MODULE 10 | MEDICINES, PHARMACY, CONTROLLED DRUGS AND BLOOD SERVICES

Blood Services Licensing, Safety and Traceability

Practical hospital governance in Punjab, Pakistan

45

LECTURE

Organise the complete transfusion pathway.
Trace every component and act on every serious event.

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SELF-STUDY PDF

Manage blood as a complete clinical service

For the Medical Superintendent (MS): reliable supply, correct patient identification and complete records must work together.

- Check the licence and the permitted processes.
- Follow the donation-to-patient safety pathway.
- Organise traceability and serious-event reporting.
- Review appropriate use, availability and quality.

OFFICIAL SOURCE

A principle tied to a named law, standard or official guidance.

WORKING METHOD

A practical control or teaching format to adapt to the authorised system.

TEACHING CASE

An invented hospital example, used to practise applying the correct process.

Study output

A blood-service readiness review and a donor-to-recipient traceability test.

Module 10 | Presentation 4 of 4. Allow 45-60 minutes with exercises. All explanations are on the pages; check the cited sources before live use.

Blood centre, hospital blood bank and ward

Identify the actual processes performed at each location.

Setting	Main work	Accountability
Blood centre	Donation, collection, testing, processing and distribution within its licence.	Qualified responsible person and licensed scope.
Hospital blood bank	Receipt, storage, compatibility testing and issue.	Qualified personnel and designated responsible person.
Clinical ward or theatre	Clinical decision, consent, patient checks, administration and monitoring.	Responsible clinical team and hospital procedures.
Hospital leadership	Resources, coordination, oversight and corrective action.	MS, executive leadership and notified committees.

A blood bank and a general laboratory are not interchangeable service descriptions.

Sources: **B1**: sections 10-11

Registration and a valid licence

PBTA means Punjab Blood Transfusion Authority. PHC means Punjab Healthcare Commission.

PBTA requirements

- Sections 16-17 require a blood establishment to be registered and hold a valid licence before receiving or supplying blood or operating.
- Check that the licence covers the actual processes and premises; keep inspection findings and conditions.

PHC hospital requirements

- The hospital must also meet the relevant healthcare-service standards.
- A hospital PHC licence does not replace the PBTA licence required for its blood establishment.

An application receipt is not proof that a licence has been issued or that every activity is permitted.

Sources: **B1**: sections 16-17 | **B2**: indicator 22

The tertiary teaching hospital baseline

The PHC standard distinguishes teaching hospitals from smaller facilities.

Teaching-hospital expectation

- Indicator 22 calls for 24/7 blood services in teaching hospitals. Its category note expects a blood centre in addition to a hospital blood bank.
- Read the complete indicator, its cited PM&DC requirements and the current licensing conditions when defining the required scope.

Do not apply a smaller-service minimum

- The PBTA October 2018 minimum-requirements document is explicitly for non-teaching hospitals with limited stated activity.
- It cannot serve as the complete staffing or equipment specification for a major tertiary teaching service.

Design the service for its licensed work, patient needs and required availability.

Sources: **B2**: indicator 22 and category notes | **B8**: scope and date

Keep a blood-service authority file

Suggested management evidence checklist.

01 Licence

Current registration, licence, scope and conditions.

02 People

Responsible person, qualifications and cover.

03 Processes

Approved procedures for each licensed activity.

04 Inspections

Findings, deadlines, responses and completion evidence.

05 Agreements

Licensed suppliers, transport and backup arrangements.

06 Reporting

Authority contacts, forms, returns and event escalation.

Verify the supplier's current licence directly; a dated website list may not establish current status.

WORKING METHOD | Illustrative material is identified in the text.

The responsible person and the MS

Operational responsibility must be explicit and supported by resources.

Blood-service leadership

- Oversee qualified staff, approved procedures, testing, release, storage and records for the licensed work.
- For a blood centre, notify PBTA of the responsible person and immediately communicate a replacement as required.

Hospital leadership

- Ensure staffing, equipment, backup power, clinical coordination and action on serious gaps.
- Escalate resource and approval needs; maintain a safe continuity plan during disruption.

Do not use a nominal appointment to cover a service without the required presence, competence and supervision.

Sources: **B1**: sections 10(2)(h)-(l), 10(4), 11

Donor safety and lawful donation

A safe blood supply begins with the donor and a reliable selection process.

Statutory requirements

- A blood centre must not accept blood from paid donors and must obtain voluntary, non-remunerated donations.
- Follow the prescribed donor-selection and deferral criteria; communicate deferral reasons through the qualified professional required by the Act.

Service controls

- Use confidential assessment, correct donor identification and documented consent.
- Have trained staff and a response plan for donor illness or an adverse reaction.

Donation targets must not override donor suitability or donor welfare.

Sources: **B1**: section 10(2)(b)-(e) | **B2**: indicator 23

Testing each donation

Section 10(2)(f) specifies testing and screening. Additional prescribed requirements also apply.

Requirement	Scope	Management check
ABO and Rh	Blood grouping for each donation.	Validated process and traceable result.
Hepatitis B and C	Screening for HBV and HCV.	Approved test system and quality controls.
HIV, malaria and syphilis	Screening for these infections.	Results linked to the donation identity.
Other prescribed screening	Any additional requirement prescribed under the framework.	Current approved procedure and staff training.

A previous donor result does not replace testing of the current donation. Screening alone does not remove every transfusion risk.

Sources: **B1**: section 10(2)(f)

Quarantine, review and release

Suggested control sequence for blood-service procedures.

1	**Identify**	Assign a unique donation identifier and maintain the link through samples and components.
2	**Hold**	Keep units awaiting required checks separate from released stock.
3	**Review**	Check complete results, eligibility, labels and any special product requirements.
4	**Release**	Only the authorised process releases a suitable unit; record the decision and status.

A label or computer status must not allow untested, unsuitable or blocked stock to enter the released supply.

Sources: **B1**: sections 12(d) and 14(1) | **B3**: testing and release controls

Quality control and equipment readiness

Quality assurance is the organised system; quality control checks whether a particular process or result is acceptable.

Routine assurance

- Control documents, staff training, equipment maintenance, validation and reagent management.
- Use internal quality controls and applicable external quality assessment; review failures before reporting affected results.

Management evidence

- Ask for maintenance status, calibration, failed controls, incident records and completed actions.
- Provide a safe backup method or service when testing or equipment cannot be relied upon.

A service should not continue routine release while a safety-critical failure remains unresolved.

Sources: **B5**: quality-system elements

Use component-specific conditions

Whole blood, red cells, platelets and plasma do not share one storage or handling rule.

Control	Evidence to maintain
Storage conditions	Approved temperature limits, usable period and any agitation or freezing requirement for each component.
Monitoring	Suitable equipment, reliable readings, alarms and documented response.
Transport	Validated container, route, time and conditions with dispatch and receipt checks.
Contingency	Backup power, alternative storage and named staff who can respond at all times.

Use current PBTA requirements, component specifications and validated procedures. This lecture is not a bedside cold-chain protocol.

Sources: **B1**: sections 4(1)(d)(iv) and 18 | **B3**: storage and transportation

Respond to a storage excursion

An excursion is a departure from the approved storage conditions.

1	**Protect**	Prevent issue of affected stock and move it safely if the approved contingency plan requires.
2	**Define**	Identify the equipment, time, temperatures, affected units and monitoring uncertainty.
3	**Assess**	Obtain a documented decision by the authorised blood-service team using the applicable criteria.
4	**Close**	Record release or disposal, trace any units already issued, and correct the cause.

A temperature returning to normal does not prove that the affected units are suitable for transfusion.

WORKING METHOD | Illustrative material is identified in the text.

Agreements with an external blood centre

Suggested content for a written service agreement, consistent with the licensed functions.

Area	What to specify
Scope	Components supplied, licensed activities and responsible contacts.
Routine supply	Ordering, acceptance, transport, delivery and records.
Urgent supply	Availability, communication, turnaround expectations and backup.
Quality and incidents	Traceability, recalls, serious-event notification and access to relevant evidence.

Section 10(2)(m) requires blood-centre distribution based on a hospital blood bank request and a written contract.

Sources: **B1**: section 10(2)(m)

Appropriate use and consent

The treating clinician decides whether transfusion is justified for the individual patient.

Clinical decision

- Record the indication and relevant clinical assessment. Consider appropriate alternatives and patient preferences.
- Use the correct component under approved clinical guidance; a single number cannot replace patient assessment.

Consent and communication

- Explain the purpose, expected benefit, material risks and reasonable alternatives in understandable language.
- Record consent or the lawful basis for urgent treatment where ordinary consent cannot be obtained.

The PHC standard requires informed consent for donation and transfusion. Use the hospital's approved consent process.

Sources: **B2**: indicators 21 and 23 | **B7**: patient blood management

Patient and sample identification

Suggested process controls for the approved sampling procedure.

1	**Identify**	Confirm the patient using the approved identifiers and the current request.
2	**Collect**	Take the sample from the identified patient through the authorised procedure.
3	**Label**	Label at the point of collection with the required details; record the collector and timing.
4	**Resolve**	Reject or resolve mismatches through the blood bank procedure; recollect when required.

Never relabel an uncertain sample merely to make the paperwork match.

Sources: **B4**: patient identification and sample procedures

Compatibility, issue and bedside checks

Each handover needs a defined check and a named responsible person.

Stage	Check	Record
Compatibility	Patient, sample, group and required compatibility testing.	Traceable laboratory result.
Issue	Correct component, status, label, expiry and special requirements.	Unit, patient, issue time and recipient.
Bedside	Match the patient, order and unit using the approved procedure.	Identity checks and staff involved.
Administration	Monitor the patient and record the actual transfusion.	Start, finish, observations and outcome.

A correct crossmatch does not prevent a wrong-patient transfusion if the final identity check fails.

Sources: **B1**: section 11 | **B4**: issue and administration procedures

Emergency release and major bleeding

Urgent transfusion needs an approved clinical and laboratory response plan.

Before an emergency

- Agree the activation criteria, decision-makers, communication route and component supply plan.
- Define identification, urgent sampling, emergency release documentation and continuation of testing.

During and after the event

- Use the authorised emergency process and record the reason, clinical authorisation and units released.
- Maintain patient and unit identity, complete required follow-up and review delays or deviations.

Emergency release is a clinical risk decision under an approved protocol, not a general exemption from blood-service law.

WORKING METHOD | Illustrative material is identified in the text.

A suspected transfusion reaction

The clinical team must act immediately under the approved reaction protocol.

1	**Respond**	Stop the transfusion when a reaction is suspected and obtain urgent clinical assessment; support the patient under the protocol.
2	**Notify**	Inform the treating team and blood bank promptly, using the emergency escalation route.
3	**Preserve**	Retain the unit, tubing, samples and records as directed; check identities and document the event.
4	**Investigate**	Follow the laboratory and clinical investigation, required reporting and prevention plan.

Do not restart or discard the implicated unit on an informal assumption. Follow the responsible clinical and blood-bank decision.

Sources: **B4**: reaction investigation procedures | **B2**: indicator 25

Haemovigilance covers the whole pathway

Haemovigilance means monitoring and learning from problems associated with donation, processing and transfusion.

Scope of review

- Include donor reactions, testing and processing errors, storage problems, wrong blood events and recipient reactions.
- Review near misses as well as harm. Identify where the safety process failed.

Follow-through

- Assess the cause and seriousness, take corrective action and check whether the action worked.
- Communicate lessons to the teams that can prevent recurrence while protecting confidential information.

Reporting is the start of a review. A closed form does not establish that a risk has been controlled.

Sources: **B6**: haemovigilance throughout the chain

Serious events require immediate PBTA notification

Section 13 requires a blood establishment to inform PBTA immediately, in the prescribed manner, of a serious adverse event or reaction.

Implement the duty

- Keep the current reporting form, contact details and responsible officer available for every shift.
- Link the initial notification, investigation, affected units and follow-up correspondence.

Separate the reporting tasks

- Provide urgent patient care and notify clinical leadership and the blood bank at once.
- Do not wait for the next committee meeting or final causality assessment before the required notification.

Use the statutory definitions of seriousness and the prescribed reporting process; internal reporting alone is insufficient.

Sources: **B1**: sections 2 and 13

Trace each donation to its final destination

The Act requires identification of each donation, unit and component so both directions can be traced.

Direction	Question	Evidence
Donor to component	Which components came from this donation?	Donation and component identifiers.
Component to recipient	Who received each component?	Issue and administration records.
Recipient to donor	Which donation supplied the transfused component?	Linked patient, unit and donation records.
Other final destination	Was it returned, discarded or remains in stock?	Documented status and final disposition.

A unit issued to a ward is not yet confirmed as transfused. Obtain its final disposition.

Sources: **B1**: sections 2(cc) and 12(d)

TEACHING CASE

A traceability test finds an unresolved unit

Invented exercise: ten components are selected from the issue register for one period.

Findings	Seven have confirmed transfusion records; one was returned; one was discarded with a record.
Unresolved	The final destination of one component is not documented.
Calculation	Nine of ten final destinations are known: 90% in this small sample.
Action	Trace the missing record and component immediately. Investigate the handover failure and repeat the check.

An overall 90% result does not make the unresolved unit acceptable. This is a teaching calculation, not a compliance threshold.

TEACHING CASE | Illustrative material is identified in the text.

Records, retention and confidentiality

Traceability requires complete records and controlled access over time.

Record retention

- Section 12 covers procedures, donor and component information, screening and traceability.
- Section 12(c) requires records to be kept safe for at least fifteen years. Apply any longer relevant hold or requirement.

Data protection

- Section 14 requires safeguards against unauthorised changes and disclosure, while preserving traceability.
- Limit access, back up data and use anonymised information for teaching and public reporting.

Do not publish donor or patient details from incident records in a course, dashboard or website.

Sources: **B1**: sections 12-14

A recall or look-back investigation

Suggested response when later information raises a safety concern about a donation or component.

1	**Identify**	Record the concern, donation identifiers and all linked components.
2	**Contain**	Block affected stock and contact all receiving facilities through the approved route.
3	**Trace**	Establish each final destination and arrange confidential clinical follow-up for recipients where indicated.
4	**Report**	Notify and coordinate with PBTA as required; reconcile units and retain the investigation and closure evidence.

Use the authorised specialist process for donor and recipient notification; avoid unsupported public identification.

Sources: **B1**: sections 12-14 | **B6**: investigation and corrective action

The hospital transfusion committee

Section 11(4) requires hospital administration to ensure rational use through this committee, following PBTA-endorsed guidance.

Suggested routine agenda

- Review appropriate use, availability, delays, consent, identification errors, reactions and wastage.
- Include the services that prescribe, supply and administer blood; use the approved membership and terms.

Evidence of effectiveness

- Record decisions, responsible people, resources, due dates and the evidence needed to close each action.
- Review repeated failures and refer unresolved risks to executive leadership.

Meeting minutes demonstrate discussion. Follow-up evidence demonstrates action.

Sources: **B1**: section 11(4)

Patient blood management

Patient blood management supports appropriate care before, during and after a possible transfusion.

Clinical programme

- Provide pathways for identifying and treating anaemia and reducing avoidable blood loss where clinically appropriate.
- Consider alternatives and use transfusion when the expected patient benefit justifies it.

Administrative support

- Connect preoperative assessment, laboratory services, pharmacy, surgery, anaesthesia and follow-up.
- Review patient outcomes, appropriateness and delays alongside component use.

The purpose is better care and appropriate use. A target to reduce units alone can create unsafe incentives.

Sources: **B7**: patient blood management

A focused monthly blood-service dashboard

Suggested measures; define each numerator, denominator, period and owner.

01 Availability

Unmet component requests and clinically important delays.

02 Identity

Sample and patient identification errors and near misses.

03 Traceability

Units with a documented final destination.

04 Safety

Reactions, serious events and notification status.

05 Resources

Equipment failures, cold-chain incidents and staffing gaps.

06 Use

Appropriate-use reviews, expiry and other wastage reasons.

Compare like components and services. A low reaction count may reflect incomplete reporting.

WORKING METHOD | Illustrative material is identified in the text.

TEACHING CASE

A refrigerator alarm overnight

Invented case: an alarm occurs and the duration outside the approved range is uncertain.

Immediate control	The on-duty team blocks affected units from issue and uses the approved backup plan.
Evidence	Record the alarm, readings, timing, affected unit identifiers and transfer conditions.
Decision	The responsible blood-service team assesses suitability under the approved criteria.
Follow-up	Trace any issued units; meet reporting duties; correct the failure and test the backup arrangement.

Restoring power does not establish product suitability. Record the authorised decision for the affected units.

TEACHING CASE | Illustrative material is identified in the text.

Apply the blood-service principles

Write your answer and the reason before turning to the next page.

1. Licence

The hospital has a PHC licence and plans to start a blood bank.

What additional authority must be established?

2. Serious event

A serious transfusion event occurs before the committee's monthly meeting.

When must PBTA be informed?

3. Traceability

A unit is recorded as issued, but its final destination is unknown.

What evidence is still needed?

Identify the immediate action, the legal requirement and the record needed.

TEACHING CASE | Illustrative material is identified in the text.

Answers and reasons

Use the evidence, the calculation and the cited source.

1. Blood-establishment registration and licence

Establish PBTA registration and a valid licence covering the intended processes. Meet the applicable staffing, facilities and quality requirements.

2. Immediately through the prescribed process

Section 13 requires immediate notification. Patient care, internal escalation and investigation proceed alongside it.

3. The final disposition

Trace whether the component was transfused to the identified patient, returned, discarded or remains held. Close the record with evidence, not assumption.

The administrative review must test the complete pathway.

Sources: **B1**: sections 12-13 and 16-17

Prepare a blood-service readiness review

Use a non-confidential real case or the invented examples in this lecture.

Authority and cover

Check licence scope, responsible staff, service availability and backup arrangements.

Traceability test

Follow selected components from receipt to documented final destination.

Improvement plan

Record gaps, immediate protection, reporting, resources, owners and review dates.

Review with transfusion medicine, laboratory, nursing, clinical and quality leaders using non-confidential evidence.

Use the applicable Act, licence conditions, PHC manual and current PBTA procedures for live decisions.

WORKING METHOD | Illustrative material is identified in the text.

Sources and continued use | 1

Select a source title or its official-source link to open the document.

B1

Punjab Blood Transfusion Safety Act 2016

Sections 10-14: blood centres, hospital blood banks, records, traceability and serious-event reporting. Sections 16-18: registration, licensing, obligations and offences.

Punjab Blood Transfusion Authority | Official Act | **Official source**

B2

PHC hospital Minimum Service Delivery Standards

2024 manual, CG-01MS-Ed2-01092023. Standard 4, indicators 21-25: rational use, legal compliance, consent, staff training and transfusion-reaction review.

Punjab Healthcare Commission | **Official source**

B3

Standards and Guidelines for Blood Establishments, Punjab

2015 document supplied through PBTA. Use the version and process standards applicable to the current licence. It predates the 2016 Act; the Act and later valid requirements take precedence.

Punjab Blood Transfusion Authority | **Official source**

Educational material by Dr Qurban Hussain Khan. Source editions are stated; verify later amendments and applicable institutional orders before live use.

Sources and continued use | 2

Select a source title or its official-source link to open the document.

B4

Standard Operating Procedures for Blood Bank

PBTA official technical resource. A reference for controlled local procedures, staff training and records; verify revisions and suitability for the licensed service.

Punjab Blood Transfusion Authority | **Official source** | **PBTA source catalogue**

B5

Guidance on a quality system in blood establishments

WHO, 2024. Quality management, trained personnel, equipment, validation, documentation, incident review and improvement. International guidance, not a Punjab licence.

World Health Organization | **Official source**

B6

A guide to establishing a national haemovigilance system

WHO, 2016. Monitoring, reporting, investigation and prevention of adverse events throughout the donation and transfusion chain.

World Health Organization | **Official source**

Educational material by Dr Qurban Hussain Khan. Source editions are stated; verify later amendments and applicable institutional orders before live use.

Sources and continued use | 3

Select a source title or its official-source link to open the document.

B7

Patient Blood Management and Clinical Use of Blood

WHO guidance on appropriate transfusion, assessment of anaemia, reducing avoidable blood loss and considering alternatives. Clinical decisions remain patient-specific.

World Health Organization | **Official source**

B8

Minimum requirement for a hospital blood bank

PBTA, October 2018. This resource specifically concerns non-teaching hospitals and a stated limited activity range. It is not a complete specification for a tertiary teaching service.

Punjab Blood Transfusion Authority | **Official source**

Educational material by Dr Qurban Hussain Khan. Source editions are stated; verify later amendments and applicable institutional orders before live use.