Assignment Reporting an adverse drug reaction

Aim
The aim of this assignment is to make students competent to make a proper adverse drug reaction report.
This assignments can be used for training PV Key aspect 3 (Recognizing ADR), 5 (Reporting 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
- … can recognize an ADR in in practice
- … can fill in a reporting form with good quality of documentation
- … develops responsibility for sharing (reporting) ADRs
- … understands how spontaneous reporting can lead to new information about adverse drug reactions.
- … develops an open mind for adverse outcomes of drug use in pharmacotherapy

Description:
Students gather information of and report a possible adverse drug reaction that occurred in a patient during internships or clerkships, to the national or regional pharmacovigilance centre.

Examples of students reports and checklist for assessment of quality on documentation

Checklist for quality on documentation – student reporting
(Lareb, the Netherlands)

Score 1 if information is available and clear, score 0 if requested information is lacking in the report.
If more than 1 ADR is described in the report, score the best documented ADR.

1.	**Timing** (score 1 if latency is clear, based on date calculation and/or narrative) • Drug start date present, and • ADR start date present OR • Given latency in narrative IF BOTH • Given latency corresponds to calculated latency (if discrepancy: score 0)	
2.	**Drug** (score 1 if all 4 are present) • Drug name • Drug strength • Dose • Indication	
3.	**ADR** • Score 1 if description makes clear what happened; • Score 0 if description is vague, like 'allergic reaction' without description of symptoms or localisation; or 'liver function abnormal' without test results	
4.	**Outcome** (if both present, score 1) • Action taken (dose reduced, dose not changed, drug withdrawn) • Outcome (recovered, recovering, recovered with sequel, not recovered)	
5.	**Additional information** (score 1 if at least 1 is present) • Concomitant drugs • Medical history • Past drug therapy • Recurrence • Test information	
	Total score	
	Interpretation of the total score: Well documented > 4 Moderately documented > 2 but <4 Poorly documented <2	

Example of a student report

Example 1 Dabigatran - oesophagitis		
A Adverse drug reactions _____		
ADR		
.	Description of the ADR	exfoliative oesophagitis by dabigatran use
.	Start date of the ADR	06-2014
.	How long did the patient use the drug before the ADR first occured?	4 weeks
.	What is the outcome of this ADR is the patient?	recovering
Information on ADR's:		
.	Has the ADR been treated?	Yes, by switching from dabigatran to phenprocoumon and addition of high dose PPI.
.	Did the patient use the drug causing this ADR before?	No
.	Are there other circumstances that could have cause or aggravate this ADR?	Yes, use of risedronate: but, this has a much smaller chance of causing GI-disorders in comparison to other bisphosphonates. Patient used risedronate for over 5 years with adequate water intake and in up right position.
.	Did the ADR lead to one of the following situations?	Yes, hospitalisation: Cause: melena, Duration admission 3 days, Treatment: gastroscopy, protonpompperfusor, bloodtransfusion (3EH)
.	Extra information	It is rather unknown that dabigatran should be administered like bisphosphonates,with lots of water and in up right position.
___ ***B Drug*** _____		
Drug [1]		
.	Suspect drug	DABIGATRAN ETEXILAAT CAPSULE 110MG
.	Startdate drug	06-2014
.	Dose	2 times a day 1 piece , extra info: 2dd110mg
.	Administration route	Oral
.	Indication	Atrial fibrillation, recently swicthed from phenprocoumon because of recurrent epistaxis (nose bleed)
.	Has the use of the drug been adjustment after the occurrence of the ADR	withdrawn
.	Withdrawn at date	08-2014
.	Possible interaction with other drugs?	No
.	Does the patient use ohter drugs (concomitant medication) ?	Yes
___ ***C PATIËNT*** _____		
.	Gender	Female
.	Birth date	1-1-1927
.	Weight	80 kg
.	Length	162 cm
.	Medical history	AF Osteoporotic collapsed vertebrae; Gonarthrosis, with knee prosthesis (left); Hypercholesterolaemia
___ ***D Reporter*** _____		
.	Profession	Junior doctor (student, clerkship)
___ **Attached files** _____		
.	1	Medication list Lareb.docx

Bisoprolol 2,5mg 1dd 1, Furosemide 40mg 1dd 1, Digoxin 0,0625mg 1dd 1, Valsartan 160mg 2dd 1, Levocetirizine fo 5mg 1dd 1, Piroxicam 20mg 1dd 1, Bisacodyl msr 5mg 4dd 1, Divisun 800 ie 1dd 1, vitamine D Psylliumvezel 3,25g 1dd 1, isphagula seeds Rabeprazol msr 10mg 1-2dd 1, Risedronate 35mg 1x/week on Monday Paracetamol/codein 500/10mg 1-3dd 1, dabigatran 110mg 2dd 1, Duratears eyedr 15ml 4-6dd 1 drops ODS, Fusidic acid creme 20mg/g 3dd, Lidocaine vaselinecreme 3% 4dd.

Score Example 1

1.	**Timing** (score 1 if latency is clear, based on date calculation and/or narrative) • Drug start date present, and (6-2014) • ADR start date present (6-2014) OR • Given latency in narrative (4 weeks) IF BOTH • Given latency corresponds to calculated latency (if discrepancy: score 0) (plausible in time frame)	1
2.	**Drug** (score 1 if all 4 are present) • Drug name (Dabigatran etexilate) • Drug strength (110 mg) • Dose (2 times a day 110 mg) • Indication (atrial fibrillation)	1
3.	**ADR** • Score 1 if description makes clear what happened; (exfoliative oesophagitis, patient had gastroscopy) • Score 0 if description is vague, like 'allergic reaction' without description of symptoms or localisation; or 'liver function abnormal' without test results	1
4.	**Outcome** (if both present, score 1) • Action taken (dose reduced, dose not changed, drug withdrawn) (withdrawn and treated) • Outcome (recovered, recovering, recovered with sequel, not recovered) (recovering)	1
5.	**Additional information** (score 1 if at least 1 is present) • Concomitant drugs (present) • Medical history (present) • Past drug therapy • Recurrence • Test information	1
	Total score	5
	Interpretation of the total score: Well documented > 4 Moderately documented > 2 but <4 Poorly documented <2	well

Example 2. Rizatriptan – acute coronary syndrome

A REACTIONS

Reaction (1)		
.	Description of the ADR	Acute coronary syndrome by coronary dissection
.	Start date of the ADR	03-2016
.	How long did the patient use the drug before the ADR first occured?	1 month
.	What is the outcome of this ADR is the patient?	Unknown

Information on ADR(s)

.	Has the ADR been treated?	Yes, with treatment for acute coronary syndrome, in 2015 with medicines and in 2016 with a stent and catheterisation.
.	Did the patient use the suspect drug use before?	Yes
.	Did the ADR occur before, at that time of use?	Yes, also myocardial infarction
.	Are there any other causes or circumstances that might have caused this ADR or aggravated this ADR?	Yes. Possibly a genetic condition, since the father and sister had a myocardial infarction at a young age based on atherosclerosis.
.	Did this ADR lead to one of the following situations?	Yes: Life threatening situation and Hospital admission for: Myocardial infarction/ACS, Duration of admission: 4 days, Treatment: catheterisation and medicines
.	Extra information	She twice had a myocardial infarction, in 2015 and in 2016 while using rizatriptan. Now, the drug rizatriptan is withdrawn because of the contraindication of coronary diseases for use of triptans.
___ ***B DRUG*** _____		
DRUG [1]		
.	Suspect drug that causes the ADR	RIZATRIPTAN
.	Start date of the drug	16-03-2015
.	Dose of the drug	1 times 1 tablet a day, as necessary when migrain occurs. Max 2 tablets in 24 hours
.	Administration route	Oral
.	Indication	migrain
.	What action has been taken with the drug in response of the ADR?	withdrawn
.	Date of withdrawal	06-2016
.	Possible drug-drug interaction?	Unknown
.	Does the patient use other drugs?	Yes
Concomitant medication [2]		
.	Name of the drug	METOPROLOL TABLET 50MG
.	Dose	1 time 1 tablet daily, extra info: as necessary
.	Startdate	05-2011
.	Stopdate	09-2016
Concomitant medication [3]		
.	Name of the drug	accenocoumarol
.	Dose	, extra info: dose according to Duth thrombosis services
.	Startdate	2002
.	Stopdate	2016
___ ***C PATIENT INFORMATION*** _____		
.	Gender	female
.	Birthdate	1-1-1966
.	Relevant medical history	Pulmonary embolism at young age
___ ***D REPORTER INFORMATION*** _____		
.	Profession	Junior doctor in general practice (student, clerkship)

Score Example 2

1.	**Timing** (score 1 if latency is clear, based on date calculation and/or narrative) • Drug start date present, and (3-2015; unknown when the first event was) • ADR start date present (3-2016) OR • Given latency in narrative (1 month); unknown when the last dose was taken) IF BOTH • Given latency corresponds to calculated latency (if discrepancy: score 0)	0
2.	**Drug** (score 1 if all 4 are present)	0

	• Drug name (rizatriptan) • Drug strength (unknown) • Dose (as necessary, unknown when and how much the patient took the drug) • Indication (migraine)	
3.	**ADR** • Score 1 if description makes clear what happened; (acute coronary syndrome or myocardial infarction based on coronary dissection not on atherosclerosis) • Score 0 if description is vague, like 'allergic reaction' without description of symptoms or localisation; or 'liver function abnormal' without test results	1
4.	**Outcome** (if both present, score 1) • Action taken (dose reduced, dose not changed, drug withdrawn) (withdrawn) • Outcome (recovered, recovering, recovered with sequel, not recovered) (unknown)	0
5.	**Additional information** (score 1 if at least 1 is present) • Concomitant drugs (present) • Medical history (present) • Past drug therapy (present) • Recurrence • Test information	1
	Total score	2
	Interpretation of the total score: Well documented > 4 Moderately documented > 2 but <4 Poorly documented <2	moderatly