

Assignment Adverse drug reaction Monograph

Aim

In this exercise students are trained in: (i) causality assessment, (ii) signal detection, (iii) literature search, (iv) clinical implications of ADR (v) presentation techniques.

This assignments can be used for training PV Key aspect 1 (Importance of PV), 2 (Preventing ADR), 3 (Recognizing ADR), 4 (Managing ADR).

Source

The Netherlands Pharmacovigilance Centre Lareb, WHO Collaborating Centre for Pharmacovigilance in Education and Patient Reporting

Learning outcomes

The student ...

- .. has knowledge about ADR classification, risk factors, confounding factors, and epidemiology
- ... knows how to apply clinical reasoning and causality reasoning when encountering a patient case with a potential ADR.
- ... can discuss the choice of action with new drug safety signals
- ... understands how spontaneous reporting can lead to new information about adverse drug reactions.
- ... develops an attitude to optimize risk-benefit balance in individual patients.

Description

This assignment ADR Monograph is based on subjects from literature, without a specific case or report. It can be used for several approaches:

- Discussion of potential new signals or ADRs that have attention in media
- Writing an in-depth overview of ADRs that any healthcare professional should know about
- Writing an overview of a certain ADR

This assignment is suitable for working in pairs or small groups.

Below, a few examples of potential signals and some ADR overviews are mentioned. You are welcome to consider other subjects, that are applicable for your audience.

Description for students

Drugs can cure, but most drugs also have side effects.

- In this assignment you will write a monograph about a drug side effect (500-600 words, excl. title and references).
- In addition you will give a short presentation about the subject (10-15 minutes per group, including discussion time).

Give a description of the side effect and give arguments for intrinsic and extrinsic causality as was explained in the lecture.

The judgment of this assignment will be based on:

- Recognizable contribution of all the members of the group
- Structure of the monograph
- Correctness of sources and literature used.
- Can fellow students learn from the presentation?

- Contents presentation
- Presentation skills

Description of individual subjects

Assignment 1 – Renal failure because of long term paracetamol (acetaminophen) use

Describe this association. How strong is it? Which are risk factors for renal failure in paracetamol use? What would you advise to prescribers and users of this medication?

Assignment 2 – Cardiac failure because of trastuzumab

Describe this association. How strong is it? What would you advise to prescribers and users of this medication?

Assignment 3 – Diabetes mellitus because of antipsychotic drugs

Describe this association. How strong is it? Is there a difference between individual drugs in the class of antipsychotics? What would you advise to prescribers and users of these medications?

Assignment 4 – Coronary artery disease because of calcium supplements

Describe this association. How strong is it? What would you advise to prescribers and users of this medication?

Assignment 5 – Myocardial infarction because of dabigatran

Describe this association. How strong is it? What would you advise to prescribers and users of this medication? Is dabigatran in favour of other anticoagulants?

Assignment 6 – Hypomagnesaemia because of omeprazole

Describe this association. How strong is it? What are the risks of hypomagnesaemia? What would you advise to prescribers and users of this medication?

Assignment 7 - Gynaecomastia

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?

Assignment 8 - Taste disorders

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?

Assignment 9 - Serotonin syndrome

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?

Assignment 10 – ACE-inhibitors and angioedema

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?

Assignment 11 – NSAIDs and stomach ulceration

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?

Assignment 12 – Antimalarials and psychiatric reactions

Describe this ADR. What are symptoms en potential complications? What is the impact on patients? What is the mechanism? Which drugs are involved? What are risk factors or contributing factors in developing this ADR? How can this ADR be prevented?