

## **Background Information on Organ Donation and Transplant**

### **PURPOSE**

This paper outlines the background on the three issues related to organ donation and transplant identified for discussion on 14 June.

### **ORGAN DONATION AND TRANSPLANT**

2. Organ donation saves lives. For patients suffering from end-stage organ failure, organ transplant is often the only cure and helps them gain a new life with much improved quality.

3. Organs/tissues used for transplant come from two sources: living and cadaveric donations. The majority of organs/tissues used for transplant are cadaveric, accounting for about 90% of all organ donations in 2010. Only individuals who are certified brain dead can be cadaveric donors. Organ transplant in Hong Kong is regulated under the Human Organ Transplant Ordinance (Cap. 465) (the Ordinance). Currently, there are seven types of solid organs and tissues for which transplants are conducted in public hospitals. On the other hand, corneal transplant is conducted in some private hospitals/clinics. The number of organ/tissue donations in public hospitals under the Hospital Authority (HA), and the number of patients waiting for transplant over the past eight years are at **Annex A**.

#### Operation under the Ordinance

4. The Ordinance was enacted in 1995 to prohibit commercial dealings of human organs intended for transplanting and restrict the transplanting of human organs between living persons and the transplanting of imported human organs.

5. The Human Organ Transplant Board (the Board) was established under section 3 of the Ordinance to give approval to the carrying out of a

restricted organ removal<sup>1</sup> or a restricted organ transplant<sup>2</sup> in accordance with the provisions in the Ordinance and to perform other functions as specified in the Ordinance.

6. The Ordinance provides for the restrictions on and relevant procedures of obtaining approval from the Board for proceeding with transplantation which involves a living donor. These restrictions apply to both living related (genetically related or spouse) and living unrelated donors. It has been expressly provided in the Ordinance that all living donors must reach the age of 18 years. Besides, the Ordinance requires that the donor is not consenting under coercion or the offer of inducement<sup>3</sup>. The Ordinance also provides the conditions which the applicants must satisfy in obtaining approval from the Board<sup>4</sup>. A person contravening the

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<sup>1</sup> Restricted organ removal refers to the act of removing from a living person an organ for the purpose of transplanting it into another person.

<sup>2</sup> Restricted organ transplant refers to the act of transplant into a person an organ removed from another person who was living at the time of removal.

<sup>3</sup> For transplants between living persons, other than the age requirement, the general requirements to be satisfied are as follows –

- (a) a registered medical practitioner has, in the absence of the recipient, explained to the donor, and the donor has understood the procedure of the proposed organ removal, the risk involved and his/her entitlement to withdraw consent to that removal at any time;
- (b) the donor has given his/her consent to the proposed organ removal without coercion or the offer of inducement and has not subsequently withdrawn his/her consent;
- (c) a registered medical practitioner has, in the absence of the donor, explained to the recipient, and the recipient has understood the procedure of the proposed organ transplant, the risk involved and his/her entitlement to withdraw consent to the transplant at any time;
- (d) the registered medical practitioner who makes the explanation under (a) and (c) above shall not be the one who is to carry out the restricted organ removal or the restricted organ transplant; and
- (e) no payment prohibited by the Ordinance has been made, or is intended to be made.

<sup>4</sup> For restricted organ removal and/or transplant which requires prior approval of the Board, the following additional requirements must be fulfilled:

- (i) the proposed operation(s) is/are referred to the Board for approval by a registered medical practitioner who has clinical responsibility for the donor concerned;
- (ii) the donor has been interviewed, in the absence of the recipient, by an interviewer, and the interviewer has reported to the Board that the donor has understood the procedure of the proposed organ removal, the risk involved and his/her entitlement to withdraw consent to the removal at any time;
- (iii) the recipient has been interviewed, in the absence of the donor, by an interviewer, and the interviewer has reported to the Board that the recipient has understood the procedure of the proposed organ transplant, the risk involved and his/her entitlement to withdraw consent to the transplant at any time; and
- (iv) either interviewer shall be a person whom the Board considers to be suitably qualified to conduct an interview but shall not be the registered medical practitioner who makes explanation to the donor or the recipient.

The requirements on explanation to and interview of the recipient can be waived if

- (a) a medical practitioner has issued a certificate certifying that –
  - (i) the recipient concerned is in fact incapable of understanding the explanation required; and
  - (ii) the fact is attributable to one or more of the following reasons –
    - (A) the recipient suffering any illness;
    - (B) the recipient being a minor;

relevant requirements is liable upon a first conviction to a fine at level 5 (i.e. \$ 50,000) and to imprisonment for 3 months and upon a subsequent conviction to a fine at level 6 (i.e. \$100,000) and to imprisonment for 1 year.

## **ISSUES**

### **A. Whether to lower the eligible age of living donors**

7. At present, the Ordinance defines the minimum age of a living organ donor as 18. The law does not allow for discretion by any party, including the Government. Recently, there have been suggestions in the community to discuss whether to lower the eligible age subject to assessment of the potential donor's physical condition as well as clinical and psychological suitability.

8. The World Health Organization (WHO) Guiding Principles on Human Cell, Tissue and Organ Transplant requires that specific measures should be put in place to protect a minor and the minor's assent should be obtained<sup>5</sup>. In the commentary on Guiding Principle 4, it is further elaborated that the major exceptions that may be authorized are familial donation of regenerative cells (when a therapeutically comparable adult donor is not available) and kidney transplants between identical twins (where avoiding immunosuppression represents a benefit to the recipient adequate to justify the exception, in the absence of a genetic disorder that could adversely affect the donor in the future). While the permission of

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(C) the recipient being a mentally incapacitated person within the meaning of the Mental Health Ordinance (Cap. 136); or

(D) the recipient suffering an impaired state of consciousness;

(b) a medical practitioner has issued a certificate certifying that it would not be in the best interest of the recipient to wait until he/she is capable of understanding the explanation required; and

(c) the medical practitioner who is to carry out the restricted organ transplant has kept a medical report in writing stating the reason why the requirement on explanation cannot be complied with.

<sup>5</sup> Guiding Principle 4 requires that “[n]o cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.”

the parent(s) or the legal guardian for organ removal is usually sufficient, they may have a conflict of interest if they are responsible for the welfare of the intended recipient. In such cases, review and approval by an independent body, such as a court or other competent authority, should be required. In any event, a minor's objection to making a donation should prevail over the permission provided by any other party. The professional counselling provided to potential living donors in order to assess, and when needed, address any pressure in the decision to donate, is especially important for minor donors.

### Consideration

9. There are three major areas of concern:

a) *Children's rights<sup>6</sup> and clinical benefit and adverse health effect of organ donation by minors*

10. With the sophisticated advancement in medical skills and technology, living donor donation is a safe and mature procedure. In 2010, the living-donor graft survival rate at one year is 93% and at five years 90%, in comparison with 88% at one year and 78% at five years in 2010 for deceased kidney transplantation in Hong Kong. For living donor liver transplant, right lobe donor has 0.5% and left lobe has 0.1% risk of mortality. The overall complication rate is about 20%. There is however uncertainty about the long-term health risk of donors.

11. The psychosocial impact on a minor donor is so far lacking conclusive evidence. A donor's psychosocial wellbeing is often closely attached to the medical and psychosocial outcomes of the recipient and be negatively affected by any undesired outcome. There is evidence that

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<sup>6</sup> The Convention on the Rights of the Child (the Convention), adopted by the United Nation General Assembly in 1989, sets out the rights that must be realized for children to develop their full potential, free from hunger and want, neglect and abuse. The Convention defines a child as "Every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier". In adopting the Convention, the international community recognised that people under 18 years of age often need special protection and care that adults do not. Articles 3 and 12 of the Convention state that, in all actions affecting children, their best interests must be a primary consideration and that their views, when they are capable of forming them, should be given due weight in accordance with their age and maturity. Both principles are reiterated in other United Nation instruments, such as the World Declaration on the Survival, Protection and Development of Children.

minors may feel lower esteem, a sense of neglect, and lack of appreciation after the donation as the attention refocuses on the recipient.

12. On the other hand, a number of psychosocial benefits of living donation have been suggested, which include increased self-esteem and self-worth as a consequence of the donors' altruistic behavior, as well as psychosocial benefits caused by the improved health status and improved relationship with the recipient who often is a close family member of the donor. The donation may also prevent the minor from possible future guilt. While some would agree that living donation should be allowed if the anticipated psychosocial benefits that the minor may experience are likely to outweigh the medical and psychosocial risks, others consider living donation as not justified because the long-term medical and psychosocial outcomes of living donation in minors are largely unknown.

*b) Capacity to consent<sup>7</sup> - the decision-making capacity of minors*

13. Minors' cognitive capacity in weighing the risks and benefits of the procedure may affect their decision making process and ability to safeguard their own rights. Family pressure could also bring upon observable influence on the decision-making capacity of minors when the intended recipient of the organ is a close relative of the minor donor.

14. While it is generally agreed that decisions made by parents/guardians are in the best interest of their children, it is possible that parents may not be able to adequately understand and appreciate the long-term medical and psychosocial risks of the donation. Moreover, parents may experience a conflict of interest in making this decision when they are at the same time responsible for the care of the intended recipient.

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<sup>7</sup> The Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (the Protocol), which aims to protect human dignity and integrity, as well as rights and fundamental freedoms, in the face of scientific and medical advances, provides that (Article 13) an organ or tissue may be removed from a living donor only after the person concerned has given free, informed and specific consent to it either in written form or before an official body and (Article 14) states that no organ or tissue removal may be carried out on a person who does not have the capacity to consent, and only in exceptional situations and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised subjected to fulfilment of certain conditions. At present, 14 countries have rectified the Protocol.

*c) Circumstances for donation by minors*

15. There would be a need to come up with a set of circumstances under which a person under 18 may be considered as a potential living donor. Such circumstances may include, but are not limited to, the following<sup>8</sup> -

- (a) recipient is in critical condition and his/her life is threatened if organ transplantation cannot be proceeded (i.e. for critical liver failure patients only);
- (b) no foreseeable compatible deceased or living donors within the critical timeframe;
- (c) donor and recipient are both highly likely to benefit;
- (d) surgical risk for the donor is extremely low;
- (e) all other opportunities for transplantation have been exhausted;
- (f) the donor freely accents to donate without coercion; and
- (g) emotional and psychological risks to the donor are minimized.

Overseas experience

16. In general, minors are legally prohibited from acting as living donors in order to maximize the legal protection of minors. In some countries, living donation by minors may be legal under well-defined conditions and circumstances.

(a) United Kingdom (UK)

- In England, Wales, and Northern Ireland, there is no minimum age limit for people to be considered as living donors. The Human Tissue Act 2004 and Transplant Regulations place an obligation on the Human Tissue Authority to assess all applications for living donation. Minors can in principle provide consent under the common law doctrine, which requires full understanding of the nature and

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<sup>8</sup> Items (c) – (g) are made with reference to the Guidelines issued by the American Academy of Pediatrics in 2008 and 2011 on living donation by minors.

consequences of the intervention, along with parental consent, if all other relevant requirements of the Human Tissue Act 2004 are met. The court is the authority to determine whether living donation would be in the best interest of the minor.

- In Scotland, only people over 16 years of age can legally consent to living organ donation.

(b) Australia

- Except for the Australian Capital Territory (ACT), the removal of non-regenerative tissue from children (e.g. under 18 and not married in New South Wales, Victoria and South Australia, under 18 in Queensland) is expressly or impliedly prohibited in all jurisdictions in Australia. In ACT, removal of non-regenerative tissue from a child is allowed in circumstances where parental consent is given, the child understands the nature and effect of the procedure and agrees, and a Minister appointed committee authorises the procedure.

(c) United States

- In the United States, the general age of consent to living organ donation is 18 years in most states but the US Courts have occasionally permitted donation by a child after gaining parental consent.

(d) Canada

- Each Canadian province and territory has its own laws governing age of consent to medical treatments, organ donation, and transplantation. The minimum age requirement for living donor varies across

provinces and ranges from 16 to 19 years, with special provision in some provinces<sup>9</sup>.

(e) Singapore

- According to the Human Organ Transplant Act (HOTA), the donor has to give his consent to the removal. The minimum age requirement for living donor is not specified in the legislation. The transplant ethics committee of a hospital has to ensure the donor is not mentally disordered and, notwithstanding his/her age, is able to understand the nature and consequence of the medical procedures he/she has to undergo as a result of his/her donation of the specified organ.

## **B. Paired Donation**

### The concept of matching living donor and recipient dyads

17. Living donation offers an alternative for individuals awaiting transplantation from a deceased donor and increases the existing organ supply. There are however cases in which the patient who is eligible for an organ transplant, and have a living related donor who is willing but unable to donate because of an incompatible blood type or tissue type. One option to overcome this barrier is paired donation. In a paired donation, a medically approved incompatible donor-patient pair is able to donate organs to another incompatible pair so that both patients receive compatible organs. In overseas jurisdictions, paired donation can be arranged to involve three or more pairs but more sophisticated matching algorithms would be needed.

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<sup>9</sup> For example, in Alberta, children under 18 can donate organs if a parent or guardian gives consent and an independent assessment committee gives approval after establishing that: the donor agrees to donate without coercion or inducement, the donation poses minimal risk to the donor and all adult members of the immediate family have been eliminated as donors. In Manitoba, a person between the ages of 16 and 18 may be a living donor if deemed mentally capable to give consent by an independent physician, the recipient is an immediate family member and a parent or legal guardian also consents.



## The proposal

18. HA has proposed a pilot Paired Kidney Donation Programme, which would adopt a simple procedure of two-way kidney donation, i.e. a two-way kidney donation occurs when two incompatible donor/recipient pairs swap organs for a better compatibility match. The donor from the first pair would donate to the recipient of the second pair, and the donor from the second pair would donate to the recipient of the first pair. Four operations for the two matched pairs must be arranged simultaneously.

19. The proposed inclusion criteria for the programme, which are subject to review, are as follows:

- (a) the donor must be aged 18 or above;
- (b) the recipient must be under the care of Renal Units of HA;
- (c) the recipient is either receiving dialysis therapy or in pre-emptive status;
- (d) the recipient is an eligible person;
- (e) the donor-recipient pairs must be medically and legally suitable for donation and transplant; the living related donation and transplant is not possible due to Blood Group incompatibility or Positive Cross-match;
- (f) both the donor and recipient must agree to donate to and accept the kidney from another donor-recipient pair;
- (g) both the donor and recipient are of competent mind; and
- (h) both the donor and recipient give consent freely.

20. The interest of the donor and the recipient is of equal importance in all living donation. HA's Renal Units have the discretionary capacity not to accept a willing donor if it is not in the best interest of the donor or the recipient.

21. The programme will be designed to address the potential concern on the ethical aspects regarding paired kidney donation, including safeguard of the altruistic nature of the donation, autonomy of participants to join and exit the programme, respect for and honouring the wish of the donor, minimizing risk of the potential donor, management of the case

according to established protocol, maintenance of confidentiality of the identity of the participants, and requirement of an informed consent. A summary of the potential measures to address the issues is at Annex B.

### Mode of operation

22. The programme would require confirmation of the legal and medical (including ABO<sup>10</sup> compatibility) eligibility of both the donors and the recipients of the matching dyads. Consent on cross-matching and the procedures required for the transplantation must be obtained and such consent must be voluntary and exit at any stage of the procedures must be allowed. The existing statutory requirement of non-coercion in obtaining the consent would also apply to such cross-matching programme. Confidentiality and privacy of the dyads must also be upheld and protected. HA would keep the identity of the donor-patient pairs confidential to avoid involvement of incentives and benefits.

23. There are concerns on the management of untoward incidents, such as withdrawal of one pair after two matched pairs are identified, etc. HA will suggest measures to address such circumstances, such as allowing withdrawal from the programme, put the orphaned recipient into the priority waiting list, etc. Further details will be developed and discussed with stakeholders.

24. As HA is exploring the feasibility of establishing such a pooling mechanism and database with a view to facilitating donation between living persons, the programme will be piloted under strict scrutiny to ensure strict adherence to the principles on living donation laid down by the WHO and relevant laws. According to internal consultation conducted by HA, the general idea/direction of implementation of such scheme is supported by patients. HA will develop further details of the scheme for further consultation with stakeholders. A legislative exercise to provide legal backing to the scheme will be necessary in due course.

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<sup>10</sup> It is a general principle in organ transplant that the ABO group and RhD type of red cell components of the donor is compatible with that of the recipient.

## Overseas experience

25. South Korea was the first in the world to perform a paired kidney donation between two end stage kidney disease patients, each had an incompatible donor due to positive cross match. Since then paired kidney donation has been realized in various overseas jurisdictions, including the United States, United Kingdom, Australia, Canada, etc. The US has been the pioneer of the practice of paired donation and has already advanced and refined their cross-matching mechanism which can now accommodate over 30 recipients across various hospitals in a chain. The level of control imposed on paired donation programmes varies in different jurisdictions. It is worthy to note that these programmes do not deviate from the WHO Guiding Principles.

26. Regarding transplants involving a living donor, the relevant UK legislation (the Human Tissue Act 2004 and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006) require that approval from the Human Tissue Authority (HTA) is needed and before the HTA can approve these cases, it must be satisfied that:

- (a) no reward<sup>11</sup> has been, or is to be, given;
- (b) consent to removal for the purpose of transplantation has been given (or removal for that purpose is otherwise lawful); and
- (c) an Independent Assessor (IA) has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient (or the person acting on behalf of the recipient) and submitted a report of their assessment to the HTA.

## **C. “Opt-Out” Scheme**

### Background

27. Deceased organ donation in Hong Kong is governed by the Ordinance and the Medical (Therapy, Education and Research) Ordinance (Cap. 278). The current model of consent seeking is a soft “opt-in” system, under which the designated person, i.e., the organ donation

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<sup>11</sup> "Reward" is defined as any description of financial or other material advantage.

coordinator, will have to seek the consent of the family members of the deceased even if the deceased has expressed his/her wish to donate organs after death. Should there be any objection from the family of the deceased, transplantation will not proceed.

28. Under an “opt-out” scheme, the deceased is presumed to have agreed to organ donation unless he/she has indicated any preference of not donating his/her organs before his/her death (“presumed consent”). A registration system with operation similar to that of the existing Centralized Organ Donation Register would need to be set up for members of the public to register their wish not to donate organs after death. The system should be established with a high standard of personal data security.

### Issues and concerns

29. The establishment of an “opt-out” scheme might bring about the following concerns:

#### *(a) Individual rights*

30. It has been brought up by members of the public that an “opt-out” scheme which presumes consent from the deceased may compromise individual rights as one may not have registered to “opt-out” for various reasons. There are also concerns that those who have not opted out might be subject to abuse. For example, medical practitioners might not provide the necessary life sustaining treatment. On balance, family members of the deceased may be consulted and other circumstantial evidence (such as whether the deceased has expressed his/her wish to “opt-out” before his/her death) should be accorded proper weight.

#### *(b) Role of family member*

31. As a check-and-balance measure, the consent of family members could be obtained for donation of the organs of the deceased. There would be scenarios as below:

(a) Where the deceased has expressed his wish to opt out (not to

- donate);
- (b) Where the deceased has expressed his wish to donate;
  - (c) Where the deceased has neither expressed his wish to donate or not to donate (not opted out).

32. Under the existing mechanism, family members would still be consulted on organ donation under scenario (b). It is for consideration if this is still required under an opt-out scheme, for example for those who have already signed up the Centralized Organ Donation Register. On the other hand, it would be legitimate to ask if a similar requirement to consult the family members should be maintained under scenario (a), so as to confirm that organ donation should not proceed; and under scenario (c), whether family members should prevail over the presumption of donation.

33. It should be noted that family members of the deceased also has a key role to inform on the medical and behavioural history of the deceased, which is important to the success of a transplant.

*(c) Effectiveness and viable alternatives*

34. Researches and overseas experience suggest that an “opt-out” scheme influences both deceased and living donation rate as it carries significant and symbolic meaning for the overall organ donation/transplantation policy. It was found in a study<sup>12</sup> that the deceased donor rates were moderately higher in “opt-out” countries than in “opt-in” countries. Although there were less living donors in “opt-out” than “opt-in” countries, the total number of kidneys transplanted was higher in “opt-out” countries. The effect remained after controlling for other confounding factors including GDP per capita, deaths from road traffic accident, number of hospital beds per 1 000 population, percentage of the population that self-identified as Catholic, legal system and percentage of people in each country involved in non-health based philanthropy. Other studies which compared organ donation rates between countries adopting “opt-out” and “opt-in” schemes indicated that other factors like transplant capacity and GDP per capita had greater predictive effect than an “opt-out” scheme. Public perception and level

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<sup>12</sup> Shepherd et al. An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study. BMC Medicine. 2014 Sep 24;12:131

of trust towards the Government, as well as transparency and medical support are also critical factors for the implementation of an “opt-out” scheme.

### Overseas experience

35. Below are examples of countries that have implemented an “opt-out” policy.

(a) Austria<sup>13</sup>

- According to the Austrian Hospitals Act, removal of organs from a potential donor is permitted unless the person, before his/her death, has explicitly objected to donation. All hospitals, before removing organs, are obliged to verify whether such an objection has been filed in an official Opting-out Registry which was established in 1995 or other written document such as a letter or health record. Doctors may remove organs of the deceased person even if the next of kin know that the deceased would object to donation but failed to register during life.

(b) Singapore<sup>14</sup>

- The Human Organ Transplant Act (HOTA), which applies the priority rule with an opt-out system limited to donation of kidneys among non-Muslims aged between 21 and 60 who had suffered accidental deaths, was enacted in 1987. If a person objects to donating their organs upon death, they give up priority for receiving an organ should they need one in future. There is a parallel opt-in system in which people can register their wish to donate organs after death. Family members have no legal right of objection, although in practice, organ retrieval is carried out with due regard to families. Between 2004 and 2009, further legislative amendments to the HOTA were made to permit living organ donation, expand removable organs, include all causes of death, ensure that organ donors are not exploited, unlawfully induced

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<sup>13</sup> Coordination Office of Transplantation Affairs, GÖG/ÖBIG Transplant.

<http://www.goeg.at/index.php?pid=arbeitsbereichdetail&ab=105&smark=organ&noreplace=yes>

<sup>14</sup> [https://www.moh.gov.sg/content/moh\\_web/home/pressRoom/Parliamentary\\_QA/2016/increasing-singapore-s-organ-transplant-rate.html](https://www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2016/increasing-singapore-s-organ-transplant-rate.html)

or forced into organ retrieval by others, allow for paired exchange and include all religion. During the same period, only 2% - 3% of Singaporeans opted out of donating organs after death. Yet, the number of deceased organ transplant has remained low.

(c) Spain<sup>15</sup>

- Spain implemented the “opt-out” policy by enacting the Transplantation Law in 1979 but it had not much impact on the rate of organ donation until 1989, when several other measures were implemented to increase the donor pool. The country established a national coordinating body and a multi-level transplant coordination network, appointed designated personnel to identify potential donors and support the donor family, provided training of medical staff in entire process of deceased organ donation, launched quality assurance programmes in the deceased donation process, reimbursed hospital for donation activities, and launched public education programmes. In 2008, Spain devised the 40 Donors pmp<sup>16</sup> Plan to further increase the donor pool. The Plan established three specific objectives: (i) promote the early identification and referral of possible organ donors from outside of the intensive care unit to consider elective nontherapeutic intensive care and incorporate the option of organ donation into end-of-life care; (ii) foster the use of expanded and nonstandard risk donors; and (iii) develop the framework for the practice of donation after circulatory death. Nowadays, Spain has the highest rate of deceased organ donation in the world, at 40.15 per million population in 2015. The Spanish Model of Donation and Transplantation has often been described as one of the most successful systems in the world.

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<sup>15</sup> [http://www.donatelife.gov.au/sites/default/files/OTA\\_Fact\\_Sheets\\_-\\_International\\_approaches\\_to\\_organ\\_donation\\_reform\\_November\\_2013.pdf](http://www.donatelife.gov.au/sites/default/files/OTA_Fact_Sheets_-_International_approaches_to_organ_donation_reform_November_2013.pdf)

<sup>16</sup> “Pmp” stands for “per million population”.

### *Options between “Opt-in” and “Opt-out”*

36. Some countries have implemented measures that are less restrictive than an “opt-out” scheme yet might increase the potential organ donation rates.

#### (a) United Kingdom<sup>17</sup>

- In the United Kingdom, if the family, or those closest to the deceased person, object to the donation when the deceased has given their explicit permission, they will be encouraged to accept the deceased’s wish and it will be made clear by healthcare professionals that they do not have the legal right to veto or overrule such wish. The Human Tissue Act defines who is the nearest relative of the deceased, ranging from a spouse or partner (including civil or same sex partner); parent or child; brother or sister and other relatives to a friend of long standing.

#### (b) The Netherlands

- In 1998, the government of the Netherlands introduced a national Donor Registry. All residents over the age of 18 would receive a donor form for indication of a “yes or no” for organ donation with the option of empowering the next of kin or another person to make the decision. Information filed in the Donor Registry can be revoked at any time. Doctors are obliged to consult the Donor Registry in case a deceased person seems to be a suitable donor. Should anyone have not made any arrangement by means of the registration form, that right is transferred to the next of kin. In addition to the Donor Registry, the donor card remains a legal document.

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17.[http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_090312](http://webarchive.nationalarchives.gov.uk/+http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312)



## **Comments sought**

37. Views are invited on the feasibility and way forward of the abovementioned three issues, namely, whether to lower the age requirement for living donation, a paired donation scheme and an opt-out scheme. A list of the key questions, which is not meant to be exhaustive, is set out in Annex C.

**Food and Health Bureau  
Department of Health  
Hospital Authority  
June 2017**

## Annex A

### **No. of patients waiting for organ / tissue transplant (2008 – 2016)**

	<b>(as at 31 December of the year)</b>								
<b>Organ / Tissue</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>
Kidney	1568	1602	1621	1781	1808	1991	1965	1941	2047
Liver	106	100	91	109	121	120	98	89	89
Heart	13	10	8	20	17	17	28	36	50
Lung	4	8	12	17	15	18	22	16	19
Cornea	400	500	500	500	500	500	465	374	298
Skin	Not applicable								
Bone	Not applicable								

Note:

Patients waiting for skin and bone transplant are spontaneous and emergency in nature. As substitutes will be used if no suitable piece of skin or bone is identified for transplant, patients in need of skin and bone transplant are not included in the organ/tissue donation waiting list.

## Annex B

### Measures to address potential ethical issues related to Paired Kidney Donation (PKD) Programme

	<b>Deceased Donor</b>	<b>Transplant between living related persons</b>	<b>PKD Programme</b>
<b>Altruistic</b>	Non-directed donation	Directed donation	Intended directed donation
<b>Autonomy</b>	Voluntary to register one's wish to donate after death	Voluntary agreement to undergo organ removal and transplant	Voluntary to join the programme
	Not applicable	Consent without coercion or the offer of inducement	Consent without coercion or the offer of inducement
	The donor can revoke his/her wish to donate after death any time	May withdraw consent to organ removal at any time	The donor and recipient pair can leave the programme at any time
	Not applicable		May withdraw consent to organ removal at any time
<b>Beneficence</b>	Prolongs life and improves quality of life of the recipient		
<b>Non-maleficence</b>			

	End of life care of the donor is not affected by organ donation	The donor's risk can be minimised by stringent protocol and life-long follow up	The donor's risk can be minimised by stringent protocol and life-long follow up
<b>Justice</b>	Transparent and fair organ allocation policy	Not applicable	Transparent and fair matching policy
<b>Confidentiality</b>	Measures to prevent identification of donor and recipient	Not applicable	Measures to prevent identification of donor and recipient pair
<b>Informed Consent</b>	Informed consent from family member is sought before removal of organ from any donor	Informed consent from the donor and recipient to the proposed organ removal and transplant	Informed consent from the donor and recipient to the proposed organ removal and transplant

Questions

Whether to lower the eligible age for living donation

1. What would be the circumstances that warrant consideration of allowing a person under 18 to donate organs?
2. What could be the new eligible age?
3. Can discretion be allowed on the eligible age, e.g. if some authorities could decide whether to lower the eligible age on a case-by-case basis?
4. Which party/parties should be the authorities to scrutinize such cases? What are the procedures to follow?
5. What would be the assessments for suitability of a minor as donor?
6. What should be the weight to be given to parental/guardian consent?

Paired donation

1. Is there any difference between a donor voluntarily donating an organ to a related person, and a donor X voluntarily donating an organ to an unrelated person when an organ from another person will be donated to a related person of donor X?
2. Should there be additional safeguards to ensure that a donor is acting voluntarily in cases of paired donation?
3. How is fairness of the cross matching process ensured and seen to be so?

“Opt-out” scheme

1. What would be the role of family members under an opt-out scheme?
2. How can the rights of individuals be safeguarded?
3. Between a full “opt-out” and “opt-in” scheme, are there other alternatives?
4. Apart from legislation on consent seeking, are there other means to increase donor pool?
5. How to address the issue of religious belief of particular population groups?