### Current practice in preventing blood-borne diseases during organ/tissue transplantation in Hong Kong

Scientific Committee of the Advisory Council on AIDS and the Hong Kong Society of Transplantation

A questionnaire survey was conducted in late September 1996 to study the current practice for preventing blood-borne diseases during organ/tissue transplantation at local institutions. Twenty-five (83%) of 30 public transplantation institutions responded. Kidney and cornea/sclera transplantations were the most commonly practised procedures. Some institutions performed bone, skin, liver, heart and lung, and bone marrow transplantations. A variety of measures have been taken by most of the institutions to uphold safety standards during transplantation. Nevertheless, a lack of protocol standardisation and inadequate awareness of communicable diseases during transplantation are apparent. The establishment of local guidelines and the implementation of an effective monitoring mechanism might minimise the transmission risk of communicable diseases that are associated with transplantation.

#### HKMJ 1998;4:361-6

Key words: Blood-borne pathogens; Organ transplantation; Risk; Virus diseases/prevention & control

#### Introduction

The majority of human immunodeficiency virus (HIV) infections worldwide that have been contracted through blood-borne contacts are due to the sharing of needles or syringes among injecting drug-users. The transfusion of HIV-contaminated blood or blood products is another mode of HIV transmission. Infection by this mode mainly occurred before 1985, when tests for anti-HIV antibodies and safe blood products were not yet available. In addition, cases of HIV transmission that resulted from the transplantation of organs such as the kidney, liver, heart, and bone have been reported overseas.<sup>1,2</sup>

Transplantation involves the transfer of an organ or tissue from one individual to another. The application of organ/tissue transplantation as a treatment option has become popular, and both the number and scope of transplantations have expanded recently. Striving to enhance the potential benefits of transplantation and implementing measures to minimise the extent of postoperative complications are equally important. One particular concern is the risk of transmitting pathogens when the donor is already infected.

As with blood donation, the risk of HIV transmission during transplantation has been minimised substantially by HIV screening of the prospective organ/ tissue donor. However, a low but genuine risk still remains if the donor is in the 'window period' of HIV infection,<sup>3</sup> during which anti-HIV antibodies are not yet detectable. Furthermore, there is a likelihood of transmitting hepatitis B virus (HBV), hepatitis C virus (HCV), or other blood-borne pathogens during transplantation. Some overseas institutions have developed specific guidelines to uphold the standard of safety during transplantation with regard to preventing transmission of communicable diseases.

In Hong Kong, local policy on acquired immunodeficiency syndrome (AIDS) is formulated by the government-appointed Advisory Council on AIDS and its three committees: the Scientific Committee of the Advisory Council on AIDS (SCA), the Committee on Education and Publicity of AIDS (CEPAIDS), and the AIDS Services Development Committee (ASDC). In 1996, the SCA and the Hong Kong Society of Transplantation (HKST) examined the current local practice for prevention of blood-borne diseases during transplantation; the findings are reported below.

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#### Box 1. Questionnaire used in study

#### Survey on current practice in preventing blood-borne diseases during organ/tissue transplantation

Transplantation carries with it inherent risk of transmission of blood-borne diseases. The Scientific Committee on AIDS, in collaboration with the Hong Kong Society of Transplantation, is conducting a stock-taking exercise on the current protocols of local units/institutions that are involved in transplantation. The aim is to collect baseline information so as to facilitate the formulation of recommended guidelines applicable for use in the local setting. Please complete the following questions. They are all referring to the **practice of your unit** unless otherwise specified. All information will be treated in confidence. Your cooperation is highly appreciated.

## Please use a <u>separate</u> form if <u>more than one</u> type of organ/tissue transplantation is performed by your unit

Name of institution \_\_\_\_\_

#### Please tick or number the boxes as per each question

- 1. What sort of organ/tissue transplantation is done in your unit?
  - a) 🗌 kidney
  - b) 🗌 bone
  - c)  $\Box$  liver
  - d)  $\Box$  bone marrow
  - e) 🗌 heart/lung
  - f) 🗌 skin
  - g)  $\Box$  others, please specify
- 2. How many transplantations have been done in the past one year?
- 3. Which is the common source of organ? (Please number 1,2,3 in descending frequency)
  - a)  $\Box$  living
  - b)  $\Box$  brain-dead cadaveric
  - c)  $\Box$  non-heart beating cadaveric
- 4. How is the prospective donor screened for history of HIV-related risk behaviours e.g. multiple sex partners, drug use with sharing of needles?
  - a)  $\Box$  generally not done
  - b) 
    interview of living donor or next-of-kin of cadaveric donor by a designated interviewer/co-ordinator in a private setting
  - c) self completion of a questionnaire by living donor or next-of-kin of cadaveric donor
  - d)  $\Box$  other methods, please specify

- 5. Is physical examination done on the prospective donor to look for evidence of HIV infection and/ or other blood-borne diseases?
  - a) 🗌 Yes
  - b) 🗌 No
- 6. What are the <u>baseline</u> blood investigations that are performed for <u>prospective donors</u> to screen for infectious agents? (can choose more than one)
  - a)  $\Box$  HIV-1 antibody
  - b)  $\Box$  HIV-2 antibody
  - c)  $\Box$  HIV antigen
  - d)  $\Box$  HIV by polymerase chain reaction
  - e) 🗌 HBsAg
  - f)  $\Box$  anti-HCV antibody
  - g)  $\Box$  Others, please specify
- 7. What are the <u>baseline</u> blood investigations that are performed for <u>potential recipients</u> to screen for infectious agents? (can choose more than one)
  a) □ HIV-1 antibody
  - a)  $\Box$  HIV-1 antibod
  - b)  $\Box$  HIV-2 antibody
  - c) 🗌 HBsAg
  - d)  $\Box$  anti-HCV antibody
  - e)  $\Box$  Others, please specify
- 8. Are repeat investigations done for living donor to screen for infectious agents before his/her organ/tissue are being used?
  - a) 🗌 Yes
  - b)  $\Box$  No (go to question 10)

<ul> <li>9. If follow-up blood investigations are done for living donors to screen for infectious agents before their organ/tissue are being used, when are these tests performed after the baseline test? (frequency can be more than once)</li> <li>a) □ HIV</li> </ul>	<ul> <li>13. When is the recipient re-tested for HIV antibody after the transplantation?</li> <li>(can choose more than one)</li> <li>a)</li></ul>
<ul> <li>b)  <ul> <li>c)  <ul> <li>HbsAg</li> <li>weeks/months</li> </ul> </li> <li>d)  <ul> <li>others</li></ul></li></ul></li></ul>	<ul> <li>14. When is the recipient re-tested for HBV markers after the transplantation?</li> <li>(can choose more than one)</li> <li>a)  <ul> <li>not done</li> <li>b)  <li>3 months</li> <li>c)  <ul> <li>6 months</li> <li>d)  </li></ul> </li> <li>Other time interval</li></li></ul></li></ul>
<ul> <li>(can choose more than one)</li> <li>a)  <ul> <li>not applicable</li> <li>b)  <ul> <li>irradiation</li> <li>c)  <ul> <li>chemicals, please specify</li> </ul> </li> <li>d)  <ul> <li>Others, please specify</li> </ul> </li> </ul></li></ul></li></ul>	<ul> <li>15. When is the recipient re-tested for HCV antibody after the transplantation?</li> <li>(can choose more than one)</li> <li>a)</li></ul>
<ul> <li>11. For how long is the prospective organ/tissue from a living donor usually quarantined, pending a retesting for HIV antibody?</li> <li>a)  <ul> <li>a) not applicable</li> <li>b)  <ul> <li>b)  </li> <li>c)  </li></ul> </li> <li>b) Other time interval</li> </ul></li></ul>	<ul> <li>16. Is there any written policy of donor/recipient screening in your unit/institution regarding transplantation? (please attach a copy)</li> <li>a)  <ul> <li>Yes</li> <li>b)  </li></ul> </li> <li>17 Specialty of your unit/institution</li> </ul>
<ul> <li>12. What are the exclusion criteria of <u>prospective</u> <u>donors</u> for the sake of preventing transmission of blood-borne diseases?</li> <li>(can choose more than one)</li> <li>a) □ confirmed HIV positive by Western Blot</li> <li>b) □ positive result of screening test for HIV,</li> </ul>	<ul> <li>18. To which service sector does your unit/institution belong?</li> <li>a)  public</li> <li>b)  private</li> </ul>
<ul> <li>e.g. ELISA</li> <li>c) □ history of HIV-related risk behaviours</li> <li>d) □ clinical presentations/physical findings suspicious of underlying HIV infection</li> <li>e) □ HIV status unknown</li> <li>f) □ HbsAg positive</li> <li>g) □ anti-HCV positive</li> <li>h) □ Other, please specify</li> </ul>	<ul> <li>19. About the formulation of recommended guidelines for preventing HIV and other bloodborne diseases in transplantation, what is the general view of your unit?</li> <li>a) □ such universal guidelines are not needed</li> <li>b) □ such universal guidelines are needed</li> <li>c) □ guidelines formulated by individual unit suffices</li> <li>d) □ guidelines formulated by individual specialty suffices</li> <li>e) □ no comments</li> </ul>
-THA Please return the completed	NK YOU - form via the enclosed envelope

#### Subjects and methods

A standard questionnaire was designed jointly by the SCA and HKST and was sent with a covering letter in late September 1996, to doctors who were in charge of the local transplantation units and institutions known to the HKST. The questionnaire covered areas such as the type and number of transplantations, source of organ/tissue, screening procedures for donors and recipients, organ/tissue processing, exclusion of donor, and existing policy or guidelines (Box 1). A reminder was issued in late October to those who had not yet responded. The results were analysed both quantitatively and qualitatively by both the SCA and HKST.

#### Results

The questionnaires were sent to 30 public institutions of the Hospital Authority. By the end of November 1996, 25 (83%) had completed and returned the questionnaire; six institutions enclosed their transplantation protocol. The SCA and HKST examined the results, and discrepant findings were identified and clarifications were made accordingly. The revised results are presented below.

#### Organ/tissue transplantation

Renal transplantation was the most commonly performed type of transplantation and was conducted by eight (32%) of the 25 institutions. Some of the respondents belonged to the medical and surgical departments of the same hospital. A few respondents did not directly participate in the transplantation process but instead collaborated with other centres in the postoperative care of patients. Other types of transplantations performed were those of the cornea or sclera (n=6), bone (n=3), skin (n=3), and liver (n=2). One unit performed a heart and lung transplantation and another a bone marrow transplantation. The total number of cornea/sclera transplantations was the highest, followed by that of the kidney and bone marrow. The source of organ/tissue varied with the type of transplantation performed. Nevertheless, brain-dead cadavers were the most common source, followed by non-heart beating cadavers, and living donors.

#### **Donor** screening

Eighteen (72%) respondents reported that they perform an "interview of living donor or next-of-kin of cadaveric donor by a designated interviewer or coordinator in a private setting" as their way of screening prospective donors for HIV-related risk behaviours. Three institutions (which performed a transplantation of a kidney, a cornea, and a liver) reported not having conducted an interview—their source of organ/tissue was either a brain-dead cadaver or a non-heart beating cadaver. Twenty (80%) institutions performed the relevant physical examination on the donors. Of the five units that reported not performing a physical examination, three had performed a transplantation of the cornea or sclera, one a liver transplantation, and one a kidney transplantation. All five institutions indicated cadavers as the most common source of organ/tissue while two had also used a living donor.

All 25 responding institutions reported screening for anti-HIV antibodies, and 23 (92%) also screened for hepatitis B surface antigen (HB<sub>s</sub>Ag). None of the institutions used the polymerase chain reaction assay for HIV testing. Approximately half (47%), however, screened for anti-HCV antibodies. Some units—four renal, one bone marrow, and one bone—also screened for antibodies against cytomegalovirus (CMV). Six institutions repeated blood investigations (the majority to detect antibodies against HIV, HBV, and HCV) in prospective donors before the organ/tissues were used.

#### **Recipient screening**

Twenty-one (84%) institutions indicated testing for the HB<sub>s</sub>Ag status of the recipient while 16 (64%) tested for anti-HIV antibodies. Between 20% to 30% of the institutions retested recipients for antibodies against HIV, HBV, and HCV 3 to 6 months after transplantation.

#### Organ/tissue inactivation and quarantine

Organ/tissue inactivation was generally not applicable for transplantations performed by two thirds of the institutions. Among the remaining institutions, three used irradiation for the inactivation of organ/tissue (two for bone transplants and one for a skin transplant), while four used chemicals for processing cornea prior to transplantation. Two orthopaedic institutions isolated the organ/tissue before use: one was stored for 3 months and the other for 2 to 3 days.

#### **Exclusion of donors**

All but one unit reported that a proven or possible HIV infection, as shown by the presence of anti-HIV antibodies (with or without confirmatory tests) was a criterion for the exclusion of a prospective donor. The one unit that did not use this criterion performed a cornea transplantation and did not indicate any criteria for the exclusion of a prospective donor. Nineteen (76%) units excluded donors with a history or presentation that was suggestive of an underlying HIV infection. About half of them also excluded donors who had HB<sub>s</sub>Ag or anti-HCV antibodies.

Fourteen (56%) units indicated that they had a written policy or guidelines for donor/recipient screening (six enclosed a copy). The policy or guidelines covered, in varying degrees of detail, the following aspects: (1) laboratory screening of the donor for antibodies against HIV, HCV, Epstein-Barr virus (EBV), and CMV, as well as HBV markers; (2) the exclusion of a potential donor if there were underlying infectious diseases or an associated risk of one, as revealed from behavioural factors, past medical history, current illness, physical examination, laboratory tests, or cause of death; (3) screening of the recipient for antibodies against HIV, HCV, EBV, and CMV, as well as HBV markers; and (4) ensuring the viability and quality of the organ (eg by excluding sepsis in the donor by performing relevant investigations). A majority (19 of 25; 76%) of the institutions considered common local guidelines for preventing HIV and other blood-borne diseases during transplantation to be necessary, while the remaining six institutions indicated that the formulation of guidelines by each individual unit or specialty would suffice.

#### Discussion

Transplantation as a treatment modality has been made possible by advances in immunology, surgical technique, and medical and supportive care, as well as by the growing availability of donors.4 Transplantation of allograft organ/tissue, either from a living or cadaveric donor, has cured many otherwise 'incurable' diseases and brought new life to patients. Morbidity and mortality rates of patients suffering from irreparable organ damage and dysfunction have been greatly reduced. The number and variety of transplantations, both overseas and locally, have been increasing. The first transplantation procedure performed in Hong Kongof a cornea—was in 1961. Since then, there has been a rapid increase in the number and quality of transplantations, particularly in the past decade. A total of approximately 370 transplantations (excluding those of skin and bone) were performed in 1996 in the public sector-a more than two-fold rise compared with the figure in 1990. Today, Hong Kong has the expertise to perform a variety of organ/tissue transplantationsfor example, of the kidney, heart and lung, liver, bone, and bone marrow-all with satisfactory results.

Yet, analogous to the consideration of drug toxicity in treating diseases, the potential pitfalls of transplantation should be considered and measures taken to minimise them as much as is possible. The safety of the organ/tissue in the context of transmitting communicable diseases is one main concern in the practice of transplantation. As shown by this study, local transplantation institutions have been taking measures, albeit not standardised, to prevent the transmission of infectious agents during transplantation. Nevertheless, there are defects in these measures, which should be updated to maximise the safety of the transplant recipients. For example, not all institutions reported checking the HB<sub>s</sub>Ag status of the donor and only about half of them tested for the presence of anti-HCV antibodies. Two responding institutions were unaware that tests for anti-HIV antibodies rather than HIV antigen were performed on the donors. The findings suggest that doctors performing transplantations have inadequate knowledge and awareness of the correct screening procedures.

There has not been any report of transplantationrelated HIV transmission so far in Hong Kong. However, a probable case of HIV transmission through blood transfusion was reported in June 1997.<sup>5</sup> (The implementation of HIV screening for blood donors started in Hong Kong in 1985). The public expects all possible mechanisms to be in place to maintain the safety of transplant and transfusion recipients. Compared with blood transfusion, transplantation is compounded by other factors such as the difference between living and cadaveric donors, and the features and requirements of individual organ transplants.6 These factors may account for the discrepancies between practices. Some institutions, for example, reported not performing physical examinations to look for evidence of infectious diseases because their major organ source is cadavers. Overseas countries have established guidelines for preventing HIV transmission during organ/tissue transplantation.<sup>7,8</sup> Only a small fraction of the local institutions questioned had written guidelines on transplantation practice. It would be desirable, therefore, to formulate a set of common local guidelines to control communicable diseases during transplantation. Such guidelines should accommodate current knowledge and experience from both overseas and Hong Kong.

Apart from establishing and promulgating professional guidelines, a monitoring mechanism (eg through legislation) is needed to enforce safety standards. In this respect, an independent watchdog body would be useful. The local Human Organ Transplant (HOT) Board regulates the import and commercial dealing of human organs, in accordance with the HOT Ordinance (Cap 456). The HOT Board, however, does not govern the safety standards of transplantations. The current practice in preventing transmission of blood-borne pathogens during organ/tissue transplan-tation in Hong Kong needs to be harmonised

# Box 2. Recommendations to prevent blood-borne diseases during organ/tissue transplantation in Hong Kong

- (1) Common local guidelines on preventing communicable diseases in transplantation procedures should be drawn up for the use of medical practitioners in Hong Kong
- (2) Safety standards in transplantation should be upheld through the promulgation of the guidelines and the implementation of a monitoring mechanism
- (3) Medical practitioners should be alerted to the possible transmission of blood-borne pathogens (eg HIV, HBV, and HCV) during transplantation procedures
- (4) The role of using organs/tissue from people infected with blood-borne pathogens needs to be reviewed

(Box 2). Measures such as establishing common local guidelines, and implementing an effective monitoring mechanism are likely to uphold transplantation safety standards.

#### Acknowledgement

The SCA and HKST would like to thank the AIDS Unit of the Department of Health for its technical support of the study.

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