

NATIONAL HEALTH SERVICE

Guidance on the allocation of organs for the purposes of transplantation

1. This guidance is issued to NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) ("**NHSBT**") to assist with the interpretation and implementation of paragraph 4 of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005 which came into force on 1st October 2005 ("**the Directions**") (attached as **Annex 3**).
2. This guidance is intended to be read in conjunction with the Directions

Paragraph 4(2)

3. Paragraph 4(2) of the Directions provides that when NHSBT allocates organs for transplantation, the people in Group 1 are to be given priority. All the people in Group 1 are to be given equal priority.
4. A person in Group 2 will only receive a UK donor organ if there is no person in Group 1 for whom the organ is clinically suitable.

Paragraph 4(3)(a) – Persons ordinarily resident in the United Kingdom

5. Paragraph 4(3)(a) applies irrespective of nationality.
6. A person should be accepted as "ordinarily resident" if lawfully living in the United Kingdom voluntarily and for settled purposes as part of the regular order of his or her life whether of long or short duration. The person should be resident in the United Kingdom with some degree of continuity and apart from accidental or temporary absences.

Paragraph 4(3)(c) – Persons covered by Regulations (EEC) No 1408/71 and 574/72

7. The European Community Social Security Regulations (Regulations (EEC) 1408/71, 574/72 and 883/2004) ("**the Regulations**") co-ordinate the healthcare schemes of the member states of the European Economic Area ("**the EEA**") and Switzerland. Regulation 883/2004 will replace Regulation 1408/71 and will apply from the date of entry into force of a further Regulation (yet to be published) which lays down the procedure for implementing this Regulation. **Annex 1** lists the member states of the EEA and Switzerland.
8. The Regulations cover:
 - (a) insured EEA nationals, stateless persons or refugees, their family members and the survivors of these groups of people, irrespective of nationality, coming from an EEA member state;
 - (b) insured Swiss or European Union ("**EU**") nationals, stateless persons or refugees, their family members and the survivors of these groups of people, irrespective of nationality, coming from Switzerland;

- (c) non-EEA nationals legally resident in any EU member state (except Denmark) who are insured; and
- (d) non-EEA nationals lawfully resident in an EU member state (except Denmark), who have moved between member states or are in a situation which is not confined in all aspects within a single member state.

Note that Bulgaria and Romania are scheduled to join the EU on 1 January 2007.

- 9. Visitors who are covered by the Regulations are entitled to **treatment which becomes medically necessary** during their visit. A European Health Insurance Card (“EHIC”) (or a Provisional Replacement Certificate if their EHIC has been misplaced or stolen) may be produced as evidence of entitlement however the UK currently also accepts evidence of residence in an EEA member state as evidence of entitlement. “Treatment which becomes medically necessary” includes treatment of chronic conditions, including routine monitoring, and in very rare cases could include a transplant. The phrase does not include people who have specifically travelled to the UK to receive elective treatment.
- 10. Visitors from EEA countries and Switzerland who come to the UK **expressly to seek treatment** need to obtain prior authorisation from their social security institution. The Regulations provide that such persons should make advance arrangements for their treatment and produce Form E112 (or Form E123 if treatment is required as a result of industrial injury or occupational disease).
- 11. Persons posted by a UK employer to other EEA countries and Switzerland remain compulsorily insured for social security purposes in the UK. These persons should produce UK-issued Forms E101 or E102 as evidence of entitlement. They are entitled to return to the UK for the full range of NHS treatment.

Paragraph 4(3)(d) – Persons covered by a bilateral reciprocal health agreement or the European Convention on Social and Medical Assistance

- 12. The UK has bilateral healthcare agreements with the countries and territories listed in **Annex 2**. The countries and territories in Column A of Annex 2 have agreements covering their nationals and UK nationals only. Such agreements only apply where nationals are living in their own country and not if they are living in another country with which the UK holds a bilateral health agreement. The agreements with countries and territories in Column B of Annex 2 cover all residents, irrespective of nationality.
- 13. All of the bilateral agreements provide for immediately necessary treatment for conditions arising or becoming acutely worsened during a temporary visit.
- 14. People covered by the bilateral agreements are entitled to treatment if **the need arose during their visit** to the UK. Treatment is interpreted as having arisen during their visit if the diagnosis of symptoms or signs occurred for the first time after the visitor’s arrival in the UK. Visitors may also be entitled to treatment which, in the opinion of a medical practitioner employed by or under contract with a Primary Care Trust (“PCT”), is required promptly for a condition which:
 - (a) became acutely exacerbated after the visitor’s arrival; or

- (b) would be likely to become acutely exacerbated without treatment.
15. The bilateral agreements with the countries or territories highlighted in bold text in Annex 2 also provide for the country or territory concerned to refer citizens or nationals to the UK specifically for treatment of pre-existing conditions, including transplantation. Normally the referrals can be made only when the countries or territories do not have adequate facilities to provide the treatment needed.
16. The main details of the bilateral arrangements which provide for patients of non-EEA countries to be referred to the UK specifically for treatment are as follows:
- (a) *Falkland Islands*
No form of referral quotas exist for this small population. The overseas authorities should make advance arrangements for acceptance by the NHS service provider of people referred for treatment.
- (b) *Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan*
Referrals are handled by the Department of Health and are extremely rare. Advance arrangements for acceptance by the NHS service provider of people referred for treatment will be made.
- (c) *Yugoslavia (ie Serbia and Montenegro), Croatia, Bosnia and the Former Yugoslav Republic of Macedonia*
The Department of Health would like to be kept informed when a person from these countries has come specifically to seek treatment.
- (d) *Anguilla, British Virgin Islands, Montserrat, St Helena, Turks and Caicos Islands*
There is a set annual quota for each territory for referrals of people specifically for treatment. Referral arrangements are made through Leeds North East PCT.
- (e) *Isle of Man and Gibraltar*
There is a variable annual quota which is monitored by the Department of Health. Referral arrangements are made through Lambeth or West Cheshire PCTs.
17. The European Convention on Social and Medical Assistance 1954 has largely been superseded by the UK's system of bilateral arrangements. However, it would apply if a Turkish national legally present in the UK required treatment, the need for which arose in the UK and he or she was unable to pay.

General application of paragraphs 4(3)(a), (b), (c), (d) and (e)

18. People who are UK nationals who are not ordinarily resident in the UK and who do not fall within subparagraphs (b), (c) or (d) of paragraph 4(3) of the Directions are not included in Group 1.

19. People covered under paragraph 4(3)(c) to (e) of the Directions are entitled to treatment under the UK system on the same terms as UK residents and should be treated with the same degree of clinical priority as UK residents. A minor correction has been made to the reference to 1954 European Convention on Social and Medical Assistance in paragraph 4(2)(d) of the Directions. The correction does not affect the position of persons who are entitled under the Convention. They remain in the same position as regards UK residents.
20. A further minor change (the addition of a new paragraph 4(2)(e)) has been made to the Directions so that persons ordinarily resident in the Channel Islands remain in the same position as regards access to transplant organs as UK residents. This specific provision is needed now that the reciprocal agreements with the Channel Islands have ended.

ANNEX 1

Member States of the European Economic Area (EEA) and Switzerland

Paragraph 7

Austria	Hungary	Norway*
Belgium	Iceland*	Poland
Cyprus	Republic of Ireland	Portugal
Czech Republic	Italy	Slovakia
Denmark	Latvia	Slovenia
Estonia	Liechtenstein*	Spain
Finland	Lithuania	Sweden
France	Luxembourg	Switzerland**
Germany	Malta	United Kingdom
Greece	Netherlands	(including Gibraltar)

* Iceland, Liechtenstein and Norway are not member states of the EU.

** Switzerland is not a member state of the EEA or the EU but it has a separate agreement with the European Union which, in effect, applies Regulation 1408/71.

ANNEX 2

Countries and territories in respect of which the UK has bilateral healthcare agreements

Paragraph 12

Column A	Column B
Armenia	Anguilla
Azerbaijan	Australia
Belarus	Barbados
Bosnia and Herzegovina	British Virgin Islands
Bulgaria	
Croatia	Falkland Islands
Georgia	Iceland*
Gibraltar	Isle of Man
Kazakhstan	Montserrat
Kyrgyzstan	St. Helena
Former Yugoslav Republic of Macedonia	Turks and Caicos Islands
Moldova	
New Zealand	
Romania	
Russia	
Tajikistan	
Turkmenistan	
Ukraine	
Uzbekistan	
Yugoslavia i.e. Serbia and Montenegro	

* Iceland is an EEA member state but the bilateral healthcare agreement also covers non-EEA nationals resident in Iceland.

For a description of the main terms of the agreements of the countries or territories highlighted in bold text, refer to paragraphs 15 and 16 of this guidance.

ANNEX 3

NATIONAL HEALTH SERVICE

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005

The Secretary of State for Health, in exercise of the powers conferred on her by sections 16D(1), 17 and 126(4) of the National Health Service Act 1977(a), and all other enabling powers, makes the following Directions—

Citation, commencement, interpretation and application

1.—(1) These Directions may be cited as the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005 and shall come into force on 1st October 2005.

(2) These Directions apply in relation to England.

(3) In these Directions—

“the Act” means the National Health Service Act 1977;

“NHS body” means a Strategic Health Authority, a Special Health Authority, an NHS trust, an NHS Foundation Trust and a Primary Care Trust;

“NHSBT” means the Special Health Authority known as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG)(b); and

“the Schemes” means the following Donor Organ Sharing Schemes(c):

- (a) Operating Principles for Pancreas Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in August 2003;
- (b) Operating Principles for Renal Transplant Units in the UK, prepared by the UKT Kidney and Pancreas Advisory Group, first published in May 1999;
- (c) Operating Principles for Liver Transplant Units in the UK and Republic of Ireland, prepared by the UKT Liver Advisory Group, first published in July 1999;
- (d) Operating Principles for Cardiothoracic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Cardiothoracic Advisory Group, first published in May 1999; and
- (e) Operating Principles for Ophthalmic Transplant Units in the UK and Republic of Ireland, prepared by the UKT Ocular Tissue Advisory Group, first published in July 1999.

Functions in relation to blood, stem cells and tissue

2.—(1) In this paragraph, “blood, stem cells and tissue” means blood, blood components, blood products, plasma, stem cells and other tissue.

(a) 1977 c.49; section 16D was substituted by section 12(1) of the Health Act 1999 (c.8) (“the 1999 Act”) and amended by sections 1(3) and 3(1) and (2) of, and paragraphs 1 and 6(a) of Part 1 of Schedule 1 to, the National Health Service Reform and Health Care Professions Act 2002 (c.17) (“the 2002 Act”); section 17 was substituted by section 12(1) of the 1999 Act and amended by section 1(3) of, and paragraphs 1 and 7 of Part 1 of Schedule 1 to, the 2002 Act and section 67(1) of, and paragraphs 5(1) and (3) of Part 1 of Schedule 5 to, the Health and Social Care Act 2001 (c.15) (“the 2001 Act”); section 126(4) was amended by section 65(2) of the National Health Service and Community Care Act 1990 (c.19), by paragraph 37(6) of Schedule 4 to the 1999 Act, by paragraph 5(13)(b) of Part 1 of Schedule 5 to the 2001 Act, by sections 6(3)(c) and 37(1) of, and paragraphs 1 and 10(a) of Schedule 8 to, the 2002 Act and by section 184 of, and paragraph 38 of Schedule 11 and Part 4 of Schedule 14 to, the Health and Social Care (Community Health and Standards) Act 2003 (c.43).

(b) Established by NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (Establishment and Constitution) Order 2005, S.I. 2005/2529.

(c) Copies of the Schemes are available on the website www.uktransplant.org.uk

(2) In order to promote or secure the effective supply of blood, stem cells and tissue for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide a collection, storage and delivery service for blood, stem cells and tissue;
- (b) to provide a screening, testing and processing service for the preparation of blood, stem cells and tissue;
- (c) to conduct or commission research into the uses of and development of blood, stem cells and tissue;
- (d) to provide diagnostic and other services in connection with the collection and use of blood, stem cells and tissue and treatments depending on or requiring their use (including, for example, reagent preparation and provision, patient pathology and therapeutic services, histocompatibility and immunogenetic services, platelet and granulocyte immunology);
- (e) to promote, by advertising, marketing and otherwise, the donation of blood, stem cells and tissue, with a view in particular to maintaining an adequate supply of blood, stem cells and tissue;
- (f) to prepare, store and distribute plasma fractions and other products for therapeutic, diagnostic and other purposes;
- (g) to promote, through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients; and
- (h) to establish and manage a register of blood and bone marrow donors and any associated services necessary for the effective treatment of patients.

Functions in relation to the transplantation of organs and tissues

3.—(1) In order to promote or secure the effective transplantation of organs and tissues for the purposes of the health service, the Secretary of State directs NHSBT—

- (a) to provide an organ and tissue matching and allocation service, having regard to the need to ensure the—
 - (i) maximum and most effective use of organs and tissues;
 - (ii) safety of persons and their survival rates; and
 - (iii) equity and integrity of the organ sharing system;
- (b) to maintain a list of persons who are in need of or are considered suitable for an organ or tissue transplant and to determine the criteria for inclusion on such list;
- (c) to consider and advise the Secretary of State and NHS bodies on ethical, legal and clinical issues which arise out of the organ and tissue donation and transplantation service;
- (d) to lead the development of donation and transplant standards and monitor the maintenance of such standards by NHS bodies;
- (e) to acquire, record, update and keep information about potential and actual donors and recipients of organs and tissues which are or may be available for transplantation and other related matters, and, having regard to the law relating to data protection and confidentiality, to make such information available;
- (f) to analyse and audit the information acquired, recorded, updated and kept under sub-paragraph (e) above;
- (g) to promote, by advertising, marketing and otherwise, the donation of organs and tissues with a view to maintaining an adequate number of organs and corneas for transplantation;
- (h) to commission organ and cornea donation programmes in the health service;
- (i) to give advice about, or make arrangements for, the transport of organs;

- (j) to secure the provision of such education and training in any matter related to its functions under this paragraph as NHSBT considers appropriate, both to NHS staff and others;
 - (k) to conduct or commission such research in connection with the field of organ donation and transplantation as NHSBT considers appropriate; and
 - (l) to work within agreed reciprocal arrangements with other established organ exchange organisations in other countries, for the exchange of organs, where appropriate.
- (2) For the purposes of sub-paragraph (1)(a), NHSBT may—
- (a) match and allocate organs and tissues from outside England; and
 - (b) to the extent that NHSBT carries out an equivalent service in relation to Scotland, Wales or Northern Ireland, in carrying out the organ and tissue matching and allocation service, have regard to the need to ensure the maximum and most effective use of organs and tissues, the safety of persons and their survival rates and the equity and integrity of the organ sharing system.
- (3) The list maintained under sub-paragraph (1)(b) may be a list which includes persons in Scotland, Wales and Northern Ireland provided that the list indicates where the person is from.
- (4) The information recorded, updated and kept under sub-paragraph (1)(e) may be recorded, updated, kept, analysed and audited with information about potential and actual donors and recipients of organs and tissues in Scotland, Wales and Northern Ireland provided that information indicates where the potential or actual donor or recipient is from or to which country the information relates.

Functions in relation to the allocation of organs for transplantation

4.—(1) Subject to sub-paragraphs (2), (3) and (4) of this paragraph, the allocation of organs by NHSBT for the purposes of transplantation shall be in accordance with the Schemes.

(2) No person in Group 2 shall receive an organ for which there is a clinically suitable person in Group 1.

(3) Group 1 shall comprise—

- (a) persons ordinarily resident in the United Kingdom;
- (b) persons who are—
 - (i) members of Her Majesty’s United Kingdom Forces serving abroad;
 - (ii) other Crown servants employed in the right of Her Majesty’s Government of the United Kingdom having been recruited in the United Kingdom and who are serving abroad;
 - (iii) employees, recruited in the United Kingdom, of the British Council or the Commonwealth War Graves Commission and who are employed abroad;
 or the spouse or any child under the age of nineteen of any person falling within sub-paragraphs (i) to (iii) above;
- (c) persons who are entitled under Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to medical treatment in the United Kingdom;
- (d) persons entitled by virtue of a bilateral reciprocal health agreement or the European Convention on Medical Assistance 1954 to medical treatment in the United Kingdom.

(4) Group 2 shall comprise persons who do not come within the categories of persons listed in Group 1.

General functions of NHSBT

5.—(1) NHSBT may exercise functions under—

- (a) section 23 of the Act (voluntary organisations and other bodies); and

- (b) section 2(b) of the Act (Secretary of State’s general powers as to services) to do anything whatsoever which is calculated to facilitate, or is conducive or incidental to, the discharge of NHSBT’s functions.

(2) NHSBT, in performing the functions described in paragraph 2, 3 and 4 above, may provide advice and make recommendations to the Secretary of State on any matter connected with its functions.

Exercise of functions

6. NHSBT, in exercising its functions, shall have regard to any guidance issued by the Secretary of State.

Land transactions

7.—(1) Subject to sub-paragraphs (2) and (3) of this paragraph, NHSBT shall exercise the functions of the Secretary of State under section 87(1) and (2) of the Act in so far as is necessary to enable it to secure and maintain such accommodation as it requires for the proper discharge of its other functions.

(2) The functions mentioned in sub-paragraph (1) do not include the powers of the Secretary of State to acquire land compulsorily.

(3) NHSBT shall not, without the prior approval of the Secretary of State, exercise the functions mentioned in sub-paragraph (1) so as to—

- (a) acquire or dispose of any land, or any interest in land, the value of which exceeds £1 million; or
- (b) acquire a leasehold interest where either—
 - (i) the term of the lease is less than one year and the rent payable exceeds £1 million; or
 - (ii) the term of the lease is not less than one year and the product of multiplying the number of years in the term by the amount of rent payable in the first year of the term exceeds £1 million.

(4) In sub-paragraph (3)(a) above “value” means the value on a disposal by sale with vacant possession on the open market.

(5) In sub-paragraph (3)(b) above “the term” in relation to a leasehold interest acquired by way of assignment means the unexpired term.

(6) Any function of the Secretary of State, under section 87 of the Act, shall be exercised in accordance with the procedures and instructions for the time being in force and issued by the Department of Health in the document entitled “Estatecode”(a), except in so far as such procedures and instructions are inconsistent with these Directions.

(7) Subject to NHSBT obtaining approval as and when required under sub-paragraph (3) above, where the exercise by NHSBT of any function to which these Directions apply requires—

- (a) the execution under seal of any document, NHSBT shall execute such document on behalf of the Secretary of State under its own seal; or
- (b) the execution of a document otherwise than under seal, NHSBT shall make arrangements for one of its officers who has been duly authorised for the purpose to sign the document for NHSBT on behalf of the Secretary of State.

Accounts

8.—(1) NHSBT must prepare and keep annual accounts in respect of each financial year which shall give a true and fair view of the income and expenditure and cash flows of NHSBT for the financial year, and the state of affairs as at the year end.

(2) The accounts shall be prepared in accordance with—

(a) Copies of this document are available on the website www.dh.gov.uk/estates

- (a) the Resource Accounting Manual(a);
- (b) the Department of Health Special Health Authority Manual for Accounts(b);
- (c) any other requests made by the Secretary of State,

except where agreed with the Secretary of State in which case the exception shall be disclosed in the notes to the accounts.

Annual report

9. The Secretary of State directs NHSBT to produce an annual report in respect of each year from 1st April to 31st March, covering its activities and finances (including officers' remuneration) and to submit that report to the Secretary of State by no later than 30th September each year, or by such other date as the Secretary of State may direct.

Revocation

10. The following directions are revoked—

- (a) The National Blood Authority Accounts Direction given on 19 March 1993;
- (b) The National Blood Authority Directions in relation to Powers of Income Generation given on 29 March 1993;
- (c) The National Blood Authority Directions in relation to Building and Engineering Functions given on 29 March 1993;
- (d) The National Blood Authority Directions in relation to Financial Management given on 5 April 1993;
- (e) The National Blood Authority (Land Transactions) Directions 1997 given on 23 July 1997;
- (f) The Directions on the Allocation of Human Organs for Transplantation given on 12 February 1996 in so far as they apply to United Kingdom Transplant(c).

Signed by authority of the Secretary of State for Health

Member of the Senior Civil Service
Department of Health

Date:

(a) This document is published by HM Treasury and is available on the website www.resource-accounting.gov.uk/current/frames.htm

(b) This document is available on the website www.info.doh.gov.uk/doh/finman.nsf

(c) United Kingdom Transplant was established by the United Kingdom Transplant (Establishment and Constitution) Order 1991, *see* S.I. 1991/407 as amended by S.I. 1996/971, 1998/1577 and 2000/1612, and abolished by the National Blood Authority and United Kingdom Transplant (Abolition) Order 2002, *see* S.I. 2005/2532.

NATIONAL HEALTH SERVICE

NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) (Amendment) Directions 2009

The Secretary of State for Health makes the following Directions in exercise of the powers conferred by sections 7, 8, 272(7) and 273(1) of the National Health Service Act 2006^(a).

Citation and commencement

11. These Directions may be cited as NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) (Amendment) Directions 2009 and shall come into force on 1st May 2009.

Amendment of paragraph 4 of the 2005 Directive

For paragraph 4(3)(d) of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (England) Directions 2005^(b) substitute—

- “(d) persons entitled by virtue of a bilateral reciprocal health agreement or the European Convention on Social and Medical Assistance 1954 to medical treatment in the United Kingdom;
- (e) persons ordinarily resident in the Channel Islands.”.

Signed by authority of the Secretary of State for Health

Date

Name
Member of the Senior Civil Service
Department of Health

(a) 2006 c.41. By virtue of section 271 of the Act the powers conferred on the Secretary of State by those sections are exercisable only in relation to England.

(b) The 2005 Directions came into force on 1st October 2005 and are annexed to the Department of Health Guidance, “Guidance on the allocation of organs for the purposes of transplantation”, available at www.uktransplant.org.uk.