

For discussion on
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Legislative Council Panel on Health Services

Legislative Proposal on Paired/Pooled Organ Donation, Thematic Household Survey Findings on Organ Donation

PURPOSE

This paper briefs Members on –

- (a) the Government's plan to amend the Human Organ Transplant Ordinance (Cap. 465) ("HOTO") in the first half of 2018 to allow paired/pooled organ donation, and
- (b) the findings of the Thematic Household Survey on organ donation.

ORGAN DONATION AND TRANSPLANT

2. For patients suffering from end-stage organ failure, organ transplant is often their only hope for gaining a new life. Currently, the most common organs /tissues for transplant conducted in Hong Kong are cornea, kidney, liver, heart, lung, skin and bone. Organs/tissues used for transplant come from two sources: cadaveric and living donations, with the latter being carried out for kidney and liver only. Majority of organs/tissues used for transplant are cadaveric in origin, accounting for about 90% of all organ donations.

3. Despite continuous efforts over the past years to promote organ donation, there has been a decrease in the number of **cadaveric donation** in Hong Kong. The number of cadaveric kidney donation carried out in public hospitals decreased from 84 in 2012 to 61 in 2017, and the number of cadaveric liver donation decreased from 45 to 40 during the same period (**Annex A**). As a result, there is a continuous increase in the number of patients waiting for organ transplant as well as the waiting time for organ transplant. As at 31 December 2017, the average waiting time for a kidney and a liver transplant is

51 months and 42 months respectively while the longest waiting time is 351 months and 217 months respectively (**Annex B**).

PAIRED AND POOLED ORGAN DONATION

4. **Living donation** offers an alternative for individuals awaiting transplantation from a deceased donor and increases the existing organ supply. There are however cases where the patient who needs an organ transplant has 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 paired donation, both medically approved incompatible donor-patient pairs donate organs to the other pair so that the patients in both pairs receive compatible organs. In some overseas countries, the practice of paired donation has gone further to pooled donation, which involves more than two pairs of donors and recipients.

5. In other jurisdictions, paired organ donation started with kidney transplantation. South Korea was the first in the world to perform a paired kidney exchange for two end stage kidney disease patients, each paired with a willing but incompatible donor due to positive cross match¹. Subsequently, South Korea also performed paired liver exchange for two end stage liver disease patients. Since then paired and pooled organ donation was realised in various overseas jurisdictions, including the United States, United Kingdom, Australia and Canada.

Regulation of living donation in Hong Kong

6. In Hong Kong, HOTO was enacted in 1995 to **prohibit** commercial dealings in human organs intended for transplanting and **restrict** the transplanting of human organs between living persons and the transplanting of imported human organs.

¹ Crossmatch is a test that shows how a recipient's antibodies react with the potential donor's cells. Positive crossmatch means that the recipient's antibodies attack the donor's cells and therefore not suitable for transplant.

7. The Human Organ Transplant Board (“**HOTB**”) was established under section 3 of the HOTO to **give approval** to the carrying out of **restricted** organ removal or a restricted organ transplant in accordance with provisions of the HOTO and to perform other functions as specified in the HOTO. Restricted organ removal refers to the act of removing from a living person an organ for the purpose of transplanting it into another person and restricted organ transplant refers to the act of transplant into a person an organ removed from a living person. Specifically, HOTB’s **prior written approval** is required before the carrying out of a restricted organ removal and/or transplant **if** the donor and the recipient are **not** genetically related or the donor and the recipient are **not** a married couple whose marriage has subsisted for more than 3 years (commonly referred as “living non-related transplant”).

Paired organ donation in Hong Kong

8. The Hospital Authority (“HA”) plans to introduce paired organ donation in Hong Kong. The HA has proposed to start with paired kidney donation. Transplantation of other organs, where applicable in future, will adopt a similar mechanism as outlined below.

9. The HA is proposing a pilot Paired Kidney Donation Programme, participation in which will be voluntary. The donor from the first incompatible donor-recipient 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.

10. As stipulated in section 5D(1)(c) of the HOTO, the donor has to give his consent to the proposed organ removal without coercion or the offer of inducement before any organ transplant between living persons can take place. Under a paired organ donation, a donor is willing to donate his/her organ to a stranger in exchange of another donor donating his/her organ to the first donor's originally intended recipient. While the term “inducement” is not specifically defined, we intend to **amend the HOTO to clear any legal ambiguity as to whether a paired organ donation involves “inducement”**. At the same time, to prohibit commercial dealing in human organs intended for transplanting, **HOTB will still assess and approve** the applications for paired or pooled organ transplant. Although the HA would be the pioneer in operating a paired-kidney donation programme in Hong Kong, the proposed

regulatory regime would not be restricted to paired donations carried out in public hospitals or particular type(s) of organ, as long as the case could satisfy the requirement stipulated in the HOTO and is approved by HOTB.

11. The HA will develop further details of the scheme for further consultation with stakeholders. Subject to the experience of the paired kidney donation scheme, the HA would explore developing a pooled donation mechanism that would involve more than two pairs of donors and recipients and expanding the scheme to cover liver.

Consultation

12. On 14 June 2017, the Food and Health Bureau (“FHB”), Department of Health (“DH”) and the HA held a meeting with medical professionals and patients’ groups to gauge their views on several topics related to organ donation, including the pilot paired donation programme by the HA. There was overwhelming support for the programme as it would increase the supply of living organs and reduce the waiting time for an organ transplant. Given the legal uncertainty, they urged the Government to complete the legislative exercise to provide legal backing for such scheme.

Way forward

13. The Government aims to introduce the proposed amendment bill into LegCo in the first half of 2018.

THEMATIC HOUSEHOLD SURVEY ON ORGAN DONATION

14. The topic of organ donation has been included in a round of Thematic Household Survey (“THS”) conducted by the Census and Statistics Department (“C&SD”) during October 2016 to January 2017 to gather views of Hong Kong residents on organ donation and related issues. Persons aged 18-64 in selected households were asked whether they were **willing** to donate organs after death, whether the family member(s) of a registered donor, upon the latter’s death, could **overturn** his/her wish to donate and whether they supported the implementation of an **opt-out system** for organ donation. Some 10 100

households were successfully enumerated in the THS and the overall response rate was 76%.

Willingness to donate organs after death

15. The findings of the THS revealed that **32.5%** of persons aged 18-64 were **willing** as opposed to 9.8% not willing to donate organs after death. The remaining 57.7% had not yet decided/considered to do so or refused to answer questions on organ donation.²

Whether the family member(s) of a donor, upon the donor's death, could overturn his/her wish

16. The current model of consent seeking is a soft “opt-in” system, under which HA’s organ donation coordinator will 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.

17. Among those persons aged 18-64 who provided their views on organ donation, the THS findings showed that **43.6% did not support** the idea that a deceased donor’s family member(s) could **overturn** the wish of the deceased, if the deceased had “registered” his/her wish. On the other hand, 38.1%, particularly those aged 55-64 (41.5%), considered that the wish of the deceased could be overturned. The remainder did not specify their views.

Implementation of an “opt-out” system and whether one would register as “non-donor”

18. 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”).

² In the THS, about 14% of persons aged 18-64 of those responded refused to provide information related to the topic of organ donation.

19. Among those persons aged 18-64 who provided their views on organ donation, the THS results revealed that about **one-third** (33.8%) **supported** the implementation of an **opt-out** system in Hong Kong, while **35.9%** were **against** and the remaining 30.3% were either neutral or did not specify their views towards the implementation of an opt-out system. About one-tenth (13.2%) claimed that they would register as “non-donor” if an opt-out system for organ donation were implemented.

Way forward

20. Over the years, the public has become more receptive to the idea of organ donation. Views on the willingness to donate organs after death had also been collected via the General Household Survey conducted by C&SD in 1992 and 1994 with coverages³ broadly similar to the THS conducted in 2016/17. Despite the difference in sample design⁴, both surveys in the 1990s showed that about 30% of persons aged 18 or over were willing to donate their organs after death while 50% of them were unwilling. For the 2016/17 THS, the percentage of persons aged 18-64 who were **willing** to donate organs after death was **comparable** to the findings in the 1990s (32.5%). However, the percentage of persons aged 18-64 who were **unwilling** to donate their organs after death has **decreased significantly** to around 10% (9.8%) in 2016/17. The 2016/17 THS showed that over half of the persons aged 18-64 was undecided or refused to specify their willingness. This would suggest that the public was giving some more thought to the issue. We will continue to encourage the public to support organ donation.

21. At the 14 June 2017 meeting with medical professionals and patients’ groups mentioned above, the overall view was that it would be premature to introduce an opt-out system in Hong Kong and public education on organ donation should be further enhanced first. The THS findings bear this out.

³ Persons aged 18 or over were covered in the surveys regarding the topic of organ donation conducted in 1990s, whereas persons aged 18-64 (excluding foreign domestic helpers) were covered in the THS conducted in 2016/17.

⁴ Only one of the relevant persons was randomly selected from each sampled household for interview in the surveys conducted in the 1990s, whereas all relevant persons from the sampled households were interviewed in the THS conducted in 2016/17.

We will continue to engage different sectors of society and enhance public education and promotion to encourage greater public support on organ donation. A summary of the promotional efforts in 2016 and 2017 is at **Annex C**.

22. With the THS findings showing that almost half of those aged 18-64 did not support the idea that a deceased donor's family member could overturn the donor's wish, we will study the feasibility of giving an option such that a deceased donor's wish will be respected in all circumstances.

**Food and Health Bureau
Department of Health
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Annex A

**Number of organ/tissue donations & patients waiting for transplantation
under Hospital Authority (2012-2017)**

| Organ/ Tissue Donated (cases) | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | No. of patients waiting for transplant <i>(as at 31.12.2017)</i> |
|--|------|------|------|------|------|------|---|
| <u>Kidney</u> <i>(total)</i> | 99 | 82 | 79 | 81 | 78 | 78 | 2153 |
| <i>Cadaveric</i> | 84 | 70 | 63 | 66 | 60 | 61 | |
| <i>Living</i> | 15 | 12 | 16 | 15 | 18 | 17 | |
| <u>Liver</u> <i>(total)</i> | 78 | 72 | 63 | 59 | 73 | 74 | 87 |
| <i>Cadaveric</i> | 45 | 38 | 36 | 36 | 37 | 40 | |
| <i>Living</i> | 33 | 34 | 27 | 23 | 36 | 34 | |
| <u>Heart</u> | 17 | 11 | 9 | 14 | 12 | 13 | 48 |
| <u>Double Lung</u> | 3 | 2 | 4 | 13 | 8 | 12 | 20 |
| <u>Single Lung</u> | 0 | 2 | 0 | 0 | 1 | 1 | |
| <u>Cornea</u> <i>(piece)</i> | 259 | 248 | 337 | 262 | 276 | 367 | 273 |

| Organ/ Tissue Donated (cases) | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | No. of patients waiting for transplant <i>(as at 31.12.2017)</i> |
|--|------|------|------|------|------|------|---|
| <u>Skin</u> | 6 | 4 | 9 | 10 | 10 | 11 | N/A ^{Note} |
| <u>Bone</u> | 3 | 3 | 1 | 4 | 1 | 3 | N/A ^{Note} |
| <u>Total</u> | 465 | 424 | 502 | 443 | 459 | 559 | -- |

Note : No. of patients waiting for skin and bone transplant are spontaneous and emergency in nature. Substitutes (e.g. pig skin or artificial limbs) 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 donation waiting list.

Statistics of organ transplant under Hospital Authority (2017)

| Organ | Average waiting time (months) ^{Note 1} | Longest waiting time (months) ^{Note 2} | No. of deaths while waiting (%) | One-year survival rate after Transplant ^{Note 3} | |
|--------|---|---|---------------------------------|---|--------|
| | | | | Cadaveric | Living |
| Kidney | 51 | 351 | N/A ^{Note 5} | 91% | 100% |
| Liver | 42 | 217 | 8.9 | 94.9% | 96.5% |
| Heart | 21.7 | 62 | 9.6 | 82.9% | N/A |
| Lung | 9.27 | 46 | 15 | 94% | N/A |
| Cornea | 11 | N/A ^{Note 4} | N/A ^{Note 5} | Average success rate : 95% | |

Note 1: “Average waiting time” is the average of the waiting time for patients on the organ transplant waiting list as at 31 December 2017.

Note 2: “Longest waiting time” is the longest waiting time among the patients who are still waiting for transplant in the organ transplant waiting list as at 31 December 2017.

Note 3: “One-year survival rate after Transplant” is the average of the patient’s one-year survival rates after organ transplant of the past five years (2013-2017) for the calendar year ending 31 December 2017, except for cornea which refers to survival rate of cornea graft.

Note 4: The figure for the longest waiting time is not available for cornea transplant cases, as some patients did not return for cornea transplant when suitable pieces were identified for them.

Note 5: N/A is used because the unavailability of such organ for transplant does not directly cause death of patients on the transplant waiting list.

Promotional Effort in 2016 and 2017

Over the years, the Government has been working to gradually inculcate a culture of organ donation in the community with a view to reducing reluctance or hesitation of individuals and family members in donating organs. DH and the HA have been working with various professional community partners such as Organ Donation Coordinators who play a supportive and coordinating role, with a view to creating a positive atmosphere for organ donation in the whole community.

The Centralised Organ Donation Register (CODR)

2. The CODR was established by DH in 2008 to provide a convenient channel for the public to register their wish to donate organs after death. It provides a reliable and effective means for Organ Donation Coordinators to ascertain, upon patients' death, their previously expressed wish to donate organs, so that they may approach the patients' families as soon as possible to seek their consent for donation of the deceased's organs to save patients in urgent need of organ transplant.

3. Members of the public can register their wish to donate organs after death at the CODR by mail, fax or through the Internet (www.organdonation.gov.hk). Upon receipt of the registrations, DH staff will contact the registrants individually for verification of personal information. Over the years, the cumulative number of registrations in the CODR has been increasing. The strengthened promotional efforts of the Government in 2016 have resulted in a faster increase in the number of registrations in 2016 and 2017. The detailed yearly breakdown is set out in the table below.

| <u>Year</u> | Number of total registrations during the year | Cumulative total no. of registrations <i>(as at 31 December of the year concerned)</i> |
|-------------------------------|--|---|
| 2009 ^{Note 1} | 45 150 | 45 150 |
| 2010 | 23 896 | 69 046 |

| | | |
|-------------------------------|--------|---------|
| 2011 | 22 610 | 91 656 |
| 2012 ^{Note 2} | 27 518 | 115 578 |
| 2013 | 24 036 | 139 614 |
| 2014 | 19 868 | 159 482 |
| 2015 | 29 357 | 188 839 |
| 2016 | 52 550 | 241 389 |
| 2017 | 37 285 | 278 674 |

Note 1: The CODR was established in November 2008 and statistics on CODR registrations in 2008 and 2009 were counted as a whole.

Note 2: For more accurate reflection on the number of persons registering their wish to donate after death, figures in 2012 present the number of persons after elimination of multiple entries.

Committee on Promotion of Organ Donation

4. The Government has set up the Committee on Promotion of Organ Donation (“the Committee”) to further promote organ donation in April 2016 to co-ordinate and integrate the work by different Government departments and organisations on organ donation, so as to amplify the promotional effect. The Committee, chaired by the Under Secretary for Food and Health, is responsible for implementing the Organ Donation Promotion Campaign, which includes formulation of organ donation promotion strategy and direction, coordination and collaboration with other partners in conducting organ donation promotional activities and programmes and conducting public education.

Organ Donation Promotion Charter

5. In June 2016, the Organ Donation Promotion Campaign introduced the “Organ Donation Promotion Charter” (“the Charter”) and invited various organisations in the community to become partners and signatories of the Charter, thus signifying their support towards promotional activities on organ donation. As at December 2017, more than 550 companies, organisations and schools have become signatories of the Charter. About 290 activities (including promotional booths, talks, campaigns, ceremonies) and 850 promotional actions (including distribution of promotional materials, broadcast

of API/video, promotion via mobile apps, social media, website, other internal channels) have been carried out.

6. Over the years, DH has taken the following promotional measures –
 - (a) establishment of an institution-based network involving public bodies, private companies and NGOs to work in collaboration with the Government to promote organ donation, and to encourage registration at the CODR in institutions;
 - (b) enhancement of public education and acceptance of organ donation through public education and promotional activities such as exhibitions and seminars. In 2016 and 2017, DH organised about 510 seminars and exhibitions in various places such as hospitals, Government buildings/offices, etc.;
 - (c) production of promotional messages on television, radio, the Internet and other media. In 2017, DH produced a new set of TV and radio Announcement of Public Interest (API) to encourage members of the public to express their wish of organ donation to their family members;
 - (d) engagement of the general public especially the younger generation through social media via the Organ Donation Facebook Fan Page. As at December 2017, there were over 27 000 fans recorded in the traditional Chinese version of the "Organ Donation@HK" Facebook fan page;
 - (e) development of promotional materials and distributing them in various occasions and events. A number of new materials, including infographics and videos have been produced in 2017 for wider distribution. Moreover, DH has distributed more than 913 000 leaflets with CODR registration forms in 2016 and 2017;
 - (f) organisation of large-scale activities with Charter signatories, e.g. FHB and DH have partnered with the Mass Transit Railway (MTR) Corporation Limited to arrange promotional booths in various MTR stations to facilitate members of the public to register at the CODR on

15 October 2016, 6 May 2017 and 11 November 2017 respectively. Charter signatories were invited to lend their support by arranging volunteers to man these promotional booths;

- (g) establishment of the Garden of Life in Kowloon Park to recognise the charitable acts of organ donors and their families and provide an amenity area for organ donation education and promotional activities.

7. To sustain the promotional momentum, the Government has designated the **second Saturday of November** every year as Organ Donation Day and the anniversary of the launching of the CODR. This year, with the theme “Organ Donation – Let’s Talk!”, FHB and DH has organised a launching ceremony and invited six religious leaders to share their views on organ donation from a religious perspective. Other than promotional booths at 18 MTR stations, DH has also arranged an organ donation promotion vehicle which visited the 18 districts in Hong Kong during November 2017. Charter signatories also organised promotional activities in response to the Government’s promotional efforts.

Further efforts to promote organ donation

8. DH will continue to promote organ donation according to the recommendations made by the Committee on Promotion of Organ Donation and provide professional support to the Charter signatories for sustaining their promotional efforts.