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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.

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