

IPC Adverse Drug Reaction Report and Causality Assessment

Experiment 3 - Practical Notes

Name: _____ Roll no.: _____ Date: _____

Aim

To complete a mock suspected-ADR record and compare two causality approaches for two cases.

Principle

Reporting a suspected ADR does not require proven causation. A structured record captures the event, exposure, timing, medicines, relevant history, outcome and reporter details.

Two Fictional ADR Cases

Case	Supplied evidence	Teaching assessment
1	Documented urticaria after amoxicillin; known reaction (+1), onset after exposure (+2), improvement after clinician-directed withdrawal (+1), observed rash (+1). Alternative causes remain unknown.	Illustrative Naranjo total 5: probable. WHO-UMC may remain possible while plausible alternatives are unresolved. No rechallenge.
2	Dry cough after starting enalapril; known reaction (+1), appropriate onset (+2), resolves after clinician-directed change (+1), alternatives assessed as unlikely (+2). Other evidence unknown.	Illustrative Naranjo total 6: probable. WHO-UMC probable/likely may fit the supplied evidence; state the assumptions.

Naranjo Scoring Guide

Use the current authorised worksheet. The concise guide below paraphrases the evidence items; unknown responses score zero.

Evidence item	Yes	No
Previously established reaction	+1	0
Event follows exposure	+2	-1
Improvement on withdrawal / antagonist	+1	0
Recurrence on re-exposure	+2	-1
Alternative explanation present	-1	+2
Response with placebo	-1	+1
Toxic concentration documented	+1	0
Dose-response pattern	+1	0
Similar prior reaction	+1	0
Objective confirmation	+1	0

Totals: 9 or above definite; 5-8 probable; 1-4 possible; 0 or below doubtful. A score is not proof and may be limited by the clinical context.

WHO-UMC Categories

- Certain, probable/likely, possible and unlikely describe assessed causal likelihood.
- Conditional/unclassified and unassessable/unclassifiable describe information or assessment limitations.
- Use the full category criteria; the same case can receive different labels under different systems.

Key Points

- Use the current IPC/PvPI healthcare-professional form for the exercise.
- Distinguish seriousness, severity and causal likelihood.
- WHO-UMC uses clinical evidence categories; Naranjo uses a scored questionnaire.
- Missing information is marked unknown rather than invented; intentional rechallenge is not undertaken.

Activity Procedure

1. Review cases

Extract event, drug, dates, dose details supplied and concomitant medicines.

2. Draft form

Complete a mock form with fictional identifiers, reaction/outcome and reporter fields.

3. Assess WHO-UMC

Judge timing, alternative causes and dechallenge using the current category definitions.

4. Score Naranjo

Score the evidence supplied for each item; sum and state the category with limitations.

5. Review

Have the supervising teacher assess the report; this exercise does not submit a real ADR report.

Record and Observations

Form section	Student record
Fictional patient / event dates	_____
Suspected medicine / exposure	_____
Reaction / seriousness / outcome	_____
Other medicines / alternatives	_____
WHO-UMC category / reason	_____
Naranjo score / category	_____

Result

Complete the record using your activity, then state the findings, the action required and the reason for that action.

Viva Questions and Answers

1. What is dechallenge?

The event course after stopping or reducing the suspected medicine under clinical direction.

2. Does probable mean proven?

No; it is a supported likelihood category.

3. Is rechallenge needed for a report?

No; it may be unsafe and is not performed for this exercise.

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