Healthcare Services (Tissue Banking Cord Blood Service) Regulations FAQ

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General

1. Who is required to hold a tissue banking (cord blood) service licence under the Healthcare Services Act (HCSA)?
• Any person or business conducting activities on the handling, processing and storage of cord blood obtained from an individual and intended for clinical use or transplant in the same or another individual is required to hold a tissue banking (cord blood) service licence under the HCSA. • Hospitals which partner with cord blood banks for the collection of cord blood during a maternal donor's delivery do not need to hold a tissue banking (cord blood) service licence under the HCSA.

Personnel

2. Why is there a need for a separate Quality Personnel to be appointed, who shall be a different individual from the CGO, or any persons designated to fulfil CGO responsbilities? Is the qualification and/or training in Quality Management (QM) generic or healthcare-specific? Does on-the-job training count?
• The Quality Personnel will need to exercise authority over and take responsibility for the maintenance of quality systems, policies and procedures established by the CGO, and therefore shall be a different individual from the CGO. • QM here can be applied in all industries and not necessarily healthcare-specific. However, relevant industrial experience is preferred, for example in blood banking, tissue banking, or the clinical laboratory, • On-the-job training is acceptable.

Staff involved in provision of service

3. What would constitute an adequate number of staff to provide the service?
• The appropriate number of staff required is not prescribed as that will depend on factors such as the scale of service provision and patient load, which may vary for different licensees. Licensees are expected to make a reasonable assessment of the appropriate number of staff needed to meet the intended outcomes.
4. What does "close supervision" of a staff member with less than 2 years of relevant experience entail?
• There should be arrangements in place whereby the CGO or a sufficiently experienced staff member can effectively monitor and guide the less

experienced staff member in performing cord blood banking activities as appropriate. The extent of supervision required (e.g. providing direct supervision on-site, or remaining contactable to give guidance when needed) should be determined by the supervisor based on an assessment of the particular staff's level of competency.

Donor recruitment, evaluation and collection

5. When should consent of maternal donors be obtained?

- Written consent of the maternal donor for the donation of cord blood must be obtained before the maternal donor is in active labour.
- This includes consent to collect and store the cord blood.

6. What are the elements required in the taking of informed consent?

- The information discussed with the donor as part of consent taking should at minimum include the following:
    a. Purpose and participation of maternal and infant donor;
    b. The possible alternatives to participation;
    c. The screening process, such as disclosure of lifestyle, medical, genetic, travel history of the donor and family medical history;
    d. Whether umbilical cord blood will be stored for public or family use;
    e. Explanation of the procurement procedure e.g. *in utero* or *ex utero*, and related activities;
    f. Benefits and limitations of cord blood in current and possible future clinical application;
    g. The right to withdraw the consent for the procurement of cord blood without prejudice at any time before delivery;
    h. Tests performed on the cord blood and maternal donor blood samples, the expected turnaround time and mode of communication of any abnormal test results (including incidental findings) to maternal donor and/or her physician (where the maternal donor has consented), and that reference samples shall be stored for future testing;
    i. The possible risks, adverse reactions and potential future complications to the mother and/or infant donor;
    j. The extent to which information identifying the donor will be kept confidential;
    k. The cord blood bank retains the right to follow up with the mother or relevant healthcare provider (e.g. the mother's physician and the

infant donor's physician) at a future date or at any time for follow-up;

l. Regulatory obligations of the cord blood bank and the regulatory agencies involved, e.g. mandatory reporting of infectious disease results to the Ministry;

m. Disclosure of conflict of interest between the cord blood bank and the person taking informed consent, physician in charge etc.;

n. If the cord blood unit may potentially be used for reasons other than the primary intent of clinical transplantation (e.g. research), this shall be fully disclosed and the consent shall be approved by relevant Institutional Review Board or ethics board in accordance with any prevailing local law.

Evaluation and screening of donors etc.

7. What should the maternal donor be screened for?

- Screening of donors include whether there is risk to the maternal/ infant donor in donating cord blood, based on the maternal donor's medical history and any potential high-risk behaviour, as well as the medical history of the egg donor in the case of donor-received children.
- The maternal donor should also be minimally screened for the following infectious diseases: Human Immunodeficiency Virus, Hepatitis B, Hepatitis C, Syphilis, Human T-cell lymphotropic virus (both types I and II) and Cytomegalovirus (CMV).

8. If a donor screens positive for any of the diseases, there may be release of the cord blood on exceptional grounds if the CGO is satisfied that there is clinical indication and urgency for its use. What are some of these exceptional circumstances?

- Cord blood from a donor screened positive for any of the diseases stipulated above may be distributed for autologous use only. The only exception is CMV as its seroprevalance in the local population is high[1] and exposure to CMV is related to the frequency of transfusion[2]. For allogenic usage of CMV positive products, recipients shall be counselled, with written consent taken, prior to use of these products.
- Cord blood tested positive for CMV does not require segregated storage, and is not an exclusion criteria for cord transplant. CMV is still tested for in both

[1] Leong, H., Tan, B., Lim, S., & Chan, K. (2010). Seroprevalence of human cytomegalovirus infection in Singapore. International Journal Of Infectious Diseases, 14, e475. doi: 10.1016/j.ijid.2010.02.673
[2] NetCord-FACT International Cord Blood Standards Accreditation Manual, Seventh Edition (2020)

donor and recipient as there is a risk of CMV infection reactivating / developing during cord blood transplantation should one party test positive.

- The CGO should decide whether such exceptional circumstance exists after considering all facts surrounding the case (e.g. views of the clinician attending to the patient receiving the cord blood).

Collection of cord blood

9. A cord blood banking licensee must ensure that cord blood is collected in a manner that is safe for the maternal donor and infant donor. What does this entail?

- There should be documentation that cord blood collection is conducted within acceptable obstetric practices and in the patients' best interest.
- Cord blood collections *in utero* shall only be obtained from infant donors after a minimum of 34 weeks' gestation. Related cord blood collected *in utero* at less than 34 weeks' gestation shall be based on an evaluation of infant donor safety by the healthcare professional delivering the infant donor.

Processing, testing and quarantine

10. There should be tests on cord blood units to determine their safety, viability and integrity. What tests are required?

- Screening tests should be performed on an appropriate sample of a cord blood unit. These include:
    a. ABO group and Rh type;
    b. HLA testing on all product intended for allogeneic use;
    c. HLA class I and II typing on all products designated for possible allogeneic use by DNA-based methods and the verification of HLA typing results is performed on a thawed segment or thawed representative sample; and
    d. Sterility testing from a representative sample of the final cord blood unit after processing using a system validated for the growth of aerobic and anaerobic bacteria and fungi.
- The sample of cord blood after processing (but before the addition of cryoprotectant) should also be tested for total nucleated cell count and its viability, total CD34 cell and its viability, nucleated red cell count or corrected total nucleated cell count, and CFU or validated functional assay.

11. Can I outsource testing to other providers? What about other cord blood banking activities?

- A licensee may outsource testing to other clinical laboratories licensed under the HCSA, or overseas clinical laboratories accredited, certified or licensed by any of the following organisations:
    a. American Society of Histocompatibility and Immunogenetics (ASHI);
    b. European Federation for Immunogenetics (EFI);
    c. College of American Pathologists; or
    d. Any comparable accreditation body acceptable to the Director.
- A licensee may outsource donor recruitment as well. However, core cord blood banking activities, namely processing, storage and distribution, should not be outsourced.
- For any outsourced activity, the licensee is expected to retain oversight and remain ultimately responsible for compliance with the relevant Regulations and ensuring donor safety and welfare, as well as the safety and quality of the cord blood.

Re-identification and notification of donors in event of incidental findings

12. Am I expected to follow-up with a donor if there are incidental findings from the screening or tests conducted?

- Yes, the licensee should follow up and inform the maternal donor, and the attending medical practitioner (where the maternal donor has consented), of any incidental findings accordingly.
- Licensees are expected to establish and implement a process to determine whether a maternal donor wishes to be re-identified and informed of any incidental findings, and be able to re-identify and inform the donor when such findings arise.