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Adverse Drug Reaction Reporting

Practical 24 - Clinical pharmacy case practical

Aim

To complete a fictional suspected-ADR report through the appropriate reporting framework.

Principle

A valid safety case needs an identifiable patient, identifiable reporter, suspected product and suspected reaction, with enough information for follow-up. Identifiable within a protected reporting system does not mean publishing personal details.

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. Use the current Indian PvPI healthcare-professional form or equivalent official local framework and keep all training identities fictional.
4. Enter reaction chronology, description, seriousness/outcome, suspected and concomitant medicines, indication, exposure dates and relevant tests.
5. Record dechallenge, alternative causes and missing information without deliberately rechallenging the patient.
6. Check completeness, protect confidentiality and document the intended local ADR-monitoring pathway and follow-up; do not send the training report.
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

Fictional report has a suspected medicine and rash but no event dates or reporter contact. Record the missing fields and a follow-up query rather than inventing them.

A suspected reaction may be reported even when causality is uncertain; reporting must not delay urgent clinical care.

Result and Interpretation

• Deliver a clearly labelled fictional report and a completeness/follow-up checklist.

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

Is proof required before reporting?

Suspicion can be enough for reporting.

Why include concomitant medicines?

They help assess interactions and alternative explanations.

Can training cases be submitted as real events?

No; the exercise remains fictional and offline.

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