



MINISTRY OF HEALTH
SINGAPORE

26 June 2023

STAKEHOLDER CONSULTATION REPORT ON PROPOSED HUMAN TISSUE BANKING SERVICE REQUIREMENTS UNDER THE HEALTHCARE SERVICES ACT (HCSA)

SUMMARY OF KEY FEEDBACK AND RESPONSES

Since the enactment of the Healthcare Services Act (HCSA) in 2020, the Ministry of Health (MOH) has been rolling out the HCSA in phases. Phase 1 of the HCSA was implemented on 3 January 2022, while Phase 2 will be implemented on 26 June 2023. Human Tissue Banking service providers will be impacted by Phase 2 of the HCSA implementation. As such, we have engaged extensively with providers on the proposed HCSA Human Tissue Banking Service requirements that aim to further strengthen patient safety and welfare.

2. From 17 February to 16 March 2023, MOH sought feedback on the proposed Human Tissue Banking service requirements from the community via an online public consultation hosted on www.hcsa.sg. MOH also reached out to our partners such as the National Organ Transplant Unit (NOTU) for feedback. In all, we received feedback from 4 out of 9 human tissue banks and NOTU via written comments and email enquiries.

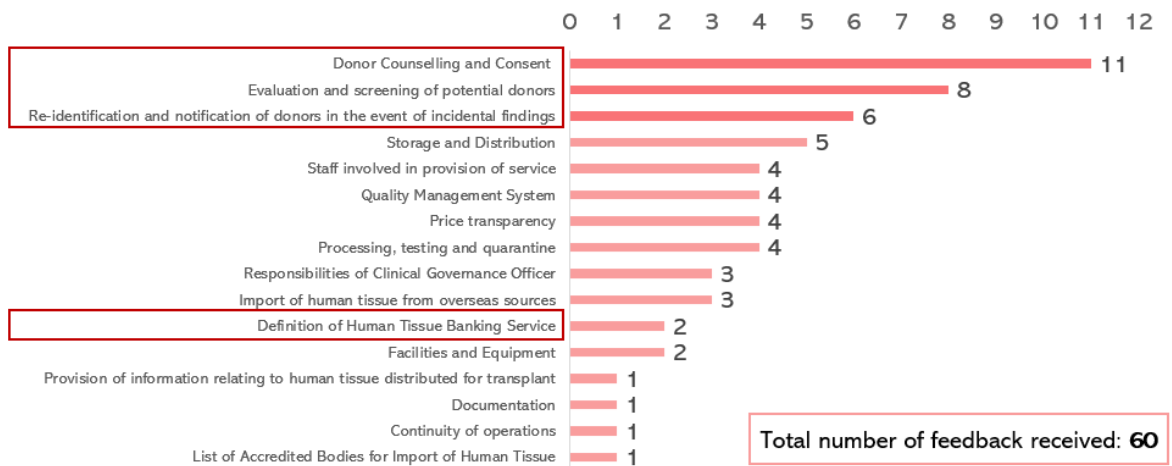
Feedback Received and MOH's Responses

3. Stakeholders were generally supportive of the proposed HCSA Human Tissue Banking service requirements. Majority of the feedback gathered from licensees requested for further clarification on the proposed requirements and implementation details. Please refer to [Figure 1](#) for the breakdown of feedback collected.



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Figure 1. Breakdown of feedback received on the proposed Human Tissue Banking Service requirements



[^]Feedback/Clarifications exclude those on transition-related administrative matters.

^{*}Others include feedback on licensees' scope of work and presentation materials.

4. Of the feedback received, the top 3 areas that licensees were concerned about were on: (i) donor counselling and consent, (ii) evaluation and screening of potential donors, and (iii) re-identification and notification of donors in the event of incidental findings.

I. Donor counselling and consent

5. Stakeholders generally agreed with the proposed regulatory requirements for donor counselling and consent, but some pointed out that pre-donation counselling is currently done by counsellors and transplant coordinators for cornea and living heart valve donors respectively, instead of transplant physicians.

6. Some stakeholders also sought clarification whether licensees who mainly handle human tissue and who do not have direct contact with donors are required to comply with the consent and counselling requirements.

7. MOH has reviewed the feedback and will allow transplant coordinators who have met certain minimum qualifications, training, and competency assessment to perform donor counselling¹, in addition to transplant physicians. MOH will also not require licensees who do not have direct contact with the donors to comply with the consent and counselling requirements.

II. Evaluation and screening of potential donors

8. Stakeholders were broadly supportive of the donor screening requirements and framework, but provided feedback that screenings for cytomegalovirus and Human T cell lymphotropic virus types I and II are not performed for tissue donors of heart

¹ For avoidance of doubt, this requirement does not apply to donation made under the Human Organ Transplant Act (HOTA) and the Medical (Therapy, Education and Research) Act (MTERA).

valves, iliac vessels, and skin tissue, and queried if licensees can independently determine the screening tests relevant to the tissue type to be banked.

9. Some stakeholders also highlighted that the current medical and social history questionnaire administered by NOTU does not require a signed declaration by Next-of-Kin in relation to the deceased donor's and his/her immediate family's medical history.

10. MOH has reviewed the feedback and will make it clearer in the Human Tissue Banking Service Regulations that the screening of cytomegalovirus and Human T cell lymphotropic virus types I and II are not mandatory infectious diseases to be screened. For avoidance of doubt, the licensee should still screen the donors for cytomegalovirus, Human T cell lymphotropic virus types I and II, as well as other transmissible diseases, if assessed to be necessary for a particular donor. MOH will also allow for declarations of medical history of the deceased donor and his/her immediate family members by Next-of-Kin to follow the workflow under the HOTA and the MTERA.

III. Re-identification and notification of donors in the event of incidental findings

11. Stakeholders largely concurred with the need to re-identify and notify donors and medical practitioners in-charge of the donor's care of incidental findings upon the donor's consent. Most clarifications pertain to whether the Next-of-Kin is required to be informed in the case of a deceased donor, particularly in the case of positive infectious diseases results.

12. MOH has reviewed the feedback and has reached out to the relevant stakeholders to clarify that the re-identification and notification of incidental findings only apply to living donors.

IV. Definition of Human Tissue Banking Service

13. Some stakeholders queried if the proposed requirements would apply to the initial collection of human tissue subsequently used to manufacture Cell, Tissue, or Gene Therapy Products (CTGTPs).

14. MOH has reviewed and has reached out to the relevant stakeholders to clarify that the requirements will apply if the intent at point of collection of the human tissue is for subsequent therapeutic use and this does not include collection for manufacturing CTGTPs.

15. To address the remaining feedback which was largely centered on clarifying various aspects of the proposed requirements, MOH will be publishing a set of Frequently Asked Questions (FAQs) on www.hcsa.sg. MOH will also share the finalised requirements and FAQs with licensees in due course.

Conclusion

16. MOH would like to thank all stakeholders who have actively engaged with us during our stakeholder consultations. This has allowed us to better understand your concerns and priorities. Together with our stakeholders, we look forward to improving patient safety, welfare and continuity of care across the sector.

17. For further clarifications, please write in to hcsa_enquiries@moh.gov.sg.

Thank you.

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