MINISTRY OF HEALTH
SINGAPORE

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

Presented by Health Regulation Group
Ministry of Health
April 2021

Agenda

Objectives

This presentation will highlight:

1. **Who** the Blood Banking Service Regulations will apply to under the Healthcare Services Act (HCSA)

2. **What** the key changes to existing requirements are for the provision of blood-related service under the Licensing Terms and Conditions (LTCs) on Blood and Blood Product Collection, Processing, Storage and Distribution

HCS Regulations

- In developing HCSA requirements, MOH has reviewed the existing Private Hospitals and Medical Clinics Regulations (PHMCR), LTCs, directives, circulars, and adapted relevant requirements from other jurisdictions, tailored to the local context, in consultation with sector leaders*

- 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 stipulates specific requirements articulated in the General Regulations

* Key officeholders of the national blood bank service providers in Singapore

HCS Regulations

Updated on 24 Aug 2021

- Blood Banking Service Licensees must comply with the General Regulations, Advertisement Regulations **and** the Blood Banking Service Regulations **from 3 Jan 2022**
  - Blood Banking Service is a Phase 1 Service
- Regulations **will be complemented with:**
  - **LTCs** that set out specific technical requirements to be met
  - **Explanatory guidance document** which will carry illustrations of good practices to help licensees interpret and meet the outcome-based approach
- Requirements that are “new” or “enhanced” compared to the PHMCR are highlighted as such

Blood Banking Service is a standalone service under HCSA

Application of Regulations

Providers involved in all five blood banking activities need a Blood Banking Service licence

- Providers that perform **all** of the five blood banking activities below will need to apply for a Blood Banking Service License:
  a) Collection
  b) Testing
  c) Processing
  d) Storage
  e) Distribution

  of blood, blood components and/or blood products which are intended for **therapeutic transfusion**

- Licensees performing only selected blood banking activities will still be required to comply with relevant standards, but there's no need to apply for a blood banking service license

[NEW] Clinical Governance Officer (CGO) [1/2]

[Applicable to Blood Banking Service licensees only] Requisite qualifications of CGO

To provide clinical and technical oversight of technical and complex services by a qualified person

- **CGO is required for Blood Banking Service under the HCS (General) Regulation 15**
  - Equivalent to the "medical director" of a blood bank
  - Supervises the provision of blood banking services

- **The CGO is required to meet the following <u>combinations</u> of qualification <u>AND</u> experience requirements:**

Qualification requirement	Experience requirement
a) A locally registered haematologist; or	At least 5 years' relevant working experience in (a) a <u>local or overseas</u> institution licensed to provide blood banking or transfusion services (under the HCSA or equivalent regulatory standards as determined by DMS), **OR** (b) a private hospital or medical clinic approved by DMS to provide blood services (under the PHMCA)
b) A locally registered specialist who has the relevant higher qualification <u>and</u> training in transfusion medicine acceptable to DMS	

- **Non-blood banking licensees will be required to meet the CGO requirements of their respective Regs (*viz.* clinical laboratory service, acute hospital service)**

[NEW] Clinical Governance Officer (CGO) [2/2]

[Applicable to Blood Banking Service licensees only] Duties and responsibilities of a CGO for blood banking services

To provide clinical and technical oversight of technical and complex services by a qualified person

- **Setting and implementing appropriate policies** of the licensee for the safe and ethical provision of blood banking services
- Providing **clinical governance and technical oversight**
  - In the **day-to-day technical / clinical management** of the blood banking service to **ensure operational and regulatory compliance**
- Implementing, maintaining and overseeing an **effective quality management system**
  - E.g. In areas of risk management, training and education for staff
- **Ensuring proper supervision of staff and ensuring their compliance** to the clinical and technical standards as well as policies and procedures
- Overseeing the **tests and examinations** conducted or provided by the licensee, and the methods and procedures for those tests and examinations

A full working list of the CGO's duties and responsibilities can be found in the Annex

[ENHANCED] Quality Management System (QMS)

[Applicable to all relevant licensees] Quality Management System

Updated on 24 Aug 2021

Ensuring safety and quality of blood, blood components and blood products, and safety of donors

- **QMS should be based on the principles of Good Manufacturing Practice (GMP), and address the following aspects:**
  - Recruitment of donors
  - Collecting, testing, processing, storage and distribution of blood, blood components and blood products
  - Donor safety
  - Notification, recall and safe disposal where it is found that unsafe blood, blood components or blood products is/are used

- **QMS should be reviewed at least annually**
  - QMS reports may be required to be submitted for inspection

- **Licensees are required to appoint at least one Serious Reportable Event Quality Assurance Committee (QAC)**

[ENHANCED] Personnel

[Applicable to licensees performing blood collection] Staff at blood donation sites

Activities at each blood donation site shall be supervised by a qualified and competent person

- **The personnel requirements are contextualised to the blood banking service setting**

- **Each blood donation site should:**
  a) Be under the supervision of a Singapore Medical Council (SMC) registered medical practitioner on-site; **OR**
  b) Have a Clinical Nurse Leader (CNL) on-site with adequate and appropriate arrangements for prompt activation and provision of medical care by a registered doctor
     i. The CNL must be a registered Nurse with the Singapore Nursing Board (SNB) for at least 3 years
     ii. The CNL must have at least 3 years' relevant working experience in an institution licensed to conduct blood banking services (under HCSA), or in a private hospital or medical clinic approved by DMS to provide blood services (under PHMCA)

- **The supervising medical practitioner or CNL shall be competent in <u>all</u> of the following:**
  a) Screening, selection and counselling of donors
  b) Appropriate and timely monitoring and management of donors so as to ensure donor safety
  c) Clinical assessment of donors before, during and after blood donation
  d) Escalation of incidents affecting donors and staff for appropriate clinical management

[ENHANCED] Premises, Conveyances, Equipment and Processes

[Applicable to all relevant licensees] General Requirements

Patients should receive care in a safe and suitable environment and using appropriate medical equipment

- **All facilities are safe, secure, adequate and appropriate**
- **All operational processes and workflows are appropriate, safe and timely**
- **The licensee uses equipment and supplies that are effective in ensuring the safety of blood, blood components and blood products**
  - All equipment is properly installed, tested, calibrated and maintained in accordance with manufacturer's specifications, and repaired or replaced prior to their use when necessary
  - All reagents and supplies are validated to ensure their suitability for use
  - All supplies that will come into contact with blood are single-use, sterile and pathogen-free
  - All supplies are stored and used in accordance with the manufacturer's specifications
  - Appropriate and comprehensive policies and procedures for the selection of equipment, reagents and supplies are implemented and complied with
- **Suppliers of all supplies and materials are evaluated and reviewed regularly**

[NEW] Premises, Conveyances, Equipment and Processes

[Applicable to licensees performing blood collection] Blood donation sites

Patients should receive care in a safe and suitable environment and using appropriate medical supplies / equipment (including emergency supplies and equipment)

- **Blood donation sites are set up for proper, safe and hygienic collection of blood from donors**
  - There is ready access to clean running water
  - Surfaces are cleanable with disinfectants
  - Areas for clean techniques are segregated from the rest of the blood donation site
  - Phlebotomy area is segregated from the rest of the blood donation site, and access is limited to donors who have passed the donor screening criteria

- **Security measures are implemented to prevent unauthorised access to the blood donation site**

- **Operational processes and workflows are implemented to ensure that all screening of donors are carried out accurately and in a safe and timely manner**

[NEW] Donor Recruitment and Evaluation [Applicable to licensees performing blood collection]

Updated on 24 Aug 2021

Donors are appropriately recruited, counselled and assessed for safe blood collection

- **All donations must be altruistic (i.e. donating blood voluntarily and not under a contract or for valuable consideration)**

- **Pre-donation information, questionnaire and counselling are adequately provided to potential donors by appropriately qualified, trained and competent personnel**
  - Use of donated blood
  - Donor's duties, responsibilities and rights
  - Withdrawal or notification process to not use blood donated for transfusion
  - Possible adverse reactions
  - Infectious diseases that are transmissible by blood, blood components and blood products

- **Donor's suitability to donate blood is assessed adequately by appropriately qualified, trained and competent personnel**
  - Assessment is documented clearly

[NEW] Blood Collection [Applicable to licensees performing blood collection]

Updated on 24 Aug 2021

Donor safety and blood safety and quality are ensured through appropriate donor management and blood collection

- **All blood collection shall be conducted safely by or under the supervision of an appropriately qualified, trained and competent personnel**
  - Donor is discharged from the blood donation site only when it is safe to do so

- **Blood is collected safely and appropriately to ensure blood safety and quality**
  - Identity of the donor is confirmed before blood collection and verification that blood unit is labelled accurately
  - Clean techniques are applied

- **There is an effective deferral system to manage the deferral of potential donors**
  - Donors who do not meet the blood donation criteria
  - Donors who indicate that their donated blood should not be used for therapeutic transfusion

- **Donors found to be infected by any infectious disease tested are informed in a timely manner and provided with appropriate info for follow-up**
  - Donor records are maintained accurately

[ENHANCED] Traceability of and inventory system for blood, blood components and blood products [Applicable to all relevant licensees]

All blood units are properly accounted for

- **Every unit of blood, blood component or blood product is traceable from the time that the blood unit is collected / derived to the point of delivery to its recipient for transfusion or disposal**

- **There is a proper inventory system for all blood units collected, stored, quarantined, processed or distributed**
  - All blood units are recorded and accounted for accurately
  - The inventory system is audited periodically to ensure accuracy

[ENHANCED] Processing and testing of blood, blood components and blood products [Applicable to licensees performing blood processing and/or testing]

Blood is processed safely and tested for safety before issuance for therapeutic transfusion

- **Processes for donor testing are appropriate, accurate and regularly reviewed**
- **There is an effective system to determine the suitability of blood units for clinical use**
- **Appropriate processes and protocols are in place to prevent contamination of blood units during processing**

[EXISTING] Storage, quarantine and distribution of blood, blood components and blood products [Applicable to licensees performing blood testing, storage and distribution]

Only blood units that are safe and appropriate are used for therapeutic transfusion

Updated on 24 Aug 2021

- **All blood units are tested for suitability of clinical use**
  - ABO group, Rh D, red cell antibody
  - Infectious diseases, including human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis

- **Only suitable blood units are provided for clinical use**
  - Any other blood units are segregated and disposed of safely
  - The exception is where the CGO approves of its clinical use of such blood units for transfusion
  - Blood units that are infected should not be used under any circumstance

- **There are proper and appropriate facilities and processes for the storage and transportation of blood units**
  - Blood units not that have yet been tested for suitability or are tested and found not suitable are quarantined and segregated
  - Integrity and quality of blood units are ensured for safe and effective clinical use, including the maintenance of cold chain at all times during transportation
  - The person engaged by the licensee to transport the blood and blood product is competent to handle biohazard substances

Donor, blood and staff records are accurate, up-to-date and kept secure

- **Donor records**
  - Donor assessment (including eligibility criteria and outcomes)
  - Donor's written consent
  - Clinical management of donors who suffer adverse events from blood donation, if any
  - Events that adversely affect the donor's safety and well-being, or the safety or traceability of blood
  - Corrective and preventive actions taken, if any, to minimise similar risk on future donors and blood

- **Staff, equipment and supplies**
  - Role and duties of staff
  - Qualifications and competencies of staff
  - Validation of equipment and supplies used

- **Blood, blood components and blood products**
  - Donor and blood unit identification, date and time of blood collection, requesting healthcare institution, results of blood tests conducted, volume of any anticoagulant or additive solution, expiry date, storage temperature

[EXISTING] Documentation [2/2]

[Applicable to all relevant licensees] Processes and procedures for documentation

Donor, blood and staff records are accurate, up-to-date and kept secure

- **The licensee must implement and maintain a system to ensure appropriate and adequate documentation of policies, processes and programmes**
- **All records are kept secure and readily accessible when required**
- **Record keeping processes and procedures are regularly reviewed and conveyed to all staff involved**
  - Processes and protocols are accessible by all staff involved

[NEW] Incident management [Applicable to licensees performing blood collection]

Processes and personnel are in place to ensure donor and staff safety in the event of an emergency

- **Appropriately trained personnel and resuscitation facilities are present for emergencies**
- **Personnel will respond in a timely manner to any emergency**
- **Appropriate supply of emergency medical supplies and equipment are available for use**
- **Appropriate processes are implemented to ensure rapid response to any injury to any donor, or other incidents affecting safety or health**

Share your feedback with us by 30 April 2021

https://go.gov.sg/hcsa-blood-banking-feedback

Stay connected with us

MOH will provide more information along the way

*Visit **HCSA.SG** for more information*

Write to us at HCSA_Enquiries@moh.gov.sg

The End

Thank you

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Annex

Full working list of Duties and Responsibilities of CGO for Blood Banking Services

Under the latest draft Regulations:

a) Assisting the licensee in **promoting safe, ethical and appropriate practices**;

b) Setting and implementing appropriate policies of the licensee for the safe and ethical provision;

c) Overseeing the **tests and examinations** conducted or provided by the licensee, and the methods and procedures for those tests and examinations;

d) Providing **clinical governance and technical oversight**;

e) Providing the **day-to-day technical/clinical management** of the blood banking service to **ensure operational and regulatory compliance**;

f) Ensuring supervision of staff and ensuring their compliance to the clinical and technical standards as well as policies and procedures;

g) Ensuring the implementation and maintenance of an **effective quality management system**, and having effective oversight of the system, including:

   i. Implementation of a risk management system;
   ii. Prompt identification and addressing of weaknesses or inadequacies in the standards and processes;
   iii. Evaluation of new processes;
   iv. Continuing training and education of staff to develop and maintain the necessary skills and competencies to perform their roles in a safe and competent manner.