tackle current and future shortcomings in organ transplantation, and in particular to improve quality and safety of organs for transplantation. In implementing the Directive's requirements, officials have sought to minimise the costs and burdens involved in setting up a new licensing regime for the authorisation of organ procurement and transplantation activities. We propose to appoint a single UK-wide Competent Authority (the Human Tissue Authority) and, in relation to the licensing of procurement activities, we intend to license NHSBT and the organ retrieval teams operating out of a transplant centre. By taking this approach, we aim to avoid requiring every donating Trust to have a procurement licence as this would have imposed onerous costs and burdens and would also have been a considerable disincentive to donation. Following consultation, we have decided to stick with our proposed implementation approach, but in view of concerns expressed during consultation at the

lack of benefits and the costs of implementing the Organ Directive in the UK, we have amended our approach to make it more light touch and reduce costs and burdens still further, as described in paragraph 9.

15. Though the UK has an advanced organ donation and transplantation programme, officials recognise that there is room for improvement, particularly in relation to strengthening the reporting of serious adverse events and reactions (SAE/R). Implementing the Directive into UK law gives us the opportunity to do this.

What policy options have been considered?

16. In view of the specific authorisation requirements in the Organ Directive for procurement organisations and transplantation centres, the UK cannot rely on the general registrations of hospitals under the CQC or equivalent to comply with this Directive. We are therefore required to set up a new licensing regime to license all organ procurement organisations and transplantation centres. This cannot be done by non-regulatory means, only through UK implementing legislation.

17. There are two options set out in this impact assessment. The first 'do nothing' option sets out the baseline should the UK choose not to implement this Directive.

18. The second option sets out our proposed implementation approach through UK implementing regulations. We propose to appoint a single UK-wide Competent Authority, the HTA, whose primary responsibility will be to grant, suspend or withdraw the licences of organisations that are carrying out procurement or transplantation activities. The HTA will also issue Directions and guidance to healthcare establishments and professionals to ensure compliance with the Directive. In terms of the licensing of procurement activities, NHSBT (the UK-wide organ donor organisation) and retrieval teams operating out of transplant centres will be licensed to carry out procurement activities. Following consultation, we have chosen to continue with this approach but with a number of amendments as described in paragraph 9.

19. It should be noted that the Directive covers all stages of organ transplantation from procurement to follow-up.

Option 0 – Do nothing

20. Option 0 would maintain the status quo. From an EU perspective, this would mean continuing to support diverging quality and safety standards across Europe. From a UK perspective, whilst there would be no additional costs introduced through additional regulation, there would be a failure to realise the potential benefits that the Directive would bring to some areas of the organ transplantation process, notably improvements in SAE/R reporting. In addition, non implementation of the Directive would risk incurring infraction costs for the UK, estimated at £10-11m.

21. The UK has high standards for safety and quality of organs for transplantation, and is already planning a number of changes to the procedures for the organ transplant pathway (for example changes to labelling on transportation boxes) which will bring additional benefits, irrespective of the Directive.

Option 1 – Implement measures set out in Directive

22. Option 1 seeks to implement the Directive's requirements into UK law by the transposition deadline of 27 August 2012. To minimise costs and ensure uniform requirements across the UK, we are proposing to appoint a single UK-wide Competent Authority. The HTA has been appointed because it already has a track record in the regulation of human tissue under the Human Tissue Act 2004. The HTA is also the Competent Authority for the EU Directive on Tissues and Cells and therefore already regulates across the UK for the procurement, testing, processing, storage, distribution and import / export of tissues and cells intended for human application. Establishments in the UK where these activities are carried out already need a licence and the HTA has agreed to look for operational synergies between the Tissues and Cells Directive and the Organ Directive to help limit start up and regulatory costs

23. The HTA's primary role will be to grant, suspend or withdraw the licences of organisations that are carrying out procurement activities or transplantation activities. Its other main responsibilities will be to issue Directions and guidance to healthcare establishments to ensure compliance with the Directive and establish and keep up to date a framework for quality and safety. NHS Blood and Tranplant (NHSBT), on behalf of the HTA, will also put in place a reporting system and management procedure for SAE/R.

24. Organisations that wish to carry out procurement and/or transplantation activities beyond 27 August 2012 will need to be licensed by the HTA. Though the proposed UK implementing Regulations separate out activities into procurement and transplantation activities (to follow the Directive's requirements), HTA has indicated that only one application and one licence will be required for organisations that carry out both procurement and transplantation activities. This, coupled with operational synergies referred to above, should help limit burdens and costs. In relation to procurement activities, NHSBT and retrieval teams operating out of a transplant centre will be licensed to carry out procurement activities. This will help reduce costs by avoiding having to license each and every NHS Trust. Following consultation, we have sought to reduce costs and burdens still further by developing operating standards at a national level, removing requirements for the development of training standards and the specification of building / theatre operating standards from HTA's remit and using existing standards instead (see paragraph 9).

25. The HTA will visit centres that apply for a license to ensure compliance with the various requirements of the Directive. Centres that apply will have been carrying out organ donation and transplantation activity for some years and we have no indications that any centre will fall short of the standards of the Directive. However, if there are issues, the HTA will work collaboratively with any individual centre to help them fully implement the requirements of the Directive. As a result, we consider that there all established centres, including those in the private sector, should be able to continue their activities post 27 August 2012. The Directive requires the establishment in the UK by 27 August 2012 of a licensing regime specifically for organ transplantation. Because of the high standards already in place in the UK, beyond standardising practice to comply with the Directive, we do not anticipate that the new regime will add significant benefits.

26. Following consultation, we have also removed the requirement for a Designated Individual (DI) as a number of consultees expressed concern at this approach – in particular, they were concerned that there could be operational difficulties for one individual DI having responsibility for a number of units in multi-organ transplant centres. Consultees also felt that the duty to meet licensing conditions would be better placed at organisational level. We have therefore removed the DI approach from our proposed regulations though the licensing conditions will still require the organisation to comply with the Directive's requirements. Therefore, the removal of the DI role by itself will not impact on costs.

Options not considered

27. Under the second option, there are two sub-options that we have considered. The Organ Directive allows Member States to set up more than one Competent Authority to implement the requirements of the Directive. In the first sub-option, UK and Devolved Administration Ministers could have chosen to appoint a Competent Authority for each country. This would have imposed extra bureaucracy and costs, as NHSBT would have had to comply with the requirements laid down by each Competent Authority, and apply for multiple licenses. This could also have led to confusion and cross-border issues, with different Competent Authority requirements across the UK. As we are not proposing to implement this sub-option, it is not discussed any further in this impact assessment.

28. The second sub-option would have been to require each and every donating NHS Trust to be licensed to enable procurement activities to be carried out. As there are 172 acute NHS Trusts, following this sub-option would have incurred considerably more regulatory costs. It would have also disincentivised donating hospitals from procuring organs in view of the costs of obtaining a licence. As we are not proposing to implement this sub-option, it is not discussed any further in this impact assessment.

Impacts, Costs and Benefits

29. The significant impacts resulting from Option 1 are summarised in Table 1. These have been identified through consultation with the Human Tissues Authority (HTA), NHS Blood and Transplant (NHSBT) and clinicians/consultants, and the involvement of the EU Organ Directive Steering Group set up by DH. According to the EU Commission, Option 1 would deliver positive health impacts through reduced health risks to organ transplant recipients through common and consistent standards for safety and quality in organs across the EU. This was tested during consultation. Views from UK consultees were that as the UK had a well developed organ donation and transplantation programme, the Directive

would bring little direct benefits for the UK, with the exception of a possible small increase in safety for transplants as a result of greater consistency in the reporting of SAE/Rs. Quantification of the costs and benefits is difficult; some can be monetised, but for others this is not possible.

30. Therefore, as part of the consultation exercise, we sought comments on the costs and benefits identified in the consultation stage impact assessment. One renal centre provided some cost figures, which we have followed up and obtained full costing estimates. This also addresses concern that a renal or liver centre should be involved in providing costs as they comprise a large proportion of the centres. NHSBT identify the need to add in extra costs for new organ boxes to take account of the Directive's requirements, and this has been included. A further comment identified that the cost of a transplant may vary according to the size of a centre and the number of types of organs that it transplants, and so we have also consulted with a multi-unit centre for guidance on how to apply the costs from the two single-unit centres appropriately. Other comments were of a more general nature.

31. The costs below are estimates, and we have involved experts to make them as robust as possible.

Costs	**Benefits and cost savings**
Central costs (see paragraph 32) • Introduction of Serious Adverse Event and Reactions (SAE/R) reporting system (estimated **£75k one-off cost**, and **£20k per year** running cost for the central IT system, and **£20k one-off cost** and **£1k** per year for the annual reporting system). SAE/Rs are currently reported to NHSBT. Following consultation, we now expect there to be no significant extra cost in reporting incidents as a result of the Directive. • Pre-implementation phase staff and IT costs at HTA and NHSBT, for developing systems and processes to support regulation of organ procurement and transplant centres (salary costs estimated at **£342.3k one-off cost** for NHSBT and **£324k one-off cost** for HTA, with a further **£39k one-off cost** for an IT system at HTA to support the licensing.) • Partner engagement costs – running a series of workshops across the UK to inform the development of a framework for Quality and Safety, and provide some training (estimated **£41k one-off cost**) • HTA will incur enforcement and compliance costs, which will include staffing costs for administering the system and issuing guidance, maintaining their regulation IT system, as well as inspection preparation and visits. These costs are to be covered by the license fee, and so these fees are included as costs for other establishments. • NHSBT will need to ensure that traceability requirements are met by the	• Greater consistency and standardisation in the reporting of serious adverse events and reactions (SAE/Rs), may lead to greater opportunities for sharing lessons learnt. Consultees have confirmed that these benefits are difficult to quantify in monetary terms. The overall view from consultees was that increased standardisation in the reporting of serious adverse events / reactions might lead to a small increase in safety for organ transplants but would not lead to any cost savings.

procuring teams that they manage (estimated cost **£21k per year**). They will also facilitate movement of organs to and from other EU countries in line with the directive (estimated cost **£0.5k per year**). • NHSBT will need a license (estimated cost of (**£7.5k in 2012/13 and 7.9k per later year**) and to ensure compliance with the Directive's requirements (estimated cost of **£171.1k per year**). They will also carry out assisted functions for HTA (estimated **£84.8k per year**). • The specification for organ boxes for procurement and transportation will need to be amended due to the directive (estimated **£130k one-off cost**) • Following consultation, National Operating Procedures will be developed. These will then be available to individual transplant centres for adoption or adaptation, rather than the individual centres having to develop them themselves (estimated **£10k** one-off cost). *NHS costs (see paragraph 33)* • Adapting National Operating Procedures for local circumstances (estimated **£3.6k - £9.9k one-off costs** per centre depending on the number of different organs transplanted, for 30 centres) • Preparing application for a license (estimated **£5.4k - £13.4k one-off costs** per centre depending on the number of different organs transplanted, for 30 centres) • Licensing costs for transplantation centres (estimated cost of **£7.5k in 2012/13 and 7.9k per later year**, for 30 NHS transplant centres). • Hospital co-ordinators to oversee compliance with the directive will be approximately **£7.5k per year** for each centre, for 30 NHS transplant centres. • Monitoring compliance with the Directive's requirements across NHS centres following implementation (estimated cost of **£8.0k - £15.4k per year** per centre depending on the number of different organs transplanted, for 30 centres) • Training staff in the requirements of the directive on their everyday job (estimated **£3.7k - £14.8k one-off costs** per centre depending on the number of different organs transplanted, for 30 centres)	

• Record keeping requirements would be more onerous, with some extra information needing to be captured and retained (estimated cost of **£11.45 per transplant** for about **3200 transplants per year**). *Private sector costs (see paragraph 34)* • Private sector centres will face implementation costs in preparation for August 2012 (estimated **£20k one-off costs** at each of the 10 centres). • Private sector hospitals will require monitoring of compliance with the Directive, and some will require extra staff to ensure that all necessary information is appropriately available (estimated **cost £7.5k per year** per centre for hospital co-ordinators to oversee compliance, and an estimated **cost £20k per year** per centre for administrative support, across 10 centres). (We anticipate that the costs of monitoring compliance will be significantly lower in the private sector as the vast majority of transplants are from living donations.) • Private sector hospitals will also be required to hold a license (estimated cost of **£7.5k in 2012/13 and 7.9k per later year**, for the 10 private centres). • The number of private transplantation centres could go up (with new commissioning arrangements) or down (if it is not cost effective for private hospitals to obtain a licence for a small number of transplants per year).	

Costs

Central Costs

32. HTA and NHSBT have provided estimated costs for their roles in implementing the directive. HTA's estimates are based on their experience of introducing similar regulatory frameworks, in particular the EU Tissues and Cells Directive (2006-7); the costs for the IT system development come from costs already incurred in development, and anticipated costs to completion of the project; figures presented are as provided, apart from aggregating individual salary and IT development costs. Similarly, NHSBT have assessed the staffing that they will require to implement the Directive, as well as the impact of individual Articles on the cost of carrying out their business. The costs presented for the SAE/R IT system come from preliminary tenders received by NHSBT. Some aspects of the NHSBT costs contain elements related both to NHSBT responsibilities and to "assisted functions" carried out in support of HTA. Apart from the costs related to the Serious Adverse Events and Reactions system, where we show the full cost in the table above, the figures presented for the individual items relate to the NHSBT component of the costs (as estimated by NHSBT), and the costs of performing the assisted functions have been combined into a single figure. The licensing costs for transplant centres are based on estimated fees for the first two years of operation provided by HTA.

NHS Costs

33. Costs at NHS transplant centres are based on figures provided by one cardiothoracic centre, where a committee-based approach is being adopted, and one renal centre, where most of the work will be undertaken by a lead consultant. Each centre estimated the amount of time required by staff at various grades to carry out each of the identified tasks (adapting national operating procedures; applying for a license; initial training of staff; performing the hospital co-ordinator role, monitoring compliance; and capturing extra information for traceability purposes. We then used the cost per hour of doctors' and nurses' time (excluding qualifications) from chapters 14 and 15 of Unit Costs of Health and Social Care 2011[4], inflated by 2011/12 prices. As each centre will choose its own approach to implementation, we do not know which of these will be most representative, and so we take their average as our best estimate for a single-unit centre. A multi-unit centre commented on one of the two single-unit centre costs to indicate how they would need to be adjusted for a two-, three- or four-unit centre. These adjustments were used to derive appropriate multipliers that were applied to the average single-unit cost. These various costs were then multiplied by the number of centres of each size to give a national total.

Private Sector Costs

34. Costs for the private sector are based on figures provided by the transplant manager at one private hospital. He estimated that centres would need to pay an individual between an extra £5,000 and £10,000 to undertake the role of co-ordinating compliance with the directive, and that the effort required in developing standard operating procedures and applying for the license would cost around £20,000. They further estimated that, while the amount of extra administrative support required to ensure that the traceability requirements would be met, on average they would need a half-time post per centre, relating to a full-time equivalent salary of around £40k. (We invited around a dozen private healthcare providers, such as BMI Healthcare, to participate in the consultation process, but have not received any consultation responses from the private sector.)

35. The total estimated set-up cost for the NHS (both centrally and at transplant centres) is £1.520m, with an ongoing cost of around £1.078 per year. We estimate a set-up cost of £200k and an annual ongoing cost to the private sector of £354k.

36. The first year's costs cover preparation for the Directive. Subsequent years run from August to August in order to cover nine full years implementation. These figures now include estimated costs of training NHS staff, and of the extra record-keeping requirements resulting from traceability.

37. Option 1 will be evaluated against the baseline of Option 0, which is the current, or "do nothing" situation.

Benefits

38. The introduction of a robust and consistent system for reporting serious adverse events and reactions should lead to a greater awareness and understanding of the risks in various stages of the transplant process. This in turn may lead to greater opportunities for sharing lessons learnt. There will be an investigation of each event to identify if improvements to the transplant procedure can be made, so that the risk of a repeat of the adverse event or reaction is reduced. For example, if a donor-derived infection is transmitted to a recipient, then consideration can be given to the feasibility of additional pre-donation screening in order to reduce the risk of future occurrence. The majority of respondents to the consultation agreed that this might bring about a small increase in safety, but were unable to provide evidence to enable quantification. They also indicated that this would be unlikely to lead to any cost savings.

39. Consultees did not believe that there would be an increase in public confidence with a new regulator in this sector and that therefore there would not be any consequential increase in transplants. Therefore, we are no longer making any reference to this previously claimed benefit.

Net Benefits

40. Table 2 shows the average total estimated annual recurring costs and benefits as a result of Option 1, and total one-off (or transition) costs for Option 1, where these can be monetised. Annual recurring costs are calculated over a 10 year period, with standard DH discount rates applied to both costs and benefits (see reference list).

Table 2 – Total costs and benefits for Option 1 (monetised costs and benefits only)

Option 1	Annual recurring	Transition
Costs to NHS	£1,078k	£1,520k
Costs to Private Sector	£354k	£200k
Benefits and cost savings	£0	£0

41. In monetary terms, the costs and benefits for Option 1 were estimated over a ten-year period. The total net cost for Option 1, in today's prices, is £13.680m.

Risks and Assumptions

42. The impact assessment assumes one Competent Authority for the UK. The first sub-option to Option 1 (outlined in paragraph 26) included four separate Competent Authorities, one for each country in the UK. Under this sub-option, costs would have increased considerably. Additional burdens would have been placed upon NHSBT who would have had to deal with potentially conflicting requirements from different Competent Authorities for each UK Health Administration, as well as requiring multiple licenses. Under this sub-option, there would also have been the risk of cross border issues within the UK: potential confusion and delays could have been caused should an organ be transported from a donor in one country to a recipient in another country.

43. All costs are estimates.

44. Costs have been included for changes in the specification for transportation requirements for donated organs, but not the full cost as NHSBT are already planning to replace the boxes. Transport costs for private hospitals are assumed to be negligible, as most will be carrying out living donor kidney transplants from donors on-site.

45. The number of private transplantation centres could go up or down, depending on the new commissioning arrangements, or the cost of licensing; the cost benefit analysis assumes that the number stays constant.

46. Many of the Directive requirements are currently in place in the UK, and therefore do not introduce additional burdens. Where transplantation centres are not currently meeting these requirements, i.e. they are non-compliant in a particular area, there will be additional burdens.

Summary and Conclusions

47. The EU Organ Directive has been drawn up by the European Commission in order to ensure that the transplantation of organs across the European Union meets minimum quality and safety standards. From a UK perspective, non-implementation of the directive would not lead to any additional costs introduced through regulation, but would fail to realise benefits that the Directive could bring to some areas of the organ transplantation process. In addition, non-implementation of the Directive would risk incurring infraction costs for the UK, estimated at £10-11m.

48. Transplant surgery in the United Kingdom is among the safest in the EU prior to the Directive, and already meets many of the standards that are laid out. As a result, implementing the Directive (Option 1) is expected to affect background activity and have a little impact on front-line activity.

49. There is a small risk that the licence fee and new requirements might cause the units with very little activity to cease working in the transplantation field from 27 August 2012. This may have a marginal impact on competition. Also, we understand that no small or micro businesses undertake organ transplants.

50. We expect that implementing the Directive will have no impact on the availability of organ transplants through the NHS. We anticipate that there will be no issues relating to statutory equality duties, health and well-being or human rights, and to have no adverse effect on rural communities.

51. We expect there to be minimal impact on the justice system. By introducing the requirement for standard operating procedures, and for explicit quality standards, implementing the Directive may reduce the likelihood of litigation but will require specific penalties and sanctions to be agreed.

52. We expect implementation of the directive to have no impact on greenhouse gas emission, sustainable development or wider environmental issues.

53. The main burdens placed by the Directive are the appointment of a new Competent Authority and the setting up of the new licensing regime for procurement and transplantation activities. The overall cost over a 10 year period for implementing the Directive in the UK is £13.680 million. These costs have been minimised, as officials have sought to implement the Directive's requirements in the least burdensome way possible, subject to the constraints of having to adopt a regulatory route to appoint a new Competent Authority and licensing regime. By appointing a single Competent Authority for the whole of the United Kingdom, and only requiring those NHS acute trusts that are directly affected to be licensed, we have limited the impact of the Directive as far as possible while maintaining its quality requirements. Following consultation, we have reduced further costs and burdens placed on licensees, as described in paragraph 9.

References:

1. Initial Directive text, plus EU Impact Assessment
   http://ec.europa.eu/health/blood_tissues_organs/organs/index_en.htm

2. Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (final compromise text)

   http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0053:EN:NOT

3. Organs for Transplants: a report from the Organ Donation Taskforce (2008)
   http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf

4. Unit Costs of Health and Social Care 2011 (2011) – Personal Social Services Research Unit, University of Kent
   http://www.pssru.ac.uk/pdf/uc/uc2011/uc2011.pdf

ANNEX 1: POST-IMPLEMENTATION PLAN

Basis of the review: The UK implementing regulations will be reviewed 5 years after they come into force, this is a Ministerial requirement. Therefore, the expected review date is expected to be by July 2017.
Review objective: The review objective will be to ascertain whether, in implementing the Directive's requirements, we have been successful in minimising the costs and burdens involved in setting up a new licensing regime for the authorisation of organ procurement and transplantation activities. We will want to examine whether the Directive has acted as an incentive or disincentive for organ donation and transplantation in the UK. We will also want to ascertain whether the UK's procedures for traceability and the reporting of SAE/R have improved over the 5-year period.
Review approach and rationale: Officials have consulted widely with the transplantation community to determine our approach to the Organ Directive (stakeholder groups were regularly held during the negotiations phase and now implementation phase. The HTA has hosted a workshop to engage the wider community on how best to implement the Directive and further training workshops will be provided in May and June 2012) We have also made some amendments to our proposed implementation approach following public consultation. During the review phase (to take place by July 2017), we would intend to seek stakeholder views to accurately determine how successful implementation of the Directive has been in the UK.
Baseline: Baseline set out under Option 0.
Success criteria: That the Directive is implemented on time, thus avoiding infraction procedings. That the Directive does not act as a disincentive to organ donation and transplantation in the UK by imposing considerable burdens on UK procurement organisations and transplantation centres. That the UK's traceability and SAE/R reporting procedures have improved over the 5 year period.
Monitoring information arrangements: The Competent Authority, the HTA, is required to publish reports on transplantation activity in the UK. NHSBT also has comprehensive statistical data on transplantation activity by centre across the UK. The European Commission will also review how the Directive is being implemented in Member States.
Reasons for not planning a reivew: N/A - review is a Ministerial requirement and will be required by July 2017.

ANNEX 2: EQUALITY ANALYSIS

Title: Consultation on Regulations to implement Organ Directive 2010/53/EC
Relevant line in DH Business Plan 2011-2015**:**

What are the intended outcomes of this work? *Include outline of objectives and function aims*
Improved safety and quality of organs procured and transplanted in the UK

Who will be affected? *e.g. staff, patients, service users etc*
All donors and recipients of donated organs for transplant and staff of transplant centres and NHS Blood and Transplant

Evidence *The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the assessment. For more information, see the current DH Transparency Plan.*

What evidence have you considered? *List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.*
The Directive underwent an 18 month negotiation with the 27 Member States to seek agreement. The implementation requirements of the Directive have been discussed by the Directive steering group consisting of officials from the four health administrations, Human Tissue Authority – the Competent Authority designate for running the regulation programme, with NHS Blood and Transplant (the organisation responsible for holding the names of all people awaiting a transplant in the UK and the allocation of organs) with representatives of the transplant community and lawyers.
In addition we have held focus group meeting with representatives from all the transplant centres across the UK and with representatives from the patient and voluntary sector.

The UK already has a very well developed transplant programme. The Directive does not therefore require the UK to change its systems greatly as it already implements so many of the Directive's requirements. The impact will be in its back office functions.

For example the UK does not currently licence specifically organ procurement and transplant activity – it has relied on general registration of hospitals through the health care regulator, such as the Care Quality Commission in England. Nor does it have a specific health care regulator for organ donation and transplantation except through the CQC and equivalent requirements and licensable activities under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 - eg requiring consent / authorisation before donation of human tissue.

Therefore the only significant changes likely to be made as a consequence of the implementation of the Directive are:

- establishment of a Competent Authority for the UK (The Human Tissue Authority)
- the setting up of a new licensing regime that will require some 30 NHS and 10 private hospitals to obtain a licence to continue to practice procurement and transplantation activities after 27 August 2012
- a single defined system for the recording and reporting of severe adverse events and reactions
- standardisation of the characterisation of the donor across the EU (not an issue for the UK as we already collect the data required)
- the requirement for data to be kept for 30 years

This is all backroom changes – and will have little direct effect on the public.

Staff will have to be trained to comply with the Directive in respect of severe adverse event reporting and being able to demonstrate that the hospital complies with the requirements of the Directive as part of the licensing regime, but this will not have an inequitable effect on patient groups.

The Directive does however give us the opportunity, via UK implementing regulations, to tighten up our procedures in relation to the reporting of serious adverse events and reactions (SAE/R).

Why is it necessary to consider further intervention?

Organ transplantation is a potentially life saving treatment, which nevertheless involves substantial risks to the patients. These risks emanate from the quality and matching characteristics of the organ as well as the medical treatment received. The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. Transplantation can also lead to the transmission of different types of cancers. In addition, the quality and safety of organs can be at risk due to organ damage during the procurement process. To reduce these risks, most transplantation systems apply quality and safety procedures throughout the complex donation process.

Currently, there are wide variations in quality and safety requirements between Member States; the UK is generally ahead of many of its EU counterparts, but there is still potential for improvement, and an increase in donation rates. A national approach could not ensure a minimum standard of quality and safety for the organs that are exchanged between EU countries each year. Member States therefore agreed that a Directive is needed to ensure a high level of health protection throughout the EU by establishing common standards of quality and safety of human organs intended for transplantation.

It is also important to note that people with long tem ill health may have conditions that may require a transplant eg liver disease or chronic kidney disease. Also people from the BME communities are 3-5 times more likely to suffer from diseases that require a transplant (eg cardiovascular disease and diabetes) . Although the implementation of the Directive is unlikely to change much of what we do in relation to taking consent, working with families, testing and allocating organs for transplant, traceability and follow-up, it will standardise some of our practice in some areas such as severe adverse event and reaction reporting and ensure occurrences are notified promptly to ensure that other recipients of the donor's organs can be identified quickly and not transplanted if appropriate. This may lead to greater opportunities for sharing lessons learnt which in turn might lead to a small increase in safety for organ transplants.

Disability *Consider and detail (including the source of any evidence) on attitudinal, physical and social barriers.*
No impact – the implementation of the Directive will not limit organ availability for transplant though we recognise that generally people with long term conditions may require a transplant such as chronic kidney or liver disease.

Sex *Consider and detail (including the source of any evidence) on men and women (potential to link to carers below).*
No impact

Race *Consider and detail (including the source of any evidence) on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.*
People from black and minority ethnic backgrounds are 3-5 times more likely to suffer a condition that could require a transplant. Work outside this Directive, through the implementation of the organ donation taskforce recommendations are taking work forward in this area.

Age *Consider and detail (including the source of any evidence) across age ranges on old and younger people. This can include safeguarding, consent and child welfare.*
No impact

Gender reassignment (including transgender) *Consider and detail (including the source of any evidence) on transgender and transsexual people. This can include issues such as privacy of data and harassment.*
No impact

Sexual orientation *Consider and detail (including the source of any evidence) on heterosexual people as well as lesbian, gay and bi-sexual people.*
No impact

Religion or belief *Consider and detail (including the source of any evidence) on people with different religions, beliefs or no belief.*
No impact - discussions with families around consent will remain unchanged through the implementation of the Directive

Pregnancy and maternity *Consider and detail (including the source of any evidence) on working arrangements, part-time working, infant caring responsibilities.*

No change

Carers *Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.*

No change

Other identified groups *Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.*
n/a

Engagement and involvement

Was this work subject to the requirements of the cross-government Code of Practice on Consultation? (Y/N) Yes
The Regulations to transpose the Directive were consulted on in late 2011. A specific question has been asked in relation to equality impact.

How have you engaged stakeholders in gathering evidence or testing the evidence available?

We have engaged stakeholders by consulting the Organ Directive Implementation Steering Group when developing implementing regulations. We have carried out a full consultation of stakeholders in late 2011 and have amended our proposed implementation approach to take account of their views, where possible, bearing in mind the requirements of the Directive. In addition to the public consultation, we have also re-approached the two original centres and engaged with two further centres to make our cost estimates more robust.

How have you engaged stakeholders in testing the policy or programme proposals?

The majority of the Directive's requirements are already in place. Workshops planned for May and June will test out the regulatory model with stakeholders before implementation in August 2012

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

See above

Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.

Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation,

advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
n/a

Advance equality of opportunity *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
n/a

Promote good relations between groups *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
n/a

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?*
n/a

Addressing the impact on equalities *Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.*
n/a

Action planning for improvement *Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.*
n/a

Please give an outline of your next steps based on the challenges and opportunities you have identified. *Include here any or all of the following, based on your assessment*

- *Plans already under way or in development to address the **challenges** and **priorities** identified.*
- *Arrangements for continued engagement of stakeholders.*
- *Arrangements for continued monitoring and evaluating the policy for its impact on different groups as the policy is implemented (or pilot activity progresses)*
- *Arrangements for embedding findings of the assessment within the wider system, OGDs, other agencies, local service providers and regulatory bodies*
- *Arrangements for publishing the assessment and ensuring relevant colleagues are informed of the results*
- *Arrangements for making information accessible to staff, patients, service users and the public*
- *Arrangements to make sure the assessment contributes to reviews of DH strategic equality objectives.*

The vast majority of consultees felt that there were no potential inequality issues.

For the record

Name of person who carried out this assessment:

Triona Norman

Date assessment completed:
02 March 2012

Name of responsible Director/Director General:
Mark Bale

Date assessment was signed:
06 March 2012

Action plan template

This part of the template is to help you develop your action plan. You might want to change the categories in the first column to reflect the actions needed for your policy.

Category	Actions	Target date	Person responsible and their Directorate
Involvement and consultation	Consultation late 2011	October 2011	Triona Norman HIP Directorate Department of Health
Data collection and evidencing	As above		,,,
Analysis of evidence and assessment	Analysis of consultation comments	January 2012	,,
Monitoring, evaluating and reviewing	January 2012 of consultation comments March / April 2012 – regulatory approach	Early 2012	Triona Norman, HIP Directorate, Department of Health Human Tissue Authority
Transparency (including publication)	Consultation Document late 2011 Draft Regulations	October 2011	Triona Norman HIP Directorate Department of Health