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

Pharmacy Governance and Safe Medicine Use

42

LECTURE

Practical hospital governance in Punjab, Pakistan

Organise the medicine system.
Make each clinical and administrative handover clear.

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SELF-STUDY PDF

Manage the complete medicine pathway

For the Medical Superintendent (MS): a medicine service must connect lawful supply with safe patient care.

- Assign clinical and administrative responsibilities.
- Control medicine selection and the prescribing process.
- Check dispensing, administration and handovers.
- Use safety reports to improve the service.

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 pharmacy responsibility map and a practical medicine-safety review.

Module 10 | Presentation 1 of 4. Allow 45-60 minutes with exercises. All explanations are on the pages; check the cited sources before live use.

The four lectures

Each lecture addresses a different part of the hospital medicine and blood system.

Lecture	Subject	Practical output
42	Pharmacy governance and safe use	A responsibility and safety review.
43	Supply, storage and stock control	A checked stock and recall plan.
44	Controlled drugs	An authority, custody and records review.
45	Blood services	A licensing and traceability review.

These are administration lessons. Patient treatment follows approved clinical protocols and qualified clinical judgement.

WORKING METHOD | Illustrative material is identified in the text.

Separate the sources of authority

An official guideline, a legal rule and a hospital procedure have different roles.

Source	What it addresses	What the MS checks
Drug law and valid licences	Lawful products, suppliers and permitted activities.	The actual product, premises and activity.
PHC standards	Hospital care processes and evidence of compliance.	The manual applicable to the service.
DRAP guidance and rules	Pharmacy standards and medicine safety reporting.	Whether the document is a rule, final guidance or draft.
Hospital procedures	Who acts, what is recorded and when to escalate.	Approval, staff training and observed practice.

DRAP = Drug Regulatory Authority of Pakistan; PHC = Punjab Healthcare Commission.

WORKING METHOD | Illustrative material is identified in the text.

The MS and the pharmacy head

Use a written responsibility map within the institution's actual powers.

MS / hospital leadership

- Ensure authorised staffing, facilities, funds and an escalation route for unsafe or unavailable services.
- Act on reported gaps, approve within delegated powers and refer decisions beyond those powers.

Pharmacy leadership

- Oversee professional pharmacy practice, medicine information, supply controls and pharmacy staff competence.
- Work with clinicians and nurses on safe medicine use and report risks requiring management action.

A named focal person needs time, access and authority to perform the assigned work.

WORKING METHOD | Illustrative material is identified in the text.

Define the pharmacy service

Suggested service description to support the DRAP organisation guidance.

01 Scope

List inpatient, outpatient, emergency and specialist services.

02 Hours

State opening times and safe access outside those times.

03 People

Name the responsible pharmacist and the approved cover.

04 Facilities

Identify secure stores, preparation areas and equipment.

05 Interfaces

Define ward, clinic, nursing, finance and purchasing roles.

06 Escalation

Name who responds to shortages, errors and unsafe conditions.

Check registration, role permissions and demonstrated competence; a designation alone does not prove capability.

Sources: **M2**: standard I, organisation and management

The PHC medication framework

Keep policies, training and evidence from real patient records together.

Area	Indicators	Core expectation
Prescribing	51-57	Authorised prescribers, clear orders, verbal-order rules and high-risk checks.
Dispensing and storage	58-61	Safe procedures, recalls, expiry checks and clear labels.
Administration	62-69	Authorised staff; patient, medicine, dose, route and time checks; documentation.
Patient-held medicines	70-71	Policies for self-administration and medicines brought from outside.

A policy file and a practice check answer different questions. Use both.

Sources: **M1**: standards 8-10

Essential list, formulary and prescription

These documents support different decisions.

Document	Meaning	Limit
Essential medicines list	A selected list for priority health needs.	Use the applicable national and provincial editions.
Hospital formulary	The hospital's approved medicine list and rules for use.	Needs a documented selection and review process.
Treatment guideline	Clinical guidance for a defined problem.	Must fit the patient and the approved clinical service.
Prescription / order	The authorised instruction for a particular patient.	Does not itself approve a purchase or create a budget.

WHO model lists inform selection; they do not independently create a Punjab supply entitlement.

Sources: **M8**: rational-use interventions | **M9**: purpose of the model list

Assess a request for a new medicine

Suggested decision record for the competent committee and approving authority.

01 Need

Which patients need it, and what is missing now?

02 Evidence

What benefit and harm are supported by reliable evidence?

03 Alternatives

What approved options already exist?

04 Resources

Include tests, storage, training and monitoring costs.

05 Controls

Define authorised use, review and exception rules.

06 Decision

Record reasons, interests, authority and review date.

A company presentation is one input. Obtain independent clinical and pharmacy assessment.

WORKING METHOD | Illustrative material is identified in the text.

Committee work must lead to action

DRAP pharmacy guidance covers formulary and medicine-use oversight. Rule 8 separately requires hospital pharmacovigilance arrangements.

Selection and use

- Use the notified committee structure and terms of reference for formulary changes, restrictions and review of medicine use.
- Keep the clinical recommendation separate from the financial and procurement approvals.

Safety oversight

- Maintain the required Pharmacovigilance Committee and hospital reporting system.
- Where duties are combined under a valid order, document how every required function is covered.

Do not rename or merge statutory functions informally. Check the order applying to the institution.

Sources: **M2**: standard III | **M3**: rule 8

Manage exceptions and commercial interests

Suggested controls for requests outside routine formulary arrangements.

Situation	Control	Evidence
Non-formulary request	Clinical justification and the approved exception route.	Decision, patient need and follow-up.
Different product or strength	Pharmacy and prescriber review before a clinical change.	Updated order and communication.
Company-funded activity	Declare interests; apply institutional approval rules.	Approval, terms and declared interests.
Trial or donated medicine	Confirm lawful source, permissions and responsibility.	Receipt, custody and patient-use records.

A donation or sample does not remove clinical, quality, legal or record requirements.

WORKING METHOD | Illustrative material is identified in the text.

A complete medicine order

Suggested review of the hospital's approved prescribing format.

1	**Identify**	Use the correct patient record and authorised prescriber.
2	**Specify**	State the medicine, formulation, dose, route, frequency and other required instructions.
3	**Check**	Review allergies, relevant patient information and interactions; clarify ambiguity.
4	**Authenticate**	Date, time and sign or use authorised electronic authentication; record changes clearly.

Do not infer a missing dose, route or unclear instruction. Obtain an authorised clarification.

Sources: **M1**: indicators 51-55

Medication reconciliation

Reconciliation means comparing the medicines actually used with the new treatment orders, then resolving differences.

At admission or transfer

- Obtain the best available medicine history from the patient, carer, records and other reliable sources.
- Include prescribed, non-prescription and herbal products. Record allergies and the source of information.

At discharge

- Explain what continues, starts, changes or stops and why. Check the final list against the discharge supply.
- Communicate the list and monitoring plan to the patient and the next care provider.

A copied list is not reconciliation. A qualified clinician must resolve intended and unintended changes.

Sources: **M5**: structured processes at transitions

Dispensing checks

Suggested bedside-to-pharmacy review: observe the process as well as the documents.

01 Patient

Is the correct patient and current order being used?

02 Clinical review

Have unclear or unsafe instructions been resolved?

03 Product

Are medicine, formulation and strength correct?

04 Condition

Are expiry, packaging and storage history acceptable?

05 Label

Can the patient and staff identify the medicine and directions?

06 Handover

Are advice, supply quantity and outstanding issues recorded?

An invoice records a transaction. It does not prove that dispensing was safe.

Sources: **M1**: indicators 58-61

Preparation and administration

Use authorised staff, approved procedures and the current patient order.

Before administration

- Identify the patient correctly and verify the medicine, dose, route and timing against the order.
- Label prepared medicines promptly. Keep one preparation identifiable throughout the process.

After administration

- Record what was actually given and when, with the responsible staff member identifiable.
- Record omissions and their reasons. Escalate clinically important delays and monitor the patient as required.

Recording a dose before it is given can conceal a missed dose or cause duplication.

Sources: **M1**: indicators 62-69

High-risk medicines and situations

High-risk medicines can cause serious harm when used incorrectly; the work setting and patient also affect risk.

Select the safeguards

- Keep a local high-risk list. Standardise approved concentrations and storage where clinically appropriate.
- Use clear labels, restricted access and independent checks at the points identified by the approved procedure.

Make the safeguards workable

- Check staffing, interruptions, handover, equipment settings and access to monitoring.
- Train staff for the actual task and test whether checks detect the likely errors.

A second signature is useful only when the required check is actually performed.

Sources: **M6**: medicine, patient and system risks | **M1**: indicators 56-57

Similar names, packs and strengths

Suggested controls for look-alike or sound-alike medicines, often shortened to LASA.

Risk	Practical control	Verification
Similar packaging	Separate locations and make key differences visible.	Observe retrieval under routine conditions.
Similar names	Use clear names and read back unclear verbal information.	Check that clarification is documented.
Several strengths	Make strength prominent in ordering and selection.	Compare label, order and product.
New supplier pack	Assess the change before placing it into routine use.	Inform affected staff and update local controls.

Colour alone is not a reliable identifier. Read the complete medicine label.

WORKING METHOD | Illustrative material is identified in the text.

Sterile and hazardous preparations

The hospital must match preparation work to trained staff, suitable facilities and approved procedures.

Service readiness

- Have pharmacy and relevant specialists define where preparation is permitted and which products may be prepared.
- Confirm equipment, cleaning, exposure protection, staff competence and emergency arrangements.

Product accountability

- Retain the order, ingredients, batch details, preparation record, checker and the final label.
- Use the approved basis for storage and the usable period after preparation. Never copy a generic shelf-life.

A routine medicine store is not evidence that the hospital can safely provide every compounding service.

Sources: **M2**: standards II and V

Medicines outside the routine supply pathway

Suggested controls, consistent with a written hospital policy.

Situation	Required local decision	Record
Patient brings medicines	Verify identity, condition, current need and approved use.	Reconciled list and custody arrangement.
Self-administration	Assess suitability under the authorised policy.	Permission, instructions and review.
Emergency trolley	Approve contents, access, checks and replenishment.	Check record and replacement after use.
Home delivery	Check recipient, prescription, packaging and delivery conditions.	Dispatch, receipt, failed delivery and return.

An unsuccessful delivery remains an unresolved medicine handover.

Sources: **M1**: indicators 70-71 | **M2**: medicine-use and supply arrangements

Errors, reactions and quality defects

Different problems can occur together. The first duty is prompt clinical assessment and protection of the patient.

Describe the event accurately

- A medication error is a preventable problem in the medicine-use process; it may occur without harm.
- A suspected adverse reaction suggests a possible harmful response to a medicine. Causation may remain uncertain.

Choose the reporting route

- A quality defect concerns the product, packaging or quality. Preserve the batch and supplier details.
- Use clinical incident reporting, pharmacovigilance and product-quality routes as relevant. Link the records.

A near miss is worth reviewing. A report of a suspected reaction is not proof of negligence.

Sources: **M4**: reporting and medication-error guidance

Hospital pharmacovigilance under rule 8

Pharmacovigilance means detecting, assessing and preventing medicine-related problems.

Provision	Requirement in plain language	MS action
8(1)	Hospital centres at secondary and tertiary public and private hospitals.	Keep the establishment and implementation orders.
8(2)	At least one pharmacovigilance officer at a 200-bed hospital; numbers may rise with size.	Check the notified staffing arrangement.
8(3)	A committee includes at least a medical specialist, pharmacist, physician and nurse.	Ensure the required functions and membership.
8(4)	Report to the provincial centre: non-serious events monthly; serious events within 15 calendar days.	Set prompt internal escalation and track submission.

The rule does not establish a simple universal one-officer-per-200-beds staffing formula.

Sources: **M3**: rule 8(1)-(4)

Respond to a suspected medicine reaction

Suggested hospital workflow supporting the statutory reporting system.

1	**Care**	Arrange clinical assessment and treatment immediately; follow the emergency protocol if needed.
2	**Capture**	Record the patient, suspected medicine, event, reporter, timing and relevant clinical facts.
3	**Report**	Send promptly through the hospital pharmacovigilance route; do not wait for certainty.
4	**Follow up**	Add investigation and outcome information to the same case, and record action taken.

The external reporting deadline is not a reason to postpone treatment or internal notification.

Sources: **M3**: rule 8 | **M4**: reporting guidance

Useful information in a safety report

Suggested information checklist. Use the official form and protect patient confidentiality.

Part	Information	Why it helps
Patient and reporter	Identifiable patient and contactable reporter.	Allows verification and follow-up.
Medicine	Name, strength, formulation, batch if available, and exposure dates.	Identifies the suspected product and timing.
Event	What occurred, when, seriousness, treatment and outcome.	Supports clinical and causality review.
Context	Other medicines, illness, tests and relevant changes.	Helps assess alternative explanations.

Report available facts promptly and follow up missing information. Use authorised channels for identifiable data.

Sources: **M4**: information required for reports

Antimicrobial stewardship

Stewardship means organising the appropriate use of antimicrobial medicines while protecting patient care.

Institutional arrangements

- Provide leadership support and a team linking clinicians, pharmacy, microbiology, nursing and infection prevention.
- Use approved treatment guidance informed by local microbiology and resistance information.

Clinical review and feedback

- Check indication, medicine choice, route, duration and review plans against the approved guidance.
- Use audit and feedback to improve practice; maintain a rapid route for urgent clinical decisions.

A spending reduction is not sufficient evidence of appropriate antimicrobial use.

Sources: **M7**: facility programme components

TEACHING CASE

A prescription-quality review

Invented example: the same review criteria are applied to a sample of 40 eligible prescriptions.

Baseline	30 of 40 meet all the stated documentation criteria. Compliance = 30 / 40 x 100 = 75%.
Intervention	Clarify the form, brief prescribers and pharmacy staff, and review the process again.
Repeat sample	36 of 40 meet the same criteria: 90%. This is an increase of 15 percentage points.
Interpretation	The record quality improved in these samples. This does not by itself prove fewer adverse events.

Retain the sampling method and criteria. Compare like with like; do not describe 15 percentage points as 15 percent.

TEACHING CASE | Illustrative material is identified in the text.

The monthly medicine review

Suggested dashboard: use a small set of measures with clear definitions.

01 Access

Critical stock-outs and treatment delays.

02 Orders

Compliance with selected prescribing criteria.

03 Use

Omitted doses and reasons requiring action.

04 Safety

Events, near misses, seriousness and follow-up.

05 Reporting

Required reports submitted and overdue actions.

06 Improvement

Whether the agreed change worked in practice.

More reports may reflect better reporting. Interpret totals with activity, case mix and reporting practice.

WORKING METHOD | Illustrative material is identified in the text.

Electronic records and downtime

Suggested controls for electronic prescribing, dispensing and administration records.

In routine use

- Use individual accounts and roles matched to professional authority. Retain a traceable history of changes.
- Check medicines, strengths, units, alerts and patient identity before introducing a system change.

During disruption

- Use an approved paper or alternative process with clear orders, stock records and handovers.
- Reconcile records when the system returns, checking for duplicate or omitted orders and doses.

A computer entry is evidence only if the user, timing and actual action can be established.

WORKING METHOD | Illustrative material is identified in the text.

TEACHING CASE

An unclear order reaches the ward

All details in this case are invented.

Event	A medicine arrives with an unclear strength. The administration time is approaching.
Immediate action	The nurse contacts the prescriber and pharmacist for a verified instruction and safe supply.
Management response	Maintain safe access to treatment. Review how the order was accepted and the product selected.
Evidence	Keep the original order, clarification, dispensing and administration record, and incident review.

The MS ensures a functioning escalation system. Clinical staff resolve the patient-specific treatment decision.

TEACHING CASE | Illustrative material is identified in the text.

Apply the medicine-governance principles

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

1. Formulary request

A medicine is promoted as cheaper, but requires extra tests and trained staff.

What should the committee compare?

2. Safety report

A suspected reaction is observed. Causation is not yet established.

Should reporting wait for proof?

3. Good dashboard

Recorded errors fell sharply after staff stopped submitting near misses.

Can the MS claim care is safer?

Write the decision, supporting evidence and responsible person for each case.

TEACHING CASE | Illustrative material is identified in the text.

Answers and reasons

Use the evidence, the calculation and the cited source.

1. Compare the whole treatment pathway

Assess clinical benefit and harm, alternatives, patient need, tests, staff, facilities and total cost. Follow the correct approval route.

2. Report the suspicion promptly

Treat the patient and preserve the facts. Use the hospital reporting system, observe the applicable deadlines and add follow-up information.

3. The total is not enough

Reduced reporting can conceal risk. Examine reporting practice, activity, harm, near misses and direct process checks before drawing a conclusion.

An answer is complete when it identifies both the patient-care action and the administrative follow-up.

Prepare a pharmacy governance review

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

Responsibility map

Name the accountable people for selection, supply, prescribing, administration and reporting.

Evidence check

Review one medicine pathway, one safety report and one handover using non-confidential evidence.

Action record

List the gap, action, authority needed, owner, due date and evidence of completion.

Discuss the review with pharmacy, medical, nursing and quality leads. Refer decisions outside your delegated authority.

Use the approved hospital system; these teaching formats do not replace statutory records.

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.

M1

PHC hospital Minimum Service Delivery Standards

2024 manual, CG-01MS-Ed2-01092023. Management of Medication: standards 8-10, indicators 51-71. These address prescribing, dispensing, storage and administration.

Punjab Healthcare Commission | **Official source**

M2

Minimum Standards for Establishment of Hospital Pharmacies

DRAP guidance, PHSR/GL/HP/012, edition 1, effective 25 May 2024. Standards I-IX cover pharmacy organisation, selection, preparation, use, monitoring and staff development.

Drug Regulatory Authority of Pakistan | **Official source**

M3

Pharmacovigilance Rules, 2022

SRO 540(I)/2022, 22 April 2022; rule 8 on hospital centres, officers, committees and reporting. Official Punjab circulation includes the rules. Check the institution-specific implementation order.

Government of Pakistan | Punjab official copy | **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.

M4

Adverse events reporting guidelines for healthcare professionals

DRAP edition 2, effective 20 October 2025. Use the reporting guidance and current official submission route. Reporting a suspected reaction does not establish causation.

Drug Regulatory Authority of Pakistan | **Official source**

M5

Medication safety in transitions of care

WHO technical report, 2019, WHO/UHC/SDS/2019.9. Supports structured reconciliation, communication and patient involvement at admission, transfer and discharge.

World Health Organization | **Official source**

M6

Medication safety in high-risk situations

WHO technical report, 2019, WHO/UHC/SDS/2019.10. Examines medicine, patient, staff and system risks. International guidance, not a Punjab statutory delegation.

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.

M7

Antimicrobial stewardship programmes: practical toolkit

WHO, 2019. Guidance for health facilities in low- and middle-income countries: leadership, multidisciplinary teams, appropriate use, audit and feedback.

World Health Organization | **Official source**

M8

Promoting rational use of medicines

WHO guidance supports treatment guidelines, essential medicine lists, multidisciplinary committees, independent information, audit and feedback. Local authority remains separately required.

World Health Organization | **Official source**

M9

WHO Model List of Essential Medicines, 24th list

2025 model list. A guide for adoption or adaptation; it is not a hospital procurement approval or a promise of free supply. Use the applicable Pakistan, Punjab and hospital lists.

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.