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A global view of undergraduate education in pharmacovigilance

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Abstract
Purpose The aim of this study was to gain insight in current pharmacovigilance educational activities and to gather information on which topics should be included in the undergraduate pharmacovigilance core curriculum.
Method A web-based questionnaire was carried out containing 45 questions divided over four sections between 28 October 2014 and 31 January 2015. Potential participants working in pharmacovigilance and/or providing training in this field were invited via email and a widespread web link and snowball sampling was used to recruit additional participants.
Results The questionnaire was filled out by 307 respondents from 88 different countries with a response rate of 29.3% for the email invitation and an unknown rate for the web link. Respondents were mainly pharmacists and physicians. Currently, lectures are the largest proportion of educational activities and all healthcare profession curricula have a mode of 2 h as number of contact hours per course. Respondents rated clinical aspects as the most important subdomain to be included in the core curriculum with prevention of adverse drug reactions as the most important subtopic. This was followed by communication aspects between parties, with communication between regulatory authorities and healthcare professionals, methodological aspects with causality assessment, and regulatory aspects with benefit-risk assessment. This is similar to subjects addressed in current educational activities with little difference between medical and pharmacy curricula.
Conclusion This study gave a good general impression in current educational activities and the respondents' needs and wishes for future activities worldwide, which both will be used for the development of the undergraduate pharmacovigilance core curriculum.

Keywords Survey · Curriculum · Pharmacovigilance · Undergraduate · Education

Introduction

Pharmacovigilance is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" [1]. One of the primary aims of pharmacovigilance is to detect signals, a signal being defined as "information that arises from one or multiple sources (including observations or experiments), which suggests a new, potentially causal association, or a new aspect of a known association between an intervention (e.g., administration of a medicine) and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action" [2]. Spontaneous reporting systems (SRSs), which have been in place since the early 1960s, are a signal-generating methodology which can be used in the early detection of previously unrecognized adverse drug reactions (ADRs). In addition, SRSs can also be useful for obtaining information on new aspects of known associations between drugs and ADRs. SRSs are sometimes criticized for their methodological shortcomings,

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but are still the sole method that identifies most signals which lead to regulatory action both in the USA and in Europe [3, 4]. An SRS is dependent on reports from healthcare professionals (HCPs) and patients, without reports a spontaneous reporting system cannot function. However, it is an ongoing challenge to engage these groups to report ADRs. Inman, who coined the concept of the seven deadly sins in reporting, broadly classified the causes for not reporting in two categories: (i) failure to recognize an ADR and (ii) failure to report a recognized ADR [5].

In order to raise awareness for pharmacovigilance among HCPs, more education is needed. A Spanish study has shown that a combination of educational efforts and financial incentives resulted in an increase in the number of reports of ADRs and the proportion of reports of serious ADRs. Importantly, there was also an increase in the number of previously unknown or poorly known suspected ADRs after the introduction of these interventions [6]. In Portugal, the effect of an educational intervention was studied both among doctors and pharmacists. It showed that the intervention improved high-quality reporting of ADRs among physicians and reporting both in terms of quantity and relevance among pharmacists [7, 8]. Experiences in the Netherlands have shown that education during the 3-year postgraduate training for general practitioners also positively influences the reporting behavior after they were registered as general practitioners [9]. In order to support education of HCPs in the field of pharmacovigilance, the WHO-International Society of Pharmacovigilance (ISoP) core elements of a comprehensive modular curriculum has been developed and made available for those interested in 2014 [10]. In order to be able to attribute to all four key features of pharmacovigilance, HCPs need to have an increased awareness about pharmacovigilance. HCPs are a large and diverse target group and if they have worked in clinical practice for years, it might be difficult to change their attitudes and behavior towards pharmacovigilance. Therefore, focus could be put on educating HCPs during their undergraduate studies on how to recognize, manage, and ultimately report ADRs.

Targeting HCPs during their undergraduate studies has several advantages. They are usually working in a setting where education is part of their daily activities working on developing professional skills (apprenticeship). In addition, they are eager to acquire new skills and being in an academic setting also provides the environment where thinking with an "open mind" is possible. Although there is more and more attention on patient safety in the medical curricula, the amount of time given to the topic is likely to be insufficient [11–15]. Greater emphasis needs to be placed on training in these areas in the curricula of medical, pharmacy, and nursing schools [16].

In order to teach undergraduate students important aspects of pharmacovigilance, ideally, there needs to be a curriculum available. The WHO-ISoP Core Elements of a Comprehensive Modular Curriculum is a broad pharmacovigilance curriculum, not specifically aimed at a certain target group [10]. One of the tasks of the WHO Collaborating Centre for Pharmacovigilance in Education and Patient reporting is to design a pharmacovigilance core curriculum, which can be used when teaching undergraduate medical and pharmacy students, as this is lacking at the moment. The undergraduate pharmacovigilance core curriculum will be presented as a framework based on four main domains identified by the WHO Collaboration Centre for Pharmacovigilance in Education and Patient reporting, namely clinical, communicational, methodological, and regulatory aspects. Each domain will include several subtopics and the subtopics will be presented as modules with a learning objective. The framework will be presented without any ready-for-use teaching materials but with examples from different countries so experiences can be shared between users.

The aim of this study was to gather information on which subtopics should be included in the four domains for undergraduate training according to those working in pharmacovigilance and/or who provides teaching and training in this field. In addition, an inventory was made of current undergraduate educational initiatives and participants were encouraged to share their experiences with undergraduate teaching. Lastly, it was investigated what support countries would need in implementing the undergraduate core curriculum.

Methods

Questionnaire setup

To gather the required information, a web-based questionnaire was carried out using the SurveyMonkey platform [17]. The questionnaire contained 45 questions divided over four sections.

The first part of the questionnaire was aimed at making an inventory of current activities in the field of pharmacovigilance education and especially about clinical aspects of ADRs. The questions in this section addressed what the respondent, or the organization the respondent works for, has already done in this field. The second part was aimed at the opinion of the respondent about the topics to be covered in the WHO pharmacovigilance undergraduate core curriculum. The questions were mainly focused on getting the respondents input on the importance of the main domains in the core curriculum. The third part of the questionnaire focused on which practical help is needed for respondents to implement the curriculum. The last part was questions about demographic and professional details of the respondent.

The questionnaire contained multiple-choice questions, 5-point Likert scale questions, and essay box questions. It included conditional branching questions, which allowed participants to skip questions that not needed to be answered based on previous answers. All questions in the questionnaire can be found in Appendix A.

A test panel tested the questionnaire on readability, functional design, and completeness of questions and answer options. The test panel consisted of employees of the Netherlands Pharmacovigilance Centre Lareb with various backgrounds, such as medical doctors, pharmacists, and a bachelor Pharmaceutical Business Administration. Amendments were made when deemed necessary and the authors performed final testing.

Participants

The target audience of the questionnaire was persons involved in pharmacovigilance at national and regional centers, regulatory agencies, pharmaceutical companies, and universities worldwide. Initially, the questionnaire was send out via email to participants of the 2014 WHO-Uppsala Monitoring Centre (UMC) National Centres Meeting in Tianjin, China. A web link for the questionnaire was also spread via newsletters and LinkedIn pages using the network of ISoP, the academic section of the International Pharmaceutical Federation (FIP), and European Association for Clinical Pharmacology and Therapeutics (EACPT). In addition, snowball sampling was used to include other potential respondents that were likely to be interested and/or involved in the topic [18, 19]. Participants were asked if they could provide us with the email addresses of two other persons outside their organization who could fill out the questionnaire. These suggested email addresses were approached as by personal invitation. Respondents could fill out the questionnaire from 28 October 2014 until 31 January 2015. Respondents who were invited by email received a reminder 2 to 4 weeks after the initial invitation.

Analyzing results

No inclusion or exclusion criteria were applied while analyzing the results. 5-point Likert scale questions were analyzed by calculating an average of the points per topic. Open-text fields were analyzed individually in duplo giving code words to the answers. Similar answers were grouped based on these code words. If percentages were calculated, these were calculated using the number of respondents that answered that question. Non-responders were excluded.

Results

The questionnaire was filled out by 307 respondents from 88 different countries (Fig. 1). The response rate of the respondents invited by email was 29.3% (n = 133). A response rate for the distributed web link could not be calculated, but it is known that 174 respondents entered the questionnaire via the web link. The respondents were mainly pharmacists (n = 136) and physicians (n = 54). The most mentioned places of employment were national and regional pharmacovigilance centers, regulatory agencies, hospitals, universities, and/or pharmaceutical companies.

Which educational activities are currently being carried out?

Of the respondents, 74.9% (n = 230) indicated that they are currently involved in education about ADRs and/or pharmacovigilance. 68.7% of these respondents (n = 158) have students (bachelor or master) as part of their target audience. Medical students are the target group of 93 respondents, 121 respondents educate pharmacy students, and 66 respondents have students of other (allied) health professions as their target audience of which the largest group is nursing students (62.9%). The respondents indicated that most of this education is given to these students during the end of the bachelor (third year or higher) or in their master. Figure 2 shows during which year in the curriculum the course is being held in which the respondents participate. Respondents chose the option “other” if the course was given during various times in the curriculum, during internships, or if there is no bachelor or master system for the selected studies.

Most of the respondents contribute actively to courses in various ways. Figure 3 shows that the most frequently applied approach was giving lectures. This was followed by providing background information for the course and providing assignments. A smaller number of respondents contribute to courses by providing e-learnings. Another way of contribution mentioned by three or more respondents over all the student groups was providing cases as education material or assignments.

Figure 4 shows the topics addressed by the respondents during current educational activities in the various student groups. The top four of the three student groups contain the same topics, e.g., spontaneous reporting, communication about ADRs and drug safety issues, clinical aspects of ADRs, and regulatory aspects. Around 15% of the respondents mentioned they address other subjects. Three or more respondents over all the student groups mentioned basics of pharmacovigilance, ADR reporting, good pharmacovigilance practice, herbal medicines, and the role of ADRs in pharmacotherapy and pharmacoeconomics as other addressed subjects.

There is a small difference in the number of contact hours during courses for pharmacy and medical students. The median of contact hours for medical students is 4 h (mode 2 h). Pharmacy students have a median of 5.5 h (mode 2 h). Students of other (allied) health professions have a lower median of contact hours, namely 3 h, but the mode was also 2 h.

Fig. 1 Overview of the 88 countries where the respondents' work highlighted in dark

What is needed in the WHO pharmacovigilance undergraduate core curriculum?

The four main domains in the core curriculum are clinical aspects, communication aspects, methodological aspects, and regulatory aspects. The respondents were asked to score their importance on a scale from 1 (unimportant) to 5 (very important). Clinical aspects scored highest on the importance scale (rating average 4.57) followed by communication aspects (rating average 4.44). Methodological aspects and regulatory aspects had the same rating average, namely 4.19.

Within the four main domains, the respondents could indicate a top three of predefined subtopics and suggest additional subtopics. Table 1 shows the predefined subtopics per main domain and the number of times that these subtopics were selected to be part of the respondents' personal top three. Additional subtopics suggested by three or more respondents were medication errors and special populations for the main domain clinical aspects and communication with media for the main domain communication aspects between parties. For the other two main domains, there were no additional subtopics mentioned by three or more respondents.

Additionally, comments could be made on the predefined subtopics. The most placed comment was that all the predefined subtopics in the questionnaire were important and choosing just three would eliminate other important topics from the list. Also, respondents commented that the importance of the subtopics depends on the target audience of the core curriculum.

What practical help is needed for implementation of the WHO pharmacovigilance undergraduate core curriculum?

The kind of support suggested for a successful implementation of the core curriculum varied widely among the respondents. Three or more respondents addressed the following suggestions for support. Firstly, providing the pharmacovigilance core curriculum itself and promoting the core curriculum. For successful implementation, it was recommended to provide course materials such as case studies, e-learnings, lectures or slides, and reference materials. The course material should be up to date all the time. Also, providing teachers and a teach-the-teacher program to ensure a constant teaching level of the core curriculum were mentioned. Other suggestions for support made by three or more respondents were time (for implementation), support from experts and peers, and financial support.

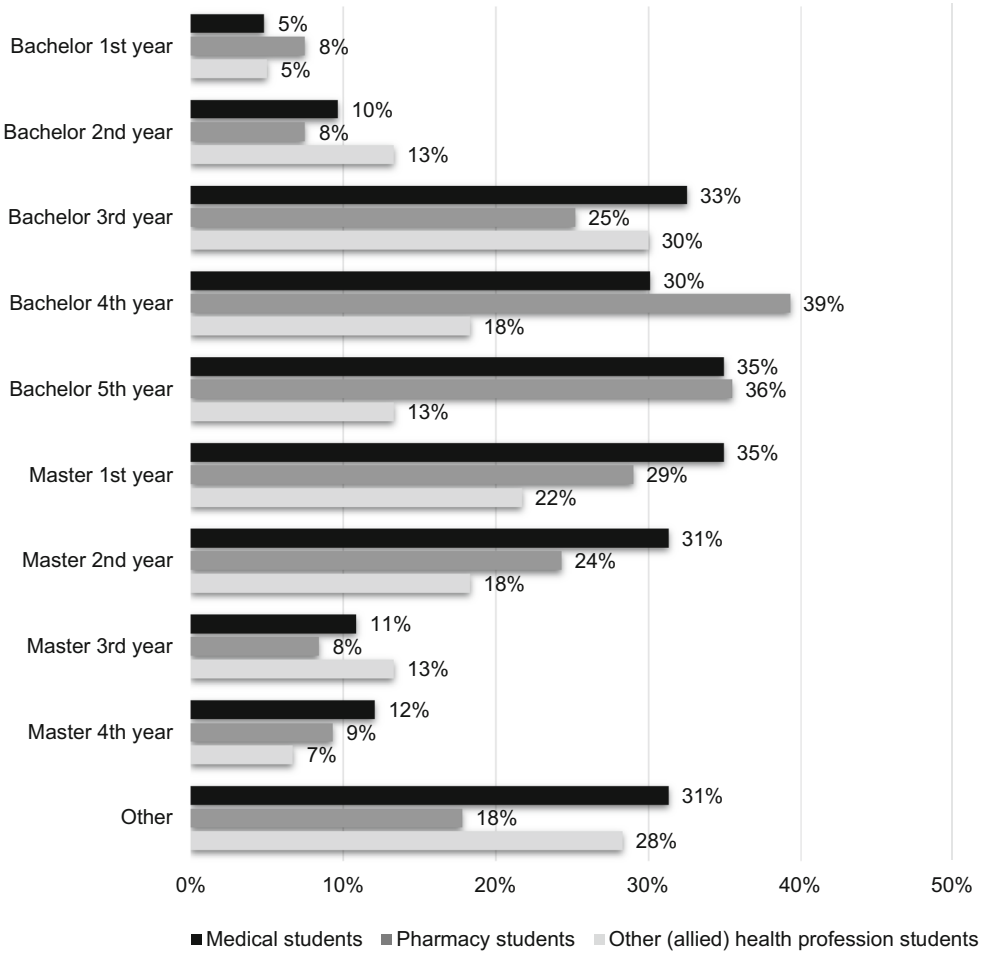

Fig. 2 Overview of when in the medical, pharmacy, or other (allied) health profession curricula the course is held in which the respondents participate

32.2% of the respondents ($n = 99$) indicated they would be happy to share their experiences on the core curriculum. Various ways to exchange experiences were mentioned. Not only face-to-face meetings, like conferences, were suggested but also the exchange of slides and presentations. Online communication was one of the preferred ways of exchange. This included training purposes like an e-learning.

Respondents were asked what else they expect of the WHO Collaborating Centre for Pharmacovigilance in Education and Patient reporting regarding the core curriculum. Training of trainers, a template of the core curriculum on various levels, continuous updating of the core curriculum, and assistance on implementation in curricula were expectations mentioned by three or more respondents.

Discussion and conclusion

This article describes a study into the needs of a core curriculum for undergraduate students for education on ADRs and pharmacovigilance and the way training and education on this topic is currently carried out.

As far as we know, this is the first study on this topic carried out on a global scale. Our study showed that in many countries, some forms of education and training on pharmacovigilance exist both in the curricula for medical and pharmacy students. Worldwide education on ADRs and pharmacovigilance is increasingly recognized as an important topic in medical and pharmacy curricula.

One of the aims of this study was to get an overview of the activities exploited so far in the field of pharmacovigilance education. Initially, the questionnaire was sent out to participants of the 2014 WHO-UMC National Centres Meeting. Since the participants of this meeting often are the heads of the regulatory agencies and frequently involved in regulatory aspects of pharmacovigilance, this may have caused a biased response. To acquire additional participants for this study, snowball sampling was used, which can be an effective method to gather information from a large number of participants with a special interest in a specific topic in a short time span [20]. In addition to snowball sampling, a web link was provided for those who also would like to participate in the study. In this way, a rather large sample can be obtained, but obviously the method applied also carries the risk for a biased response. Nevertheless, the respondents are likely to be

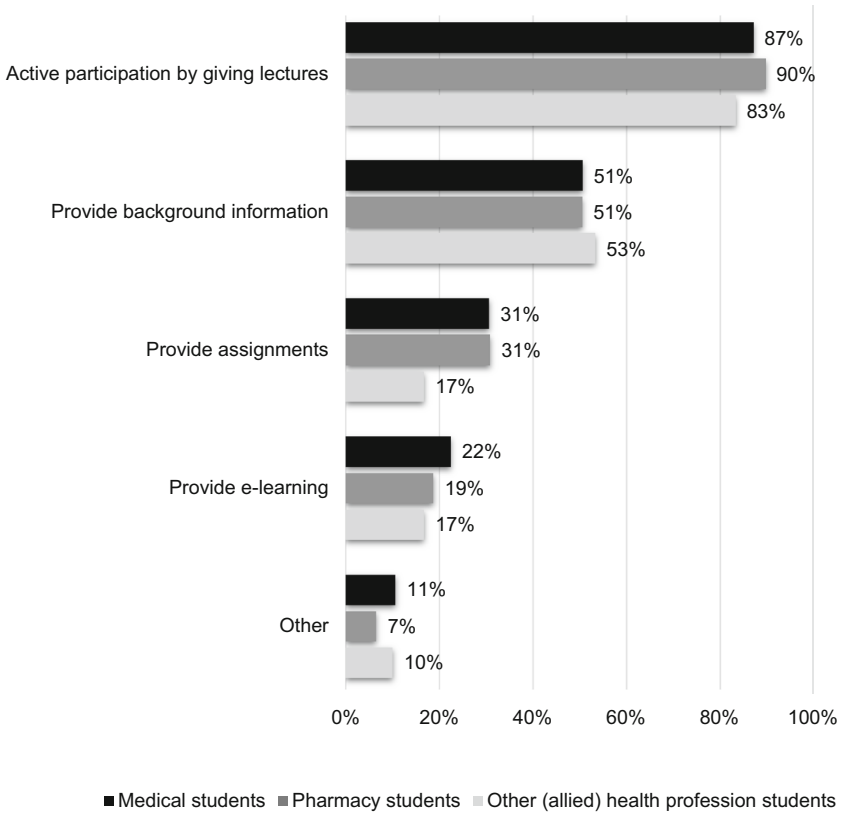

Fig. 3 Overview of the percentage of respondents contributing in a certain way to the courses or lectures in the medical, pharmacy, or other (allied) health profession curricula

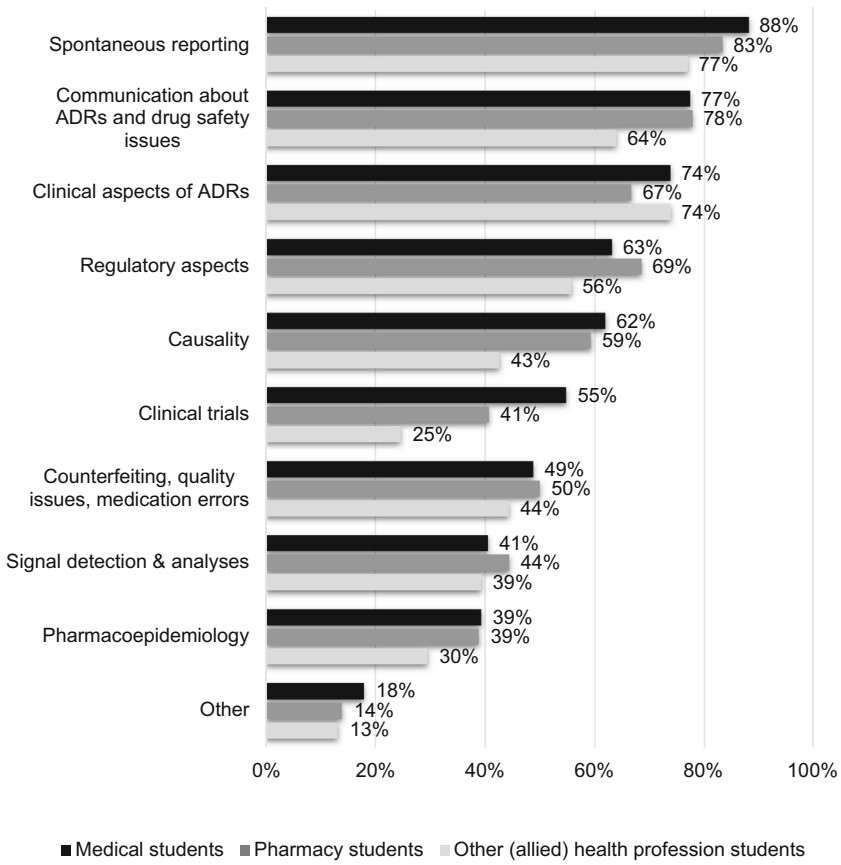

Fig. 4 Overview of the percentage of respondents addressing a certain subject in their contribution in the medical, pharmacy, or other (allied) health profession curricula

Table 1 Overview of subtopics per main domain and the number of times these subjects were chosen by a respondent to be part of their personal top three (n = 260 for clinical and communication aspects and n = 258 for methodological and regulatory aspects)

Main domain	Subtopic	Number of times chosen
Clinical aspects	Prevention of ADRs	180
	Clinical manifestations of ADRs	159
	Clinical management of ADRs	147
	Drug interactions	130
	Pharmacological background of ADRs	116
	Genetic risk factors	32
	Non-genetic risk factors	16
Communication aspects between parties	Regulatory authorities with HCPs	213
	HCPs with patients	202
	Pharmaceutical industries with regulatory authorities	100
	Between HCPs	99
	Pharmaceutical industries with HCPs	78
	Regulatory authorities with patients	69
	Pharmaceutical industries with patients	19
Methodological aspects	Causality assessment	187
	Spontaneous reporting	181
	Signal detection	153
	Epidemiological studies	136
	Scope of pharmacovigilance	117
Regulatory aspects	Benefit-risk assessment	171
	Pharmacovigilance guidelines	156
	Risk management plans	140
	Counterfeit, quality issues, medication errors	96
	Post-authorization safety study	94
	Legislation	74
	Quality assessment	43

involved in training and education in this field and could provide valuable information. Although from a methodological perspective, collecting information from those educational centers *not* providing this type of training may have been preferred in order to be able to get an impression on how often educational activities were absent in medical and pharmaceutical curricula, it was unfortunately not possible to contact all or a sample of the educational centers or universities since their addresses were not available. Focusing mainly on persons working in and/or providing teaching and training in pharmacovigilance can also result in a biased response as the scope on pharmacovigilance from this group may differ from persons working in clinical practice.

In respect to those who were invited for the questionnaire by direct email, the response rate was 29.3%, which is low, but considered satisfactory based on previous experience. Unfortunately, a similar rate could not be calculated for the web link. A worldwide view on pharmacovigilance education was obtained as respondents came from 88 different countries. But as the total number of respondents was 307 (3.5 respondents per country), it should be noted that the results can only be generalized. For this study, this was sufficient as it was meant to be an inventory of a global impression only. Focus groups and tailored interviews to discuss the findings of this study, for instance with those working in clinical practice, would be useful to get a more complete picture of the needs and possibilities for pharmacovigilance undergraduate training.

There were hardly any differences between the place in the curriculum of the current educational activities for both medical and pharmacy students. A relative large proportion of the training for both curricula was given in the first years of the master phase. However, in respect of the timing of courses and lectures, the end of the master phase is to be preferred over the end of the bachelor or the first years of the master phase. Students are more likely to apply the acquired knowledge and skills learned in practice and therefore are more likely to continue doing so in the course of their professional career [9].

Large differences between the type and extend of educational activities exist. Lectures still form the largest proportion of educational activities as over 80% of the respondents participate actively in this, while assignments and e-learnings are only provided by less than one third of the respondents. The effect of

lectures may not be as efficient as other forms of training [21]. Since lecturers have only a limited amount of time available, this is obviously spent on lectures or timesaving provision of background information about ADRs and pharmacovigilance. However, the use of assignments has been proven to be one of the most effective ways of transferring knowledge; although more time consuming, this is the preferred method for transferring knowledge [21].

There is little difference in topics addressed during current educational activities between medical and pharmacy curricula. Topics addressed by the respondents are mainly spontaneous reporting and communication about ADRs and drug safety issues. Also, clinical aspects are often addressed as well as regulatory issues. Apparently, the topics addressed are of interest for both groups, but given the different backgrounds of the students, it seems inevitable that details in which the topics are discussed should differ. The limited time of contact hours (mode 2 h) for all student groups could also be a limit for differentiation, since educators want to teach the students at least the most important subjects in this limited amount of time.

The topics that are addressed during current educational activities are also the ones that respondents find the most important to be part of the core curriculum. This is most apparent in the main domain methodological aspects, as causality assessment and spontaneous reporting score high as most chosen subtopics. What respondents consider to be most important depends on their target groups. For example, we could assume that respondents who currently also educate pharmaceutical company employees or regulatory authority employees selected a different top three important topics compared to the average of the respondents. Regarding the subtopics for regulatory aspects, especially risk-benefit assessment, pharmacovigilance guidelines and risk management plans were often chosen as subjects to be discussed.

The goal of WHO Collaborating Centres is to support activities worldwide with specific expertise on various topics. The undergraduate core curriculum will be presented as a framework based on the four main domains. The various subtopics will be presented as modules with a learning objective. The primary aim is to present this framework without any ready-for-use slides, assignments, or other teaching materials. In respect to the way of contribution, the majority of teachers still give lectures instead of the more modern forms of training and education, like assignments and e-learning. It should be explored if it would be possible to develop assignments that can be shared by those actively involved in training and education. The development of assignments that can be used by various parties among the world might provide an effective way of implementing more modern techniques in pharmacovigilance training and education. In order to do this, a platform has to be developed on which these assignments can be shared. Both in the training for future doctors and pharmacists, all topics should be discussed preferably at a moment in the curriculum, which is closely linked to the practical training.

In our impression, worldwide education on adverse drug reactions and pharmacovigilance is increasingly recognized as a separate discipline in medical and pharmacy curricula. It is essential that future HCPs gain knowledge in recognizing, managing, and reporting of ADRs during their professional training. In many countries, educational activities have been developed to do so. As a pharmacovigilance society, we need to provide training and education in pharmacovigilance, both at the level of the national centers as well as in academia. The undergraduate pharmacovigilance core curriculum plays a role in this in both medical and pharmacy curricula. Increasing knowledge and awareness of ADRs by future HCPs will result in better pharmacotherapy and more vigilance towards unexpected ADRs.

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Contributions of authors JH is responsible for the questionnaire setup, planning, and analysis of the data. LH and EP are responsible for the acquisition of respondents. JH, LH, and EP are responsible for the drafting and the revision of the manuscript.

Compliance with ethical standards

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