

Legislative Council of the Hong Kong Special Administrative Region

Delegation of the Panel on Health Services

Duty visit to the Big Data Centre of National Health Commission for Human Tissue, Organ Transplant and Medicine

Report

29 July 2023

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Purpose of the report

1.1 The delegation of the Legislative Council ("LegCo") Panel on Health Services ("the Panel") conducted a duty visit to the Big Data Centre of National Health Commission for Human Tissue, Organ Transplant and Medicine ("Big Data Centre for Organ Transplant") in Guangzhou on 29 July 2023 to learn about the operation of systems and mechanisms relating to organ donation, allocation and transplant in the Mainland. This report presents the main findings and observations of the delegation.

Background

1.2 In December 2022, Tsz-hei, a four-month-old baby girl in Hong Kong, suffered from heart failure due to dilated cardiomyopathy and was urgently in need of a heart transplant, but regrettably, no suitable donor had been found in Hong Kong. The Government of the Hong Kong Special Administrative Region ("HKSAR") hence sought assistance from the Central Government. With a high-level command and coordination mechanism established swiftly between the Mainland and HKSAR, coupled with timely support and effective cooperation from relevant Mainland authorities, the approval of transfer of a cadaveric heart donated selflessly by a brain-dead child patient in the Mainland to Hong Kong was obtained within a very short period of time after confirming that there was no suitable recipient in the Mainland through the China's Organ Transplant Response The organ was then promptly and successfully System ("COTRS"). transported to Hong Kong for transplant. This unprecedented crossboundary organ donation case was completed, saving the life of Tze-hei.¹

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Import of human organs into Hong Kong for transplant purposes is regulated by sections 4 and 7 of the Human Organ Transplant Ordinance (Cap. 465) and section 4 of the Human Organ Transplant Regulation (Cap. 465A). Currently, Hong Kong does not have any standing mechanism for sharing donated cadaveric organs with medical institutions outside Hong Kong (including those in the Mainland). Nonetheless, cross-border organ import and transplant have all along been permitted on a case-by-case basis under the laws of Hong Kong as the situation warrants. With regard to Hong Kong and the Mainland, while the two places have different regulations, allocation systems and clinical treatment of patients in terms of organ donation and transplant, they are both subject to stringent requirements adhering to international standards for organ acquisition, allocation, cross-border transportation, etc.

- In the light of the successful case mentioned above, the HKSAR Government is now actively exploring with the Mainland the establishment of a standing organ transplant mutual assistance mechanism, with the objective of setting up a second-tier allocation mechanism. When there is a donated organ in either the Mainland or Hong Kong but no suitable local patient can be identified for receiving the organ for transplant and matching is unsuccessful in the local queuing system, the mechanism will be activated immediately so that the organ will be donated across the border for matching, with a view to ensuring that each organ can be utilized in a safe, legal, fair and equitable manner.
- 1.4 As regards Members' concern about the establishment of a standing organ transplant mutual assistance mechanism between the two places, the Panel agreed at its meeting on 17 January 2023 to arrange for the discussion of the "Proposal on cooperation with the Mainland in organ transplantation" to explore the relevant legal policy framework and technical procedural details.
- 1.5 At the Council meetings of 11 January and 14 June 2023, questions were raised on "Promoting organ donation and cross-boundary matching" and "Promoting organ donation". At the Council meeting of 24 May 2023, a motion was also passed urging the Government to expeditiously implement the legal framework of cooperation with the Mainland in organ transplant, and proactively explore the technical aspects and relevant procedures relating to organ donation, matching, transportation and certification.
- 1.6 To enhance Members' understanding of the operation of the systems and mechanisms relating to organ donation, allocation and transplantation in the Mainland, the Panel agreed at its meeting on 9 June 2023 to Dr Hon David LAM Tzit-yuen's proposal to conduct a duty visit to the Big Data Centre for Organ Transplant on 29 July 2023. The House Committee also endorsed the proposal of conducting the duty visit at its meeting on 23 June 2023.

A letter (LC Paper No. CB(4)1114/2022(01)) was jointly issued by some Members to the Panel on 19 December 2022 requesting discussion of the legal framework and procedures for promoting organ donation and initiating cooperation with the Mainland on organ transplantation.

Objectives of the duty visit

- 1.7 The objectives of the duty visit were as follows:
 - (a) to understand how the Big Data Centre for Organ Transplant manages the information of organ donors and recipients nationwide through a computer system for organ allocation;
 - (b) to keep abreast of the development of human organ donation and transplantation in the Mainland in recent years; and
 - (c) to exchange views on establishing a standing organ transplant collaboration mechanism between the two places.

Members of the Delegation

1.8 The delegation consisted of the following eight Members:

Members of the Panel

Hon Tommy CHEUNG Yu-yan, GBM, GBS, JP
(Chairman of the Panel and leader of the delegation)
Hon SHIU Ka-fai, JP
Dr Hon David LAM Tzit-yuen
Dr Hon Dennis LAM Shun-chiu, JP
Hon CHAN Hoi-yan
Prof Hon CHAN Wing-kwong

Non-Panel Members

Hon Dennis LEUNG Tsz-wing, MH Prof Hon William WONG Kam-fai, MH

1.9 At the invitation of the Panel, the Health Bureau, the Department of Health and the Hospital Authority also sent staff members to participate in the visit. The list of the participants is as follows:

Health Bureau

Mr Sam HUI Chark-shum, JP (Deputy Secretary for Health 1) Mr Keith KEI Chi-hung (Political Assistant to the Secretary for Health)

Mr GURUNG Marco Ben (Assistant Secretary for Health 5C)

Department of Health

Dr LEUNG Yiu-hong (Head, Health Promotion Branch)

Hospital Authority

Dr Simon TANG Yiu-hang (Director (Cluster Services))

1.10 Mr Colin CHUI, Clerk to the Panel and Ms Macy NG, Senior Council Secretary, accompanied the delegation during the visit.

Visit programme

- 1.11 The delegation departed for Guangzhou in the morning of 29 July 2023 and visited the Big Data Centre for Organ Transplant in the afternoon of the same day. The visit programme is as follows:
 - Visiting the China Organ Donation and Transplant Development Museum
 - Visiting the COTRS Coordination Center, which operates on a 7x24 basis
 - Receiving the Centre's briefing on human organ transplantation work in the Mainland
 - Holding discussion and drawing conclusion
 - Deserving the Centre's office environment and the inscriptions written by Professor HUANG Jiefu, Chairman of the China National Organ Donation and Transplantation Committee, for Tsz-hei



The delegation departs for the Big Data Centre for Organ Transplant in Guangzhou by high-speed train

Overview

2.1 Located in Guangzhou International Bio Island, the Big Data Centre for Organ Transplant is responsible for duties in respect of security protection, operation management and data analysis of a number of national medical data systems, including COTRS. A brief introduction of the Centre provided by it is in the **Appendix**.

Visit to the China Organ Donation and Transplant Development Museum

2.2 Accompanied by Professor WANG Haibo, Director of the Big Data Centre for Organ Transplant, the delegation first visited the China Organ Donation and Transplant Development Museum located in the Centre. The Museum showcases the development history of organ transplantation worldwide and in the Mainland from the 1950s to the present.

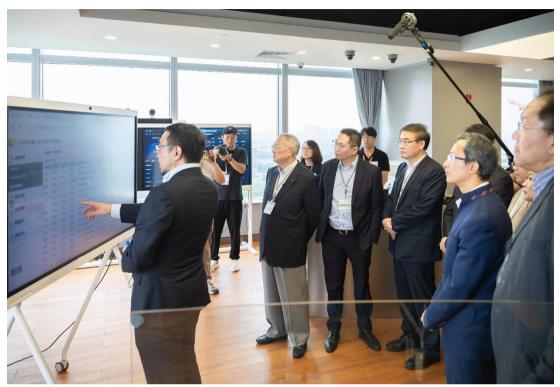


Accompanied by Professor Wang Haibo (first right), Director of the Big Data Centre for Organ Transplant, Hon Tommy CHEUNG Yu-yan (third left), Chairman of the Panel, and other LegCo Members, visit the China Organ Donation and Transplant Development Museum

- 2.3 The delegation noted the following salient points:
 - (a) since 1 January 2015, the nation has completely banned the use of organs from executed prisoners for transplantation, and as stipulated in laws and regulations, organs donated voluntarily and unconditionally are the only legal source of organs for transplant;
 - (b) as at July 2023, operations to obtain donated organs in the Mainland could only be performed by 108 approved Human Organ Procurement Organizations, and organ transplant operations could only be performed in 183 hospitals that were qualified for transplanting human Currently, there are more than 1 100 organ transplant surgeons and more than 2 500 organ donation coordinators in total in the Mainland. Since 1 January 2015, there have been about 43 600 and 130 000 donors and recipients respectively involved in unconditional donation of cadaveric organs in the There are more than 6 million people who Mainland. have voluntarily registered as organ donors nationwide; and
 - (c) the mechanism for human tissue and organ transplant in China emphasizes and respects the wish of family members. Even if the deceased have registered as donors during their lifetime, the wish of their family members remain the basis for the final decision.

Visit to the China Organ Transplant Response System Coordination Centre, which operates on a 7x24 basis

2.4 The delegation then visited the COTRS Coordination Centre and learnt that the Centre operated round the clock, keeping abreast of the clinical data of organ donors and recipients nationwide through a computer system, and using an advanced mathematical model to calculate patients' medical urgency in real time to implement the allocation and sharing of organs without human intervention to ensure fairness and impartiality.



LegCo Members learn about the latest development of organ allocation and sharing in the Mainland at the COTRS Coordination Centre

2.5 The delegation noted the following salient points:

- (a) COTRS is a key information system for implementing laws and regulations as well as scientific policies related to human organ allocation and sharing in China. It is highly recognized by the World Health Organization and The Transplantation Society. Behind the system lies rigorous scientific logic of organ allocation, which has been developed based on medical expertise and medical ethical principles. The transparency, traceability, comprehensiveness, and real-time updating of data allow data to be used to monitor organ donation and transplantation practices throughout the nation;
- (b) COTRS is the only official mandatory system recognized by the National Health Commission. Donated cadaveric organs must be allocated and shared through COTRS. The purpose is to eliminate to the greatest extent the risk of human intervention and ensure that

donated organs are allocated in a fair, equitable, scientific and highly efficient manner and in accordance with the law, and transplanted into patients with the greatest medical need. In addition, the Scientific Committee of COTRS will annually enhance and revise the scientific policy relating to organ allocation based on the latest progress of international and domestic medical research, as well as the results of analyzing system data such as the efficiency of organ matching and survival rate of patients to ensure that organ wastage is reduced and more lives are saved;

- (c) COTRS serves as the core pillar of the national organ donation and transplantation efforts. Through applying cross-disciplinary knowledge such as clinical medicine, public health and computer science, big data analytics and artificial intelligence technology, COTRS enhances the accuracy and efficiency of organ allocation and ensures that organ allocation is scientific and accurate;
- (d) With its big data functions, COTRS provides real-time information on the number of potential donors and the number of people waiting for organ transplant in hospitals nationwide, as well as the cases handled, etc. These functions are conducive to enhancing the efficiency and quality of centralized information management decisions for organ donation, transplantation, etc.; and
- (e) COTRS utilizes big data technology to address various complex issues arising in organ transplant operations, such as how to acquire and intelligently process relevant medical data in real time to accurately match patients with medically suitable transplantable organs; how to store the medical data of organ donors and recipients to ensure traceability of organ matching while protecting the privacy of patients; how to carry out real-time logistics intelligent enhancement calculations to find out the best transportation plan; how to design the most effective and

safest transplantation surgical plan to reduce the rate of surgical failures.

Receiving a briefing from the Director of the Big Data Centre for Organ Transplant on the development of human organ donation and transplantation in the Mainland

2.6 The delegation then received a briefing from Professor WANG Haibo on the development of organ donation and transplantation work in the Mainland, including the implementation timetable of the "Project Tsz-hei", and exchanged views on the establishment of a standing organ transplant collaboration mechanism between Hong Kong and the Mainland.



The delegation receives a briefing from Professor WANG Haibo on the development of human organ donation and transplantation work in the Mainland

³ Please refer to paragraph 1.2 above.

2.7 The delegation noted the following salient points:

- (a) In Hong Kong, there is an insufficient supply of organs that may be used for transplant, resulting in a steady increase in the number of people waiting for transplant.⁴ In 2022, there were only 29 cadaveric donors in Hong Kong. However, in the same year, a total of 1 116 donated organs in the Mainland were not used (accounting for 5.97% of the total number of donated organs in the Mainland in that year), and they included 384 livers, 373 kidneys, 212 hearts and 147 lungs;
- (b) COTRS's scientific policy on organ allocation clearly specifies that the relatives of organ donors have priority when they are in need of human organ transplantation. Moreover, this scientific policy has been implemented in COTRS's organ matching algorithm to ensure that the relatives of organ donors are given such priority;
- (c) The four basic ethical principles for regional organ sharing are as follows:
 - (i) agreement between the governments concerned;
 - (ii) not jeopardizing the opportunity of patients in the organ donation region to receive transplant;
 - (iii) the principle of reciprocity; and
 - (iv) healthcare protection that is open and transparent, traceable and continuous should be guaranteed; and
- (d) The above "principle of reciprocity" can be understood from a macro point of view rather than solely from the

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As at June 2023, there were more than 2 600 organ failure patients in Hong Kong waiting for organ transplants. The average waiting time for kidney transplant was almost five years and the rate of heart, lung and liver transplant patients dropping out of the queue or dying while waiting for organs was as high as 40%.

number of organ transplants between the two places. In fact, as of July 2023, 10 Hong Kong residents donated 30 organs after passing away in the Mainland, saving the lives of 27 Mainland patients. On the other hand, from 2015 to July 2023, there were a cumulative total of 1 011 cases in which Hong Kong people underwent transplant operations in the Mainland with organs donated by citizens when they passed away. Among these cases, 115 involved liver transplants, 880 kidney transplants, five heart transplants, and 11 lung transplants.



The delegation takes actions to support organ donation. It takes the opportunity of this visit to submit to the Centre a batch of organ donation volunteer registration forms it specially collected from LegCo Members



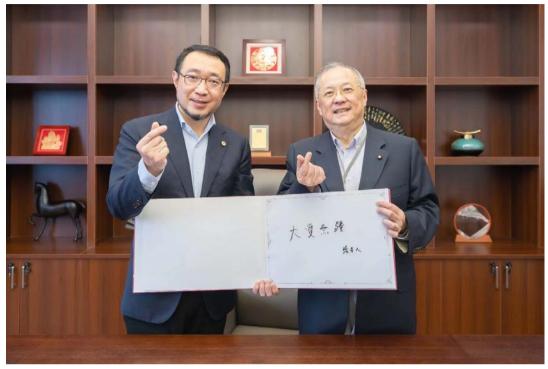
Members of the delegation of the LegCo Panel on Health Services and representatives of the Big Data Centre for Organ Transplant pose for a group photo with electronic China Organ Donation Volunteer Registration Cards held in their hands. (From left: Mr Keith KEI Chihung, Political Assistant to the Secretary for Health, Prof Hon William WONG Kam-fai, Dr Hon David LAM Tzit-yuen, Hon Dennis LEUNG Tsz-wing, Prof Hon CHAN Wing-kwong, Hon CHAN Hoi-yan, Hon Tommy CHEUNG Yu-yan, Professor WANG Haibo, Director of Big Data Centre for Organ Transplant, Hon SHIU Ka-fai, Dr Hon Dennis LAM Shun-chiu, Dr Simon TANG Yiu-hang, Director (Cluster Services) of Hospital Authority, Mr Sam HUI Chark-shum, Deputy Secretary for Health, Dr LEUNG Yiu-hong, Head of Health Promotion Branch, Department of Health, Mr GURUNG Marco Ben, Assistant Secretary for Health, Ms SHI Ying, Data Analysis Director of the Big Data Centre for Organ Transplant)

Group photo in front of the inscriptions written by Prof Huang Jiefu, Chairman of the China National Organ Donation and Transplantation Committee, for Tsz-hei, and signing the guest book

2.8 The delegation concluded the visit by posing for a group photo in front of the inscriptions written by Professor Huang Jiefu, Chairman of the China National Organ Donation and Transplantation Committee, for Tsz-hei. Hon Tommy CHEUNG Yu-yan, Chairman of the Panel, left the message "Great Love Knows No Bounds" ("大愛無彊") in the guest book.



LegCo Members observe the inscriptions written by Professor HUANG Jiefu, Chairman of the China National Organ Donation and Transplantation Committee, for Tsz-hei, Hong Kong's youngest ever heart transplant receiver, and pose for a group photo



Hon Tommy CHEUNG Yu-yan, Chairman of the Panel, leaves a message in the guest book of the Big Data Centre for Organ Transplant

CHAPTER 3—OBSERVATIONS AND CONCLUSIONS

Matters involved in the establishment of a human organ transplant mutual assistance mechanism between the Mainland and Hong Kong

Laws and the organ allocation mechanism

- 3.1 As mentioned in paragraphs 2.3 and 2.5 above, human organs donated voluntarily and unconditionally are the only legal source of organs for transplant in the Mainland. The organ transplant system in the Mainland is governed by the Regulation on Human Organ Transplant, and organ donation, acquisition, allocation, transplantation and relevant regulatory matters are centrally supervised by the China National Organ Donation and Transplantation Committee, which was established by the National Health Commission and the Red Cross Society of China. organs used for transplant in the Mainland must be allocated centrally through COTRS, and allocation outside COTRS is strictly prohibited. addition, at present, the nation accords national treatment to the residents of Hong Kong, Macao and Taiwan and they may choose to wait for organ transplant under the mechanism of the Mainland hospitals qualified for transplanting organs. The mechanism for human tissue and organ transplant in the Mainland emphasizes and respects the wish of family Even if the deceased have registered as donors during their lifetime, the wish of their family members remain the basis for the final decision.
- As for Hong Kong, the importation of human organs into Hong Kong for transplant purposes is regulated by the Human Organ Transplant Ordinance (Cap. 465) and the Human Organ Transplant Regulation (Cap. 465A). Currently, Hong Kong does not have any standing mechanism for sharing donated cadaveric organs with medical institutions outside Hong Kong (including those in the Mainland). Nonetheless, cross-border organ import and transplant have all along been permitted on a case-by-case basis under the laws of Hong Kong as the situation warrants. Same as the Mainland, Hong Kong adopts an "opt-in" system for cadaveric organ donation, as well as emphasizes and respects the wish of family members.
- 3.3 The HKSAR Government has also pointed out that the human organ transplant mutual assistance mechanism between the Mainland and Hong Kong being considered will be a second-tier allocation mechanism. It means that the cross-border mutual assistance mechanism will only be activated when organs donated by deceased persons in the Mainland or Hong Kong cannot be successfully matched with patients suitable for

CHAPTER 3—OBSERVATIONS AND CONCLUSIONS

transplant under the respective systems of the two places. In other words, the current arrangements in Hong Kong, from allocation of cadaveric organs to queueing of patients, will in no way be affected. The first-tier allocation mechanism, which follows the principle of "Hong Kong organs for Hong Kong use", will be maintained. Only when the organs donated in Hong Kong cannot be matched with suitable patients locally will the authorities fully utilize the organs by allocating them to the Mainland for mutual assistance under the second-tier allocation mechanism. Likewise, when cadaveric organs donated in the Mainland cannot be matched locally, they will be allocated to Hong Kong for mutual assistance under the second-tier allocation mechanism.⁵

3.4 As can be seen from the above, voluntary and unconditional donation as well as priority for local patients will be the principles of mutual assistance in organ transplant between the two places. In addition, the delegation notes that Tsz-hei's case was specially coordinated and approved by various parties. At present, the Mainland's Regulations on HIV/AIDS Prevention and Treatment still impose restrictions on the importation and exportation of human organs. Therefore, to set up a standing organ transplant mutual assistance mechanism between the two places, further improvements to the relevant laws and regulations are necessary. Given that there were a total of 1 116 unused donated organs in the Mainland in 2022, and over 2 600 patients with organ failure are currently awaiting organ transplant in Hong Kong, the delegation has urged the governments of the two places to set up the above mutual assistance mechanism as soon as possible in the hope that the mechanism will help avoid wastage of donated organs and benefit more patients with organ failure in Hong Kong.

Connecting the electronic health systems

3.5 As mentioned in paragraph 3.3 above, the mechanism being considered by the HKSAR Government will not affect the respective waiting lists of the two places, nor will it change the order of patients waiting for organs. The cross-border mechanism will only be activated when the organs of donors in Hong Kong or the Mainland cannot be successfully matched under the respective systems of the two places. Nevertheless, the delegation is of the view that "one cannot make bricks

The first speech given by the Secretary for Health on a Member's motion on "Implementing cooperation with the Mainland in organ transplant" at the Legislative Council meeting on 24 May 2023.

CHAPTER 3—OBSERVATIONS AND CONCLUSIONS

without straw". While COTRS is particularly crucial for the effective utilization of the cross-border mechanism, it seems that Hong Kong's electronic health systems still cannot be connected to COTRS. One of the fundamental problems that prevent access to COTRS is that medical data cannot be shared across the border. In this regard, the delegation hopes that the HKSAR Government will step up efforts in connecting the relevant systems.

ACKNOWLEDGMENTS

The delegation would like to express their gratitude to the Director and staff members of the Big Data Centre of National Health Commission for Human Tissue, Organ Transplant and Medicine for their warm hospitality, detailed briefings on the development of human organ donation and transplantation in the Mainland, as well as exchange of views and sharing of ideas with members of the delegation during its visit to the Centre, which made the visit greatly rewarding. The delegation would also like to express its heartfelt thanks to the representatives from the Health Bureau, the Department of Health and the Hospital Authority for accompanying the delegation throughout the duty visit to enhance exchanges.

The delegation would also like to thank the Hong Kong Economic and Trade Office in Guangdong of the HKSAR Government for arranging staff members to receive the delegation on the day of the visit and assisting in arranging transportation for the delegation in Guangzhou, which facilitated the smooth conduct of the duty visit.

APPENDIX (CHINESE VERSION ONLY)



国家卫生健康委员会人体组织器官移植 与医疗大数据中心

中心简介

国家卫生健康委员会人体组织器官移植与医疗大数据中心位于广州国际生物岛,承担包括中国人体器官分配与共享计算机系统(COTRS)在内的多个国家医疗数据系统的安全保障、运行管理和数据分析工作任务。

中国人体器官分配与共享计算机系统(COTRS)是执行我国人体器官分配与共享相关法律法规和科学政策的高度专用的关键信息系统,是我国人体器官捐献与移植工作体系的核心支柱,是我国公民逝世后人体器官捐献工作赢得人民群众信任的重要基石。

COTRS 是国务院《人体器官移植条例》和《刑法》第八修正案相关条款的重要体现和具体技术实现。2013 年 8 月,国家卫计委颁布《人体捐献器官获取与分配管理规定(试行)》(国卫医发〔2013〕11 号),2019 年 1 月国家卫健委颁布《国家卫生健康委关于印发人体捐献器官获取与分配管理规定的通知》(国卫医发〔2019〕2 号),均明确了 COTRS 唯

APPENDIX (CHINESE VERSION ONLY)



国家卫生健康委员会人体组织器官移植与医疗大数据中心 Big Data Centre of National Health Commission for Human Tissue Organ Transplant and Medicine

一官方强制性国家系统的地位,要求我国所有公民逝世后捐献的人体器官必须通过 COTRS 进行分配和共享,严禁系统外分配。COTRS 依据国家卫健委公开颁布的人体器官分配科学政策建立数学模型,自动实施人体器官分配和共享,最大限度地排除人为干预,建立了人体器官获取和分配的溯源性,向国家和地方卫生健康主管机构提供全程监控,确保器官分配的公平、公正和公开。

COTRS 的核心是基于人体器官分配科学政策动态变化的器官匹配算法数学模型。COTRS 需要在临床医学、公共卫生、生物统计和计算机科学等跨学科跨专业研究的支撑下,持续实施复杂数学模型的研究、构建、维护与优化,以维系器官分配的科学、精准和效率。COTRS 科学委员会每年根据 COTRS 器官匹配、患者生存率和系统运行效率的数据分析结果,结合国内外器官移植领域最新研究成果,进行器官分配科学政策的更新优化,以保证 COTRS 的科学时效性,减少器官的浪费,最大化公民逝世后爱心捐献器官的利用,拯救更多器官衰竭患者的生命。

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