Electronic Supplementary Material 1 – Questionnaires

Feasibility and educational value of a student-run pharmacovigilance programme – a prospective cohort study

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Question	*Answer option*
1. If you suspect a patient to have an adverse drug reaction, how would you act?	*Open question*
2. I know where to report an ADR (in the Netherlands)?	*yes / no (if yes, please specify)*
3. I know which essential information is needed for a qualitative good ADR-report.	*yes / no*
4. I know how an ADR-report is handled by the Dutch pharmacovigilance center Lareb.	*yes / no*
5. I know how a ADR-reports are used after the Dutch pharmacovigilance center Lareb has handled the ADR-reports.	*yes / no*
6. I know why ADR's should be reported to the Dutch pharmacovigilance center Lareb.	*yes / no*

Table ESM 1-1: *Student pre-participation e-questionnaire, comprising 6 questions.*

Question	*Answer option*
1. Was the assessment was scientifically sound?	*5 point Likert scale (1: strongly disagree - 5 strongly agree)*
2. Was the assessment was useful?	*5 point Likert scale (1: strongly disagree - 5 strongly agree)*
3. The assessment lacked relevant information.	*yes / no (if yes, please specify)*
4. The assessment consisted inaccuracies.	*yes / no (if yes, please specify)*
5. The time I spent on this ADR report was … compared to self-handeling the entire ADR-assessment.	*5 point Likert scale (much less – 5 much more)*
6. Overall rating of entire student ADR-assessment.	*Mark 1-10 (1 (min) – 10 (max))*

Table ESM 1-2: *Lareb supervisor e-questionnaire, comprising 6 questions.*

Question		*Answer option*
1. If you suspect a patient to have an adverse drug reaction, how would you act?		*Open question*
2. I know where to report an ADR (in the Netherlands)?		*yes / no (if yes, please specify)*
3. I know which essential information is needed for a qualitative good ADR-report.		*yes / no (if yes, please specify)*
4. I have previously reported an ADR tot the Dutch pharmacovigilance center Lareb.		*yes / no*
5. Could you indicate how likely it is you will report an ADR to the Dutch pharmacovigilance center Lareb in the following situations:	*I intend to report serious ADRs that I will encounter to the competent authority.*	*7 point Likert scale (1: extremely unlikely – 7 extremely likely)*
	I intend to report unknown ADRs that I will encounter to the competent authority.	
	I intend to report all ADRs that I will encounter to the competent authority.	
6. How likely do you think the following outcomes will be if you report an ADR to the Dutch pharmacovigilance center Lareb?	*It contributes to the safe use of medicines.*	*7 point Likert scale (1: extremely unlikely – 7 extremely likely)*
	Improves patient safety.	
	Educates others about drug risks.	
	Personally beneficial.	
	Time consuming to report.	
	Disrupts the normal workflow.	
	Increases risk of malpractice.	
	Breaks trust with patients.	
7. What are the correct answers to the following statements?	*I know how an ADR-report is handled by the Dutch pharmacovigilance center Lareb.*	*yes / no*
	I know how assessed ADR-reports are used by the Dutch pharmacovigilance center Lareb.	
	I know why ADR's should be reported to the Dutch pharmacovigilance center Lareb.	
	All ADRs, irrespective of severity, are obliged to be reported.	
	Medical doctors should report serious ADEs even if uncertain that product caused the event.	
	Medical doctors should report serious ADEs even if do not have all details of event.	
	All serious ADRs are known before a drug is marketed.	
	Lareb does not disclose ADR reporter's identity.	
	One can report ADRs anonymously to Lareb.	
	Adverse experiences with cosmetics & special nutritional products may be reported to Lareb.	
	One case reported by a doctor does not contribute much to knowledge on drug risks.	
	With my present knowledge, I am very well prepared to report any ADRs in my future practice.	
	Medical students can report ADRs to Lareb.	
	Patients can report ADRs independent from a healthcare professional.	
	I know what pharmacovigilance means.	
8. What is the meaning of "The black triangle" on the packaging of medication?		*Open question*
9. Which sources can I consult when I encounter a possible ADR in one of my patients?		*Open question*
10. What is the meaning of the terms: positive dechallenge and positive rechallenge?		*Open question*
11. Which patient bound factor can play a role in the development of an ADR?		*Open question*
12. What have you learned by participating in the SR-LC-PP?		*Open question*
13. Statements concerning educational value of the LC-SR-PP.	*I found assessing ADR reports educational.*	*5 point Likert scale (1: strongly disagree – 5 strongly agree)*
	I felt responsible for assessing the ADR-reports.	
	Learning by doing (by assessing the ADR-reports) is more pleasurable than learning with fictive casuistry.	
	Learning by doing (by assessing the ADR-reports) is more instructive than learning with fictive casuistry.	
	Assessing ADR-reports should be added to the current medical curriculum.	
	There should be more pharmacovigilance education in the current medical curriculum.	
	Pharmacovigilance is covered well in the current medical curriculum.	
14. Assessing the ADR-reports on average cost me …		*0-1 hours, 1-2 hours, 2-3 hours, 3-4 hours, 4-5 hours, 5-6 hours or >6 hours.*
15. Statements concerning organization of the LC-SR-PP.	*I had enough time to assess the ADR-reports.*	*5 point Likert scale (1: strongly disagree – 5 strongly agree)*
	Assessing the ADR-reports could easily be combined with the regular curriculum.	

Table ESM 1-3: *Student post-participation e-questionnaire, comprising 15 questions.*