ORIGINAL RESEARCH ARTICLE

Awareness and Utilization of Reporting Pathways for Adverse Events Following Immunization: Online Survey Among Pediatricians in Russia and Germany

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Abstract

Objectives Vaccine safety surveillance is highly dependent on accurate reporting of adverse events following immunization (AEFI). An online survey was conducted to assess the utilization of AEFI reporting standards and pathways among pediatricians in Germany, and in Russia where pediatric specialization begins in medical school.

Methods In May 2011, a 31-item online questionnaire was sent to members of the German Professional Association for Pediatricians (BVKJ) and the Union of Pediatricians of Russia (UPR), capturing information on vaccine safety training, awareness of AEFI reporting pathways, and use of standardized case definitions for the ascertainment of AEFI. A convenience sample of 1,632 completed online surveys was analyzed.

Results Participating pediatricians reported spending approximately 50 min per 8-hour workday on vaccine safety consultations, but only 42 % (56 % UPR, 26 % BVKJ) have ever received any formal vaccine safety training. Two-thirds reported having observed AEFI in their practice, but only one-third utilized

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German Professional Association for Pediatricians (BVKJ), Mielenforster Straße 2, 51069 Cologne, Germany standardized case definitions for case ascertainment. Only 35 % of participants named accurate AEFI reporting pathways. Every second pediatrician would report AEFI to institutions that are not primarily in charge of vaccine safety surveillance; the remaining reports would either be lost or delayed. Pediatricians who had received formal vaccine safety training were significantly more likely to apply international safety standards and to report adequately, both at the p < 0.05 level.

Conclusion Pediatricians play a key role in the post-marketing surveillance of vaccine safety. The lack of training represents a missed opportunity. There may be a role for professional societies to improve vaccine safety training.

Abbreviations

ACIP	Advisory Committee on
	Immunization Practices
AE	Adverse Event
AEFI	Adverse Event Following
	Immunization
ADR	Adverse Drug Reaction

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BC BVKJ	Brighton Collaboration German Professional Association for Pediatricians (association for pediatricians in private practice in Germany; Berufsverband der Kinder- und Jugendärzte e.V.)	
CDC	US Centers for Disease Control	
DCGMA	Drug Commission of the German	
	Medical Association	
	(Ärztekammer der Deutschen	
	Ärzteschaft)	
DOH	Department of Health	
ECDC	European Center for Disease	
	Prevention and Control	
EMA	European Medicines Agency	
HCP	Health care professional	
MOH	Ministry of Health	
OSCE	Objective structured clinical	
	examination	
PEI	Paul Ehrlich Institute	
PHAC	Public Health Agency of Canada	
PROSPER	Patient-Reported Outcomes	
	Safety Event Reporting	
UN	United Nations	
UPR	Union of Pediatricians of Russia	
VAERS	Vaccine Adverse Event	
	Reporting System	
WHO	World Health Organization	
ГИСК им Тарасевича	Russian Federal State Institution	
	for Scientific Research, the	
	Institute for Standardization and	
	Control of Medical and	
	Biological Preparations "L.	
	A. Tarasevich"	
СЭЗ	Sanitary-Epidemiological	
	Commission	
ФГУЗ	Federal Centre of Hygiene	
	and Epidemiology	

Key Points

Pediatricians in Germany and Russia spend nearly 1 hour a day on vaccine safety consultations, but only 42 % received formal vaccine safety training

About one-third were aware of the accurate adverse events following immunization (AEFI) reporting pathway and standardized AEFI case definitions

Pediatricians with vaccine safety training were significantly more likely to report AEFI correctly

Pediatric societies, as trusted sources of vaccine information, may help to improve the situation

1 Introduction

Most vaccines are administered during childhood [1]. In the vast majority of cases, vaccines are tolerated very well. Rarely, an untoward medical occurrence may be encountered in a person who was administered a vaccine. The adverse event (AE) does not necessarily have to have a causal relationship with the vaccination [2]. Parents tend to rely on primary care pediatricians with questions or concerns about vaccine safety, and pediatricians and primary care providers are often the first to encounter adverse events following immunization (AEFI) [3, 4]. Post-marketing vaccine safety surveillance systems, however, are only as good as the quality of the safety data that they rely upon [5].

A recent investigation by the Paul Ehrlich Institute (PEI) revealed that 26.8 % of AEFI reports sent to the German vaccine-pharmacovigilance agency were, in fact, incomplete. Timely and accurate safety assessments were either not possible at all or delayed [6]. While AEFI reports in Germany are to be issued to the PEI, adverse drug reactions (ADRs) are to be reported to the Federal Institute for Drugs and Medical Devices (BfArM). Similarly, in Russia, AEFI surveillance is conducted by the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Роспотребнадзор), whereas the Russian pharmacovigilance agency (Фармакопейный комитет) remains in charge of ADR surveillance.

This separation of reporting pathways for ADR and AEFI may cause confusion among practitioners who, unless they have received adequate training, may not be sufficiently familiar with the regulatory system in their respective country.

Furthermore, a number of standardized case definitions have been developed to assist in the ascertainment of AE, independent of the trigger [7]. International consensus on AEFI terminologies, reporting standards, and follow-up periods should be utilized, and primary care pediatricians should be familiar with these standards [8, 9]. A recent survey in the USA revealed that 61 % of health care professionals (HCPs) cited uncertainty about case definitions as a barrier to AEFI reporting [10]. Pediatricians who remain uncertain about the interpretation and reporting of vaccine safety signals will be missing out on an important aspect of their work.

This anonymous online survey aimed to assess AEFI ascertainment and reporting practices among pediatricians working in different health care settings in Germany and Russia. Furthermore, the study aimed to explore the role of vaccine safety training with respect to accurate utilization of AEFI standards and reporting pathways.

This study represents the scientific collaboration between two international professional societies: the

German Professional Association for Pediatricians (BVKJ) and the Union of Pediatricians of Russia (UPR). In both countries, vaccines are usually administered by primary care pediatricians, who are also expected to be the first to encounter AEFI.

We chose the Russian and the German pediatric societies specifically because of differences in their educational systems. The Russian "academy system" allows students to focus on pediatrics from the beginning, i.e., at the time of entry into university (attending "pediatric" rather than "medical school"), whereas students in Germany first complete 6 years of medical school before specializing in pediatrics during postgraduate residency training. The Russian academy system provides additional room for pediatric infectious disease and vaccine safety training throughout the university years [11].

2 Methods

2.1 Study Population

Eligible subjects were members of either the Russian (UPR) or the German (BVKJ) pediatric professional association. In May 2011, the vaccine safety online survey was announced via UPR and BVKJ membership Listservs with approximately 10,000 and 3,500 registered members, respectively. The resulting convenience sample of pediatricians fulfilling inclusion criteria consisted of 1,632 pediatricians (824 of the UPR and 808 of the BVKJ).

For inclusion in the analysis, participants had to complete the questionnaire up to the final question, confirm ongoing or completed pediatric training, and provide email verification.

2.2 Survey Instrument

The survey instrument, approved by the respective institutional review boards, was provided online via the Vienna Vaccine Safety website (www.vi-vi.org) in Russian and German language. The 31 survey items consisted of 27 multiple-choice and four free-text items. The duration of survey completion was documented. Items describing training and workplace included type of medical practice, pediatric subspecialty, and formal vaccine safety training, if applicable. Information on the participant's age and gender was not gathered in this survey, for the sake of anonymity. Pediatricians were asked to estimate the amount of time spent on vaccine safety consultations. Participants were also provided with checklists of potential sources of information on vaccine safety and reporting pathways. With respect to reporting pathways in the multiple-choice checklist, the PEI and the local Department of Health (DOH) in Germany and the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Роспотребнадзор) were identified as "correct pathways" in the analysis presented below [12]. Institutions that may be in a position to forward reports to the respective vaccine-pharmacovigilance authorities were counted as "indirect AEFI reporting pathways," including the German BfArM, the Drug Commission of the German Medical Association (DCGMA), the Russian DOH, the Russian Federal State Institution for Scientific Research, the Institute for Standardization and Control of Medical and Biological Preparations "L. A. Tarasevich" (ГИСК им Тарасевича), the Sanitary-Epidemiological Commission (СЭЗ, Госанэпиднадзор), or the Federal Centre of Hygiene and Epidemiology ($\Phi\Gamma$ Y3). All remaining options in the checklist were considered "incorrect answers" in the analysis of the surveys.

Additional questions dealt with the familiarity with (real or perceived) AEFI.

As an example of ascertainment criteria for AEFI, the "aseptic meningitis case definition" by the Brighton Collaboration (BC) was provided along with the survey [7]. The final eight items assessed the source, awareness, and applicability of the BC meningitis case definition.

2.3 Statistical Analysis

Statistical analysis was performed with SPSSTM, version 19, and MATLABTM 17, version 7.10 (MathWorks), using the statistics toolbox. Power analysis predicted a minimum sample size of 800–850 participants per subgroup to detect differences between participants with formal vaccine safety training versus those who did not, with respect to utilization of international safety standards as well as accurate AEFI reporting, and with a minimum significance level of 0.05. All figures were generated with MATLABTM. Quantitative data were compared by using Wilcoxon ranksum test statistics (this test only concerns survey duration). *P* values of pairwise categorical (yes/no-type) count data were calculated using chi square test statistics. Unless otherwise stated, this test was used in the analysis.

For classification of survey participants according to their respective workplace or medical setting, we applied the Declaration of Alma-Ata [13] as follows: "primary health care" included national health services, private (single or group) practice, public hospitals, polyclinics, community health, and primary or secondary care centers; "specialized health care" included tertiary care and academic medical centers; and "other health care setting" included academic settings, administrative, regulatory, public health, or research institutions (basic or clinical), pharmaceutical and biotech industries, as well as governmental [including the Ministry of Health (MOH)] and nongovernmental organizations.

3 Results

3.1 Study Population

Statistical analysis was performed on a total number of 1,632 completed online questionnaires fulfilling eligibility criteria (824 Russian and 808 German surveys). The average time required to complete the questionnaire was 17.2 min (± 102 % coefficient of variation) for German participants and 20.6 min (± 100 % coefficient of variation) for Russian participants.

3.2 Participant Characteristics

Table 1 shows an overview of participant characteristics (Russian and German survey participants, N = 1,632).

3.3 Vaccine Safety Consultation and Training

Among surveyed pediatricians, 98.9 % are spending nearly 1 hour per workday on vaccine safety consultations

Table 1 Participant characteristics

Participant characteristics	Value
Completed medical studies in the country of residence (Russia or Germany)	96.9 % (1,582/1,632)
Time since graduation from medical school	
Range	1-58 years
Median	22 years
Mean	21.9 years
Pediatric specialization	
Pediatric specialization ongoing or completed	100 % (1,632/1,632)
Pediatric specialization in the country of residence (Russia or Germany)	99.3 % (1,621/1,632)
Pediatric subspecialty training	
Received pediatric subspecialty training	48.8 % (785/1,607)
Pediatric subspecialty training in the country of residence (Russia or Germany)	98.5 % (766/778)
Type of pediatric subspecialization (if applica	ble)
Pediatric allergy/immunology	23.9 % (188/785)
Pediatric pulmonology	13.2 % (104/785)
Adolescent medicine	9.1 % (72/785)
Pediatric cardiology	8.4 % (66/785)
Pediatric neurology	8.2 % (64/785)
Infectious diseases and vaccinology	7.0 % (55/785)
Setting of current practice	
Current practice in country of residence (Russia or Germany)	97.6 % (1,593/1,632)
Primary care	83.9 % (1,370/1,632)
Specialized care	11.5 % (188/1,632)
Other	4.5 % (74/1,632)

(48 min in primary care and 54 min in specialized health care settings; p = 0.3; Wilcoxon rank-sum test). Nevertheless, the majority of surveyed pediatricians (56.7 %) had never received any formal vaccine safety training during medical school or postgraduate training.

About half of all Russian participants (55.3 %, p < 0.01) had been exposed to vaccine safety training, compared with only one-quarter of German participants (26 %; p < 0.01).

3.4 Sources of Vaccine Safety Information

Russian and German pediatricians uniformly named their respective pediatric association as their preferred source of vaccine safety information, along with the MOH (both at the p < 0.05 level), scientific publications, personal experience/colleagues, and vaccine manufacturers (not statistically significant). Publications in biomedical journals were highly relevant to German survey participants but less so to their Russian counterparts (90.9 % of BVKJ and 55.8 % of UPR participants, p < 0.01). Regulatory authorities were mentioned by 47.3 % of German and 11.8 % of Russian participants (p < 0.01). The US Vaccine Adverse Event Reporting System (VAERS) was mentioned by 31.6 % of the Russian compared with only 11.2 % of German participants (p < 0.01).

Tables 2 and 3 compare information sources for pediatricians with and without vaccine safety training, as well as pediatricians utilizing AEFI standards versus those who do not. VAERS, the Advisory Committee on Immunization Practices (ACIP) (p < 0.001, respectively), and the MOH (p = 0.025) were more likely to be named by pediatricians with previous vaccinology training. Of note, survey participants utilizing AEFI standards were more likely to be aware of VAERS, ACIP, and recommendations by the respective MOH (p < 0.001; Table 3). Pediatricians without formal vaccine safety training were more likely to resort to scientific publications (p = 0.01) and the mass media (p = 0.005), respectively.

3.5 Awareness of AEFI Reporting Pathways

When asked about AEFI reporting pathways, approximately 35 % of participating pediatricians (29 % in Germany and 39 % in Russia) were able to name the regulatory agency in charge of vaccine-pharmacovigilance in their respective country. The majority (65 %) would report to other institutions, resulting in either significant delay (i.e., 20 % of German and 21 % of Russian pediatricians) or complete loss (i.e., 51 % of German and 40 % of Russian pediatricians) of safety reports.

Preferred source of vaccine safety information	Participants with previous vaccine safety training (N = 685) (%)	Participants with no previous vaccine safety training (N = 947) (%)	p value
Publications	69	80	0.010
Media	15	21	0.005
Manufacturer	72	73	0.814
Pediatric professional societies	73	84	0.013
Other professional societies	29	27	0.449
VAERS	31	18	<0.001
ACIP	14	9	0.002
CDC	8	6	0.127
ECDC	7	8	0.046
Package leaflet	65	61	0.313
WHO/UN	49	52	0.401
Ministry of Health	70	61	0.025
National pharmacovigilance center	21	35	<0.001
EMA	10	16	0.001
Other health agencies	18	20	0.362
Personal experience/ colleagues	59	69	0.013
Other	5	12	<0.001

Table 2 Preferred sources of vaccine safety information in relation to vaccine safety training

 Table 3 Preferred sources of vaccine safety information vs. utilization of AEFI definitions

Preferred source of vaccine safety information	Participants utilizing AEFI case definitions (N = 598) (%)	Participants not utilizing AEFI case definitions (N = 1034) (%)	p value
Publications	68	79	0.013
Media	15	20	0.022
Manufacturer	71	73	0.646
Pediatric professional societies	72	83	0.015
Other professional societies	31	26	0.065
VAERS	36	16	<0.001
ACIP	16	8	<0.001
CDC	9	6	0.028
ECDC	10	7	0.040
Package leaflet	67	60	0.084
WHO/UN	52	50	0.584
Ministry of Health	74	59	<0.001
National pharmacovigilance center	21	34	<0.001
EMA	11	15	0.034
Other health agencies	18	20	0.375
Personal experience/ colleagues	60	67	0.089
Other	7	11	0.011

Bold values indicate p < 0.05

Previous experience with AEFI in routine practice was not associated with an improved knowledge of AEFI reporting pathways (p = 0.73).

There was a significant association between formal vaccine safety training and knowledge of AEFI reporting pathways, both at the p < 0.05 level.

3.6 Awareness and Utilization of AEFI Case Definitions

AEFI (real or perceived) have been observed by 68 % of all survey participants (AEFI perception; Fig. 1a). Regardless of the setting, two-thirds were either unaware of, or unwilling to use, AEFI ascertainment criteria (utilization of AEFI definitions, Fig. 1a). Twelve percent had never encountered AEFI in their practice, but reported having utilized AEFI case definitions for research or diagnostic purposes.

Overall, 598 pediatricians (36.6 %) reported having ever utilized AEFI case definitions.

Bold values indicate p < 0.05

Primary care pediatricians were most likely to have encountered AEFI (Fig. 2a), but were the least likely group to utilize AEFI case definitions (Fig. 2b; p < 0.001).

More than half (55 %) of Russian survey participants, compared with only 15 % of German survey participants, mentioned having ever utilized an AEFI case definition. The most commonly used BC case definitions, in order of frequency, were fever [14] (81.3 %), intussusception [15] (68.4 %), rash [16] (60.9 %), seizure [17] (58.2 %), and anaphylaxis [18] (54.0 %).

3.7 Awareness and Utilization of a Case Definition for Aseptic Meningitis

When presented with the BC definition for aseptic meningitis as an AEFI [7], 73 % of participants were completely unaware of the existence of case criteria; 52 % of primary care pediatricians and 72 % of pediatric subspecialists would consider using the meningitis case definition in everyday practice. There was a highly significant association between

Fig. 1 AEFI ascertainment using case definitions [utilization of AEFI definitions (Def.)] in relation to AEFI perception. a All health care settings. b Other health care settings. c Primary health care settings. d Specialized health care settings. Each field in the two-by-two table illustrates the total number and percentage of pediatricians working in different health care settings in relation to utilization of AEFI definitions (y-axis) and AEFI perception (x-axis)

а

% that stated AEFI experience

100

80

60

40

20

0

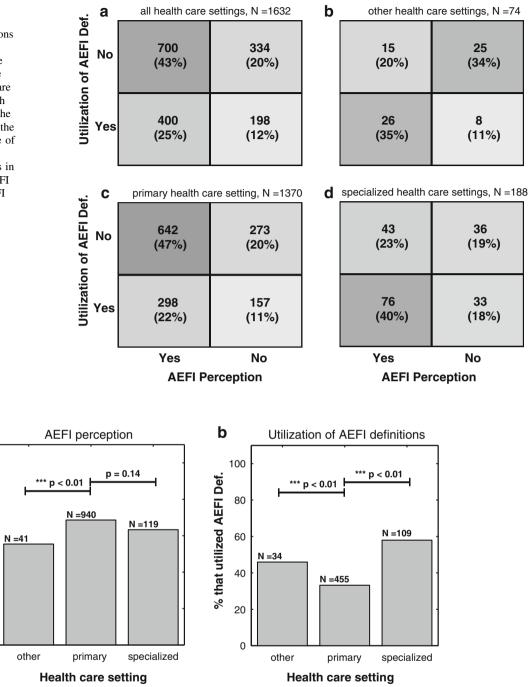


Fig. 2 a Perception of AEFI in distinct health care settings. **b** AEFI ascertainment using case definitions (utilization of AEFI definitions) in distinct health care settings. **a** Represents the percentage of participants who reported having observed AEFI in everyday practice (AEFI perception), classified according to workplace or practice

formal vaccine safety training and awareness of the BC definition for aseptic meningitis (p < 0.001).

Interestingly, 10 % of pediatricians affiliated with the BVKJ in Germany and 7 % of UPR pediatricians commented in the free-text section that they would never

setting (primary, specialized, or other health care setting). **b** Illustrates the percentage of participants utilizing AEFI definitions for case ascertainment, classified according to workplace or practice setting (primary, specialized, or other health care setting)

ascertain cases of meningitis themselves but rather refer to nearby emergency rooms for further work-up. Among pediatricians unwilling to use standardized criteria for case ascertainment, 70 % reported having previously encountered AEFI in clinical practice.

3.8 The Impact of Vaccine Safety Training

There is a significant association between vaccine safety training and the utilization of standardized AEFI definitions in pediatric primary care (p < 0.001). Most pediatricians utilizing AEFI definitions received vaccine safety training during pediatric (sub)specialization (26.3 %) and university studies (23.1 %).

3.9 Summary of Results

This study in collaboration with pediatric professional societies in Germany and Russia provides a first assessment of the utilization of vaccine safety standards in pediatric practice. The resulting convenience sample yielded 1,632 eligible and completed surveys for analysis. Pediatricians reported spending nearly 1 hour per 8-hour workday on vaccine safety consultations, but <50 % have ever received any formal vaccine safety training. No more than 35 % were informed about accurate reporting pathways for AEFI. In Russia, where pediatric specialization usually occurs during medical school, about twice as many pediatricians have been formally trained in vaccine safety.

About two-thirds of pediatricians in this survey reported having encountered AEFI in routine practice, but only onethird have ever ascertained these events according to international standards. Pediatricians with formal vaccine safety training were significantly more likely to utilize standardized criteria for AEFI ascertainment as well as accurate reporting pathways (both at the p < 0.05 level).

4 Discussion

Pediatricians administering childhood vaccines are playing a key role in vaccine safety consultations and the reporting of safety signals to regulatory authorities [19, 20]. The survey was specifically designed to focus on primary care pediatricians; hence, two pediatric associations focusing on primary care pediatrics (UPR in Russia and BVKJ in Germany) were selected for the survey.

An overall survey response rate of 12 % was achieved, which is within the usual range for online surveys [21, 22]. As anticipated in the sample size calculation, 1,632 completed questionnaires yielded significant power to produce significant findings and possible new avenues for further research.

It can be assumed that the majority of participants volunteering their time to complete a full-length questionnaire belong to a highly motivated group with an active interest in the topic of vaccine safety. With this potential bias in mind, it is even more surprising that the majority of survey participants were devoid of any formal training in vaccine safety.

It also needs to be mentioned that participants were allowed as much time as necessary to look up information (if so desired) while taking the online survey; hence, awareness of standards may have been over-reported.

Inequalities in computer access may also bias the participation in online surveys. This was anticipated in this study, where several survey items referred to internet resources, such as VAERS, BC, and websites of regulatory authorities. In times of social media connectivity, online surveys are able to reach an increasingly wide range of participants, including those in remote areas.

To preserve trust in immunization programs, regulatory and public health authorities issuing vaccine recommendations must be in a position to deliver transparent, complete, and accurate safety information [23]. Our findings are in line with previous studies indicating a need to improve vaccine safety training. A survey by the US Centers for Disease Control (CDC) revealed that among US physicians who have observed AEFI, only 17 % of HCPs have ever reported to VAERS [24]. A recent survey in Australia showed that parents, when suspecting vaccine AE, would first inform their doctor and the DOH [25]. A qualitative study among HCPs by the same group, however, revealed that most doctors were uncertain how to report AEFI [26]. Online surveys and face-to-face interviews in Bulgaria and Romania yielded similarly alarming findings, including a lack of awareness of reporting standards for ADR [27, 28]. It has also been shown, however, that the knowledge of reporting and ascertainment mechanisms can be modified to improve the quality of AE reporting [29].

While our study was not designed to explore differences in reporting depending on the type of AEFI (local, systemic, serious vs. non-serious, etc.), this might be an interesting topic for future studies.

Our study presents some evidence that institutional separation of regulatory agencies monitoring ADR versus AEFI may increase the risk of misguided and delayed safety reports. In a clinical setting, it may not be clear *a priori* whether an observed AE may have been triggered by a drug or a vaccine. It remains to be investigated (in different settings) how many AEFI reports are actually lost or delayed by misdirection to institutions other than those officially in charge of vaccine-pharmacovigilance.

Regulatory agencies may contribute to facilitating AE reporting mechanisms. Free-text AEFI data acquisition forms are provided by the PEI in Germany and VAERS in the USA [30, 31]. The Public Health Agency of Canada (PHAC) uses a questionnaire format directing physicians to report in compliance with BC standards [32]. Simple Q&A

tools, user-friendly technical aids, and data mining systems may further facilitate AEFI reporting [33–36].

The Patient-Reported Outcomes Safety Event Reporting (PROSPER) Consortium has taken the initiative to crosslink industry, regulatory authorities, academics, private sector and patient representatives to implement guidelines for the monitoring of AE [37]. Simplification, standardization, and interdisciplinary collaboration are all needed to ensure the timely detection, ascertainment, and reporting of AEFI in different parts of the world [38–40].

In times of international travel and migration, there is room for greater collaboration between regulatory agencies, particularly for the streamlining of ADR and AEFI reporting pathways, as well as for international training activities. Our data suggest that key differences between Russian and German participants were tightly linked to previous exposure to vaccine safety training. Exposure to vaccine safety training was linked to adequate utilization of AEFI definitions and reporting pathways. Future research should explore modalities of collaboration between regulatory authorities monitoring drugs and biologicals, improved communication between doctors and regulator, including e-health and m-health technologies, and between regulators, professional societies, and universities with respect to vaccine safety training for medical students and doctors [41–43]. It is of concern that some primary care pediatricians tend to refer patients with complications (including potential AEFI) to subspecialists, who may themselves be unaware of the immunization history. Regardless of the setting, vaccination histories should be routine in every doctor-physician encounter, and regular vaccine safety training should be obligational during medical school and thereafter [44, 45]. Recent changes in medical curricula in Germany and elsewhere may provide the opportunity to offer enhanced vaccine safety training in medical schools [46]. Theoretical principles should be refreshed and applied in objective structured clinical examination (OSCE) training (using so-called "standardized patients") in small groups in which participants have an opportunity to practice individual scenarios in real-time involving vaccine safety communication skills with OSCE patients and concerned consumers [47, 48].

It needs to be emphasized that in many countries, nurses or physician assistants may be administering vaccines. Allied HCPs should thus remain actively involved in vaccine safety training initiatives [49–51].

Our data also revealed that pediatric associations are considered important sources for vaccine safety information. Approximately 90 % of pediatricians in Germany and Russia are members of professional societies. Pediatric professional societies, as important sources for vaccine safety information, should take a lead in promoting the certification and evaluation of formal vaccine safety training programs. Modern e-learning technologies by

WHO/CDC and others may also help to disseminate

5 Conclusions

Physicians are at the core of the vaccine safety communication chain—but awareness and utilization of the correct pathways for AEFI reporting seems to be limited. Formal vaccine safety training should be offered repeatedly throughout medical school and pediatric specialization to improve the quality of vaccine safety reports from pediatricians to regulatory authorities. Pediatric societies, as trusted sources of vaccine-related information among pediatricians, are playing a crucial role in the improvement of pediatric core competencies to improve patient safety.

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