Deutscher Bundestag **Drucksache 16/11781**

16. Wahlperiode 28. 01. 2009

Beschlussempfehlung und Bericht

des Ausschusses für Gesundheit (14. Ausschuss)

zu der Unterrichtung durch die Bundesregierung – Drucksache 16/11517 Nr. A.30 –

Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe (inkl. 16521/08 ADD 1 und 16521/08 ADD 2) (ADD 1 in Englisch) KOM(2008) 818 endg.; Ratsdok. 16521/08

A. Problem

Nach einer Erhebung der Europäischen Kommission gibt es in den Rechtsvorschriften der Mitgliedstaaten für Organe, die zur Transplantation bestimmt sind, erhebliche Unterschiede bezüglich der Qualitäts- und Sicherheitsanforderungen. Dies hat nach Auffassung der Europäischen Kommission Rückwirkungen auf den Organtausch zwischen den Mitgliedstaaten. Folge seien ein Mangel an bestimmten Organen und Versorgungsengpässe in kleineren Mitgliedstaaten. Außerdem rufe ein Mangel an legal verfügbaren Organen illegalen internationalen Handel mit Organen hervor.

Im Rahmen eines Testlaufs, der auf Anregung der Konferenz der Ausschüsse für Gemeinschafts- und Europaangelegenheiten der Parlamente der Europäischen Union (COSAC) durchgeführt wird, ist vor der weiteren inhaltlichen Auseinandersetzung mit diesem Vorschlag zu prüfen, ob der Entwurf der Richtlinie mit den Grundsätzen der Subsidiarität vereinbar ist.

B. Lösung

Feststellung, ob Bedenken hinsichtlich der Einhaltung des gemeinschaftsrechtlichen Grundsatzes der Subsidiarität bestehen. Dabei wird eine Klärung vorausgesetzt, dass Artikel 18 des Richtlinienentwurfs keinen Eingriff in die innerstaatliche Organisationshoheit der Bundesrepublik Deutschland bedeutet und die derzeitige Stiftungslösung nicht tangiert ist. Außerdem besteht in weiteren Einzelpunkten Klarstellungsbedarf. Die Verhältnismäßigkeit kann zurzeit nicht abschließend bewertet werden.

Annahme einer Entschließung mit den Stimmen der Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN gegen die Stimmen der Fraktion DIE LINKE. bei Stimmenthaltung der Fraktion der FDP

C. Alternativen

Ablehnung der von den Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN vorgelegten Entschließung und Annahme des Entschließungsantrages der Fraktion DIE LINKE.

D. Kosten

Die Kosten können wegen fehlender Grundlagen nicht ermittelt werden.

Beschlussempfehlung

Der Bundestag wolle beschließen,

in Kenntnis der Unterrichtung durch die Bundesregierung auf Drucksache 16/11517 Nr. A.30 folgende Entschließung anzunehmen:

Der Deutsche Bundestag stellt fest:

Der Deutsche Bundestag hat den Vorschlag der EU-Kommission für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe KOM(2008) 818 endg.; Ratsdok. 16521/08 im Hinblick auf die Wahl der Rechtsgrundlage und das Subsidiaritätsprinzip überprüft. Im Hinblick auf die Wahl der Rechtsgrundlage bestehen keine Bedenken. Im Hinblick auf die Einhaltung des Subsidiaritätsprinzips sieht der Bundestag in Einzelpunkten Klarstellungsbedarf. Ob der Richtlinienentwurf dem Grundsatz der Verhältnismäßigkeit genügt, kann nicht abschließend beurteilt werden, da der Entwurf zu den voraussichtlichen finanziellen und administrativen Belastungen für die Mitgliedstaaten keine detaillierten Angaben enthält.

Berlin, den 28. Januar 2009

Der Ausschuss für Gesundheit

Dr. Martina Bunge	**Michael Hennrich**
Vorsitzende	Berichterstatter

Bericht des Abgeordneten Michael Hennrich

I. Überweisung

Der Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe KOM(2008) 818, Ratsdok. 16521/08 wurde dem Ausschuss für Gesundheit federführend zur Beratung und dem Rechtsausschuss sowie dem Ausschuss für die Angelegenheiten der Europäischen Union mitberatend überwiesen.

II. Wesentlicher Inhalt der Vorlage

Der Richtlinienvorschlag soll sicherstellen, dass zu Transplantationszwecken verwendete Organe in der Europäischen Union einheitlichen Qualitäts- und Sicherheitsanforderungen genügen. Auf diese Weise soll die Richtlinie den Austausch von Organen unter den Mitgliedstaaten erleichtern.

In den Mitgliedstaaten sollen zuständige, amtlich anerkannte Stellen die Einhaltung der EU-weiten Qualitäts- und Sicherheitsstandards gewährleisten.

Zu diesen Standards soll die Einrichtung eines Rückverfolgbarkeitssystems für menschliche Organe sowie eines Meldesystems für schwerwiegende Zwischenfälle und unerwünschte Reaktionen gehören.

Um eine geeignete Nutzen-Risiko-Analyse zu ermöglichen, soll die Datenerhebung bestimmter Organ- und Spendercharakterisierungen standardisiert werden. In den Mitgliedstaaten soll ein nationales Qualitätsprogramm festgelegt werden, das den gesamten Prozess der Organspende und -transplantation abdecken soll. Durch dieses Qualitätsprogramm soll eine ständige Überwachung der Leistungen, Verbesserungen und Lernprozesse sichergestellt werden. Der Vorschlag sieht Maßnahmen zum Schutz des Lebendspenders vor: die Mitgliedstaaten sollen die korrekte Beurteilung der Gesundheit des Spenders, eine umfassende Aufklärung sowie die Einführung eines Registers für lebende Spender sicherstellen.

Zudem sollen die Mitgliedstaaten die Freiwilligkeit und Unentgeltlichkeit der Spende menschlicher Organe von lebenden und verstorbenen Spendern sicherstellen.

III. Stellungnahmen der mitberatenden Ausschüsse

Der **Rechtsausschuss** hat in seiner 124. Sitzung am 28. Januar 2009 festgestellt, dass der Testlauf zur Subsidiaritäts- und Verhältnismäßigkeitsprüfung unkoordiniert verlaufen sei und sich das Verfahren damit als verbesserungswürdig erwiesen habe. Er bittet den Ausschuss für Wahlprüfung, Immunität und Geschäftsordnung darum, das Verfahren der Subsidiaritätsprüfung grundsätzlich in Abstimmung mit den anderen Ausschussvorsitzenden zu klären und Regeln für dieses Verfahren aufzustellen.

Der **Ausschuss für die Angelegenheiten der Europäischen Union** hat in seiner 77. Sitzung am 28. Januar 2009 zu dem Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe – KOM(2008) 818 endgültig; Ratsdok. 16521/08 – ein Votum zur Subsidiaritätsprüfung abgegeben. Das Votum wurde mit den Stimmen der Fraktionen CDU/CSU, SPD, FDP und BÜNDNIS 90/DIE GRÜNEN gegen die Stimmen der Fraktion DIE LINKE. gefasst. Das Votum hat folgenden Wortlaut:

„Der Ausschuss für die Angelegenheiten der Europäischen Union hat den Entwurf im Hinblick auf die Wahl der Rechtsgrundlage und das Subsidiaritätsprinzip überprüft. Im Hinblick auf die Wahl der Rechtsgrundlage bestehen keine Bedenken. Im Hinblick auf die Einhaltung des Subsidiaritätsprinzips sieht der Ausschuss Klarstellungsbedarf. Ob der Richtlinienentwurf dem Grundsatz der Verhältnismäßigkeit genügt, kann nicht abschließend beurteilt werden, da der Entwurf zu den voraussichtlichen finanziellen und administrativen Belastungen für die Mitgliedstaaten keine detaillierten Angaben enthält.

Vorbemerkung

Die Subsidiaritätsprüfung findet im Rahmen eines durch die COSAC verabredeten Testlaufs statt, bei dem Erfahrungen im Hinblick auf das Frühwarnverfahren zur Subsidiaritätskontrolle gesammelt werden sollen, das durch den Vertrag von Lissabon eingeführt wird und das den nationalen Parlamenten erweiterte Kontrollmöglichkeiten eröffnet. Da gegenwärtig noch kein eigenständiges geschäftsordnungsrechtliches Verfahren zur Subsidiaritätskontrolle nach dem Vertrag von Lissabon existiert, erfolgt der Beschluss im Rahmen des zur Mitwirkung gegenüber der Bundesregierung vorgesehenen Verfahrens. Er richtet sich aber primär an die Europäische Kommission. Die Prüfung der Einhaltung des Grundsatzes der Subsidiarität beinhaltet nicht die inhaltliche Befassung mit dem Richtlinienvorschlag. Diese bleibt der weiteren parlamentarischen Beratung durch die Fachausschüsse und das Plenum des Deutschen Bundestages zu einem späteren Zeitpunkt vorbehalten.

Begründung

Grundlage des mitberatenden Votums ist die Begründung des Antrages der Fraktionen CDU/CSU, SPD, FDP und BÜNDNIS 90/DIE GRÜNEN (Ausschussdrucksache 16(21)768), der in der 77. Sitzung des Ausschusses für die Angelegenheiten der Europäischen Union am 28. Januar 2009 mehrheitlich angenommen wurde. Die Begründung lautet wie folgt:

I.

Die Europäische Kommission hat am 8. Dezember 2008 einen Vorschlag für eine Richtlinie des europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe verabschiedet. Im Entwurf der Richtlinie wird als wesentliches Ziel formuliert, dass ‚in allen Phasen des Verfahrens – Spende, Beschaffung, Testung, Konservierung, Beförderung und Übertragung' – einheitliche Qualitäts- und Sicherheitsstandards gelten und damit ein hohes

Gesundheitsschutzniveau gewährleistet wird. In dem gleichzeitig veröffentlichten – nichtlegislativen – Aktionsplan werden Maßnahmen vorgeschlagen, die zu einer Erhöhung der Organverfügbarkeit und zu einer Förderung der Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme beitragen sollen.

II.

Der Richtlinienvorschlag basiert auf Artikel 152 Abs. 4 EGV. Dieser sieht auf Gemeinschaftsebene ausdrücklich Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für Organe vor. Ziel der Richtlinie ist es, einen einheitlich hohen Qualitäts- und Sicherheitsstandard in den Mitgliedstaaten der Europäischen Union zu schaffen.

Was die Schaffung eines europaweit einheitlich hohen Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte Organe betrifft, bestehen bezüglich der Rechtsgrundlage keine Bedenken. Der Ausschuss weist jedoch nachdrücklich darauf hin, dass nach Artikel 152 Abs. 5 Satz 2 des EG-Vertrags (EGV) die Spende und die medizinische Verwendung von Organen in der ausschließlichen Zuständigkeit der Mitgliedstaaten liegen und daher der Rechtsetzungskompetenz der Gemeinschaft entzogen sind.

III.

Nach dem Subsidiaritätsprinzip wird die Gemeinschaft in den Bereichen, die nicht in ihre ausschließliche Zuständigkeit fallen, nur tätig, sofern und soweit die Ziele der in Betracht gezogenen Maßnahmen auf der Ebene der Mitgliedstaaten nicht ausreichend erreicht werden können und daher wegen ihres Umfangs oder ihrer Wirkungen besser auf Gemeinschaftsebene ausgeführt werden können. Der Vertrag von Lissabon bezeichnet diese Zuständigkeit als geteilte Zuständigkeit und schreibt für diese in Artikel 5 Abs. 3 weiterhin die Einhaltung des Subsidiaritätsprinzips vor.

Der Richtlinienentwurf muss daher den Nachweis erbringen, dass die darin verfolgten Ziele auf Ebene der Mitgliedstaaten nicht ausreichend erreicht werden können. Was die Schaffung eines europaweit einheitlich hohen Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte Organe betrifft, bestehen insoweit keine Bedenken, als durch eine europäische Richtlinie EU-weit einheitliche Standards verbindlich festgelegt werden können. Allerdings ist in dem Zusammenhang auch darauf hinzuweisen, dass zwischen einer Reihe von Mitgliedstaaten und Drittstaaten schon heute im Verbund von Eurotransplant der Organaustausch gängige Praxis ist.

Bei der Prüfung der Einhaltung des Subsidiaritätsgrundsatzes bedarf insbesondere Artikel 18 des Richtlinienentwurfs einer intensiveren Prüfung. Dieser schreibt die Benennung zuständiger Behörden in den Mitgliedstaaten vor, die auf Grundlage nationaler Qualitätsprogramme arbeiten und die Einhaltung der Qualitäts- und Sicherheitsstandards gewähren. Der Wortlaut des Artikels 18 legt mit dem Begriff Behörde nahe, dass dies ausschließlich Stellen sein können, die als Organ des Staates Aufgaben der öffentlichen Verwaltung wahrnehmen. Andere Strukturen, etwa die in Deutschland praktizierte Betrauung einer Stiftung, wäre damit ausgeschlossen. Ein derartiger Eingriff in die innerstaatliche Organisation des Gesundheitswesens wäre mit dem Subsidiaritätsprinzip nicht vereinbar.

Die Einrichtung bzw. Anerkennung zuständiger, amtlich anerkannter Stellen, die auf Grundlage nationaler Qualitätsprogramme arbeiten und in den jeweiligen Mitgliedstaaten die Einhaltung der Qualitäts- und Sicherheitsstandards gewähren, wie es der Inhalt des Artikels 18 des Richtlinienentwurfs vorsieht, dient allerdings der Erreichung der Zielsetzung. Aus dem Erwägungsgrund (19) des Richtlinienvorschlags geht hervor, dass die konkrete Ausgestaltung der Behördenstruktur jedem einzelnen Mitgliedstaat vorbehalten ist. Damit wäre für Deutschland der Aufbau einer neuen Behördenstruktur nicht erforderlich.

Um zu verdeutlichen, dass auch Artikel 18 des Richtlinienentwurfes keinen Eingriff in die innerstaatliche Organisationshoheit darstellt, ist eine Klarstellung im Wortlaut des eigentlichen Textes der Richtlinie erforderlich.

IV.

Nach dem Grundsatz der Verhältnismäßigkeit (Artikel 2 EUV i. V. m. Artikel 5 Absatz 3 EGV; nach dem Lissabonner Vertrag: Artikel 5 Absatz 4 EUV) dürfen Maßnahmen der Gemeinschaft bzw. Union inhaltlich wie formal nicht über das zur Erreichung der Ziele der Verträge erforderliche Maß hinausgehen. Zu prüfen ist, ob die Bindungswirkung und Regelungsdichte des Gesetzgebungsvorschlags erforderlich sind.

Zentrales Problem im Hinblick auf Organspende und Transplantation in den Mitgliedstaaten ist der verbreitete Organmangel. Institutionen aus dem Gesundheitssektor, wie die DKG und GKV als Auftraggeber der Deutschen Stiftung Organtransplantation und von Eurotransplant, weisen darauf hin, dass es in keinem Mitgliedstaat Organüberschuss gibt. Es ist allerdings ungewiss, ob die im Richtlinienentwurf enthaltenen angestrebten Qualitäts- und Sicherheitsstandards tatsächlich dazu beitragen können, diesen Mangel zu beseitigen oder den Austausch von Organen zwischen den Mitgliedstaaten zu befördern.

Die Richtlinie setzt Mindeststandards, d. h. die Mitgliedstaaten können in ihrem Hoheitsgebiet höhere Qualitäts- und Sicherheitsstandards regeln oder beibehalten. Gleichzeitig ist mit Blick auf den verbleibenden Regelungsspielraum für die Mitgliedstaaten zu bedenken, dass in einem Ausschussverfahren Durchführungsmaßnahmen erlassen werden können (vgl. Artikel 25 und 26 des Richtlinienvorschlags). Es ist anhand des Richtlinienvorschlags selbst nicht ohne weiteres zu beurteilen, ob durch derartige Regelungen die Regelungsdichte zu Lasten der Mitgliedstaaten unangemessen erhöht werden kann.

Zu den voraussichtlichen finanziellen und administrativen Belastungen für die Mitgliedstaaten enthalten die Ausführungen keine detaillierten Angaben. Es kann daher nicht abschließend beurteilt werden, ob sich die von der Kommission angeführten Regelungsbestandteile wie die Errichtung einzelstaatlicher Aufsichtsbehörden, die Zulassung von Einrichtungen und Programmen für Organspende und Organbeschaffung und die Einrichtung von Inspektionsstrukturen nachteilig auf die in vielen EU-Ländern vorhandene, leistungsfähige Organisationsstruktur auswirken und mit einem erheblichen bürokratischen Aufwand verbunden sein könn-

ten. Um die Verhältnismäßigkeit des Richtlinienentwurfs abschließend bewerten zu können – insbesondere im Hinblick auf die Frage nach alternativen Lösungen mit einer geringeren Regelungsdichte, wie zum Beispiel der Abschluss von Abkommen durch die Kommission mit Mitgliedstaaten, die sich bislang nur in geringer Weise am Organaustausch beteiligen – sind genaue Angaben zu den bürokratischen Belastungen erforderlich. Auch nach Auffassung der Bundesregierung kann die Frage des rechtlichen Anpassungsbedarfes erst im weiteren Verfahren geklärt werden."

IV. Beratungsverlauf und Beratungsergebnisse im federführenden Ausschuss

Der Ausschuss für Gesundheit hat in seiner 104. Sitzung am 21. Januar 2009 die Beratung über die Vorlage auf Ratsdok. 16521/08 aufgenommen. In seiner 106. Sitzung am 28. Januar 2009 hat der Ausschuss die Beratung fortgesetzt und abgeschlossen. Als Ergebnis empfiehlt er mit den Stimmen der Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN gegen die Stimmen der Fraktion DIE LINKE. bei Stimmenthaltung der Fraktion der FDP, die in der Beschlussempfehlung wiedergegebene, von den Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN vorgelegte Entschließung anzunehmen. Die Entschließung wird wie folgt begründet:

„Vorbemerkung

Die Subsidiaritätsprüfung findet im Rahmen eines durch die COSAC verabredeten Testlaufs statt, bei dem Erfahrungen im Hinblick auf das Frühwarnverfahren zur Subsidiaritätskontrolle gesammelt werden sollen, das durch den Vertrag von Lissabon eingeführt wird und das den nationalen Parlamenten erweiterte Kontrollmöglichkeiten eröffnet. Da gegenwärtig noch kein eigenständiges geschäftsordnungsrechtliches Verfahren zur Subsidiaritätskontrolle nach dem Vertrag von Lissabon existiert, erfolgt der Beschluss im Rahmen des zur Mitwirkung gegenüber der Bundesregierung vor gesehenen Verfahrens. Er richtet sich aber primär an die Europäische Kommission. Es ist darauf hinzuweisen, dass die Bewertung der Einhaltung der Grundsätze der Subsidiarität die inhaltliche Befassung mit dem Richtlinienvorschlag nicht präjudiziert. Diese bleibt der weiteren parlamentarischen Beratung durch die Fachausschüsse und das Plenum des Deutschen Bundestages vorbehalten.

Ziel der Richtlinie

Die Europäische Kommission hat am 8. Dezember 2008 einen Vorschlag für eine Richtlinie des europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe verabschiedet. Im Entwurf der Richtlinie wird als wesentliches Ziel formuliert, dass ‚in allen Phasen des Verfahrens – Spende, Beschaffung, Testung, Konservierung, Beförderung und Übertragung' – einheitliche Qualitäts- und Sicherheitsstandards gelten und damit ein hohes Gesundheitsschutzniveau gewährleistet wird. In dem gleichzeitig veröffentlichten – nichtlegislativen – Aktionsplan werden Maßnahmen vorgeschlagen, die zu einer Erhöhung der Organverfügbarkeit und zu einer Förderung der Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme beitragen sollen.

Rechtsgrundlage

Der Richtlinienvorschlag basiert auf Artikel 152 Abs. 4 EGV. Dieser sieht auf Gemeinschaftsebene ausdrücklich Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für Organe vor. Ziel der Richtlinie ist es, einen einheitlich hohen Qualitäts- und Sicherheitsstandard in den Mitgliedstaaten der Europäischen Union zu schaffen.

Was die Schaffung eines europaweit einheitlich hohen Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte Organe betrifft, bestehen bezüglich der Rechtsgrundlage keine Bedenken. Der Ausschuss weist jedoch nachdrücklich darauf hin, dass nach Artikel 152 Abs. 5 Satz 2 des EG-Vertrags (EGV) die Spende und die medizinische Verwendung von Organen in der ausschließlichen Zuständigkeit der Mitgliedstaaten liegen und daher der Rechtsetzungskompetenz der Gemeinschaft entzogen sind.

Subsidiarität

Nach dem Subsidiaritätsprinzip wird die Gemeinschaft in den Bereichen, die nicht in ihre ausschließliche Zuständigkeit fallen, nur tätig, sofern und soweit die Ziele der in Betracht gezogenen Maßnahmen auf der Ebene der Mitgliedstaaten nicht ausreichend erreicht werden können und daher wegen ihres Umfangs oder ihrer Wirkungen besser auf Gemeinschaftsebene ausgeführt werden können. Der Vertrag von Lissabon bezeichnet diese Zuständigkeit als geteilte Zuständigkeit und schreibt für diese in Artikel 5 Abs. 3 weiterhin die Einhaltung des Subsidiaritätsprinzips vor.

Der Richtlinienentwurf muss daher den Nachweis erbringen, dass die darin verfolgten Ziele auf Ebene der Mitgliedstaaten nicht ausreichend erreicht werden können. Was die Schaffung eines europaweit einheitlich hohen Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte Organe betrifft, bestehen insoweit keine Bedenken, als durch eine europäische Richtlinie EU-weit einheitliche Standards verbindlich festgelegt werden können. In diesem Zusammenhang ist auch darauf hinzuweisen, dass zwischen einer Reihe von Mitgliedstaaten und Drittstaaten schon heute z. B. im Verbund von Eurotransplant der Organaustausch gängige Praxis ist.

Bei der Prüfung der Einhaltung des Subsidiaritätsgrundsatzes bedarf insbesondere Artikel 18 des Richtlinienentwurfs einer intensiveren Prüfung. Dieser schreibt die Benennung zuständiger Behörden in den Mitgliedstaaten vor, die auf Grundlage nationaler Qualitätsprogramme arbeiten und die Einhaltung der Qualitäts- und Sicherheitsstandards gewähren. Der Wortlaut des Artikels 18 legt mit dem Begriff ‚Behörde' nahe, dass dies ausschließlich Stellen sein können, die als Organ des Staates Aufgaben der öffentlichen Verwaltung wahrnehmen. Andere Strukturen, etwa die in Deutschland praktizierte Betrauung einer Stiftung, wäre damit ausgeschlossen. Ein derartiger Eingriff in die innerstaatliche Organisation des Gesundheitswesens wäre mit dem Subsidiaritätsprinzip nicht vereinbar.

Die Einrichtung bzw. Anerkennung zuständiger, amtlich anerkannter Stellen, die auf Grundlage nationaler Qualitätsprogramme arbeiten und in den jeweiligen Mitgliedstaaten die Einhaltung der Qualitäts- und Sicherheitsstandards gewähren, wie es der Inhalt des Artikels 18 des Richtlinienentwurfs vorsieht, dient allerdings der Erreichung der Zielset-

zung. Aus dem Erwägungsgrund (19) des Richtlinienvorschlags geht hervor, dass die konkrete Ausgestaltung der Behördenstruktur jedem einzelnen Mitgliedstaat vorbehalten ist. Damit wäre für Deutschland der Aufbau einer neuen Behördenstruktur nicht erforderlich.

Um zu verdeutlichen, dass auch Artikel 18 des Richtlinienentwurfes keinen Eingriff in die innerstaatliche Organisationshoheit darstellt, ist eine Klarstellung im Wortlaut des eigentlichen Textes der Richtlinie erforderlich.

Verhältnismäßigkeit

Nach dem Grundsatz der Verhältnismäßigkeit (Artikel 2 EUV i. V. m. Artikel 5 Absatz 3 EGV; nach dem Lissabonner Vertrag: Artikel 5 Absatz 4 EUV) dürfen Maßnahmen der Gemeinschaft bzw. Union inhaltlich wie formal nicht über das zur Erreichung der Ziele der Verträge erforderliche Maß hinausgehen. Zu prüfen ist, ob die Bindungswirkung und Regelungsdichte des Gesetzgebungsvorschlags erforderlich sind.

Zentrales Problem im Hinblick auf Organspende und Transplantation in den Mitgliedstaaten ist der verbreitete Organmangel. Institutionen aus dem Gesundheitssektor, wie die DKG und GKV als Auftraggeber der Deutschen Stiftung Organtransplantation und von Eurotransplant, weisen darauf hin, dass es in keinem Mitgliedstaat Organüberschuss gibt.

Die Richtlinie setzt Mindeststandards, d. h. die Mitgliedstaaten können in ihrem Hoheitsgebiet höhere Qualitäts- und Sicherheitsstandards regeln oder beibehalten. Gleichzeitig ist mit Blick auf den verbleibenden Regelungsspielraum für die Mitgliedstaaten zu bedenken, dass in einem Ausschussverfahren Durchführungsmaßnahmen erlassen werden können (vgl. Artikel 25 und 26 des Richtlinienvorschlags). Es ist anhand des Richtlinienvorschlags selbst nicht ohne weiteres zu beurteilen, ob durch derartige Regelungen die Regelungsdichte zu Lasten der Mitgliedstaaten unangemessen erhöht werden kann.

Zu den voraussichtlichen finanziellen und administrativen Belastungen für die Mitgliedstaaten enthalten die Ausführungen keine detaillierten Angaben. Es kann daher nicht abschließend beurteilt werden, ob sich die von der Kommission angeführten Regelungsbestandteile wie die Errichtung einzelstaatlicher Aufsichtsbehörden, die Zulassung von Einrichtungen und Programmen für Organspende und Organbeschaffung und die Einrichtung von Inspektionsstrukturen nachteilig auf die in vielen EU-Ländern vorhandene, leistungsfähige Organisationsstruktur auswirken und mit einem erheblichen bürokratischen Aufwand verbunden sein könnten. Um die Verhältnismäßigkeit des Richtlinienentwurfs abschließend bewerten zu können – insbesondere im Hinblick auf die Frage nach alternativen Lösungen mit einer geringeren Regelungsdichte, wie zum Beispiel der Abschluss von Abkommen durch die Kommission mit Mitgliedstaaten, die sich bislang nur in geringer Weise am Organaustausch beteiligen – sind genaue Angaben zu den bürokratischen Belastungen erforderlich. Auch nach Auffassung der Bundesregierung kann die Frage des rechtlichen Anpassungsbedarfes erst im weiteren Verfahren geklärt werden."

Des Weiteren lag dem Ausschuss ein Entschließungsantrag der Fraktion DIE LINKE. vor. Der Ausschuss hat den im Folgenden wiedergegebenen Antrag mit den Stimmen der Fraktionen CDU/CSU, SPD, FDP und BÜNDNIS 90/DIE GRÜNEN gegen die Stimmen der Fraktion DIE LINKE. abgelehnt:

Der Deutsche Bundestag wolle beschließen:

In Kenntnis der Unterrichtung Drucksache 16/11517 Nr. A 30 folgende Entschließung anzunehmen:

Der Deutsche Bundestag stellt fest:

Der Deutsche Bundestag hat den Vorschlag für eine Richtlinie des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe im Hinblick auf die Wahl der Rechtsgrundlage sowie auf die Einhaltung der Prinzipien der Subsidiarität und Verhältnismäßigkeit überprüft.

Der Deutsche Bundestag äußert im Hinblick auf die Wahl der Rechtsgrundlage hinsichtlich eines Teils der vorgeschlagenen Regelungen Bedenken.

Der Deutsche Bundestag stellt fest, dass im Hinblick auf die Einhaltung des Grundsatzes der Subsidiarität Anlass zu Bedenken bestehen.

Es kann nicht abschließend festgestellt werden, dass der Richtlinienentwurf dem Grundsatz der Verhältnismäßigkeit entspricht.

Im Übrigen bleibt der Vorschlag für eine Richtlinie über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe einer späteren Befassung vorbehalten.

Begründung:

Vorbemerkung

Die Subsidiaritätsprüfung findet im Rahmen eines durch die COSAC verabredeten Testlaufs statt, bei dem Erfahrungen im Hinblick auf ein gegebenenfalls zu schaffendes Frühwarnverfahren zur Subsidiaritätskontrolle gesammelt werden sollen. Da gegenwärtig kein eigenständiges geschäftsordnungsrechtliches Verfahren zur Subsidiaritätskontrolle existiert, erfolgt der Beschluss im Rahmen des zur Mitwirkung gegenüber der Bundesregierung vorgesehenen Verfahrens. Er richtet sich aber primär an die Europäische Kommission. Es ist darauf hinzuweisen, dass die Bewertung der Einhaltung der Grundsätze der Subsidiarität die inhaltliche Befassung mit dem Richtlinienvorschlag nicht präjudiziert. Diese bleibt der weiteren parlamentarischen Beratung durch die Fachausschüsse und das Plenum des Deutschen Bundestages vorbehalten.

Ziel der Richtlinie

Die Europäische Kommission hat am 8. Dezember 2008 einen Vorschlag für eine Richtlinie des europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe verabschiedet. Im Entwurf der Richtlinie wird als wesentliches Ziel formuliert, dass in allen Phasen des Verfahrens Spende, Beschaffung, Testung, Konservierung, Beförderung und Übertragung einheitliche Qualitäts- und Sicherheitsstandards gelten und damit ein hohes Gesundheitsschutzniveau gewährleistet wird. In dem gleichzeitig veröffentlichten nichtlegislativen Aktionsplan werden Maßnahmen vorgeschlagen, die zu einer Erhöhung der Organverfügbarkeit und zu einer Förderung der Leistungsfähig-

keit und Zugänglichkeit der Transplantationssysteme beitragen sollen.

Rechtsgrundlage

Der Richtlinienvorschlag basiert auf Art. 152 Abs. 4 EGV. Dieser sieht auf Gemeinschaftsebene ausdrücklich Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für Organe vor. Ziel der Richtlinie ist es, einen einheitlich hohen Qualitäts- und Sicherheitsstandard in den Mitgliedstaaten der Europäischen Union zu schaffen.

Nur was die Schaffung eines europaweit einheitlich hohen Mindeststandards für Qualitäts- und Sicherheitsanforderungen für zur Transplantation bestimmte Organe betrifft, bestehen bezüglich der Rechtsgrundlage keine Bedenken.

Die Spende und die medizinische Verwendung von menschlichen Organen ist gem. Art. 152 Abs. 5 Satz 2 EGV der gemeinschaftlichen Zuständigkeit vollständig entzogen. Der Richtlinienvorschlag überschreitet diesen klaren Kompetenzrahmen in mehreren Punkten und greift so in unzulässiger Weise in die originäre Zuständigkeit der Mitgliedstaaten ein. Dies gilt ebenso für die in Art. 4 Nr. 2b, 13, 14, 15 Nr. 1 und 17 getroffenen Regelungen. Eine EU-Richtlinie über die Qualität und Sicherheit von menschlichen Organen darf sich ausschließlich auf die Anwendung von Testverfahren zum Nachweis von Infektions- bzw. Tumorerkrankungen (Risikobewertung), Konservierung, Beförderung und Sicherstellung der Rückverfolgbarkeit von Organen sowie die Meldung etwaiger schwerer unerwünschter Zwischenfälle nach der Transplantation erstrecken.

Auch die vorgesehenen Regelungen über die Schaffung und Benennung zuständiger Behörden, über Beschaffungsorganisationen und Transplantationszentren sowie Organisationen zum Organaustausch in den Artikeln 18 ff. sind nicht von der Kompetenznorm des Art. 152 EGV gedeckt.

Schließlich findet die Einrichtung einer als Ausschuss bezeichneten neuen Institution (Art. 26), deren Aufgabenstellung, Zusammensetzung und Zustandekommen nicht geregelt sind, in Art. 152 EGV keine hinreichende Rechtsgrundlage.

Subsidiarität

Nach dem Subsidiaritätsprinzip wird die Gemeinschaft in den Bereichen, die nicht in ihre ausschließliche Zuständigkeit fallen, nur tätig, sofern und soweit die Ziele der in Betracht gezogenen Maßnahmen auf der Ebene der Mitgliedstaaten nicht ausreichend erreicht werden können und daher wegen ihres Umfangs oder ihrer Wirkungen besser auf Gemeinschaftsebene ausgeführt werden können.

Was die Schaffung eines europaweit einheitlich hohen Mindeststandards für Qualitäts- und Sicherheitsanforderungen bei zur Transplantation bestimmten Organen betrifft, bestehen keine Bedenken gegen den Richtlinienvorschlag.

Diese einheitlichen materiellen Standards können aber in den Mitgliedsstaaten in unterschiedlichen Verfahren und im Rahmen unterschiedlicher organisatorische Systeme und Institutionen in gleicher Weise qualifiziert umgesetzt und kontrolliert werden. So bestehen in Deutschland wie in anderen Mitgliedstaaten bereits jetzt leistungsfähige Transplantationssysteme. Allerdings ist dies nicht in allen EU-Mitgliedsländern der Fall. Dadurch besteht die Gefahr, dass höhere Standards abgesenkt werden. Es ist nicht ersichtlich, inwiefern die Schaffung neuer einzelstaatlicher Aufsichtsbehörden sowie die Zulassung von Einrichtungen und Genehmigung von Programmen zur Organbeschaffung und -transplantation – so wie im Richtlinienvorschlag vorgesehen der Erreichung der Ziele der Richtlinie besser dienen könnte.

Das gilt insbesondere hinsichtlich der aufwendigen Regelungen in Artikel 18 des Richtlinienentwurfs. Der Wortlaut des Artikels 18 legt mit dem Begriff Behörde nahe, dass dies ausschließlich Stellen sein können, die als Organ des Staates Aufgaben der öffentlichen Verwaltung wahrnehmen. Andere Strukturen, etwa die in Deutschland praktizierte Betrauung einer Stiftung, wären damit ausgeschlossen. Ein derartiger Eingriff in die innerstaatliche Organisation des Gesundheitswesens wäre mit dem Subsidiaritätsprinzip nicht vereinbar. Selbst wenn der Wortlaut der Richtlinie oder einer ihrer Erwägungsgründe es erlaubte, die gegenwärtige konkrete Ausgestaltung der Behördenstruktur in Deutschland aufrecht zu erhalten, wäre das unerheblich. Entscheidend ist, dass durch die Richtlinie in die Regelungsbefugnis der Mitgliedsstaaten eingegriffen ist und sie an einer eigenverantwortlichen Gestaltung, gegebenenfalls Umgestaltung der gegenwärtigen, hindert, ohne das dadurch die angestrebten Ziele besser erreicht werden könnten.

Verhältnismäßigkeit

Nach dem Grundsatz der Verhältnismäßigkeit (Artikel 2 EUV i. V. m. Artikel 5 Absatz 3 EGV) dürfen Maßnahmen der Gemeinschaft bzw. Union inhaltlich wie formal nicht über das zur Erreichung der Ziele der Verträge erforderliche Maß hinausgehen. Zu prüfen ist, ob die Bindungswirkung und Regelungsdichte des Gesetzgebungsvorschlags erforderlich sind sowie die finanziellen und organisatorischen Belastungen für die Mitgliedsstaaten nicht unangemessen sind.

Zu den voraussichtlichen finanziellen und administrativen Belastungen für die Mit-gliedstaaten enthalten die Ausführungen keine detaillierten Angaben. Es kann daher schon aus diesem Grund nicht ausgeschlossen werden, dass sich die von der Kommission angeführten Regelungsbestandteile wie die Errichtung einzelstaatlicher Aufsichtsbehörden, die Zulassung von Einrichtungen und Programmen für Organspende und Organbeschaffung und die Einrichtung von Inspektionsstrukturen nachteilig auf die in vielen EU-Ländern vorhandene, leistungsfähige Organisationsstruktur auswirken und mit einem erheblichen bürokratischen Aufwand verbunden sein könnten. Um die Unverhältnismäßigkeit des Richtlinienentwurfs ausschließen zu können, wären genaue Angaben zu den bürokratischen Belastungen erforderlich. Solange die Kommission einen Richtlinienentwurf ohne solche Angaben vorlegt, muss der Entwurf wegen Verletzung des Grundsatzes der Verhältnismäßigkeit beanstandet werden.

Die Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN waren prinzipiell der Auffassung, dass der vorliegende Richtlinienvorschlag wegen seiner Komplexität für den Testlauf zur Subsidiarität nur bedingt geeignet sei. Darüber hinaus betonten sie, es sei wichtig, zwischen den inhaltlichen und subsidiaritätsbezogenen Fragen des Richtlinienvorschlags zu unterscheiden. Vorliegend gehe es zunächst lediglich um die Frage der Subsidiarität und hier bestünden hinsichtlich der gewählten Rechtgrundlage aus Sicht

der für den Antrag auf Ausschussdrucksache 16(14)478 maßgeblichen Fraktionen keine Bedenken. Dennoch gebe es nach ihrer Auffassung einen Klärungsbedarf zu einzelnen Punkten. Dies betreffe insbesondere Artikel 18 des Richtlinienvorschlags und den dort verwendeten Begriff der „zuständigen Behörde“. Es sei fraglich, ob dieses Modell mit der in Deutschland praktizierten Betrauung einer Stiftung mit der Koordinierung von Organspenden vereinbart werden könne. Zwar deute der Erwägungsgrund 19 des Vorschlags darauf hin, dass dies ggf. der Fall sein könnte, doch bedürfe es an dieser Stelle einer klarstellenden und eindeutigen Formulierung in der Richtlinie selbst. Im Übrigen ergäben sich auch Unklarheiten hinsichtlich der Einhaltung des Verhältnismäßigkeitsgrundsatzes insoweit, als sich u. a. aus der von der Europäischen Kommission vorgesehenen Behördenstruktur erhebliche zusätzliche administrative und finanzielle Belastungen für die Mitgliedstaaten ergeben könnten.

Der Antrag der Fraktion DIE LINKE. auf Ausschussdrucksache 16(14)479 berücksichtige nicht hinreichend, dass seitens der Europäischen Kommission keine bestimmte Behördenstruktur vorgegeben werde. Stattdessen stelle die Kommission nach dem Erwägungsgrund 19 des Entwurfs ausdrücklich auf die jeweilige Zuständigkeitsverteilung in den Mitgliedstaaten ab. Daher müsse der Antrag aus Sicht der Fraktionen CDU/CSU, SPD und BÜNDNIS 90/DIE GRÜNEN abgelehnt werden.

Die Fraktion der FDP war der Ansicht, dass es hinsichtlich der Frage der Einhaltung der Subsidiarität weiterhin Klärungsbedarf gebe. Für die Fraktion der FDP sei es prinzipiell vorstellbar gewesen, sich dem Antrag der Koalitionsfraktionen der CDU/CSU und SPD und der Fraktion BÜNDNIS 90/DIE GRÜNEN anzuschließen, doch sehe sie einen Bedarf zur Ergänzung des Antrags hinsichtlich des Erfordernisses einer kompletten Überprüfung des Kapitels III des Richtlinienvorschlags auf Vereinbarkeit mit dem Subsidiaritätsprinzip. Dies werde jedoch von den Koalitionsfraktionen abgelehnt und deshalb werde sich die Fraktion der FDP bei der Abstimmung über den Antrag auf Ausschussdrucksache 16(14)478 der Stimme enthalten.

Den Antrag der Fraktion DIE LINKE. auf Ausschussdrucksache 16(14)479 lehne die Fraktion der FDP ab, da er bezüglich der Frage der Rechtsgrundlage eine andere Zielrichtung verfolge.

Die Fraktion DIE LINKE. ist darüber verwundert, dass sich das Meinungsspektrum innerhalb des Ausschusses mehrheitlich dahingehend entwickelt habe, keine Bedenken hinsichtlich der Einhaltung des Grundsatzes der Subsidiarität anzumelden. Aus diesem Grund habe die Fraktion einen eigenen Entschließungsantrag im Ausschuss vorgelegt. Ihrer Meinung nach gebe der Richtlinienvorschlag sehr wohl Anlass zu Bedenken. Dies gelte zum einen im Hinblick auf die Wahl der Rechtsgrundlage hinsichtlich eines Teils der vorgeschlagenen Regelungen. Zum anderen werde das Subsidiaritätsprinzip durch den Richtlinienvorschlag verletzt, denn zur Einhaltung von Qualitätsstandards seien detaillierte institutionelle Regelungen nicht erforderlich. Darüber hinaus könne abschließend nicht festgestellt werden, dass der Richtlinienentwurf dem Grundsatz der Verhältnismäßigkeit entspreche. Hier fehlten die erforderlichen Angaben seitens der EU-Kommission. Im Übrigen solle der Richtlinienvorschlag einer späteren Befassung vorbehalten werden.

Die Fraktion betont abschließend, dass sie nicht gegen, sondern für ein soziales Europa eintrete und den Weg der europäischen Integration weiter gehen möchte. Es sei jedoch wichtig, dass es nicht zu einer Absenkung höherer Standards komme. Grundsätzlich sei zu klären, welche Kompetenzen der Europäischen Union und welche den Mitgliedstaaten zugeordnet werden.

Die von den Koalitionsfraktionen sowie der Fraktion BÜNDNIS 90/DIE GRÜNEN vertretene Zielrichtung, die Kommission zu einer Klarstellung aufzufordern, reiche nach Überzeugung der Fraktion DIE LINKE. nicht aus, um den Gefahren des Richtlinienvorschlags in wirksamer Form zu begegnen. Der Antrag der Koalitionsfraktionen und der Fraktion BÜNDNIS 90/DIE GRÜNEN auf Ausschussdrucksache 16(14)478 sei daher abzulehnen.

Berlin, den 28. Januar 2009

Michael Hennrich
Berichterstatter

RAT DER EUROPÄISCHEN UNION

Brüssel, den 10. Dezember 2008 (11.12)
(OR. fr)

16521/08

Interinstitutionelles Dossier: 2008/0238 (COD)

SAN 306
CODEC 1691

ÜBERMITTLUNGSVERMERK

Absender:	Europäischen Kommission
Eingangsdatum:	8. Dezember 2008
Empfänger:	der Generalsekretär/Hohe Vertreter, Herr Javier SOLANA
Betr.:	Vorschlag für eine RICHTLINIE DES EUROPÄISCHEN PARLAMENTS UND DES RATES über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe

Die Delegationen erhalten in der Anlage das Kommissionsdokument - KOM(2008) 818 endgültig.

Anl.: KOM(2008) 818 endgültig

KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN

Brüssel, den 8.12.2008
KOM(2008) 818 endgültig

2008/0238 (COD)

Vorschlag für eine

RICHTLINIE DES EUROPÄISCHEN PARLAMENTS UND DES RATES

über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe

{COM(2008) 819 endgültig}
{SEC(2008)2956}
{SEC(2008)2957}

(von der Kommission vorgelegt)

BEGRÜNDUNG

EINLEITUNG

1. Organtransplantation ist die Übertragung menschlicher Organe zu therapeutischen Zwecken, bei der ein nicht funktionsfähiges Organ durch ein Spenderorgan ersetzt wird. Gegenwärtig stellt die Organtransplantation die kostengünstigste Behandlung bei Nierenversagen im Endstadium dar; bei Leber-, Lungen- und Herzversagen ist sie zurzeit die einzige Behandlungsmöglichkeit.

2. Der therapeutische Einsatz von Organen birgt jedoch auch ein Risiko der Krankheitsübertragung auf den Empfänger. Möglicherweise können Infektionskrankheiten oder Krebs übertragen werden. Zwar haben die meisten Mitgliedstaaten Rechtsvorschriften zu den ethischen Aspekten der Organtransplantation erlassen, doch müssen sich viele noch auf Qualitäts- und Sicherheitsvorschriften einigen. Im Jahre 2003 führte die Kommission eine Erhebung über die Rechtsvorschriften für Organtransplantation in der EU durch; diese ergab wesentliche Unterschiede zwischen den Mitgliedstaaten, was die Qualitäts- und Sicherheitsanforderungen betrifft.[1]

3. Der Organaustausch zwischen den Mitgliedstaaten zwecks qualitativer Verbesserung des Zuteilungsverfahrens ist bereits gängige Praxis. Es gibt allerdings große Unterschiede bei der Zahl der Organe, die zwischen denjenigen Mitgliedstaaten ausgetauscht werden, welche für den internationalen Organaustausch Einrichtungen, wie Eurotransplant und Scandiatransplant, geschaffen und Vorschriften erlassen haben, und den anderen Mitgliedstaaten.

4. Der Organmangel ist ein wichtiger Faktor, der die Transplantationsprogramme beeinträchtigt. Fast 56 000 Patienten stehen derzeit auf Wartelisten.[2] Die Sterblichkeitsraten während der Wartezeit für eine Herz-, Leber- oder Lungentransplantation betragen in der Regel zwischen 15 und 30 %. Die Spenderaten und die Organverfügbarkeit sind in Europa höchst unterschiedlich, wobei machbare bewährte Verfahren in einigen Mitgliedstaaten zu weitaus besseren Ergebnissen führen als in anderen.

5. Eine der möglichen Folgen des Organmangels ist der Handel mit menschlichen Organen durch Gruppen des organisierten Verbrechens. Der Organhandel kann mit Menschenhandel zum Zweck der Organentnahme verbunden sein, einer schweren Verletzung der Grundrechte und insbesondere der menschlichen Würde und körperlichen Unversehrheit. Der Organhandel lässt sich anerkanntermaßen am besten bekämpfen, indem mehr Organe zur Verfügung gestellt und deren Qualität und Sicherheit gewährleistet werden. Die vorliegende Richtlinie zielt zwar primär auf die Sicherheit und die Qualität von Organen, sie wird jedoch durch die Errichtung zuständiger Behörden, die Zulassung von Transplantationszentren, die Festlegung der Beschaffungsbedingungen und die Sicherstellung der Rückverfolgbarkeit auch indirekt dazu beitragen, den Organhandel zu bekämpfen.

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1 http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf.

2 Europarat (2007).

6. Seit 1999 ermöglicht es der mit dem Vertrag von Amsterdam eingeführte Artikel 152 EG-Vertrag dem Europäischen Parlament und dem Rat, Maßnahmen zur Festsetzung hoher Qualitäts- und Sicherheitsstandards für Organe und Substanzen menschlichen Ursprungs sowie für Blut und Blutderivate zu treffen. Die Gemeinschaft hat bereits im Jahre 2003 eine Richtlinie für Qualitäts- und Sicherheitsstandards für Blut und im Jahre 2004 eine weitere für Gewebe und Zellen erlassen.

7. Es gibt wesentliche Unterschiede zwischen der Transplantation von Organen und anderen Substanzen menschlichen Ursprungs wie Blut, Gewebe und Zellen. Angesichts des gegenwärtigen Organmangels sind zwei Faktoren gegeneinander abzuwägen: die Notwendigkeit der Transplantation von in der Regel lebenswichtigen Organen und die Notwendigkeit, hohe Qualitäts- und Sicherheitsstandards zu gewährleisten.

8. Im Rahmen der italienischen Präsidentschaft fand am 17.-18. September 2003 in Venedig die Konferenz über Qualität und Sicherheit von Organspenden und -transplantationen statt. Die Schlussfolgerungen der von der italienischen Regierung während ihrer Ratspräsidentschaft veranstalteten Expertenkonferenz führten den Organmangel als vorrangiges Problem in diesem Bereich an und hoben hervor, wie wichtig es ist, angesichts der aktuellen Lage bei Angebot und Nachfrage von Organen die Qualitäts- und Sicherheitsaspekte zu thematisieren.

9. Bei der Annahme der Richtlinie über Gewebe und Zellen am 31. März 2004 hat die Kommission sich verpflichtet, eine gründliche wissenschaftliche Überprüfung der Lage in Bezug auf die Organtransplantation vorzunehmen. Am 31. Mai 2007 nahm die Kommission eine Mitteilung über Organspende und -transplantation[3] an, die sich auf die genannte Analyse stützte. Diese Mitteilung enthält Vorschläge für EU-Maßnahmen im Bereich der Organtransplantation. Die Mitteilung kommt zu der Schlussfolgerung, dass ein flexibler europäischer Rechtsrahmen zur Festlegung von Qualitäts- und Sicherheitsstandards die richtige Gemeinschaftsreaktion auf das Mandat gemäß Artikel 152 Absatz 4 Buchstabe a des Vertrags wäre.

10. Am 6. Dezember 2007 nahm der Rat Schlussfolgerungen zum Thema Organspende und -transplantation an. Ert stellte fest, dass es wichtig ist, hohe Anforderungen an die Qualität und die Sicherheit von Transplantationsorganen zu stellen, damit ein hohes Schutzniveau für Patienten in ganz Europa gewährleistet ist, und ersuchte die Kommission, die Mitgliedstaaten zu konsultieren und die Prüfung der Notwendigkeit eines EU-Rahmens für Qualität und Sicherheit menschlicher Organe fortzusetzen.

11. Das Europäische Parlament stellte in seiner Entschließung vom 22. April 2008 fest, „dass die Verbesserung der Qualität und der Sicherheit von Organspende und -transplantation von entscheidender Bedeutung ist", um Transplantationsrisiken zu senken. Daher sieht das Parlament dem Vorschlag der Kommission für eine Richtlinie mit Vorschriften zur Sicherstellung der Qualität und Sicherheit der Organspende in der gesamten EU mit Interesse entgegen.

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[3] Mitteilung der Kommission an das Europäische Parlament und den Rat Organspende und -transplantation: Massnahmen auf EU-Ebene, Brüssel, - KOM(2007) 275 30.5.2007.

GELTUNGSBEREICH UND ZIELE

12. Unter diesen Richtlinienvorschlag fallen menschliche Organe, die zur Transplantation verwendet werden, in allen Phasen des Verfahrens – Spende, Beschaffung, Testung, Konservierung, Beförderung und Übertragung. Ziel des Richtlinienvorschlags ist die Sicherstellung ihrer Qualität und Sicherheit und somit eines hohen Gesundheitsschutzniveaus.

13. Nicht unter den Vorschlag fallen Blut und Blutbestandteile, menschliche Gewebe und Zellen sowie Organe, Gewebe und Zellen tierischen Ursprungs. Blut und Blutprodukte fallen unter die Richtlinien 2002/98/EG, 2004/33/EG, 2005/61/EG und 2005/62/EG; für menschliche Gewebe und Zellen gelten die Richtlinien 2004/23/EG, 2006/17/EG und 2006/86/EG.

14. Forschung an menschlichen Organen zu anderen als zu Transplantationszwecken soll nicht unter diese Richtlinie fallen. Organe, die bei klinischen Versuchen in den menschlichen Körper verpflanzt werden, sollten jedoch die in dieser Richtlinie festgelegten Qualitäts- und Sicherheitsstandards erfüllen.

15. Dieser Vorschlag soll sicherstellen, dass zu Transplantationszwecken verwendete Organe in der EU einheitlichen Qualitäts- und Sicherheitsanforderungen genügen. Auf diese Weise wird die Richtlinie ihren Austausch unter den Mitgliedstaaten erleichtern.

DER MEHRWERT DER RICHTLINIE

Gewährleistung von Qualität und Sicherheit für die Patienten auf EU-Ebene

16. Die Verwendung von Organen zu therapeutischen Zwecken birgt erhebliche Risiken; diese lassen sich jedoch mit dem Einsatz von Qualitäts- und Sicherheitsverfahren wirksam abwenden. Ein gut geregeltes Spende- und Transplantationssystem ist von entscheidender Bedeutung, wenn Organe rechtzeitig, mit korrekten Informationen und ohne ein vermeidbares Risiko der Krankheitsübertragung auf den Patienten bereitgestellt werden sollen.

17. Diese Richtlinie legt die in jedem Transplantationssystem notwendigen grundlegenden Qualitäts- und Sicherheitsanforderungen fest. Als wichtigste Faktoren eines erfolgreichen Transplantationssystems wurden eine solide Infrastruktur und verantwortungsvolle Einrichtungen für die Organbeschaffung und -transplantation genannt. Der Richtlinienvorschlag sieht die Schaffung oder Benennung einer zuständigen nationalen Behörde in jedem Mitgliedstaat vor. Diese zuständigen Behörden werden sicherstellen, dass die Vorschriften der Richtlinie eingehalten werden. Die Richtlinie sieht außerdem ein System für die Genehmigung von Programmen zur Organbeschaffung und -transplantation auf der Grundlage gemeinsamer Qualitäts- und Sicherheitskriterien[4] vor. Dieses System würde eine vollständige Liste aller in der Europäischen Union zugelassenen Zentren liefern, die Fachleuten und der Öffentlichkeit gleichermaßen zugänglich wäre.

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[4] Europarat-Empfehlung Rec(2004)19 des Ministerkomitees an die Mitgliedstaaten über die Kriterien für die Zulassung von Einrichtungen zur Organtransplantation.

18. Beschaffung der Organe, Bewertung und Auswahl des Spenders sind die ersten und entscheidenden Schritte in der Transplantationskette. Die vorgeschlagene Richtlinie wird gemeinsame Qualitäts- und Sicherheitsstandards für das Verfahren zur Bewertung von Spendern und menschlichen Organen festlegen, womit die Gesundheit der Empfänger sichergestellt wird.

19. Von ebensolcher Bedeutung ist es, die Qualität der von den verschiedenen einschlägigen Organisationen eingesetzten Verfahren sicherzustellen. Zur Verbesserung dieser Verfahren wird in der Richtlinie die Einführung nationaler Qualitätsprogramme vorgeschlagen, um eine ständige Überwachung der Leistungen, Verbesserungen und Lernprozesse sicherzustellen. Spezifische Standards für die Beschaffung und Beförderung menschlicher Organe sowie die Schulung der Fachleute sind Bestandteile der nationalen Qualitätsprogramme.

20. Die Einrichtung eines Systems zur Verfolgung aller Organe vom Spender bis zum Empfänger und zurück ist ein Schlüsselfaktor, um Sicherheit zu gewährleisten, aber auch um Organhandel und Organentnahmen gegen Bezahlung zu vermeiden. Der Richtlinienvorschlag wird dafür sorgen, dass die Mitgliedstaaten Rückverfolgbarkeitssysteme für Organe einrichten. Die Kommission wird Verfahren zur Gewährleistung der lückenlosen Rückverfolgbarkeit von Organen festlegen, die zwischen den Mitgliedstaaten ausgetauscht werden. Rückverfolgbarkeit bedeutet allerdings nicht, dass der Organempfänger den Namen und weitere Einzelheiten des Spenders erfährt oder umgekehrt. Die Rückverfolgbarkeit soll somit die Gesundheit der Spender und Empfänger schützen und dient keinem anderen Zweck, als die Qualität und die Sicherheit der Organe sicherzustellen. Die Anonymität sowohl des Spenders als auch des Empfängers bilden weiterhin einen Eckpfeiler für deren Schutz. Doch die jeweiligen zuständigen Behörden sollten die erforderlichen Unterlagen und Aufzeichnungen aufbewahren, aus denen beispielsweise hervorgeht, woher das Organ stammte, wer es bereitgestellt hat und unter welchen Umständen.

21. Da Organspender oft auch Zellen und Gewebe spenden, ist es von zusätzlicher Bedeutung, dass Informationen über Zwischenfälle und Infektionen rasch bis zur Spende zurückverfolgt und unverzüglich dem Gewebeüberwachungssystem gemeldet werden können, das die Richtlinie 2004/23/EG über Gewebe und Zellen vorsieht. Derzeit gibt es ein solches System noch nicht.

22. Darüber hinaus umfasst der Vorschlag Maßnahmen zur Registrierung schwerwiegender Zwischenfälle bei der Beschaffung, Testung und Beförderung von Organen ebenso wie schwerwiegender unerwünschter Reaktionen, die während oder nach der Transplantation beobachtet werden und auf die Beschaffung, Testung und Beförderung des Organs in der Europäischen Union zurückgeführt werden können. Die Kommission wird Verfahren festlegen, welche die Kompatibilität zwischen den Meldesystemen für Zwischenfälle und unerwünschte Reaktionen sicherstellen.

Sicherstellung des Spenderschutzes

23. Der Einsatz menschlicher Organe sollte unter Bedingungen erfolgen, bei denen die Rechte und die Gesundheit der Spender geschützt sind. Grundsätzlich sollten Organtransplantationsprogramme auf den Prinzipien der freiwilligen und unentgeltlichen Spende, der Uneigennützigkeit des Spenders und der Solidarität zwischen Spender und Empfänger beruhen unter gleichzeitiger Wahrung der

Anonymität aller Spender und Empfänger sowie unter Einhaltung des Datenschutzes. Sie sollten mit der Charta der Grundrechte der Europäischen Union im Einklang stehen und die Grundsätze des Übereinkommens des Europarates über Menschenrechte und Biomedizin in vollem Umfang berücksichtigen.

24. Die Frage der Einwilligung in die Entnahme ist im Allgemeinen von den Mitgliedstaaten in sehr unterschiedlicher Weise geregelt worden. Die Bestimmungen reichen von vorausgesetzter Einwilligung bis zu anderen Regelungen, bei denen die Einwilligung von Familienangehörigen benötigt wird. Die Kommission betrachtet dies als sehr heikle Angelegenheit, die eine Reihe ethischer Fragen aufwirft, welche in die Zuständigkeit der Mitgliedstaaten fallen und nicht in dieser Richtlinie behandelt werden sollten.

25. Immer häufiger wird auf lebende Spender zurückgegriffen, da der wachsende Bedarf an Organen durch postmortale Spenden nicht mehr gedeckt werden kann. Der Anstieg der Lebendspenden ist auf mehrere Faktoren zurückzuführen, unter anderem auf den Druck durch den Mangel an Spenderorganen von Verstorbenen, auf Fortschritte in der Chirurgie und überzeugende Nachweise günstiger Transplantationsergebnisse und geringer Spenderrisiken.

26. Der Richtlinienvorschlag enthält eine Reihe von Maßnahmen zum Schutz lebender Spender. Dazu gehören die korrekte Beurteilung der Gesundheit des Spenders und eine umfassende Aufklärung über die Risiken vor der Spende, die Einführung von Registern für lebende Spender, damit ihre Gesundheit weiter beobachtet werden kann, und Maßnahmen zur Sicherstellung uneigennütziger und freiwilliger Lebendspenden.

Erleichterung der Zusammenarbeit zwischen den Mitgliedstaaten und grenzüberschreitender Austausch

27. Der vorliegende Vorschlag soll ein hohes Qualitäts- und Sicherheitsniveau in der gesamten Organtransplantationskette in allen Mitgliedstaaten sicherstellen, unter Berücksichtigung der Freizügigkeit der Bürger und der Notwendigkeit, innerhalb der Europäischen Union Organe grenzüberschreitend auszutauschen. Die Festlegung von Qualitäts- und Sicherheitsstandards wird dazu beitragen, in der Bevölkerung das Vertrauen darauf zu stärken, dass für menschliche Organe, die von Spendern aus anderen Mitgliedstaaten stammen, die gleichen Garantien bestehen wie in ihrem eigenen Land.

28. Der grenzüberschreitende Organaustausch bietet klare Vorteile. Da Spender und Empfänger zueinander passen müssen, ist ein großer Spenderpool wichtig, um den Bedarf aller Patienten auf den Wartelisten zu decken. Werden keine Organe zwischen den Mitgliedstaaten ausgetauscht, haben Empfänger, die ein Organ mit seltenen Merkmalen benötigen, sehr geringe Aussichten auf ein geeignetes Organ. Gleichzeitig werden manche Spender nicht berücksichtigt, weil es keinen kompatiblen Empfänger auf den Wartelisten gibt. Dies gilt insbesondere für problematische Fälle (Kinder, Notfälle oder immunologisch problematische Patienten, die Organe mit ganz bestimmten Merkmalen benötigen) und kleine Mitgliedstaaten.

29. Die Richtlinie wird die nötigen Qualitäts- und Sicherheitsbedingungen schaffen, um den grenzüberschreitenden Austausch zu erleichtern. Sie wird die zur ordnungsgemäßen Risikobewertung erforderliche Erhebung der relevanten Informationen über die Merkmale des Organs standardisieren. Außerdem wird sie einen Mechanismus für die Informationsübermittlung einrichten. Transplantationsteams in allen Mitgliedstaaten wird versichert, dass sie, ungeachtet der Herkunft des Organs, die notwendigen, angemessenen und vollständigen Informationen erhalten. Dies wird die Risiken für den Empfänger minimieren und die Organzuteilung auf EU-Ebene optimieren.

30. Ferner wird die Richtlinie die nötigen Mechanismen für den grenzüberschreitenden Austausch von Organen liefern, um die Rückverfolgbarkeit der Organe sicherzustellen und schwerwiegende Zwischenfälle zu vermeiden.

31. Die Einrichtung zuständiger Behörden in allen Mitgliedstaaten und die Organisation regelmäßiger Zusammenkünfte zwischen ihnen werden dazu beitragen, die Zusammenarbeit auf EU-Ebene in diesem Bereich zu fördern, wie es im Bereich von Blut, Gewebe und Zellen bereits der Fall ist. Die Koordinierung zwischen diesen Behörden würde für eine effizientere Organzuteilung sorgen (was insbesondere für kleinere Mitgliedstaaten und bei Notfällen sowie problematischen Patienten hilfreich wäre). Da immer mehr Menschen ins Ausland reisen, dürfen auch Informationen nicht an den Grenzen Halt machen, damit Spende und Transplantation optimiert werden können und gleichzeitig das Vertrauen der Bürger in das System des Gastlandes erhalten bleibt.

2008/0238 (COD)

Vorschlag für eine

RICHTLINIE DES EUROPÄISCHEN PARLAMENTS UND DES RATES

über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe

DAS EUROPÄISCHE PARLAMENT UND DER RAT DER EUROPÄISCHEN UNION –

gestützt auf den Vertrag zur Gründung der Europäischen Gemeinschaft, insbesondere auf Artikel 152 Absatz 4 Buchstabe a,

auf Vorschlag der Kommission[5],

nach Stellungnahme des Wirtschafts- und Sozialausschusses[6],

nach Stellungnahme des Ausschusses der Regionen[7],

nach Anhörung des europäischen Datenschutzbeauftragten[8],

gemäß dem Verfahren des Artikels 251 des Vertrags[9],

in Erwägung nachstehender Gründe:

(1) In den vergangenen 50 Jahren hat sich die Organtransplantation weltweit als gängige Praxis etabliert und damit Hunderttausenden von Patienten ungeheuren Nutzen gebracht. Die Verwendung menschlicher Organe zu Transplantationszwecken ist in den letzten zwanzig Jahren ständig gestiegen; sie stellt gegenwärtig die kostengünstigste Behandlung bei Nierenversagen im Endstadium dar; bei Leber-, Lungen- und Herzversagen ist sie zurzeit die einzige Behandlungsmöglichkeit.

(2) Allerdings sind mit dem Einsatz von Organen zu Transplantationszwecken auch Risiken verbunden. Die extensive therapeutische Verwendung menschlicher Organe zu Transplantationszwecken erfordert eine Qualität und Sicherheit der Organe, die das Risiko der Krankheitsübertragung minimieren.

(3) Darüber hinaus hängt die Verfügbarkeit von Organen menschlichen Ursprungs für therapeutische Zwecke von der Bereitschaft der EU-Bürger ab, Organe zu spenden. Um die öffentliche Gesundheit zu schützen und die Krankheitsübertragung durch

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solche Organe zu vermeiden, sollten bei ihrer Beschaffung, Beförderung und Verwendung Vorsorgemaßnahmen getroffen werden.

(4) Jedes Jahr werden Organe zwischen den Mitgliedstaaten ausgetauscht. Der Organaustausch ist eine wichtige Möglichkeit, die Zahl der verfügbaren Organe zu erhöhen, eine bessere Übereinstimmung zwischen Spender und Empfänger zu gewährleisten und damit die Transplantatsqualität zu verbessern. Dies ist insbesondere für die optimale Versorgung bestimmter Patienten, wie Notfälle, immunologisch problematische Patienten oder Kinder, von Bedeutung. Verfügbare Organe sollten ohne unnötige Probleme und Verzögerungen ins Ausland gebracht werden können.

(5) Am Transplantationsverfahren sind jedoch Krankenhäuser und Berufsangehörige beteiligt, für die unterschiedliche Rechtsordnungen gelten, und die Qualitäts- und Sicherheitsanforderungen der einzelnen Mitgliedstaaten sind höchst unterschiedlich.

(6) Deshalb bedarf es gemeinsamer Qualitäts- und Sicherheitsstandards für die Beschaffung, Beförderung und Verwendung menschlicher Organe auf Gemeinschaftsebene. Solche Standards würden den Organaustausch zugunsten Tausender europäischer Patienten erleichtern, die diese Art Therapie jedes Jahr benötigen. Die gemeinschaftlichen Rechtsvorschriften sollten sicherstellen, dass menschliche Organe akzeptablen Qualitäts- und Sicherheitsstandards entsprechen. Daher werden solche Standards dazu beitragen, das Vertrauen der Bevölkerung darauf zu stärken, dass für menschliche Organe, die von Spendern aus anderen Mitgliedstaaten stammen, die gleichen Garantien bestehen wie in ihrem eigenen Land.

(7) Zur Minimierung der Risiken und zur Maximierung des Nutzens des Transplantationsverfahrens müssen die Mitgliedstaaten ein wirksames nationales Qualitätsprogramm durchführen. Dieses Programm sollte während der gesamten Transplantationskette von der Spende bis zur Transplantation oder Entsorgung durchgeführt und beibehalten werden, es sollte für Personal und Organisation, Räumlichkeiten, Ausstattung, Material, Dokumentation und Aufbewahrung der Aufzeichnungen gelten. Das nationale Qualitätsprogramm sollte erforderlichenfalls Rechnungsprüfungen umfassen. Die Mitgliedstaaten sollten die Zuständigkeit für Teile dieses Programms durch schriftliche Vereinbarungen an europäische Einrichtungen für den Organaustausch delegieren können.

(8) Die Beschaffungsbedingungen sollten von den zuständigen Behörden durch die Zulassung bestimmter Beschaffungsorganisationen überwacht werden. Die Zulassung sollte ordnungsgemäße Organisation, qualifiziertes Personal sowie geeignete Einrichtungen und Materialien voraussetzen.

(9) Die Nutzen-Risiko-Abwägung ist ein grundlegendes Konzept in der Organtransplantation. Aufgrund des Organmangels und der mit Organtransplantaten verbundenen Lebensgefahren ist der allgemeine Nutzen der Organtransplantation hoch, und es werden mehr Risiken hingenommen als bei Blut oder den meisten auf Geweben und Zellen basierenden Therapien. Der Kliniker spielt eine wichtige Rolle in diesem Zusammenhang, da er entscheidet, ob ein Organ sich für die Transplantation eignet oder nicht; deshalb legt diese Richtlinie fest, welche Informationen für diese Beurteilung erforderlich sind.

(10) Die Beurteilung potenzieller Spender im Vorfeld der Transplantation ist zentraler Bestandteil der Organtransplantation. Diese Beurteilung muss genügend Informationen liefern, damit das Transplantationszentrum eine geeignete Nutzen-Risiko-Analyse vornehmen kann. Die Risiken und die Merkmale des Organs müssen festgestellt und dokumentiert werden, damit das Organ einem geeigneten Empfänger zugeteilt werden kann. Dazu sollten Informationen zur vollständigen Charakterisierung des Organs und des Spenders erhoben werden.

(11) Es sollten wirksame Vorschriften für die Beförderung von Organen erlassen werden, die Ischämiezeiten minimieren und Organschädigungen verhindern. Bei gleichzeitiger Wahrung der medizinischen Vertraulichkeit muss der Organbehälter klar beschriftet werden und die erforderliche Dokumentation enthalten.

(12) Das Transplantationssystem muss sicherstellen, dass die Spur vom Spender zum Empfänger verfolgt werden kann. Das System muss im Falle einer unvorhergesehenen Komplikation warnen können. Deshalb muss ein System vorhanden sein, mit dem sich schwerwiegende Zwischenfälle und unerwünschte Reaktionen erkennen und untersuchen lassen, damit die lebenswichtigen Interessen der Betroffenen geschützt werden.

(13) Organspender sind oft auch Gewebespender. Die Qualitäts- und Sicherheitsanforderungen für Organe sollten mit dem bestehenden Gemeinschaftssystem für Gewebe und Zellen gemäß der Richtlinie 2004/23/EG des Europäischen Parlaments und des Rates vom 31. März 2004 zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Verarbeitung, Konservierung, Lagerung und Verteilung von menschlichen Geweben und Zellen[10] verbunden werden. Eine unerwünschte Reaktion beim Spender oder Empfänger einer Organspende sollte von der zuständigen Behörde zurückverfolgt und über das Gewebevigilanzsystem gemäß der genannten Richtlinie gemeldet werden.

(14) Das unmittelbar mit der Spende, Beschaffung, Testung, Konservierung, Beförderung und Transplantation menschlicher Organe betraute Personal sollte angemessen qualifiziert und geschult sein.

(15) Generell sollte der Austausch von Organen mit Drittländern von der zuständigen Behörde überwacht werden. Es sollte nur dann eine Zulassung erteilt werden, wenn Standards erfüllt werden, die den in dieser Richtlinie vorgesehenen gleichwertig sind. Allerdings ist zu berücksichtigen, welch wichtige Rolle die vorhandenen europäischen Einrichtungen für den Organaustausch zwischen den Mitgliedstaaten und Drittländern spielen, die an solchen Organisationen beteiligt sind.

(16) Diese Richtlinie sollte im Einklang mit den Grundrechten und Grundsätzen stehen, die insbesondere in der Charta der Grundrechte der Europäischen Union[11] anerkannt wurden. Gemäß dieser Charta und unter Berücksichtigung des Übereinkommens des

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[10] Richtlinie 2004/23/EG des Europäischen Parlaments und des Rates zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Verarbeitung, Konservierung, Lagerung und Verteilung von menschlichen Geweben und Zellen(ABl. L 102 vom 7.4.2004, S. 48).

[11] ABL. C 364 vom 18.12.2000 , S. 1.

Europarates über Menschenrechte und Biomedizin[12] sollten sich Organtransplantationsprogramme auf die Grundsätze der freiwilligen und unentgeltlichen Spende, der Uneigennützigkeit des Spenders und der Solidarität zwischen Spender und Empfänger bei gleichzeitiger Wahrung der Anonymität der verstorbenen Spender und der Empfänger stützen.

(17) Artikel 8 der Richtlinie 95/46/EG des Europäischen Parlaments und des Rates vom 24. Oktober 1995 zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten und zum freien Datenverkehr[13] verbietet grundsätzlich die Verarbeitung von Gesundheitsdaten. Für dieses Verbot gilt eine begrenzte Zahl von Ausnahmen. Gemäß der Richtlinie 95/46/EG muss zudem der für die Verarbeitung Verantwortliche die geeigneten technischen und organisatorischen Maßnahmen durchführen, um die personenbezogenen Daten vor versehentlicher oder unrechtmäßiger Zerstörung, zufälligem Verlust, Änderung, unberechtigter Weitergabe oder unberechtigtem Zugang und vor jeder anderen Form der unrechtmäßigen Verarbeitung zu schützen.

(18) Der Lebendspender sollte einer angemessenen Beurteilung unterzogen werden, damit seine Eignung für die Spende festgestellt und damit das Risiko der Krankheitsübertragung auf den Empfänger minimiert wird. Zudem sind Lebendorganspender sowohl bei den Untersuchungen zur Feststellung ihrer Eignung als auch beim Entnahmeverfahren Risiken ausgesetzt. Es kann zu medizinischen, sozialen, finanziellen oder psychologischen Komplikationen kommen. Die Höhe des Risikos hängt weitgehend davon ab, welches Organ gespendet wird. Daher ist bei Lebendspenden das körperliche, seelische und soziale Risiko des einzelnen Spenders und des Empfängers zu minimieren, und das Vertrauen der Bevölkerung in das Gesundheitswesen darf nicht beeinträchtigt werden. Der potenzielle Lebendspender muss eine unabhängige Entscheidung auf der Grundlage aller sachdienlichen Informationen[14] treffen können und sollte im Voraus über Zweck und Art der Spende, Folgen und Risiken aufgeklärt werden, wie im Zusatzprotokoll des Übereinkommens zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin über die Transplantation von Organen und Geweben menschlichen Ursprungs des Europarats festgelegt. Dies wird dazu beitragen, Personen von der Spende auszuschließen, deren Spende ein Risiko für andere, wie beispielsweise das der Krankheitsübertragung, oder ein schwerwiegendes Risiko für sie selbst darstellen könnte.

(19) Die zuständigen Behörden der Mitgliedstaaten sollten eine Schlüsselrolle bei der Gewährleistung der Qualität und Sicherheit von Organen über die gesamte Kette von der Spende bis zur Transplantation spielen. Wie in der Europarat-Empfehlung des Ministerkomitees an die Mitgliedstaaten über den Hintergrund, die Aufgaben und Zuständigkeiten einer nationalen Transplantationsorganisation (NTO)[15] betont wird, ist es am besten, eine einzige, amtlich anerkannte, gemeinnützige Einrichtung mit der Gesamtverantwortung für Spende, Zuteilung, Rückverfolgbarkeit und

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12 Übereinkommen zum Schutz der Menschenrechte und der Menschenwürde im Hinblick auf die Anwendung von Biologie und Medizin: Übereinkommen über Menschenrechte und Biomedizin.

13 ABl. L 281 vom 23.11.1995, S. 31.

14 Konsenserklärung des Amsterdamer Forums über die Versorgung lebender Nierenspender und des Forums von Vancouver Forum über die Versorgung verstorbener Nierenspender.

15 Rec(2006)15.

Rechenschaftspflicht zu betrauen. Je nach Zuständigkeitsverteilung in den Mitgliedstaaten kann jedoch auch eine Kombination lokaler, regionaler, nationaler und/oder internationaler Stellen zusammenarbeiten, um Spende, Zuteilung und/oder Transplantation zu koordinieren, sofern es einen Rahmen gibt, der Rechenschaftspflicht, Zusammenarbeit und Effizienz sicherstellt.

(20) Die Mitgliedstaaten sollten für Verstöße gegen die aufgrund dieser Richtlinie erlassenen Vorschriften Sanktionen festlegen und sicherstellen, dass diese Sanktionen angewendet werden. Die Sanktionen müssen wirksam, angemessen und abschreckend sein.

(21) Die Maßnahmen zur Umsetzung dieser Richtlinie sollten gemäß dem Beschluss Nr. 1999/468/EG des Rates vom 28. Juni 1999 zur Festlegung der Modalitäten für die Ausübung der der Kommission übertragenen Durchführungsbefugnisse[16] erlassen werden.

(22) Insbesondere sollte die Kommission ermächtigt werden, sofern die betreffenden Organe zwischen den Mitgliedstaaten ausgetauscht werden sollen, die Verfahren zur Übermittlung der Informationen über die Merkmale der Organe an die Transplantationszentren, die notwendigen Verfahren zur Sicherstellung der Rückverfolgbarkeit der Organe, einschließlich der Kennzeichnungsvorschriften, und die Verfahren zur Meldung schwerwiegender Zwischenfälle oder unerwünschter Reaktionen festzulegen. Da dies Maßnahmen von allgemeiner Tragweite zur Änderung von nicht wesentlichen Bestimmungen der Richtlinie 2004/49/EG oder zur Ergänzung der Richtlinie durch Hinzufügung neuer nicht wesentlicher Bestimmungen sind, sollten sie gemäß dem Regelungsverfahren mit Kontrolle des Artikels 5 a des Beschlusses Nr. 1999/468/EG erlassen werden.

(23) Da die Ziele dieser Richtlinie, nämlich die Festlegung von Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe, von den Mitgliedstaaten nicht ausreichend und deshalb unter Berücksichtigung des Umfangs der Maßnahmen auf Gemeinschaftsebene besser erreicht werden können, kann die Gemeinschaft nach dem Subsidiaritätsprinzip gemäß Artikel 5 EG-Vertrag tätig werden. Im Einklang mit dem im genannten Artikel niedergelegten Verhältnismäßigkeitsprinzip geht diese Richtlinie nicht über das für die Erreichung dieser Ziele erforderliche Maß hinaus –

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[16] ABL. L 184 vom 17.7.1999, S.23. Zuletzt geändert durch den Beschluss Nr. 2006/512/EG (ABL. L 200 vom 22.7.2006, S. 11).

HABEN FOLGENDE RICHTLINIE ERLASSEN:

KAPITEL I

GEGENSTAND, GELTUNGSBEREICH UND BEGRIFFSBESTIMMUNGEN

Artikel 1

Gegenstand

Diese Richtlinie legt Vorschriften zur Sicherstellung eines hohen Qualitäts- und Sicherheitsstandards für zur Transplantation in den menschlichen Körper bestimmte Organe menschlichen Ursprungs fest, um ein hohes Gesundheitsschutzniveau zu gewährleisten.

Artikel 2

Geltungsbereich

1. Diese Richtlinie gilt für die Spende, Beschaffung, Testung, Charakterisierung, Konservierung, Beförderung und Transplantation von Organen menschlichen Ursprungs, die zu Transplantationszwecken bestimmt sind.

2. Werden solche Organe zu Forschungszwecken verwendet, gilt diese Richtlinie jedoch nur, insofern sie zur Transplantation in den menschlichen Körper bestimmt sind.

Artikel 3

Begriffsbestimmungen

Im Sinne dieser Richtlinie bezeichnet der Ausdruck:

(a) ‘Zulassung’ die Zulassung, Akkreditierung, Designierung oder Lizenzierung, je nach den in den einzelnen Mitgliedstaaten verwendeten Begriffen;

(b) ‘Entsorgung’ den endgültigen Verbleib eines Organs, wenn es nicht zur Transplantation verwendet wird;

(c) ‘Spender’ jeden lebenden oder verstorbenen menschlichen Organspender;

(d) ‘Spende’ die Spende menschlicher Organe zu Transplantationszwecken;

(e) ‘Spendercharakterisierung’ die Erhebung der sachdienlichen Informationen über die Merkmale des Spenders, die für eine ordnungsgemäße Risikobewertung erforderlich sind, um die Risiken für den Empfänger zu minimieren und die Organzuteilung zu optimieren;

(f) ‘europäische Organisation für Organaustausch‘ eine öffentliche oder private gemeinnützige Organisation, die sich insbesondere mit dem grenzüberschreitenden Organaustausch beschäftigt und deren Mitglieder hauptsächlich Mitgliedstaaten der Gemeinschaft sind;

(g) ‘Organ’ einen differenzierten und lebensnotwendigen Teil des menschlichen Körpers, der aus verschiedenen Geweben besteht und seine Struktur, Vaskularisierung und Fähigkeit zum Vollzug physiologischer Funktionen mit deutlicher Autonomie aufrechterhält;

(h) ‘Organcharakterisierung’ die Erhebung der sachdienlichen Informationen über die Merkmale eines Organs, die für eine ordnungsgemäße Risikobewertung erforderlich sind, um die Risiken für den Empfänger zu minimieren und die Organzuteilung zu optimieren;

(i) ‘Beschaffung’ einen Prozess, durch den gespendete Organe verfügbar gemacht werden;

(j) ‚Beschaffungsorganisation’ eine Einrichtung des Gesundheitswesens, ein Team oder eine Abteilung eines Krankenhauses oder einer anderen Einrichtung, die von der zuständigen Behörde für die Beschaffung menschlicher Organe zugelassen ist;

(k) ‘Konservierung’ den Einsatz chemischer Stoffe, veränderter Umgebungsbedingungen oder sonstiger Mittel während der Verarbeitung mit dem Ziel, eine biologische oder physikalische Beeinträchtigung von Organen von der Beschaffung bis zur Transplantation zu verhüten oder zu verzögern;

(l) ‘Empfänger’ die Person, die ein Organtransplantat erhält;

(m) ‘schwerwiegender Zwischenfall’ jedes unerwartete Ereignis im Zusammenhang mit irgendeinem Glied der Kette von der Spende bis zur Transplantation, das zur Übertragung einer Infektionskrankheit, zum Tod oder zu Zuständen führen könnte, die lebensbedrohlich sind, eine Behinderung oder einen Funktionsverlust zur Folge haben oder eine Krankenhausbehandlung oder Morbidität nach sich ziehen oder verlängern;

(n) ‘schwerwiegende unerwünschte Reaktion’ jede unbeabsichtigte Reaktion, einschließlich einer Infektionskrankheit, beim Spender oder Empfänger im Zusammenhang mit irgendeinem Glied der Kette von der Spende bis zur Transplantation, die lebensbedrohlich ist, eine Behinderung oder einen Funktionsverlust zur Folge hat oder eine Krankenhausbehandlung oder Morbidität nach sich zieht oder verlängert;

(o) ‘Standardverfahrensanweisungen’ schriftliche Anweisungen, welche die Schritte eines spezifischen Verfahrens beschreiben, einschließlich der zu verwendenden Materialien und Methoden und des erwarteten Endprodukts;

(p) ‘Transplantation’ das Verfahren zur Wiederherstellung bestimmter Funktionen des menschlichen Körpers durch die Übertragung entsprechender Organe auf einen Empfänger;

(q) ‘Transplantationszentrum’ eine Einrichtung des Gesundheitswesens, ein Team oder eine Krankenhausabteilung oder eine andere Stelle, die von der zuständigen Behörde für die Transplantation menschlicher Organe zugelassen ist;

(r) ‘Rückverfolgbarkeit’ die Möglichkeit einer zuständigen Behörde, das Organ in jeder Phase von der Spende bis zur Transplantation oder Entsorgung zu lokalisieren und zu identifizieren; diese ist unter in dieser Richtlinie spezifizierten Bedingungen ermächtigt,

– den Spender und die Beschaffungsorganisation zu identifizieren,

– die Empfänger in den Transplantationszentren zu identifizieren,

– alle sachdienlichen nicht personenbezogenen Informationen über Produkte und Materialien, mit denen das Organ in Berührung kommt, zu lokalisieren und zu identifizieren.

KAPITEL II

QUALITÄT UND SICHERHEIT VON ORGANEN

Artikel 4

Nationale Qualitätsprogramme

1. Die Mitgliedstaaten stellen sicher, dass ein nationales Qualitätsprogramm festgelegt wird, das alle Phasen von der Spende bis zur Transplantation oder Entsorgung abdeckt, um die Einhaltung der in dieser Richtlinie festgelegten Vorschriften sicherzustellen.

2. Die nationalen Qualitätsprogramme sehen Erlass und Durchführung folgender Vorschriften vor:

(a) Standardverfahrensanweisungen zur Überprüfung der Spenderidentität;

(b) Standardverfahrensanweisungen zur Überprüfung der Einzelheiten der Einwilligung seitens des Spenders oder seiner Angehörigen oder der Ermächtigung nach den einzelstaatlichen Gesetzen;

(c) Standardverfahrensanweisungen zur Überprüfung des Abschlusses der Charakterisierung von Spender und Organ gemäß Artikel 7 und nach dem im Anhang angegebenen Muster;

(d) Verfahren für die Beschaffung, Konservierung, Verpackung und Kennzeichnung von Organen gemäß Artikel 5, 6 und 8;

(e) Vorschriften für die Beförderung menschlicher Organe gemäß Artikel 8.

3. Die nationalen Qualitätsprogramme legen Folgendes fest:

(a) Vorschriften zur Sicherstellung der Rückverfolgbarkeit der Organe in allen Phasen von der Spende bis zur Transplantation oder Entsorgung gemäß Artikel 10, einschließlich

– Standardverfahrensanweisungen, nach denen die Rückverfolgbarkeit der Organe auf nationaler Ebene sichergestellt wird,

– für die Sicherstellung der Rückverfolgbarkeit erforderliche Daten sowie Art und Weise, wie die gesetzlichen Vorschriften über den Schutz personenbezogener Daten und der Geheimhaltung eingehalten werden;

– Zuständigkeiten der Beschaffungsorganisationen und Transplantationszentren mit Blick auf die Rückverfolgbarkeit;

(b) Standardverfahrensanweisungen für

– die korrekte, unverzügliche und überprüfbare Meldung schwerwiegender Zwischenfälle und unerwünschter Reaktionen gemäß Artikel 11 Absatz 1,

– den Rückruf von Organen im Sinne des Artikels 11 Absatz 2,

– die Zuständigkeiten der Beschaffungsorganisationen und Transplantationszentren bei der Meldung;

(c) Qualifikationen, über die das Personal verfügen muss, das an den Phasen von der Spende bis zur Transplantation oder Entsorgung beteiligt ist, sowie die Entwicklung spezifischer Personalschulungsprogramme nach anerkannten internationalen Standards.

Artikel 5

Beschaffungsorganisationen

1. Die Mitgliedstaaten stellen sicher, dass die Beschaffung in Organisationen erfolgt, die den in dieser Richtlinie festgelegten Vorschriften genügen.

2. Organisationsstruktur und Verfahrensanweisungen der Beschaffungsorgansationen umfassen:

(a) ein Organigramm, das Aufgabenbeschreibungen, Rechenschaftspflicht und Berichtskette eindeutig festlegt;

(b) Standardverfahrensanweisungen, wie in den nationalen Qualitätsprogrammen spezifiziert.

3. Die Mitgliedstaaten legen auf Ersuchen der Kommission oder eines anderen Mitgliedstaats Informationen über die einzelstaatlichen Anforderungen für die Zulassung von Beschaffungsorganisationen vor.

Artikel 6

Organbeschaffung

1. Die Mitgliedstaaten stellen sicher, dass ärztliche Tätigkeiten in Beschaffungsorganisationen, wie die Spenderauswahl, unter Beratung und Aufsicht eines Arztes im Sinne der Richtlinie 2005/36/EG erfolgen.

2. Die Mitgliedstaaten stellen sicher, dass die Beschaffung in eigens dafür vorgesehenen Einrichtungen erfolgt, die nach den in dieser Richtlinie festgelegten Vorschriften gestaltet und konstruiert sind bzw. instand gehalten und betrieben werden und die Minimierung bakterieller oder anderer Kontaminationen der beschafften menschlichen Organe nach den besten medizinischen Verfahren ermöglichen.

Diese Einrichtungen genügen dem normalen Standard für Operationssäle, dazu gehört

(a) Zutrittsbeschränkung,

(b) Personalbekleidung, die für sterile Operationen geeignet ist, mit sterilen Handschuhen, Kopfbedeckung und Mundschutz.

3. Die Mitgliedstaaten stellen sicher, dass Beschaffungsmaterial und -ausrüstung nach den einschlägigen nationalen und internationalen Vorschriften, Standards und Leitlinien für die Sterilisierung von Arzneimitteln und Medizinprodukten gehandhabt werden. Zur Beschaffung werden qualifizierte sterile Instrumente und Entnahmevorrichtungen verwendet.

Artikel 7

Organ- und Spendercharakterisierung

1. Die Mitgliedstaaten stellen sicher, dass alle beschafften Organe und deren Spender vor der Transplantation mittels Erhebung der Daten und Informationen charakterisiert werden, die im Vordruck für Organcharakterisierung im Anhang aufgeführt sind. Die zur Organcharakterisierung erforderlichen Tests sind von einem qualifizierten Labor durchzuführen.

2. Die Mitgliedstaaten stellen sicher, dass die mit der Organ- und Spendercharakterisierung befassten Organisationen, Stellen und qualifizierten Labore über geeignete Standardverfahrensanweisungen verfügen, welche gewährleisten,

dass die Informationen zur Organ- und Spendercharakterisierung das Transplantationszentrum rechtzeitig erreichen.

Artikel 8

Organbeförderung

1. Die Mitgliedstaaten stellen sicher, dass folgende Anforderungen erfüllt werden:

(a) die mit der Organbeförderung befassten Organisationen, Stellen oder Unternehmen verfügen über geeignete Standardverfahrensanweisungen, die dafür sorgen, dass das Organ während der Beförderung unversehrt bleibt und die Beförderungsdauer minimiert wird;

(b) die für die Organbeförderung verwendeten Transportbehälter sind mit folgenden Informationen versehen:

– Kennung der Beschaffungseinrichtung, einschließlich Anschrift und Telefonnummer;

– Kennung des Bestimmungstransplantationszentrums, einschließlich Anschrift und Telefonnummer;

– Erklärung, dass der Behälter ein menschliches Organ enthält, und die Aufschrift „HANDLE WITH CARE“;

– empfohlene Beförderungsbedingungen, einschließlich Anweisungen für Umgebungstemperatur und Position des Behälters;

– Sicherheits- und ggf. Kühlungsanweisungen.

Buchstabe (b) gilt nicht für die Beförderung innerhalb derselben Einrichtung.

Artikel 9

Transplantationszentren

1. Die Mitgliedstaaten stellen sicher, dass Transplantationen in Transplantationszentren erfolgen, welche die in dieser Richtlinie festgelegten Vorschriften erfüllen.

2. Die zuständige Behörde führt in der Akkreditierung, Designierung, Zulassung oder Lizenzierung auf, welche Tätigkeiten das betreffende Transplantationszentrum ausüben darf.

3. Vor einer Transplantation überprüfen die Transplantationszentren, dass

a) die Organ- und Spendercharakterisierung nach dem Muster im Anhang abgeschlossen ist und dass die in diesem Vordruck genannten Informationen aufbewahrt werden;

b) die angegebene Aufbewahrungstemperatur und sonstige Bedingungen für die Beförderung menschlicher Organe eingehalten wurden.

4. Die Mitgliedstaaten legen auf Ersuchen der Kommission oder eines anderen Mitgliedstaats Informationen über die nationalen Vorschriften für die Zulassung von Transplantationszentren vor.

Artikel 10

Rückverfolgbarkeit

1. Die Mitgliedstaaten stellen sicher, dass alle auf ihrem Hoheitsgebiet beschafften und zugeteilten Organe vom Spender bis zum Empfänger und zurück verfolgt werden können, um die Gesundheit von Spendern und Empfängern zu schützen.

2. Die Mitgliedstaaten sorgen für die Einführung eines Spenderidentifikationssystems, das jede Spende und jedes damit verbundene Organ identifizieren kann. Die Mitgliedstaaten stellen sicher, dass dieses Spenderidentifikationssystem entsprechend dem Ziel gestaltet und ausgewählt wird, keine persönlichen Daten oder so wenige wie möglich zu erheben, zu verarbeiten oder zu verwenden. Insbesondere ist von den Möglichkeiten zur Pseudonymisierung oder Anonymisierung der einzelnen Personen Gebrauch zu machen.

3. Die Mitgliedstaaten stellen Folgendes sicher:

   a) Gemäß den nationalen Qualitätsprogrammen bewahrt die zuständige Behörde oder andere an der Kette von der Spende bis zur Transplantation oder Entsorgung beteiligte Stellen die Daten auf, die zur Sicherstellung der Rückverfolgbarkeit in allen Phasen von der Spende bis zur Transplantation oder Entsorgung erforderlich sind;

   b) die zur Sicherstellung einer lückenlosen Rückverfolgung erforderlichen Daten werden mindestens 30 Jahre nach der Spende aufbewahrt. Die Datenspeicherung kann elektronisch erfolgen.

Artikel 11

Meldesysteme für schwerwiegende Zwischenfälle und unerwünschte Reaktionen

1. Die Mitgliedstaaten sorgen für ein Meldesystem für die Meldung, Untersuchung, Registrierung und Übermittlung der sachdienlichen und notwendigen Informationen über schwerwiegende Zwischenfälle und unerwünschte Reaktionen, welche die Qualität und Sicherheit menschlicher Organe beeinträchtigen und auf die Beschaffung, Testung und Beförderung der Organe zurückgeführt werden können, sowie über etwaige schwerwiegende unerwünschte Reaktionen, die während oder nach der Transplantation beobachtet werden und ebenfalls hierauf zurückgeführt werden können.

2. Die Mitgliedstaaten sorgen für ein Verfahren zum unverzüglichen Rückruf jedes Organs, für das ein Zusammenhang mit einem schwerwiegenden Zwischenfall oder einer unerwünschten Reaktion, wie im nationalen Qualitätsprogramm spezifiziert, hergestellt werden kann.

3. Die Mitgliedstaaten sorgen für die Verbindung des in Absatz 1 dieses Artikels genannten Meldesystems mit dem gemäß Artikel 11 der Richtlinie 2004/23/EG eingerichteten Meldesystem.

Artikel 12

Personal

Die Mitgliedstaaten stellen sicher, dass das Personal, das unmittelbar an der Kette von der Spende bis zur Transplantation oder Entsorgung beteiligt ist, für seine Aufgaben entsprechend qualifiziert und einschlägig geschult ist, wie im nationalen Qualitätsprogramm spezifiziert.

KAPITEL III

SCHUTZ DES SPENDERS UND DES EMPFÄNGERS

Artikel 13

Grundsätze der Organspende

1. Die Mitgliedstaaten stellen sicher, dass Spenden menschlicher Organe von lebenden und verstorbenen Spendern freiwillig und unentgeltlich sind.

2. Die Mitgliedstaaten verbieten die Bekanntmachung des Bedarfs an menschlichen Organen oder ihrer Verfügbarkeit, die den Zweck verfolgt, finanziellen Gewinn oder vergleichbare Vorteile anzubieten oder zu erzielen.

3. Die Mitgliedstaaten stellen sicher, dass die Beschaffung von Organen nicht zu Erwerbszwecken erfolgt.

Artikel 14

Einwilligungs- und Zulassungsvoraussetzungen für die Beschaffung

Die Beschaffung erfolgt nur, wenn alle im betreffenden Mitgliedstaat geltenden zwingenden Vorschriften für die Einwilligung oder Zulassung erfüllt sind.

Artikel 15

Schutz des lebenden Spenders

1. Die Mitgliedstaaten treffen alle notwendigen Maßnahmen, um sicherzustellen, dass potenzielle Lebendspender alle erforderlichen Informationen über Zweck und Art der Spende, Folgen und Risiken sowie alternative Therapien für den potenziellen Empfänger erhalten, damit sie eine aufgeklärte Entscheidung treffen können. Die Informationen sind vor der Spende zu erteilen.

2. Die Mitgliedstaaten stellen sicher, dass Lebendspender anhand ihrer Gesundheit und Anamneseerhebung durch qualifiziertes und geschultes Personal, einschließlich erforderlichenfalls einer psychologischen Beurteilung, ausgewählt werden. Solche Beurteilungen können zum Ausschluss von Personen führen, deren Spende ein Gesundheitsrisiko für andere, wie beispielsweise die Möglichkeit der Krankheitsübertragung, oder ein schwerwiegendes Risiko für sie selbst darstellen könnte.

3. Die Mitgliedstaaten stellen sicher, dass die zuständige Behörde im Einklang mit den Bestimmungen über den Schutz personenbezogener Daten und die statistische Geheimhaltung nach der Spende ein Register der lebenden Spender führt und Informationen über deren Nachsorge erhebt sowie insbesondere über Komplikationen im Zusammenhang mit ihrer Spende, die möglicherweise kurz-, mittel- oder langfristig auftreten.

Artikel 16

Schutz personenbezogener Daten, Vertraulichkeit und Sicherheit der Verarbeitung

Die Mitgliedstaaten stellen sicher, dass bei allen Tätigkeiten im Zusammenhang mit der Organtransplantation das Grundrecht auf Schutz personenbezogener Daten im Einklang mit den Gemeinschaftsvorschriften über den Schutz personenbezogener Daten, insbesondere Artikel 8 Absatz 3, Artikel 16, 17 und Artikel 28 Absatz 2 der Richtlinie 95/46/EG, vollständig und wirksam gewährleistet wird.

Artikel 17

Anonymisierung von Spendern und Empfängern

Die Mitgliedstaaten treffen alle notwendigen Maßnahmen, um sicherzustellen, dass alle verarbeiteten personenbezogenen Daten von Spendern und Empfängern, die in den Geltungsbereich dieser Richtlinie fallen, anonymisiert werden, so dass weder Spender noch Empfänger identifizierbar bleiben.

KAPITEL IV

PFLICHTEN DER ZUSTÄNDIGEN BEHÖRDEN UND INFORMATIONSAUSTAUSCH

Artikel 18

Benennung und Aufgaben der zuständigen Behörden

Die Mitgliedstaaten benennen die für die Durchführung der Vorschriften dieser Richtlinie zuständige(n) Behörde(n) (im Folgenden „zuständige Behörde“).

Die zuständigen Behörden treffen insbesondere folgende Maßnahmen:

(a) Einführung und Aktualisierung eines nationalen Qualitätsprogramms gemäß Artikel 4;

(b) Sicherstellung, dass Beschaffungsorganisationen und Transplantationszentren regelmäßig kontrolliert und geprüft werden, um festzustellen, ob sie die Vorschriften dieser Richtlinie einhalten;

(c) Gewährung, Aussetzung oder ggf. Entzug der Zulassungen von Beschaffungsorganisationen oder Transplantationszentren, wenn Kontrollmaßnahmen ergeben, dass diese Organisationen oder Zentren die Vorschriften dieser Richtlinie nicht einhalten;

(d) Einführung eines Meldesystems und eines Systems für den Rückruf von Organen gemäß Artikel 11 Absätze 1 und 2;

(e) Erteilung geeigneter Anleitungen für Einrichtungen des Gesundheitswesens, Angehörige der Gesundheitsberufe und andere an der Kette von der Spende bis zur Transplantation oder Entsorgung Beteiligte;

(f) Beteiligung an dem in Artikel 20 genannten Gemeinschaftsnetz und Koordinierung der Beiträge zur Arbeit des Netzes auf nationaler Ebene;

(g) Überwachung des Organaustauschs mit anderen Mitgliedstaaten und Drittländern;

(f) Sicherstellung in Zusammenarbeit mit der gemäß Artikel 28 der Richtlinie 95/46/EG errichteten Aufsichtbehörde, dass bei allen Tätigkeiten im Zusammenhang mit der Organtransplantation das Grundrecht auf Schutz personenbezogener Daten im Einklang mit den Gemeinschaftsvorschriften über den Schutz personenbezogener Daten, insbesondere der Richtlinie 95/46/EG, vollständig und wirksam gewahrt wird.

Artikel 19

Register und Berichte über Beschaffungsorganisationen und Transplantationszentren

1. Die Mitgliedstaaten stellen sicher, dass die zuständige Behörde

   (a) gemäß den Bestimmungen über den Schutz personenbezogener Daten und der statistischen Geheimhaltung die Tätigkeiten der Beschaffungsorganisationen und Transplantationszentren aufzeichnet, einschließlich der aggregierten und anonymisierten Zahlen der lebenden und verstorbenen Spender sowie der Arten und Mengen der beschafften und transplantierten oder entsorgten Organe;

   (b) einen Jahresbericht über die genannten Tätigkeiten erstellt und veröffentlicht;

   (c) ein Register der Beschaffungsorganisationen und Transplantationszentren erstellt und auf dem neuesten Stand hält.

2. Die Mitgliedstaaten legen auf Ersuchen der Kommission oder eines anderen Mitgliedstaats Informationen über das Register der Beschaffungsorganisationen und Transplantationszentren vor.

Artikel 20

Informationsaustausch

1. Die Kommission errichtet ein Netz der zuständigen Behörden zum Zweck des Informationsaustauschs über die bei der Durchführung dieser Richtlinie gewonnenen Erfahrungen.

2. Diesem Netz können gegebenenfalls Experten für Organtransplantation, Vertreter europäischer Organisationen für Organaustausch sowie Datenschutzaufsichtsbehörden und andere Beteiligte angegliedert werden.

KAPITEL V
ORGANAUSTAUSCH MIT DRITTLÄNDERN UND EUROPÄISCHE ORGANISATIONEN FÜR DEN ORGANAUSTAUSCH

Artikel 21

Organaustausch mit Drittländern

1. Die Mitgliedstaaten stellen sicher, dass jeglicher Organaustausch mit Drittländern – aus diesen Ländern in die Gemeinschaft oder umgekehrt – von der zuständigen Behörde genehmigt wird.

2. Genehmigungen für den Organaustausch im Sinne von Absatz 1 werden nur erteilt, wenn die Organe

   (a) vom Spender bis zum Empfänger und zurück verfolgt werden können;

   (b) Qualitäts- und Sicherheitsanforderungen erfüllen, die den in dieser Richtlinie festgelegten gleichwertig sind.

Artikel 22

Europäische Organisationen für den Organaustausch

Die Mitgliedstaaten können schriftliche Vereinbarungen mit europäischen Organisationen für den Organaustausch treffen, sofern diese Organisationen sicherstellen, dass die in dieser Richtlinie festgelegten Anforderungen erfüllt werden; dabei können die Mitgliedstaaten an diese Organisationen Folgendes delegieren:

   (a) die Durchführung der Tätigkeiten gemäß den nationalen Qualitätsprogrammen;

   (b) die Erteilung von Zulassungen und Durchführung spezifischer Aufgaben im Zusammenhang mit dem Organaustausch zwischen den Mitgliedstaaten und mit Drittländern.

KAPITEL VI
ALLGEMEINE BESTIMMUNGEN

Artikel 23

Berichte über diese Richtlinie

1. Die Mitgliedstaaten berichten der Kommission bis spätestens zum […] und danach alle drei Jahre über die Maßnahmen, die sie im Hinblick auf diese Richtlinie durchgeführt haben, und über die Erfahrungen bei deren Umsetzung.

2. Die Kommission übermittelt dem Europäischen Parlament, dem Rat, dem Europäischen Wirtschafts- und Sozialausschuss und dem Ausschuss der Regionen einen Bericht über die Umsetzung dieser Richtlinie.

Artikel 24

Sanktionen

Die Mitgliedstaaten legen für Verstöße gegen die aufgrund dieser Richtlinie erlassenen innerstaatlichen Vorschriften Sanktionen fest und treffen die zu ihrer Anwendung erforderlichen Maßnahmen. Die Sanktionen müssen wirksam, angemessen und abschreckend sein. Die Mitgliedstaaten teilen der Kommission diese Vorschriften bis spätestens zum [...] mit und melden ihr spätere Änderungen unverzüglich.

Artikel 25

Durchführungsmaßnahmen

1. Für die folgenden Maßnahmen werden ausführliche Vorschriften nach dem in Artikel 26 Absatz 3 genannten Verfahren erlassen:

   (a) Regelungen zur Aktualisierung und Übermittlung von Informationen über die Charakterisierung menschlicher Organe, wie im Anhang spezifiziert;

   (b) Verfahren zur Sicherstellung der lückenlosen Rückverfolgbarkeit der Organe, einschließlich Kennzeichnungsvorschriften;

   (c) Verfahren zur Sicherstellung der Meldung schwerwiegender Zwischenfälle und unerwünschter Reaktionen.

2. Zur einheitlichen Umsetzung dieser Richtlinie und insbesondere für die folgenden Maßnahmen werden ausführliche Vorschriften nach dem in Artikel 26 Absatz 2 genannten Verfahren erlassen:

(a) die Verbindung zwischen den in Artikel 11 Absatz 3 genannten Meldesystemen für schwerwiegende Zwischenfälle und unerwünschte Reaktionen;

(b) die Errichtung und den Betrieb des in Artikel 20 genannten Netzes der zuständigen Behörden.

Artikel 26

Ausschuss

1. Die Kommission wird von einem Ausschuss für Organtransplantation („der Ausschuss“) unterstützt.

2. Wird auf diesen Absatz Bezug genommen, gelten die Artikel 5 und 7 des Beschlusses Nr. 1999/468/EG, unter Beachtung von dessen Artikel 8. Der Zeitraum nach Artikel 5 Absatz 6 des Beschlusses Nr. 1999/468/EG wird auf drei Monate festgesetzt.

3. Wird auf diesen Absatz Bezug genommen, gelten die Artikel 5a Absätze 1 bis 4 und Artikel 7 des Beschlusses Nr. 1999/468/EG, unter Beachtung von dessen Artikel 8.

Artikel 27

Umsetzung

1. Die Mitgliedstaaten erlassen die erforderlichen Rechts- und Verwaltungsvorschriften, um dieser Richtlinie bis spätestens zum nachzukommen. Sie teilen der Kommission unverzüglich den Wortlaut dieser Vorschriften mit und übermitteln ihr eine Tabelle der Entsprechungen zwischen ihren Vorschriften und den Bestimmungen dieser Richtlinie.

   Wenn die Mitgliedstaaten diese Vorschriften erlassen, nehmen sie in den Vorschriften selbst oder durch einen Hinweis bei der amtlichen Veröffentlichung auf diese Richtlinie Bezug. Die Mitgliedstaaten regeln die Einzelheiten der Bezugnahme.

2. Die Mitgliedstaaten teilen der Kommission den Wortlaut der wichtigsten innerstaatlichen Rechtsvorschriften mit, die sie auf dem unter diese Richtlinie fallenden Gebiet erlassen.

KAPITEL VII
SCHLUSSBESTIMMUNGEN

Artikel 28

Inkrafttreten

Diese Richtlinie tritt am zwanzigsten Tag nach ihrer Veröffentlichung im *Amtsblatt der Europäischen Union* in Kraft.

Artikel 29

Adressaten

Diese Richtlinie ist an die Mitgliedstaaten gerichtet.

Geschehen zu Brüssel, am]

Im Namen des Europäischen Parlaments	*Im Namen des Rates*
Der Präsident	*Der Präsident*

ANHANG

ORGAN- UND SPENDERCHARAKTERISIERUNG

Im Sinne des Artikels 7 muss die Beschaffungsorganisation oder das Beschaffungsteam ggf. nach Testung folgende Informationen über die Merkmale des Organs und des Spenders erheben und im Einklang mit den Rechtsvorschriften über den Schutz personenbezogener Daten und Geheimhaltung verarbeiten.

KATEGORIE	**UNTERKATEGORIE**	**ITEM**	**ABK.**
ALLGEMEINE ANGABEN		Spenderkennung	
		Krankenhaus	
		örtl. Koordinator/Kontaktperson	
SPENDERDATEN		Spendertyp*	
		Geburtsdatum	
		Alter	
		Geschlecht	
		Gewicht	
		Größe	
		(ggf.) Brustumfang	
		(ggf.) Abdominalumfang	
		AB0-Gruppe	
		(ggf.) HLA	
		Todesursache	
		Todeszeitpunkt	
AUFNAHME INTENSIVSTATION		Datum und Zeit der Versorgung auf der Intensivstation	
		Datum und Uhrzeit der Intubation	
SPENDERANAMNESE (allgemeine Beschreibung)		Neoplasie	
		Angabe aller relevanten nephro-, hepato- kardio-, pneumo-, pankreas- und neuro-pathologischen Befunde sowie aller relevanten früheren Operationen, Traumata oder Parasitenerkrankungen	

		Diabetes	
		Hypertonie	
		Alkohol	
		Rauchen	
		Drogen	
KÖRPERLICHE/KLINISCHE DATEN		Blutdruck	
		Hypotonie (Dauer)	
		Körpertemperatur	
		Diurese (mindestens 24 Stunden)	
		Diurese letzte Stunde	
		(ggf.) Kardiorespiratorische Reanimation (Dauer)	
		Herzfrequenz	
LABOR		Datum Uhrzeit Werte	
	HÄMATOLOGIE	Prothrombin	PT
		Auszählung weißer Blutkörperchen	WBC
		Blutplättchen	
		Hämoglobin	Hb
		Hämatokrit	PCV
	BIOCHEMIE	Na+	
		K+	
		Alk. Phos. (Leber)	AP
		Glukose	
		Bilirubin Tot_Dir (Leber)	
		Amylase oder Lipase (Pankreas)	
		Glut.-Oxalacetat-Trans. (GOT)	AST
		Glut.-Pyruvat-Trans. (GPT)	ALT
		Gamma-Glutamil-Trans. (GGT)	GGT

		(Leber)	
		Kreatinin	
		Troponin (Herz)	
		Harnstoff (bei Nieren-transplantation)	BUN
		LDH	
		GESAMT-Protein (dringend empfohlen)	
		Albumin (dringend empfohlen)	
	MIKROBIOLOGIE (Diese Informationen könnten nach der Transplantation verfügbar sein)	Blutkultur (dringend empfohlen zum Zeitpunkt der Beschaffung)	
		Urinkultur (dringend empfohlen zum Zeitpunkt der Beschaffung)	
		Trachealsekrete (dringend empfohlen zum Zeitpunkt der Beschaffung)	
	SEROLOGIE	HIV 1-2	
		HBsAg	
		AntiHbc (dringend empfohlen)	
		HCV	
		Anti CMV IgG (empfohlen)	
		Anti CMV IgM (empfohlen)	
		Syphilis	
		HTLV I II (bei Spendern aus Gebieten mit hoher Inzidenz oder mit Risikofaktoren für eine Virusexposition)	
	URIN	Glukose (ja/nein)	
		Protein (ja/nein)	
DIAGNOSTIK		Abdominalechographie (wenn erforderlich)	
		Thorax-Radiographie	

		EKG	
		Kardial-ECHO (Herz)	
BLUT, GAS UND BEATMUNG		FiO2 %	
		PEEP	
		PaO2 (mit FiO2-Angabe)	
		PaCO2 (mit FiO2-Angabe)	
		PH	
		HCO3	
		Sat O2	
		FiO2 1,0 / PEEP 5 (Lunge)	
		PaO2 (Lunge) mit FiO2 1,0 / PEEP 5 (Lunge)	
		PaCO2 (Lunge) mit FiO2 1,0 / PEEP 5 (Lunge)	
THERAPIE (allgemeine Beschreibung)		Antibiotika	
		Diuretika	
		Inotrope Unterstützung (Adrenalin, Noradrenalin, Dobutamin, Dopamin…)	
		Bluttransfusion	
		Sonstige Medikation	

FINANZBOGEN ZU VORSCHLÄGEN FÜR RECHTSAKTE, DEREN FINANZIELLE AUSWIRKUNGEN SICH AUF DIE EINNAHMEN BESCHRÄNKEN

1. BEZEICHNUNG DES VORGESCHLAGENEN RECHTSAKTS:

Vorschlag für eine Richtlinie zur Festsetzung von Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe

2. ABM/ABB-RAHMEN

Öffentliche Gesundheit

3. HAUSHALTSLINIEN

3.1. Haushaltslinien (operative Linien sowie Linien für entsprechende technische und administrative Unterstützung (vormalige BA-Linien)), mit Bezeichnung:

XX0101: Beamtenvergütung

XX010211: Ausschusskosten

3.2. Dauer der Maßnahme und ihrer finanziellen Auswirkungen:

Ab 2009, Dauer unbegrenzt

Diese Mittel sind bestimmt zur Deckung der Kosten des künftigen Regelungsausschusses (Komitologie) und des Netzes (Sitzung der zuständigen Behörden) für Organspende und -transplantation, die gemäß den Bestimmungen der Richtlinie nach deren Annahme durch das Europäische Parlament und den Rat eingerichtet werden:

2 Sachbearbeiter (VZÄ), jeweils 122 000 EUR (gemäß spezifischen Leitlinien) zur Unterstützung der Umsetzung und der Ausschussverfahren.

Kosten der Plenarsitzung (erste Sitzung der zuständigen Behörden), mit je einem Teilnehmer aus jedem der 27 Mitgliedstaaten. 3 geplante Sitzungen pro Jahr (in den ersten 2 Jahren nach der Verabschiedung), jeweils 20 000 EUR; diese Zahl wird sich von 3 Sitzungen pro Jahr auf 2 pro Jahr und danach auf 1 pro Jahr reduzieren. Die tatsächlichen Kosten der einzelnen Sitzungen und deren Häufigkeit müssen ggf., in Abhängigkeit von der endgültigen Form der Richtlinie nach Verabschiedung durch Rat und Parlament und der nötigen Ausschussstrukturen, angepasst werden. Darüber hinaus sollten 3 Ausschusssitzungen pro Jahr zu Kosten von je 20 000 EUR veranschlagt werden.

3.3. Haushaltstechnische Merkmale:

Haushalts-linie	Art der Ausgaben	Neu	EFTA-Beitrag	Beiträge von Bewerber-ländern	Rubrik der Finanziellen Vorausschau

XX 0101	OA	NGM[17]	NEIN	NEIN	NEIN	**5**
XX 010211	NOA	NGM[18]	NEIN	NEIN	NEIN	**5**

17 Nichtgetrennte Mittel
18 Nichtgetrennte Mittel

4. RESSOURCEN IM ÜBERBLICK

4.1. Finanzmittel

4.1.1. Überblick über die erforderlichen Verpflichtungsermächtigungen (VE) und Zahlungsermächtigungen (ZE)

in Mio. EUR (3 Dezimalstellen)

Art der Ausgaben	Abschnitt		2009	2010	2011	2012	2013	*Insgesamt 2009-2013*	*2014 und Folgejahre*
Operative Ausgaben[19]									
Verpflichtungsermächtigungen (VE)	8.1.	a							
Zahlungsermächtigungen (ZE)		b							
Im Höchstbetrag enthaltene Verwaltungsausgaben[20]									
Technische & administrative Unterstützung (NGM)	8.2.4.	c							
HÖCHSTBETRAG									
Verpflichtungsermächtigungen		a+c							
Zahlungsermächtigungen		b+c							
Im Höchstbetrag <u>nicht</u> enthaltene Verwaltungsausgaben[21]									
Personal- und Nebenkosten (NGM)	8.2.5.	d	0,244	0,244	0,244	0,244	0,244	1,220	*0,244*
Verwaltungskosten außer Personalkosten und damit verbundene Kosten (NGM)	8.2.6.	e	0,120	0,120	0,100	0,100	0,080	0,420	*0,080*
Geschätzte Gesamtkosten für die Finanzierung der Maßnahme									
VE insgesamt, einschließlich Personalkosten		a+c+d+e	0,364	0,364	0,344	0,344	0,324	1,640	*0,324*
ZE insgesamt, einschließlich Personalkosten		b+c+d+e	0,364	0,364	0,344	0,344	0,324	1,640	*0,324*

19 Ausgaben, die nicht unter Kapitel xx 01 des betreffenden Titels xx fallen.
20 Ausgaben, die unter Artikel xx 01 04 des Titels xx fallen.
21 Ausgaben, die unter Kapitel xx 01 fallen, außer solche bei Artikel xx 01 04 oder xx 01 05.

Angaben zur Kofinanzierung: Entfällt.

Sieht der Vorschlag eine Kofinanzierung durch die Mitgliedstaaten oder sonstige Einrichtungen vor (bitte auflisten), so ist in der nachstehenden Tabelle die voraussichtliche Höhe der entsprechenden Beiträge anzugeben (beteiligen sich mehrere Einrichtungen an der Kofinanzierung, so können Zeilen in die Tabelle eingefügt werden):

in Mio. EUR (3 Dezimalstellen)

Kofinanzierung durch		Jahr 2009	2010	2011	2012	2013	Insgesamt 2009-2013	*2014 und Folgejahre*
……	f							
ZE insgesamt, einschließlich Kofinanzierung	a+c +d+ e+f							

4.1.2. Vereinbarkeit mit der Finanzplanung

☒ Der Vorschlag ist mit der derzeitigen Finanzplanung vereinbar.

☐ Der Vorschlag macht eine Anpassung der betreffenden Rubrik des mehrjährigen Finanzrahmens erforderlich.

☐ Der Vorschlag erfordert möglicherweise eine Anwendung der Interinstitutionellen Vereinbarung[22] (z. B. Inanspruchnahme des Flexibilitätsinstruments oder Änderung des mehrjährigen Finanzrahmens).

4.1.3. Finanzielle Auswirkungen auf die Einnahmen

☒ Der Vorschlag hat keine finanziellen Auswirkungen auf die Einnahmen.

☐ Der Vorschlag hat folgende finanzielle Auswirkungen auf die Einnahmen:

in Mio. EUR (1 Dezimalstelle)

		vor der Maßnahme [Jahr n-1]	Stand nach der Maßnahme					
Haushaltslinie	Einnahmen		[Jahr 2009]	[+1]	[+2]	[+3]	[+4]	[+5][23]
	a) Einnahmen nominal							
	b) Veränderungen bei den Einnahmene	*Δ*						

22 Siehe Nummer 19 und 24 der Interinstitutionellen Vereinbarung.

23 Wenn die Dauer der Maßnahme mehr als 6 Jahre beträgt, sind weitere Spalten anzufügen.

4.2. Personalbedarf (Vollzeitäquivalente - Beamte, Zeitbedienstete und externes Personal) - Einzelheiten hierzu siehe Abschnitt 8.2.1.

Jährlicher Bedarf

	Jahr 2009	2010	2011	2012	2013	*2014 und Folge-jahre*
Personalbedarf insgesamt	2	2	2	2	2	*2*

5. MERKMALE UND ZIELE

5.1. Kurz- oder längerfristig zu deckender Bedarf

Entfällt.

5.2. Durch die Gemeinschaftsintervention bedingter Mehrwert, Kohärenz des Vorschlags mit anderen Finanzinstrumenten sowie mögliche Synergieeffekte

Entfällt.

5.3. Ziele, erwartete Ergebnisse und entsprechende Indikatoren im Rahmen der ABM-Methodik

Entfällt.

5.4. Durchführungsmodalitäten (indikative Angaben)

☐ ***Zentrale Verwaltung***

- ☒ direkt durch die Kommission
- ☐ indirekt im Wege der Befugnisübertragung an:
  - ☐ Exekutivagenturen
  - ☐ die von den Gemeinschaften geschaffenen Einrichtungen im Sinne von Artikel 185 der Haushaltsordnung
  - ☐ einzelstaatliche öffentliche Einrichtungen bzw. privatrechtliche Einrichtungen, die im öffentlichen Auftrag tätig werden
  - ☐ Geteilte oder dezentrale Verwaltung
  - ☐ mit Mitgliedstaaten
  - ☐ mit Drittländern

☐ ***Gemeinsame Verwaltung mit internationalen Organisationen (bitte auflisten)***

Einschlägige Bemerkungen:

6. ÜBERWACHUNG UND BEWERTUNG

6.1. Überwachungssystem

Die Arbeitsgruppen werden regelmäßige Berichte vorlegen, die an die Mitgliedstaaten und die Kommissionsdienststellen weitergeleitet werden.

6.2. Bewertung

6.2.1. Ex-ante-Bewertung

Entfällt.

6.2.2. Maßnahmen im Anschluss an Zwischen-/Ex-post-Bewertungen (aus ähnlichen bereits durchgeführten Maßnahmen gewonnene Erkenntnisse)

Entfällt.

6.2.3. Modalitäten und Periodizität der vorgesehenen Bewertungen

Eine Bewertung der Arbeit der Arbeitsgruppe wird nach 5 Jahren erfolgen.

7. BETRUGSBEKÄMPFUNGSMASSNAHMEN

Entfällt.

8. RESSOURCEN IM EINZELNEN

8.1 Ziele des Vorschlags und Finanzbedarf

Verpflichtungsermächtigungen, in Mio. EUR (3 Dezimalstellen)

Ziele, Maßnahmen und Outputs (bitte angeben)	**Art der Outputs**	**Durchschnittskosten**	**Jahr 2009**		**Jahr 2010**		**Jahr 2011**		**Jahr 2012**		**Jahr 2013**		**2014 und Folgejahre**		**INSGESAMT**	
			Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten	Zahl der Outputs	Gesamt-kosten
OPERATIVES ZIEL Nr. 1[24]																
Maßnahme 1…																
Output	Sitzungs-zahl															
Output 2																
Maßnahme 2…																
Output 1																
Ziel 1 insgesamt																
OPERATIVES ZIEL Nr. 2																
Maßnahme 1…																
Output 1																
Ziel 2 insgesamt																
OPERATIVES ZIEL Nr. n																
Ziel n insgesamt																
GESAMTKOSTEN																

[24] Wie in Abschnitt 5.3 beschrieben.

8.2. Verwaltungsausgaben

8.2.1. Art und Anzahl des erforderlichen Personals

Art der Stellen		Zur Verwaltung der Maßnahme einzusetzendes, vorhandenes und/oder zusätzliches Personal **(Stellenzahl/Vollzeitäquivalente)**					
		Jahr 2009	Jahr 2010	Jahr 2011	Jahr 2012	Jahr 2013	*Jahr 2014*
Beamte oder Bedienstete auf Zeit[25] (XX 01 01)	A*/AD	2	2	2	2	2	*2*
	B*, C*/AST						
Aus Artikel XX 01 02 finanziertes Personal[26]							
Sonstiges, aus Artikel XX 01 04/05 finanziertes Personal[27]							
INSGESAMT		2	2	2	2	2	*2*

8.2.2. Beschreibung der Aufgaben, die im Zuge der vorgeschlagenen Maßnahme auszuführen sind

2 Sachbearbeiter (VZÄ), jeweils 122 000 EUR (gemäß spezifischen Leitlinien) zur Unterstützung der Umsetzung und der Ausschussverfahren. Regelungsausschuss und Netz (Sitzungen der zuständigen Behörden) gemäß Artikel 26 bzw. 20 dieser Richtlinie und ihre möglichen Arbeitsgruppen, die an der Umsetzung der Richtlinie arbeiten werden.

8.2.3. Zuordnung der Stellen des damit betrauten Statutspersonals

☒ Derzeit für die Durchführung des Programms zugewiesene Stellen, die ersetzt oder aufgestockt werden sollen

☐ im Rahmen des JSP/HVE-Verfahrens für das Jahr n vorab zugewiesene Stellen

☐ im Rahmen des anstehenden JSP/HVE-Verfahrens anzufordernde Stellen

☐ innerhalb des für die Verwaltung zuständigen Dienstes neu zu verteilende vorhandene Stellen (interne Personalumsetzung)

☐ für das Jahr n erforderliche, jedoch im Rahmen des JSP/HVE-Verfahrens für dieses Jahr nicht vorgesehene neue Stellen

---

25 Die Kosten hierfür sind NICHT im Höchstbetrag enthalten.
26 Die Kosten hierfür sind NICHT im Höchstbetrag enthalten.
27 Die Kosten hierfür sind im Höchstbetrag enthalten.

8.2.4. Sonstige im Höchstbetrag enthaltene Verwaltungsausgaben (XX 01 04/05 – Verwaltungsausgaben)

in Mio. EUR (3 Dezimalstellen)

Haushaltslinie (Nummer und Bezeichnung)	Jahr 2009	Jahr 2010	Jahr 2011	Jahr 2012	Jahr 2013	Insgesamt 2009-2013	*2014 und Folgejahre*
1 Technische und administrative Unterstützung (einschließlich Personalkosten)							
Exekutivagenturen[28]							
Sonstige technische und administrative Unterstützung							
- *intra muros*							
- *extra muros*							
Technische und administrative Unterstützung insgesamt							

8.2.5. Im Höchstbetrag nicht enthaltene Personal- und Nebenkosten

in Mio. EUR (3 Dezimalstellen)

Art des Personals	Jahr 2009	Jahr 2010	Jahr 2011	Jahr 2012	Jahr 2013	*2014 und Folgejahre*
Beamte und Bedienstete auf Zeit (XX 01 01)	0,244	0,244	0,244	0,244	0,244	*0,244*
Aus Artikel XX 01 02 finanziertes Personal (Hilfskräfte, ANS, Vertragspersonal usw.) (Angabe der Haushaltslinie)						
Personal- und Nebenkosten insgesamt (NICHT im Höchstbetrag enthalten)	**0,244**	**0,244**	**0,244**	**0,244**	**0,244**	***0,244***

Berechnung – ***Beamte und Bedienstete auf Zeit***

[28] Hier ist auf den entsprechenden Finanzbogen für die betreffende(n) Exekutivagentur(en) zu verweisen.

Zur Quantifizierung der Kosten werden gemäß BUDG-Leitlinien pro Beamtem/Bedienstetem 122 000 EUR angesetzt.

Berechnung – ***Aus Artikel XX 01 02 finanziertes Personal***

[…]

8.2.6.Sonstige nicht im Höchstbetrag enthaltene Verwaltungsausgaben

in Mio. EUR (3 Dezimalstellen)

	Jahr 2009	Jahr 2010	Jahr 2011	Jahr 2012	Jahr 2013	Total 2009-2013	*2014 und Folge-jahre*
XX 01 02 11 01 – Dienstreisen							
XX 01 02 11 02 – Sitzungen & Konferenzen							
XX 01 02 11 03 – Ausschüsse[29]	0,120	0,120	0,100	0,100	0,080	*0,420*	0,080
XX 01 02 11 04 – Studien & Konsultationen							
XX 01 02 11 05 - Informationssysteme							
2 Gesamtbetrag der sonstigen Ausgaben für den Dienstbetrieb (XX 01 02 11)	0,120	0,120	0,100	0,100	0,080	*0,420*	0,080
3 Sonstige Ausgaben administrativer Art (Angabe mit Hinweis auf die betreffende Haushaltslinie)							
Gesamtbetrag der Verwaltungsausgaben, ausgenommen Personal- und Nebenkosten (NICHT im Höchstbetrag enthalten)	0,120	0,120	0,100	0,100	0,080	*0,420*	0,080

[29] Angabe des jeweiligen Ausschusses sowie der Gruppe, der dieser angehört.

Berechnung – ***Sonstige nicht im Höchstbetrag enthaltene Verwaltungsausgaben***

Regelungsausschuss und Netz (Sitzungen der zuständigen Behörden) gemäß Artikel 23 bzw. 19 dieser Richtlinie und ihre möglichen Arbeitsgruppen, die an der Umsetzung der Richtlinie arbeiten werden.

Kosten der Plenarsitzung (erste Sitzung der zuständigen Behörden), mit je einem Teilnehmer aus jedem der 27 Mitgliedstaaten. 3 geplante Sitzungen pro Jahr (in den ersten 2 Jahren nach der Verabschiedung), jeweils 20 000 EUR; diese Zahl wird sich von 3 Sitzungen pro Jahr auf 2 pro Jahr und danach auf 1 pro Jahr reduzieren. Die tatsächlichen Kosten der einzelnen Sitzungen und deren Häufigkeit müssen ggf., in Abhängigkeit von der endgültigen Form der Richtlinie nach Verabschiedung durch Rat und Parlament und der nötigen Komitologiestrukturen, angepasst werden. Darüber hinaus sollten 3 Ausschusssitzungen pro Jahr zu Kosten von 20 000 EUR veranschlagt werden.

Der Bedarf an Humanressourcen und Verwaltungsmitteln wird mit den Mitteln gedeckt, die der zuständigen GD im Rahmen des jährlichen Haushaltsverfahrens in Abhängigkeit von den verfügbaren Mitteln zugeteilt wurden.

COUNCIL OF THE EUROPEAN UNION

Brussels, 10 December 2008

16521/08
ADD1

Interinstitutional File: 2008/0238 (COD)

SAN 306
CODEC 1691

COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	9 December 2008
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	COMMISSION STAFF WORKING DOCUMENT accompanying the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation and the COMMUNICATION FROM THE COMMISSION Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States - Impact Assessment

Delegations will find attached Commission document SEC(2008) 2956.

_____

Encl.: SEC(2008) 2956

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 8.12.2008
SEC(2008) 2956

COMMISSION STAFF WORKING DOCUMENT

accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on standards of quality and safety of human organs intended for transplantation

and the

COMMUNICATION FROM THE COMMISSION

Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

Impact Assessment

{COM(2008) 818 final}
{COM(2008) 819 final}
{SEC(2008) 2957}

INTRODUCTION

Lead DG: Health and Consumer Directorate-General

Other services involved: BEPA (prime responsibility for application of Capability Approach), as well as DG RESEARCH, DG INFSO, DG JLS, LS and SG.

Agenda Planning and CLWP: the legislative proposal was foreseen by the Commission Agenda Planning for 2008, with reference 2008/SANCO/018.

1. EXECUTIVE SUMMARY

Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure and the only available, life saving treatment for end-stage failure of organs such as liver, lung and heart.

The advancement of transplantation medicine has led, however, to a shortage in available organs and poses new quality and safety challenges. An analysis of donation and transplantation variation across the European Member States shows that there is considerable potential to increase the availability of organs in Europe. While Spain identifies more than 33 deceased organ donors per million population (pmp), some other Member States just identify one organ donor per million population. Similar differences can be seen in living donation rates: Norway has a very high rate of living donation, of 17 pmp. Thus, if good practices (organisational changes and improvements) were to become standard there is a large potential for increasing organ donation (deceased and living) in Europe.

The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. The risk includes communicable diseases such as HIV, Hepatitis B and C, as well as other bacterial, viral and fungal infections. Transplantation can also lead to the transmission of different types of cancers. There are currently no common standards of quality and safety on human organ in place in Europe. Article 152 of the Treaty provides the European Community with an opportunity, as well as an obligation, to implement binding measures laying down high standards of quality and safety for the use of blood, organs, and substances of human origin. Thus, the European Commission has a clear mandate to ensure the quality and safety of organ donation and transplantation and to improve public health.

In 2006, the European Commission adopted a Communication on organ donation and transplantation, defining the main policy challenges and setting out the key objectives for the European Commission by identifying areas for

future European action. To address these challenges, DG SANCO identified four policy options, which differ predominantly in their regulatory approach:

Under **Option 1**, the European Commission will continue with its current activities in the field of organ donation and transplantation, which involves primarily sponsoring research and pilot programmes in this field, and participating in international cooperation such as in the Council of Europe

Option 2 proposes a non-regulatory approach to the field of organ donation and transplantation. This option will establish a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015.

Option 3 combines the Action Plan described under Option 2 with a "flexible" directive, supporting key elements of the Action Plan in the area of quality and safety.

Finally, **Option 4** combines the Action Plan described under Option 2 with a "stringent" directive. This stringent directive will be modelled on the Tissue and Cells Directive and will therefore contain detailed regulation about the quality and safety systems Member States have to put in place.

To assess these policy options a combination of methods and approaches were used:

(1) The starting point for the analysis of impacts was an **extensive document and literature review.**

(2) **Country studies** of the organ donation and transplantation systems in a sample of six countries. The countries studied are Germany, Greece, Spain, Poland, Sweden and the United Kingdom.

(3) **Stakeholder interviews** with ten stakeholders, including national country experts as well as stakeholders concerned with organ donation in general.

(4) To develop an idea of the scope of potential improvements that can be achieved, four scenarios of different changes in living and deceased donation rates were developed, which were subsequently used to identify likely health and economic impacts of the policy proposals.

(5) A cost consequence framework and an impact matrix were used to analyse the evidence, identify the key impacts and compare them across the four policy options.

(6) In addition to normal 3-pillar analysis of options, this IA was also used as a case study for application of the **capability approach**. This analysis presented in the annex and in 3 boxes throughout the IA was prepared

under the auspices and initiative of BEPA, the Bureau of European Policy Advisers.

Box 1: The capabilities approach

The capabilities approach, first formulated by Nobel Prize laureate Amartya Sen, focuses on the well-being of individuals. It provides a complete description of individual wellbeing. According to Sen, a person's well-being is a combination of achievements and opportunities. Both are important. For example, someone who has ample job opportunities but chooses not to work has a different level of well-being than someone who is involuntarily unemployed.

To make the capabilities approach operational, a pragmatic multi-dimensional space of nine dimensions has been defined. The list is a consolidated version of different lists that have been proposed in the literature, e.g. by Martha Nussbaum. The aim of the list is that it is a complete and non-negotiable list applicable to all policies. The list consists of: 1) health and longevity; 2) safety; 3) education; 4) standard of living; 5) productive and valued activities; 6) quality of social interactions; 7) environment; 8) culture and entertainment; 9) basic rights. For many policy proposals of course only a subset of these capabilities is relevant.

In the IA on organ donation the policy proposals have three objectives: enhancing efficiency, quality and safety and the number of successful transplants. Most of the impacts of the policy proposals run through these three objectives. The CA converts impacts into final objectives, i.e. how the chosen proposals influence peoples' well-being, e.g. in the form of health. For this IA, well-being is measured by the capabilities: (i) health; (ii) safety (feelings of safety); (iii) quality of social interactions; (iv) productive and valued activities (employment); (v) standard of living.

The different proposals are analysed by measuring impact on each capability. A specific light is shed on distributional impacts, since the individual well-being approach enables easy structuring (impact on different groups on the various capabilities). For convenience, we have separated impacts on relevant categories from total monetary costs, without specifying to which capability these costs belong. This allows for an easier communication on benefits and costs.

The key health impacts of DG SANCO proposals emanate from an increase in donation rates and reduced risks to patients. The policy options are likely to increase donation rates in Europe. A best case scenario established a potential of up to 21,000 more organs transplanted per year in the European Union. This would translate into saving 230,000 life years or gaining 219,000 quality adjusted life years.

The analysis of the policy options suggest that Options 2 to 4 can lead to substantial economic benefits across the European Union, although Member states will have to invest in the national infrastructure of organ donation and the improvement of processes to realise these gains. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. The scenarios developed see a potential of saving up to €1.2 billion Euro in treatment costs, and reaching productivity gains of up to €2.4 billion.

Increased organ transplantation will result in positive social impacts for organ recipients and donor families. In general, organ transplantation has a positive effect on the quality of life of organ recipients. Evidence shows that transplantation of organs increases the possibilities for patients to participate in social and working life. European action can be expected to contribute to increased trust and confidence in the organ donation and the transplantation system, by establishing common quality and safety standards, increasing public awareness, and improving processes to deal with relatives of deceased donors.

Option 3 was considered to be the best option in reconciling the policy objectives with the principle of subsidiarity and proportionality at this stage. Firstly, a flexible Directive plus an Action Plan optimises the European Community's contribution to public value by providing a platform for implementation and mutual learning which combines standardisation of reporting with diversity of delivery mechanisms. Secondly, this combination allocates decision making to the level where it can be most efficient and effective by distributing decision-making among the local, hospital level, the Member States, and the European level.

2. ORGANISATION AND TIMING

The Commission adopted a Communication on organ donation and transplantation in May 2007[1] accompanied with a first impact assessment[2]. Three priority areas of action were identified : 1) improving quality and safety of organs, 2) increasing organ availability and 3) making transplantation systems more efficient and accessible. In order to respond to these objectives the Communication suggested two different mechanisms of action[3]:

▪ An Action plan for strengthened coordination between Members States on organ donation and transplantation

▪ An EU legal framework (Directive) on quality and safety of human organs.

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1 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_com_en.pdf

2 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

3 This combination of actions was foreseen by the Commission Agenda Planning for 2008, with reference 2008/SANCO/018.

On 6 December 2007, the Health Council adopted conclusions[4] in line with the Commission's Communication and invited the Commission to continue its examination of the need for an EU framework on quality and safety and to coordinate, promote and strengthen the cooperation between the Member States. Following the Commission Communication, on 22 April 2008 the European Parliament adopted a resolution on organ donation and transplantation[5]. The resolution was adopted by huge majority. It welcomes the approach taken in the Commission's Communication, and clearly acknowledges the need for action at European level.

DG SANCO set up an Impact Assessment Inter-service Steering Group (ISSG) in September 2007 in the light of the Commission Communication, which supported the work linked to the present impact assessment report. The Group was led by the Directorate General for Health and Consumer Protection (DG SANCO). The following DGs were involved in the exercise: BEPA, DG RTD, DG ENTR, DG INFSO, DG RELEX, DG AIDCO, DG JLS, SJ and S-G.

This draft impact assessment report has been submitted to the Impact assessment on 18 June. The IAB recommended a number of changes in the report. Following the opinion of the Impact Assessment Board on the draft impact assessment report on improving Organ Donation and Transplantation in the European Union, the following modifications have been introduced in the text:

1- Reformulated the problem definition and give a clear outline of expected developments under the baseline scenario.

1) The problem definition has been strengthened in section 2.

2) Tables I and II have been added in the annexes I and II specifying the baseline scenario and the policy options for the main policy objectives. Information on the specific arrangements and their expected evolution has beed added on the tables

3) Drivers of organ availability have been better explained in section 2.1.3. Differentiating organisational aspects from other aspects and clarifying the role of consent systems.

4) The Spanish model is exhaustive explained in Annex III, including the ideal conditions for its implementation.

5) Living donation is addressed separately in all the sections of the document.

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4 ttp://ec.europa.eu/health/ph_threats/human_substance/documents/organs_council15332_en.pdf

5 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2008-0130+0+DOC+XML+V0//EN

6) A section on ethical issues has been incorporated.

2- Provide more solid arguments for the choice of the preferred option and the differences between Option 3 and 4.

The Impact assessment board gave a favourable opinion on 3 September.

2.1. Consultation and expertise

In order to give stakeholders and Member States the occasion to put forward their positions related to organ donation and transplantation DG SANCO launched an open consultation from June to September 2006[6]. The Commission received 73 contributions from regulators, the medical community and patient or donors associations.[7].[8]

As part of the stakeholder dialogue DG SANCO has created a key stakeholder group on organ donation and transplantation, grouping 16 European associations of professionals, hospitals, patients, donors, organ exchange organisations and industry, all active in the area of organ transplantation.

This group first met on 19 February 2008[9]. The consultation yielded important information on the problem definition and assessment of the policy options. Stakeholders' views were incorporated into the definition of the policy options.

Complementary to the work of the stakeholders group, a one-day open workshop with stakeholders was organised on 23 May 2008. The purpose of the workshop was to discuss the effects of the different policy options in the field of organ donation and transplantation at the EU.

In addition, the Commission also held more than 20 face-to-face meetings with key actors during the last six months.

Since November 2007[10], the Commission has held **four meetings with national experts of all MS** and representatives of Eurotransplant and Scandiatransplant focusing on technical discussions on quality and safety requirements of human organ donation and transplantation and key priority areas for the proposed action plan.

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6 http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/consultation_paper.pdf

7 A full report of the consultation is published in the public health web site

8 http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/oc_organs_frep_en.pdf

9 http://ec.europa.eu/health/ph_threats/human_substance/documents/ev_20080219_mi_en.pdf

10 (13 July, 23 October, 20 November and 31 January)

3. PROBLEM DEFINITION

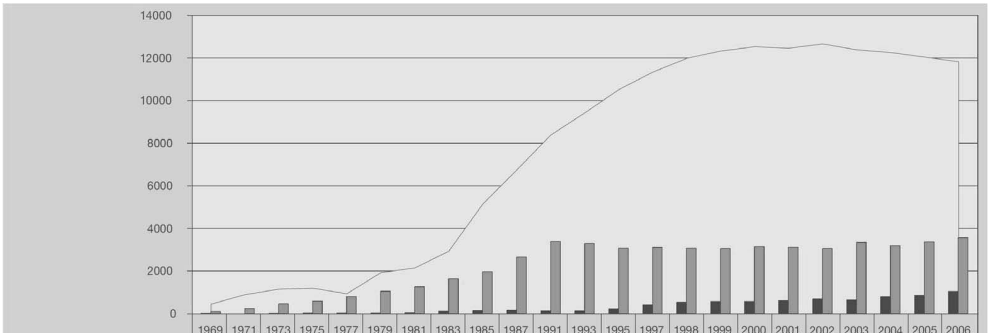
The Commission presented a comprehensive description of the situation on organ donation and transplantation in Europe in the impact assessment attached[11] to the Commission Communication adopted in May 2007.

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. 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 who are in need.

3.1. Organ availability

3.1.1. Demand for organs is increasing

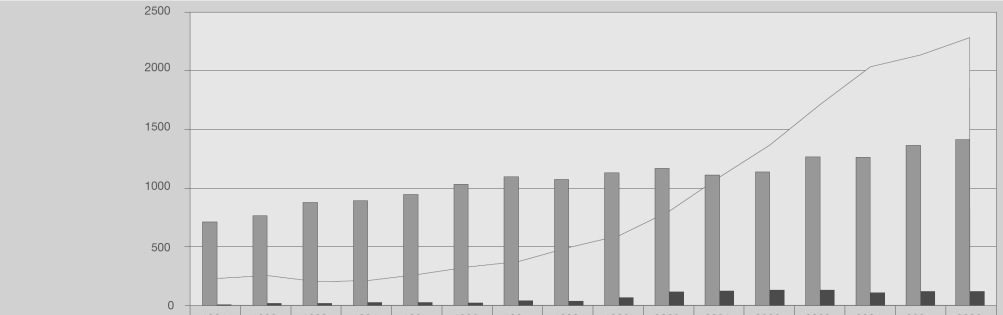
Currently, demand for organs exceeds their availability in all Member States and demand increases faster than organ donation rates in most Member States.[12] (See figure 1 below)



	1969	1971	1973	1975	1977	1979	1981	1983	1985	1987	1991	1993	1995	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Kidney waiting list	450	892	1147	1200	934	1929	2135	2928	5150	6740	8376	9418	10510	11324	11975	12313	12524	12450	12653	12382	12251	11814	11391
Living donor transplants	9	5	11	33	33	33	53	108	150	161	129	127	212	411	526	579	569	617	697	646	796	864	894
Cadaveric donor transplants	102	228	454	583	800	1050	1263	1645	1965	2665	3395	3293	3064	3110	3068	3050	3145	3121	3047	3352	3185	3383	3519

11 http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

12 See e.g. For the UK see e.g. Department of Health (2008a).; for Germany see DSO (2007).



	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Liver waiting list	229	253	203	212	263	327	374	492	593	803	1093	1366	1714	2035	2134	2319
Living donor transplants*	5	15	14	24	25	22	41	38	64	116	124	129	133	106	121	116
Cadaveric donor transplants	710	765	878	892	944	1032	1097	1071	1132	1168	1112	1136	1264	1262	1364	1436

SOURCE: Eurotransplant (2006)

Dynamics of Eurotransplant kidney and liver waiting lists and transplantations between 1969 and 2006

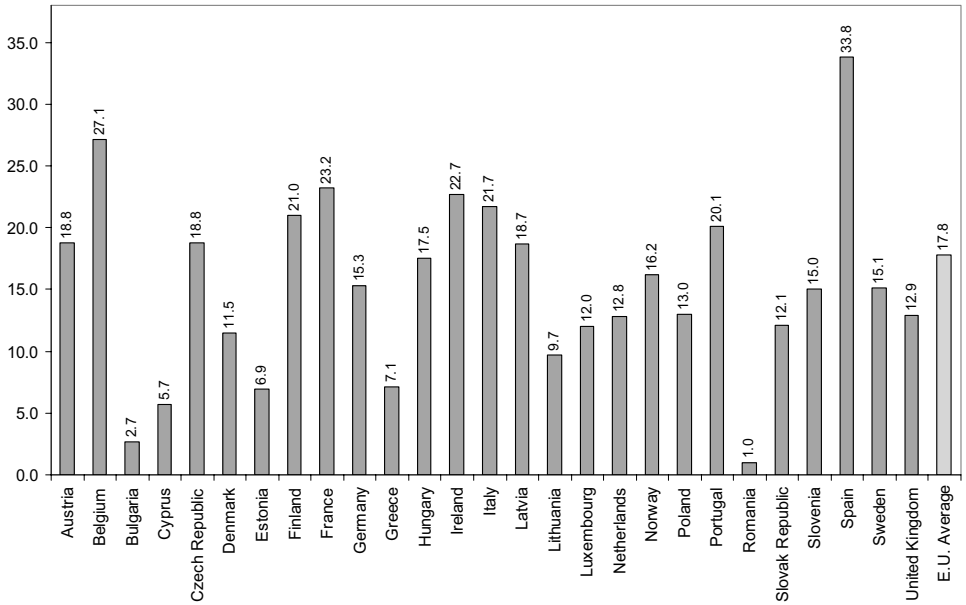
In total, there are currently more than 56,203 patients waiting for a suitable donor organ (as of 31 December 2006) within the European Union.[13]. In 2006, more than 5,500 patients died while on the waiting list in the European Union.

3.1.2. Donation rates and organ availability varies across Europe

While there is an increasing demand for organs, the availability of organs varies widely between the Member States. The next Figure shows the differences in the availability of deceased donors between Member States, ranging from 33.8 deceased donors per million of population in Spain to 1 deceased donor per million population in Romania.

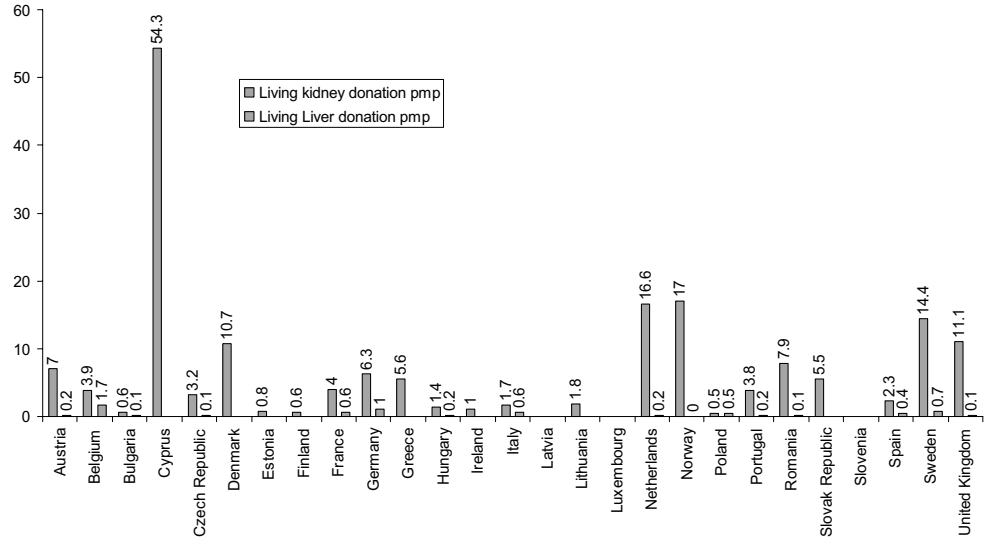
European donation rate is far below from the US donation rate (16.6 versus 26.6 in 2007) and has decreased continuously in the last three years (2005-2006 and 2007). Donation rates and transplantation activity varies widely between the Member States, only Spain and few others Member States have succeeded in increasing significantly the number of donors. These increases are linked to the introduction of organisational practices

13 Council of Europe (2007).



SOURCE: Council of Europe (2007) Deceased organ donors in the European Union

Living donation rates also differ substantially between Member States, and not all countries realise their potential for living donation. Interestingly it seems to be substituting the availability of organs from deceased donors. Figure 03 of Annex I provides an overview of living donations. In 2006, a total of 2,855 transplantations from a living donor (kidney and liver) were conducted.[14]



14 Ibid.

SOURCE: Council of Europe (2007)

Living kidney and living liver transplantations performed in 2006

3.1.3. Drivers of organ availability

The availability of organs is naturally limited by the supply of suitable donors, which are often victims of road accidents and strokes. Only around 3% of all hospital deaths are potential donors.[15] The conversion of this potential in turn depends on the willingness of patients and their families to donate and the participation of hospitals in organ retrieval activities.

While public debate often centres on public awareness for organ donation and the organisation of consent systems, recent research and experience from piloting new approaches point to the organisational aspects of organ donation as one of the most important factor influencing organ procurement rates.[16] In this section we analyse the main drivers of organ donation:

1. Consent systems. Extensive debate focusing on whatever a present consent law could an increase donation rate has not produced clear results. Detailed information on the organisation of consent systems are given in our previous IA., as mentioned in that paper basically two kinds of consent can be distinguished: systems of explicit consent (opting in) and systems of presumed consent (opting out). In the former the donor himself has to authorise organ removal after his death (in the form of an advanced directive or donor card or by filling in a form in order to record consent in a national register). In the latter kind of system, explicit consent is not required: it is sufficient that the deceased donor has not objected during his life (according to national law); in that case consent is presumed. It has to be noted that the dichotomy between pure opting in and opting out systems represent an oversimplification that fails to recognise the nuances with which these systems function in practice.

The "Alliance O" project (funded by RTD under the 6FWP) grouped the main European transplant organisations and aimed to identify the best possible framework for efficient organ donation and transplantation patterns across Europe. Alliance O concluded that "The choice between the legal concept of presumed consent and informed consent is amongst others based on historical, social and cultural reasons. The detailed analysis revealed within the ALLIANCE-O working group that the two concepts do not differ in day to day practice and that the family or next of kin must be in favour of donation in order to proceed with the donation process. A change of the legal framework therefore would not be a guarantee for an increase in donation rates."

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15 ALLIANCE-O (2007b).

16 DeJong, et al. (1995).

2. Organisation The importance of the organisational systems is also underlined in the conclusions of the project Alliance-O. In its "White book"[17] the project provides a list of recommendations to increase the donor pool; these recommendations are focused on organisational aspects. Improvements in the complex process of donor identification to the transplantation of an organ can have a large impact on donation rates.[18] Reviews of the organisational models for organ donation in Europe show a strong potential for the exchange of best practice and learning between Members States on these issues.[19].

Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models are performing better than others. In some countries the transplantation activity exceeds 80 transplanted organs pmp, compared to others with a rate of 40 pmp, and these differences are not necessarily explained by the donation rates

A prerequisite for any action in this area is the establishment of adequate transplant systems at national level. This system needs an appropriate legal framework, a good technical approach and organisational support. The role of competent authorities is crucial in the organisational system. These authorities must ensure compliance with basic standards and organise the donation and transplantation activities.

3. Willingness to donate and family refusals. Organ donation and transplantation are the only medical treatments that require the participation of society for their full development. One of the main reasons of the shortage of organs is the family refusals to donation. The willingness to donate and the family refusals also vary widely within Europe. They could be explained by important cultural, economic or social factors that influence the perception of the society of the benefit of donation and the trust in the transplant systems. .Public awareness and opinion also has an important role to play in increasing organ donation.

The willingness to donate in the different Member States do not correlate with the actual donation rates, this could indicate that some countries are more successful transforming this positive attitude of the society into actual donors.

4. New alternatives for expanding the donor pool. Three main alternatives have been pointed out to increase the donor pool. 1) The promotion of living donation, 2) considering other potential donors (“expanded donors”) who are not ideal donor candidates and 3) the implementation non heart beating donation programmes. All of these alternatives have ethical and safety that need to be

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17 http://www.alliance-o.org/wfile/Alliance-O_White_Paper.pdf

18 See e.g. Roels, et al. (2002). and Simini (2000).

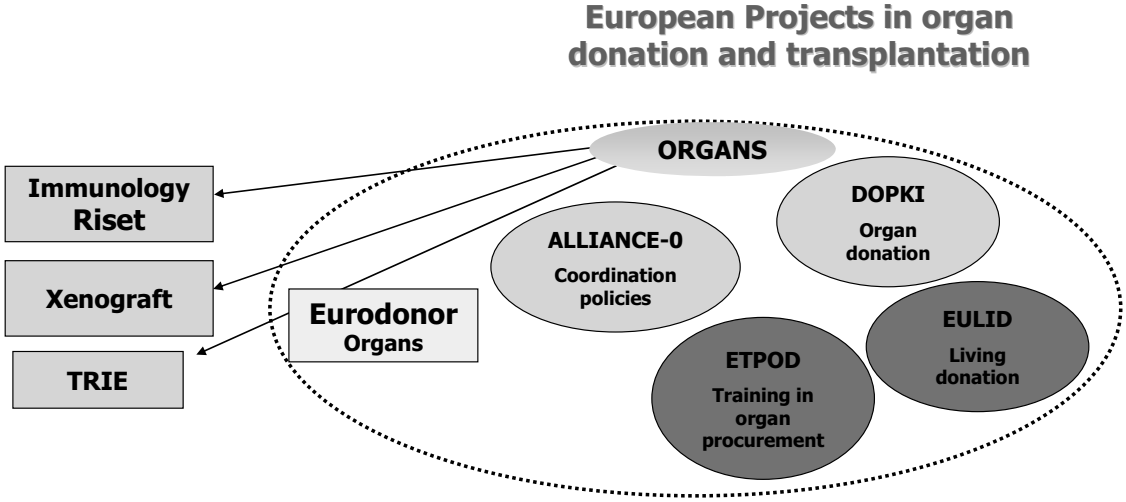
19 DOPKI (2006);ALLIANCE-O (2007c).

addressed. Cooperation at EU level is necessary to establish safety limits in the practices.

3.1.4. European exchange of best practice

The importance of organisational aspects of organ procurement and the large differences in practices and performance across Member States show a clear benefit of exchanging best practice between the Member States of the European Union. Exchange of best practice would in particular benefit those Member States, which are just starting national transplantation programmes and do not have national experiences yet.

During the past years, the Commission has put considerable effort into supporting organ transplantation through the different community programmes. The results of all these projects are providing a considerable amount of information useful for active policies in this area, however these projects have a limited time frame with the risk that once the project is finished the continuity of the results is not ensured. In addition the projects not always have the capacity to transfer the results of their investigation to the political level in order to make them operative. It is also important that the results of these projects are accessible to all the Community.



The Council of Europe, which groups together 46 countries, including 21 countries from Central and Eastern Europe, has been actively involved in this area. The Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO) was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects of organ transplantation, recently it has been transferred into the Scope of the EDQM.

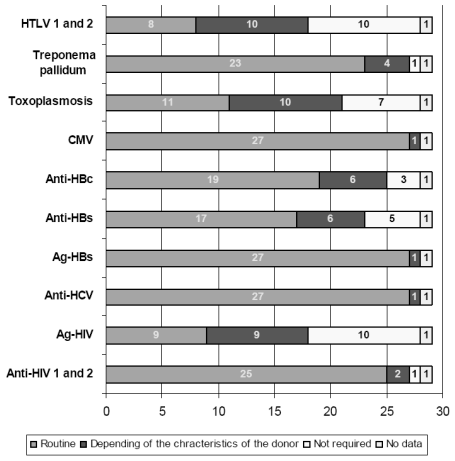
Although recognising the work of the Council of Europe and the World Health Organisation in this area, there is not currently a effective framework to strengthen the cooperation between MS in the EU. The EU meetings of Competent authorities on blood and tissues and cells have been a very useful instrument during the last years to implement and complement policies in these fields.

3.2. Quality and Safety in organ transplantation

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.

3.2.1. Reducing risks to patients

The use of organs in therapy poses a risk of infectious diseases being transmitted to the organ recipient. The risk includes communicable diseases such as HIV, Hepatitis B and C, as well as other bacterial, viral and fungal infections. Transplantation can also lead to the transmission of different types of cancers.[20] 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 quality and safety standards differ widely across Member States.[21] (See Figure)



Biological tests performed

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20 For a detailed description of the risks and prevalence of graft related diseases see Annex B.

21 DG SANCO (2003).

Once transplantation has been successfully performed, it is important to monitor the organ recipient and to record all adverse events and possible infections acquired through an organ and to be able to trace the organ back to a donor. This is of particular importance as multiple organs are retrieved from a single donor, and most organ donors are also tissue and cell donors.[22] Currently 25 of the 29 countries surveyed (EU + Turkey and Norway) have a national register containing data on the origin and destination of organs; in 18 of these, the register is legally binding. However, a system of reporting adverse events exists only in 20 countries, of which 8 made it mandatory in legislation.

3.2.2. Traceability and follow up of organ donation

To manage the risks of organ transplantation, most Member States have registers to trace organs back to specific donors and to report acquired infections. Once transmission of a disease is found in a recipient, there is an urgent need to trace the organ to the donor in order to prevent the transmission of the disease to other potential recipients. There is currently however no system in place which would allow for such tracing in urgent cross-boarder cases, although there are more than 4,000 organs exchanged between Member States each year.

As organ donors are often also tissue and cell donors, it is additionally important that information about adverse events and infections in a solid organ transplant can be quickly traced to a donor and immediately relayed to the tissue vigilance system which is foreseen by the European tissue and cell directive.[23] Currently such a system does not exist.

Finally, a systematic and European wide follow up of the medical outcomes (post transplant results) is required to further improve the success of organ transplantations and reduce risks of adverse events and reactions to patients. Currently the only register actually in place of sufficient size is in the United States. National registers of European Member States are too small to achieve the required reliability of a transplantation monitoring system. A large enough sample of cases for scientific follow up is especially important for testing the efficacy of new and emerging alternatives to increase the number of donors. This includes living donation, expanded criteria donors, as well as non-heart-beating donors.

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22 For a detailed description of the process, see Annex XX (copy eduardo's description of the process)

23 Directive 2004/23/EC of the European Parliament and of the Council setting high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJ L 102, 7.4.2004, p.48-58

3.3. Enhancing the efficiency and accessibility of transplantation systems

3.3.1. Cross border exchange of organs

The exchange of organs between Member States is already common practice between Member States. There are however large differences between the number of organs exchanged across borders between Member States which set up bodies and rules for the international exchange of organs such as Eurotransplant and Scandiatransplant and the other Member States.

Participants of the Eurotransplant area exchange around 20% of all organs transplanted each year (around 3,300 organs), while only 2% of organs leave or enter the Eurotransplant area. Within the Scandiatransplant area, between 10 % (Kidney) and 27% (Heart) of organs were exchanged between members. Without such comprehensive exchange agreements Member States exchange far fewer organs, but the rate can increase if there are bilateral agreements in place.[24] .

The differences in exchange rates indicate that the full potential of exchanging organs has not yet been reached. This is problematic as the cross border exchange of organs has clear benefits. Given the need of matching between donor and recipient, a large donor pool is important to cover the needs of all patients on the waiting lists. If there is no exchange of organs between Member States, then recipients that need an infrequent match will have very low possibilities of receiving an organ, while at the same time donors are not considered because there is not a compatible recipient in the waiting lists. This holds particularly true for difficult to treat patients (paediatric, urgent or hyper-sensitised patients that require very specific matching) and small Member States[25]. Data from Eurotransplant shows that in these cases, small Member States receive the organs from another Member State in the majority of the cases.[26] Those small Member States not participating in these agreements can thus not cope adequately with these patients. Hence, small Member States and difficult to treat patients are both key stakeholders with a ‘specific need’ for cross border exchanges and for adequate measures to ensure equal benefit of this activity.

3.3.2. Patient and donor mobility

The mobility of potential organ donors and recipients is the second major challenge for the current quality and safety frameworks, after organ shortage. In

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24 e.g. Italy now exchanges more organs with Greece and Slovakia, with which it recently signed bilateral agreements, see IGE (2007).

25 Data from Eurotransplant shows that in these cases, small Member States receive the organs from another Member State in the majority of the cases.

26 Eurotransplant (2008).

a recent pilot survey[27], it is clear that a large proportion of dialysed patients cross state borders in Europe for both holiday-making and for work (Figure), and the same could be expected for transplanted patients.

Table 3.1: Patients who travel to other European countries receiving haemodialysis in other centres

	Germany	Ireland	Latvia	Netherlands	Sweden	U.K.
Yes	44.8%	18.7%	1.3%	45.2%	20.6%	35.5%
No	55.2%	81.3%	98.7%	54.8%	79.4%	64.5%

SOURCE: CEAPIR (2006)

There is a strong need for all results of transplantations and potential adverse events and infections to be reported in a monitoring and learning system. Even if an organ recipient is a national from outside the Member State in which the transplantation was performed, it is especially important that there are systems in both Member State which allow for the reporting of an event and which can be linked to trigger the necessary actions required to ensure the health and safety of other organ, tissue and cell recipients.

People might become organ donors while residing in another Member State. In 2007, close to 10 % of the donors in Spain were foreigners, more than 50% of these were Europeans. To ensure that organs available for therapy are not wasted, it is important that there are no legal barriers to the use of these organs and that the families of these donors have trust in the donation system so that they do not refuse donation.

3.3.3. Living donation

Currently, living organ donation represents 17% of kidney transplant activity in Europe.[28] The number of living donors differs significantly from country to country: from 2 transplants from living donors pmp in Spain to 20.7 in Norway. Living organ donation is currently allowed in every European country, but sometimes is only permitted under certain conditions. In Austria there are deductive legal provisions but no law directly regulating living donation.(Annex IV table 05) provides an overview of the current (legal) frameworks across a sample of Member States.

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27 CEAPIR (2006).

28 COM (2007) 275 Final. Organ Donation and Transplantation: Policy Actions at EU level. 30.05.2007

Living donation poses a third set of challenges to the current regulation in European Member States through the mobility of living donors. As the removal of an organ from a living donor is a substantial intervention which is related to a significant morbidity risk,[2930] the living donor requires continuous follow up after surgery and access to healthcare and to social care. Currently, there are no rules in place concerning the long term medical treatment (including social care) of the living donors, in particular if living donors decide to change their country of residence within the European Union.

Finally, living donation opens up opportunities for non-voluntary and/or non-altruistic donations. While there is only limited evidence on the prevalence of organ trafficking and organ trade in the EU, all Member States have rules in place banning the trade in organs and usually limiting the possible donors to relatives and spouses of the patients.

3.4. Ethical issues

There are many complex and sensitive ethical issues in this area that have could have repercussion on the availability, and it became clear that several of these aspects are dealt differently in Member States. It is generally accepted that the donation should be voluntary and altruistic with legal and ethical contexts clearly defined, the data from donors and recipients should be protected, provided that traceability is ensured, except in the case of a living donor with a close relationship to the recipient.

Most of the Member States that responded to the Commission survey2 have legislation to protect the donor in respect of anonymity (measures ensuring that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa); confidentiality (measures ensuring that all data collated, including genetic information, have been rendered anonymous so that the donor and the recipient are no longer identifiable) and non remuneration for the donation (measures preventing organ trade or trafficking).

There is a general agreement that cadaveric organ retrieval is only allowed if some form of consent is available from the deceased or his relatives. This is also reflected in international guidelines; according to the additional protocol to the Convention of Biomedicine of the Council of Europe concerning Transplantation of Organs and Tissues of Human Origin10. Member States should ensure that there is a legal basis for ensuring valid consent or objection to organ donation. The results of the Commission survey showed that in 28

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29 The risk of complications and adverse events ranges from 2% to 16% for kidney donation, these are short-term surgical (and medication-related) risk and long-term risks of impaired renal function, hypertension and psychological problems. (Najarian (2005).).

30 Living kidney donation also entails a small mortality risk of 0.03%, the morbidity risk for living liver donation is substantial higher.

countries the consent for a donation from the deceased donor is embedded in a binding law. Only in one is it organised through guidelines.

Basically two kinds of consent can be distinguished: systems of explicit consent (opting in) and systems of presumed consent (opting out). It has to be noted that the dichotomy between pure opting in and opting out systems represent an oversimplification that fails to recognise the nuances with which these systems function in practice.

There are mainly four forms of consent found among the countries surveyed. In 8 of the countries consent required always the agreement of those close to the deceased. 7 countries have in place a present consent law, but the family agreement is requested if the wishes of the deceased are unknown, in other 7 countries there are present consent law but in practice the confirmation of the family is needed, and in the rest of the countries surveyed (7) the presumed consent law applies and no family confirmation is needed. An important operational aspect of consent systems (whether explicit or presumed) is the way the consent of objection is being recorded. A growing number of European countries have established national registers so that the information on the willingness to donate is readily available and easily accessible for health professionals confronted with potential donors in a hospital or elsewhere.

Regarding the consent of the living donor is also regulated by law in most of the countries2

Transparency, Equity and Accessibility – It is also generally accepted that all transplant systems rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled. Death certification - Organ retrieval from the deceased may take place only after death certification. Death certification should be a matter of national legally binding rules that should be made public.

Of the countries surveyed, 86% (25) have binding legislation in place establishing a definition of brain death, three more have technical guidelines with definitions. As to which criteria are needed in the different countries for diagnosing brain death, differences are in evidence as indicated in figure 5 (the bars indicate the number of countries):

The number of doctors that have to confirm brain death also varies between the countries. The situation is different regarding a binding definition of death in non-heart beating donors. Only 45% (13) of the countries have this definition in their legislation and five more in technical guidelines.

4. SUBSIDIARITY - THE CASE FOR EUROPEAN ACTION

4.1. The legal base to act

Article 152(4)(a) of the EC Treaty provides a legal basis for the adoption by the European Parliament and the Council of 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;*"*.

The same Article says that *The Community shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action.*

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination.

4.2. Previous European activities in the field of organ donation and transplantation

Already in 1958, the Council of Europe's Agreement No 26 on the exchange of therapeutic substances of human origin became the starting point for cross-border activities in this field. While specifically referring to human blood and its derivatives, provisions were made for the Agreement's extension to cover other therapeutic substances. Its main purpose was to facilitate exchanges of human substances between Member States of the Council of Europe in cases of urgent need and under the expressed condition that no profit was made. In 1986[31], the European Community became a contracting party to this Agreement. Subsequent agreements, recommendations and guidelines that have emanated from the Council of Europe for more than fifty years[32] are the starting point for what now occurs in relation to safety and quality of substances of human origin in Europe.

In the resolution adopted in 1991 by the Council of Ministers for health[33] concerning fundamental health choices, the Council took note that the analysis of the Community's possible contribution concerning the availability of organs for transplants was identified as one of the topics which warrant joint consideration, regular joint discussions and/or joint efforts to assist Member States in framing their health policies.

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31 Genetet (1998).

32

33 Resolution of the Council and the Ministers for health, OJ C304 23/11/1991 p5-6.

On the basis of Article 152 of the EC Treaty, as it results from the Treaty of Amsterdam since 1999, the Community has already adopted Directives of the Parliament and the Council on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004.

However, it was already recognized during the discussions of the Tissues and Cells Directive that organs need a different approach. The Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union was held on 17-18 September 2003 under the Italian presidency. The conclusions of the expert conference organised by the Italian government during its presidency of the EU Council, listed the shortage of organs as the main priorities in this area and stressed the importance of addressing the quality and safety aspects fully considering the current framework of supply and demand for organs.

4.3. Political momentum

In 2007 the Commission adopted a Communication on organ donation and transplantation intended to respond to the main policy challenges in the field. The Commission communication proposed a combination of actions oriented to respond to the above mentioned problems. Its aims at is to strengthening the cooperation between Member States introducing the basic principles and the technical requirements on donation, procurement, testing preservation, transport and distribution for human organs.

On 6 December 2007, the European Council adopted conclusions on organ donation and transplantation. The Council recognised the importance of having high standards with respect to the quality and safety of organs for transplantation, invited the Commission to continue its work under the proposed Action Plan and its examination of the need for an EU framework on quality and safety for human organs.

On 22 April 2008 the European Parliament adopted a draft resolution on the Communication. The Resolution fully shares the Commission's analysis of the situation of organ donation and transplantation in the EU, and confirms the priorities for action outlined in the Communication. The EP recognises that it is “vitally important to improve the quality and safety of organ donation and transplantation”, looks forward to the Commission action plan for strengthened cooperation between MS and asks the Commission to establish an EU mechanism which would promote coordination activities between MS.

4.4. European action is required: necessity test

It might be helpful to briefly review the evidence presented this far. We have noted that organ transplantation has increased significantly during recent decades. We will also show that the cost-benefit analysis in favour of more organ transplantations is compelling. Yet donation rates and availability of organs varies considerably across Europe with achievable good practice

delivering far greater benefits in some Member States than others. More generally there are significant risks in using organs in therapy that can be effectively managed through the application of quality and safety procedures.. A well-regulated donation and transplantation system is essential if organs are to be delivered on time, with accurate information and without unnecessary risk of transmitting disease to the recipient. Such a system should also improve the traceability and follow up of organ donation. Another important contextual factor is the shortage of organs, with more than 56,000 patients on waiting lists in Europe.

In the light of this evidence, arguments supporting EU action might be summarised as follows. Despite the advantages of intra-Community co-operation on organs donation and transplantation (analysed more in-depth under 'added-value' section), we know that so far the current arrangements have been sufficient to allow two voluntary agreements – Eurotransplant and Scandiatransplant – to emerge. The former group 6 Member States and 1 candidate country (Croatia), while the latter 3 Member States and 2 EEA countries (Norway and Iceland). However, even within these groups the average exchange rates remain relatively low (i.e. for kidneys between partner countries in the Eurotransplant region it is 19.7%) Outside of these two organisations (18 MSs), cross-border movement of organs is negligible. As transplantation poses a risk of transmitting disease to recipients, the conditions essential for increasing intra-Community co-operation require European consensus about the quality and safety standards. When organs cross borders, there is a trans-national need to ensure traceability and report adverse reactions.

In addition, currently transplantation is carried out by professionals working under different jurisdictions. This both limits the transmission of good practice between systems and adds to the transaction costs of professionals moving from one national system to another. Moreover, coordination between donor data sets would allow for a more efficient allocation of organs (especially helpful for smaller Member States and for urgent and difficult to treat patients). Differences between national approaches may slow down medical treatment through (medically) unnecessary delays. As more people move across borders information will need to move with them to optimise donation and transplantation while maintaining citizens' confidence in the system in the country they are visiting. Lastly, EU involvement can partially mitigate perceptions of unfairness or waste in other countries may have an effect on donation rates if organs harvested in one country are to be transplanted in another.

4.5. The added value of European action: Why would European action be better than national action?

The response to this question is shaped by two aims:

Optimising the EU's contribution (e.g. not asking Community bodies to do what they are too remote or too weakly-endowed to do)

- Making best use of Europe's diversity – this means fitting local solutions to local issues, of course, but also allowing European regions to learn from each other.

The EU added-value factors justify EU action but also might helpfully be considered when assessing how to optimise the EU's contribution. The list includes:

EU facilitation of consensus building allowing quicker implementation

- Economies of scale:
    - Lower transition costs in establishing the new Quality and Safety system and reduced running costs
- Greater fairness and contribution to solidarity
- Enhanced donor and recipient confidence stemming from more legal clarity

Considering these factors, some important issues arise. First, despite the growing consensus around Quality and Safety issues, requiring each Member State to conform to an identical Quality and Safety regime would conflict with the variety of health systems and would at the very least require considerable negotiations covering implementation. It may also fail to gain the sort of commitment and understanding at the local hospital level which is a pre-requisite for a successful Quality and Safety system. EU proven experience in consensus building can provide a flexible solution that could accommodate these differences. Furthermore, by creating common reporting structures amongst diverse systems, not only would lessons be more easily transferred, and good practice identified, but by having a (minimal) level of compulsion the system would probably be implemented more quickly with consequent benefits for potential recipients currently on waiting lists.

Furthermore, a degree of compulsion caused by action at EU level would add to fairness by ensuring that all European citizens had access to reasonable Quality and Safety standards, and would provide a more effective conduit for learning and comparing across regimes. As organs are sourced on a more trans-European basis, and as patients and donors become more mobile, it would enhance confidence in the system.

4.6. Subsidiarity: Some conclusions

An EU measure in the area of organ transplantation and donation can be reconciled with the principle of subsidiarity on the following grounds:

- The European Community has a clear opportunity and obligation to implement binding measures laying down high standards of quality and safety for the use of blood, organs, and substances of human origin

- The European Community action is likely to contribute to public value by providing a platform for implementation and mutual learning which combines standardisation of reporting with diversity of service.

4.7. Proportionality analysis

The subsidiarity analysis makes a strong case for EU action in the field of organ donation and transplantation. This analysis will also be referred to in the subsequent 'Analysis of Impacts' where the principle of proportionality is applied. Application of this principle requires that the proposed policy measures leave as much scope for national decision as possible, and respect well established national arrangements and legal systems. Hence, even despite strong legitimacy of EU action, the costs and benefits of various available options will be considered so that the most efficient and effective instrument is chosen.

5. THE POLICY OBJECTIVES

5.1. Objective Tree

Ultimately, the strategic goal of DG SANCO is to achieve a high standard of human health protection. In the area of organ donation and transplantation, this goal can be broken down into three objectives to tackle current and future shortcomings and to guide European policy: 1) increasing organ availability; 2) enhancing the efficiency and accessibility of transplantation systems: and, 3) improving quality and safety. The following figure illustrates the three main policy objectives of the Commission.

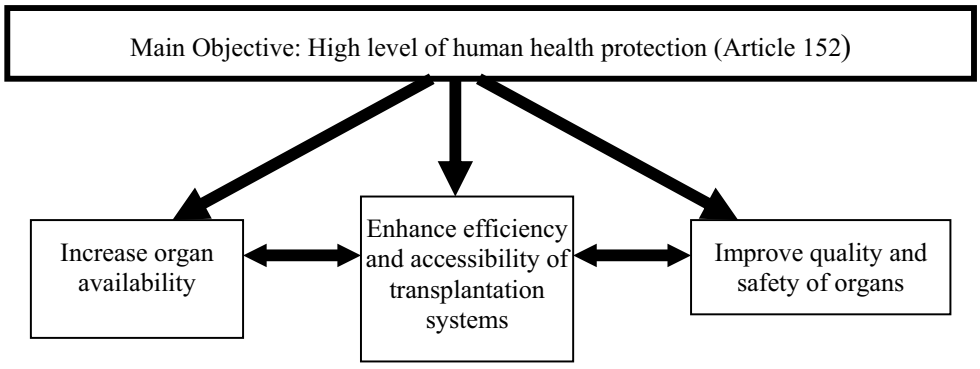


Diagram of the three Main Policy Objectives

5.2. Increasing organ availability

The Commission seeks to support Member States in increasing the number of donors as actions to fulfill this objective are expected to help reduce the gap between supply and demand and may even achieve an absolute reduction in the waiting list.

This policy objective has two dimensions. First, Member States should reach the full potential of deceased donations and secondly, Member States should increase living donation to complement donation from deceased donors.

5.3. Enhancing the efficiency and accessibility of transplantation systems

Like other healthcare access issues, this objective has to be seen in relation to other initiatives at Community level in the area of health system quality improvement. There are a number of Member States with less developed transplant systems which can be supported and guided in their efforts to improve donation rates, the number of organ transplantations performed and post-transplant results.

Even among EU countries having well-developed health and organ transplant services, there are still considerable differences in organ donation and transplantation activity. It is clear that some organisational systems are performing better than others. Thus, initiatives focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics are critical to fulfilling the need for all Member States to have well organized and efficient transplant systems for optimal health outcomes (i.e. the main objective) and cost savings.

5.4. Improving quality and safety

Quality and safety is at the core of the main political objective of ensuring a high level of human health protection (Article 152). Quality and safety standards are essential to maximize the safety and efficacy of the use of human organs in the health system, which includes reducing the likely risk of adverse medical events related to the transplantation pathway, as well as ensuring adequate handlings of all steps on the donation pathway. Taking into account the mentioned specificities of organ donation and transplantation, the European policy initiative is designed, ultimately, to improve procedures related to organ transplants.

6. THE POLICY OPTIONS

6.1. Introduction

To achieve the above objectives a two-step approach based on four different policy options is proposed. The policy options proposed promote **policy actions** in five broad areas of **policy intervention** (creation of national institutions, improving processes, reducing risks to patients, living donation and cross border aspects). These can be distinguished by their regulatory approach which ranges from voluntary cooperation to a stringent Directive

6.2. Areas of intervention

Creating national institutions for organ donation and transplantation

A sound national infrastructure and responsible institutions for organ procurement and transplantation have been identified by DG SANCO as an important element of a successful transplantation system. Creating competent national institutions is thus a key element of the proposed policy options. The proposals include the creation or nomination of a competent national authority in each Member State, the authorisation of establishments and activities and for the creation of a register of establishments. In addition, proposals include regular national reporting obligations and improved cooperation between competent authorities.

Improving Processes

Of equal importance to an adequate organisation of an organ donation and transplantation systems is to ensure the quality of processes performed by the various organisations in the field. The initiatives propose the introduction of quality programmes to ensure continuous monitoring of performance and improvement and learning. This also includes specific standards for the procurement and transport of human organs.

The proposed policy options aim to promote the role of a transplant coordinator and to encourage training of the personnel involved in the process. Knowledge about organ donation and communication skills among health care professionals as well as patient support groups are an additional target for action.

Reducing risks to patients and improving quality of transplantation

Organ transplantation is a potentially life saving treatment, which nevertheless involves substantial risks to the patients. The proposed policy option encompasses the establishment of a common set of criteria to assess the risks for organ recipients. In addition, the proposals include measures to capture serious adverse events and reactions. Systems to ensure that organs can be traced back to the original donor are vital to quickly notify other organ recipients in case a dangerous infection has been discovered. Finally, the proposals contain

measures to improve the knowledge about transplantation outcomes in particular for relatively new donor groups, such as expanded criteria donors or non-heart beating donors.

Living Donation

As an alternative to organs from deceases donors living donation has not reached its full potential yet. The policy options contain a number of measures to promote living donation. These include the development of a register for living donors to follow up their health status; measures to ensure the altruistic and voluntary donation of organs by living donors;

Cross border aspects of organ donation

Measures are proposed to address shortcomings in the exchange of organs between Member States, problems resulting from the mobility of donors across borders and also the introduction of measures to improve the identification of organ donors between Member States. To facilitate the exchange of organs and to ensure the quality of the transplantation and donation process a process to better share information is proposed about available organs between Member States.

It would be difficult to define an "optimal" rate of cross border exchange, this rate could varies according with different criteria, the size of the donor pool, the type of organ to be transplanted , the type of recipient. What is clearly identified is that cross border exchanges are needed to increase the quality of the match between door and recipient and to treat specific patients such hyposensitise patients, paediatric or urgent patients where a sizeable donor pool is required. But also to ensure that all organs are utilise regardless there is or not a specific recipient in an specific waiting list of a Member States. This is obviously crucial for small Member States with small donor pools.

Therefore the objective is not "a specific rate of exchange" but to put in place the conditions that favours the exchange of organs when needed along the EU.

6.3. The policy options

All four options are presented in detail below. Having in mind subsequent analysis of impacts, this chapter aims at demonstrating how each of the options attempts to fulfil the objectives. The graphs below and Annexes I and II explain it in detail. Option 2, due to the nature of the instrument proposed, furthers all three objectives, however focuses mainly on the first two. Options 3 and 4, again thanks to adding an instrument binding in nature, open more possibilities to further quality and safety objective, which eventually also assists in meeting the first two objectives.

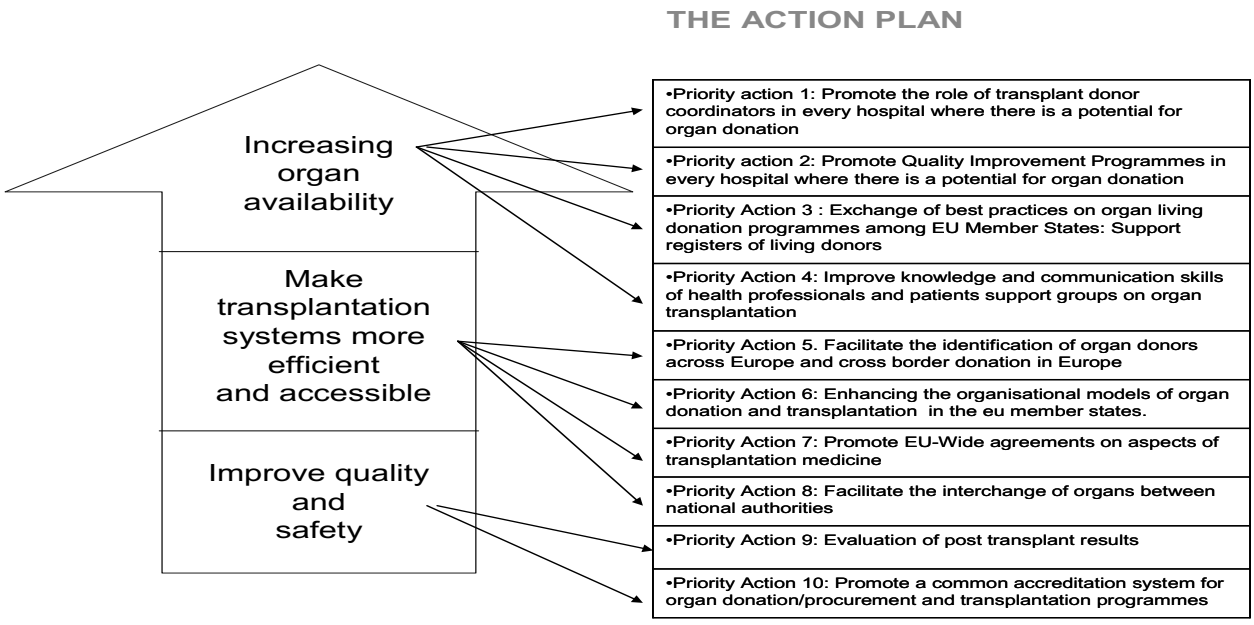
Option 1: Continuing Status quo

Under this option, the European Commission would continue with its current activities in the field of organ donation and transplantation, which involves predominantly sponsoring research and pilot programmes in this field and participating in international cooperation such as in the Council of Europe. (Figure on section 2.1.4 provides an overview over the different European projects currently supported by the European Union), detailed information on the projects could be found in Annex I and II.

Option 2: Action plan

This option proposes a non-regulatory approach establishing a European Action Plan on Organ Donation and Transplantation for the period from 2009 to 2015which sets out a cooperative approach of European and Member State based on national action plans. This approach is based on the identification and development of common objectives, agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

The Commission having gathered the information, knowledge and expertise generated in the field of organ donation and transplantation, has identifying a detailed list of priority actions.The 10 priority actions proposed by the European Action Plan are listed below::



The action plan will promote a number of initiatives aimed to improve organisational systems in order to increase organ donation that have been proved effective in some Member States, will help Member States to evaluate the performance of their transplant systems and exchange best practices to improve them, will facilitate the cross border donation in Europe and promote to set up the necessary structures to facilitate the organ exchanges for better care of patients in Europe. It also incorporates mechanisms to promote the quality and safety of the systems by evaluating the results in order to lead to a safer and more effective use of organ donors and will set up the basis of a voluntary accreditation system.

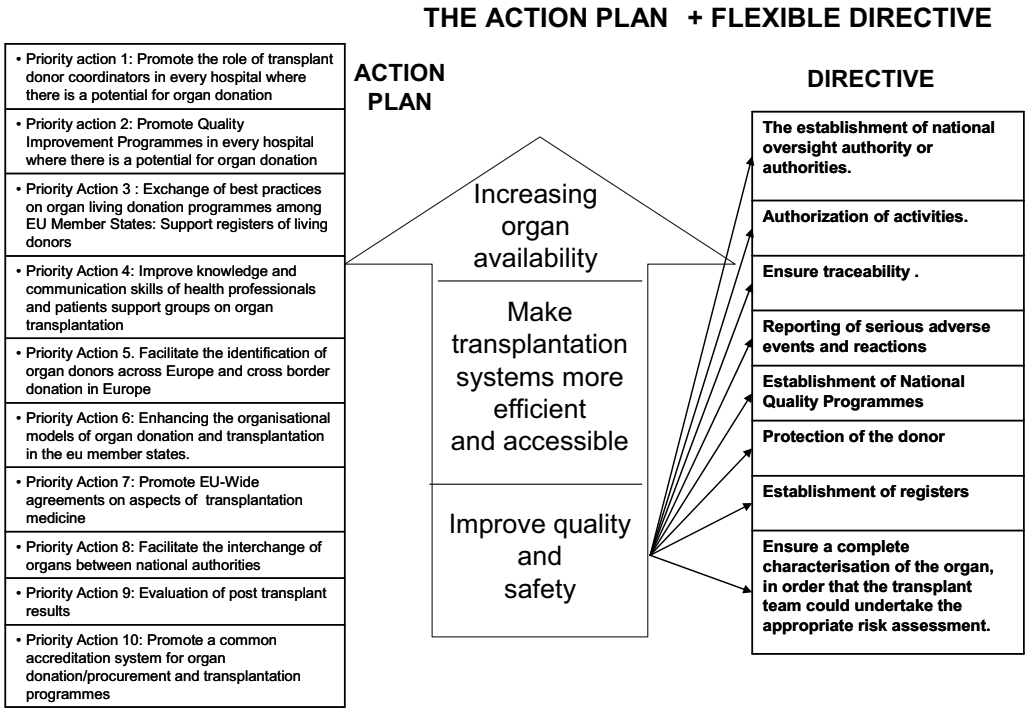
Option 3: Action plan + "flexible directive"

Option three combines the Action Plan already described with a "flexible" directive. The regulatory approach of this directive will be very much a framework approach, ensuring that national legislation is put in place to deal with key aspects of organ donation and transplantation but without prescribing detailed policy measures.

The Directive will ensure that the quality and safety structures are in place. These will facilitate the conditions for cross border exchanges and ensure a basic level of quality and safety for patients.

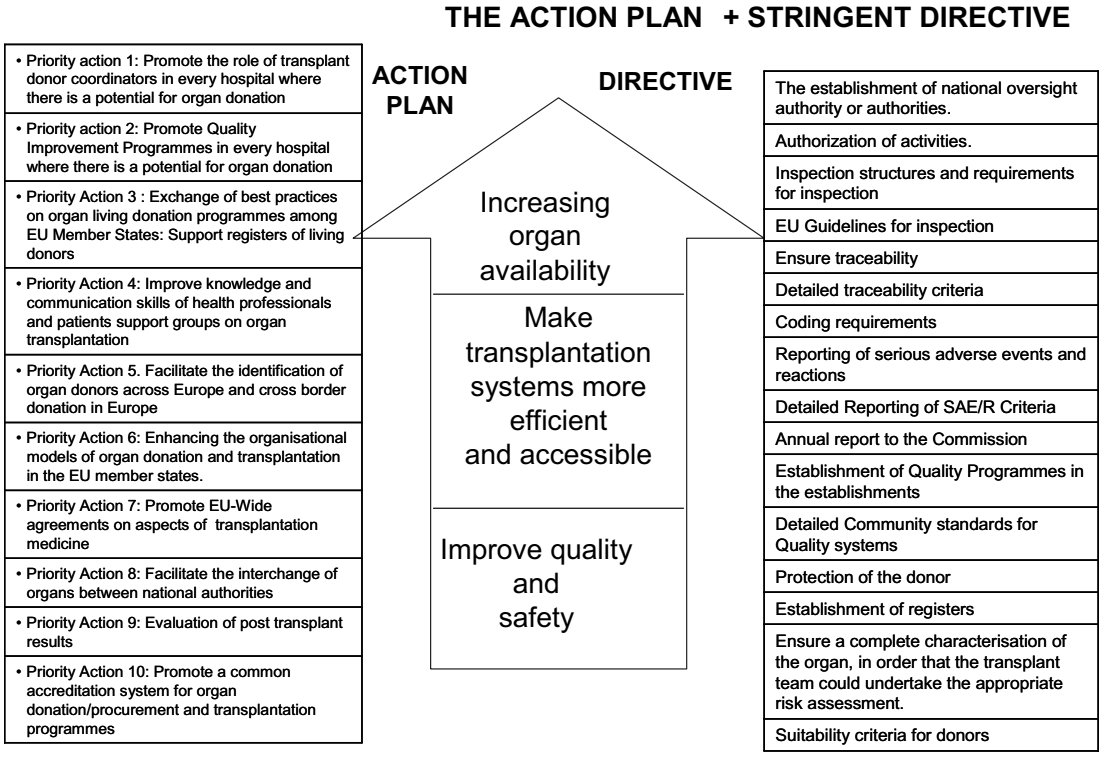
The proposed framework approach in the Directive will deal with the key aspects of organ donation: establishing of competent authorities, authorisation of the conditions of procurements and basic standards for procurement, traceability of the organ, reporting of serious adverse events and reactions, basic protection of the donor and organ characterisation (collection of the relevant information on the characteristics of the organ and the donor needed to undertake an adequate risk assessment in order to minimise the risks for the recipient and to optimise the allocation of the organ.).This option will leave enough flexibility to Member States to adapt the existing systems where in place and reducing to the maximum red tape and administrative burden.

In addition the Directive will complement the action plan (Annex I). The action plan establishes key priority actions promoting objectives depending on MS cooperation, coordination and voluntary level of commitment. The Directive, given its binding nature, will support and trigger the implementation of key priority actions of the Action Plan. For example the Directive will support the first priority of the action plan (promote the role transplant donor coordinators), by requiring adequately qualification for the personnel and adequate training. These interactions are detailed in Annex II



Option 4: Action plan + "stringent directive"

Option 4 will combine the action plan described under Option 2 with a stringent directive. This stringent directive will be modelled after the Tissue and Cells Directive and will therefore contain detailed regulation about the quality and safety systems Member States have to put in place, leaving little national discretion in transposing the directive. The more detailed prescriptions of Option 4 are detailed below



Option 4 provides for a stricter regulatory approach. This option will include a more complex accreditation process for procurement sites, including regular inspections which entail the need to put in place a specific inspection structure. It requires also a detailed quality system in place in every donation site. The Directive will laid down exclusion criteria for donors following the same approach that in the blood and tissues and cells Directives

In order to further clarify the details of each option, in addition to above graphs, please find in the Annexes a detailed description and comparative tables of the different policy options on the quality and safety elements (Annex I) and element related to organ availability and making the system more efficient and accessible (Annex II).

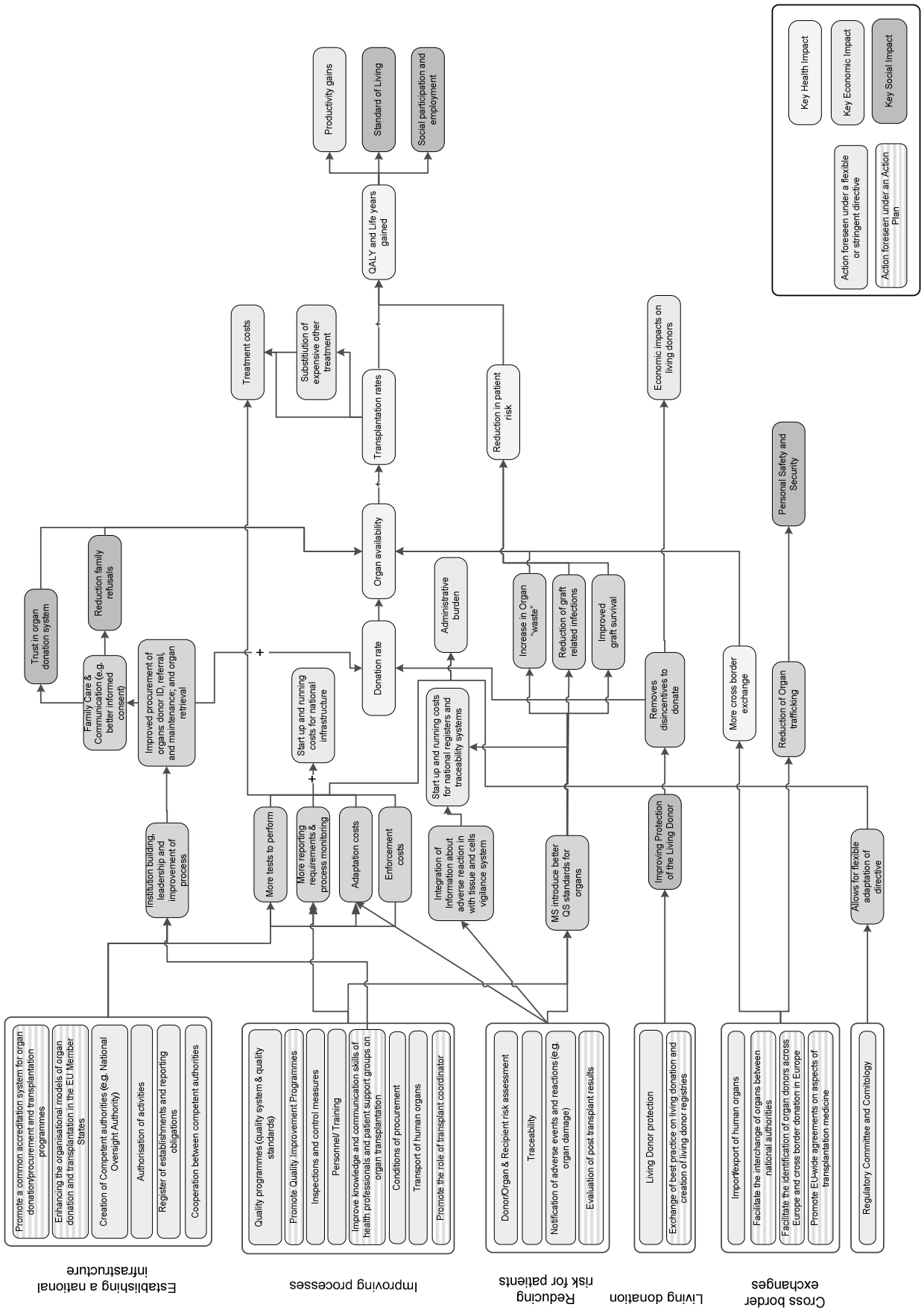
7. ASSESSMENT OF IMPACTS

7.1. Introduction

A model of the policy intervention

The policy options proposed include a variety of policy interventions with the ultimate objectives of increasing the availability of organs, making the transplantation systems more efficient and accessible as well as improving the

quality and safety of organs. The following figure illustrates the causal link between the policy interventions and the desired outcomes and the objectives. For clarity, the actions foreseen under the action plan (Option 2) and the flexible (Option 3) or stringent directive (Option 4), are grouped into the broad areas of policy intervention identified in the previous section.


Key Health Impact
Key Economic Impact
Key Social Impact
Action foreseen under a flexible or stringent directive
Action foreseen under an Action Plan
Productivity gains
Standard of Living
Social participation and employment
QALY and Life years gained
Treatment costs
Substitution of expensive other treatment
Transplantation rates
Reduction in patient risk
Economic impacts on living donors
Personal Safety and Security
Trust in organ donation system
Reduction family refusals
Organ availability
Administrative burden
Increase in Organ "waste"
Reduction of graft related infections
Improved graft survival
Family Care & Communication (e.g. better informed consent)
Improved procurement of organs donor ID, referral, and maintenance; and organ retrieval
Donation rate
Start up and running costs for national infrastructure
Start up and running costs for national registers and traceability systems
Removes disincentives to donate
More cross border exchange
Reduction of Organ trafficking
Tnsitution building, leadership and improvement of process
More tests to perform
More reporting requirements & process monitoring
Adaptation costs
Enforcement costs
Integration of information about adverse reaction in with tissue and cells vigilance system
MS introduce better QS standards for organs
Improving Protection of the Living Donor
Allows for flexible adaptation of directive
Promote a common accreditation system for organ donation/procurement and transplantation programmes
Enhancing the organisational models of organ donation and transplantation in the EU Member States
Creation of Competent authorities (e.g. National Oversight Authority)
Authorisation of activities
Register of establishments and reporting obligations
Cooperation between competent authorities
Quality programmes (quality system & quality standards)
Promote Quality Improvement Programmes
Inspections and control measures
Personnel/ Training
Improve knowledge and communication skills of health professionals and patient support groups on organ transplantation
Conditions of procurement
Transport of human organs
Promote the role of transplant coordinator
Donor/Organ & Recipient risk assessment
Traceability
Notification of adverse events and reactions (e.g. organ damage)
Evaluation of post transplant results
Living Donor protection
Exchange of best practice on living donation and creation of living donor registries
Import/export of human organs
Facilitate the interchange of organs between national authorities
Facilitate the identification of organ donors across Europe and cross border donation in Europe
Promote EU-wide agreements on aspects of transplantation medicine
Regulatory Committee and Comitology
Establishing a national infrastructure
Improving processes
Reducing risk for patients
Living donation
Cross border exchanges

7.2. Assessment criteria

The four Policy options have been assessed by considering:

- Health impacts, including gains in QALYs and life years, avoiding risks for patients and donors and health benefits of cross border exchanges.

- Social impacts, including impacts on the quality of life, on the possibility of transplant patients for social participation and employment and finally on the trust and confidence of donors and their families in European donation and transplantation systems.

- Economic effects, distinguished into two categories. First, economic impacts that directly emerge from the implementation of the proposed policy measures. These include start-up and running costs for a national infrastructure, costs of running national registries and traceability systems as well as reporting obligations and administrative burden. Secondly, economic impacts arising if these policies achieve the key objectives of increasing donation and transplantation rates.

The following sections analyse in general way each of the assessment criteria and explain their parameters. Additional background information to this section could be found at Annex V and VI. These parameters are then used to assess and compare the four policy options, which are presented Chapter 7 ('Comparison of Options'), and in more detail in Annex VII.

7.3. Health Impacts

7.3.1. Donation and transplantation rates

Increasing donation and transplantation rates have a clear and significant health impact for organ recipients. Several studies of the Spanish model, and a recent study in Greece, indicate the positive impact of improving processes in the increase of donation and transplantation rates. These results are mainly a consequence from investing in the more developed organisation of the transplant system: putting more staff on the ground; training them better; and improving coordination between the different actors and agencies involved in the procurement process. Similar priorities are outlined in the Commission proposed initiatives.

7.3.2. QALYs and Life years

Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.[34] The average predicted lifetime survival rates for patients undergoing dialysis treatment is 10 years, while it is 20 years for kidney

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[34] Miranda and Matesanz (1998).

transplantation patients. The average number of kidney transplants per year is about 1,000 with a 93% survival rate in one year following kidney transplantation. The **5-year survival rate is 77% in Poland**. The positive health impact of organ transplantation can also be measured by the QALY gained[35]. For example, liver transplantation has the highest QALY gain (11.5); heart has 6.8 QALY gain and lung has 5.2 QALY gain (Tables).

Comparison of predicted survival rates for dialysed patients and for kidney transplant patients in Poland

Age group	Predicted survival times for dialysed patients	Predicted survival times for kidney transplant patients
20-39	14 years	31 years
40-59	11 years	22 years
60-74	6 years	10 years

SOURCE: Narodowy Program Rozwoju Medycyny Transplantacyjnej na lata 2006-2009, Polgraft, available from <http://www.poltransplant.pl/Download/polgraft.pdf>, accessed 25FEB08.

Health Impact Data on Survival Rates for Organ Transplants from the Polish Traceability System for years 2005-6

			3 months survival rates		12 months survival rates	
Organ	Number of transplantations in 2005-2006	Number of patients under observation	Organ recipients (%)	Transplanted organs	Organ recipients (%)	Transplanted organs
Kidney from cadaveric donors	1939	1107	1107 (97%)	1020 (92%)	1043 (94%)	972 (88%)
Kidneys	47	29	29	29 (100%)	29	29 (100%)

[35] The most complete information obtained from our countries studies on the general health impact of organ donation and transplantation comes from the UK Transplant Supplement Report

from living donors			(100%)		(100%)	
Liver from cadaveric donors	379	223	199 (89%)	192 (86%)	195 (87%)	185 (83%)
Liver from living donor	33	16	15 (94%)	15 (94%)	15 (94%)	15 (94%)
Pancreas and kidney (survival of both organs)	58	27	23 (85%)	19 (70%)	20 (74%)	16 (59%)
Heart	190	105	78 (74%)	78 (74%)	77 (73%)	77 (73%)
Lung	9	3	0 (0%)	0 (0%)	0 (0%)	0 (0%)
SOURCE: Poltransplant, Biuletyn Informacyjny, nr. 1 (15), 2007, available at <http://www.poltransplant.org.pl/biuletyn_2007.html>, accessed 06FEB08						

Comparison of the QUALY gain (and cost effectiveness) of liver, heart, lung transplants; Source Department of Health 2008

	DHCIB	Ouwens[36]	
	ICER ($)	QALY gain	ICER ($)
Liver	25,600	11.5	31,000
Heart	36,900	6.8	46,000
Lung	61,000	5.2	61,000

Compared to dialysis, the benefits of different treatments strategies for Type 1 Diabetes with End Stage Renal Failure range from 2.01 to 5.77 additional QALYs. (table)

[36] Ouwens, et al. (2003).

Benefits Derived From Different Treatment Strategies in the UK for Type 1 Diabetes With End Stage Renal Failure

	Life Expectancy (LY)	Δ LY	QALY	Δ QALY
Dialysis	7.82	-	4.52	-
Cadaveric Kidney Transplant	11.4	3.62	6.53	2.01
Simultaneous Pancreas-kidney Transplant	15.74	7.92	9.09	4.57
Pancreas after Kidney Transplant	17.21	9.39	10.00	5.48
Living Kidney Transplant	18.30	10.48	10.29	5.77

SOURCE: Knoll and Nichol (2003) pp.506, Table 3

In addition, evidence from the international literature shows that **a typical donor generates about 13 QALYs** at an added medical cost of about US$ 214,000 ($16,000 per QALY), with a highest estimate of $57,000; at this value then, the benefit obtained from one added donor would be $214,000.[37] (Background info in Annex VI points 5-7)

7.3.3. Risks to patients

Transmission of communicable diseases and malignant diseases

As discussed in the problem definition, the use of organs in therapy poses potential risks of communicable diseases being transmitted to the recipient (Viral, bacterial, and fungal infections). Several types of protozoan and worm parasites have also been transferred via organ transplants. Since organs cannot be subjected to sterilization steps, the risk of infectious disease transmission is higher. A complete revision of the main risks is provided in the Annex VI.

[37] Mendeloff, et al. (2004).

In addition, the transmission of malignant diseases, i.e. cancer, is also a risk of organ transplantation.[38] Annex VI provides an overview of the relevant findings. These risks can be minimised through appropriate measures.

Adverse events and patients safety

Apart from the risks of transmission of disease, organ transplantation is a high-risk surgical procedure that also requires long-term exposure to strong medication such as immunosuppressive drugs; this means that organ transplant patients constitute a patient group at great risk of suffering a patient safety incident. [39]

It has been shown[40] that over half of all adverse events are considered to be preventable. Between 6.7 and 15 million hospital discharges are associated with an adverse event.[41] More specific to the organ transplantation process, a study in the US found that 19% of kidneys procured are damaged from the extraction procedure. Organ damage was found to be associated with team expertise whereby multi-organ transplant teams had a reduced rate of kidney damage than a kidney transplant team.[42]

It has been demonstrated that Quality Assurance Systems in organ donation and transplantation reduce missed information on organ abnormalities or organ damage from the procurement operation.

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38 Consensus Document Criteria for Preventing the Transmission of Neoplastic Diseases in Organ Donation. Organizacion Nacional de Transplantes Spain http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

39 The first major risk is surgery. Of all general surgery in-patients, 39% suffer one or more adverse event: 1% of these were fatal, 7% were life-threatening, and 63% were of moderate severity. More specifically, a French national survey found the highest density of adverse events was observed in cardiothoracic surgery (e.g. heart and lung transplantation), gynaecology and urology (e.g. kidney transplantation). Invasive procedures formed the main exposure situation for adverse events occurring during hospitalisation: in particular, peri-operative care was related to 42% of adverse events whereas adverse drug events represented 20%. The second major risk is adverse drug events which have been found to be associated also with almost a doubling in the risk of death, making them one of the most dangerous types of adverse events. The third major risk to patients is process-related blood transfusion adverse events. While less attention has been paid to improving the safety of the transfusion chain within hospitals (Sini et al 2008), it is known that the risk of an error occurring during transfusion of a blood component is estimated at 1 in 16,500, an ABO incompatible transfusion at 1 in 100,000, and the risk as a result of an "incorrect blood component transfused" is around 1 in 1.5 million (RCOP 2005)

40 internationally and in European Member States

41 Conklin, et al. ((forthcoming)).

42 Wigmore, et al. (1999).

7.3.4. Living donation

For many years, living donation has become a real alternative to improve the organ availability offering some advantages compared to that from deceased donor. The survival rates of non-related living donation are the same as in parental donation and higher than in deceased donation The use of organs from living donors has positive repercussions on waiting list mobility; however, it is important to assure that donation is voluntary, there is no financial gain and there is proportionality between the harm caused to the donor and the benefits created for the recipient.

It has been proven that, in most cases of living donation the remaining kidney functions of a living kidney donor remain stable during long term follow up. However, safety for the donor is crucial. Research shows that the risk of death exists and is very small (0.03%). The risk of any complication ranges from 2% to 16%, depending on how complications are defined and the type of organs (complications are more frequent in living liver donation). Major complications occur at a rate of about 2% - 6%.[43]

To cover risks, living donors need to be adequately protected and it must be ensured that living donors receive the treatment they require. The scenarios designed show the potential increase of the number of living donors.

Institutional context of living donation in a sample of European countries

Organisation	Country	Regulated by Law (In parliamentary Transplantation act)	Informed Consent required	Allowed for Minors/persons lacking legal capacity	Principle of Subsidiarity	Requirement for Donor-recipient- Relationship	Approval by ethical committee	Approval by court	Altruistic/No remuneration	Organ trafficking penalized
./.	Austria	No; only position paper	Yes	No		No	No	No	Yes	Yes
BTS	Belgium	Yes	Yes	No		No	Not mandatory	No	Yes	Yes
MZSS	Croatia	Yes	Yes	No		No	Yes		Yes	Yes
KST	Czech Republic	Yes	Yes	Yes		Yes	Yes	No	Yes	Yes

[43] http://www.livingdonorsonline.org/

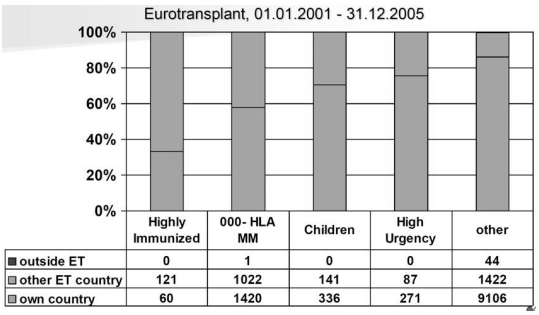
ABM	France	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes
DSO	Germany	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Hu-T	Hungary	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
CNT	Italy	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
./.	Luxembourg	Yes	Yes	No		Yes	No	No	Yes	Yes
NTS	Netherlands	Yes	Yes	No		No	No	No	Yes	Yes
Poltransplant	Poland	Yes	Yes	No	No	Yes		Only in case of non relatives	Yes	Yes
OPT	Portugal	Yes	Yes	No	Yes	Yes	Yes	No	Yes	yes
Slovenia - Transplant	Slovenia	Yes	Yes	Yes,with obligations		Yes	Yes	Yes	Yes	Yes
ONT	Spain		Yes	No	Yes	No	Yes	Yes	Yes	Yes
Swiss transplant	Switzerland	from 2007	Yes	Yes, with some obligations		No	Yes	Yes	Yes	Yes
UK - Transplant	United Kingdom	Yes	Yes	Yes, rare	No	No	Yes	Yes	Yes	Yes

SOURCE: DOPKI (2006)

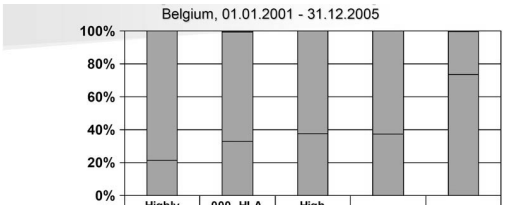
7.3.5. Health benefits of cross border exchange

The cross border exchange of organs can be linked to positive health impacts. For specific patient subgroups, such as highly immunised, high urgency patients and children, a larger donor pool is beneficial, as it increases the chances of a suitable organ being available in time. Evidence from Eurotransplant presented in the Figure below shows that for these groups of patients, international exchange is very important. Across the Eurotransplant area, two thirds of kidneys for highly immunized patients come from another Member States. In a small country like Belgium, this percentage is even higher, at around 79% of all kidneys for highly immunized patients.

Kidney exchange for special patient groups in Eurotransplant and Belgium



	Highly Immunized	000- HLA MM	Children	High Urgency	other
outside ET	0	1	0	0	44
other ET country	121	1022	141	87	1422
own country	60	1420	336	271	9106



	Highly Immunized	000- HLA MM	High Urgency	Children	other
outside ET	0	1	0	0	5
other ET country	11	129	5	37	418
own country	3	64	3	22	1176

SOURCE: Eurotransplant

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But also the cross border exchange is important to improve the matching of the organ with the recipient, this has obviously very positive effects in the outcome. Eurotransplat has succeeded in achieving 21.6 % of kidney transplants with 0 mismatches (complete matching).

In Italy, organisational improvements showed that that there is a potential for exchanging more organs across national borders. The creation of the Italian Gate to Europe (IGE)[44] resulted in an increase in the exchange of organs between Italy, Greece and Slovakia, while at the same time having no detriment to the probability of Italian citizens being transplanted as a result of these international agreements.[45] The actions proposed would have similar impacts particularly for difficult-to-treat and paediatric patient groups.

However, as discussed in the problem definition (Chapter 2), the full potential of cross border exchange of organs has not yet been reached in the European Union.

Cross border exchange of organs in the European Unions

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44 a single national coordinating centre for the exchange of organs and patients with the rest of Europe in 2005

45 Pretagostini, et al. (2007).

	Organs transplanted from abroad	Organs transplanted abroad
Greece (2006)	1	30
Italy[46] (2006)	26	2
Poland		8
Spain (2007)	34	6
Eurotransplant	(exchange of organs from deceased donors within ET area, as % of all deceased organs transplanted)	20% (≈ 3,300
Eurotransplant	(exchange of organs from deceased donors outside ET area, as % of all deceased organs transplanted))	2% (≈ 330
Scandiatransplant	Exchange of organs, 2007	Kidney 10%
		Liver 19%
		Heart 27%
		Lung 21%

7.4. Social Impacts

7.4.1. Quality of life

A recent review[47] concluded that the impact of heart, lung, kidney and liver transplantation on recipients' quality of life is strongly positive. The improvement in quality of life is significant and perceived early after surgery, with larger gains in the dimensions of Quality of Life most affected by physical health and more modest improvements in areas affected by psycho-social functioning (including also sexual function, pregnancy, schooling for paediatric patients, sports (both adults and children), and work. Studies showed a significant Hamilton depression variation among living donor kidney transplant recipients, with improvement in the gained score and reduction of depressive symptoms.[48] In addition, studies of adults who received a kidney transplant in

46 IGE (2007).

47 Ibid.

48 Virzi, et al. (2007).

childhood found that their activity level is similar to that of the general population's.[49]

From the living donor perspective, living donors experience a boost in self-esteem and a greater sense of well-being.

Even in the highly controversial Living Donor Liver Transplantation (LDLT), QoL is high for live liver donors, indicating a positive psycho-social outcome for the majority of donors irrespective of donation-related medical complications. Satisfaction of donation among live liver donors is evident in their experience of having their lives "changed for the better" as a result of the process[50] and more than 90% of living liver donors would donate again.

Another important element of quality of life are the social and in particular family networks. It was found that the majority of living donors reported no change or an improved relationship with their recipient (86 to 100%), spouse (82 to 98%), family members (83 - 100%) and non-recipient children (95 - 100%).

7.4.2. Employment and social participation

A systematic review of employment status (and social participation) after successful kidney transplantation was conducted by van der Mei et al. (2006). Among the seventeen studies selected out of 1443 identified references, the authors found that employment was the most used indicator of social participation with rates ranging from 18% to 82% after kidney transplant. Other studies are showed in the next table

Employment rates after transplantation

Organ	Employed after transplantation
Kidney transplant (Matas et al)[51]	47%
Kidney transplant (van der Mei, Krol et al. 2006).[52]	18% to 82%
Liver transplant (Saab, Wiese et al. 2007)[53]	27%

[49] Broyer, et al. (2004).
[50] Parolin, et al. (2004).
[51] Matas, et al. (1996).
[52] van der Mei, et al. (2006).
[53] Saab, et al. (2007).

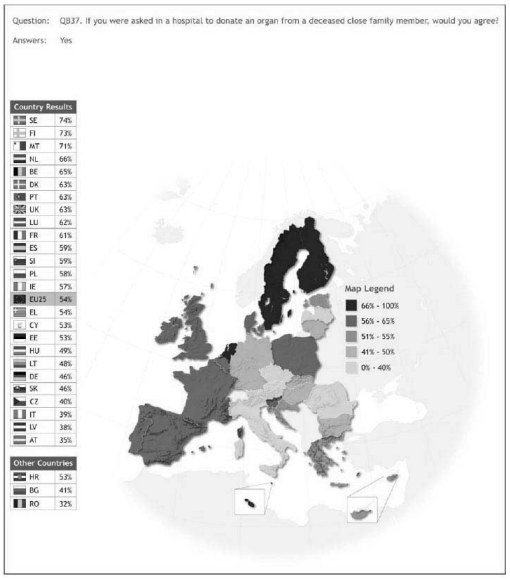
Heart transplant (Petrucci, et al. 2007).[54]	39%
Lung transplant (Petrucci, et al. 2007)	39%

7.4.3. Trust and confidence in organ donation and the transplantation system

Creating robust donation and transplantation systems, ensuring the quality and safety of donation and transplantation and raising public awareness can be expected to have an influence on citizens' trust and confidence. This is important because a high level of trust and confidence might ultimately lead to a higher willingness to donate organs.

Family refusals

Trust in the health care system and the organ donation system plays an important role in increasing the donation rate, and is of value in itself. A good indicator of this trust is the declared willingness to donate a family member's organ as well as the actual family refusal rates. A recent Eurobarometer survey[55] shows considerable differences in the hypothetical willingness to donate a family member's organs. In particular, the Nordic countries have a strong willingness to donate their organs, indicating a strong level of trust in the systems.



SOURCE Eurobarometer (2007)

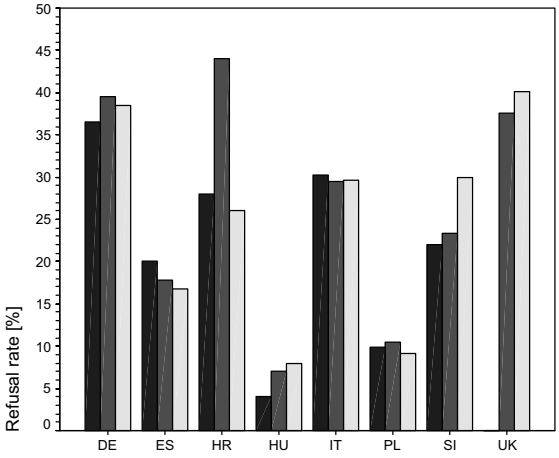
Figure **Error! No text of specified style in document.**.1: Estimated 30-year discounted savings from additional kidney transplants

54 Petrucci, et al. (2007).

55 Eurobarometer (2007).

There is some evidence, that the proposed policy measures might increase confidence and trust in the system and reduce family refusal rates. Data suggest that training programs for health professionals specifically dedicated to every step of the transplantation process has contributed to the approach of obtaining consent from donor families.[56]

With the professionalisation of transplant services, Poland witnesses a sharp decline in family refusal rates from over 1,000 in 2000 to 272 refusals in 2006. Yet, family refusals are still the main reason for 10.4% of potential organ donors being rejected in 2006. By contrast, 40% of families in the UK refuse to give consent to organ donation, sometimes even when the potential donor was carrying a donor card giving their explicit consent.[57] Also in Greece, family refusal rates have been consistently above 40% during the last years: 46% (2005); 44% (2006) and 41% (2007).



Blue=2003; Red=2004; Yellow=2005

SOURCE: (DOPKI 2007);

Refusal rate across countries in Europe

[56] Rosel, et al. (1999).

[57] Department of Health (2008a);Department of Health (2008b).

7.5. Economic impacts

7.5.1. Start up and running costs for a national infrastructure and better processes

The different policy options contain a number of proposals to establish a national infrastructure for organ procurement and donation which might result in start up and increased operating costs.

Creating a competent authority

Most of the 29 European countries surveyed in a Commission survey[58] have an organisation (25) in charge of the organ transplantation/organ exchange.

As most of the Member States have national organisations in place already that are in charge of organ donation, the nomination of competent national authorities is not expected to have a major economic impact. In cases where such organisations do not yet exist (e.g. Austria or Sweden), interviews suggest, that there are suitable organisations in place which could take on this task.

The DOPKI project[59] has evaluated these organisational systems in many European Countries: All national organisations are in charge of the coordination of organ donation, as shown in the next Table. Only a very small percentage of countries that have installed a national organ procurement agency are not in charge at the same time for organs and tissues

ORGANISATIONAL RESPONSIBILITIES IN A SAMPLE OF MEMBER STATES

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[58] DG SANCO (2003).
[59] DOPKI (2006).

Field of Activity					
Organisation	**Country**	**Organs**	**Tissues**	**Cells**	**Others**
./.	Austria	./.	./.	./.	./.
BTS	Belgium	Yes	Yes	Yes (but not mentioned in the law 1986)	./.
MZSS	Croatia	Yes	Yes	./.	./.
KST	Czech Republic	Yes	Yes	./.	./.
ABM	France	Yes	Yes	Yes	Assisted reproductive technologies; embryo research; genetic testing
DSO	Germany	Yes	New law pending	./.	./.
Hu-T	Hungary	Yes	./.	./.	./.
CNT	Italy	Yes	Yes	Yes	./.
Luxembourgtransplant	Luxembourg	Yes	Yes	Yes	./.
NTS	Netherlands	Yes	Yes	No	./.
Poltransplant	Poland	Yes	./.	Yes	./.
OPT	Portugal	Yes	Yes	Yes	./.
Slovenija-Transplant	Slovenia	Yes	Yes	Yes	./.
ONT	Spain	Yes	Yes	Yes	./.
Swisstransplant	Switzerland	Yes	./.	Islets	./.
UK - Transplant	United Kigdom	Yes	Yes	./.	./.
ET	Netherlands	Yes	./.	./.	./.

Source: DOPKI (2006)

While the evidence does not support the direct assessment of costs of establishing a national authority, the total operational budget of the Spanish national authority, ONT, for 2008 is **€4,207,000**, with €3 million a year (73.5%) distributed in grants and financial assistance to support hospitals for organ extraction and transplantation, support promotion and dissemination activities of regional transplant authorities, and support specific training, development and other projects.[60]

Authorisation of establishments

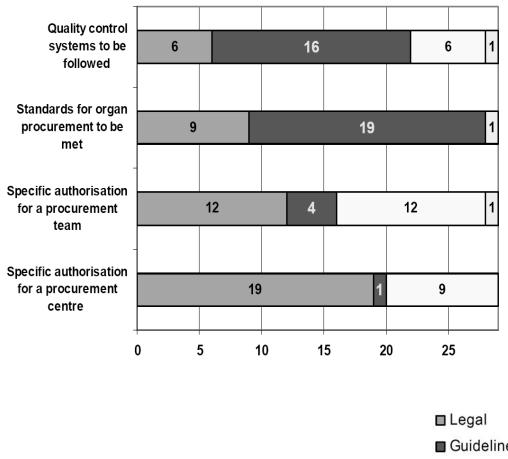
To ensure that transplant activities are only carried out in qualified transplantation and procurement centres, the initiatives propose measures to authorise the conditions of procurement and transplantation centres. Introducing such requirements would crucially depend on the decision of whether it is just designating particular hospitals, or whether hospitals would have to run through a whole licensing procedure. While the former can be expected to create only

60 ONT, personal communication, 3rd April 2008

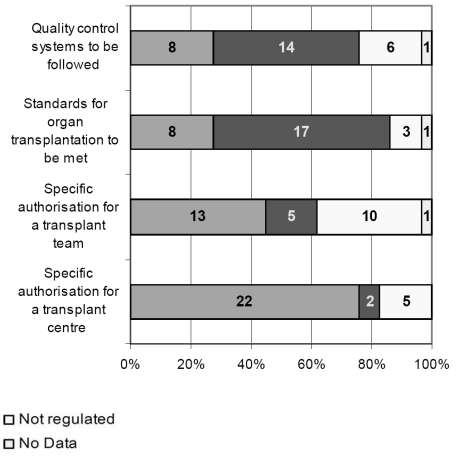
marginal costs, the latter might be more expensive. (Background info in Annex VI points 24-25)

Data collected in 2003 show Annex VI Figure 01, that procurement and transplantation standards in most, varies in the different Member States. Not all hospitals have to be specifically authorised to procure or transplant organs.

Procurement



Transplantation



SOURCE DG SANCO (2003)

Transplant coordinators

Recognising the important role transplant coordinators play in procuring organs, the proposals include the promotion of the role of the transplant coordinator in hospitals. Currently there are wide differences in Member States about the role and the availability of transplant coordinators. The economic impact of promoting the role of transplant coordinators would differ by country and approach (e.g. full-time vs. part- time, centrally vs. hospital employed coordinator, nurse vs. physician) and the current existing system.

In the United Kingdom the organ donation task force quantified its recommendations for improvement, which also includes strengthening the coordinators' network, to increase donation rates. They calculate additional annual costs of £ 13m for the set up of a system with 250-275 (i.e. increase by 150 to 175 staff) centrally employed transplant coordinators, of which the majority are pay costs (£ 11m).

Role and qualification of coordinators in selected European countries

Organisation	Country	In donor hospital	Linked to donor hospital	Outside hospital	Linked to tx-centres	Qualification	Number of coordinators

./.	Austria	planned	./.	./.	Yes		3-4 per region, 4 regions
BTS	Belgium	Local coordinator in some donor hospitals	No	No	Yes	Registered paramedics	Min 2 per tx center per law, currently
MZSS	Croatia	Yes	./.	./.			
KST	Czech Republic	./.	./.	./.	Yes	Physicians and nurses	
ABM	France	Yes	./.	./.	./.	Physicians and nurses	IR1 : 15 full time coordination and population 7,7 millions *IR2 : 38 pop 6,54 *IR3 : 36 pop 9,56 *IR9 : 41 pop 13,08 *IR6 : 35 pop 11,55 IR7 : 49 pop 13,35
DSO	Germany	./.	./.	Yes	./.	Physicians and nurses	50 (0,6 pmp)
Hu-T	Hungary	./.	./.	Yes		Registered nurses, mostly with specialisation in ICU or anaesthesiology	
CNT	Italy	Yes	Yes, (regional coordinators	./.	./.	physicians but nurses are of assistance	One regional coordinator for each region. Usually one/two local coordinators for each hospital.
luxembourg Transplant	Luxembourg	yes	./.	./.	Yes	physicians and nurses	Only one region- 2 part time coordinators
NTS	Netherlands	No	No	No	Yes	Physicians and nurses	4-6 per region; 3 regions á 6 Mio pop
Poltransplant	Poland	Yes some	Yes, (regional coordinators	Yes, (central coordinators	Yes, regional coordinators	Physicians (mostly anaesthesiologist) and nurses	37

OPT	Portugal	Yes	./.	./.		Physicians and nurses	5 regional chef coordinators
Slovenija-Transplant	Slovenia	Yes	./.	./.	Yes		2 central coordinators per 2 million population. are always 24 hours on call (there are 9 of them shifting) 9 hospital coordinators daily involved, backup are central coordinators
ONT	Spain	Yes	./.	Yes	Regional coordinator	Physicians and nurses	There are approximately 800 transplant coordinators in the country, within 155 hospitals authorised as centres for extraction[61]
UK - Transplant	United Kigdom	Yes	./.	./.	Yes	Coordinators are usually nurses	1.5 pmp

SOURCE: DOPKI (2006)

Setting up and running national quality programmes

The policy proposals contain the establishment of nation quality assurance programmes at national and/or hospital level. These programmes shall ensure that standards of good practice are followed throughout the donation and transplantation process. Comprehensive, specific quality systems for donation and transplantation, which include systematic audits and targeted training for staff to achieve continuous improvement, are not yet well developed. An overview of the different national quality programmes are provided in Annex VI tables 03

Little evidence is available on the costs of national quality programmes; however some information is available on elements of quality programmes. One such example is the Donor Action Programme which has been used in several Member States already and in hospitals all over the world. The target of Donor Action is, somewhat limited, as it is only concerned with the first step of the whole process, i.e. organ donation and procurement. Donor Action Programmes have proven to be highly effective in increasing donation rates, and there is some information available on the costs of Donor Action.

61 Personal communication with ONT.

Whiting et al.[62] report average implementation costs for Donor action of around € 35,000 pmp (Ca$ 55,000) and maintenance costs of around € 45,000 pmp (Ca$ 70,000). For Europe, Donor Action[63] reports on cost of implementing Donor action in Belgium, where the donor action methodology had been applied to 62 hospitals at an annual cost of € 500,000 which is a cost of around € 8,000 per year per hospital, including a financial incentive for hospitals of € 3,000 to participate and €60 per reviewed patient record. Similar numbers are reported from Switzerland, where the programme was rolled out in 15 hospitals at a total cost of €80,000 per year, which translates into an annual cost of just above € 5,300 per hospital

7.5.2. Costs for setting up and running national registers and traceability systems

Potentially the most cost intensive element of the proposal is the requirement of establishing systems to trace organs from recipient to donor and vice versa, to systematically follow up the post transplant results and systems to report adverse events and reactions. These costs would depend on the existing systems in the countries and the final detailed policy proposals.

Register of establishments

The policy proposals include a publicly accessible register of all establishments in which organ transplantations are performed or where organ procurement takes place. The total number of transplantation centres and procurement centres is relatively low (and information readily available. There are no cost estimates on the cost of national registers of all establishments, but it can be assumed that information about involved establishments is readily available to all Member States' competent authorities.

Donor registers

Many Member States currently collect data on the organ donors and store it in national, regional or transplant centre based information systems. Most countries have a registry of post mortem donors and recipient of organs from post mortem donation in place. Registers for living donation are however less well developed. Annex VI table 04 provides an overview of the existing registers. We can thus conclude that in most Member States, the basic information to trace organs from a donor to recipient and vice versa are already in place to some degree. Interview evidence shows in addition, that this information is also exchanged between Member States in case e.g. an infection has been discovered.

Outcome registers

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62 Whiting, et al. (2004)..

63 Personal communication Donor Action Leo Roels.

To assure the scientific follow up of transplantation results, transplant organisations or single transplant centres provide, often on a voluntary basis, information to organisations and international studies. These are often organised along the lines of the different transplanted organs. Unfortunately, there is no evidence available on the costs of these registries to follow up post transplant results, in particular as they are founded on the principle of voluntary participation. Data collection in many cases is done by individual doctors who do not get reimbursed for this activity.

International registries such as the European Donor and Organ Registry (EURODONOR), the International Society for Heart and Lung Transplantation (ISHLT), the Collaborative Transplant Study (CTS), the European Liver Transplant Registry (ELTR), the European Transplant Coordinators Organisation (ETCO), the International Pancreas Transplantation Registry (IPTR) and Transplant Procurement Management (TPM).

Contribution to European registries to follow up transplant results

	EURODONOR	ISHLT	CTS	ELTR	ETCO	IPTR	TPM
France (ABM)							
Germany (DSO)	Data delivered by transplant centres on voluntary basis						
Hungary (Hu-T)*					X		X
Italy (CNT)			**X**				
Portugal (OPT)				**X**	**X**	**X**	**X**
Spain (CENATMER)	X	**X**			X	X	
UK (UKT)	X	**X**	**X**	**X**			
Eurotransplant	Cooperation with all registries						

* The HLA laboratory provides data to the CTS and the transplant centres provide data to the ELTR.

SOURCE: ALLIANCE-O (2007d)

Adverse event registers and traceability systems

Currently all Member States are implementing a reporting system under directive 2004/23/EC to allow for the traceability of human tissues and cells and to register serious adverse events and reactions.. The proposed policy actions include a similar provision for human organs, which would require a traceability and a reporting system for serious adverse events.

In the five Member States studied in detail for this Impact Assessment, no systematic adverse event and reactions reporting system for organs are currently in place; evidence on the costs of such systems is thus rare.

Based on adverse event reporting systems for fresh gamete at the Human Fertilisation and Embryology Authority (HEFA) and the SHOT system for blood transfusion run by the National Blood Transfusion Services in the United Kingdom, annual costs between £ 425 and £ 990 per establishment are reported.[64] As reporting systems have a considerably element of fix costs for running and maintaining the computer system, these costs estimates are likely to underestimate the true costs, since they would be shared between fewer establishments in organ donation. For implementing the serious adverse event and reaction system a total cost range between £102,000 and £238,000 was estimated, across a total number of 150 tissue banks.

Cost estimates for full blown adverse reaction events and reaction reporting systems come from the United States where such systems have been implemented in various states[65]. . For the 20 state reporting systems in place in 2002 annual funding ranged from $200,000 to $1,500,000 (with only 3 having more than 4 full-time staff members). The table below shows the 2001 cost estimates of the key components of the mandatory reporting systems in New York and Florida. These are however only reporting costs incurred at the state level, without taking into account the costs incurred in hospitals through data entry and reporting.

Cost ranges for reporting program activities in Florida and New York, 2001

Function	In-house FTE[1]	Estimated costs for in-house or contractual work
Administration	0.5 - 0.75 FTE	
Systems design and maintenance[2]		$50,000 - $275,000

64 For a total of 101 regulated Unit at HEFA and 400 units for the SHOT system. Department of Health (2006).

65 In the US, there are a few key documents which provide insight into the administrative costs of the reporting and learning (R&L) mechanisms: namely, Leape {, 2002 #116}, Rosenthal and Barry {, 2001 #87}, Woolf et al {Woolf, 2003 #117}, and Runciman {, 2002 #118}

Investigation	5 - 6 (1 FTE per 100-200 investigations)	
Data analysis and validation		$200,000 - $675,000

SOURCE: Rosenthal et al. (2001). Notes: 1)FTE= full time employees ; 2) Assumes underlying system in place.

7.5.3. Reporting obligations and administrative burdens

A number of measures are proposed which require procurement as well as transplantation centres to submit information during the transplantation progress and to report on their activities. These obligations might be considered as administrative burden for hospitals[66]. For the proposed policy action the total administrative costs and in particular the additional administrative burdens, seem however to be small. [67] . This is due to a number of reasons:

- The affected population of institutions, i.e. hospitals and transplant centres is very small. There are around 300 transplant centres with a total of around 760 transplant programmes across Europe, and procurement takes place in a selected sample of hospitals (e.g. only 45% of hospitals with ICUs in Germany = 613).

- The total case load is relatively low, with a total number of currently around 27,000 transplantations performed in the European Union.

- As shown above, most Member States capture most of the information required already, so the costs for additional information gathering can be expected to be very low. Administrative burdens might even be reduced if the European Union proposals lead to more standardised reporting systems.

7.5.4. Treatment costs

Treatment costs, defined as the costs of transplanting an organ and the follow up costs of transplantation aftercare and long term immunosuppressive therapy, arise directly from the availability of organs. Thus, these will only change if the policies are successful in achieving increased donation and transplantation rates. In assessing treatment costs, it is important to consider the net impact on treatment cost. In most cases a kidney transplant replaces dialysis treatment, and

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66 European Commission (2005).

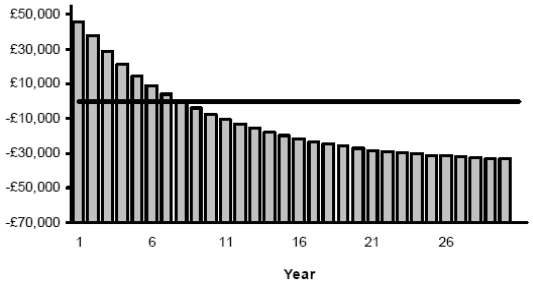
67 "A back of the envelope" calculation, which would assume 10 hours of total reporting time per transplantation at a specialist salary of around € 100,000 would result in total administrative burden of € 13 million for the whole EU 27.

although there is limited data on which to base any estimate of cost savings that may follow transplantation of the liver, heart or lung, there is some evidence that the care of patients with life-threatening organ failure (e.g. liver failure) may involve many days or weeks of in-hospital care, including significant time in intensive care (very expensive) that would be avoided if transplantation had taken place.

There exists a wide body of literature around the cost-effectiveness of transplantations. For all organs, in particularly kidneys, transplantation has been shown as cost-effective - only in lung transplantation is there some ambiguity.[68]

Next tables list some of the international findings on the cost effectiveness of kidney transplantation versus dialysis over the lifetime of a patient in a number of OECD countries. In all countries, transplantation is cost-effective as compared to dialysis treatment.

Cumulative cost effects and net savings from a 50% Increase in Organ Donation in a One Year Cohort of Patients Assessed Over 30 Years (discount rate of 3.5%)

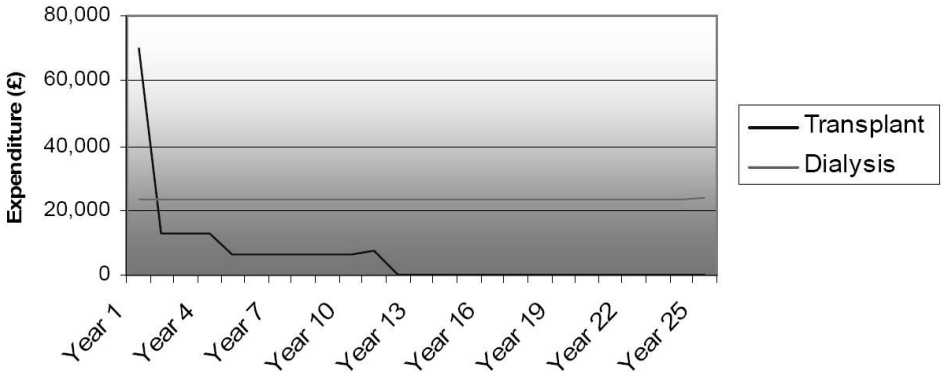


Cost component	Net cost, £000s	
	Undiscounted	Discounted
Kidney transplants	-£109,754	-£73,952
Liver transplants	£29,740	£23,816
Heart transplants	£8,909	£7,694
Lung transplants	£8,293	£8,044
Donation	£993	£993
All	-£61,819	-£33,405

SOURCE: Department of Health (2008b)

Figure 7.1: Cumulative cost effects and net savings from a 50% Increase in Organ Donation in a One Year Cohort of Patients Assessed Over 30 Years (discount rate of 3.5%)

68 This section draws in particular on the findings of the Organ Donation Taskforce in the UK, which analysed British and international health economic literature. See Department of Health (2008b)..



SOURCE: Department of Health (2008b)

Cost profile of transplant versus dialysis in 2006 UK prices

Table 07. Lifetime costs of transplant versus dialysis in industrialised countries

Table 7

Country	Kidney Transplant Cost (£)	Dialysis Cost (£)	Difference (£)	Reference
US	260,106	430,498	170,391	Yen et al. (2004)
Canada	246,022	332,425	86,403	Whiting et al. (2004)
Germany	168,589	272,406	103,816	Roels et al. (2003)
Hungary*	86,036	133,646	47,609	Kalo et al. (2003)
Japan**	44,231	-		Nakajima et al. (2001)

Note: All costs are uplift and converted into 2005/6 prices in British Pounds.

* Denotes the first three years of transplant only.

** First two years post transplant

SOURCE: Department of Health (2008b)

Despite substantial costs, the study conducted by the Organ Task Force concluded that liver and heart transplantations are cost effective, while the lung transplantation is on the edge of cost-effectiveness. Next table gives an overview of the cost effectiveness of liver, heart and lung transplants based on studies conducted in the Netherlands

Cost effectiveness of liver, heart and lung transplants. Source: Department of Health 2008

	DHCIB	Ouwens[69]	
	ICER ($)	QALY gain	ICER ($)
Liver	25,600	11.5	31,000
Heart	36,900	6.8	46,000
Lung	61,000	5.2	61,000

7.5.5. Productivity impacts

Besides the impact of treatment costs, organ transplantation can contribute to the economic performance of a country, by keeping people in the workforce or by allowing them to participate in the economy where they could not do so previously. Employment rates after kidney transplantation range from 18% to 82%, whereas for heart lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants[70] and 39% for thoracic organs.[71]

7.5.6. Economic impacts on living donors

When donating their organs, living donors not only expose themselves to an increased risk of mortality and morbidity, but might also incur a negative economic impact. These impacts arise from direct costs, such as non-reimbursed health care costs as well as indirect costs, such as losses of income due to extended hospital stays. A recent systematic review demonstrates however the current difficulties in producing a reliable overall cost impact.[72]

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69 Ouwens, et al. (2003).
70 Saab, et al. (2007).
71 Petrucci, et al. (2007).
72 Clarke, et al. (2006).

8. COMPARING THE OPTIONS

8.1. Four scenarios of future transplantation rates

Four scenarios were developed to define the scope of possible impacts of the policy options. The scenarios allow the policy makers to assess the range in which possible impacts would occur. For more detail please see the summary of the scenarios in the methodology section of Annex III:

The key scenario assumptions are the donation rates. The following section provides a more detailed rationale behind the choice of this key assumption.

- Scenario 1 assumes that all Member States achieve the transplantation rate of the best performing European Country. This means, all Member States achieve Spanish transplantation rates from deceased donors, and Norwegian rates for living organ donation. This scenario defines the outer boundary of the benefits and costs that can be expected from implementing the policy proposals.

- Scenario 2 assumes all countries achieve at least the EU average transplantation rates. This is a less ambitious scenario, as it assumes that in particular low performing countries could improve their transplantation activities, while the above average performers maintain their current levels, even if they are still well below the Spanish levels.

- Scenario 3 assumes an across the board increase of 30 per cent. The 30 per cent would be a substantial increase, yet a conservative estimate of the effect of changes in the organisation of organ donation. Indeed, much higher increases have been reported from a wide range of measures in a wide range of Member States:

    - The Spanish reforms led to an increases in donation rates of 130% over a 10 year period (Miranda et al. (2003)

    - The introduction of transplant coordinators lead to 132% increase in transplantation rates between 2001 and 2005 in Greece. The consolidation and professionalisation of the transplant coordinator network in 2005 lead to an increase of 38 per cent alone between 2004 and 2005 (Karatzas et al., 2007) .

    - The implementation of the Donor action programme in 12 hospitals in Finland lead to an increase of 59% in organ retrievals.[73]

[73] see Donor action Facts and Figures Donor Action website www.donoraction.org accessed on 30 April 2008

- By introducing the Spanish Model, the Italian region of Tuscany doubled their donation rate in the space of only one year (Simini, 2000).

Still, this scenario is likely to overestimate the gains that can be achieved in the already good performing Member States, but is a very realistic estimate for the low performing countries.

- The assumption for Scenario 4 is based on the same evidence, but an even more conservative estimate by assuming only a modest increase of 10% for all countries.

The next table provides an overview of these assumptions and the actual transplantation rates used. We suggest that Scenario 2 and Scenario 4 in particular are realistic and achievable for European Member States.

Key Scenario assumptions

Transplant rate assumptions	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Description	All countries achieve the transplantation rate of the best performing country*	All countries achieve at least European average transplantation rates	All countries improve their transplantation rate by 30%	All countries improve their transplantation rate by 10%
Transplantations from deceased donors				
Kidney, from deceased donors	At least Spanish rate 46 pmp	At least European average: 29.1 pmp	+30%	+10%
Liver, from deceased donors	At least Spanish rate 23.1 pmp	At least European average: 12.3 pmp	+30%	+10%
Heart	At least Spanish rate 6.1 pmp	At least European average: 4.3 pmp	+30%	+10%

Lung	At least Spanish rate 3.8.pmp	At least European average: 2.5 pmp	+30%	+10%
Transplantations from living donors				
Kidney, from living donors	At least Norwegian rate 17 pmp	At least European average: 5.4 pmp	+30%	+10%
Liver, from living donors	At least Spanish rate 0.4 pmp	At least European average: 0.5 pmp	+30%	+10%

*If national rates are higher, the higher national rate is maintained for these countries.

The four scenarios give an impression of the number of additional transplanted organs that could be achieved. In the best case Scenario 1, an additional number of 21,000 organs would be transplanted, while a ten percent increase across all Member States (Scenario 4), would still generate an additional 2,636 transplanted organs a year.

Changes in number of transplanted organs under different scenarios

Organ type	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Transplantations from deceased donors				
Kidney, from deceased donors	8,250	1,940	4,261	1,420
Liver, from deceased donors	5,276	1,347	1,803	601
Heart	928	432	626	209
Lung	789	365	361	120
Transplantations from living donors				

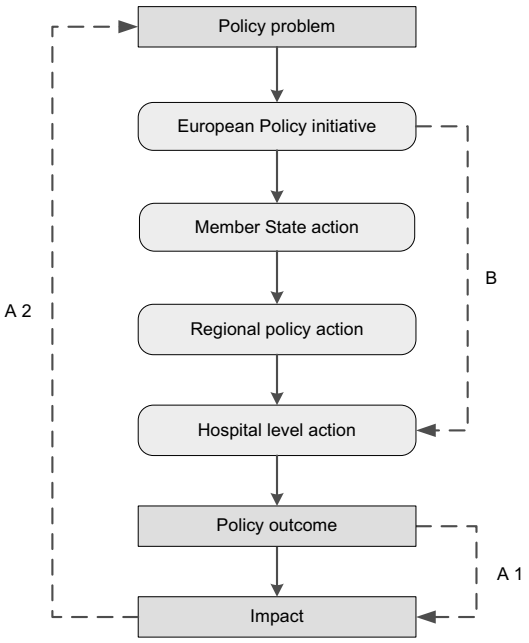
Kidney, from living donors	5,712	830	785	262
Liver, from living donors	50	70	71	24
Total				
Total additional transplanted organs	21,006	4,983	7,908	2,636

8.2. Scenarios and policy options

In assessing the impacts of the policy options, different scenarios were used to assess the potential scope of impact of different policy options. The reasoning for this was as follows**:**

(1) The causal chains between the proposed policy options and the desired outcome are very long, and outcomes are dependent on a diversity of intervening factors. This creates substantial difficulties in assessing the impacts of a single policy intervention. This holds particularly true for the organ donation and transplantation rates, which depend on a multitude of different factors, which not all are addressed in the policy options. In contrast, the proposals focus mostly on the organisation of the national transplant system as a key driver of organ donation. This multitude of causal factors is of particular importance, as we are assessing future policy impacts. Next figure illustrates this uncertainty as link “A 1” between policy outcomes and actual impacts and as the link between policy impacts and policy problem. Even if the desired policy outcome has been achieved, it is uncertain, whether this will achieve the desired impacts and whether these in turn will help tackle the policy problem identified at the outset of the policy initiative.

(2) Secondly, and centrally to this impact assessment, the multi-level governance character of the organ donation and transplantation systems make policy outcomes more uncertain. Improvements of organ donation and transplantation systems are delivered at the hospital level, while the proposed policy action contain policies which will first have to be transposed into national legislation and be implemented by the Member States and have to be supplemented by the Member States through investment in infrastructure and personnel, and which often have to be channelled through regional structures as well. Given the voluntary approach of Option 2 and the discretion in implementation for Option 3 and even for Option 4, there is some uncertainty in how European action would actually reach hospitals level.



(3) To overcome these difficulties in assessing potential impacts, the report compared the policy options to similar policies that have been implemented in Member States. An obvious choice for such a comparison is the Spanish Model, which demonstrated that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates.

(4) The results of this comparison are presented in section 7.3 in the table which shows that in particular policy options 3 and 4 contain most of the important elements of success of the Spanish model.

(5) This comparison was used to define the maximum effect that could be achieved by improving the organisation of organ donation processes. The assumption made was: “If all Member States would be fully committed to implement the European policy options, they could achieve Spanish transplantation rates”. This is Scenario number 1.

(6) As this is however a somewhat overly optimistic scenario, The IA also used three scenarios that assume a somewhat more modest increase: to the European average rate, and by 10% and 30% respectively.

(7) The uncertainty in implementation of high level European Policy options creates however uncertainty on the actual effect of the policy options This has been reflected in the table below . The policy options need to meet the commitment and capacity of member states to achieve their full potential, which is reflected in the ranges for each policy option.

Scenarios and policy options

Key element	Option 1: Baseline	Option 2: Action Plan	Option 3: AP + flexible approach*	Option 4: AP + stringent directive*
Low commitment and or low capacity Member States	No increase	No substantial increase	Modest increase (Scenario 2 and 4)	Modest increase (Scenario 2 and 4)
High commitment and sufficient capacity of Member States	No substantial increase anticipated	High increase (Scenario 1 and 3)	High increase (Scenario 1 and 3)	High increase (Scenario 1 and 3)

(8) The key differences between the options is, that Option3 and 4 make some changes mandatory, and which are thus more likely to occur than voluntary changes in Option 2.

As discussed earlier, the impact of each policy option not only depends on the proposed policy measures, but also on the approach to implementation by Member States and the capacity of health care systems in the Member States.

Taking into account the findings from benchmarking the policy options against the Spanish model, we can nevertheless try to assign different degrees of change to each policy option. For Option 1, the continuation of the status quo, with no or only incremental increases of organ donation rates across the European Union can be expected. However some Member States will continue with their already existing efforts to implement good practice. Option 2 might lead to a high increase in organ donation rates, if Member States are committed to implementing the rather general elements of the Action Plan. As these are largely voluntary, no substantial effect can be expected when there is a lack of commitment from the Member States or Member States reach their capacity limits. Thus, achieving a substantial increase in organ donation rates for Option 2 is related to high levels of uncertainty.

Options 3 and 4 are likely to increase organ donation rates at least modestly, even if Member States are not fully committed and/or should have insufficient capacities as they prescribe key elements and make national implementation mandatory. In turn, if capacity is sufficient and Member States' commitment is high, higher increases in organ donation rates are possible. We have used Scenarios 1 and 3 to define the upper boundaries of what could be achieved under these circumstances, while Scenarios 2 and 4 can be seen as the lower boundary of expected increases in transplanted organs.

For Option 4, a less positive outcome is conceivable, which has not been covered by the benchmarking exercise. If the stringent directive is very prescriptive and Member States 'gold plate' the European directive by adding more requirement and complexity, the directive may create disincentives for some establishments to participate in organ procurement and thus reduce the organ donation rate. Most of the stakeholders interviewed for this research expressed the concern that, if the directive were to be modelled along the lines of the EU Tissues and Cells Directive, organ donation would be disrupted. Several of the expert respondents provided anecdotal first-hand experiences of the negative impact of the EU Tissues and Cells Directive as a warning of the risk of a similar outcome of a stringent directive for organs modelled on the it.

8.3. Comparing the options against the Spanish model

The Spanish Model is widely acknowledged as an outstanding example of how organisational changes of the transplantation system can increase the number of available organs. The comparison shows that the policy options address most of the key features of the Spanish Model.

Previous efforts to adopt the Spanish model in other countries, in particular in Italy and South America, show that the Spanish Model could be totally or partially replicable in other countries, but its effectiveness depends on a number of conditions. [74]

The Table below provides an overview of the comparison of the policy proposals taking into account the key elements of the Spanish model. The comparison shows that the policy options address all but one of the key features of the Spanish Model. The issue of reimbursement of procuring hospitals is not touched on by any of the policy options, although interviewees pointed out that reimbursement of hospitals might be an important factor to get small hospitals to participate in organ procurement.

Table 8.1: Benchmarking the policy option against the Spanish Model

Key element	Option 1: Baseline	Option 2: Action Plan	Option 3: AP + flexible approach*	Option 4: AP + stringent directive*
Transplant Coordinators and coordinating teams in each hospital	Variable within and across MS	All MS to "promote the role of transplant donor coordinators in hospitals"	All MS to "promote the role of transplant donor coordinators in hospitals"	All MS to "promote the role of transplant donor coordinators in hospitals"
Reimbursement of hospitals to recover	Variable across MS.	n.a.	n.a.	n.a.

[74] Matesanz (2003).

procurement costs				
A Quality Assurance System (or Programme) in all Autonomous Communities, with two stages of evaluation	Variable within and across MS	All MS to (1) "[p]romote quality improvement programmes in every hospital where there is a potential for organ donation, which is primarily a self-evaluation of the whole process or organ donation, aiming to identify areas for improvement"; and (2) "evaluation of post transplant results"	Legal mandate for (1) Quality programmes, including quality systems and quality standards in all MS; and, (2) inspections and control measures, subject to MS decision-making/ implementation	Legal mandate for Quality programmes, including quality systems and quality standards in all MS and (2) inspections and control measures, directed by the EU Commission
Adequate training for transplant coordinators and personnel involved in organ donation and procurement	Variable within and across MS	Promotion of the Implementation of effective training programmes for transplant donor coordinators	Legal mandate for Personnel/ Training in all MS, subject to MS decision-making/ implementation	Legal mandate for Personnel/ Training in all MS, directed by EU Commission
Public awareness and proactive management of mass media opportunities.	Variable within and across MS	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"	All MS to "[i]mprove knowledge and communication skills of health professionals and patient support groups on organ transplantation"

*In addition, all actions foreseen under the Action plan will be implemented

Overall, we can conclude that the policy proposals contain considerable elements of the Spanish model, but implementation will not necessarily lead to a similar model given the latitude in implementing the regulations. As discretion for Member States is lower in Option 3 and Option 4, and as these prescribe more key elements of the Spanish model, a better outcome on the donation rate can be expected.

8.4. Comparing the options according to their health, social and economic impacts

A detailed comparative table by policy option is provided in Annex VII. This section synthesises that table and the previous chapter and compares the four policy options according to their health, social and economic impacts[75]. First, we introduce a scoring mechanism[76], secondly we compare health, social and economic impacts; and thirdly distributional aspects are considered before the best policy option will be identified.

8.5. Health Impacts

The key health impacts emanate from an increase in donation rates and reduced risks to patients. The policy options are likely to increase donation rates in Europe. In addition, the policy options are likely to increase cross border exchange of organs, which results in clear health benefits for paediatric, highly sensitised and urgent patients.

Option 1 would not change the current unsatisfactory status quo, with diverging quality and safety standards across Europe, an undeveloped potential for cross border exchange of organs and no link between the tissue and cell vigilance system and organ donation. Option 2 can create substantial health gains though increases in donation rates. These gains could range normally from 0-113.000 QALYss gained. Nonetheless these increases are uncertain as the option allows for a high level of discretion in national implementation, therefore an estimation

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[75] This scoring method assesses each option according to its impact in comparison to the current policy regime, which is used as the baseline of our assessment. Thus, a policy option which maintains the status quo will be scored as no change in benefits or costs. In addition, this scoring system allows us to rank the policy options across the impact categories.

[76] To overcome difficulties in quantifying the impacts, we decided to employ a framework for comparison, which combines a basic multi-criteria analysis along the impact categories previously identified with a scoring mechanism. This approach allows us to compare the policy options by using at least some kind of "standard measure", without loosing the richness of the qualitative assessment. The framework summarises the evidence, discussed in the previous chapters, the likely impact of each policy option and attributes a certain assessment of the impacts to each policy options. We used the following scoring system:

++ Evidence of substantial additional health /economic/ social benefits compared to the status quo

\+ Evidence of some additional health /economic/ social benefits compared to the status quo.

≈ Evidence of no additional health /economic/ social benefits compared to the status quo.

\- Evidence of some reduction in health /economic/ social benefits compared to the status quo.

-- Evidence of substantial reduction in health /economic/ social benefits compared to the status quo.

? There is no available evidence to assess changes in health /economic/ or social benefits compared to the status quo.

of 60,000 QALYs. Option 2 will not have an impact on the quality and safety of organs, but will remove disincentives to become a living donor by ensuring access to health care for living donors, without however including provisions for eventually necessary social care.

Option 3 and 4 supplement Option 2 through legal standards and will have a more certain effect on donation rates to the degree that positive changes will become mandatory. It is likely that this option ensure at least a modest increase of 2.600 organs transplanted can be achieved, resulting in 39.000 saved life years or 37.000 more QALYs, we can assume that the average on QALYs gain will be superior, around 90.000 QALYs. In addition, Option 3 and 4 will establish common quality and safety standards across the European Union, which will reduce risks to patients and stimulate cross border exchange of organs.

However Option 4 in turn ensuring a stringent quality and safety standards across Europe might lead to substantial difficulties in implementation for the facilities, the need to implement strong quality system could disincentive small and medium hospitals, it might even have a negative impact on donation rates for some facilities due also to restriction on the use of expanded donors for particular patients

Thus Option 3 and 4 have the highest positive health impacts of the four options assessed.

8.6. Social impacts

Increased organ transplantation will result in positive social impacts for organ recipients and donor families. Evidence shows that transplantation of organs increases the possibilities for patients to participate in social and working life. In general, organ transplantation has a positive effect on the Quality of Life of organ recipients. Thus, the different options will generate additional social benefits, depending on the additional transplantations achieved from increased donation rates.

European action can be expected to contribute to increased trust and confidence in the organ donation and the transplantation system, by establishing common quality and safety standards, increasing public awareness, and improving processes to deal with relatives of deceased donors. However, the available evidence on such social impacts as social participation and improved standards of living does not allow for an adequate assessment of the precise impact to compare the options.

Given the social impacts of increasing donation rates and the importance of having more robust donation and transplantation processes, we would expect the highest social benefits from option 3 and 4, which increase donation rates with higher certainty and are more likely to enforce standards of good processes.

8.7. Economic Impacts

The analysis of the policy options suggest that Options 2 to 4 can lead to substantial economic benefits across the European Union, although Member states will have to invest in the national infrastructure of organ donation and the improvement of processes to realise these gains. However, the evidence does not allow for producing detailed cost estimates for Member States. The economic benefits arise primarily from saved treatment costs as transplanted kidneys replace dialysis treatment. Scenarios developed by RAND Europe see a potential of saving up to €1.2 billion Euro in treatment costs, and reaching productivity gains of up to €2.4 billion.

Policy Option 1 continues the *status quo* and is expected to create no additional costs or economic benefits. Option 2 could generate substantial economic benefits of up €1.2 billion savings in treatment costs and an additional productivity impact of €3.6 billion at low costs for process and infrastructure improvement. Due to the voluntary nature of the Action Plan, it is recognised that the impacts are highly uncertain because the extent of implementation by Member States is unknown.

Policy Option 3 combines the Action plan with a flexible directive. Option 3 will lead to substantial costs to implement national registers, reporting activities and a national vigilance system. However, due to the mandatory character of the option, we see cost savings and productivity to occur under less uncertainty, at a range between €132 million and €1.2 billion for cost savings, and €460 million and €2.4 billion for productivity impacts. Finally, Option 4 is expected to bring the same economic benefits as Option 3, however at higher implementation costs, as Member States have less freedom to use existing systems and devise tailor-made national solutions.

Impact on the EU budget

Option 2, proposes the establishment of a European Action Plan on Organ Donation and Transplantation. This approach will be based on a cooperation mechanism between Member States based on national action Plans. Through this option further initiatives and projects will be funded under the Public Health Programme while the current projects will continue. Resources will be reserved in the Public Health Programme to secure continuity and consistency in promoting actions and coordination in the field. Under this Option certain meetings (expert group meetings and small preparatory meetings) will also have to take place in order to help Member States coordinate their activities. A far as human resources are concerned, it is estimated that one EU official working full time will be required for this option.

Option 3, entails the costs of all the above coordination activities required under the Action Plan plus those of the Directive. More precisely a larger amount of meetings with national representatives will be required. Once the Directive is adopted Regulatory Committee Meetings will have to take place as well as

Comitology Meetings. Moreover, as far as human resources are concerned, one and a half (1.5) EU officials will be required.

Since the Directive under Option 4 will be modelled after the Tissues and Cells Directive, it will contain detailed regulation thereby demanding more resources. Option 4 therefore will require more Regulatory Committee Meetings and even more Comitology Meetings since a lot of its aspects will have to be decided in Comitology. Given its detailed regulatory nature, the Directive under Option 4 will require two EU officials working full time.

Box 2 : Results of the capabilities approach – comparison of options

We have concentrated on comparing the Action Plan (AP) with the Action Plan plus Flexible Directive (AP+D). The Baseline scenario cannot be the preferred option since there are clear net benefits to actions at the European level, while the stringent Directive does not seem to meet the subsidiarity test. The AP+D yields higher returns on all relevant capabilities. The QALY differences (a measure of health and standard of living effects) between the two options are due to indirect effects caused by enhanced feelings of safety and quality of social interactions, an indirect but crucial (though difficult to quantify) impact since it implies that more donors are available in the future. There are also direct effects on other capabilities that are in favour of the Directive. The safety capability has appeared as highly relevant for policy proposals on organ donation by itself.

The analysis of cost, albeit it rather crude, shows that both proposals seem to be cost effective. Nonetheless, whether the gains stemming from the Directive outweigh costs depends on the extent to which total costs should be attributed to the Directive, on which we have insufficient information yet.

As already mentioned above the following Tables provide a comparison between each of the 3 assessment criteria and the four policy options.

A detailed comparative table by policy option is provided in Annex VIII.

Table 8.2 Comparison of the Health impacts of proposed policy actions

Intervention	Option 1: Baseline		Option 2: Action Plan		Option 3: AP + flexible approach		Option 4: AP + stringent directive	
Donation rates	Donation rates will continue to be too low to meet rising demands for organs; thus leading to growing waiting lists	≈ to -	Depending on Member State commitment, zero to substantial increases are possible: 0 to between 7,908 and 21,006 organs	≈ to ++	Medium to high increase possible: Lower estimate 2,636 and 4,983 Upper boundary between 7,908 and 21,006 organs	+ to ++	Medium to high increase possible: Lower estimate 2,636 and 4,983 Upper boundary between 7,908 and 21,006 organs	+ to ++
QALYs and life years saved	No major change expected, but longer waiting lists and waiting times might reduce the medical outcomes of transplantation	≈ to -	Estimates of donation rates will lead to: Lower predictions show no major change Up to of 119,314 to 231,006 life years saved Up to 113,348 to 219,456 QALYs gained	≈ to ++	Estimates of donation rates will lead to: Lower estimate of between 39,771 and 54,320 life years saved Lower estimate of between 37,783 and 51,604 QALYs gained Up to of 119,314 to 231,006 life years saved Up to 113,348 to 219,456 QALYs gained	+ to ++	Estimates of donation rates will lead to: Lower estimate of between 39,771 and 54,320 life years saved Lower estimate of between 37,783 and 51,604 QALYs gained Up to of 119,314 to 231,006 life years saved Up to 113,348 to 219,456 QALYs gained	+ to ++
Risk to patients	No changes to the currently diverse regulatory landscape of quality and safety standards	≈	- Better knowledge about organ transplantation outcomes will improve future transplantations for patients	+	Common quality and safety standards will ensure equal health protection in all Member States Adverse event reporting systems will improve the quality of donation and transplantation	++	Common quality and safety standards will ensure equal health protection in all Member States Adverse event reporting systems will improve the quality of donation and transplantation	++
Living donation	No change expected	≈	Will encourage more living donation; May increase the knowledge about medical outcomes; Increases trust in system	+	Legal standards will supplement the measures under the action plan and make them less uncertain to occur	+	Legal standards will supplement the measures under the action plan and make them less uncertain to occur	+
Health benefits of cross border exchange	Currently only very few are organs exchanged outside Eurotransplant and Scandiatransplant area, but there is a potential for substantial health benefits	≈	Improved processes and the removal of barriers to exchange of organs can increase exchange of organs and benefit small MS and difficult to treat patients	+	Common quality and safety standards will supplement the measures under the action plan which can increase organ exchange and make it safer	+	Common quality and safety standards will supplement the measures under the action plan which can increase organ exchange and make it safer	+
Health Inequalities	Evidence suggest health inequalities in the practice of organ transplantation and donation along lines of gender, ethnicity and certain specific diseases	≈	Health inequalities are not addressed by this policy option	≈	Health inequalities are not addressed by this policy option	≈	Health inequalities are not addressed by this policy option	≈

"++" substantial health benefit; "+" some health benefit; "≈" no substantial health impact; "-" some additional negative health impact; "- -" substantial negative health impact; "?" no evidence

Table Comparison of the Social impacts of proposed policy actions								
Intervention	Option 1: Baseline		Option 2: Action Plan		Option 3: AP + flexible approach		Option 4: AP + stringent directive	
Quality of life	only marginal increases in quality of life	≈	increases through better care for living donors increases through higher number of transplantations	+	increases through legally prescribed better access to care for living donors increases through higher number of transplantations reaching at least minimum improvement	++	increases through legally prescribed better access to care for living donors increases through higher number of transplantations reaching at least minimum improvement	++
Social participation and employment	Continuation of status quo, end stage organ failure limiting the possibilities for patients for social participations	≈	Does not address obstacles to social participation and employment for the individual Might increase overall social participation through an increase in transplanted organs	(+)	Does directly not address obstacles to social participation and employment (absence of quantitative data) Might increase overall social participation through an increase in transplanted organs	(+)	Does not address obstacles to social participation and employment for the individual Might increase overall social participation an increase in transplanted organs	(+)
Trust and Confidence in transplantation system	Very different refusal rates and willingness to donate rates across Europe will continue	(≈)	Better training of transplant coordinators might increase confidence of donor families Public awareness campaigns might increase trust and confidence	(+)	Better training of transplant coordinators might increase confidence of donor families Quality and safety standards might increase perception of patient safety and empower patients Public awareness campaigns might increase trust and confidence.	(+)	Better training of transplant coordinators might increase confidence of donor families Quality and safety standards might increase perception of patient safety and empower patients Public awareness campaigns might increase trust and confidence.	(+)
"++" substantial social benefit; "+" some social benefit; "≈" no substantial social impact; "-" some additional negative social impact; "- -" substantial negative social impact; "?" no evidence								

Table Comparison of the Economic impacts of proposed policy actions

Intervention	Option 1: Baseline		Option 2: Action Plan		Option 3: AP + flexible approach		Option 4: AP + stringent directive	
Costs for national infrastructure and better processes	Status quo will continue at no additional costs	≈	Low to medium costs for voluntarily investing in more transplant coordinators; Low to medium cost for voluntary measures to designate or accredit establishments	-	No to very low cost for setting up competent authorities Low to medium costs for designating or authorising establishments Medium costs for running national quality systems	-	No to very low cost for setting up competent authorities High costs for applying standardised accreditation system Medium to high costs through mandatory, legal quality system at hospital level	--
Costs for setting up and running national registers and traceability systems	Status quo will continue with separate, incompatible reporting systems	≈	Possible cost saving through standardised reporting of medical outcome information	+	No to very low costs for establishing a national register of establishments Medium to high costs of introducing or adapting national traceability and adverse event reporting systems	-	No to very low costs for establishing a national register of establishments High costs for introducing a standardised European traceability and adverse event reporting systems	--
Reporting obligations and administrative burden	Status quo would continue with already extensive data collection through international bodies	≈	Low cost of reporting requirements under the OMC, would result in small burden for Member States	-	Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	-	Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	-
Treatment costs	Status quo, with possible increasing long term costs if waiting times increase	≈	Savings in treatment costs between € 458 million and € 1.2 billion possible for best case scenario, if MS commit themselves fully	≈ to ++	Savings of € 132 million and € 152 million as a result of modest increase in donation rates, Savings of € 458 million and € 1.2 billion in the best case scenarios	+ to ++	Savings of € 132 million and € 152 million as a result of modest increase in donation rates, Savings of € 458 million and € 1.2 billion in the best case scenarios	+ to ++
Productivity Impact	Status quo, loss of productivity if more people have to wait longer for an organ	≈	Potential productivity impact of between € 1.3 billion and € 2.4 billion under best case scenario, no gains if Member State commitment is low	≈ to ++	Productivity gains of € 460 million and € 882 million as a result of modest increase in donation rates, Productivity gains of € 2.6 billion and € 5 billion for best case scenarios	+ to ++	Productivity gains of € 460 million and € 882 million as a result of modest increase in donation rates, Productivity gains of € 2.6 billion and € 5 billion for best case scenarios	+ to ++
Economic Impact on Living donor	Living donors are currently exposed to economic risk through need for health care and loss of income in case of reduced ability to work.	≈	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+	Option will reduce the economic risks related to health care Option does not tackle other economic risks	+

"++" substantial economic benefit; "+" some economic benefit; "≈" no substantial economic impact; "-" some additional economic cost; "- -" substantial additional economic cost; "?" no evidence

9. DISTRIBUTION OF COSTS AND BENEFITS

It is also important to assess how these impacts would be distributed between different groups of stakeholders. The stakeholder groups which would most likely be affected by the policy proposals are as follows:

(1) Patients

(2) Difficult to treat patients

(3) Living donors

(4) Families of deceased donors

(5) Member States authorities

(6) Hospitals

(7) National health services and insurance

(8) Member States with developed donation and transplantation systems

(9) Member States with less developed transplantation systems

Patients with end stage renal, liver, heart or lung disease and other diseases requiring transplantation of an organ are naturally one of the key stakeholder groups, and they will be a key beneficiary of actions. Currently there are around 50,000 patients in Europe waiting for an organ transplant. Option 2, 3 and 4 are likely to increase transplantation rates and will thus benefit this group substantially by increasing life expectancy and quality of life for those who receive transplants.

For difficult to treat patients, i.e. urgent, paediatric or highly immunised patients, which either need a suitable organ very quickly or which need an organ with very specific characteristics; benefits will be even greater, as increased border exchange increases the donor pool and thus the likelihood of finding a suitable organ in time. These benefits are higher for Option 3 and 4, nevertheless, difficult to treat patients will benefit from all European policy action. Given the importance of the size of the donor pool, patients in small Member States will have even higher benefits than those in large Member States, because they will gain access to more suitable organs.

Better knowledge about medical outcomes of living organ donation will benefit living donors across the European Union under Policy Option 2. In addition, Options 3 and 4 would increase benefits by ensuring access to health care for living donors; thereby reducing some of the associated economic risks

The families of deceased donors have a substantial influence on donation rates by allowing or refusing the donation of their deceased relatives' organs. The analysis of social impacts shows that all three policy measures could help improving the care for donor families during the donation process by improving transplant coordinators skills. This could not only benefit transplantation rates, but also increase the families' trust and confidence in the transplantation system.

Member State authorities have to transpose and implement the proposed policy measures and adjust their organisational structures to meet the requirements of the European policies to be put in place. This will involve in any case some costs for Member States' authorities. As discussed earlier, such costs will vary between options, with Option 2 involving the least and Option 4 the highest costs.

Hospitals are involved in the donation process as procurement and/or transplantation centres and are thus directly affected by the policy proposals. Indeed, as they have a crucial role in the donation and transplantation pathway, they are the target of the policy measures proposed. Costs would increase for hospitals, through increased procurement activities, through administrative burdens related to reporting, and finally through the implementation of quality programmes, including staff training, at the hospital level. These increases will be strongest for policy Option 4, and least for Option 2. However, hospitals could be compensated for these costs and procurement costs could be adequately reimbursed as in the Spanish model. Assessing these net impacts was however beyond the scope of this research.

National health services or the national health insurances, which are responsible for financing medical treatment, stand to substantially gain from the policy proposals. Every kidney transplanted generates a net saving in treatment costs for health care providers saving money for dialysis treatment. Policy Option 2 would achieve these savings under higher uncertainty, while Policy Option 3 and 4 make these savings more likely to occur.

Due to the cross-national differences in transplantation rates and the development of transplantation systems it is useful to distinguish between Member States with developed donation and transplantation systems and Member States who have not yet, or only recently started, to develop robust donation and transplantation systems.

For Member States with less developed systems, we expect both benefits as well costs to be higher than for Member States who have already well established systems. This is due to two main factors. Firstly, increasing donation rates will be much easier to achieve from a low baseline; secondly less developed states will be much more likely to have to invest in expanded infrastructure and robust donation and transplantation processes.

Table 7.1 provides a more detailed overview of this discussion by comparing the different options along their impacts on the identified stakeholder groups

Table Distribution positive and negative impacts							
Intervention	Option 1: Baseline	Option 2: Action Plan		Option 3: AP + flexible approach		Option 4: AP + stringent directive	
Patients	No change	Option can increase donation rates, but high uncertainty Increased cross border exchange benefit particularly patients in small Member States	≈ to ++	Option will increase donation rates Increased cross border exchange will benefit patients in small Member States	+ to ++	Option will increase donation rates Increased cross border exchange will benefit patients in small Member States	+ to ++
Difficult to treat patients	No change	Removal of barriers for organ exchange will benefit difficult to treat patients in particular	+	Removal of barriers for organ exchange and common quality and safety standards will benefit difficult to treat patients	++	Removal of barriers for organ exchange and common quality and safety standards will benefit difficult to treat patients	++
Living donors	No change	Better knowledge about living donation allows for better care of living donors pre and post transplantation	+	Better knowledge about living donation allows for better care of living donors pre and post Tx. Option ensures long term access to health care for living donors	+	Better knowledge about living donation allows for better care of living donors pre and post Tx. Option ensures long term access to health care for living donors	+
Donor families	No change	More and better trained coordinators will have better skills in supporting grieving relatives	+	More and better trained coordinators will have better skills in supporting grieving relatives	+	More and better trained coordinators will have better skills in supporting grieving relatives	+
Member State authorities	No change	Costs for setting up and running a national authority Costs for voluntarily increasing the number of coordinators	-	Medium cost for setting up and running authorisation procedures and national reporting and traceability systems Costs for increasing the number of transplant coordinators	-	High costs for authorisation of establishments and processes High costs for setting up and running authorisation procedures and national reporting and traceability systems	--
Hospitals	No change	Costs of increased procurement activities	-	Costs of increased procurement activities Administrative burden of reporting and traceability systems	-	Costs of increased procurement activities Administrative burden of reporting and traceability systems Costs for quality programme at hospital level	--
National health services/Health insurance	No change	Very substantial savings in treatment costs of up to € 2.4 billion possible, but uncertain.	≈ to ++	Very substantial cost savings, between € 460 million and € 2.4 billion, with less uncertainty than Option 2	+ to ++	Very substantial cost savings, between € 460 million and € 2.4 billion, with less uncertainty than Option 2	+ to ++
Member States with developed transplant systems	No change	Only small increases in donation rates for the highest developed systems likely	≈ to +	Only small increases in donation rates for the highest developed systems likely	≈ to +	Only small increases in donation rates for the highest developed systems likely	≈ to +
	No change	No costs for already well developed systems	-	Low costs for adjusting already well developed systems	-	Potentially high costs, if current system does not comply with new requirements	--
Member States with less developed transplant systems	No change	Very large benefits from increase in donation rates possible	≈ to ++	Very large benefits from increase in donation rates possible Health benefits through new quality and safety standards	+ to ++	Very large benefits from increase in donation rates possible Health benefits through new quality and safety standards	+ to ++
	No change	Costs will be high, as most of the infrastructure has to be developed	--	Costs will be high, as most of the infrastructure has to be developed	--	Costs will be high, as most of the infrastructure has to be developed	--

"++" substantial positive impact; "+" some positive impact; "≈" no substantial positive or negative impact; "-" some negative impact; "- -" substantial negative health impact; "?" no evidence

Box 3 : Results of the capabilities approach – distributional impacts

In terms of distributional impacts, the directive has bigger impact on capabilities in small and undeveloped countries (in terms of organ donation). It is mainly due to the safety and feeling of social justice in undeveloped countries and to health in developed countries. But the cost is not sufficiently detailed to conclude.

As regards, groups of actors, the proposals have of course an impact on the recipients of the organ. But the CA approach draws the attention on the impact on living donor through the feeling of safety and to the family f the donor trough social cohesion

10. IDENTIFYING A PREFERRED OPTION

In weighing the available evidence, Option 3, which combines an action plan using the open method of coordination with a flexible directive creating a European framework regulation for quality and safety, will help to achieve the objectives at the best cost consequence ratio.

The following table show a detailed comparison between option 2 and 3:

	Option 2: Action Plan		**Option 3: AP + flexible approach**
Benefits/advantages	**Health** Exchange of best practices has a potential to increase donation rates, but implementation is highly uncertain. Could save up to 230,000 life years, but effect rather uncertain	+	**Health:** The directive containing key elements of the Spanish best practice model will increase donation rate at least modestly, but substantial increases are possible Would save between 39,000 and 230,000 life years Establishment of common, mandatory quality standards will: reduce risks to patients facilitate cross-border exchange of organs

			Increased cross border exchange benefits in particular vulnerable patients in small countries	
	Economic (Uncertain) Increases in donation rates could lead to savings in treatment costs of up to €1.2 billion and productivity gains of up to €5 billion, possible but uncertain. Option will reduce the economic risks for living donors	+	**Economic** Increases in the donation rates would lead to savings in treatment costs between €132 million and €1.2 billion and Productivity gains between €2.6 billion and €5 billion. Option will reduce the economic risks for living donors	++
	Social Organ recipients will have a higher quality of life	+	**Social** Organ recipients will have a higher quality of life Quality and safety standards increase trust and confidence in Organ donation system	++
Costs/disadvantages	**Health** Health risks for an increasing number of living donors	-	**Health** Health risks for an increasing number of living donors	-
	Economic Low to medium costs for voluntarily investing in more transplant coordinators; Low to medium cost for voluntary measures to designate or accredit establishments Possible cost saving through standardised reporting of medical outcome information Low cost of reporting	-	**Economic** No to very low cost for setting up competent authorities (most MS have a CA already) Low to medium costs for designating or authorising establishments (Most MS do authorise centres already, costs could be around € 10.000 for licensing per establishment (UK example) Medium costs for running	--

	requirements under the OMC, would result in small burden for Member States	national quality systems estimate of €45,000 pmp for Donor action i.e. a European estimate of € 22.5 million) No to very low costs for establishing a national register of establishments (There are only few, already well known establishments) Medium to high costs of introducing or adapting national traceability and adverse event reporting systems Low cost of reporting of activities at transplantation centres. Data can be expected to be readily available	

The least costly option, Option 2, will not be sufficient to create a robust quality and safety framework and thus not help to achieve the third objective. In addition, the potential positive health and economic impacts are more uncertain than for the other two options. Even more so than Option 3 and 4, Option 2 relies on the commitment of Member States to voluntarily change organisational structures, improve processes and invest into organ donation and transplantation.

Option 4 in turn will ensure the most stringent quality and safety standards across Europe, which comes however at the risk of creating unnecessary administrative burden. These requirements fully justified in the case of the tissues and cells[77] field could by creating unnecessary administrative burden disincentive donation activity in small and medium hospitals, while the objective should be to increase the involvement of these actors in the donation process

A strict regulatory approach might lead to substantial difficulties in implementation and might even have a negative impact on donation rates for

[77] Tissues and cells are not life saving treatments in the majority of cases, there is no shortage and are subject to processing and storage for many years in specific establishments. The objective is to ensure that only high quality and safe tissues/cells are transplanted. The shortage of human organs makes it necessary that every organ should be considered for transplantation. The conditions of the recipient should be taken into consideration balancing risks and benefits.

some facilities. In addition, Option 4 can be expected to have the highest overall implementation costs, as even countries with already well established donation and transplantation systems will need to change some of their infrastructure and processes to comply with EU prescriptions. Nevertheless, Option 4 will have also substantial economic benefits through saved treatment costs and the productivity impacts of longer life expectancy.

There is however a clear need to ensure that the conditions of procurement comply with basic quality and safety standards and to designate those procurement sites entitled to carrying out these activities. Option 3 will achieve these objectives tailoring the quality and safety requirements to this particular field. However Option 4 by introducing stringent quality system could disincentive small and medium donation hospitals to carried out these activities.

In addition Option 4, as in the Tissues and cells legal framework, would also include suitability criteria for the donor (including exclusion criteria of donors). In the contrary Option 3 will introduce a new approach by ensuring a complete characterisation of the organ without prejudging the suitability of the donor and therefore respecting the clinical decision that has to take into account the condition of the recipient. This will allow to the transplant team to undertake the appropriate (and full informed) risk assessment.

This approach is key to respecting the use of expanded donors (donors that are not in theory ideal) for specific recipients in waiting list (e.g. very aged donors can be used to aged recipients in particular circumstances). In the contrary Option 4 could restrict the potential of increasing organ donation by diminishing the use of "expanded donors". Option 3 provides the enough flexibility to the transplant team to undertake the appropriate risk assessment and balance it with the potential benefit

Overall, Option 3 will be best suited to achieve the objectives of increasing donation rates, making transplant systems more accessible and efficient and ensuring quality and safety standards. By allowing a certain degree of flexibility for the Member States, this option reduces implementation costs and administrative burden, while at the same time safeguarding minimum quality and safety standards. The introduction of a flexible set of binding requirements on quality and safety will not only cover properly the third objective but also will trigger and stimulate the objectives under the action plan. It is likely to increase donation rates which would result in substantial benefits for patients as well as substantial cost savings for the national health systems.

11. MONITORING AND EVALUATION FRAMEWORK

For the systematic ex-post evaluation of the policy actions, a framework based on a logic model is proposed.

In a **first step**, such a model would map out the European Union's and Member States planned work to achieve the policy objectives. In a **second step** these would be compared against the intended outputs and outcomes of the policy actions. In a **third step** this evaluation would analyse the final impacts of the policy action, taking into account the unintended outcomes of planned work as well as intervening factors beyond the reach of the policy.

The following section will briefly outline the key indicators that could be used for the monitoring as well as the evaluation of policy implementation and outcomes.

The indicators used to monitor progress in increasing organ availability are:

- Number of transplant procurement hospitals
- Number of transplant coordinators per million population
- National Donation rates (living and deceased) (donors per million population).
- Refusals to donate
- National multi-organ donation rates
- Conversion rates of potential into actual donors
- National number of transplant procedures per organ and per million population

The quality and safety of organ transplantation is the second important objective of the European policy. The following indicators could be used to measure progress in ensuring and improving quality and safety of organ donation and transplantation:

- Existence of a national quality programme
- Number of hospitals with quality assurance programs
- National survival rates:

    - For different organs
    - Living and deceased donation
- Numbers of adverse events related to organ quality:
    - Infections
    - Transmission of malignant diseases
    - Organ damage
- Reports to and from the tissue and cell vigilance system

Indicators to measure progress against the objective of enhancing efficiency and accessibility could include the following:

- Number of organs interchanged within the Community and with third countries
- Percentage of organs for difficult to treat patients exchanged across borders
- Number of people on waiting lists
- Mortality while on waiting list
- Access to waiting lists
- Inequality in access to transplantation services at all stages of the donation pathway
    - Gender/Ethnic or minority status/resident /non-resident status/low social economic status/Type of diseases (rare diseases)

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ANNEXES

IMPROVING ORGAN DONATION AND TRANSPLANTATION IN THE EUROPEAN UNION

ASSESSING THE IMPACTS OF EUROPEAN ACTION

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ANNEX I –COMPARATIVE TABLE QUALITY AND SAFETY BY OPTIONS

Quality and safety principles	Base line Option	Action Plan + No Directive	Action Plan + Directive flexible approach	Action plan + Directive stringent approach
Creation of Competent authorities	Most of the Member States have already national organisations in place that are in charge of organ donation. The nature and responsibility of these organisations divers . The Council of Europe will continue its annual meeting with its committee of experts.	It will create a Committee of national experts or designated representatives. However the situation is very different between MS and difficult to find the same level of representation and decision capacity.	It will establish the principle of national authority(ies) which is a basic element in the EU policy already proven effective in the area of blood and tissues and cells; these competent authorities are responsible for the implementation of the quality and safety framework.	It will establish the principle of national authority(ies) which is a basic element in the EU policy; already proven effective in the area of blood and tissues and cell these competent authorities are responsible for the implementation of the quality and safety framework.
Authorisation of activities	There are currently large discrepancies between EU countries in relation with the authorisation of activities.	The Action plan could establish guidelines as the existing ones of the Council of Europe; Experience shows that the implementation of these guidelines differs in different Member States. The action plan could also promote as priority action a common (non binding) accreditation system for organ donation/procurement and transplantation programmes.	This approach will establish a common system for the authorisation of the conditions of procurement + basic European standards. It also will request the authorisation of transplantation centres under national standards. These actions will be complemented with the action plan promoting a common accreditation system for organ donation/procurement and transplantation programmes.	This approach will establish a specific type of authorisation for every hospital and for each of the activities of the process: authorisation of the donation process; this process includes the detection, maintenance, testing and evaluation of the donor; authorisation of the different medical/surgical team; the third one on the conditions for the transport/preservation of the organs, often coordinated by a supra-hospital body and the last one is for the transplantation programmes where the legal framework should be limited to

				establish the need of an authorisation, but under national rules. These actions will be complemented with the action plan promoting a common accreditation system for organ donation/procurement and transplantation programmes.
Register of establishments and reporting obligations	Not in place at the moment The Council of Europe with the support of the Spanish agency (ONT) will continue to produce its annual news letter with activity data. EUROCET project will continue its work with the support of the committee of Competent authorities on Tissues and cells. (register on tissues and cells transplantation)	Not planned under the action plan	This approach will provide a record of the activities, including the number of donors, and the types and quantities of organs procured and transplanted, or otherwise disposed. It will also provide for a publicly accessible register of establishments where procurement or transplantation of human organs takes place.	This approach will require an even more detailed record of activities, including the types and quantities of organs donated, procured, tested, preserved, and transplanted, or otherwise disposed. It will also provide for a publicly accessible register of establishments where procurement or transplantation of human organs takes place.
Donor/Organ risk assessment	Wide variability between Member States The Council of Europe has a guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States	The action plan could promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ	This approach will introduce system of 'organ characterisation' means the collection of the relevant information on the characteristics of the organ and the donor needed to undertake an adequate risk assessment to minimise the risks for the recipient and to optimise the allocation of the organ.	This approach will introduce strengthen requirements related to the suitability of donors of human organs and the screening of donated organs. This implies a detailed technical annex on selection criteria for donors, included exclusion criteria, and testing requirements. The

		donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors	This system implies a European donor data set and a system of transmission of this information. Final decision of the acceptance of the organ is taken by the medical doctor taking into account the information on the characteristics of the organ and the status of the recipient. These actions could be complemented with the action plan could also promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors	final decision on the suitability of donors is given at least partially in the legal framework, status of the donor is not always considered. See directive 2006/17 Annex I-II-III on tissues and cells These actions could be complemented with the action plan could also promote the evaluation of post transplant results. This action would facilitate to promote a EU wide register or the comparability of the results of existing registers to follow-up on organ recipients, monitor their health and evaluate results. This will permit the elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results. This is of especial relevance in the case of the use expanded donors
Traceability	In many MS thee are not in place a consistent traceability system The Council of Europe has guide on quality and safety on tissues	Not planned under the action plan. .	The approach will establish systems for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa. These rules will be	The approach will establish systems for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa. Basic rules will be

	and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States No system at EU level currently established to ensure traceability for cross border exchanges		established at national level, the commission will complement these systems in case of cross border exchanges.	established by the commission including a detailed technical annex on the information that has to be kept to ensure full traceability also at national level. See 2006/86 Annex VI
Notification of serious adverse events and reactions	More than one third of Member States have not this system in place No system in place or guidelines for cross border exchanges	Not planned under the action plan.	The approach will establish systems for ensuring the detection and reporting of serious adverse event and reaction These rules will be established at national level, the commission will complement these systems in case of cross border exchanges.	The approach will establish systems for ensuring the detection and reporting of serious adverse event and reaction Basic rules will be established by the commission including a detailed technical annex on the information that has to be reported. An annual report to the Commission will be also required. See 2006/86 annex III-IV and V
Import/export of human organs	Only 15 Member States have regulation in place.	Not planned under the action plan	The approach will establish a system for the regulation of imports of human organs from third countries that ensure equivalent standards of quality and safety	The approach will establish a system for the regulation of imports of human organs from third countries that ensure equivalent standards of quality and safety
Donor protection	Wide variability between Member States in some aspects The Convention of the Council of Europe on Biomedicine is in place. However it is not ratified	Action plan could establish guidelines and sharing of best practices mainly for living donation programmes.	The approach will establish the basic rules for donor protection	The approach will establish the basic rules for donor protection

	by all Member States The project LIVING donation funded by the EU under the public health programme aims to create a consensus on European common standards regarding legal, ethical, protection and registration practices in relation to organ living donors			
Quality programmes	Not in place in most of Member States	Action plan could contribute to the quality programmes by promoting methodology of quality improvement programmes for the donation process.	This approach will request Member States to put in place national quality programmes based on the principles of good practice which establishes standardised protocols. This programme should implemented and maintained throughout the entire process, from donation to transplantation, to ensure the compliance of the quality and safety requirements laid down in this framework. But is up to Member States how to organise these programmes.	This approach will request that Member States take all necessary measures to ensure that each establishment puts in place and updates a quality system based on the principles of good practice which establishes standardised protocols. The technical details of such quality systems will be establish in a implementing directive. See 2006/86 Annex I. and II, and 2006/17 Annex IV
Inspections and control measures	Wide variability between Member States	Not planned under the action plan	This approach will require under the national quality programmes to put in place control measures, including auditing where relevant, to evaluate and verify in a regular basis the procedures and the activities carried out that are relevant for the requirements of the quality and safety framework.	This approach will require Member States to put in place inspections structures and ensure that the competent authority or authorities organise inspections in a regular basis and that establishments carry out appropriate control measures in order to ensure compliance with the requirements

				of this EU legal framework. Such inspections and control measures shall be carried out by officials representing the competent authority. Guidelines concerning the conditions of the inspections and control measures and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance, shall be established by the Commission.
Personnel	Wide variability between Member States	The action plan will address a number of actions on training of professionals and accreditation	This approach will establish basic requirements under the national quality programmes This approach will be complemented with the action plan that addresses a number of actions on training of professionals.	This approach will establish personnel requirement as a part of the authorisation of the activities and under the specifications of the quality systems of the establishments. See 2006/86 annex I This approach will be complemented with the action plan that addresses a number of actions on training of professionals
Conditions of procurement	Wide variability between Member States The Council of Europe has guide	The action plan could promote as priority action a common (non binding) accreditation system for organ donation/procurement and	This approach will establish basic requirements under the national quality programmes for the authorisation of the conditions of	This approach will establish detailed specifications on procurement procedures as part of the authorisation of the activities

	on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States	transplantation programmes	procurement	and under the specifications of the quality systems of the establishments. See 2006/17 annex IV
Transport of human organs	Wide variability between Member States The Council of Europe has guide on quality and safety on tissues and cells and organs. Experience shows that the implementation of these guidelines widely differs in different Member States	Not planed under the action plan.	This approach will establish basic requirements under the national quality programmes	This approach will establish detailed specifications on transport procedures and labelling as part of the authorisation of the activities and under the specifications of the quality systems of the establishments. See 2006/17 annex IV; 2006/86 Annex II
Cooperation between competent authorities	No competent authorities are officially designated. The Committee of transplantation of the Council of Europe meets one-two times per year. This is however a technical committee of experts. Although recognising the work of the Council of Europe and the World Health Organisation in this area, there is not currently a effective framework discuss quality and safety issues between MS in the EU.	It is the key element of the action plan. This approach should be based on the identification and development of common objectives , agreed quantitative and qualitative indicators and benchmarks, regular reporting, and identification and sharing of best practices. The mechanism of coordination serves as a platform for	This mechanism could reinforce and complement the coordination action suggested in the action plan. As already in place in the blood and tissues and cells area the designated CAs provide advice to the Commission, channelling communication between Commission and Member States. The Committee has a particular role in helping to achieve a coherent implementation of the Community acquis. Their tasks: Monitor the development of	This mechanism could reinforce and complement the coordination action suggested in the action plan. As already in place in the blood and tissues and cells area the designated CAs provide advice to the Commission, channelling communication between Commission and Member States. The Committee has a particular role in helping to achieve a coherent implementation of the Community acquis. Their tasks: Monitor the development of

		discussion, exchange of expertise, and identification of best practices. However the situation is very different between MS and could be difficult to find the same level of representation and decision capacity.	national policies and the enforcement of EU legislation by national policies; assist the Commission in the preparation of legislation or in policy definition and coordinates with Member States/exchange of views	national policies and the enforcement of EU legislation by national policies; assist the Commission in the preparation of legislation or in policy definition and coordinates with Member States/exchange of views
Regulatory Committee and Comitology	NA	NA	This approach will create a regulatory Committee in order to update: (a) requirements for ensuring traceability at community level for cross border exchange at community level., (b) requirements for serious adverse events and reactions reporting for cross border exchanges at community level (c) requirements for organ characterisation	This This approach will create a regulatory Committee in order to update: (a) requirements for the accreditation, designation, authorisation or licensing of establishments where donation and procurement of human organs take place; (b) requirements for the donation, procurement, testing transport and preservation of human organs (c) requirements for ensuring traceability, including labelling (d) requirements for serious adverse events and reactions reporting (e) information to be given to the donors and recipients

(f) Guidelines of inspections (g) requirements for organ characterisation

ANNEX II –COMPARATIVE TABLE ACTION PLAN ELEMENTS BY OPTIONS

Priority actions	Base line Option	Action Plan + No Directive	Action Plan + Directive flexible approach	Action plan + Directive stringent approach
Priority action 1 **Promote the role of transplant donor coordinators in hospital where there is a potential for organ donation**	DG SANCO under the public health programme is running a project: EPTOD focused on training of health professionals on organ transplantation. The European Transplant donor Coordination associations groups these professionals.	The action plan should designate this action as a priority, and promote its implementation thought: (a) Incorporating in the national action plans the objective of gradually appointing transplant donor coordinators in every hospital with an intensive care Unit. Design indicators to monitor this action. (b) Promote the international recognised standards for transplant donor coordinators programmes. (c) Promote the Implementation of effective training programmes for transplant donor coordinators (d) Promote the establishment of national or international accreditation schemes for transplant donor coordinators	It could contribute to this action of the action plan as it will require adequately qualification for the personnel directly involved in activities relating to the donation, procurement, testing preservation and distribution of human organs. It will also require adequate training.	It could contribute to this action of the action plan as it will require adequately qualification for the personnel directly involved in activities relating to the donation, procurement, testing preservation and distribution of human organs. It will also require adequate training.

Priority action 2 **Promote Quality improvement programmes in every hospital where there is a potential for organ donation**	No current action at EU level. Could be a future objective under the public health programme Donor action is a private, non for profit Foundation that develops training programmes, having activities in hospitals of 10 European countries. DA has been able to increase donation rates with 50 to 70%	The action plan should designate this action as a priority, and promote its implementation thought: (a) Incorporating in the national action plans the objective of gradually put in place quality improvement programmes in every hospital where there is a potential for organ donation. Design indicators to monitor this action. (b) Promote the accessibility to specific methodology on quality improvement programmes.	The Directive could contribute as it will request Member States to put in place national quality programmes based on the principles of good practice which establishes standardised protocols. These programmes should be implemented and maintained throughout the entire process, from donation to transplantation, to ensure the compliance of the quality and safety requirements laid down in this framework. Donation quality improvement programme could be easily incorporated. as part of the national quality programmes.	The Directive could contribute to this objectives as it will request that Member States take all necessary measures to ensure that each establishment puts in place and updates a quality system based on the principles of good practice which establishes standardised protocols. A donation quality improvement program could be incorporated also in the establishments as part of the quality system.
Priority Action 3 **Exchange of best practices on organ living donation programmes among EU Member States: Support registers of living donors**	DG SANCO under the public health programme is running a project: EU living donor focused on To contribute to create a consensus on European common standards regarding legal, ethical, protection and registration practices in relation to organ living donors in order to guarantee these donors health and safety.	The action plan should designate this action as a priority, and promote its implementation thought: (a) Creating a consensus on European common standards regarding legal, ethical, protection in relation to organ living donors. (b) Incorporating in the national action plans the promotion of	The Directive will contribute as it will establish rules for the protection of the living donor, and the registration of these activities.	The Directive will contribute as it will establish rules for the protection of the living donor, and the registration of these activities.

		altruistic donations programmes from living donors, on the basis of appropriate safeguards concerning the protection of the living donors and the prevention of organ trafficking. Sharing best practices from those MS more advanced. (c) Promote registration practices regarding living donors to evaluate and guarantee their health and safety		
Priority Action 4 Increase Public awareness.	No current action at EU level. Could be a future objective under the public health programme	The action plan should designate this action as a priority, and promote its implementation thought: (a) Promotion of donation campaigns focus in specific groups and populations (b) Facilitate the identification of organ donors across Europe in order to increase organ availability (c) Improvement of knowledge about transplantation issues by health care professionals, the media and the general public	The Directive could contribute as donation rates in all countries depend on public confidence in the use of organs in therapy, and it is therefore essential that EU provisions ensure their quality and safety at similar level in the EU. A problem in one country can affect others, too. People in a foreign country may become donors. Last year in Spain close to 10 % of the donors were foreigners, more than 50% of these were Europeans. This has steadily increased from 2 % in 2000. Legal certainty is needed to ensure that the organs available for therapy are not wasted. On the other hand, citizens also need to have trust	The Directive could contribute as donation rates in all countries depend on public confidence in the use of organs in therapy, and it is therefore essential that EU provisions ensure their quality and safety at similar level in the EU. A problem in one country can affect others, too. People in a foreign country may become donors. Last year in Spain close to 10 % of the donors were foreigners, more than 50% of these were Europeans. This has steadily increased from 2 % in 2000. Legal certainty is needed to ensure that the organs available for therapy are not wasted. On the other hand, citizens also need to have trust

			and certainty in their handling by the donation system in the foreign country.	and certainty in their handling by the donation system in the foreign country
Priority Action 5 **Facilitate the identification of organ donors across Europe and cross border donation in Europe**	No current action at EU level.	The Action plan will focus on Collecting and disseminate information about citizen's rights concerning organ donation across the EU, and will explore mechanisms to facilitate the identification of cross border donors	Common quality and safety rules of donor protection will reassure families and donors trust in the transplantation systems.	Common quality and safety rules of donor protection will reassure families and donors trust in the transplantation systems
Priority Action 6 **Enhancing the organisational models of organ donation and transplantation in the EU Member States**	No current action at EU level. Some general indications were the results of Alliance O project funded by RTD (ERANET coordination action) . The project had 7 Member States partners (UK, Spain, France, Italy, Germany, Poland and Hungary). The project finished in 2007. A follow up group intends to meet regularly to continue the work on organ allocation tools. The Committee of transplantation	The action plan should designate this action as a priority, and promote its implementation thought: (a) Ad hoc recommendations of the committee of experts to Member States on the basis of the regular reporting to be included in the national actions plans (b) Promotion of twinning projects and peer reviews (c) Assessment on the use of structural funds and other community instruments for the development of transplantation	The Directive could contribute as it will request to put in place the basic structure needed for a safe and quality performance of the transplant systems. It will create competent authorities in Member States that will have a role of oversight. The committees of competent authorities will be a perfect body to discuss the different national plans. It will also require the collection of information on transplant activities, needed to evaluate and design policies in this field.	The Directive could contribute as it will request to put in place the basic structure needed for a safe and quality performance of the transplant systems. It will create competent authorities in Member States that will have a role of oversight. The committees of competent authorities will be a perfect body to discuss the different national plans. It will also require the collection of information on transplant activities, needed to evaluate and

	of the Council of Europe meets one-two times per year. This is however a technical committee of experts.	systems (d) Promoting the development of transplant centres of excellence		design policies in this field.
Priority action 7 **Promote EU-wide agreement on issues concerning transplant medicine**	No current action at EU level. The main European organ exchange organisations (EOEOs) (Eurotransplant, Swiss transplant, Italian Transplant Centre, Hungaro transplant, UK Transplant, Organização Portuguesa de Transplantação, Etablissement Français des Greffes, Skandiatransplant Poltransplant, Greek transplant organisation and the Spanish Organización Nacional de Transplantes,) meet on a regular basis. Normally once a year. The Committee of transplantation of the Council of Europe meets one-two times per year. This is however a technical committee of experts.	The action plan should designate this action as a priority, and promote its implementation thought: (a) EU Wide agreement on basic rules for internal EU patient mobility and transplantation (b) EU-wide agreement on all issues concerning transplant medicine for extra-Community patients (c)EU Wide agreement on monitoring organ trafficking (d) EU Wide agreement on common priorities and strategies on future research programmes	Having common standards and equivalent systems for authorisation of activities could indeed contribute to these EU Wide agreements. The Directive will provide this common ground.	Having common standards and equivalent systems for authorisation of activities could indeed contribute to these EU Wide agreements. The Directive will provide this common ground.
Priority Action 8 **Facilitate the interchange of organs between national authorities**	No current action at EU level. European Organ Exchange organisations will continue to meet once a year and will continue with its informal agreements.	The action plan should designate this action as a priority, and promote its implementation thought: (a) Systems for offering surplus organs to other countries can be	The Directive will contribute because for the optimal treatment of specific patients the available organs should be able to cross borders without unnecessary problems and delays. National legislations differ between	The Directive will contribute because for the optimal treatment of specific patients the available organs should be able to cross borders without unnecessary problems and delays. National legislations differ between

	Eurotransplant and Scandiatranlant areas will continue with the high level of exchanges: The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands Croatia and Slovenia. The Eurotransplant region numbers well over 118 million inhabitants. Scandiatransplant is a Nordic organ exchange organisation and it covers a population of 24 million inhabitants in five countries Some bilateral agreements on concrete programmes between MS will persue (e.g.Spain with Portugal, France and Switzerland or Italia and Slovakia).	evaluated (b) Systems for the exchange of organs for urgent patients and difficult-to treat patients	Member States. A national approach could not ensure the same minimum standard of quality and safety for organs and the smooth exchange. Any organ exchange should precise minimum quality and safety standards and a uniform donor data set, both will be provided by the Directive.	Member States. A national approach could not ensure the same minimum standard of quality and safety for organs and the smooth exchange. Any organ exchange should precise minimum quality and safety standards and a uniform donor data set, both will be provided by the Directive.
Priority Action 9 **Evaluation of post transplant results**	No current action at EU level. Could be a future objective under the public health programme A project funded by DG RTD; DOPKI is looking into a register of	The action plan should designate this action as a priority, and promote its implementation thought: (a) Develop common definitions of	Fully complement the Directive and vice versa	Fully complement the Directive and vice versa

	rare diseases and guidelines for the assessment of these type of expanded donors. DOPKI, focus on improving knowledge and developing applicable methodology that could be used to increase the potential of organ donation. In order to achieve such an objective, the project aims to promote cooperation and sharing of information and practices among seven EU countries	terms and methodology to evaluate the results of transplantation (b) Development of register or network of registers to follow-up on organ recipients (c) Elaboration and promotion of good medical practices on organ donation and transplantation on the basis of the results, specially for the use of expanded donors		
Priority Action 10 **Promote a common accreditation system for organ donation/procurement and transplantation programmes**	No current action at EU level. Could be a future objective under the public health programme	The action plan should designate this action as a priority: The aim is to develop methodology that could support the EU legal framework for the accreditation of programmes of organ donation, procurement and transplantation. This could help to build a common voluntary accreditation system at EU level.	Fully complement the Directive and vice versa	Fully complement the Directive and vice versa

ANNEX III -FOUR SCENARIOS OF FUTURE TRANSPLANTATION RATES

METHODOLOGY: Scenario Development and Data Analysis

Data from *International Figures on Organ Donation and Transplantation Activity Year 2006*[78] is used for the quantitative scenario analysis.

Table A2 gives the organ types from the 2006 data that are used for the analysis.

Table Type of Organ Transplant

Deceased	Kidney
	Liver
	Heart
	Lung
Living	Kidney
	Liver
Paediatric	Kidney
	Liver
	Heart
	Lung

SOURCE: Council of Europe 2007

From the 2006 data, it has been observed that Spain has better transplantation rates as well as donation rates, compared to EU countries. On these grounds, four possible scenarios are defined to capture not only the most optimistic (but perhaps unrealistic) situation where all Member States reach the highest current donation rates (i.e. Spanish level), but also the 'most likely' situation where Member States achieve a moderate level of the European average.

The types of scenarios that are developed are given in the Table below. The procedure for developing these scenarios is explained in the next section.

[78] {Council of Europe, 2007 #4}

Table Description of the scenarios

Transplant rate assumptions	**Scenario 1**	**Scenario 2**	**Scenario 3**	**Scenario 4**
Description	All countries achieve the transplantation rate of the best performing country*	All countries achieve at least European average transplantation rates	All countries improve their transplantation rate by 30%	All countries improve their transplantation rate by 10%
Transplantations from deceased donors				
Kidney, from deceased donors	At least Spanish rate 46 pmp	At least European average: 29.1 pmp	+30%	+10%
Liver, from deceased donors	At least Spanish rate 23.1 pmp	At least European average: 12.3 pmp	+30%	+10%
Heart	At least Spanish rate 6.1 pmp	At least European average: 4.3 pmp	+30%	+10%
Lung	At least Spanish rate 3.8.pmp	At least European average: 2.5 pmp	+30%	+10%
Transplantations from living donors				
Kidney, from living donors	At least Norwegian rate 17 pmp	At least European average: 5.4 pmp	+30%	+10%
Liver, from living donors	At least Spanish rate 0.4 pmp	At least European average: 0.5 pmp	+30%	+10%

*If national rates are higher, the higher national rate is maintained for these countries.

Development of Scenarios

Scenario 1

The transplant rates of each organ type for each country are calculated using the equation:

$$\mathbf{R_{cx} = O_{cx}/POP_c}$$

Where, $R_{cx=}$ Transplantation Rate for organ type *x* for country *c*

O_{cx}= Transplants for organ type *x* for country *c*

POP_c= Population of the country *c*

Spanish rates are used as the base for all transplant types excluding Living Kidney transplants, for which the Norwegian rate is used. The number of extra organs, if required, for each EU country to reach the Spanish rates (and Norwegian rate for Living Kidney transplants) are calculated using the following equations:

$$\textbf{Extra Organs Required} = (R_{sx}-R_{cx})*POP_c$$

$$\textbf{Extra Living Kidneys} = (R_{nx}-R_{cx})*POP_c$$

Where, $R_{sx=}$ Transplantation Rate for organ transplant type *x* for Spain

$R_{nx=}$ Transplantation Rate for organ transplant type *x* for Norway

Scenario 2

The average European Transplantation Rate for each organ type is calculated using the equation:

$$(AVE)_x = (OA)_x / \text{Tot.Pop.}$$

Where, AVE_x = Average European rate for the organ transplant type *x*

OA_x= Total number of organs in the EU for organ transplant type *x*

Tot. Pop. =Total Population of the EU

The organ transplant types for each EU country having transplant rates less than the EU Average rate for that organ type are identified, and the extra number of organs required for that particular transplantation to reach the EU level is calculated using the following equation:

$$\textbf{Extra Organs Required}=[(AVE)_x-R_{cx}]*POP_c$$

Scenario 3

This scenario is arrived at by assuming a strong improvement in donation rates of 30% in the EU. The number of organs required to reach this donation rate are estimated in the following way:

Extra Organs Required = Total number of Transplants per each organ transplant type * 0.3

Scenario 4

This scenario is arrived at by assuming a slight improvement in donation rates of 10% in the EU. The number of organs required (if the country is not up to EU level) to reach this donation rate are estimated as follows:

Extra Organs Required = Total number of Transplants per each organ transplant type * 0.1

After the development of these scenarios, the type of organ transplants considered are further aggregated into four types Kidney, Liver, Heart and Lung transplants.

Quality Adjusted Life Years Gained

The total number of Quality Adjusted Life Years (QALYs) gained for a scenario is the product of the number of the QALY's gained for each type of transplant and the number of transplants for each transplant type in that scenario, as below:

$$\mathbf{QALY_{isc} = QALY_i * O_{isc}}$$

Where, $QALY_{isc}$ =Total QALY's gained for transplant type *i* in scenario s for country *c*

$QALY_i$ = Quality life years gained for each organ transplant type *i*

O_{isc} = Number of organs *i* in scenario *s* for country *c*.

The number of QALYs gained for each type of organ transplant is given in the next Table .

Table QALYs gained for each organ transplant

Tx (Transplantation Type, *i*)	QALY's gained
Kidney transplant	3.1
Liver transplant	11.5
Heart transplant	6.8
Lung transplant	5.2

SOURCE: {Department of Health, 2008 #2}

Productivity Estimation

The total Productivity is estimated by the following equation:

$$P_{isc}=W_c * LY_i * O_{isc}*EP_i$$

Where, P_{isc}= Productivity (in currency of the respective country) for organ transplant type *i* in scenario *s* for country *c*

W_c = Average wage of a production worker in country *c*

*(*Source: OECD Health Data, July 07)

LY_i = Life Years gained for organ transplant type *i*

O_{isc} = Number of organs *i* in scenario *s* for country *c.*

EP_i = Percentage of people employed after undergoing transplant type *i*

The next table shows the life years gained for each transplant type and the percentage of people employed after the transplant (assuming that every organ available and transplanted is successful).

Table Life years gains and percentage of employed people after each transplant

Tx(Transplantation Type)	Life years gained	Employed after Tx
Kidney[1]	2.0	47%
Liver[2]	16.5	27%
Heart[3]	6.0	39%
Lung[3]	3.5	39%

SOURCES: 1) Matas et al (1996); 2) Saab et al (2007); and, 3) Petrucci et al (2007)

Cost Estimation

Thirty-year discounted costs are estimated for each type of organ transplant (using UK wide data) from the following equations:

$$\mathbf{C_{isc} = HE_c * O_{isc} * pcf_i}$$

$$\mathbf{pcf_i = N_i / HE_{UK}}$$

Where, C_{isc} = 30 Year discounted cost for organ transplant type *i* in scenario *s* for country *c* (In Euro)

HE_c = Health Expenditure per captia for country *c* (Source: OECD Health Data)

O_{isc} = Number of organs *i* in scenario *s* for country *c.*

pcf_i = Per captia factor for organ transplant type *i*.

N_i = 30-year discounted net costs per donor for organ transplant type *i*

HE_{UK} = Health expenditure per captia in United Kingdom

The tavble below shows the discounted net costs (UK wide) for each type of transplant from 50% increase in donation rates.

Table 30 year discounted net costs for each type of organ transplant

Cost component by organ type	30-year discounted net costs (UK wide) from 50% increase in donation rate (£)	Donors baseline	Donors 50% increase	Difference	30-year discounted net costs per donor (N_i) (£)	Per capita factor (pcf_i)
Kidney[1]	- 73,952,000	1914	2576	662	-111,710	-66.30
Liver[2]	23,816,000	610	911	301	79,123	46.96
Heart[3]	7,694,000	764	1147	383	20,089	11.92
Lung[3]	8,044,000	116	174	58	138,690	82.31

SOURCES: 1) Matas et al (1996); 2) Saab et al (2007); and, 3) Petrucci et al (2007)

ANNEX IV THE SPANISH MODEL

The Spanish Model is widely acknowledged as an outstanding example of how organisational changes of the transplantation system can increase the number of available organs. Based on the premise that the greatest barrier to organ transplantation was not a lack of suitable donors but the failure to identify and "convert potential into real donors" the Spanish Government founded the National Transplant Organization (ONT) in 1989 and began to set up a nationwide system to monitor potential organ donors.79 Since then, the ONT coordinates and facilitates the donation, extraction, preservation, distribution, exchange and transplantation of organs and tissues for the Spanish health system. The agency is attached to the Ministry of Health. Each Autonomous Community, however, has sovereignty over the issuing of accreditations for the extraction and transplantation of organs and tissues.

The responsibilities and activities of the ONT include the following:

- maintain and manage waiting lists of patients for organ transplant;
- coordinate transplant processes;
- produce statistical data on organ and tissue transplants;
- promote continuing education, training and research in the field of organ donation and transplant (including training for healthcare professionals on all aspects of organ transplants, such as approaching grieving families, drawing up registries of potential donors, donor maintenance, and so forth);
- provide information to all stakeholders involved in organ donation and transplant;
- provide a 24-hour, 7-day-a-week phone service for public enquiries;
- collaborate with relevant national and international organisations with the aim of promoting organ donation and transplants.

The reorganisation of the Spanish procurement and donation system in 1989 increased donation rates by more than 130% within ten years. In 1989, 14.3 organs per million population were donated, in 1999 already 33.6 organs per million population were donated, and donation rates have since stabilised at this high rate - Spain has the highest donation rates in the world. In 2006 a total of 35.52 organs per million population (pmp) were donated among 17 autonomous health regions. The variation across the 17 health regions in Spain ranges from 24.4 to 48.4. The top 20% of health regions have donation rates ranging from 42 to 48.4 organs pmp. These increases have been the result of changes in logistics and process management.[80] In particular, the success of the Spanish approach to organ donation is commonly attributed to five interlinked elements of the Spanish system:[81]

1. The presence of hospital co-coordinators and coordinating teams in hospitals is one of the most salient features of the system (smaller hospitals may have only one or two

[79] Miranda, et al. (1999).

[80] Healy (2006).

[81] See e.g. Miranda, et al. (1999).; Matesanz and Miranda (2002);Matesanz (2003).

healthcare professionals involved in transplant management). This 'grass roots' approach to the hospital-level management of transplants ensures that hospitals are involved and accountable for performance within the system. From 1989 the number of transplant coordinator teams rose from below twenty to 139 in 1998 [82,83]

2. The second crucial feature of the Spanish model is the system of funding and reimbursement to hospitals for organ transplant activity. Small hospitals which are not able to finance the entire transplant operation are reimbursed by the relevant authorities. This system, and the non-pecuniary support provided by the national and regional transplant authorities, enables these small hospitals to be involved in the transplant process.[84]

3. The third element is a comprehensive quality assurance system. The ONT has developed a quality assurance system (or programme), to control the process of organ and tissue donation, extraction and transplantation set up in 1998 with the aim to identify weakness in the process and develop ways to make improvements that would maximise the potential in organ transplants, including the pool of potential donors. The programme is in place in all Autonomous Communities. The programme consists of evaluations in each participant hospital, which is conducted in two phases. The first phase is an *internal evaluation* carried out by the transplant co-ordinating team in each hospital. The team reviews all clinical histories of deaths within the hospital's Intensive Care Unit and provides the ONT with a description of the circumstances, including the reasons for why a patient is not a donor. This evaluation must be conducted at least every three months. In the second phase, an *external evaluation* is conducted by a transplant coordinating team from another hospital, in which the data collected is verified, the efficiency of the process of organ donation and extraction is assessed, and areas for improvement are identified.

4. Adequate training of involved staff, in particular transplant coordinators has been identified as a key success factor in Spain. The Spanish case shows that family refusals, which are one key reason why potential donors are not used, can be substantially reduced if staff are well trained to adequately respond to and support the grieving relatives of deceased donors.[85]

5. An important element in the Spanish Model is the adequate, proactive management of mass media opportunities. Much attention has been given by the ONT to informing the media, and to the provision of systematic and comprehensive, sensitive information to both healthcare professionals and the lay public about organ donation and transplantation *through* media outlets. Researchers have argued that the use of mass media in Spain on the issue of organ donation has greatly influenced the creation of a positive social atmosphere around organ donation and transplantation.[86] However, the Spanish did not invest heavily in public awareness campaigns or similar measures due to shortages of funds.

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[82] Miranda, et al. (1999).

[83] Matesanz (2001).

[84] See for example: Miranda, et al. (2003).

[85] Matesanz (2001).

[86] Matesanz and Miranda (2002).. Also: Matesanz and Miranda (1996).

Previous efforts to adopt the Spanish model in other countries, in particular in Italy and South America, show that the Spanish model could be totally or partially replicable in other countries, but its effectiveness depends on a number of conditions. These include: the presence of universal healthcare provision, adequate reimbursement to hospitals on the basis of transplant activity, the availability of capacity within the medical community to develop expertise in the field, an adequate ratio of nurses to ICU beds/patients, and adequate availability of facilities for donor patients (Matesanz, 2003).

ANNEX V- BACKGROUND ADFDITIONAL INFORMATION ON IMPACTS

Health Impacts

Donation and transplantation rates

- In re-organising its procurement system in the early 1990s, Spain substantially increased its donation rates. This can mainly be attributed to changes in logistics and process management.[87]. The positive effects of **Spain**'s model for improving processes have come from training and organisational innovation to improve the process of organ procurement,[88] namely training/personnel; inspections and control measures, or systematic audits, conditions of procurement and adequate reimbursement.

- Training programs for health professionals, specifically dedicated to every step of the donation process have contributed to the approach of obtaining consent from donor families.89 In addition, local transplant coordinators help increase the use of older donors who previously would not have been considered viable candidates for procurement.9091

- Similar positive impacts from these 'inputs' have been described for the Italian region of Tuscany. After regional transplant authorities in Italy copied the Spanish approach in its entirety, Tuscany alone "doubled its organ donation rate to 26.9 donors per million population in the space of just one year."92

- The health impact of instituting a formal responsible service of the Ministry of Health in Greece (i.e. the competent national authority) has been significant. Compared to 2001, the H.T.O. has resulted in 448% increase in potential donor referrals and 132% increase in transplantations performed.93 The latter results having a clear and significant health impact for patients.

QALYs and Life years

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[87] Healy (2006).

[88] Matesanz (2001).

[89] Rosel, et al. (1999).

[90] Chang, et al. (2003).

[91] Miranda et al. (2003) attribute the 130% increase in donation rates over 10 years (from 14 to 34 donors per million population) to the permanent network of trained staff.

[92] Simini (2000).

[93] Karatzas, et al. (2007).

- In the UK, the average waiting time for an adult kidney transplant is 2.5 to 3 years while in Greece it is 5 years. In Poland, the mortality rate among patients undergoing dialysis treatment is about 13% per year, with cardiovascular illnesses being responsible for the majority of deaths.

- Estimates, on how improvement in donation process can result in QALY gains have also been conducted. For instance the DA Programme—demonstrated to increase donation rates by 59.2%—will result in 33 QALYs per million population94. In addition, we know that transplant coordinators help increase the use of older donors who previously would not have been considered viable candidates for procurement,95 leading to an amplification of QALYs gained as more organs become availability through policy measures to improve processes.

- In addition, by "enhancing the organisational model of organ transplantation" in Italy, ISMETT96 has had a clear positive health impact: one-year survival rates from transplantation (liver, kidney, heart, lung, pancreas) are 5-10% above the national average in Italy. More specifically, patients in the Liver Transplantation Program have over a 90% one-year survival rate and an 80% five-year survival rate, and the number of paediatric liver transplantations at ISMETT have risen steeply from less than 5 in 2003 to 30 in 2006—an increase paralleled in only Milan between 1997 and 1998.97

Quality of life

- From the living donor perspective, living donors experience a boost in self-esteem and a greater sense of well-being: in one study, 96% of living kidney donors felt it was a positive experience and, in another study, 100% of kidney donors stated after donation that they would again favour it.98 Clemens et al. (2006) found that the majority of living kidney donors had no depression (77-95%) or anxiety (86-94%), with similar questionnaire scores as controls. In fact, Virzi et al (2007) found that there was somehow a reduction in depressive symptom frequency among donors from 37.5% to 33.3% and a decrease among 18 scores from 12.5% to 0%.

- In addition, Corley et al. (2000) determined that QoL scores were high for all donors and expected to improve in the next 5 years. Significantly higher levels of predicted self-esteem and independence (i.e. mobility and choice of how to live one's life) were found in African-American donors, those with higher levels of education, and those who had recently donated a kidney. Nevertheless, some prospective studies describe a decrease in QoL after donation.99 Finally, while living donor kidney transplantation may not adversely affect the lives of donors and may significantly improve many aspects of the lives of recipients, physical and psychological aspects may be impaired by living donation.[100]

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94 study by Roels et al (2003)

95 Chang, et al. (2003).

97 Gridelli (2008).

[98] Cabrer, et al. (2003).

[99] Clemens, et al. (2006).

[100] Virzi, et al. (2007).

Employment and social participation

- The social outcome in a cohort of 366 French children who underwent kidney transplantation between 1973 and 1985 was investigated recently by Broyer et al (2004). The authors found that 73% of male patients (n=149) and 72% of female patients (n=95) had paid employment, whereas 6.5% and 10.5%, respectively, were unemployed.101

- In another study in the US, there was low pre-transplantation employment (39% of kidney-pancreas transplant recipients and 33% of kidney alone transplant recipients). However, post-transplantation, significantly more dual organ recipients were working (73%) compared with transplant recipients of kidney alone (27%). This US study also found that pre-transplant employment was independently associated with post-transplant work status. Similarly, in Italy, Petrucci et al (2007) found that having had an occupation previously and having been off work for less than 24 months were independent predictors of return to work: 87% of patients worked before thoracic organ transplantation and 39% of patients went back to work after transplantation and 3 of the 131 patients in total started working.102

- While there is thus little convincing evidence on social participation more general after transplantation, the literature provides some evidence on employment rates after transplantation, which were also used in this study to assess the productivity impacts of organ donation. Annex V Table 01 provides an overview of some estimates of employment rates after transplantation.

Trust and confidence in the organ donation and transplantation system

Creating a competent authority

- While the evidence does not support the direct assessment of costs of establishing a national authority, there is evidence on the costs of the establishment of the Human Tissue Authority in the United Kingdom. The Human Tissue Authority is the national oversight authority to implement the EU Tissues and Cells Directive (EUTCD), and is responsible for licensing more than 500 establishments across five different sectors, and for approving donations of organs and bone marrow from living people.103 In creating a competent authority (as proposed in the soft Legal Directive), the total expenditure of HTA, as an example of a "new regulatory system," was over £2.8 million. Fifty two percent of the direct costs were related to staff salaries and include actions of investing in personnel who conduct the mandatory inspections and control measures. 104

[101] Broyer, et al. (2004).

[102] Petrucci, et al. (2007).

[103] HTA (2007).

[104] Ibid.

Authorisation of establishments

- There is cost information available on the licensing of establishments under the Human Tissue Act in the UK. The Human Tissue Authority charges up to £ 7,600 for licensing an establishment.105 In Germany, the responsible authority charges up to € 25,600 for the licensing of tissue products.106

Transplant coordinators

- In an interview with the German DSO, our contact estimated the additional need for transplant coordinators to be around 80 to 90 staff in addition to the current 50 coordinators employed by DSO each at a cost of €60,000 to €70,000 for a physician coordinator and around €45,000 to €50,000 for a nurse coordinator. This would result in additional costs of between €4.8m and €6.3m for physicians and €3.6m and €4.5m for nurse coordinators.107

Setting up and running national quality programmes

6. Staff training courses form are another element of a quality programme. One provider of training courses for transplant coordinators reports costs of around €3,000 for an advanced training course as "organ donor manager" at the local level and € 9,000 for a master programme as a "regional donor manager".[108]
7.

Table. Information on national quality programmes in some European Countries

One of the most comprehensive quality programmes is in place in **Spain**. The programme to control the process of organ and tissues donation, extraction and transplant was set up in 1998 with the aim to identify weaknesses in the process and develop ways to make improvements that would maximise the potential in organ transplants, including the pool of potential donors. The programme, in place in all Autonomous Communities, has also been adopted in other European countries (such as Italy) and in a number of Latin American countries. [109]
In **Germany**, there exist elements of a quality programme, but no systematic overarching programme. As an organisation, DSO is currently in the process of being ISO certified according to ISO:9001, and all transplant and procurement centres have to report their activities to DSO on an annual basis. In addition, organ donation and transplantation are covered by the Quality Assurance processes required by the general health legislation (§ 137 SGB V). The transplant and procurement centres have to report to the Bundesgeschäftstelle

[105] http://www.hta.gov.uk/licensing/guide_to_licensing_and_application/fees_and_payment.cfm

[106] www.pei.de

[107] Interview with DSO official.

[108] Personal communication SANCO- TPM

[109] ONT (www.ont.es)

für Qualitätssicherung (BQS) on the performance of their activities. The BQS benchmarks this performance and targets outliers for in-depth scrutiny of processes and cases if necessary. This audit does however not include e.g. an analysis of the use of the donor pool.

In **Greece** there are no specific quality systems in place. Greece follows most of the European guidelines (CoE, EU, EOEO, ETCO/ESOT). Regarding donation, there is a minimum standard of information and criteria for suitability and quality of the donated organs. Ultimately, organ quality is a decision of the Transplant centres based on professional standards.

While following national and international guidelines in the process of transplantation, **Sweden** does not have a national quality programme for the whole transplantation process, due to its very decentralised infrastructure centred on the transplant centres and an only emerging role of national institutions such as the Swedish Council for Organ and Tissue Donation (donationsrådet).

In **Poland,** a quality and safety programme is emerging around four organ transplant databases/systems required and regulated by Polish law: a national transplant waiting list, national organ traceability system, national living donors' database, non-related donor bone marrow and umbilical cord blood database. It is envisaged that data in electronic form from all four databases/systems will be widely accessible when the systems are fully implemented and operating (work on the systems started in 2007). It would enable continuous safety and quality monitoring, reporting the data to and analysing the data by Ministry of Health and Quality in Medicine Monitoring Centre (Centrum Monitorowania Jakości w Medycynie) (currently Poltransplant produces reports on an annual basis).[110]

The **United Kingdom** has different elements of national quality systems already in place at all steps of the organ donation and transplantation, including transplant coordinators performance audit tool, a potential donor audit, best practice and staff guidance and medical follow up.

Table Quality Programmes in France, Germany, Hungary Italy and Spain (Alliance – O)

Quality Programmes in France, Germany, Hungary Italy and Spain

Donation Sub-process
In the majority of the countries, the local hospital is responsible for the phases of the donation sub-process, apart from some direct responsibility of the regional coordination or of the national organization. Moreover, the responsible unit is usually supported in the development of the activities by either the regional coordination or the national centre. All countries declared the presence of a quality programme made of

[110] Finansowanie, nadzór, monitorowanie, ocena jakości działalności transplantacyjnej w Polsce, PowerPoint presentation by Prof. Dr. Hab. med. Piotr Kalaciński, Przewodniczący Krajowej Rady Transplantacyjnej, from the Conference in Senate – Przeszczepianie narządów i szpiku. Potrzeby i możliwości. On 12th of June 2007 Available from <http://www.uniatransplantacyjna.pl/images/stories/senat/P_Kalicinski.pdf>, accessed 12Feb08.

trainings, procedures, guidelines and audits. Audits are deeply developed in France, Spain and UK, whereas the other countries developed a programme only for the phase of identification of a potential donor.

Allocation Sub-process

In this case most of the countries reported that the regional or the national organizations are responsible for the management of the phases belonging to the allocation sub- process. Laboratories and transplant centres usually cooperates with them for the development of some activities. All countries reported the presence of quality programmes as trainings, procedures, guidelines and audits. France, Hungary, Italy and Spain manage full procedure, guideline and auditing programmes either at a national level and/or at a local one.

Transplantation Sub-process

Transplant centres are the responsible units for the transplantation sub-process phases. In some countries transplant centres are supported by regional coordination, while in a few countries are supported by the national transplant centre. Italy, Spain and UK have a national auditing programme, while Germany, Hungary, Italy and UK apply procedures and guidelines to all phases, even though they are produced at different levels.

Follow-up and quality of life sub-process:

Transplant centres are responsible for the phases of the sub-process. In some specific cases, it is also foreseen the cooperation of the regional or national coordinating centre, this is the case of France, Germany, Italy and Spain. Quality programmes in this phase are not frequent: only Italy and Spain have an auditing programme in place, whereas Germany, Hungary and Italy developed procedures and guidelines regulating the phases of the sub-processes.

SOURCE: ALLIANCE-O (2007a)

8.

Costs for setting up and running national registers and traceability systems

Donor registers

9. The table below provides an overview of the existing registries in the Member States participating in the DOPKI project (without databases to register non-/consent.

10. In Sweden, registries for post mortem and living donation for traceability purposes are maintained at the transplant centre level. In Greece, the Hellenic Transplant Organization (HTO) maintains registries for organ & tissue donors and candidate recipients.

11.

Existing registries in a sample of Member States

Organisation	Country	Donor registry		Recipient registry	
		Post mortem	Living	From post mortem	from living
./.	Austria	Yes*	Yes*	Yes*	Yes*
BTS	Belgium	On voluntary base in Tx centers-working group in the ministery of	on voluntary base in tx centers	Database in tx centers, annual report for the Minister on the activities	Annual report for the Minister

			health		
MZSS	Croatia				
KST	Czech Republic	Yes	Yes	Yes	Yes
ABM	France	Yes	Yes	Yes	Yes
DSO	Germany	Yes	Not at DSO	No, but annual report from tx-centres about activity	No
Hu-T	Hungary	No	No	Yes	Yes
CNT	Italy	Yes	Yes	Yes	Yes
Luxembourgtransplant	Luxembourg	Yes	Yes	Yes	Yes
NTS	Netherlands	Yes	Yes	Yes	Yes
Poltransplant	Poland	Yes	Yes	Yes	Yes
OPT	Portugal	Yes	Yes	Yes	Yes
Slovenija-Transplant	Slovenia	Yes	Yes	Yes	No
ONT	Spain	Yes	Developing	Yes	Included in the post mortem registry
Swisstransplant	Switzerland	Yes	Yes	Yes	Yes
UK - Transplant	United Kingdom	Yes	Yes	Yes	Yes
Eurotransplant	Netherlands	Yes	No	Yes	No

* hospital based, ET based

SOURCE: DOPKI (2006)

12.

Treatment costs

All organs

13. The Organ Task Force in the UK modelled the impact of a 50% increase in donation rates on treatment costs over a thirty year period.111 Table VI Annex presents the cumulative cost effect and net savings112 from this increase in donation rates. Overall, the modelling shows that a 50% increase of organ donation rates would provide a net benefit, even without taking into account the additional life years saved and the gains in quality of life for the individual patients.

Kidney

[111] Ibid.

[112] At a discount rate of 3.5%

14. These benefits can be primarily attributed to the cost saving effects of kidney transplantation versus dialysis treatment. While transplantation has high initial costs, the post transplant costs are substantial lower than the dialysis costs, thus offsetting the initial investment.

Liver, heart and lung transplantation

15. As a transplantation is the only available treatment for end stage liver, heart and lung diseases, the assessment of cost effectiveness is less clear cut, as there is no available treatment against which to compare the costs. In a situation of scarcity and decreasing resources for healthcare, transplantation has thus to be compared against other available treatments for other diseases. To do this, many countries use standardised effectiveness measures such as ICER (Incremental Cost-Effectiveness Ratios), comparing the costs for each life year, or each quality adjusted life year (QALY) gained. Treatments are considered cost effective, if they stay below a commonly accepted limit, which differs between societies.

Productivity Impacts

16. Besides the impact of treatment costs, organ transplantation can contribute to the economic performance of a country, by keeping people in the workforce or by allowing them to participate in the economy where they could not do so previously. A prime measure of productivity impact is the participation in the labour market. In a recent review, van der Mei et al. (2006) analysed seventeen studies, reporting employment rates after kidney transplantation ranging from 18% to 82%. For heart lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants113 and 39% for thoracic organs.114

Economic Impacts on Living donors

17. Two studies reviewed produced an estimate of overall costs incurred by living donors, estimating the average costs at $ 837 per donor and $ 107 per donor. However the variation is very strong with, a range of $0 to $28,906 in the first study and $0 to $13,788 in the second study. These cost estimates are however likely to underestimate the true costs for the donors. Further on, this study cites estimates of lost income as another indirect impact of Living Donation. The study reports estimates of average losses of $3386 in the United Kingdom from one study, and $682 in another study from the Netherlands. Lost income from living organ donation affects between 14% and 30% of donors. In addition, the indirect costs for dependent care—an 'externality' of the organ donation pathway—were incurred by 9-44% of donors, while costs for domestic help were incurred by 8% of donors. Return to work usually occurs 16-105 days.

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[113] Saab, et al. (2007).

[114] Petrucci, et al. (2007).

ANNEX VI TRANSPLANT RISKS

Transmission of communicable diseases

18. **Human immunodeficiency virus (HIV).** The majority of the cases of HIV-1 transmission through organ transplantation were described before the existence of the serological tests. However there are also cases of HIV-1 transmission described after the introduction of the tests, they were false negatives during the "window" period – the time delay between viral exposure and detectible antiviral antibodies.115 There are not cases described of HIV-2 transmission. The effectiveness of the transmission is difficult to know, but it is assumed that is nearly 100% through solid organ transplantation from a donor HIV positive116. HIVAc (+) donors carry a high risk of viral transmission, the infectivity of a small inoculum has been demonstrated by blood transfusion studies. All potential organ donors have been screened for HIV since 1985. The rare instances of HIV transmission despite negative HIVAc test results illustrate some limitations of serologic testing. In one instance, massive transfusion of blood and blood components decreased the antibody titer below the sensitivity limits of EIA. In a second case, transmission occurred from a donor during the "window period".The transmission through these false negatives should be prevented through a good clinical and behavioural history of the donor.

19. **Hepatitis B virus (HBV)** The cases of HVB transmission have decreased due to the serological screening, which normally includes Ag HBs test. Kidney was the first graft involved in a case of HBV transmission. There are studies that indicate that more than 1% of potential donors have an active HBV infection and over 12% in hyper endemic areas. 3-4% donors have a past history of HBV infection in countries with low prevalence like USA and over 10% in some European countries. The risk of transmission from donors with test against Antigen Hepatitis B (Ag HBV) positive is nearly 100%. However the transmission of HBV to the recipients is also possible from donors Ag HBV negative that have other serological markers positives117. The risk of transmission by liver transplantation from a donor with a serological antibody (HBVAb test positive against hepatitis B is higher because HBV resides principally within the hepatocytes.118 119 120 The donor's Hepatitis B Antigen status do not mitigate transmission risks.121 This type of donors represent in some countries between the 5-15% of all donors.122

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115 Green, et al. (2004)..

116 Criterios de selección del donante de órganos respecto a la transmisión de infecciones. 2ª edición. 2004. Organizacion Nacional de Transplantes. http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

117 Feng, et al. (2002).

118 Frutos, et al. (2003).

119 Dodson, et al. (1997).

120 Uemoto, et al. (1998).

121 Dickson, et al. (1997).

122 Data from ONT, Spain.

In contrast with liver transplantation, transplantation of kidneys from HBcore antibody positive donors seems to carry a minimal risk of clinical transmission. A meta-analysis of the literature shows that only 1 of 133 recipients converted to HBs Antigen positive after transplantation of a kidney from an HBc antibody positive donor.[123] [124] [125] It should be noted, however, that the actual rate of viral exposure as measured by development of anti-HBV antibodies (either HBsAb or HBcAb) is considerably higher. 27 % of kidney recipients from HBcAb + donors demonstrated seroconversion compared with 4% of kidney recipients from HBcAb - donors, for an odds ratio of 4.94 4.Some studies indicate that the risk of transmission is 15-78% for liver transplantation, 2% in kidney and 0% in heart transplantation.An additional problem that could be found in donors Ag HBs positive is the co-infection with the virus of hepatitis delta (VHD). It has been described the transmission of this virus trough kidney transplantation resulting on severe acute hepatitis.

20. **Hepatitis C virus (HCV)** Transplantation of an organ from an HCV+ donor is known to be an efficient mode of viral transmission 126 127 128 129. Approximately 5% of all potential donors in USA and Europe are positive for Antibody HCV 130 A positive HCV-RNA, indicative of viral replication, has been associated with a higher risk of transmission.131. The transmission from donors with RNA positive is estimated to be nearly 100%. The risk of transmission from a non RNA positive donor is not known. The consequences for the recipient of an organ from a HVC positive donor are the seroconversion in 50-67% of the cases and the percentage of development of hepatic disease is around 35%. Overall, limited available data validate the assumption that heart or lung transplantation presents a similar risk of HBV or HCV transmission as kidney transplantation. Finally with regard to outcome, no conclusions can be drawn because the specific impact of the donor's positive serology cannot be discerned from the available data.

21. **Other Viruses** Human T- Linphotrofic virus (HTLV-I and II) is endemic in certain areas; out of these areas the prevalence of this infection is low (lower that 1 % or even 0.1%). Infection with HTLV progress after years or decades to associated myelopathy spastic paraparesis or to adult cell leukaemia/lymphoma (ALT); progression occurs in less that 1% and 2% respectively. Cases of ALT after transplantation have been reported.

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[123] Madayag, et al. (1997).

[124] Satterthwaite, et al. Ibid.

[125] Miranda, et al. (2003).

[126] Frutos, et al. (2003).

[127] Wreghitt, et al. (1994).

[128] Tesi, et al. (1994).

[129] Pereira, et al. (1995).

[130]Candinas, et al. (1994).

[131] Fishman, et al. (1996).

West Nile virus (WNV) is a flavivirus which can cause meningoencephalitis. In the fall of 2002, transmission of WNV from a single donor to four organ donors has been reported. An additional case through liver transplantation has appeared. In August 2002, fever and mentalstatus changes developed in recipients of organs from a common donor; transmission of WNV through solid organ transplantation was suspected. Transplant recipients can acquire WNV in 1 of 3 ways: (1) transfusion transmission, (2) organ donor transmission, and (3) transmission in the community. Post transplant immunosuppression increases the risk of developing severe disease after WNV infection. In the general population, WNV causes severe neurologic disease in < 1% of infected patients. However, data from a seroprevalence study suggest that the incidence is as high as 40% in organ transplant recipients.Although prevention strategies are critical, there is disagreement within the transplant community about the use of nucleic acid testing for screening of organ donors for WNV because screening results can be affected by a number of factors, including local WNV activity, test availability, and test characteristics.

22. **Bacterial and fungal infections** A bacterial or micotic infection or colonisation can be present in 60 % of deceased organ donors and mainly affect the respiratory and urinary tract. Bacterial and fungal donor to host transmission with the allograft with result of loss of the infected graft or death of the recipient has been widely documented. Nevertheless an adequate antibiotic treatment of donor and/or recipient should prevent infection in the latter.

Micobacterium tuberculosis has been transmitted by transplantation, donor transmission accounted for approximately 4% of reported post-transplant TB cases in a large review of 511 patients.[132]

Transmission of histoplasmosis by transplantation has been described, but most cases appear to be the result of reactivation of past infection in the recipient. Transmission of Coccidiodomycosis by lung transplantation has also been reported.

23. **Parasitic infections** There are 342 parasitic species that are known to infect humans, mostly affecting those intropical and subtropical regions.[133] Recently however there are been a considerable spread of these infections to the rest of the world as result mainly of travel and migration. Only 5% of the known human pathogenic parasitic infections have been reported in transplant recipients.

Malaria transmission has been reported with kidney, bone marrow and multi-organ transplantation. Toxoplasmosis is a major concern particularly on heart transplantation. Toxoplasma has rarely been transmitted to liver and kidney recipients.

Transmission of Chagas diseases is a significant problem in endemic areas, and recently has been reported in the US.

[132] Singh and Paterson (1998).

[133] Barsoum (2004).

24. **Prion infections** Creutfeld Jacob disease has been transmitted with treatment with growth factors and with transplantation of cornea and duramater grafts. In July 2004, the United Kingdom announced that a second instance of probable vCJD (new variant) transmission via blood transfusion had been identified. The patient received the blood donated by an individual who was confirmed in 2001 as a definitive vCJD case.

Transmission of malignant diseases

Table B.1: Evidence on transmission of malignant diseases

Source	Findings
United Network for Organ Sharing (UNOS) transplant tumour register[134]	First report of the UNOS (1994-96) showed a frequency of donors with malignant cancer history of 1.7% and a rate of transmission of cancer from donor to recipient of 4.3%.
	A more recent report from this registry (1994-2000 period) showed 14 donors with tumour from a total of 35.503 donors (4 per 10.000) and tumour transmission to 15 recipients of 109.749 transplants (1.3 per 100.000). The tumors transmitted were the following: 4 melanomas, 1 neuroendocrine tumor, 1 adenocarcinoma, 1 cancer of the pancreas, 1 nondifferentiated squamous carcinoma, 2 lung cancers, 1 small cell carcinoma, 1 oncocytoma, 1 papillary tumor, 1 breast cancer, 1 prostate cancer)
Organización Nacional de Transplantes (ONT) register	The frequency of donors with no detected tumour was 6.1 per 1000 donors during the last 15 years. Five of these donors transmitted the disease (2.9 per 10.000 donors). Ten recipients of the 155 that received an organ from a donor with undetected cancer developed a tumour (4.6%). The tumours transmitted were 1 sarcoma, 1 germ cells carcinoma, 1 undifferentiated carcinomatosis and two kidney carcinomas.
Danish Register[135]	Birkeland studied a cohort of donors during 27 years funding 13 malign tumours within 626 donors (2% of the donors) From these donor only one has transmitted the tumour (a melanoma) to the recipient (2 per 1000 donors)
Centro Nazionale per i Trapianti (CNT) register	The CNT has put in place a new strategy for the evaluation of donors since 2002. The analysis of the period 2001-2002 showed 2.9 % of donors with tumours.
The Israel Penn International Transplant Register. (IPTTR)[136]	The I. Penn register shows higher frequencies of tumour transmission that the ones above. During 1994-2001 it registered 68 recipients of organs coming from donors with renal carcinoma, with a tumour transmission in 43 of them (43%). 30 recipients of organs received from donors with melanoma, with tumour transmission in 23 (77%); 14 recipients received from donors with melanoma, 14 recipients with coriocarcinoma, with tumour transmission in 13 (93%). Other tumours that have presented transmission to recipients were lung (41%), colon (19%), prostate (29%), Kaposi Sarcoma (67%).

SOURCE: DG SANCO 2003

[134] Kauffman, et al. (2000).

[135] Birkeland and Storm (2002).

[136] Feng, et al. Ibid.

ANNEX VII

IMPACTS BY POLICY OPTION

HEALTH IMPACTS

Donation and transplantation rates

If we use the assessment on the expected impact under high/low commitment and implementation from the Member States we would arrive at the increased number of transplantations depicted

Possible increase in transplanted organs

Key element	**Option 1: Baseline**	**Option 2: Action Plan**	**Option 3: AP + flexible approach***	**Option 4: AP + stringent directive***
Low commitment and or low capacity Member States	No increase	No substantial increase	2,636 to 4,983	2,636 to 4,983
High commitment and sufficient capacity of Member States	No substantial increase anticipated	7,908 to 21,006	7,908 to 21,006	7,908 to 21,006

SOURCE: Europe

While the transplantation rate under Option 1 would remain stable, Option 2 could lead to a high increase in transplantations (between 7,908 and 21,006) - if Member States are committing to these largely voluntary measures, although there is a high uncertainty in this outcome. For Option 3 and 4, we expect at least a modest increase in transplantation to occur, even if Member States are reluctant to fully commit to improve their donation systems due to the mandatory nature of the proposal. Thus we expect a minimum increase of between 2,636 and 4,983 organs, and a maximum boundary defined by Scenario 3 and 1, i.e. a 30% increase in donation rates (a total of 7,908 more organs), or even transplantation rates of the current best performers Spain and Norway (21,006 more organs).

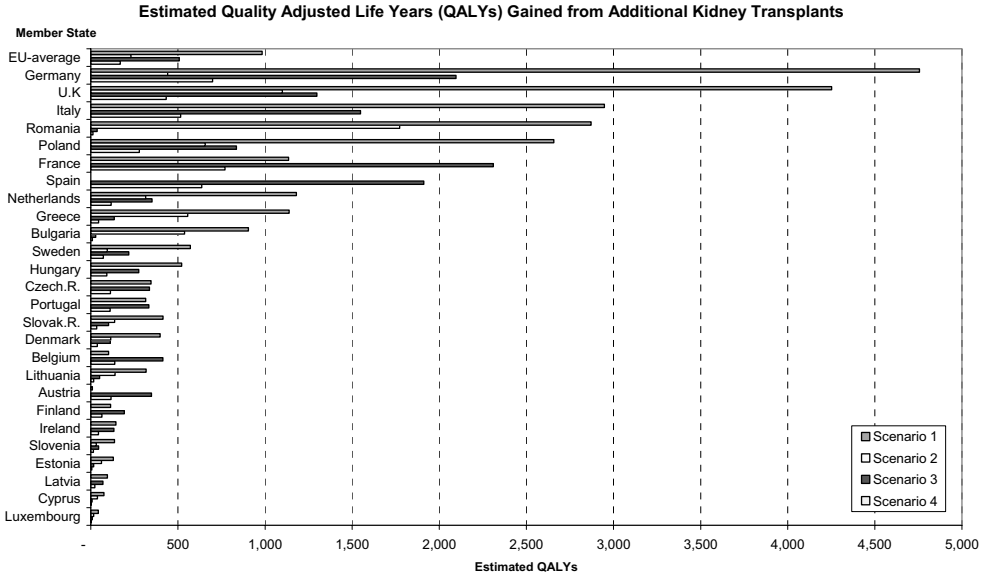
QUALYs and live years

The potential scope of the QALYs and Life years to be saved through policy measures in the field of organ procurement and donation can be assessed through the scenarios presented above. If the proposals lead to substantial gains in transplantation rates, more than 219,000 QALYs could be gained under Scenario 1 and at least 38,000, if transplantation rates would only slightly increase under Scenario 4. The gain in QALY and life years stem primarily from the transplantation of liver, lungs and hearts, as their currently exists no other life saving treatment. In turn, kidney transplantations predominately increase QALYs, while there are only modest increases in the number of life years that could be saved through increased transplantations of kidneys.

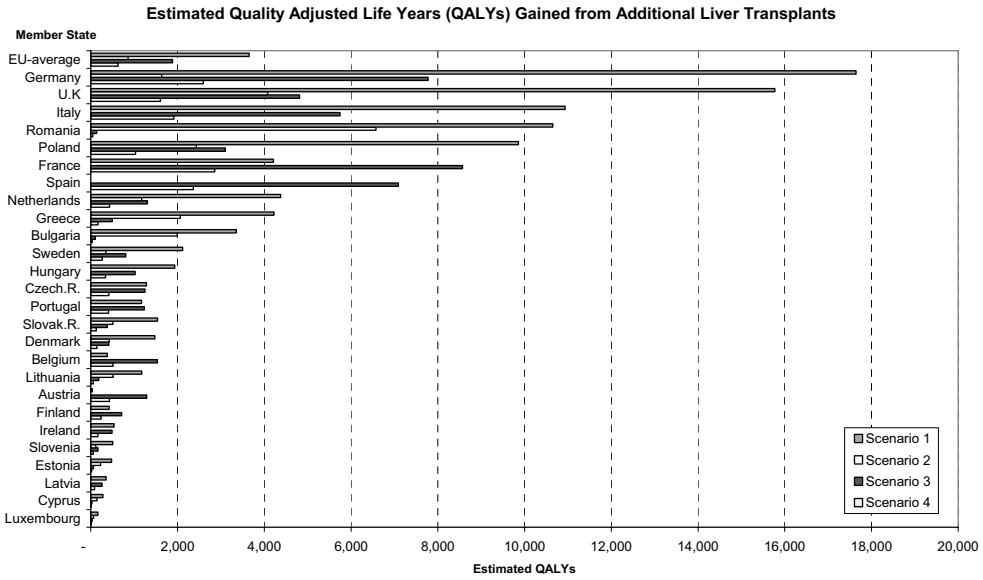
Estimated QALYs and Life years gained

	Scenario 1		**Scenario 2**		**Scenario 3**		**Scenario 4**	
	QALY	LY	QALY	LY	QALY	LY	QALY	LY
Kidney	25,576	16,500	6,014	3,880	13,210	8,522	4,403	2,841
Liver	94,877	136,128	22,310	32,010	49,004	70,310	16,335	23,437
Heart	56,101	49,501	13,192	11,640	28,976	25,567	9,659	8,522

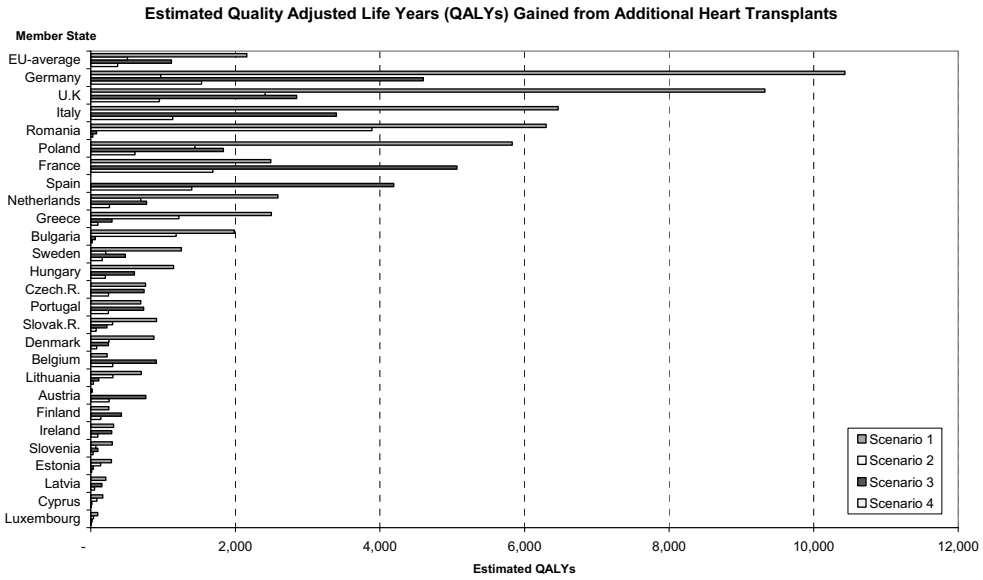
Lung	42,901	28,876	10,088	6,790	22,158	14,914	7,386	4,971
Total	**219,456**	**231,006**	**51,604**	**54,320**	**113,348**	**119,314**	**37,783**	**39,771**



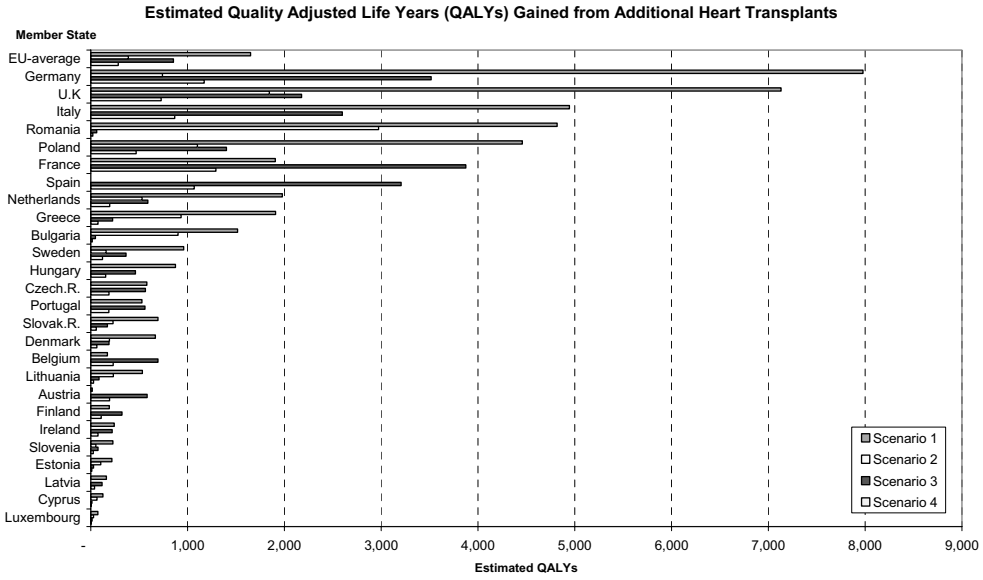
QALYs gained over 30 years through additional kidney transplantations



QALYs gained over 30 years through additional liver transplantations



QALYs gained over 30 years through additional heart transplantations



QALYs gained over 30 years through additional lung transplantations

If these estimates are assigned to the policy options ranges of possible life years saved and QALYs gained can be established for the policy options. The baseline Option 1 would not lead to additional life years saved and QALY gains, on contrary, under the assumption of stable donation rates, waiting lists are likely to further increase, which has negative

	repercussions on life expectancy and QALYs. First, with longer lists, patients are less likely to receive an organ, and secondly, if they receive an organ, they will be in a less good health condition, which reduces the QALY and LY gain per transplantation. Under Option 2, the action plan, depending on the commitment of Member States substantial life year and QALY gains could be achieved. Using the estimates for Scenario 2 and 4, would give a maximum range of 119,314 to 231,006 life years to be gained, which would translate into a maximum of 113,348 to 219,456 QALYs, there is however a high level of uncertainty attached to this maximum estimate. Due to their more stringent character, we expect Option 3 and 4 to reach a modest increase in donation rates with a high certainty, Using Scenarios 4 and 2, this would translate into 39,771 to 54,320 life years saved and a QALY gain between 37,783 and 51,604. The maximum effect that can be expected would be defined as for Option 2 as Scenario 1 and 3.
Risk for patients	Option 1 will lead to no changes in the currently diverse regulatory landscape of quality and safety standards across Europe. While there is a wide range of initiatives already to follow up medical results of transplantation and these different systems will be likely to further co-exist and improve, however no integration of system is expected across Europe. In addition, adverse events are not systematically captured in most member states leaving a large potential to improve the processes of transplantation and donation as well as improving the medical outcomes of transplantation. The action plan envisaged under Option 2 would introduce measures to improve the evaluation of post transplant results by agreeing on common definitions and by developing a European register or network of registers. While this option does not directly address the risks incurred by patients during transplantation, it will contribute to better treatment in the long term, as knowledge about transplantation outcomes increases. Option 3 goes substantially further than Option 2 by establishing mandatory elements of European quality and safety standards. Under Option 3, common standards for the characterisation of organs would be established as the basis for organ matching and the decision-making of transplant teams. This data would be stored in such a way, that it can be transmitted quickly between Member States to facilitate the exchange of organs. Despite these European standards the final decision of transplanting a particular organ would still rest with the local transplant teams. The common system of organ characterisation would be supplemented with a reporting system for adverse events related at all steps of the organ donation and transplantation process. Overall Option 3 can be expected to reduce the risks for patients in countries with currently insufficient quality and safety standards and in addition supports cross border exchange of organs, which has been proven to be beneficial. Adverse event reporting systems have been proven to lead to improvements in the quality of processes and the quality of care, so the introduction of such systems will benefit patients in the medium and long term. Option 3 thus leads to substantial health benefits. Under Option 4, similar quality and safety standards and adverse event reporting systems would be introduced, which will lead to the same positive health outcomes. The substantial difference is the regulatory approach. Option 4 would give the Member States less discretion in implementing standards and would even limit the decisions that can be taken by transplant

	teams, by e.g. defining a list of exclusion of certain types of organs
Living Donation	Option 1 will not change the current practice of living organ donation in European Member States, with a wide variation in donation rates and a large potential for increased donation and differing legal frameworks for the acceptance of living donation. Nevertheless, given the current organ shortage and witnessing the development in particular in the Nordic countries or the Netherlands, where living donation has become a very important substitute to donation from deceased donors, we can assume that even under option 1, the importance of living donation might increase in the medium and long term. Option 2, in contrast, tackles three important elements of living donation: It would encourage Member States to ensure altruistic and voluntary donation while promoting living donation, it would promote the establishment of living donor registries to systematically follow up the health effects on the donors, and it aims to ensure adequate health protection and health care coverage for living donation. Estimates based on our scenarios see a maximum of 5,762 additional living donors possible across the EU, if all Member States would have living donation rates similar to Norway. As this is in particular under a voluntary agreement, a very optimistic assessment we would expect that under full commitment from Member States donation rates will be somewhat below this value. However, it is clear that Member States could substantially increase their living donation rates if they learn from best practice. The second provision, the evaluation of the medical status of living donors can contribute to bridging the current knowledge gaps about living donation and will help to decrease adverse effects for donors in the medium to long term. In addition, long term medical outcome data would help in providing more accurate advice to potential donors about the risks (health and other) of the donation. Finally the third provision, i.e. ensuring voluntary and altruistic donation, will reinforce national practice in the Member States and can contribute to building more trust in living donation in the transplantation pathway. Options 3 and 4 are based on the action plan, but would anchor the protection of the living donor and the evaluation of outcomes in European law. While such legal protection would have no immediate effect on donation rates, this measure might increase the trust in the overall system and reinforce an increase in living donation rates.
Exchange of organs	Although the exchange of organs between Member States and with Third Countries is currently low, there are clear health benefits for special patient groups, including highly immunised patients, high urgency cases and paediatric patients. Under the baseline option 1, we expect numbers of exchange to remain largely stable, although slight increases are possible through emerging cooperation between Member States. Facilitating the interchange of organs within the European Union is an identified priority action of the action plan under Option 2. Since it foresees the creation of improved and more efficient processes for offering surplus organs to other countries, in particular for urgent and difficult to treat patients, such measures are likely to increase the exchange of organs, as regional improvements show. And, as the importance of the exchange of organs for such patient groups in the Eurotransplant shows, any increase in cross border exchange will lead to benefits for difficult to treat and high urgency patients, in particular in small Member States that do not currently participate in international cooperation agreements. Option 3 and 4 also enclose this provision, but supplement it by defining common quality

	and safety standards for the organs to be exchanged and by defining clear standards for the exchange of organs with non-Member States. Common quality and safety standards will both remove some barriers to organ exchange and ensure that the (increasing) exchange of organs is safe and adheres to best medical practice. As several stakeholders pointed out in our interviews, trust in other Countries' quality and safety standards is both important in their transplant teams' willingness to consider and accept organs, as well as in sending organs to other countries. It seems thus reasonably to assume, that Option 3 and 4 could further increase the exchange of organs, it is however important, that new authorisation requirements for the exchange of organs, do not lead to delays in the transport of organs, resulting in longer ischemia times and worse transplant outcomes.
SOCIAL IMPACTS	
Quality of life	As is apparent from the available evidence about the quality of life of organ recipients, it would be difficult to assess whether a policy intervention leads to an increased quality of life for individual organ recipients or donors, with the exception of living donation, there improved health care services might reduce some of the negative impacts on the QoL of organ donors. At the same time it is evident that increased donation rates will allow more patients to experience a better quality of life, which will be the main impact of the proposed policy Options. The status quo will persist under Option 1 and therefore it is unlikely that any change to the standard of living of organ recipients will occur. As there will be a wide variation in donation rates and differing legal frameworks, it is likely that there will continue to be diversity in the extent and level of quality of life experienced by organ recipients in Europe. Nevertheless, for those individuals who do receive a transplant, their standard of living will increase in terms of greater control over their lives and mobility through increased quality of life. For living donors, the mixed evidence on whether quality of life improves or worsens for these individuals underscores the great difficulty in predicting the baseline from which to compare the options. There is potential for Option 2 to increase the quality of living organ donors as the Action Plan alone aims to protect their health by promoting the establishment of living donor registries to systematically follow up the health consequences of their altruism. Options 3 and 4 would make living donor protection a legal obligation, thus creating a higher level of protection for the living donors. Yet, it remains unclear whether these measures in themselves are sufficient to improve the standard of living of living donors by preventing or at least mitigating any adverse psychosocial outcomes. The main impacts are however to be expected from the possible increase in donation and transplantation rates. As Option 2, i.e. the Action plan without the supporting directive, is less likely to achieve large increases in donation; the positive social impacts of better quality of life for more patients will be smaller than for Option 3 and 4. Thus it is reasonable to expect that Options 3 and 4 will lead to higher standards of living for a greater number of transplant recipients, given that these policy options are intended to both increase the donation rates and improve the improved quality and safety of transplantation systems generally.
Employment and social participation	Policy Option 1 means that the current situation will basically continue with incremental improvements in treatment allowing for a small increase in social participation and employment. These small increases will be the same for all policy options as they are not likely and not designed to increase social participation and employment at an individual

	level, as none of the policy options will address the obstacles to employment and social participation identified in the literature. The options can however, through an increase in transplantation rates, increase the number of patients who will be able to work, either because their life has been saved or because they do not have to receive dialysis treatment three times a month. Based on this relationship we can expect better social impacts of policy Options 3 and 4, which would deliver increases in the donation rates with more certainty than Option 2. Overall the evidence base on the impact on social participation is still weak which has to be taken into account while assessing the options.
Trust and confidence in organ donation and the transplantation system	This section presented somewhat limited evidence on the trust and confidence impacts of the proposed policy options. Option 1 would see a continuation of the differences across Europe in trust and confidence. By promoting the role of trained transplant coordinators, which might involve training in management of potential donor families, Option 2 has the potential to increase the confidence of donors and donor families which might subsequently even lead to higher donation rates. Similarly, Option 3 and 4 support the training of key personnel along the donation pathway which would support the action under Option 2. Quality and safety measures are, while encouraged under Option 2, primarily included in Options 3 and 4. These have the potential to improve the quality of the processes, and in particular they will establish a reporting system for adverse events. Such measures can increase the confidence in the transplantation system, in particular if the results of a quality and safety monitoring would be publicly available. The limited available evidence does not allow us to assess whether, for example, the existence of European quality and safety standards would have a positive impact on the general public's trust and confidence or whether measures to increase public awareness are a more efficient way of increasing wider trust and confidence in the system. To summarise the comparison of options, we would expect positive impacts for all three options for donor families and transplant patients, with slightly higher benefits from Options 3 and 4 as these will make important elements of training and quality and safety mandatory. However, the evidence base for these qualitative findings is under-developed.
ECONOMIC IMPACTS	
Start up and running costs for a national infrastructure and better processes	Under **Option 1**, the status quo would continue. There would be no systematic change to the organ donation and transplantation infrastructure. It is reasonably to expect some countries to invest in improving the infrastructure and processes of organ donation, through quality programmes such as the Donor Action programme; however this will not lead to new costs for extending and running the national infrastructure Although not prescribing the creation of a competent authority, **Option 2** implies that there is a national responsible body for reporting and liaising with the European Commission and the other Member States under the Open Method of Coordination. In addition, this option would promote quality programmes in the Member States and encourage the use of transplant coordinators, and finally tries to establish agreement on common accreditation standards for organ procurement and transplantation programmes. All of these measures would be on a voluntary basis and could take into account the current situation in the Member States to a

	maximal extent. The designation of a competent authority, typically the department of health or a national organ donation agency would require little resources, as these organisations are typically already in place. The economic implication of the other measures to build up the national infrastructure depends on the Member States decision on how to implement common recommendations. Many Member States do already have some kind of quality system in place, run initiatives such as the donor action programme and do use transplant coordinators, which would reduce the costs of such measures. Accreditation and authorisation, as foreseen through common accreditation standards, might however involve substantial costs, judging from the available evidence from the UK and Germany and might in addition have the negative side effect of discouraging hospitals to participate in organ procurement. Similarly, increasing the number of transplant coordinators will create substantial running costs. Proposals to introduce transplant coordinators in the UK were costed at around € 14 million for 150 to 175 new transplant coordinators, i.e. a cost between € 80,000 to € 100,000 per transplant coordinator (including non pay costs), which is similar to estimates for Germany of pay costs between € 45,000 and € 70,000 for a nurse or physician transplant coordinators. The total cost of this policy option will depend on the willingness and the necessity for Member States to increase the number of transplant coordinators. Given the voluntary character of measures under the action plan, we would however expect the costs to Member States as being low under this action. **Option 3** combines the measures of the Action Plan with supporting regulation: The requirement to designate a competent authority, the requirement for national authorisation schemes for transplant and procurement centres, the request to establish national quality programmes and enforcement and monitoring activities. There is little evidence available on how much the implementation of these flexible regulations would costs. The annual running costs of the Spanish National Transplantation Organisation of around € 4 million (≈ € 100,000 pmp), might give an indication of the maximum cost that would be incurred by implementing Option 3. As most Member States have substantial or some elements of such systems already in place, the additional costs can however be expected to be well below this boundary. The Donor Action, a quality programme for the procurement of organs costs as little as around € 8,000 annually per hospital, which illustrates that national quality programmes could be implement at relatively low costs.[137] For Canada, the running and maintenance costs of the Donor Action programme were estimated at € 45,000 pmp. Accreditation or authorisation of activities might create costs, depending on whether Member States would decide to designate or authorise/accredit activities. While the former can be achieved at no or very low additional costs, the latter might result in substantial additional burden In the UK licensing of facilities under the tissue and cell regime costs currently around € 10,000 per establishment. However, the majority of Member States runs some kind of authorisation and accreditation process already. If these costs are substantial, hospitals which are currently involved in organ procurement might however stop the identification of suitable donors all together, as they already nowadays feel, that they are not adequately reimbursed for the efforts of organ procurement. **Option 4** covers the same policy measures as Option 3, but would introduce a more stringent

[137] This would e.g. result in total costs of around € 4.9 million for all 613 organ procuring hospitals in Germany.

	approach, which would mean less discretion for the Member States in implementing the European initiative. Lesser discretion means however, that fewer elements of the current systems are already pre-compliant with the regulation and more changes to the current systems are required. Option 4 would use the same mechanism as Option 3 to establish competent national authorities, which should not result in substantial costs for Member States. The authorisation of activities would be prescribed in detail under Option 4, with separate authorisation programmes for each stage of the organ donation and transplantation process. In the comparison of options, this would lead to the highest costs for authorising activities, as Member States have to follow a common set of standards and cannot use their current authorisation schemes if existing. There is however not enough cost information available, to assess the costs of such an extensive authorisation activity. The cost information from the UK, which imply licensing costs of around €10,000 per establishment, would be incurred by not only the around 300 transplantation centres across Europe, but also by the much higher number of potential procurement centres, which basically are all hospitals with an ICU. Policy Option 4 proposes strict requirement, supported by an implementing directive, to put in place a quality programme in every hospital, rather than just prescribing a national quality programme as under Option 3. In most countries, such comprehensive quality systems are not in place yet and the proposed option would thus entail substantial cost. The € 8,000 per hospital or € 45,000 pmp for the Donor Action programme can be expected to be a lower boundary for costs per country to introduce a comprehensive quality system, as this quality programme, covers only the procurement and donation phase. In addition Option 4 clashes with the predominant form of governance in the Member States, in which quality control systems for procurement and transplantation of organs are established through guidelines rather than legal acts **Error! Reference source not found.**.
Costs for setting up and running national registers and traceability systems	As shown in the previous section, Member States do collect already substantial amounts of data about transplantation and organ donation and store information in various databases, however these systems are not necessarily integrated on a national level and data is provided to a multitude of recipients. Option 1 would leave the current system untouched and thus not create additional costs. However, this option would also do not help to achieve certain efficiency gains, if reporting about outcomes would for example be standardised across organ types and transplant centres. The working plan foreseen under Option 2 would encourage Member States to develop systems to systematically evaluate post transplant results. Currently Member States, and often single transplant centres, provide medical outcome data voluntarily to various different registers and medical research projects, such as the Collaborative Transplant Study (CTS). As suggested by some stakeholders interviewed, common guidelines and a more centralised system of reporting have the potential to streamline this reporting, by reducing the number of places information has to be submitted to and the frequency of reporting. Clearly, this could lead to efficiency gains for transplant centres and Member States, while at the same time generating comparable data across the European Union. Option 3 would supplement this voluntary improvement of the transplant result reporting by a requirement to introduce a publicly accessible register of establishments, a national donor register and traceability system, and a national adverse event reporting system, both complemented by European guidelines on the exchange of data between Member States. Given the small number of transplant centres, in each country (on average 28 transplantation programmes per country), a register of establishments will generate only marginal costs, in

	particular as it can be safely assumed, that the list of establishments is readily available and does not change frequently. The costs for a traceability and adverse event reporting system can only be roughly estimated. A British regulatory impact assessment of the tissue and cells directive estimated costs for a traceability system between € 130,000 and € 300,000 for the UK, with costs per establishment of € 550 and €1,300 per establishments. Costs per establishment would however be higher in the case of organ donation, as the number of transplant centres is low (e.g. 58 transplantation programmes in the UK, which would lead to per centre costs of between € 1,800 and € 4,100). This does not however take into account, the savings that could be achieved by integrating the organ traceability and vigilance system into the emerging reporting infrastructure for tissues and cells, and that some Member States are already pre-compliant with the regulation. Option 4 contains similar requirements as Option 3, but would base the traceability and adverse event reporting systems on a European directive, prescribing the characteristics of these systems in detail. There are no other cost estimates available for this option than for Option 3; however we can reasonably assume this option to be more expensive than Option 3. As shown in **Error! Reference source not found.** a substantial number of Member States has already some kind of traceability system in place, which would not necessarily comply with a uniform European system. While Option 3 would allow for some variation between Member States, Option 4 would not. This would clearly result in higher adaptation costs.
Reporting obligation and administrative burden	Each of the different options contains reporting obligations, potentially resulting in additional administrative burden for hospitals and Member States authorities. Currently (**Option 1**) hospitals and Member States are reporting a variety of information to national and international bodies, including the Council of Europe, the supranational transplant organisations Eurotransplant and Scandiatransplant and international organisations such as the WHO. However, not all countries contribute equally to these national reporting systems. Option 1 would thus maintain this fragmented reporting at no additional costs for Member States and hospitals. The Action plan foreseen under Option 2 would not fundamentally change this system, but would introduce reporting requirements under the open method of coordination, requiring to annually providing key data on donation and transplantation activities as well as progress in implementing the national action plans and quality programmes. As most of this data is already available, it can be assumed not to generate a high burden for Member States. In addition, **Option 3** and **Option 4** require additional reporting about the activities of procurement and transplantation establishments, including the number of donors, the types and quantities of organs procured and transplanted or otherwise disposed etc. Option 4 would include a longer list of indicators. However, most of these indicators are already available, and should thus not put a major burden on the hospitals to collect and transmit this information to the competent authorities of the Member States.
Treatment Costs	Based on this evidence and not taking into account the value of a statistical life, it is clear, that a an increased number of kidneys will result in substantial cost savings, and that the costs of liver, heart and lung transplantation are usually considered to be cost-efficient, i.e. that costs do not exceed the commonly accepted limits of costs for treatment. As the

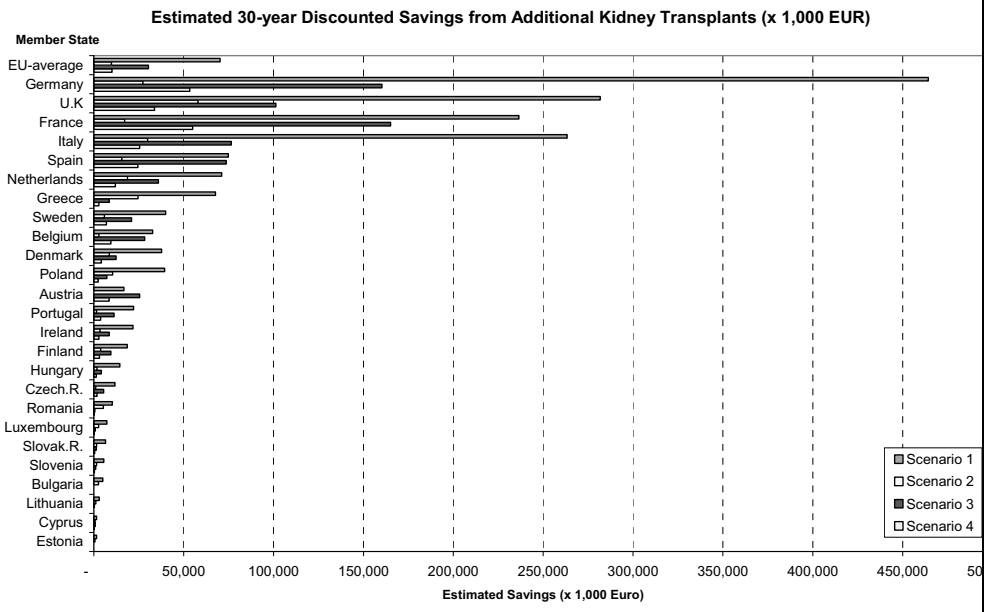
treatment costs depend on the number of organs transplanted, we first present the possible ranges of treatment costs, before relating these to the policy options.

Using four scenarios calculated the impact on treatment costs across Europe. Table 11 provides an overview of the cost estimates of having additional transplants available. These savings would occur over a thirty year period for a single cohort of transplant patients, i.e. these would be the benefits of a single year of having high donation rates. Even in the most conservative scenario 4, assuming a 10% increase in transplantation from deceased and living donors, there would be substantial economic benefits of € 152 million across the European Union. Cost savings would even increase up to € 1,185 million in Scenario 1, which is the most optimistic scenario and assumes all countries would reach the transplantation rates of the best performers in deceased (Spain) and living donation (Norway).

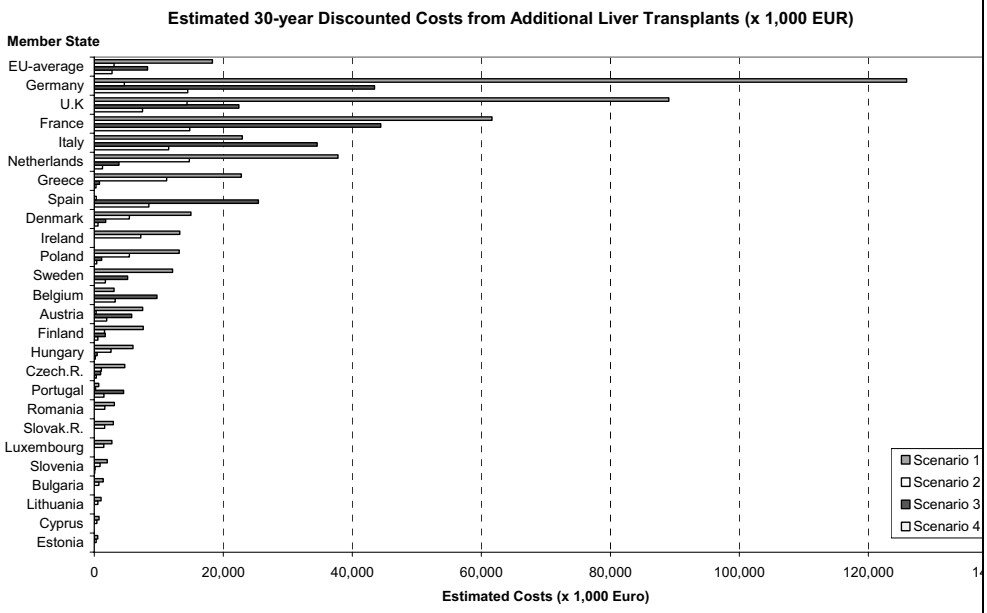
Estimated 30 year discounted treatment costs/cost savings from additional transplants across EU-27 in 1000

	Scenario 1	**Scenario 2**	**Scenario 3**	**Scenario4**
Kidney	-1,755,691	-246,961	-759,949	-253,316
Liver	457,657	76,619	206,343	68,781
Heart	17,371	6,720	17,512	5,837
Lung	95,375	31,413	78,015	26,005
Total	-1,185,288	-132,208	-458,078	-152,693

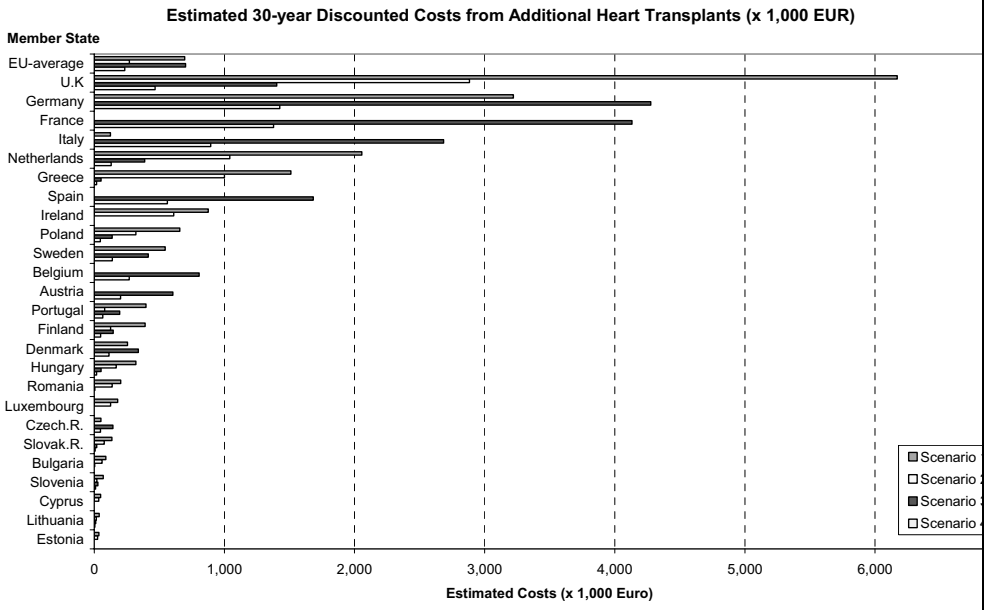
The cost saving effect is entirely due to the cost saving effect of kidney transplantation. Figures 5.12 to Figure 5.15 provide a detailed overview of the cost implications per organ type and country.



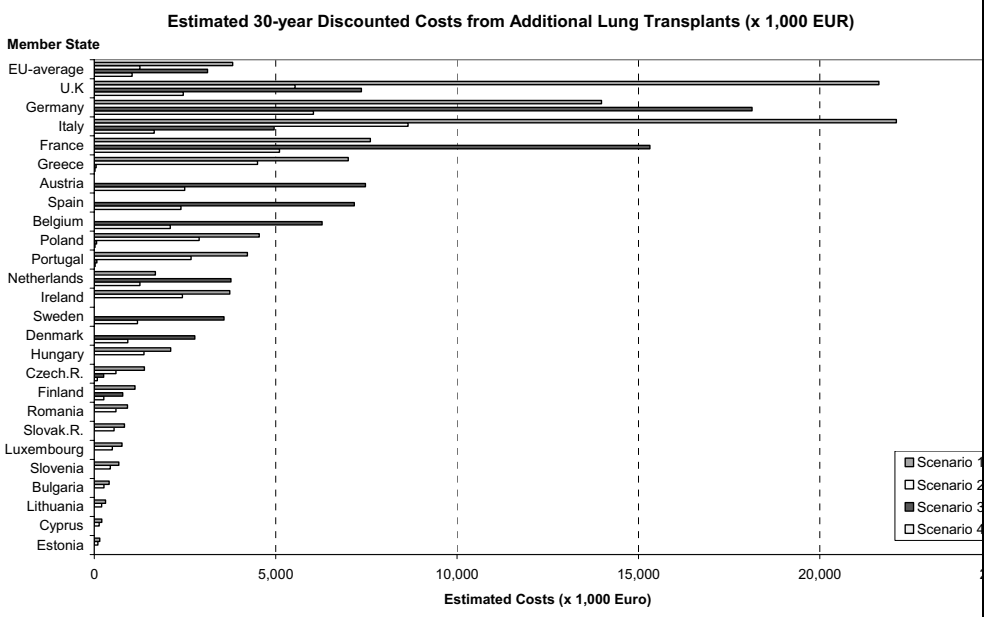
30-year discounted savings from additional kidney transplants



30-year discounted costs from additional liver transplants



30-year discounted costs from additional heart transplants

	 30-year discounted cost from additional lung transplants Applying our assumptions of section **Error! Reference source not found.** on how the policy options would influence donation rates, we can illustrate the likely scope of the impacts on treatment costs. Under Option 1 no immediate changes to treatment costs can be expected, however Member States are likely to face rising treatment costs if waiting lists and prevalence of end stage renal disease increase in the medium and the long term. For option 2, for which we consider the outcomes to be most uncertain, the calculation based on the treatment costs reveals a range of cost savings between € 458 million and € 1.2 billion, which can be attributed to savings from dialysis treatment. For Option 3 and 4, in which we assume at least a modest increase in donation rates, costs savings can be expected to be in the range between € 132 million and € 152 million at the lower end and between € 458 million and € 1.2 billion in the best case scenarios.
Productivity impacts	It was calculated the possible productivity impacts from the four scenarios. Scenario 4 has the highest productivity impact with around € 5 billion for a cohort of patients, while scenario 2 would only have a productivity impact of around € 460 million over time. Due to the non live saving character of kidney transplants, the total impacts for this group are relatively small.

	Productivity impacts of increased transplantation rates over a 30 year period (Euro) **Scenario 1** **Scenario 2** **Scenario 3** **Scenario 4** Kidney 513,484,237 47,505,707 273,194,277 91,064,759 Liver 2,433,587,527 225,146,728 1,294,766,494 431,588,831 Heart 1,278,247,994 118,258,887 680,079,370 226,693,123 Lung 745,644,663 68,984,351 396,712,966 132,237,655 Total 4,970,964,420 459,895,673 2,644,753,107 881,584,369 Transferring the scenario estimates to the policy options again, Option 1 would not result in productivity gains, if patients are longer on waiting lists and have to receive dialysis treatment; they are less likely to work than transplanted patients. The maximal gains under Option 2 will be productivity gains of between € 1.3 billion and € 2.4 billion if Member States fully commit to implement all voluntary elements of the Action Plan. With the assumed minimum level of compliance under Options 2 and 3, productivity gains between € 460 million and € 882 million would be expected. For the best case scenario, the higher estimates of Scenarios 1 and 3, i.e. productivity gains between € 1.3 billion and € 2.4 billion seem feasible.
Economic Impacts on Living donors	Option 1 will not change the current practice of living organ donation in European Member States, with a wide variation in donation rates and a large potential for increased donation and differing legal frameworks for the acceptance of living donation. Nevertheless, given the current organ shortage and witnessing the development in particular in the Nordic countries or the Netherlands, where living donation has become a very important substitute to donation from deceased donors, we can assume that even under Option 1, the importance of living donation might increase in the medium and long term, which would result in more patients being exposed to the economic risks of living donation. By promoting the provision of adequate healthcare coverage for living donors, DG SANCO's proposals will reduce the cost risks related to health care expenses for living donors, the proposed action would however not protect the living donor from other economic risks. There is however enough evidence to suggest, that living donors can incur substantial economic costs, through for example, reduced possibility to work or even partial disability in case of adverse physical and psychological events. However, due to the relative low number of living donors (5, 762 additional donors under best case scenario), the aggregated economic impact will be relatively small. So while, we expect increasing numbers of living donors, the measures proposed will only cover the costs of health care, but no wider economic risks to the living donors. Similarly, Options 3 and 4 concentrate on the provision of health care, but do not touch upon wider economic impact of living donation on the living donors.

ANNEX VIII

CAPABILITY APPROACH [138]

INTRODUCTION

This annex presents how 'capabilities approach' contributed to the analysis and presentation of the impact assessment (IA) on Organ Donation. This IA forms a pilot, the purpose of which is to verify whether the capabilities approach (CA henceforth) can be usefully applied in future IA's. Our task was not to do the input part but to use material provided by Rand[139].

The CA, as first formulated by Nobel Prize laureate Amartya Sen,[140] focuses on the well-being of the individuals, and thereby enriches the set of policy goals that is used in IA's. This enrichment can make the IA's more operational and more consistent. This is particularly true in the social dimension, for which it is difficult to make benefits operational using traditional methods.

The CA's focus on the individual and on freedom implies that it puts human beings central to the discussion. This is also in line with the citizens agenda. According to Sen, a person's well-being is a combination of achievements and opportunities. Both are important. For example, someone who has ample job opportunities but chooses not to work has a different level of well-being than someone who is involuntarily unemployed.

While the literature clearly shows that the move to a multi-dimensional framework could be a considerable enrichment for policy analysis, there is no consensus about how to define a multi-dimensional 'space' that can be applied to policy assessments[141].

Our first task was to define a pragmatic multi-dimensional space that could sharpen the goals on which one wants to achieve progress. This has led us to a list of nine dimensions (see Box below). The list is a consolidated version of lists that have been constructed in the literature, e.g. by Martha Nussbaum[142]. The list below is fully consistent with current IA practices and in first instance only regroups benefits into nine different categories.

These nine categories are all aimed at final goals (health, safety etc) but also include important elements of freedom and opportunities (ability to…). Together they form a closed set of well-being, i.e. there are no aspects of well-being that fall outside the scope of these categories, with two exceptions. The first exception is costs. While cost aspects of policy proposals could in theory be attributed to the categories, in practice it will often be more convenient to compare impacts on relevant categories with total monetary costs, without specifying to which category these costs belong. The second exception is that beyond well-

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[138] The paper was written by Marcel Canoy (Professor of health economics, TILEC, University of Tilburg, chief economist ECORYS. During most of this work Marcel was working for BEPA), Frédéric Lerais (BEPA), Erik Schokkaert (Professor of Economics, Catholic University of Leuven) in close collaboration with DG SANCO and using data input from RAND Europe.

[139] Rand Europe (2008): *Improving Organ Donation and Transplantation in the EU*, June 2008.

[140] See e.g. Sen, A. (1999). *Development as freedom*. New York: Knopf.

[141] See e.g. Schokkaert, E. (2007) 'The capabilities approach', Catholic University of Leuven, Centre for Economics Studies: *Discussion Paper* 07.34 and Alkire, S. (2002) 'Dimensions of Human Development' in *World Development* 30(2):181-205.

[142] Some modifications of the lists of the literature were needed, since the available lists were not designed for our purpose.

being as measured by the categories, there could be overarching ethical issues that need attention.

Box 1 Applied basic capabilities*

1 ***Health, longevity.*** Being able to live to the end of a human life of normal length; not dying prematurely; in good health, including reproductive health.

2 ***Safety.*** Being able to be secure against violent assault and perceived danger, including sexual assault; being able to have adequate shelter; feeling safe.

3 ***Education.*** Being able to use the senses; being able to imagine, to think, and to reason-and to do these things in a way informed and cultivated by an adequate education; being able to use imagination and thought in connection with experiencing, and producing expressive works and events of one's own choice; being able to form a conception of the good and to engage in critical reflection about the planning of one's own life.

4 ***Standard of living.*** Material control over one's environment: being able to hold property (both land and movable goods); having the possibility to seek employment; being able to purchase goods and services beyond basic ones.

5 ***Productive and valued activities (Employment).*** Being able to find and keep a job at an adequate level, having adequate working conditions, having a good work-life balance, being able to develop oneself within job, being able to develop valued activities outside the job.

6 ***Quality of social interactions.*** Being able to live for and in relation to others, to recognize and show concern for other human beings, to engage in various forms of social interaction; being able to imagine the situation of another and to have compassion for that situation; having the capability for both justice and friendship. Being able to be treated as a dignified being whose worth is equal to that of others. Feelings of social justice.

7 ***Environment.*** Being able to live with concern for and in relation to animals, plants, and the world of nature. Being able to contribute to a sustainable world.

8 ***Culture and entertainment.*** Being able to enjoy oneself, to play, to enjoy recreational activities; engaging in sport and cultural activities.

9 ***Basic rights.*** Having freedom of speech and religious, absence of discrimination, freedom to move.

* based on a modified list proposed by Martha Nussbaum (Martha C. Nussbaum, Capabilities as Fundamental Entitlements: Sen and Social Justice (2003))[143]

THE FIVE STEPS TO APPLY CAPABILITIES

Since we want to test whether the CA can also be applied beyond this IA, we first explain its general mechanics. The way the capabilities list is used in policy assessments is as follows.

[143] See also http://www.wku.edu/~jan.garrett/ethics/nussbaum.htm

Step 1: Selection The potentially relevant capabilities are selected. For most policy proposals only a subset of the nine capabilities is relevant. Others are omitted. Yet, because one always first considers the nine capabilities, attention is drawn to potential (negative or positive) side-effects of the policy proposal.

Step 2: Impacts The impacts on the chosen capabilities will be assessed, using a variety of tools including traditional tools such as cost benefit analysis. It follows that the CA in itself does not replace traditional tools.

Step 3: Distribution Distributional issues are an important part in the capabilities approach. Since an individual well-being approach cannot be realistically achieved in its full form, we mimic this by defining groups. These groups are relevant partitions of the people on which the policy proposal is expected to have impact.

Step 4: Ethical considerations As discussed above, ethical considerations can go beyond the categories and hence need to be discussed separately, if relevant. One could also say that the evaluation of the impacts is in terms of "well-being freedom", while there are additional considerations with respect to "process-freedom". The former refers to the scope of individual choice, the latter to the process of choosing.

Step 5: Overall assessment Combines steps 1 and 4 and adds costs considerations, inter alia also taking into consideration possible relationships (mutual reinforcements or trade offs) between categories.

The steps need to be replicated for each policy option. In fact, the full potential advantages of the CA in terms of coherency and consistency can be demonstrated best when it is applied to different IA's as it shows the various capabilities that can be at stake when dealing with a proposal. The next section will apply the CA to the organ donation proposals.

STEP 1: APPLYING THE CA TO ORGAN DONATION

Background

The main challenge of the proposal (in whatever option) is relatively clear: there is an insufficient number of donors and hence also an insufficient number of successful transplants. There is a whole array of reasons behind that: lack of public awareness, lack of confidence in the system, lack of public respect for donors, lack of confidence in the quality of organs, lack of donor protection, lack of a proper training of medical personnel and lack of possibilities for cross-border exchange of organs, to mention a few. Because of this array and the persistence over time of the problem, the policy proposal - and in particular the preferred option Action plan and flexible Directive - aim at the broad range of underlying reasons behind shortages. Partial methods have been tried before, but with mixed successes at best.

Many years of efforts by Member States have not closed the gap between the supply and demand for organs. Actions at EU level can only be motivated if they are likely to achieve something that has not been achieved before. To be able to do this, one has to be specific in what ultimately drives the number of high quality transplants and how this enhances the well-being of the citizens.

The mechanism of benefits

The Commission aims to enhance well-being through increases in high quality organ transplants. All elements of the Directive and the Action Plan are targeted at the different categories that influence organ availability (and successful transplants in the end). Enhancing organ availability requires sufficiently high quality, removal of disincentives to donate, enhancement of exchange, building public confidence etc.

Final objectives

DG SANCO has identified three objectives: enhancing efficiency, quality and safety and the number of successful transplants. These chosen objectives are useful since they are direct reflections of what the policy proposals aim at, and are recognizable as such for all involved parties. Most of the effects of the policy proposals indeed run through these objectives. Therefore they do not only perform a communication role but also an analytical one. However, they are intermediary objectives. In the end we are interested in final objectives, i.e. how the chosen proposals influence peoples' well-being, e.g. in the form of health. Converting the chosen objectives into final goals (i.e. well-being) is one of the benefits of the CA. *For this IA, well-being is measured by the capabilities: (i) health; (ii) safety; (iii) standard of living (iv) quality of social interactions; (v) productive and valued activities (Employment).*

There are at least three reasons for concentrating on objectives that directly influence individual wellbeing, i.e. impact on capabilities can be interpreted as final outcomes. The first reason is that final outcomes ultimately reflect better what the real impact for society is of any given policy proposal. Second, there is a risk that there are direct effects of the policy proposal that do not run through the three chosen intermediary objectives. In the current example of organ donation there are e.g. a number of actions that provide information to families of deceased donors or that provide protection to living donors. Such actions have impact on intermediary objectives (quality and safety) but also have direct benefits irrespective of their impact on the quality and safety or the number of transplants. Finally, there are causal relations between the chosen intermediary objectives, which may lead to confusion or double counting. For instance, improvements of quality and safety could lead to more transplants (if trust is enhanced), or to less transplants (if the quality requirements are increased). Conversely, increasing the number of transplants can be achieved by reducing standards. Concentrating on final objectives with the aid of capabilities will reduce this problem.

Note that it is important to carefully distinguish the "instrumental" and the "final" value of the policy effects. To give an example: providing protection to living donors has a direct effect on the "health" outcome for donors; it may also be instrumental in leading to a higher number of transplants. The former effect is important even if the instrumental effect is absent. The value of the latter (instrumental) effect will be determined on the basis of the effect of the number of transplants on the final objectives.

The mechanics of capabilities, irrespective of the chosen policy option

From above it follows that there is merit in concentrating on capabilities. Since this has to be done for all policy options, we will first have to establish *in general* (i.e., irrespective of the policy proposal) what, e.g. an increase in the number of high quality transplants means for health, standard of living etc. So if we have established that e.g. policy proposal A is likely to yield and increase in X transplants, we need to establish a link between the number of transplants and the chosen capabilities. This is done in section 5.

STEP 2: IMPACTS ON THE FIVE CAPABILITIES

Step 2 involves assessing the impact of the policy proposal on the five capabilities. As discussed above we first need to establish the mechanics of measuring impacts, ie without going into the details of the different options.

We have chosen five basic capabilities as being relevant. One could say that health is a central capability for the policy proposal, for two reasons. First of all, there would be little merit in the proposal if no health effects materialize. Second, benefits on other capabilities directly follow from the health effect, i.e. the fact that people are healthier enables them to engage in a variety of activities that enhances their well-being in other dimensions. Health is also the effect that is most directly observable and measurable. While this is convenient from a communication point of view, it does not mean that just because it is easier to measure it is the only or most important issue.

To exemplify that point, consider the following case of dual causality. Indeed, a better health creates better conditions for other dimensions of well-being. But in the case of organ donation, we know from the policy experiences around the world, that health outcomes (in the form of increases in the number of transplants) can only be achieved if the public is better informed and has a greater confidence in the system, impacts that are mentioned in the capabilities 'safety' and 'social interaction'. It is for this reason that successful policy proposals (example Spain) target at these so-called softer goals.

Health and Standard of living

The impact on health of the policy proposals is well-documented. An increase in organ donations has an impact on death rates on waiting lists, direct health effects after transplants, survival rates, reductions in the transmission of diseases and health effects on donors. All these dimensions can be expressed in QALY's.[144]

From the Rand report the most complete information on the general health impact of organ donation and transplantation comes from the UK Transplant Supplement Report[145]. For example, liver transplantation has the highest QALY gain (11.5); heart has 6.8 QALY gain and lung has 5.2 QALY gain. Compared to dialysis, the benefits of different treatment strategies for Type 1 Diabetes with End Stage Renal Failure range from 2.01 to 5.77 additional QALYs. In addition, evidence from the international literature shows that a typical donor generates about 13 QALYs[146].These benefits in terms of QALYs do only occur if increases in transplants are realized as a result of the policy proposals. Analyzing the Spanish (and also Italian and Greek) model reveals that policy proposals similar to the ones suggested by DG SANCO have led to substantial increases in transplants (Rand p.55). In the (unrealistic) case that all Member states achieve Spanish levels, the gains in QALYs are even in the order of 219,000 QALYs. But even under more moderate assumptions the gains can still be substantial (Rand p.61).

There is no consensus in the literature or among health practitioners how to monetarize the benefits of QALY's. The range is between 20,000 to 100,000 euro per QALY. The main

[144] Quality Adjusted Life Years (QALYs)

[145] Rand Europe (2008) op. cit.

[146] Mendeloff et al., 2004.

reason behind this wide range is that there is no universally accepted way of measuring the monetarization of QALYs[147].148 The value can be measured on the basis of collective preferences, on the basis of medical practice, or on the basis of the value of a statistical life, all of which can yield different outcomes. What is accepted in the literature is that life saving medical activities should be assessed at the high end of the spectrum, since this reflects collective preferences for such activities. Although this range is wide, it still gives an indication of what a QALY is worth. Moreover, there is a large degree of consensus that in the case of life saving situations the upper part of the range is more appropriate. The reason why health and standard of living are taken together here, is that health is measured by QALYs, which typically involve benefits for patients in terms of standard of living. Adding separate effects of the proposals on standard of living (e.g. in terms of productivity gained) threatens to double count benefits.

In addition to the effects picked up with QALYs, there are also quality of life (QoL) studies which include elements of standard of living (being able to control one's environment, mobility). The few studies that link QoL to organ donation come to very positive results, but it is too early to draw definitive conclusions (Rand 77).

Safety

This capability is highly relevant for policy proposals on organ donation. An indirect, but crucial, consequence of enhancing feelings of safety can be that more donors are available in the future. This however is an indirect effect leading ultimately to more QALYs. Therefore this effect is dealt with below in the category 'interactions between capabilities'. We have to bear in mind that the feeling of security should not to be confused with the physical safety of organs themselves, although there is obviously a link between the two.

In addition to the indirect effect, enhancing feelings of safety is also a benefit by itself in terms of well-being. It is very difficult to quantify in how far feelings of safety are enhanced as a consequence of public policy, nor is it easy to assess how important feelings of safety are for the citizens in this context. Special Eurobarometer 272 "Europeans and organ donation" shows that organ donation cards are perceived very positively by European citizens: 81% of them are in favour of their use, but such cards are for the time being rarely used, in particular in NMS10 countries (12% of citizens have an organ donation card). An enhanced public debate will likely have positive consequences. The importance that citizens attach to a donor card can be used as a proxy for the general importance of feelings of safety but it cannot be used to compare safety with the other capabilities, nor does it reveal much on the benefits of public policy (except for the NMS10 example mentioned above, where those benefits seem clearcut).

The fact that direct measurement is difficult does not disqualify the category: neither in general (Eurobarometer surveys show that citizens find safety one of the most important aspects of well-being), nor in the particular case of organ donation. We know that there exist benefits, but we have to assess them in a qualitative way. It is important to keep in mind that

[147] http://www.cpb.nl/nl/pub/cpbreeksen/document/152/doc152.pdf

this category may vary according to the policy options. In this sense, it can also help to differentiate the outcomes of various options.

Feelings of safety can be specified into the following categories.

(i) family of deceased donors will feel more secure;

One intended consequence of enhancing quality and safety is that families of deceased donors feel more secure. The importance of this is exemplified by special Eurobarometer 272 “Europeans and organ donation”: 41% of Europeans have discussed the organ transplantations with their family. The subject is far less frequently discussed in NMS10. 56% would be willing to donate one of their organs to a specialized organ donation service after their death, 54% would agree to donate an organ from a deceased close family member. The Canadian Council for Donation and Transplantation (2005) shows that 56% of people surveyed think that "if your loved ones would feel comforted by your donation" is an important reason to donate. Data suggest that training programs for health have contributed to the approach of obtaining consent from donor families. See also De Jong et al for a discussion on the importance of family discussions. '*Public education has a limited but vital role to play in increasing organ donation. What happens at the hospital is key. Potential donors have to be identified, and the families have to be approached in the right way. All public education can do is "help the process be successful once the process has begun" (Davis 1991, 92). The goal should be to dispose families favorably toward donation so that they will grant consent.'*

(ii) public has confidence in the system;

Again there is a link between confidence in the system and the number of future donors (see below), but here the impact we focus on is the feeling itself. Experience from US and Spain have revealed that improving confidence was an outcome of successful policies (see e.g. DeJong et al).' In the UK the Living Donation Protection through the Human Tissue Act (HTA) has included the training of 140 Independent Assessors and 55 Accredited Assessors and, as the HTA annual report suggests, Living Donation Protection by HTA personnel has had the social impact of “giv[ing] everyone confidence in the system: clinicians, organ donors, recipients and families.” The HTA helps clinicians find the right balance between the needs of the patient with kidney failure, for example, and the needs of the living organ donor. Furthermore, it is possible to tackle the complex issues around Living Donation Protection without creating extra barriers or over-complicating things. Apart from the indirect effect, enhancing feelings of confidence is a benefit in itself.

(iii) feelings of safety by living donors;

There are major ethical issues involved in living donors (there is abundance of literature on this). Clearly, ethical issues could be alleviated by improving feelings of safety by living donors. Such benefits clearly stretch out beyond any effect on numbers.

(iv) reductions in trafficking and less fear of involuntary donors

There are sufficient indications that the problem of organ trafficking exists (albeit less in Europe than in some other parts of the world), and that citizens consider this as an act of serious crime. Reductions will therefore enhance their feelings of safety. People probably do not want to live in a society where trafficking is needed to save lives. It is very difficult to quantify this, since it is not known what people are prepared to pay for such reductions. The

WHO assesses the number of sold and trafficked organs to 5000–8000 per year, worldwide. Similar to other parts of crime one could perform a cost-benefit analysis on reducing trafficking, but no material seems available at this stage. Also there are serious ethical issues involved that cannot be easily monetarized. In Europe, organ trafficking is closely linked with criminal organizations that deal in human trafficking.

All in all, enhancing feelings of safety is an important goal of organ donation policy. This can be inferred from surveys, and numerous policy documents are backed up by the literature. The magnitude of the effects is very difficult to quantify. Furthermore, there are ethical issues involved mainly around living donors and trafficking that warrant special attention.

Quality of social interaction

Quality of social interaction can be specified into the following categories.

(i) belonging to a society that does not let patients die in waiting lists if it can be avoided.

There is little evidence available that reports to what extent citizens' feeling of social justice is affected by the fact that people are dying on a waiting list for organs. Yet, according to Naci Mocan and Erdal Tekin (2005)[149], in Europe, individuals who reveal that they are familiar with the rules and regulations governing the donation and transplantation of human organs are more likely to donate. This has not only an indirect effect through the numbers of transplants but also indicates that education appeals to ethical and moral stance of the public, which constitutes a benefit in itself.

(ii) belonging to a society that does not let recipients be exposed to unnecessary infectious risks;

There is little evidence available that reports to what extent citizens' feeling of social justice is affected by the fact that recipients are exposed to infectious risks. Yet, that does not mean the category is unimportant.

(iii) quality of social interaction after transplantation

The literature is more important in this field. It mainly discusses quality of life after transplants and combines elements that are also relevant for the capabilities reviewed below. Quality of life (QoL) assessments are used to evaluate the physical, psychological and social domains of health, e.g. sexual function, pregnancy, schooling, sport and work. Burra and De Bona (2006) conclude that (i) A survey of sexual concerns among 768 organ transplant recipients showed that transplantation had a positive impact on sexuality: 69.9% reported having intimate relationships, 66.7% were satisfied with their relationship, and only 26% were not sexually active. (ii) Up to 40% of chronically ill children and adolescents experience problems at school, including learning difficulties, social maladjustment and problems with peer relationships. School performance was found to improve after renal transplantation, less so for heart and lung. (iii) Organ transplantation offers the best prospect of pregnancy in fertile women with various types of end-stage organ disease. (iv) Most transplanted people

[149] The Determinants of the Willingness to be an Organ Donor*, NBER* w11316

report a better QoL not only in psychological and social, but also in physical domains after surgery, returning to the same sort of physical activity as before their chronic illness.

In Clemens et al. fifty-one studies examined 5139 donors who were assessed an average of 4 years after nephrectomy. The majority experienced no depression (77-95%) or anxiety (86-94%), with questionnaire scores similar to controls. The majority reported no change or an improved relationship with their recipient (86-100%), spouse (82-98%), family members (83-100%) and non-recipient children (95-100%).

Broyer Michel et al give figures about various social aspects of life in the adulthood of children who had received a kidney: marital life (12% against 8% for the general population), educational level (31% reached the baccalaureate level. This is lower than the educational performance of the general population, but it shows than a activity is present after transplantation). From M. C. Corley, et al: scores on quality of life were high for all donors, and they expected that their quality of life would improve in the next 5 years. All these examples show that social benefits after transplants are significant. But this seems a relatively unexplored domain. As it is difficult to have a consistent view of all the results in this domain, the most effective way to communicate the results is qualitative, with a list of examples, although there could also be attempts to quantify as much as possible.

Productive and valued activities (employment)

There is a wide literature on the impact on employment. For instance, White K. et al. show that after transplantation (heart and lung), 39% of patients went back to work and 3% more started working[150]. An overview article (van der Mei et al 2006) provides a systematic review of social participation after a successful kidney transplant. Employment was the most used indicator of social participation. Employment rate ranged from 18% to 82%. For heart, lung and liver transplantations, this number is lower and estimates are between 27% for liver transplants151 and 39% for thoracic organs[152].

The social outcome in a French cohort of 366 children who underwent kidney transplantation between 1973 and 1985 was investigated recently by Broyer et al (2004). The authors found that 73% of male patients (n=149) and 72% of female patients (n=95) had paid employment, whereas 6.5% and 10.5%, respectively, were unemployed.[153] In another study in the US, there was low pre-transplantation employment (39% of kidney-pancreas transplant recipients and 33% of kidney alone transplant recipients). However, post-transplantation, significantly more dual organ recipients were working (73%) compared with transplant recipients of kidney alone (27%). Similarly, in Italy, Petrucci et al (2007) found that having had an occupation previously and having been off work for less than 24 months were independent predictors of return to work: 87% of patients worked before thoracic organ transplantation and 39% of

[150] *The Journal of Heart and Lung Transplantation*

[152] Saab S, Wiese C, Ibrahim AB, Peralta L, Durazo F, Han S, Yersiz H, Farmer DG, Ghobrial RM, Goldstein LI, Tong MJ, Busuttil RW. Employment and quality of life in liver transplant recipients. Liver Transpl. 2007 Sep;13(9):1330-8.

[153] Broyer et al 2004

patients went back to work after transplantation, while 3 of the 131 patients in total started working[154].

Interactions between capabilities

The literature is full of examples that establish a link between the number of transplants and the feelings of safety as e.g. measured by increases in public confidence[155]. A similar story can be held for feelings of social justice. According to Naci Mocan and Erdal Tekin (2005)[156], in Europe, individuals who reveal that they are familiar with the rules and regulations governing the donation and transplantation of human organs are more likely to donate. Insofar as these indirect effects lead to increased transplants, this leads to positive health effects, and should therefore be added to the direct effects mentioned above. Therefore the Directive, though not directly contributing to increases in the number of transplants through this indirect channel, contributes not only to quality and safety, but also to the number of transplants.

Conclusion

Health outcomes and standard of living can be measured (in terms of QALYs). When the impacts of the various options in terms of QALYs are clear, it is possible to have a full cost analysis. Indeed, it enables one to assess for each policy option the impact in terms of expected euro per QALY minus costs (where a range is more likely than a point estimate). This will be the first important signal: expected euro per QALY minus costs brings together two types of impacts on capabilities (health and standard of living) with the costs. This number (whether positive or negative) can then be benchmarked against the three other types of capabilities, notably social interactions, feelings of safety and employment, which are all more difficult (and sometimes impossible) to quantify.

The table below presents a crude estimation of benefits and costs, using the following logic:

1. There is partial (country) information on implementation costs. Some of these costs can be attributed to the Action Plan, others to the Directive.
2. We calculate the upper bound of costs by multiplying full implementation costs in a large MS (U.K., Germany or Spain) by 27.
3. We use the most pessimistic Rand benefit scenario in order to obtain a lower bound for the benefits.
4. We then compare the lower bound of benefits with the upper bound of costs.
5. The table below reveals that the very lower bound of net benefits in terms of QALYs gained are 440 million euro. In other scenarios the benefits are higher, sometimes much higher.
6. The large net benefits accrue even if we assume that all MS achieve only the EU average.

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[154] Petrucci L, Ricotti S, Michelini I, Vitulo P, Oggionni T, Cascina A, D'Armini AM, Goggi C, Campana C, Vigano M, Dalla-Toffola E, Tinelli C and Klersy C. (2007). Return to work after thoracic organ transplantation in a clinically-stable population. *European Journal of Heart Failure*, 9 (11): 1112-9.

[155] see e.g. '25 Years of Organ Donation: European Initiatives to Increase Organ Donation', G.R. Schutt, Transplantation Proceedings, 34, 2005–2006 (2002)

[156] The Determinants of the Willingness to be an Organ Donor*, NBER* w11316

7. The reasons for the large net benefits are that the literature reveals that (i) transplants yield substantial QALYs gained; (ii) the QALYs gained are evaluated at 20.000 which is the very lower bound used in the literature; (iii) policy proposals that are similar to the ones suggested by DG SANCO have proven to yield substantial gains in terms of increases in the number of transplants.

   One caveat applies. One cannot establish a direct causal link between the policy proposals and the benefits. This is so because in order for the proposal to meet subsidiarity requirements important tasks are left to the MS to implement. This forces the researchers to use scenarios. Even in pessimistic scenarios the cost-benefit ratio looks very favourable though.

Table 2 The maximum cost of the proposals

Illustration of the maximum annual cost for EU27, in million euros per year*
Under two assumptions A1 or A2, reflecting two pieces of information

		Maximum cost	Comments	Reference to Rand Report***
Start-up and running costs**	A1	€ 60	€ 2,2 The UK of the national authority (HTA)	p80
	A2	€ 86	€ 3,2 Spain, Spanish national authority (annual cost)	p80
Autorisation of establisment	A1	€ 82	€ 3,0 Charge by HTA on licencing an etablisment in the UK	
	A2	€ 346	€ 12,8 Charge licensing tissue product, Germany	
Transplant coordinators	A1	€ 270	€ 10 Germany	p81
	A2	€ 281	€ 10 UK, for 250 coordinators	p81
National quality programme	A1	€ 14	€ 0,50 Implementation cost in Canada	p85
	A2	€ 14	€ 0,50 Idem	
Register	A1	€ 5	€ 0,19 to implement serious adverse reaction	p91
	A2	€ 5	€ 0,19 Idem	
Administrative burden	A1	€ -	No figures	
	A2	€ -	No figures	
Total cost	**A1**	**€ 431**		
	A2	**€ 731**		
Qalys Gains monetarized	**A1**	**€ 3.000**	€ 0,05 per Qalys	
	A2	**€ 1.200**	€ 0,02 per Qalys	
Net gains monetarized	**A1**	**€ 2.569**		
	A2	**€ 469**		

* We illustrate here the highest level possible of the cost by assuming that the cost of a typical country is applied to EU-27
It gives an upper bound of the cost and a lower of the net gain
The number Qalys gains is assumed to be 60 000
** the running cost here is a reccurent one. A one-off cost can be added, which was 4 million for Spain for instance.
****Rand Europe (2008): *Improving Organ Donation and Transplantation in the EU*, June 2008.

What can we conclude from this?

1. There is a policy option that has a favourable, possibly even very favourable, cost-benefit ratio.
2. We don't know yet at this stage of the analysis whether the preferred policy option is the Action Plan or the Action Plan plus Directive. But even if we use the lower bound for benefits of the Action Plan and we (unjustifiably) attribute all the costs to the AP, the cost benefit ratio is favourable. This is even more so since we only looked at QALYs in terms of benefits leaving other benefits undiscussed in the equation so far.

Below we discuss what is needed before a proper comparison of options is possible.

STEP 2 (CONTINUING): COMPARING OPTIONS

To evaluate the consequences of policy options, the above described approach needs to be replicated for each policy option. In our discussion here we limit ourselves to comparing the AP with AP plus flexible Directive (AP + D)[157]. This is because the AP already clearly yields positive net returns and the stringent Directive does not meet subsidiarity requirements.

On health, the Rand report estimates the ranges of possible life years saved and QALYs gained for the various policy options, using different scenarios depending on the extent to which Member States implement actions. What are the differences in impacts between AP and AP+D in terms of QALYs? Evidence on country studies reveals that success depends on approaches that are inclusive. The AP alone is therefore unlikely to yield the optimistic scenario where an increase of 30% transplants is assumed. The AP +D has a higher chance of achieving that, but with a lot of uncertainty still. It is very difficult to put numbers to the value added of combining the AP with a Directive. The following observations are relevant: (i) the success of inclusive policies; (ii) the substantial benefits that extra transplants yield and (iii) the fact that the Directive improves the quality of social interaction and feelings of safety, which indirectly yield a higher number of transplants.

This leads us to the tentative conclusion that the optimistic scenario (30% increase) might be achievable under AP+D, with a high bandwidth of uncertainty remaining.

Rand takes only direct effects into account, implying that the AP plus Directive (in whichever form) yields the same QALY range as the AP. But from our analysis above it follows that there are indirect effects working through the safety and quality of social interaction capability. The Directive and AP aim inter alia at enhancing quality and safety and at working on public awareness. Enhanced quality and safety improve public confidence which then feed into enhanced availability and ultimately into the number of transplants. This indirect effect has not been taken into account by Rand.

If we accept this reasoning and compare it to the table above it seems that it does not matter which costs are exactly attributable to the AP or the Directive, since the extra benefits of the Directive are so large that this effect always dominates. A caveat applies here though. In the table above we deliberately have been very pessimistic on the benefits of the AP. This was done to check whether positive net benefits could be sustained even under these pessimistic scenarios. If we want to compare options honestly, we should allow for more variation in the AP benefits, in particular since it remains true that most QALY gains are due to the direct effect created by the AP.

As regards the other dimensions, there are numerous pieces of information, but with (even) less clarity than for QALYs. For the non-health and non-productive capabilities we have to rely on using qualitative assessment through "+" and "++" signs in the tables.

The Action Plan has a positive effect on the various ‘social’ dimensions. For the "social" capabilities, the Directive has added value in these various dimensions, notably on feelings of safety and feelings of social justice. In a certain number of cases, the directive will not add much. This is typically the case for what we can call the "large" and "developed" countries. The main added value is the link to better quality standards. This is supposed to have two

[157] The policy options are fully described in the main text of the IA or in Rand(2008) p31

effects: an increase in the number of exchanges between countries, and probably an improvement of the "confidence in the system". This is very difficult to measure, but what seems important to have in mind is that the Directive will add value on small and undeveloped countries' social capabilities because it can probably help to increase the trade (then the number of organs), to reinforce the confidence of people in the system, and to improve (possibly strongly) the well-being of the living donors. This latter effect will become more important if the number of living donations increases. More on this in our section on distribution.

Table 3 Comparison of the impacts of proposed policy actions on capabilities

Intervention	Option 2: Action Plan		Option 3: AP + flexible Directive	
QALYs **(health and standard of living)**	**Estimates of donation rates will lead to:** **37,350 to 113,348 QALYs, most in the lowest part** **(average 60 000)**	**≈** **to** **++**	**Estimates of donation rates will lead to:** **37,350 113.348 QALYs , most in the upper part** **(average 90 000)**	**+** **to** **++**
Safety	**Some effects due to exchanges of best practices an awareness raising**	**+**	**Stronger effects due to improvements in quality and safety standards**	**+** **to** **++**
Quality of social interaction	**Some effects due to exchanges of best practices an awareness raising**	**+**	**Stronger effects due to improvements in quality and safety standards**	**+** **To** **++**
Employment	**Positive effects result of increases in transplants**	**+**	**Stronger effects due to higher increases in transplants**	**+** **To** **++**

"++" substantial benefit; "+" some benefit; "≈" no substantial impact; "-" some additional negative impact; "- -" substantial negative impact;

To conclude: the AP+D yields higher returns on all dimensions (The QALY differences are due to indirect effects, and there are also direct effects on other capabilities that are in favour of the Directive. Whether these gains outweigh costs depend on the attribution of costs between AP and Directive, on which we have no information.

STEP 3: DISTRIBUTIONAL ASPECTS

Only looking at aggregate effects may be very misleading, as each and every policy proposal has always distributional consequences. In principle, the CA focuses on the distribution of individual well-being in society, but this is of course impossible to operationalize in its ideal form. An acceptable short-cut is to consider different groups in society. One then has to decide first what are the main distributional dimensions of the policy proposal and then to analyse the results for the resulting classification in groups.

In the case of organ donation, there are three main types of distributional aspects to take into consideration. The first one is related to the heterogeneity of Member States. Various options have various impacts according to the group of MS and the organ systems they have in place (developed, large). The second one is related to the position of different individuals in the process of organ donation itself. The effect of the policy is different according to the fact that we consider the recipients, living donors, family or potential donors. The third aspect to be taken into consideration is related to social and economic inequalities. We will discuss in some detail the results for the first dimension. Since the data are sparser for the other classifications, our discussion of them will be more concise.

Country groups

We first consider the heterogeneity of the countries. Two dimensions are particularly relevant as regards the proposal: the size of the country (because of the trade aspect in particular) and the level of development of the system of transplants. We suggest measuring the first with the number of transplants and the second with the number of transplants per head. A reasonable classification of the countries could then be as follows:[158] (i) Large and developed as Spain; (ii) Large and undeveloped as Romania; (iii) Small and developed as Austria; (iv) Small and undeveloped as Bulgaria.

Let us now analyse the differential impacts of the policy proposal for this country classification. To facilitate our task and make the results more transparent we only consider two options: Flexible Directive + Action Plan / Action Plan only.

We have used a qualitative system from one + to four ++++. This is to be able to make a difference between the groups of countries and also between the different policy options. Of course, this qualitative scoring system gives only a first rough indication. Three caveats are in order. First, the “scores” in the different rows are not directly comparable, i.e. ++++ in health does not necessarily give the same numerical indication as ++++ in employment. Each row gives the relative effects per capability just to show the differences between the groups of MS. Second, at the bottom of the table we give an “overall” evaluation. This again has to be interpreted only as a qualitative indication. Third, it might seem that everything is positive, but this is misleading, since there are costs as well. In particular it seems that the option with the directive is always 'Pareto' superior (ie never worse and sometimes better), but this is not necessarily true if we also include cost considerations.

Some further comments on the Table:

[158] There is of course room for discussion about this classification. However, in principle other criteria could be used without problem

Small countries face problems because of the shortage of own supply. Therefore the directive would be beneficial for them since it is likely to enhance trade. Underdeveloped countries face the problems that they simply do not have enough high quality transplants, so that they benefit from the action plan mainly.

For all options the benefits are the largest for small and undeveloped countries, as expected, and the smallest (but still positive) for large and developed MS.

On the difference between the middle groups, it seems that the large and undeveloped do well with the directive. Notice, however, that the health effects are larger for small and developed countries, and that these health effects are the most important.

Overall, the main difference between the options is that the directive produces more benefits in the green area, which is mainly linked to safety and feelings of social justice in undeveloped countries, and to health in small developed countries (for the trade reason). Again, from this it cannot be automatically concluded that the directive option is better since there are costs involved. Notice e.g. that for large developed countries the directive is probably strictly worse, since it does not add anything for them in terms of benefits, while it does increase the costs. This kind of differentiated conclusions is exactly what we aim at with this distributional analysis.

Table 4 Member State-distribution matrix: Action Plan plus flexible directive

	Large and developed	Large and undeveloped	Small and developed	Small and undeveloped
Health	+	++	+++	++++
safety	+	+++	++	++++
Quality soc.interactions feeling of justice	+	+++	++	++++
standard of living	+	+++	++	++++
Employment	+	+++	++	++++
Overall evaluation	+	+++	++/+++	++++

Table 5 Member State-distribution matrix: Action plan without directive

	Large and developed	Large and undeveloped	Small and developed	Small and undeveloped
Health	+	++	++	++++
safety	+	++	++	+++
Quality soc. interactions feeling of justice	+	++	++	+++
Standard of living	+	+++	++	++++
Employment	+	+++	++	++++
Overall evaluation	+	++/+++	++	+++/++++

Groups of actors: donor, family etc.

There is no doubt that the policy proposals have differential impacts for the different groups in society that play a different role in the process of organ donation and transplantation[159].Although the information about these impacts has not yet been collected in a systematic way, the picture that results from the existing data is rather clear. Using the same qualitative method as used before (and hence with the same caveats attached), we present the distributional picture in the following table. At this stage, it is not very useful to distinguish between the various options. The table has to be seen as a first description of the different impacts to be expected for different groups in society (and in this case the different policy options are mainly a matter of degree). The red cells in the table refer to capabilities which are not relevant for the social groups concerned.

Again, some comments are in order:

- The recipients and potential recipients are of course the main beneficiaries of the policies. As described before, the main impacts work through the health

[159] Note that we focus here on final outcomes, and hence, on groups of individual citizens. Of course, there are institutional stakeholders too (e.g. the transplant organisations and hospitals), but these are intermediary players. The effects on them have been captured when describing the effects of the policy proposals on the number of transplants.

dimension, but it is essential to bring into the picture also the derived effects on employment (and standard of living). The analysis has shown that it is necessary to make a specific column for recipients with special needs (such as paediatric patients): for them the positive effects of a better organisation of organ donation and transplantation (and more trade) will be even more outspoken.

- Taking distributional aspects explicitly into account also draws in a natural way attention to the living donors. A safer system of living donation will of course enhance the number of donations and of successful transplants. This effect is taken up in the first two columns. In addition, however, there are also direct effects on the capabilities of living donors, which go beyond the instrumental evaluation. Their feelings of safety will undoubtedly increase – with, in addition, positive effects for the other capabilities.
- To some extent, similar effects are found for potential donors. As mentioned before, empirical research shows that people who are better informed about the rules in their country, feel safer and are therefore also more willing to donate.
- Given the sensitive nature of the process of organ donation, the families of deceased donors are another crucial group. Of course, there will be no health effects for them. However, a well-structured system of organ donation will increase their feelings of being treated in a fair way, of being part of a just system – and may even increase the overall quality of their social interactions.

Table 6 Actor-distribution matrix

	Recipients	Recipients (special needs)	Living donors	Family of deceased donor	Potential donors
Health	+++	++++	++		
Safety	+++	+++	++++		+++
Quality soc. interactions feeling of justice	+++	++++	++	++	++
Standard of living	++	+++	+		
Employment	++	+++	+		

Overall evaluation	++/+++	+++/++++	++/+++	++	++

Social and economic inequalities

There is a large literature on socio-economic health inequalities and on differential access to the health care system. The Rand report used this literature extensively. There are various elements to take into consideration here. Rather than putting them in a separate table, as we did for the other distributional dimensions, we summarize some of the most important effects in a verbal way and we link our discussion to the groups appearing in the previous table[160].

First, given the (well documented) differential access to the health care system for different socio-economic groups, it is probably advisable to distinguish between different groups of recipients. There will be a positive health effect for all groups in society, but this positive effect may be less pronounced for groups with lower incomes and for BME-groups. At the same time, their needs for transplants are higher. So: all groups will gain, but some groups will probably gain more than others. The consequences for the feelings of justice in society are not yet clear.

Second, it seems that the willingness to donate may also be lower amongst BME-groups[161]. We could therefore also split in the previous table the last three columns "living donors", "family of deceased donors" and "potential donors". However, in the present state of our knowledge it is not possible to describe carefully the effects of the policy options for these specific categories. We know (cf. supra) that more and better information and transparency increases the feelings of safety and trust in the system and thereby the willingness to donate: we do not know, however, whether this effect will be stronger or weaker for those groups that now have a smaller propensity to donate.

It is clear that the information on this latter category of distributional issues is still very incomplete. The CA-approach as such cannot remedy this lack of information. Yet, for the evaluation of policies, an informed guess is preferable over complete neglect. Moreover, taking up distributional issues explicitly (and not as a kind of afterthought) directs our attention to the remaining lacunae in our knowledge.

STEP 4 ETHICAL CONSIDERATIONS

There are lot of ethical considerations related to organ donation that move beyond the impacts on capabilities. Most of these are related not to the final outcomes, but to the process through which these final outcomes are reached. One can think of issues around opt out or opt in systems, impact on black market transactions and trafficking, implications of exchanges in

[160] In principle, the comments in this section could be taken up by splitting some of the columns in the previous table.

[161] See, e.g., Tekin and Mocan (2005), The determinants of the willingness to be an organ donor, *NBER Working Paper* 11316.

organs, payment for organs, ethical issues in communication with families, issues around brain death.

The ethical issues can be grouped in three categories.

- ethical issues that fall out outside the realm of these policy proposals

Discussions on opt-out or opt in, on organ trade (payments) or issues around brain death fall in this category.

- ethical issues that are positive influenced by the proposal

The AP+D lead to an expected reduction in black market activities and trafficking. This is an important positive ethical side effect. The same applies to action geared at families of deceased donors. However, these ethical issues have already been taken into account in the quality of social interaction capability above.

- ethical issues that need to be discussed as a consequence of this proposal

Finally, there are ethical issues related to organ exchanges, living donation and acceptance of organs of lower quality.

STEP 5: CONCLUSION

Synthesis of the results of the IA

All in all, the Action Plan plus the Directive yields higher returns on all relevant capabilities. The QALY differences are due to indirect effects (on feeling of safety), and there are also direct effects on other capabilities that are in favour of the Directive. The proposals seem also be cost effective. Nonetheless, whether these gains stemming from the Directive outweigh costs due to the Directive depend on the attribution of costs between Action Plan and Directive, on which we have no information.

In terms of distributional impacts, the directive has bigger impact on capabilities in small and undeveloped countries (in terms of organ donation). It is mainly due to the safety and feeling of social justice in undeveloped countries and to health in developed countries. But the cost is not sufficiently detailed to conclude. As regards, groups of actors, the proposals have of course an impact on the recipients of the organ. But the CA approach draws the attention on the impact on living donor through the feeling of safety and to the family of the donor trough social cohesion.

Added value of the application of the CA to IA

In our view, the CA had added value to the IA. he added value of the capabilities' approach is (i) to concentrate on final outcomes rather than on intermediary objectives; (ii) The focus on distribution and opportunities is justified from the fact that there are often major impacts of policies on these two dimensions, which tend to be underdeveloped in policy assessments and evaluations; (iii) it facilitates communication of policies to the citizens, because it deals with well-being in concrete terms; (iv) that it reduces the risk that important impacts are overlooked; (v) it provides a natural way to analyze interactions between various dimensions

(capabilities). We have seen that is of paramount importance here when we deal with feeling of security.

But his added value had a cost in the sense that the approach requires more data. And some dimensions are difficult to quantify, this is the case for the feeling of safety and quality of social interactions. So we needed to rely on qualitative assessments.

The advantages of the capabilities approach are explained in detail in Box 2 (below).

Box 2 Advantages of the capabilities approach

We see the following advantages from integrating the capability framework into the Impact Assessments:

1. completeness

The applied capabilities list attempts to provide a full description of wellbeing as a basis for the evaluation of policy objectives and action. The list takes into account the various facets of well-being at an aggregated level to adapt the capability approach to policy-making.

2. transparency

The applied capabilities list of nine distinctive elements of wellbeing is more transparent than a list where a somewhat amorphous 'social category' is used as a wide umbrella for everything that is not environmental or economic. It paints a clearer, more accessible 'picture'.

3. reinforcements and trade-offs

As a consequence of the transparency gained, the list of nine allows for an easier public discussion on trade-offs and interactions between the different categories. Our list starts from the assumption that all pillars are a priori important (in the sense that we do not attach a priori weights to the different items, not that we attach equal weights). A discussion on trade-offs and interactions is a prerequisite for a fruitful policy debate: different conceptions of the good society differ precisely in their views about the relative importance of (and hence the desirable trade-offs between) the different capabilities.

4. capabilities and distribution

A further fundamental advantage of the applied capabilities list is that it purposefully and explicitly takes into account Sen's original idea, namely that not only achievements count, but also freedom. The importance of freedom is exemplified in the way the issues are described and in the way they are made operational. Moreover, the focus on individual (or group well-being) makes it possible to integrate distributional issues into the analysis in a natural way, rather than as a kind of afterthought following an aggregate analysis.

5. consistency with traditional methods, no need for extra data

A main advantage is that the CA does not require more data or new data, nor does it replace traditional methods such a cost-benefit analysis.

6. universal applicability consistent with IA guidelines

Given point 5 above, the CA can be applied to al all impact assessments without difficulty and without overhauling the IA guidelines.

RAT DER EUROPÄISCHEN UNION

Brüssel, den 10. Dezember 2008 (12.12)
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Absender:	Herr Jordi AYET PUIGARNAU, Direktor, im Auftrag des Generalsekretärs der Europäischen Kommission
Eingangsdatum:	9. Dezember 2008
Empfänger:	der Generalsekretär/Hohe Vertreter, Herr Javier SOLANA
Betr.:	ARBEITSPAPIER DER KOMMISSIONSDIENSTSTELLEN als Begleitpapier zum Vorschlag für eine RICHTLINIE DES EUROPÄISCHEN PARLAMENTS UND DES RATES über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe und zur MITTEILUNG DER KOMMISSION Aktionsplan im Bereich Organspende und -transplantation (2009-2015): Verstärkte Zusammenarbeit zwischen den Mitgliedstaaten Zusammenfassung der Folgenabschätzung

Die Delegationen erhalten in der Anlage das Kommissionsdokument - SEK(2008) 2957.

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KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN

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ARBEITSPAPIER DER KOMMISSIONSDIENSTSTELLEN

Begleitpapier zum

Vorschlag für eine

RICHTLINIE DES EUROPÄISCHEN PARLAMENTS UND DES RATES

über Qualitäts- und Sicherheitsstandards für zur Transplantation bestimmte menschliche Organe

und zur

MITTEILUNG DER KOMMISSION

Aktionsplan im Bereich Organspende und -transplantation (2009-2015): Verstärkte Zusammenarbeit zwischen den Mitgliedstaaten

Zusammenfassung der Folgenabschätzung

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ZUSAMMENFASSUNG DER FOLGENABSCHÄTZUNG[1] BETREFFEND DIE VERBESSERUNG DER ORGANSPENDE UND –TRANSPLANTATION IN DER EUROPÄISCHEN UNION

1. PROBLEMSTELLUNG

Aufgrund des schnellen Fortschritts der Transplantationsmedizin ist die Zahl der Transplantationen menschlicher Organe in den letzten Jahrzehnten ständig angestiegen. Dank der Organspende kann das Leben vieler Menschen gerettet und die Lebensqualität der betroffenen Patienten beträchtlich verbessert werden. Dieses Potenzial kann allerdings nur dann umfassend genutzt werden, wenn genügend Spenderorgane zur Verfügung stehen, wenn angemessene Qualitäts- und Sicherheitsmaßnahmen zur Reduzierung des Risikos der Übertragung von Krankheiten ergriffen werden und wenn die Verfahren leistungsfähig und für alle Patienten, die ein Spenderorgan benötigen, zugänglich sind.

1.1. Verfügbarkeit von Organen

Derzeit übersteigt die Organnachfrage in allen Mitgliedstaaten das Organangebot und wächst in den meisten Mitgliedstaaten schneller als die Organspenderaten. Der Organbedarf steigt, aber die Anzahl verfügbarer Organe ist von einem Mitgliedstaat zum anderen sehr unterschiedlich; so gibt es in Spanien 33,8 postmortale Organspenden pro Million Einwohner, in Rumänien dagegen nur eine. Lediglich Spanien und wenigen anderen Mitgliedstaaten ist es gelungen, ihre Spenderraten signifikant zu erhöhen. Nachweislich stehen diese Erhöhungen in Zusammenhang mit der Einführung organisatorischer Verfahren.

Auch bei den Lebendspenderaten sind große Unterschiede zwischen den Mitgliedstaaten zu verzeichnen und einige Länder scheinen ihr Potenzial an Lebendspenden nicht auszuschöpfen.

Die Bedeutung organisatorischer Aspekte bei der Organbeschaffung und die großen Unterschiede in den Verfahren und Leistungen der einzelnen Mitgliedstaaten belegen deutlich, dass der Austausch bewährter Verfahren zwischen den Mitgliedstaaten der Europäischen Union von Vorteil ist.

1.2. Qualität und Sicherheit bei der Organtransplantation

Eine Organtransplantation ist eine potenziell lebensrettende Behandlung, die allerdings mit erheblichen Risiken für die Patienten verbunden ist. Die Risiken ergeben sich aus den Qualitäts- und Übereinstimmungsmerkmalen des Organs und der medizinischen Versorgung.

Der therapeutische Einsatz von Organen birgt das Risiko einer Übertragung von Infektionskrankheiten auf den Empfänger. Auch verschiedene Krebsarten können bei einer Transplantation übertragen werden. Überdies kann eine Organschädigung während des Beschaffungsprozesses die Qualität und Sicherheit der Organspende gefährden. Um diese Risiken zu verringern, basieren die meisten Transplantationssysteme auf der Anwendung von Qualitäts- und Sicherheitsverfahren während des komplexen Prozesses der Organspende. Derzeit unterscheiden sich die Qualitäts- und Sicherheitsstandards der einzelnen Mitgliedstaaten erheblich voneinander.

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[1] Gemäß SEK(2005) 791 vom 15. Juni 2005 (Leitlinien für Folgenabschätzungen).

1.3. Förderung von Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme

Der Organaustausch zwischen den Mitgliedstaaten ist bereits gängige Praxis. Es gibt allerdings große Unterschiede in der Zahl der Organe, die zwischen denjenigen Mitgliedstaaten ausgetauscht werden, welche für den internationalen Organaustausch Einrichtungen, wie Eurotransplant und Scandiatransplant, geschaffen und Vorschriften erlassen haben, und den anderen Mitgliedstaaten.

Die unterschiedlichen Austauschraten lassen jedoch darauf schließen, dass das Potenzial für den Organaustausch noch nicht voll ausgeschöpft wird. Das ist insofern bedauerlich, als der grenzüberschreitende Organaustausch klare Vorteile bietet. Da Spender und Empfänger zueinander passen müssen, ist ein großer Spenderpool wichtig, um den Bedarf aller Patienten auf den Wartelisten zu decken. Werden keine Organe zwischen den Mitgliedstaaten ausgetauscht, haben Empfänger, die eine seltene Übereinstimmung benötigen, sehr geringe Chancen, ein Organ zu erhalten. Gleichzeitig werden Spender nicht in Erwägung gezogen, weil es keine kompatiblen Empfänger auf den Wartelisten gibt. Dies gilt insbesondere für problematische Fälle (Kinder, Notfälle oder immunologisch problematische Patienten, die eine ganz bestimmte Übereinstimmung benötigen) und kleine Mitgliedstaaten. Neben dem Organmangel stellt die Mobilität potenzieller Organspender und Empfänger die zweite Herausforderung für die derzeitigen Qualitäts- und Sicherheitsrahmenbestimmungen dar. Nachweislich könnte eine wachsende Zahl von Menschen mit Wohnsitz in einem anderen Mitgliedstaat Organspender werden. Damit keine potenziellen Spenderorgane ungenutzt bleiben, ist es wichtig, dass ihr therapeutischer Einsatz nicht durch rechtliche Barrieren gehemmt wird und die Familien der Spender Vertrauen in die Spendersysteme haben, damit sie sich nicht gegen eine Organentnahme aussprechen.

2. SUBSIDIARITÄT

Mit Artikel 152 EG-Vertrag ist eine eindeutige Rechtsgrundlage für die vorgeschlagene Initiative gegeben. Eine EU-Maßnahme im Bereich der Organspende und –transplantation ist aus folgenden Gründen mit dem Subsidiaritätsprinzip vereinbar:

1) Die Europäische Gemeinschaft ist eindeutig in der Lage und verpflichtet, zwingende Maßnahmen zur Festlegung hoher Qualitäts- und Sicherheitsstandards für die Verwendung von Blut, Organen und Substanzen menschlichen Ursprungs durchzuführen.

2) Ein Tätigwerden der Europäischen Gemeinschaft dürfte einen öffentlichen Nutzen erbringen, da eine Plattform für die Umsetzung und das gegenseitige Lernen bereitgestellt und die Standardisierung der Berichterstattung mit Leistungsvielfalt kombiniert wird.

3. STRATEGISCHE ZIELE

Strategisches Endziel ist ein hohes Gesundheitsschutzniveau. Im Bereich der Organspende und –transplantation umfasst dieses Ziel drei Einzelziele, bei denen es darum geht, derzeitige und künftige Unzulänglichkeiten zu beheben und eine Richtschnur für die europäische Politik vorzugeben: 1) Erhöhung der Organverfügbarkeit; 2) Förderung von Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme sowie 3) Verbesserung von Qualität und Sicherheit.

4. STRATEGISCHE OPTIONEN

Option 1: Beibehaltung des Status quo

Bei dieser Option wird die Europäische Kommission ihre derzeitige Tätigkeit im Bereich der Organspende und -transplantation fortsetzen, die vor allem in der finanziellen Unterstützung einschlägiger Forschungs- und Pilotprogramme und der Beteiligung an der internationalen Zusammenarbeit, u. a. im Rahmen des Europarats, besteht.

Option 2: Aktionsplan

Bei dieser Option wird ein nicht-gesetzgeberisches Konzept vorgeschlagen, nämlich ein europäischer Aktionsplan im Bereich Organspende und -transplantation für den Zeitraum 2009-2015, der ein gemeinsames Vorgehen der Mitgliedstaaten auf der Grundlage einer Reihe von Schwerpunktmaßnahmen vorsieht. Dieses Konzept beruht auf der Ermittlung und Weiterentwicklung gemeinsamer Ziele, auf vereinbarten quantitativen und qualitativen Indikatoren und Benchmarks, einer regelmäßigen Berichterstattung sowie der Ermittlung vorbildlicher Verfahren.

Option 3: Aktionsplan + „flexible“ Richtlinie

Bei Option 3 wird der beschriebene Aktionsplan mit einer „flexiblen“ Richtlinie kombiniert. Das Regulierungskonzept bei dieser Richtlinie wird in Richtung Rahmenbestimmungen gehen; auf diese Weise soll sichergestellt werden, dass nationale Rechtsvorschriften zur Regelung der wesentlichen Aspekte der Organsspende und –transplantation eingeführt werden; es werden jedoch keine detaillierten Strategiemaßnahmen vorgeschrieben.

Mit der Richtlinie soll gewährleistet werden, dass Qualitäts- und Sicherheitsstrukturen vorhanden sind, die den grenzüberschreitenden Austausch erleichtern und eine Mindestqualität und –sicherheit für die Patienten sicherstellen.

Option 4: Aktionsplan + „verbindliche“ Richtlinie

Bei Option 4 geht der unter Option 2 beschriebene Aktionsplan mit einer verbindlichen Richtlinie einher. Diese wird sich an der Richtlinie über Gewebe und Zellen orientieren und folglich ausführliche Vorschriften für die von den Mitgliedstaaten vorzusehenden Qualitäts- und Sicherheitssysteme enthalten, so dass den Mitgliedstaaten wenig Ermessensspielraum bei der Umsetzung bleibt. Wie bereits erwähnt, sieht Option 4 ein strengeres Regulierungskonzept vor. Diese Option umfasst ein komplexeres Verfahren für die Zulassung der Beschaffungseinrichtungen mit regelmäßigen Kontrollen, was die Schaffung spezifischer Kontrollstrukturen voraussetzt. Überdies ist bei dieser Option ein detailliertes Qualitätssystem in jeder Spendeneinrichtung erforderlich. In der Richtlinie werden in Anlehnung an die Richtlinien über Blut sowie über Gewebe und Zellen Ausschlusskriterien für Spender festgelegt.

5. FOLGENABSCHÄTZUNG: VERGLEICH DER EINZELNEN OPTIONEN

5.1. Auswirkungen auf die Gesundheit

Die wichtigsten Auswirkungen auf die Gesundheit ergeben sich aus einer Steigerung der Spendenraten (Erhöhung der Lebenserwartung und der Lebensqualität der Organempfänger) sowie einem verringerten Risiko für die Patienten. Die strategischen Optionen dürften zu höheren Spendenraten in Europa führen. Darüber hinaus wird sich voraussichtlich der grenzüberschreitende Organaustausch intensivieren, was für bestimmte Patientengruppen (Kinder, hochempfindliche und Notfallpatienten) zweifelsohne von Vorteil wäre.

Mit Option 1 bliebe der derzeit unbefriedigende Status quo unverändert, mit unterschiedlichen Qualitäts- und Sicherheitsstandards in Europa und einem unzureichend ausgeschöpften Potenzial des grenzüberschreitenden Organaustauschs. Mit Option 2 kann aufgrund der Erhöhung der Spendenraten ein wesentlicher Gewinn für die Gesundheit bewirkt werden, wobei in der Regel eine Spanne von 0-113 000 QALYs („quality-adjusted life years" – qualitätsberichtigte Lebensjahre) denkbar ist. Allerdings ist bei diesen Zahlen Vorsicht geboten, da die Option viel Spielraum für die Umsetzung in den Mitgliedstaaten einräumt. Es ist daher realistischer, von einem Schätzwert von 60 000 QALYs auszugehen. Option 2 hat keine Auswirkung auf die Organqualität und –sicherheit; indem sie den Zugang zur Gesundheitsversorgung für Lebendspender gewährleistet, wird sie jedoch beispielsweise etwaige Vorbehalte gegen eine Lebendspende ausräumen. Nicht vorgesehen sind allerdings Bestimmungen über eine erforderliche soziale Betreuung.

Die Optionen 3 und 4 ergänzen Option 2 durch Rechtsvorschriften und dürften sich eindeutiger auf die Spendenraten auswirken, da vorgeschrieben wird, positive Ergebnisse zu erzielen. Bei diesen beiden Optionen ist mit einem bescheidenen Anstieg der Zahl transplantierter Organe um mindestens 2 600 zu rechnen, was 39 000 gewonnenen Lebensjahren oder 37 000 weiteren QALYs entspricht. Im Durchschnitt dürfte die Anzahl der zusätzlichen QALYs (bis zu 90 000) noch höher ausfallen. Des Weiteren werden bei den Optionen 3 und 4 gemeinsame Qualitäts- und Sicherheitsstandards in der gesamten Europäischen Union festgelegt, wodurch das Risiko für die Patienten verringert und der grenzüberschreitende Organaustausch gefördert wird. Da Option 4 für die ganze Europäische Union verbindliche Qualitäts- und Sicherheitsstandards festlegt, könnten sich allerdings für die zuständigen Einrichtungen Schwierigkeiten bei der Umsetzung ergeben, was sich gegebenenfalls sogar negativ auf die Spendenraten in einigen dieser Einrichtungen auswirken könnte.

5.2. Soziale Auswirkungen

Eine Erhöhung der Organtransplantationszahlen wird für die Organempfänger und Spenderfamilien positive soziale Auswirkungen haben. Es ist nachgewiesen, dass Patienten nach einer Organtransplantation sich stärker am sozialen und Berufsleben beteiligen können. Im Allgemeinen wirkt sich eine Organtransplantation positiv auf die Lebensqualität des Organempfängers aus. Die einzelnen Optionen werden also einen zusätzlichen sozialen Nutzen erbringen und zwar je nachdem, wie viele zusätzliche Transplantationen infolge erhöhter Spendenraten vorgenommen werden können.

Maßnahmen auf europäischer Ebene dürften zu einem größeren Vertrauen in die Systeme für Organspende und –transplantation führen, indem sie gemeinsame Qualitäts- und Sicherheitsstandards einführen, das Bewusstsein der Öffentlichkeit für die Thematik schärfen und die Verfahren für den Umgang mit den Angehörigen verstorbener Spender verbessern. Allerdings ist es aufgrund der verfügbaren Daten über soziale Auswirkungen wie soziale Teilhabe und verbesserte Lebensbedingungen nicht möglich, die genauen Auswirkungen korrekt abzuschätzen und einen Vergleich der Optionen anzustellen.

Angesichts der sozialen Auswirkungen einer Erhöhung der Spendenraten und der Notwendigkeit, die Spenden- und Transplantationsprozesse zu stabilisieren, dürfte sich der größte soziale Nutzen aus den Optionen 3 und 4 ergeben, bei denen eher von einer Erhöhung der Spendenraten und einer Durchsetzung von Standards für vorbildliche Verfahren auszugehen ist.

5.3. Wirtschaftliche Auswirkungen

Die Analyse der strategischen Optionen legt nahe, dass bei den Optionen 2 bis 4 europaweit erhebliche wirtschaftliche Vorteile zu erwarten sind, auch wenn die Mitgliedstaaten hierfür in nationale Infrastrukturen für die Organspende investieren und die Verfahren verbessern müssen. Allerdings ist es auf der Grundlage der vorliegenden Informationen nicht möglich, genaue Angaben zu den voraussichtlichen Kosten für die Mitgliedstaaten zu machen. Die wirtschaftlichen Vorteile ergeben sich in erster Linie aus den Einsparungen bei den Behandlungskosten, da etwa nach einer Nierentransplantation die Dialyse entfällt. Gemäß Schätzungen könnten bis zu 1,2 Mrd. EUR Behandlungskosten eingespart und bis zu 2,4 Mrd. EUR Produktivitätsgewinne erzielt werden.

Mit Option 1 wird der Status quo beibehalten und es entstehen keine zusätzlichen Kosten oder wirtschaftliche Vorteile. Option 2 könnte einen erheblichen wirtschaftlichen Nutzen bringen: bis zu 1,2 Mrd. EUR Einsparungen bei den Behandlungskosten sowie ein zusätzlicher Produktivitätsgewinn in Höhe von 3,6 Mrd. EUR bei geringen Kosten für Prozess- und Infrastrukturverbesserungen. Es ist festzuhalten, dass es aufgrund des nichtverbindlichen Charakters des Aktionsplans äußerst unsicher ist, welche Auswirkungen zu erwarten sind, da weitgehend ungewiss ist, inwieweit der Aktionsplan von den Mitgliedstaaten umgesetzt wird.

Bei Option 3 wird der Aktionsplan mit einer „flexiblen“ Richtlinie kombiniert. Bei dieser Option entstehen erhebliche Kosten in Zusammenhang mit der Einführung der nationalen Register, der Berichterstattung über die Maßnahmen und eines nationalen Vigilanzsystems. Angesichts des bindenden Charakters der Option herrscht bei den Kosteneinsparungen (zwischen 132 Mio. EUR und 1,2 Mrd. EUR) und den Produktivitätsgewinnen (zwischen 460 Mio. EUR und 2,4 Mrd. EUR) weniger Ungewissheit. Option 4 schließlich dürfte dieselben wirtschaftlichen Auswirkungen haben wie Option 3, sie ist allerdings mit höheren Umsetzungskosten verbunden, da die Mitgliedstaaten weniger Spielraum haben, um bestehende Systeme zu nutzen und an die nationalen Gegebenheiten angepasste Lösungen zu konzipieren.

6. AUSWAHL DER AM BESTEN GEEIGNETEN OPTION

Nach Abwägung aller vorliegenden Erkenntnisse ist es Option 3, bei der ein Aktionsplan und eine flexible Richtlinie zur Schaffung eines europäischen Regulierungsrahmens für Qualität und Sicherheit kombiniert werden, die das beste Kosten-Nutzen-Verhältnis aufweist und es ermöglicht, die Ziele zu erreichen.

Die kostengünstigste Option ist zwar Option 2, sie wird jedoch nicht ausreichen, um einen stabilen Qualitäts- und Sicherheitsrahmen zu schaffen, und insofern nicht zur Verwirklichung des dritten Ziels beitragen. Außerdem sind die möglichen positiven Auswirkungen auf die Gesundheit und die Wirtschaft weniger gewiss als bei den drei anderen Optionen. Option 2 hängt stärker als die Optionen 3 und 4 von der Bereitschaft der Mitgliedstaaten ab, freiwillig Änderungen an den Organisationsstrukturen vorzunehmen, die Verfahren zu verbessern und in die Organspende und –transplantation zu investieren.

Mit Option 4 kann gewährleistet werden, dass EU-weit die strengsten Qualitäts- und Sicherheitsstandards gelten, allerdings mit der Gefahr von unnötigem Verwaltungsaufwand. Die entsprechenden Anforderungen, die im Bereich Gewebe und Zellen vollauf berechtigt sind, könnten in kleinen und mittleren Krankenhäusern aufgrund eines zu hohen

Verwaltungsaufwands abschreckend auf die Organspendentätigkeit wirken, während das Ziel doch darin bestehen sollte, diese Akteure stärker in den Spendenprozess einzubinden.

Ein strikter Regulierungsansatz könnte zu erheblichen Umsetzungsschwierigkeiten führen und sich sogar negativ auf die Spendenraten bestimmter Einrichtungen auswirken. Darüber hinaus ist davon auszugehen, dass bei Option 4 insgesamt gesehen die höchsten Umsetzungskosten entstehen, da selbst Länder mit gut funktionierenden Organspende- und -transplantationssystemen einige Änderungen bei ihren Infrastrukturen und Verfahren vornehmen müssen, um diese mit den EU-Vorschriften in Einklang zu bringen. Gleichwohl wäre Option 4 aufgrund von Einsparungen bei den Behandlungskosten und den Produktivitätsauswirkungen infolge einer längeren Lebenserwartung mit wesentlichen wirtschaftlichen Vorteilen verbunden.

Es besteht jedoch eindeutig die Notwendigkeit sicherzustellen, dass die Bedingungen für die Organbeschaffung grundlegenden Qualitäts- und Sicherheitsstandards entsprechen und Beschaffungseinrichtungen benannt werden, die zur Organbeschaffung befugt sind. Mit Option 3 können diese Vorgaben erfüllt werden, indem die Qualitäts- und Sicherheitsanforderungen an diesen spezifischen Bereich angepasst werden.

Option 4 würde ferner – wie die Rechtsvorschriften für Zellen und Gewebe – Kriterien für die Spendereignung (einschließlich Kriterien für den Ausschluss von Spendern) festlegen. Option 3 hingegen wird ein neues Konzept einführen mit einer umfassenden Organcharakterisierung, ohne der klinischen Entscheidung über die Eignung des Spenders vorzugreifen, aber unter Berücksichtigung des Zustands des Empfängers. Somit wird das Transplantationsteam eine ordnungsgemäße Risikobewertung (in Kenntnis aller sachdienlichen Informationen) durchführen können.

Dieses Konzept ist der Schlüssel für die Nutzung von Organen eines erweiterten Spenderkreises (von Spendern, die theoretisch nicht als Idealspender gelten) für bestimmte Empfänger auf der Warteliste (so kommen z. B. alte Menschen unter gewissen Umständen als Spender für ältere Empfänger in Frage). Option 4 dagegen könnte das Potenzial für eine Erhöhung der Organspendenzahlen einschränken, indem sie die Nutzung von Organen eines erweiterten Spenderkreises reduziert. Option 3 räumt dem Transplantationsteam ausreichend Flexibilität ein, um eine angemessene Risikobewertung durchzuführen und um Risiko und potenziellen Nutzen gegeneinander abzuwägen.

Alles in allem eignet sich Option 3 am besten, um die Ziele zu erreichen: Erhöhung der Spendenraten, Förderung der Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme und Gewährleistung von Qualitäts- und Sicherheitsstandards. Indem sie den Mitgliedstaaten einen gewissen Handlungsspielraum lässt, verringert diese Option die Umsetzungskosten und den Verwaltungsaufwand, während sie gleichzeitig Mindeststandards für die Qualität und Sicherheit niederlegt. Mit der Einführung eines flexiblen Bündels bindender Qualitäts- und Sicherheitsanforderungen wird nicht nur das dritte Ziel angemessen abgedeckt, auch der Verwirklichung der Ziele des Aktionsplans wird Impuls verliehen. Die Spendenraten dürften sich erhöhen, wodurch wesentliche Verbesserungen für die Patienten und substanzielle Einsparungen für die nationalen Gesundheitssysteme zu erwarten sind.

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