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M.Pharm Practical Notes

Pharmacy Practice Practicals II

Semester 2

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ADR Causality Assessment - ACE-Inhibitor Cough

Practical 1 - Clinical pharmacy case practical

Aim

To assess a suspected adverse drug reaction using a structured causality approach.

Principle

A temporal association raises suspicion but does not prove causation. Chronology, known reaction information, competing causes, dechallenge and any ethically available evidence support a graded assessment; deliberate rechallenge is not required.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Build a dated exposure/event timeline including concomitant medicines, illness and previous reactions.
4. Review objective findings, severity, seriousness and alternative explanations separately.
5. Apply the selected current causality framework transparently and record missing evidence.
6. Prepare a suspected-ADR report and immediate clinical safety actions without waiting for certainty.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned fictional reaction case below. Do not label causality certain solely because the event followed a medicine.

Fictional reaction case

• A dry cough starts after an ACE inhibitor, with no complete work-up yet. Review timing, other causes, clinical assessment and any authorised withdrawal response; classify the suspicion with stated uncertainty.

Result and Interpretation

• Provide a reasoned causality category, supporting/conflicting evidence and a reporting plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Are severity and seriousness identical?

Severity describes intensity; seriousness relates to specified outcomes such as hospitalisation or life threat.

Is certainty needed to report?

Suspected reactions can be reported.

Why avoid deliberate rechallenge?

It may expose the patient to avoidable harm.

ADR Causality Assessment - Medicine-Associated Rash

Practical 2 - Clinical pharmacy case practical

Aim

To assess a suspected adverse drug reaction using a structured causality approach.

Principle

A temporal association raises suspicion but does not prove causation. Chronology, known reaction information, competing causes, dechallenge and any ethically available evidence support a graded assessment; deliberate rechallenge is not required.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Build a dated exposure/event timeline including concomitant medicines, illness and previous reactions.
4. Review objective findings, severity, seriousness and alternative explanations separately.
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7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned fictional reaction case below. Do not label causality certain solely because the event followed a medicine.

Fictional reaction case

• A rash develops after a new medicine while an infection is also present. Record distribution, mucosal/systemic signs and timing; urgent severe features require immediate assessment. Do not deliberately rechallenge.

Result and Interpretation

• Provide a reasoned causality category, supporting/conflicting evidence and a reporting plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Are severity and seriousness identical?

Severity describes intensity; seriousness relates to specified outcomes such as hospitalisation or life threat.

Is certainty needed to report?

Suspected reactions can be reported.

Why avoid deliberate rechallenge?

It may expose the patient to avoidable harm.

ADR Causality Assessment - Anticoagulant Bleeding

Practical 3 - Clinical pharmacy case practical

Aim

To assess a suspected adverse drug reaction using a structured causality approach.

Principle

A temporal association raises suspicion but does not prove causation. Chronology, known reaction information, competing causes, dechallenge and any ethically available evidence support a graded assessment; deliberate rechallenge is not required.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Build a dated exposure/event timeline including concomitant medicines, illness and previous reactions.
4. Review objective findings, severity, seriousness and alternative explanations separately.
5. Apply the selected current causality framework transparently and record missing evidence.
6. Prepare a suspected-ADR report and immediate clinical safety actions without waiting for certainty.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned fictional reaction case below. Do not label causality certain solely because the event followed a medicine.

Fictional reaction case

• Bleeding occurs during anticoagulant therapy after a new interacting medicine. Arrange urgent assessment as indicated and review drug, dose history, interactions, renal function, relevant coagulation tests and competing causes.

Result and Interpretation

• Provide a reasoned causality category, supporting/conflicting evidence and a reporting plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Are severity and seriousness identical?

Severity describes intensity; seriousness relates to specified outcomes such as hospitalisation or life threat.

Is certainty needed to report?

Suspected reactions can be reported.

Why avoid deliberate rechallenge?

It may expose the patient to avoidable harm.

Medication Error - Incorrect Units

Practical 4 - Clinical pharmacy case practical

Aim

To analyse a fictional medication error and propose a system improvement.

Principle

Medication-error review examines the process and contributing conditions rather than assigning blame. Harm prevention, factual reporting and system redesign are separate from determining drug causality.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Identify the intended order and the erroneous step, containing the risk through the authorised clinical pathway.
4. Map prescribing, transcription, dispensing, administration and monitoring to locate failures and detection opportunities.
5. Assess patient impact with the team and distinguish actual harm from a near miss.
6. Propose a specific system change and an effectiveness measure rather than relying only on reminders.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

The assigned case below contains an intentional teaching error. It must never be copied as a valid medication order.

Intentional error exercise

• The intended fictional order is in micrograms but the transcription uses the same number in milligrams: this is a 1,000-fold unit discrepancy. Stop the simulated workflow, clarify the order and propose unit standardisation and independent checks.

Result and Interpretation

• Deliver a factual incident map, contributing-factor analysis, immediate response and prevention plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What is a near miss?

An error intercepted before reaching the patient under the stated reporting definition.

Why assess the system?

Workflow and design can make errors more or less likely.

Why measure effectiveness?

A change must demonstrably reduce the relevant failure.

Medication Error - Look-Alike Names

Practical 5 - Clinical pharmacy case practical

Aim

To analyse a fictional medication error and propose a system improvement.

Principle

Medication-error review examines the process and contributing conditions rather than assigning blame. Harm prevention, factual reporting and system redesign are separate from determining drug causality.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Identify the intended order and the erroneous step, containing the risk through the authorised clinical pathway.
4. Map prescribing, transcription, dispensing, administration and monitoring to locate failures and detection opportunities.
5. Assess patient impact with the team and distinguish actual harm from a near miss.
6. Propose a specific system change and an effectiveness measure rather than relying only on reminders.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

The assigned case below contains an intentional teaching error. It must never be copied as a valid medication order.

Intentional error exercise

• A medicine is selected from a look-alike/sound-alike name pair. Compare active ingredient, indication, strength and packaging and propose selection-screen, storage and verification improvements.

Result and Interpretation

• Deliver a factual incident map, contributing-factor analysis, immediate response and prevention plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What is a near miss?

An error intercepted before reaching the patient under the stated reporting definition.

Why assess the system?

Workflow and design can make errors more or less likely.

Why measure effectiveness?

A change must demonstrably reduce the relevant failure.

Medication Error - Therapeutic Duplication

Practical 6 - Clinical pharmacy case practical

Aim

To analyse a fictional medication error and propose a system improvement.

Principle

Medication-error review examines the process and contributing conditions rather than assigning blame. Harm prevention, factual reporting and system redesign are separate from determining drug causality.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Identify the intended order and the erroneous step, containing the risk through the authorised clinical pathway.
4. Map prescribing, transcription, dispensing, administration and monitoring to locate failures and detection opportunities.
5. Assess patient impact with the team and distinguish actual harm from a near miss.
6. Propose a specific system change and an effectiveness measure rather than relying only on reminders.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

The assigned case below contains an intentional teaching error. It must never be copied as a valid medication order.

Intentional error exercise

• A combination product duplicates an active ingredient already prescribed separately. Reconcile ingredients, determine intended treatment and seek authorised correction before further supply.

Result and Interpretation

• Deliver a factual incident map, contributing-factor analysis, immediate response and prevention plan.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What is a near miss?

An error intercepted before reaching the patient under the stated reporting definition.

Why assess the system?

Workflow and design can make errors more or less likely.

Why measure effectiveness?

A change must demonstrably reduce the relevant failure.

Rational Medicine Use - Paediatric Case

Practical 7 - Clinical pharmacy case practical

Aim

To assess rational medicine use in a patient with special clinical considerations.

Principle

Age, organ function, pregnancy, formulation and evidence availability can alter medicine suitability. A mathematical scaling rule cannot replace product- and patient-specific clinical assessment.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify exact age, weight, relevant organ function or pregnancy stage, indication and complete medicines.
4. Check the evidence and product information for the relevant population, including formulation, monitoring and alternative options.
5. Perform only the calculation needed to check an existing authorised plan, with independent unit verification.
6. Document benefits, risks, uncertainty and the specialist or prescriber decision needed.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the population-specific fictional assignment below; do not create a patient dose from a general formula.

Assigned population

• Fictional child: verify current measured weight, age, indication, formulation concentration and the authorised paediatric reference. If an existing order is 50 mg from 10 mg/mL, the volume check is 5 mL; this is not a recommended dose.

Result and Interpretation

• Produce an individualised review with information gaps, a justified clinical query and follow-up.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Can adult doses always be scaled by weight?

No; developmental and product-specific evidence matters.

Why specify the kidney estimate?

The relevant dosing evidence may use a particular measure.

Does pregnancy automatically require stopping every medicine?

The benefit-risk assessment must be individualised with the treating team.

Rational Medicine Use - Renal Impairment Case

Practical 8 - Clinical pharmacy case practical

Aim

To assess rational medicine use in a patient with special clinical considerations.

Principle

Age, organ function, pregnancy, formulation and evidence availability can alter medicine suitability. A mathematical scaling rule cannot replace product- and patient-specific clinical assessment.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify exact age, weight, relevant organ function or pregnancy stage, indication and complete medicines.
4. Check the evidence and product information for the relevant population, including formulation, monitoring and alternative options.
5. Perform only the calculation needed to check an existing authorised plan, with independent unit verification.
6. Document benefits, risks, uncertainty and the specialist or prescriber decision needed.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the population-specific fictional assignment below; do not create a patient dose from a general formula.

Assigned population

• Fictional patient has changing kidney function during acute illness. Do not assume a stable-state eGFR is a reliable substitute for every dosing method. Check the drug-specific measure and seek reassessment and monitoring.

Result and Interpretation

• Produce an individualised review with information gaps, a justified clinical query and follow-up.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Can adult doses always be scaled by weight?

No; developmental and product-specific evidence matters.

Why specify the kidney estimate?

The relevant dosing evidence may use a particular measure.

Does pregnancy automatically require stopping every medicine?

The benefit-risk assessment must be individualised with the treating team.

Rational Medicine Use - Pregnancy Case

Practical 9 - Clinical pharmacy case practical

Aim

To assess rational medicine use in a patient with special clinical considerations.

Principle

Age, organ function, pregnancy, formulation and evidence availability can alter medicine suitability. A mathematical scaling rule cannot replace product- and patient-specific clinical assessment.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify exact age, weight, relevant organ function or pregnancy stage, indication and complete medicines.
4. Check the evidence and product information for the relevant population, including formulation, monitoring and alternative options.
5. Perform only the calculation needed to check an existing authorised plan, with independent unit verification.
6. Document benefits, risks, uncertainty and the specialist or prescriber decision needed.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the population-specific fictional assignment below; do not create a patient dose from a general formula.

Assigned population

• Fictional patient is pregnant and asks about a regular medicine. Verify gestational stage, indication, alternatives and reliable pregnancy evidence; coordinate clinician review and do not recommend abrupt withdrawal solely because of pregnancy.

Result and Interpretation

• Produce an individualised review with information gaps, a justified clinical query and follow-up.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Can adult doses always be scaled by weight?

No; developmental and product-specific evidence matters.

Why specify the kidney estimate?

The relevant dosing evidence may use a particular measure.

Does pregnancy automatically require stopping every medicine?

The benefit-risk assessment must be individualised with the treating team.

Pharmaceutical Care Plan - Epilepsy

Practical 10 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Assess urgent features, seizure history, adherence, triggers and interactions; verify the exact antiseizure medicine.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Arrange clinical review and an individual seizure plan; do not advise abrupt withdrawal or an improvised replacement schedule.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Track seizures, adherence, adverse effects and patient-specific safety counselling.

Worked Example

Fictional case: A 24-year-old reports a breakthrough seizure after missed maintenance doses.

Assigned care priorities

• Assess urgent features, seizure history, adherence, triggers and interactions; verify the exact antiseizure medicine.
• Arrange clinical review and an individual seizure plan; do not advise abrupt withdrawal or an improvised replacement schedule.
• Track seizures, adherence, adverse effects and patient-specific safety counselling.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Parkinson Disease

Practical 11 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Reconcile exact product and timing, swallowing ability and interacting medicines, including dopamine-blocking drugs.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Escalate time-critical administration discrepancies and plan continuity with the specialist team.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Track mobility fluctuations, swallowing, postural symptoms and medicine timing.

Worked Example

Fictional case: A 72-year-old with Parkinson disease receives levodopa later than the usual home schedule in hospital.

Assigned care priorities

• Reconcile exact product and timing, swallowing ability and interacting medicines, including dopamine-blocking drugs.
• Escalate time-critical administration discrepancies and plan continuity with the specialist team.
• Track mobility fluctuations, swallowing, postural symptoms and medicine timing.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Stroke

Practical 12 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Activate emergency stroke assessment and record onset/last-known-well information from the case.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Do not delay referral for oral medicines; acute therapy and swallowing assessment belong to the stroke team.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	After stabilisation review authorised secondary prevention, rehabilitation, adherence and bleeding or other adverse effects.

Worked Example

Fictional case: A 67-year-old develops sudden one-sided weakness and speech difficulty.

Assigned care priorities

• Activate emergency stroke assessment and record onset/last-known-well information from the case.
• Do not delay referral for oral medicines; acute therapy and swallowing assessment belong to the stroke team.
• After stabilisation review authorised secondary prevention, rehabilitation, adherence and bleeding or other adverse effects.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Chronic Kidney Disease

Practical 13 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Promptly alert the treating team to the potassium result in context; verify specimen quality, trend, symptoms and current medicines.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Review renal dosing by the correct product-specific kidney measure and reduce avoidable nephrotoxic exposure through clinician review.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Track kidney function, potassium, volume status and medicine-specific safety endpoints.

Worked Example

Fictional case: A 65-year-old has eGFR 28 mL/min/1.73 m^2 and potassium 5.6 mmol/L in the supplied record.

Assigned care priorities

• Promptly alert the treating team to the potassium result in context; verify specimen quality, trend, symptoms and current medicines.
• Review renal dosing by the correct product-specific kidney measure and reduce avoidable nephrotoxic exposure through clinician review.
• Track kidney function, potassium, volume status and medicine-specific safety endpoints.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Urinary Tract Infection

Practical 14 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	The systemic and flank symptoms require prompt assessment for an upper or complicated infection rather than routine uncomplicated-cystitis assumptions.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Review pregnancy possibility, culture plan, allergy, kidney function and local susceptibility evidence with the clinician.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Follow clinical response, culture-directed review, adverse effects and escalation if symptoms worsen.

Worked Example

Fictional case: A 29-year-old has dysuria with fever and flank pain.

Assigned care priorities

• The systemic and flank symptoms require prompt assessment for an upper or complicated infection rather than routine uncomplicated-cystitis assumptions.
• Review pregnancy possibility, culture plan, allergy, kidney function and local susceptibility evidence with the clinician.
• Follow clinical response, culture-directed review, adverse effects and escalation if symptoms worsen.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Tuberculosis

Practical 15 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Clarify the exact regimen, susceptibility, prior treatment, adverse effects and access barriers; use the current national TB programme pathway.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Refer the interruption for programme/clinician assessment; do not invent a restart or double-dose schedule.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Track adherence support, clinical and microbiological follow-up and drug-specific toxicity monitoring.

Worked Example

Fictional case: A 40-year-old receiving tuberculosis treatment reports a ten-day interruption.

Assigned care priorities

• Clarify the exact regimen, susceptibility, prior treatment, adverse effects and access barriers; use the current national TB programme pathway.
• Refer the interruption for programme/clinician assessment; do not invent a restart or double-dose schedule.
• Track adherence support, clinical and microbiological follow-up and drug-specific toxicity monitoring.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - HIV Care

Practical 16 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Verify the actual regimen, supplement ingredients and timing; some integrase-inhibitor regimens interact with polyvalent cations.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Check the exact product instructions and discuss a workable administration plan with the HIV team.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	Review viral-load follow-up, adherence, tolerability and new medicine or supplement use.

Worked Example

Fictional case: A 36-year-old on antiretroviral therapy starts a mineral supplement without informing the clinic.

Assigned care priorities

• Verify the actual regimen, supplement ingredients and timing; some integrase-inhibitor regimens interact with polyvalent cations.
• Check the exact product instructions and discuss a workable administration plan with the HIV team.
• Review viral-load follow-up, adherence, tolerability and new medicine or supplement use.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Pharmaceutical Care Plan - Cancer Supportive Care

Practical 17 - Clinical pharmacy case practical

Aim

To prepare a prioritised pharmaceutical care plan for the assigned fictional disease case.

Principle

A pharmaceutical care plan links patient information to medicine-related problems, agreed goals, evidence-based actions and measurable follow-up. Urgent triage precedes routine optimisation.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Summarise symptoms, diagnoses, medicines, allergies, laboratory trends, adherence and the person goals.
4. Identify safety, effectiveness, untreated-need and access problems and rank them by urgency.
5. For each problem specify the objective, evidence, proposed action, clinician responsibility and reassessment time.
6. Present the case clearly and record which changes require authorised review rather than prescribing from the exercise.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Assessment needs	Identify urgency and information gaps	Escalate urgently to the oncology/emergency pathway; assess potential infection, dehydration and regimen-specific complications.	Document clinical review

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Medicine-related care	Agree an individualised clinical goal	Provide treatment dates, medicines, allergy and supportive-care details to the team; do not delay assessment for routine dispensing.	Authorised team review
Continuity and response	Measure the agreed response	Document plan and responsible clinician	After acute review assess antiemetic plan, hydration, counts, interactions, adherence and patient warning-sign understanding.

Worked Example

Fictional case: A 58-year-old receiving chemotherapy reports fever and inability to retain fluids.

Assigned care priorities

• Escalate urgently to the oncology/emergency pathway; assess potential infection, dehydration and regimen-specific complications.
• Provide treatment dates, medicines, allergy and supportive-care details to the team; do not delay assessment for routine dispensing.
• After acute review assess antiemetic plan, hydration, counts, interactions, adherence and patient warning-sign understanding.

Result and Interpretation

• Deliver a complete problem-goal-action-monitoring table and explain the rationale and uncertainty for each priority.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What makes a goal measurable?

A defined clinical or patient-reported endpoint and review time.

Why include patient priorities?

A feasible plan must reflect the person needs and preferences.

Why distinguish proposals from orders?

Treatment changes require the responsible authorised clinical decision.

Absolute and Relative Bioavailability Calculations

Practical 18 - Clinical pharmacy case practical

Aim

To calculate absolute and relative bioavailability from suitable exposure data.

Principle

Dose-normalised AUC comparisons estimate systemic availability when exposure is comparable and the relevant kinetic and study assumptions are met. Different subjects or nonlinear kinetics can complicate the ratio.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Check route, dose, analyte, units, sampling adequacy and AUC definition.
4. Calculate dose-normalised oral and intravenous exposure for absolute availability, or test and reference exposure for relative availability.
5. Assess whether linearity, comparable clearance and design support interpretation.
6. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
7. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

- Absolute F = (AUC_oral / Dose_oral)/(AUC_IV / Dose_IV)
- Relative F = (AUC_test / Dose_test)/(AUC_reference / Dose_reference)

Worked Example

Illustrative oral AUC 20 mg.h/L after 100 mg and IV AUC 25 mg.h/L after 50 mg give F = (20/100)/(25/50) = 0.40, or 40%.

For test and reference at equal dose with AUC 24 and 30, relative availability is 80%.

Result and Interpretation

- Report the ratio and assumptions; a single point estimate is not a bioequivalence decision.

Precautions

- Protect confidentiality and use actual units and timing.
- Check allergy, indication, organ function, interactions and the complete medicine list.
- Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why normalise dose?

Different administered amounts otherwise confound the exposure comparison.

Why use IV for absolute F?

It provides the systemic-input reference under suitable conditions.

Is relative F alone bioequivalence?

A suitable study and interval-based analysis are needed.

Bioequivalence Confidence-Interval Interpretation

Practical 19 - Clinical pharmacy case practical

Aim

To interpret a bioequivalence confidence interval with the applicable decision rule.

Principle

A conventional average-bioequivalence analysis uses log-transformed exposure endpoints and back-transformed confidence intervals for test/reference geometric mean ratios. Product-specific or narrow-therapeutic-index requirements can differ.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify design, endpoint, analysis population, period/sequence handling and missing-data rules.
4. Review the log-scale treatment estimate, standard error and appropriate confidence interval under the prespecified model.
5. Back-transform and compare the entire interval with the applicable limits for every required endpoint.
6. Explain why a point estimate inside the limits is insufficient.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

- Geometric mean ratio = exp(log-scale treatment difference)

• Back-transformed CI = exp(lower log limit) to exp(upper log limit)

Worked Example

Illustrative geometric mean ratio 0.98 with 90% CI 0.92 to 1.04 meets a conventional 0.80 to 1.25 interval rule for that endpoint. Ratio 1.00 with CI 0.78 to 1.28 does not.

Apply the actual product and jurisdiction requirements rather than assuming these limits fit every study.

Result and Interpretation

• Deliver endpoint-level interval decisions, model assumptions and the overall evidence gaps.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why log transform?

Exposure ratios and multiplicative variation are often modelled on the log scale.

Does a nonsignificant difference prove equivalence?

Equivalence needs the prespecified interval within its limits.

Why assess all required endpoints?

Passing one exposure measure may be insufficient.

Therapeutic Drug Monitoring - Digoxin

Practical 20 - Clinical pharmacy case practical

Aim

To interpret a drug concentration using dose timing and clinical context.

Principle

Therapeutic drug monitoring links a valid measurement to timing, exposure, organ function, response and toxicity. A concentration without a reliable dose and sample history can be misleading.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify indication, exact formulation, doses, administration times, sample time, clinical state and kidney/liver trend.
4. Check assay units, timing suitability and steady-state or model assumptions.
5. Compare with the indication-specific target only after assessing clinical response, toxicity and interactions.
6. Prepare an interpretation and clinician review request; do not change treatment from an isolated number.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned drug-specific timing and interpretation exercise below.

Drug-specific TDM record

- Record the last dose and draw time. Routine concentration interpretation generally uses a sample at least 6 hours after the dose, ideally 8-12 hours under the relevant guidance.

• Illustrative a sample 2 hours after dosing is unsuitable for routine post-distribution interpretation. Review symptoms, renal function, potassium and interacting medicines; targets depend on indication and clinical context.

Result and Interpretation

• Deliver a timing diagram, qualified interpretation and monitoring recommendation for authorised review.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why record sample time?

Distribution and elimination change concentration over time.

Does a target-range result exclude toxicity?

Clinical state and individual susceptibility remain important.

Why verify units?

Different concentration units can cause dangerous misinterpretation.

Therapeutic Drug Monitoring - Lithium

Practical 21 - Clinical pharmacy case practical

Aim

To interpret a drug concentration using dose timing and clinical context.

Principle

Therapeutic drug monitoring links a valid measurement to timing, exposure, organ function, response and toxicity. A concentration without a reliable dose and sample history can be misleading.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify indication, exact formulation, doses, administration times, sample time, clinical state and kidney/liver trend.
4. Check assay units, timing suitability and steady-state or model assumptions.
5. Compare with the indication-specific target only after assessing clinical response, toxicity and interactions.
6. Prepare an interpretation and clinician review request; do not change treatment from an isolated number.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned drug-specific timing and interpretation exercise below.

Drug-specific TDM record

- Record the exact formulation and schedule; a standard monitoring comparison generally uses a level 12 hours after the last dose.

• Illustrative a 6-hour sample cannot be compared uncritically with a 12-hour target. Review renal function, hydration, sodium balance, symptoms and interactions; use the individual treatment target.

Result and Interpretation

• Deliver a timing diagram, qualified interpretation and monitoring recommendation for authorised review.

Precautions

• Protect confidentiality and use actual units and timing.
• Check allergy, indication, organ function, interactions and the complete medicine list.
• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why record sample time?

Distribution and elimination change concentration over time.

Does a target-range result exclude toxicity?

Clinical state and individual susceptibility remain important.

Why verify units?

Different concentration units can cause dangerous misinterpretation.

Therapeutic Drug Monitoring - Vancomycin

Practical 22 - Clinical pharmacy case practical

Aim

To interpret a drug concentration using dose timing and clinical context.

Principle

Therapeutic drug monitoring links a valid measurement to timing, exposure, organ function, response and toxicity. A concentration without a reliable dose and sample history can be misleading.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Verify indication, exact formulation, doses, administration times, sample time, clinical state and kidney/liver trend.
4. Check assay units, timing suitability and steady-state or model assumptions.
5. Compare with the indication-specific target only after assessing clinical response, toxicity and interactions.
6. Prepare an interpretation and clinician review request; do not change treatment from an isolated number.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Worked Example

Use the assigned drug-specific timing and interpretation exercise below.

Drug-specific TDM record

• For serious invasive MRSA infection, current consensus supports AUC-guided assessment, commonly AUC24 400-600 mg.h/L when MIC by broth microdilution is assumed 1 mg/L; this context does not apply universally to every infection.

• Illustrative model-derived AUC24 500 mg.h/L lies in that contextual range, but sample timing, model validity, renal trend and clinical response still need review. A trough alone is not the AUC.

Result and Interpretation

• Deliver a timing diagram, qualified interpretation and monitoring recommendation for authorised review.

Precautions

• Protect confidentiality and use actual units and timing.

• Check allergy, indication, organ function, interactions and the complete medicine list.

• Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

Why record sample time?

Distribution and elimination change concentration over time.

Does a target-range result exclude toxicity?

Clinical state and individual susceptibility remain important.

Why verify units?

Different concentration units can cause dangerous misinterpretation.

Cost-Effectiveness and Incremental Analysis

Practical 23 - Clinical pharmacy case practical

Aim

To compare costs and outcomes using a defined economic perspective.

Principle

Economic evaluation requires a comparator, perspective, time horizon, outcome and uncertainty analysis. Cost-minimisation is justified only when equivalent relevant outcomes are supported, not merely assumed.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Identify the question, patient-specific information and missing data. Use the supplied fictional record; do not create a prescription or administer a preparation.
3. Define comparator, perspective, time horizon and included resource categories.
4. Calculate total expected cost and the appropriate outcome for each option, avoiding double counting.
5. For cost-effectiveness calculate incremental cost per incremental outcome; for cost-minimisation first justify equivalent outcomes.
6. Perform sensitivity and budget-impact checks and distinguish an arithmetic result from a policy recommendation.
7. Document the assessment, evidence, proposed action, responsible clinician and follow-up. Separate a student recommendation from an authorised treatment decision.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

- ICER = (Cost_B - Cost_A)/(Effect_B - Effect_A)
- Budget impact = eligible patients x uptake change x incremental per-patient cost, with the defined complete cost model

Worked Example

Illustrative A costs 1,000 with outcome 0.70 and B costs 1,200 with outcome 0.80. ICER = 200/0.10 = 2,000 currency units per additional outcome unit.

No universal willingness-to-pay threshold is assigned by this example.

Result and Interpretation

- Provide a transparent cost/outcome table, uncertainty analysis and conclusion conditional on the evidence.

Precautions

- Protect confidentiality and use actual units and timing.
- Check allergy, indication, organ function, interactions and the complete medicine list.
- Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What is the perspective?

Whose costs and consequences are included.

When is cost-minimisation appropriate?

When comparable relevant outcomes are adequately established.

Is budget impact the same as cost-effectiveness?

Budget impact concerns affordability over a defined population and period.

Cost-Minimisation and Budget-Impact Analysis

Practical 24 - Clinical pharmacy case practical

Aim

To compare costs and outcomes using a defined economic perspective.

Principle

Economic evaluation requires a comparator, perspective, time horizon, outcome and uncertainty analysis. Cost-minimisation is justified only when equivalent relevant outcomes are supported, not merely assumed.

Materials and Requirements

- Fictional or approved de-identified case, medicine chart and laboratory record
- Current local policy, relevant product information and clinical guidance
- Pharmaceutical-care and communication worksheet
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Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
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Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Problem / evidence	Goal / priority	Proposed action / owner	Monitoring / follow-up
Safety or urgent issue	Define	Escalate appropriately	Specify
Effectiveness / adherence	Define	Discuss with team	Specify
Information gap	State	Obtain evidence	Review

Calculations

- ICER = (Cost_B - Cost_A)/(Effect_B - Effect_A)
- Budget impact = eligible patients x uptake change x incremental per-patient cost, with the defined complete cost model

Worked Example

Illustrative equivalent-outcome options cost 100 and 90 per eligible patient on the complete defined basis. At 1,000 patients and full substitution, potential annual saving is 10,000 currency units.
Include switching, administration, monitoring and wastage costs; equivalence must first be supported.

Result and Interpretation

- Provide a transparent cost/outcome table, uncertainty analysis and conclusion conditional on the evidence.

Precautions

- Protect confidentiality and use actual units and timing.
- Check allergy, indication, organ function, interactions and the complete medicine list.
- Urgent clinical findings need timely clinical assessment; teaching notes do not replace care.

Viva Questions and Answers

What is the perspective?

Whose costs and consequences are included.

When is cost-minimisation appropriate?

When comparable relevant outcomes are adequately established.

Is budget impact the same as cost-effectiveness?

Budget impact concerns affordability over a defined population and period.

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