MINISTRY OF HEALTH
SINGAPORE

Stakeholder Consultation on the Healthcare Services Tissue Banking (Cord Blood) Service Regulations

Presented by Health Regulation Group
Ministry of Health
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Objectives

This presentation will highlight:

1. **Who** the Tissue Banking (Cord Blood) Service Regulations apply to under the Healthcare Services Act (“HCSA”)

2. **What** the key changes are for the provision of Tissue Banking (Cord Blood) service under the HCSA, from the existing requirements under the Private Hospitals and Medical Clinics Regulations (“PHMCR”) and Guidelines for Healthcare Institutions Providing Tissue Banking (“Guidelines”)

HCS Regulations

- In developing HCSA requirements for Tissue Banking (Cord Blood) service, MOH has reviewed and adapted requirements from the existing PHMCR and the Guidelines, in consultation with the Tissue Banking Advisory Committee

- Regulations are structured into **General Regulations, Advertisement Regulations** and **Service-specific Regulations**

  - **General Regulations and Advertisement Regulations**: General requirements broadly applicable to **all licensees**

  - **Service-specific Regulations**: Unique requirements contextualised to each service or stipulate specific requirements articulated in the General Regulations

- This presentation gives an overview of the service requirements that will apply to Tissue Banking (Cord Blood) service licensees under the HCSA.

HCS Regulations

- The General Regulations, Advertisement Regulations, and the Tissue Banking (Cord Blood) service Regulations will be **published in October 2021**.

- Licensees must comply with the abovementioned Regulations from **January 2022**.

- Regulations **will be complemented with:**

  - **LTCs** that set out specific technical requirements to be met
  - **Explanatory guidance document** which will help licensees interpret specific requirements that further elaboration is needed on

- Requirements that are “new” or “enhanced” compared to the existing PHMCR requirements and Guidelines are highlighted as such

Definition of Tissue Banking (Cord Blood) Service

Tissue banking (cord blood) service under the HCSA would mean the handling, **processing and storage of cord blood** derived or obtained from human placental and umbilical cord blood vessels, which is distributed for subsequent use in the body of the same or another individual, and includes the screening of any donor, but does not include any blood banking service.[1]

→ "Cord blood" means the whole blood (including haematopoietic progenitor cells) collected from placental and umbilical cord blood vessels after an umbilical cord has been clamped

[1] "blood banking service" means a service relating to blood and blood products for therapeutic transfusion, comprising the following: (a) collection of blood and blood products; (b) testing, processing, distribution and storage of blood and blood products

Requirements under Tissue Banking (Cord Blood) Service Regulations

A. Governance and personnel

- Oversight of cord blood banking [NEW]
- Duties and responsibilities of Clinical Governance Officer [NEW]
- Staff involved in provision of service [ENHANCED]

B. Facilities and equipment

C. Service provision

- Donor recruitment, evaluation and collection
- Evaluation and screening of potential donors, etc. [ENHANCED]
- Collection of cord blood [NEW]
- Processing, testing and quarantine
- Storage and distribution
- Re-identification and notification of donors in event of incidental findings [NEW]
- Provision of information relating to cord blood for clinical use
- Information relating to cord blood for transplant
- Outsourcing of tests
- Price transparency

Cord blood bank licensees are subject to price transparency requirements as stipulated in the General Regulations (please refer to the presentation slides here).

D. Systems

- Quality Management System [ENHANCED]

E. Documentation

F. Preserving continuity of care [NEW]

Governance and Personnel

Enhanced governance

Layers of governance required

Personnel	Responsibilities	Who can be appointed
Licensee	The licensee is **responsible and accountable for overall compliance** with HCSA.	Licensee can be a corporation (e.g. the company that owns the Tissue Banking (Cord Blood) Service) or an individual (e.g. CEO of the company).
Key Appointment Holders	Responsible for the **strategic leadership and general management oversight** of the licensable service.	E.g. Board of Directors (of the corporate entity or of the owner of a subsidiary)
Principal Officer	**Oversees general day-to-day management** of the service and ensures operational compliance with HCSA.	E.g. CEO or COO for larger set-ups, or individual previously appointed as Laboratory Manager under PHMC Reg 49 for smaller set-ups.
Clinical Governance Officer (CGO)	Responsible for **clinical and technical oversight**[1] and implementation of complex services that require specialised expertise.	E.g. individual previously appointed as Licensee under the PHMC Reg 47 for cord blood banking

[1]CGOs may designate suitably qualified personnel (e.g. medical director, lab director) to support them in fulfilling their CGO responsibilities. Notwithstanding any such arrangements, the CGO remains overall responsible for the scope above.

Enhanced governance

[NEW] Oversight of Cord Blood Banking service

Cord blood bank licensee must appoint the following individuals to oversee the provision of the service:

Personnel	Requirement
Clinical Governance Officer	• Currently registered as a medical practitioner under section 20 of the Medical Registration Act • Has **at least 5 years' experience in haematopoietic stem cell transplant, transfusion medicine (with clinical responsibilities), blood banking or cord blood banking activities**
Quality Personnel	• Has relevant qualifications or training in Quality Management The Quality Personnel is responsible for maintaining quality systems and the review and management of all policies and procedures relating to the quality of the cord blood banking service

Enhanced governance

[NEW] Duties and responsibilities of Clinical Governance Officer (CGO)

To prescribe specific duties and responsibilities of the CGO that are essential to ensure proper clinical governance

- Set and implement appropriate policies, processes and programmes for the clinical and technical aspects of the service
- Provide **clinical and technical governance and oversight** of the service
- Assist licensee in the **day-to-day clinical and technical management** of the service to ensure compliance with relevant regulatory requirements
- **Implement and regularly review systems** for clinical governance, risk management and quality management
  - Detect and address in a timely manner any risks affecting the safety, welfare and the continuity of care provided to patients
  - Ensure any weaknesses or inadequacies in the provision of the service are promptly addressed and remedied

[NEW] Duties and responsibilities of Clinical Governance Officer (CGO)

To prescribe specific duties and responsibilities of the CGO that are essential to ensure proper clinical governance

- Establish and implement **policies and procedures relating to clinical and technical standards** for compliance by staff
- Ensure **proper supervision, continuous competency assessment and continuing training** of staff involved in the clinical and technical aspects of the service
  - Staff acquire and maintain the requisite skills and competencies to perform their work and the relevant knowledge to ensure their safety when performing their work
  - The focus of the CGO is to provide oversight on staff training (e.g. advise on the type and frequency of training needed), and develop the supervisory framework which encompasses delegation of work, escalation of issues, etc.
- Ensure that any clinical or scientific information published by the licensee in relation to the service is factually accurate and supported by credible scientific evidence

[ENHANCED] Staff involved in provision of service

To ensure staff providing the service are appropriate, qualified and adequate

- There is an **adequate number** of staff to provide the service in a safe manner
- Every staff member has the **necessary qualifications, training and competence**, having regard to the type and nature of the work performed by that staff member
- Licensee must ensure that every staff member —
  a) Is adequately trained for the work performed by the staff member and attends regular training in accordance with a continuing training programme;
  b) has the relevant awareness and knowledge of, and attends regular training, to ensure the safe provision of the service; and
  c) is assessed periodically on the competencies and work performance, and competency is assessed before independent performance of the assigned tasks.
- Staff with less than 2 years' relevant work experience must perform any task or provide any service **under the close supervision** of the CGO or another staff member with at least 2 years' relevant work experience.

Facilities and Equipment

Premises, Equipment And Products

Facilities, equipment, supplies etc.

To ensure that service is provided in a safe and suitable environment, using appropriate equipment

The licensee must ensure that every licensed premises is **safe, secure, appropriate and adequate** for the provision of the service:

Aspect	Requirements
Access to banking facilities	• Access to the banking facilities is **restricted** to individuals authorised by the CGO to do so
Environment	• Procedures in place to **monitor and maintain the conditions** in which all cord blood is stored, including the immediate notification of and response to temperature deviations outside acceptable ranges • **Safety procedures** developed and implemented that are compliant with requirements under any other written law relating to workplace safety and health
Power supply for laboratory equipment	• Adequate, stable and appropriate electric supply is provided for all laboratory equipment, including an adequate number of grounded electrical outlets and an emergency power supply for each equipment that is essential for maintaining the integrity of cord blood

Premises, Equipment And Products

Facilities, equipment, supplies etc.

To ensure that service is provided in a safe and suitable environment, using appropriate equipment

Aspect	Requirements
Equipment, supplies and reagents	• Instruments and equipment are **validated and certified fit for use** • Refrigerators / storage tanks undergo **periodic maintenance** to ensure quality and usability of cord blood and reagents, and have **clearly demarcated and labelled** areas for cord blood stored • All equipment and supplies are **effective to ensure the safety, quality and potency of cord blood** • Procedures are in place to monitor, inspect, sterilise and clean each piece of used equipment • **Appropriate tests and procedures are carried out periodically** to ensure equipment or reagent used complies with at least the tolerance limits determined by the manufacturer • Information on the name of manufacturer, lot number and expiration date of supplies and reagents is identified and recorded • Sterilised instruments, supplies and reagents are **clearly labelled** to indicate the date that they have been sterilised and the expiry date of the sterilisation • Suppliers of any material, which use has or is likely to have a material impact on the safety and quality of cord blood, are selected and **evaluated regularly**

Provision of Healthcare Service

Donor recruitment, evaluation and data collection

[ENHANCED] To obtain informed consent for donation of cord blood and pre-donation counselling

- **Prior written consent must be obtained** for the donation of any cord blood. This must entail:
  - Specifying the purposes for which the cord blood is to be used, and any tests necessary to assess the suitability of the cord blood for the specified purposes

- Cord blood banking licensee must ensure that the following is obtained from a maternal donor **before the maternal donor is in active labour**:
  - Written consent of the maternal donor for donation of cord blood in accordance with the requirements stipulated above;
  - Written consent of the maternal donor to collect and store the cord blood.

Donor recruitment, evaluation and data collection

[ENHANCED] To obtain informed consent for donation of cord blood and pre-donation counselling

- Prior to obtaining consent, the licensee must provide **adequate and appropriate counselling** to the individual donating the cord blood (i.e. the maternal donor)
  - Counselling is conducted by competent personnel who have appropriate qualifications or training
  - Adequate records are maintained of the counselling provided

- Licensee must ensure that the individual's consent is not obtained by means of coercion, intimidation, deception or misrepresentation by any employee or agent

Donor recruitment, evaluation and data collection

To collect and secure information about donors of cord blood

- Cord blood banking licensee must —
  - Collect all information in relation to the collection of cord blood that ensures linkage between cord blood units of the maternal donor and infant donor;
  - Protect the confidentiality of all such information in its custody or under its control; and
  - Keep and maintain accurate records of all such information indefinitely.

[ENHANCED] Evaluation and screening of potential donors, etc.

- A system must be implemented to **evaluate the fitness and suitability** of every individual who will be donating any cord blood, including a review of the potential donor's **clinical history**, and **clinical evaluation** of the potential donor by a medical practitioner.
  - There should be a **signed declaration** made by a potential donor in relation to her personal medical history, including whether she has previously engaged in high risk behaviour (e.g. drug use, unprotected sex with multiple partners) in the past

- As part of the evaluation and screening for the donors, for every maternal or infant donor, the cord blood banking licensee must ensure:
  - Information about the maternal donor's medical history, and any high risk behaviour of contracting or developing communicable diseases should be collected
  - Where the maternal donor bears a child conceived using a donated egg or sperm, the donor's medical history is collected
  - **Communication of any abnormal results (including incidental findings)** that may have significant consequences for the health or fertility of the maternal/ infant donor to the maternal donor,

[ENHANCED] Evaluation and screening of potential donors, etc.

- **Every maternal donor is screened** using appropriate donor screening kits for the following diseases:
  a) HIV infection
  b) Hepatitis B
  c) Hepatitis C
  d) Syphilis
  e) Human T-cell lymphotropic virus types I and II
  f) Cytomegalovirus (CMV)
- Cord blood from a donor screened positive for any of the diseases stipulated above may be banked, at the discretion of the CGO. Such cord blood (excluding CMV) shall only be distributed for autologous use only. There should be segregated storage of products known to contain infectious disease agents (excluding CMV) to reduce the likelihood of cross-contamination. Warning labels are required when CB unit testing or screening is positive for infectious disease risk or is incomplete.
- Cord blood tested positive for CMV does not require segregated storage, and is not an exclusion criteria for cord transplant.

[NEW] Collection of cord blood

- For the purpose of any subsequent testing that may be necessary, cord blood banking licensee should **collect sufficient cord blood and maternal reference samples** and ensure that these are stored for the duration of the contract or other arrangement between the licensee and the maternal donor.
- 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, and with acceptable product end point (e.g. cell viability, level of contamination).
- The cord blood and maternal samples are transported between collection site and processing facility under validated conditions that protect:
  a) the integrity of the cord blood unit; and
  b) the health and safety of personnel.

Processing, testing and quarantine

To ensure quality assurance of cord blood for clinical use

The licensee shall **implement processes for the processing, testing and quarantine** of cord blood to **ensure their safety, quality and effectiveness** for transplant or clinical use, and identify and implement all tests that may be necessary.

Processing

- Develop and implement guidelines for the processing of the cord blood
- Environment is appropriate to ensure the safety and quality of the cord blood, and safety of personnel handling the cord blood
- Cord blood is collected and **preserved within the appropriate time period** to retain the biological functions compatible with the intended use
- Cord blood collected from a donor is not mixed together with that from any other donor
- All reasonable steps taken to **minimise the risk of contamination** of the cord blood
- Use **validated methods and appropriate protocols** for the processing (including preservation) of cord blood to maintain its quality, integrity and potency
- Establish or validate time period within which processing of cord blood has to be completed with acceptable end point, where relevant
- **Maintain the traceability** of all materials and equipment used to process cord blood

Processing, testing and quarantine

To ensure quality assurance of cord blood for clinical use

Testing

- Establish **written criteria for evaluation and assessment** of the quality of cord blood
- **Representative microbiological cultures** must be obtained for any cord blood that is to be released for transplant or clinical use, and the cultures are **tested for bacteria or fungi**
  - Results are to be documented in the donor record
- **Discard** cord blood **or treat it with a disinfection or sterilisation process** that has been validated if any of the pathogens are found to be present:
  a) Fungi such as yeasts and moulds;
  b) Clostridium species;
  c) Streptococcus pyogenes

Processing, testing and quarantine

To ensure quality assurance of cord blood for clinical use

Testing

- Cord blood banking licensee has tests and procedures for **measuring and assaying cord blood units** to determine their safety, viability, integrity and potency

- The following must be **reviewed by the CGO** or his designee before the cord blood is released for transplant or clinical use:
  a) Results of any microbial culture performed on any cord blood, including any variance from relevant standard or benchmark,
  b) Donor's suitability and test results, including any variance from relevant standard or benchmark
  c) Any unit of cord blood which was banked at the CGO's discretion

Processing, testing and quarantine

To ensure quality assurance of cord blood for clinical use

Quarantine

- Any cord blood must be **quarantined** while it is being processed or tested where the safety, quality or effectiveness of the cord blood is likely to be affected by its release into the inventory
- There shall be no inadvertent distribution of cord blood
  - There are processes in place to confirm and verify that the correct cord blood unit is distributed in the right condition
  - Cord blood intended for allogeneic use with incomplete donor eligibility is not released for distribution unless there is an urgent medical need

Processing, testing and quarantine

Suitability of recipient of cord blood

- The CGO must, in relation to the release of any cord blood in its custody for transplant or clinical use, **evaluate whether the cord blood is suitable** —
  a) for transplant or clinical use generally; and
  b) for transplant to or clinical use by the proposed recipient of the cord blood.

- Where the licensee is aware of any adverse reaction in relation to the transplant or clinical use of any cord blood provided by the licensee, the CGO must **review all available information about the adverse reaction** to identify and remedy any errors, inadequacies or shortcomings in relation to the licensee.

- Cord blood tested positive for any infectious diseases (excluding CMV), shall only be distributed for autologous use. For allogenic usage of CMV positive products, recipients shall be counselled, with written consent taken, prior to use of these products.

Storage and distribution

Proper storage of cord blood to ensure safety and quality for clinical use

To establish and implement an ***inventory management system*** *that ensures the* ***biological and functional properties of the cord blood is preserved,*** *and the* ***risk of contamination is minimised****.*

- Cord blood is stored in a **validated container** that is appropriate for the intended use
- All cord blood is packaged appropriately
- Maintain and periodically audit the inventory system
- Implement an appropriate **labelling system** to ensure that all cord blood is correctly identified and traceable from the time of its collection until the time it is released/ distributed
- All cord blood that has been processed are stored at an appropriate temperature
- There should be segregated storage of cord blood known to contain infectious disease agents to reduce the likelihood of cross-contamination
- **Storage requirements must be appropriate**, having regard to the packaging and processing requirements for cord blood and its intended use

Storage and distribution

Proper storage of cord blood to ensure safety and quality for clinical use

To establish and implement an ***inventory management system*** *that ensures the* ***biological and functional properties of the cord blood is preserved,*** *and the* ***risk of contamination is minimised****.*

- Maximum storage period for cord blood must be appropriate
- Any cord blood that is under quarantine must be **clearly labelled and segregated** from that intended for distribution
- Any cord blood determined to be unsuitable for transplant or clinical use must be clearly labelled as such, and released only in accordance with the written consent by the donor and the requirements of any other applicable written law.
    - The purpose for which the human biological material is released (e.g. research) must also be clearly labelled

Storage and distribution

Proper distribution of cord blood to ensure safety and quality for clinical use

*All cord blood is **distributed** by the licensee such that the **biological and functional properties of the cord blood is preserved**, and the **risk of contamination is minimised**.*

- Cord blood must be packaged and transported in a **validated container**
- Licensee must implement and maintain a system to prevent or control the spread of any communicable disease due to the contamination or infection of any cord blood in its custody
- Final representative microbiological cultures must be obtained for any cord blood that is to be distributed for the purpose of transplant, before the cord blood is packaged
- The distribution of microbial contaminated cord blood for transplant or clinical use is subject to the discretion of the CGO and the treating physician of the recipient.
- Appropriate measures are taken to ensure the proper distribution of cord blood
- Written procedures are established and implemented to **recall** cord blood where its suitability for its intended use is adversely affected, and any institution that receives that cord blood is notified

Storage and distribution

Proper distribution of cord blood to ensure safety and quality for clinical use

*All cord blood is **distributed** by the licensee such that the **biological and functional properties of the cord blood is preserved**, and the **risk of contamination is minimised**.*

- An **instruction sheet** must accompany every cord blood released/ distributed by the licensee which includes all of the following information:
  - Results of all screenings of the donor of the cord blood;
  - The appropriate storage condition for the cord blood prior to its transplant or clinical use;
  - Any special requirement or measure that the medical practitioner using the cord blood must take to ensure its safe and effective use;
  - Measures that must be taken if there is any evidence of damage to or mislabelling of the cord blood or its packaging.

Storage and distribution

Proper distribution of cord blood to ensure safety and quality for clinical use

*All cord blood is **distributed** by the licensee such that the **biological and functional properties of the cord blood is preserved**, and the **risk of contamination is minimised**.*

- Licensee must release/ distribute any cord blood only to the following persons, with written consent by the donor and approval of the CGO:
  - Another licensee;
  - A person licensed to provide a licensable healthcare service under the HCSA;
  - A private hospital or medical clinic licensed under the PHMCA; or
  - A person established or incorporated outside Singapore that is licensed, registered, approved or otherwise regulated to carry on the activities of a tissue bank or healthcare institution under the laws of that jurisdiction
- Licensee must ensure the quality and safety of any **imported** cord blood
  - Licensee should not accept cord blood from overseas cord blood banks unless they are accredited by an accreditation body approved by the Director.

Safeguarding patient safety and welfare

[NEW] Re-identification and notification of donors in event of incidental findings

- Licensee must establish and implement a process for the following:
  a) To re-identify and inform a donor of any cord blood of any incidental finding; and,
  b) Inform the medical practitioner caring for the maternal donor of any incidental finding (where the maternal donor has consented)

Provision of information relating to cord blood for clinical use

- Licensee must, in relation to any cord blood distributed for clinical use, provide the following information to the healthcare institution where treatment is carried out:

  a) the results of the screening of the donor;
  b) the results of all tests conducted on the cord blood.

Information relating to cord blood for transplant

- With regard to cord blood distributed by the licensee for the purpose of transplant, the licensee must make available the following information to a transplanting clinician:
  a) the medical history of the donor of the cord blood;
  b) information relating to the licensee's processing of the cord blood.

- The applicable licensee must obtain the following information from the transplanting clinician within such time as the CGO considers appropriate after the transplant has taken place:
  a) information concerning any adverse reaction arising from the use of the cord blood for transplant;
  b) information about the recipient of the cord blood.

Outsourcing of tests

Requirements of outsourced service providers

- Licensee may appoint the following persons to conduct any test of any cord blood that may be necessary in relation to the provision of the service:

Outsourced provider	Requirements
Local clinical laboratory	Licensed under the HCSA
Foreign (overseas) clinical laboratory	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 Any clinical laboratory operating outside Singapore which is approved by the Director

Systems

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service

The Quality Management System (QMS) shall entail the following:

- **Investigation** of any occurrence or complaint that discloses or may disclose any **weakness or inadequacy affecting the quality** of service
- Identification and implementation of **appropriate and effective actions to prevent a recurrence**
- Audit of the provision of the service
- Implementing **quality control measures for all cord blood** collected, processed and distributed, including measures pertaining to the safety and quality of cord blood in relation to:
  - Recruitment of donors
  - Collection and transport of cord blood
  - Processing (including testing and quarantine) of cord blood
  - Preservation, storage and distribution of cord blood

[ENHANCED] Quality Management System

To establish an effective Quality Management System (QMS) for the purpose of quality assessment and assurance of the safe delivery of the service

- Maintain **adequate and accurate documentation** on the clinical outcomes of the transplant or clinical use of all cord blood, including any **adverse event** affecting any recipient that is or is believed to be attributable directly from the transplant or clinical use
- The QMS is updated periodically and reviewed at least annually for effectiveness.

Documentation

Documentation

Proper, accurate and complete records relating to all procedures and practices for cord blood banking activities

Licensee must maintain **complete and accurate records** of all procedures and practices in relation to the service, and take all reasonable steps to **ensure the security** of all such records.

- Appropriate documentation of licensee's policies, processes and programmes
- Establish and implement a process for the identification, approval and review of documents by an appropriate staff member before use
- Licensee's procedures and practices for the service are set out in procedure manuals
  - All procedures for or in relation to the service listed in the procedure manual are approved, signed and dated by the CGO
  - Procedure manuals are made available at all times to the licensee's staff and are regularly updated
- Accurate records are kept and maintained of the time at which any cord blood is accepted into the processing facility
- There are written agreements setting out the terms of the transfer and storage where any cord blood is to be transferred to another licensee or qualified facility
- Any system modification must be documented and validated before it is implemented

Preserving Continuity of Care

[NEW] Continuity of operations

Ensure that all cord blood continues to be maintained properly

- Licensee must **establish a contingency plan** to ensure that the safety, quality and potency of all cord blood in the licensee's custody is preserved in the event of any disruption to the licensee's operations.
  - Contracts or other arrangements for or in relation to the prompt restoration of the licensee's operations or the transfer of cord blood to another licensee;
  - Processes to inform any donor or recipient of any transfer or disposal of cord blood as a result of the disruption to the operations and to obtain the consent of the donor or recipient for any such transfer or disposal.

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The End

Thank you

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