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Knowledge, practice and approaches of health professionals to adverse events following immunization and their reporting in Albania

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Abstract

In Albania, the reporting of an adverse events following immunization (AEFI) is done not only by immunization providers but also from clinicians providing clinical treatment of AEFI in health posts, health centers and private or public hospitals. The AEFI reporting system in Albania has started in 2001 with the establishment of National Regulatory Authority of Vaccines in the Institute of Public Health. The most important problems of passive surveillance systems include underreporting, deficiency and inaccuracy of information. A structured questionnaire containing 68 questions constructed from immunization experts constituted the study tool. The questionnaire addressed health professionals working at child consultant's facilities and primary health centers in the district of Tirana. There were a total of 102 health professional interviewed. The majority of the respondents working at health centers in the district of Tirana in general, had poor knowledge levels on AEFI surveillance. The lowest score were received in knowledge about the role of different stakeholders involved in AEFI surveillance. The number of years practicing the profession did not influence in the total score of "practice and attitude toward reporting and managing an AEFI". Although the

majority of health care professionals have encountered an AEFI during their practice (72/102, 70,5%), only half of them have never reported an AEFI (37/102, 36,2%). Barriers to reporting included lack of interest, unclear definition of AEFI and lack of awareness of what to report. Nevertheless, the main reason for not reporting was because a respondent thought he or she had not observed an AEFI in the last years (44,1%). Majority of the respondents did not have any training about AEFI (68,6%, 70/102). From this study it is concluded that it is necessary to develop training and educational programs in order to increase awareness of all health professionals involved in child health toward reporting of adverse events following immunization. It is necessary to build feedback systems to give information on AEFI. This study shows the influence of knowledge, perceptions and practices of health care workers in the surveillance of adverse events following immunization. Thus, information generated from this study might be valuable for the public health regulators to generate new guidelines about AEFI surveillance and update existing information.

Keywords: Health profession, Medicine, Evidence-based medicine, Pediatrics, Public health, Nursing, Vaccines

1. Background

Vaccine safety issues and concerns have permeated the healthcare system, reducing the acceptance of vaccines and affecting the effectiveness of vaccination programs [1]. There are few studies about knowledge, perception, attitudes and practices of health care workers toward AEFI reporting. Furthermore, the actual published studies are more concerned on adverse drug reactions and are not specific to vaccines [2, 3].

In Albania the reporting of adverse events following immunization relies on passive surveillance which consists in routinely reporting to jurisdictional public health from health care professionals like nurse, vaccinator, family physician, primary care physician, pediatrician, gynecologist, neonatologist and hospital doctor through a standard reporting form. Ascertainment for a causal association with vaccination is not a pre-requisite for reporting [4]. The limitations of passive surveillance systems include underreporting, variability in report quality and completeness, lack of denominator data, and potential reporting bias [5]. The consequences of this limitation are delays in detecting, investigating and giving information for adverse effects to the public and health authorities, impossibility to treat appropriately the patients suffering from unidentified adverse reactions and delays in taking actions and adjusting the problem to.

Immunization providing facilities in Albania include maternity hospitals and child primary health care post situated at primary health care centers in urban and rural areas which in total are counted 2,282. Among the tools necessary for well practice

of AEFI surveillance designed by IPH it is an AEFI reporting form along with an investigation form and guideline on how to report adverse events, instructions on vaccine counteractions and precautions before vaccination, protocols for managing severe adverse events that might happen after vaccination and a guideline on vaccine schedule.

The cooperation between the front line professionals at the immunization providing level and the professionals at sub national and national level is essential to a successful surveillance system [6]. The knowledge, perceptions, and practices of health workers towards surveillance of AEFI influence the quality and safety of the vaccination services as well as monitoring and reporting rates [7]. Differences in healthcare provider AEFI knowledge and practice of reporting results in inconsistent adverse event data collection and inaccurate measurement of the incidence of vaccine adverse events [8]. Setting up awareness on the importance and relevance of the reporting Adverse Events following immunization and the vaccine safety monitoring is important for sustaining NIP and increasing vaccine coverage.

Moreover, the knowledge of health care workers about AEFI becomes more important when new vaccines are being thought to be introduced to the immunization schedule and the extensive use of established vaccines into the immunization campaigns where there is an increased need for effective surveillance of serious adverse events following immunization [9]. Primary care health workers are the first to come in contact with parents and should provide evidence-based information on the benefits and risks of vaccines, demonstrate to have competence and identify properly adverse events following immunization [10].

Given that health professionals provide the majority of AEFI reports to surveillance systems, it is important to understand not only the factors such as awareness of and frequency of reporting, but also how health professionals perceive and practice the reporting of AEFI [11]. The success of immunization programs depends on a rigorous approach to vaccine safety [12]. Vaccine post-marketing surveillance is essential to ensure that the safety profile of vaccines is acceptable [13].

2. Theory

The main objective of this study was to explore and evaluate the perception, knowledge, practice and approaches of all health professionals involved in immunization practices and primary health care of the infant from birth to 18 years old.

Through this study we also intend to identify vaccine resistant groups and figure out their patterns in order to develop practices and strategies to deal with them.

Another aim of this study is to observe whether there exists a correlation between socio-demographic characteristics of health workers and their practices, perception and knowledge about adverse events following immunization. If there exists any relation between these two factors we further aim to find predictive factors that might influence reporting or non-reporting of AEFI through more compels analysis.

Identifying barriers and difficulties to the use of existing AEFI surveillance system in Albania provides a view of current situation and helps to identify the obstacles that encumber the well functioning and productive results of AEFI surveillance system.

The findings of the study will help guide decisions toward appropriate interventions which will target those health care professionals who encounter an AEFI and may not report it and to improve the awareness of reporting AEFI. This will lead to improved monitoring of vaccine safety in Albania.

3. Materials and methods

A structured questionnaire containing 68 questions designed from immunization experts at the Institute of Public Health constituted the study tool.

3.1. Study area

Twenty four health care facilities belonging to the district of Tirana, 10 urban and 14 rural were visited. Tirana is the capital city of Albania. The targeted health care providers included family physicians, pediatricians, primary health care doctors, nurses, gynecology physicians and vaccinators working at child consultants and primary health care centers. We aimed to interview those professionals who might come in contact with an AEFI case during their daily work. All interviews were conducted at participants' workplace. Only health workers working at public health care units were targeted. The study took place from May 2016 until July 2016.

3.2. Design

Face to face interviews were developed with health workers working at these health centers. The questionnaire was prepared by immunization experts in the Institute of Public Health and piloted in one child consultancy center to assess the time to completion, any other question to be added and the legibility of the content. The time to completion was assessed to be 15 minutes. The pre testing of the study tool helped to validate its effectiveness and make corrections before applying it to the full scale study. The final questionnaire consisted in 68 questions and the

majority of questions were multiple choice questions, while a few open answer questions. The questions were categorized in 5 sections;

Demographic and professional characteristics (5 questions)

Knowledge about adverse events after immunization and perception (10 questions)

Practice and attitude regarding toward reporting an AEFI (34 questions)

Knowledge about AEFI surveillance and monitoring system (10 questions)

Training received (9 questions)

Moreover, the interview aimed to detect factors that impede or facilitate reporting of AEFI.

3.3. Ethical considerations

To conduct this survey, permission was granted from the Institute of Public Health of Albania and authorization letter from the Tirana Directorate of Public Health. An information letter, attached to the permission and authorization letter received from District Directorate of Public Health were sent to the principal of the health facility. The participation of health care workers was voluntary. Codes were used to maintain anonymity of all participants and keep their information confidential.

3.4. Analysis

Data collection took place from May 2016 to July 2016. The collected data was coded and entered into an excel software (Microsoft office Excel 2010) database. Data was analyzed using Statistical Package for Social Sciences, IBM® SPSS version 21 (SPSS Inc., USA). Statistical significance was assessed at $P \leq 0.05$. Qualitative data were expressed in terms of frequency and percentage, while quantitative data in terms of mean \pm standard deviation and median. Each correct response was scored with 1 point while the incorrect response was allocated a score of 0 points. Some answers were scored with 2 points dependently of whether they were given an argument or not about the previous “yes” or “no” answer. The overall score was calculated for all responses for each individual and a maximum of 40 points was expected. Each section was scored to make a quantitative analysis and graded as $<50\%$ - poor, $50-70\%$ - fair and $\geq 70\%$ - good. Data was summarized using frequency tables and pie-charts. One-way ANOVA test was conducted to compare the mean difference of outcomes of interest between job categories. If significant mean differences were detected, post hoc comparisons using the Tukey’s HSD test were performed. Binary logistic regression tests were used to determine associations between the dependent variables (knowledge, perception and practice) and independent variables (age, years of experience, AEFI training, type of profession). Chi-square test was used to establish comparisons between

categorical variables. We conducted several other analyses to identify variables significantly associated with knowledge and practices of health workers toward reporting AEFI. These variables included, previous training about AEFI, age, type of profession and years of experience.

Besides the statistical analysis, personal experiences with AEFI cases of each participant were considered.

4. Results

4.1. Demographic and professional characteristics

The demographic section of the questionnaire included questions on gender, age, practice setting, current occupational category, and number of years in practice.

There were a total of 102 health professional interviewed. The median age of the health care professionals was 46 (26–60) years, while the mean (\pm SD) was 44 (\pm 9,31) years old. Many of the respondents were female 96 (94.1%). The median number of years of experience by the respondents was 12.5 (1–42) years, while the mean was 2,6 (\pm 1,4) years.

4.2. General knowledge levels between health care professionals

The knowledge levels of health care professionals are represented in Fig. 1. The knowledge levels varied on different aspects of AEFI surveillance. The majority of the respondents working at health centers in the district of Tirana in general, had poor knowledge levels on AEFI surveillance. Each correct response was assigned a

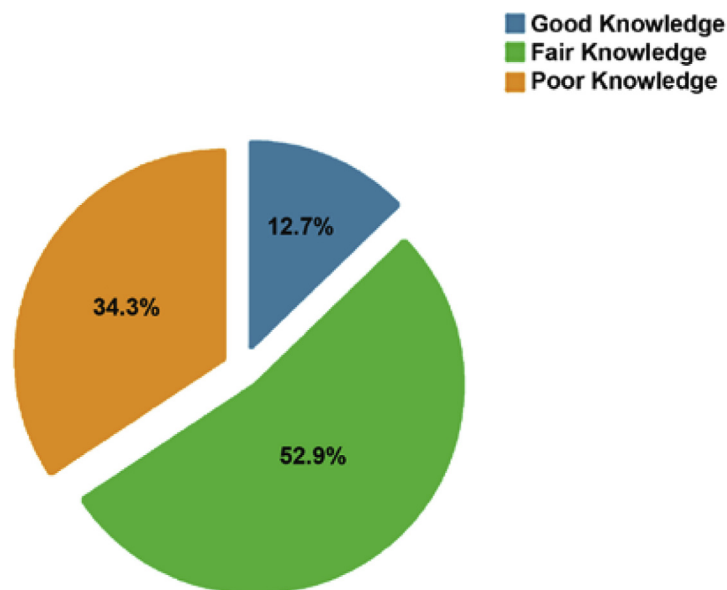


Fig. 1. Knowledge levels of Health Care Professionals.

score of 1.0 and each incorrect response was allocated a score of 0.0, then the overall score was calculated for all the questions. The maximum expected score was 50. The lowest score were received in the block of questions about the role of different stakeholders involved in AEFI surveillance. Only 13 respondents out of 102 had good knowledge level on adverse events following immunization. Most of them (54/102) had fair knowledge level and a considerable proportion (35/102) had poor knowledge level. The overall mean knowledge score was 21,66 ($\pm 5,52$) CI: 20,56–22,73, $p < .0001$.

A one-way ANOVA was conducted to determine if there was a statistically significant difference between groups of health care professionals regarding mean knowledge score. There were no outliers, as assessed by box plot; data was normally distributed for each group, as assessed by Shapiro-Wilk test ($p > .05$); and there was homogeneity of variances, as assessed by Levene's test of homogeneity of variances ($p = .994$). There was a statistically significant difference in total scoring points between categories of health professionals as determined by one-way ANOVA ($F(4,97) = 7,565$, $p < .0001$). A Tukey post hoc test revealed that the mean total score points were significantly lower in the pediatrician group ($15,42 \pm 4,52$) compared with other groups of professionals; Consultancy physicians ($24,61 \pm 5,26$, $p = .000$), family physician ($21,13 \pm 4,56$, $p = .023$), child consultancy nurse ($22 \pm 4,08$, $p = .003$) but there was no significant difference when compared with general nurse category ($20,22 \pm 5,31$, $p = .235$).

A Spearman's rank-order correlation was run to determine the relationship between the total score points in the interview and years of experience in practicing the profession. There was no significant correlation between these two variables ($r_s(100) = .143$, $p = .153$).

An independent samples t-test was run to determine if there were differences in total knowledge score between urban and rural health centers. Mean knowledge scores for rural (20,82) and urban (22,14) was not statistically significantly different, $t(100) = 1,174$, $p = .243$, mean difference = 1,325 (95% CI: $-0,914$ to 3,563).

4.3. Correlation between socio-demographic factors and practices of HW's toward reporting AEFI

A binomial logistic regression was performed to ascertain the effects of age, type of profession and years of experience on the likelihood that participants report an adverse event following immunization. The logistic regression model was statistically significant, $\chi^2(6) = 18,393$, $p < .0005$. The model explained 22.6% (Nagelkerke R^2) of the variance in reporting an AEFI and correctly classified 70.6% of cases. Sensitivity was 51.4%, specificity was 81.5%. Of the four predictor

Table 1. Binomial logistic regression data about the factors that influence the reporting of AEFI.

	B	S.E.	Wald	df	p	Odds ratio	95% C.I. for Odds ratio	
							Lower	Upper
Age	-0,021	0,041	0,262	1	0,609	0,979	0,903	1,062
Profession			14,768	4	0,005			
Pediatrician	-1,849	0,793	5,43	1	0,02	0,157	0,033	0,745
Family Physician	-2,289	0,783	8,542	1	0,003	0,101	0,022	0,47
Vaccinator nurse	-1,451	0,546	7,059	1	0,008	0,234	0,08	0,683
Nurse	-3,162	1,205	6,884	1	0,009	0,042	0,004	0,449
Years of experience	0,05	0,036	1,963	1	0,161	1,051	0,98	1,128
Constant	0,927	1,534	0,365	1	0,546	2,527		

variables one was statistically significant: type of profession (as shown in Table 1). Pediatricians were 6,3 times less likely than other profession categories to report an AEFI, Family physicians were 9,9 less likely than other categories to report an AEFI, the consultancy nurses (vaccinators) were 4,27 times less likely to report an AEFI while the other nurses were 23,8 less likely to report an AEFI. Age and years of profession were not a predicting factor of whether to report or not an AEFI. When comparing differences related to AE reporting and awareness by job category, we found that both consultancy physicians and vaccination nurses were more likely to have ever reported an AEFI compared to other groups of professions.

4.4. Practice and attitude regarding identifying and reporting an AEFI

There were in total 34 questions to assess the practice of health professionals toward reporting an AEFI, methods of reporting, management of an AEFI, communication and consulting with other health care professionals, communication with parents and public. The maximum expected score was 21 because some of the questions were not given a score since they were designed to evaluate the information and not the knowledge of the respondents. The overall mean practice and attitudes score on managing and reporting of AEFI was 14.06 (± 4.25) out of a maximum 21 and median; 14.00. Data was not normally distributed, Shapiro-Wilk's test ($p < .05$), skewness of -0.239 (standard error = 0.239) and kurtosis of -1.040 (standard error = 0.474). As it is demonstrated in Fig. 2, 23 (22,5%) of the respondents had poor knowledge, 32 (31,4%) had fair knowledge and 47 (46,1%) had good knowledge.

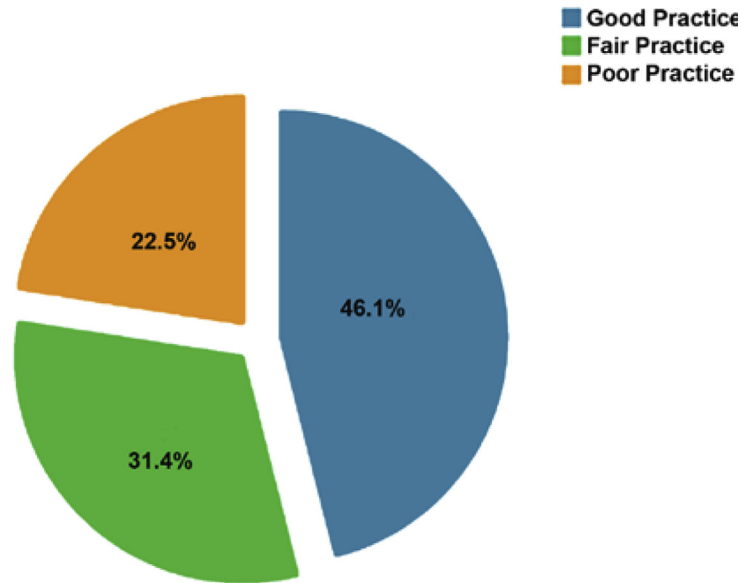


Fig. 2. Level of practice and attitude of health care professionals toward AEFI management and reporting.

4.4.1. Differences between type of profession

A Kruskal-Wallis H test was run to determine if there were differences between categories of health professionals in the score received in this section. Distributions of the scores were not similar for all groups, as assessed by visual inspection of a box plot. The distributions of this score were statistically significantly different between groups, $\chi^2(4) = 23.996$, $p < .001$. Subsequently, pair wise comparisons were performed using Dunn's (1964) procedure. A Bonferroni correction for multiple comparisons was made with statistical significance accepted at the $p < .01$ level. This post hoc analysis revealed statistically significant differences in practice and attitude scores between the pediatricians (mean rank = 18,17) and consultancy physicians (mean rank = 64,13) ($p < .001$) and between pediatricians (mean rank = 18,17) and consultancy nurses (mean rank = 57,96) ($p < .001$), but not between the family physicians (mean rank = 44.56) and nurses (mean rank = 42,44) or any other group combination.

4.4.2. Encountering and reporting an AEFI

To the question "Have you ever reported an AEFI", 37/102 (35,9%) of the respondents answered "Yes" and 65/102 (63,1%) answered "No". The proportion of "yes" answer was statistically significant between profession categories, $p = 0.006$. There was statistically significant difference regarding AEFI reporting between professions categories. Child consultancy physicians (64,3%) had the highest proportion of "yes" answers with regard to family physicians category

(18,8%), pediatricians category (25%), child consultancy nurse (32,4%) and general nurse category (11,1%), $p < .05$. There were no differences in other groups. The difference between proportions was conducted using Fisher exact test.

A chi-square test was conducted between the group of respondents who have encountered an AEFI and those who have reported the AEFI. All expected cell frequencies were greater than five. There was a statistically significant difference between the number of respondents who have encountered an AEFI and those who have reported it.

The difference between the percent of HW's who encountered an AEFI and those who reported one increases in the following way; Consultancy physician for childrens < Vaccinator nurse < Family physician < Pediatrician < Nurse (Fig. 3).

A Mann-Whitney U test was run to determine if there were differences in years of experience between groups of "having ever reporting an AEFI" and groups of "Never Reporting an AEFI". Distributions of the experience years between the two groups posts were similar, as assessed by visual inspection. The difference between the median years of experience for "Having reported an AEFI" (14) and "Never reported an AEFI" (11) was not statistically significantly different, $U = 1360$, $z = 1.098$, $p = .27$.

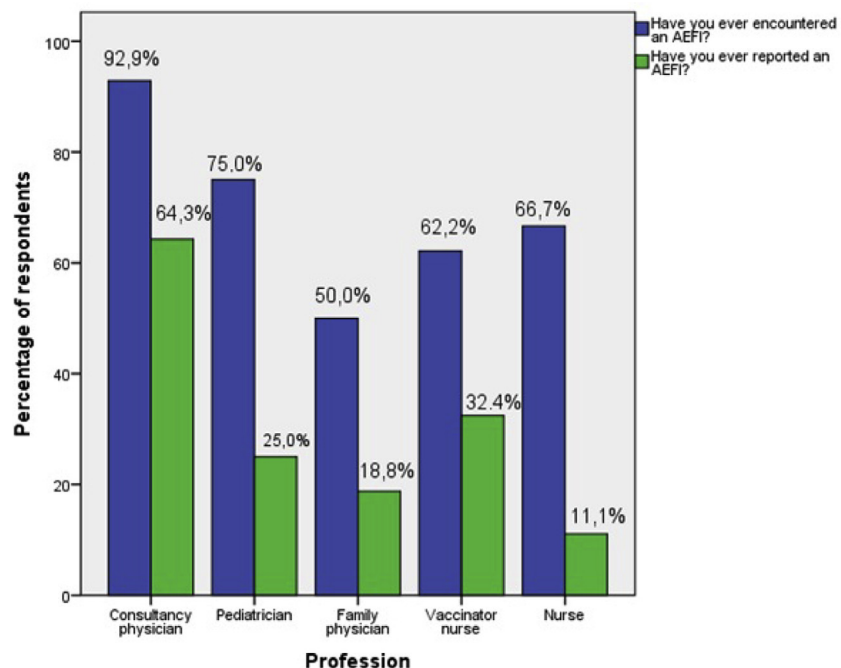


Fig. 3. The percentage of health workers who encounter an AEFI and the percentage of those who report an AEFI.

4.4.3. Differences between urban and rural areas

A Mann-Whitney U test was run to determine if there were differences in practice and attitude score between urban and rural health centers. Distributions of the practice and attitude scores for urban and rural health posts were similar, as assessed by visual inspection. Median knowledge scores for rural (13) and urban (14) was not statistically significantly different, $U = 1294,5$, $z = 0.545$, $p = .586$.

There was a statistically significant association between proportion of health workers of urban areas (78,1%) and health workers of rural areas (57,9%) having ever encountered an AEFI ($\chi^2(1) = 4.700$, $p = .030$). Despite this, the difference between health workers of urban areas (39,1%) and health workers of rural areas (31,6%) having ever reported an AEFI was not statistically significant, ($\chi^2(1) = 0.578$, $p = .447$).

This illustrates again the fact that the health care workers lack knowledge about AEFI surveillance system in Albania. The years of practicing the profession did not influence in the total score of “Practice and attitude toward reporting and managing an AEFI”.

Although the majority of health care professionals have encountered an AEFI during their practice (72/102, 70,5%), half of them have never reported an AEFI (37/102, 36,2%) and only 31,37 (32/102) of them claimed having ever filled an AEFI reporting form. This suggests that other ways other than the formal reporting form are practiced. The same difference in proportions is noted when they were asked if they have seen and reported any AEFI during the last year. This indicates lack of familiarity and knowledge about AEFI surveillance system and practice. Although most of the respondents replied that they did know how to fill an AEFI reporting form (65/102, 63,7%), almost half of them have never filled an AEFI reporting form (32/102, 31,3%). Although 70,6% (72/102) of them did know from where to supply AEFI reporting form, only 63,7% (65/102) of them actually had the AEFI reporting form in their work setting. It is noticed also that even though parents reported to health care workers for every event of the child, only 58,8% (60/102) of them reported this events to a higher authority. 68% (49/72) of the respondents who reported to have seen a serious AEFI referred that they managed the AEFI in their setting without reporting it to a more specialized consult. Some of the pediatricians declared that dealing with AEFI was not part of their professional practice and delegated that to the child consultancy staff. None of the interviewed pediatrician had the AEFI reporting form in her/his work setting and they even declared that whenever a child was presented to them with a post-vaccination event they immediately sent him back to the child consultancy physician where the vaccine was administered. Only 1/12 (8,3%) of the pediatricians knew how to fill an AEFI reporting form. They reported they did not have an instruction manual to deal with AEFI (4/12, 33,3%).

92/102 claimed that they have been facing in continuity with parents refusing the vaccination of the child, especially when rumors about vaccination were given space in media. MMR is the vaccine which is refused the most, but generally care givers do not differentiate between this and other vaccines and refuse all vaccination schedule of their child. 83,3% of the respondents reported that the number of refutations and hesitations about vaccination has increased ultimately.

4.5. Perception and knowledge of health care workers about reporting adverse events following immunization

There were 8 questions to assess the perception and attitude of health care professionals toward AEFI reporting for a maximum of 7 points scored. The frequency of perception level are given in the Fig. 4.

As it is noticed from Fig. 3 the overall perception level is “good” with 76,5% of the respondents having a score of total perception points over 50%. Only 7,8% (8/102) of the respondents had poor perception level.

A Kruskal-Wallis H test was run to determine if there were differences in knowledge and perception of AEFI score between five groups of health care professionals. Distributions of knowledge and perception scores were not similar for all groups, as assessed by visual inspection of a box plot. The mean rank of scores was not statistically significantly different between groups, $\chi^2(4) = 7.082$, $p = .132$.

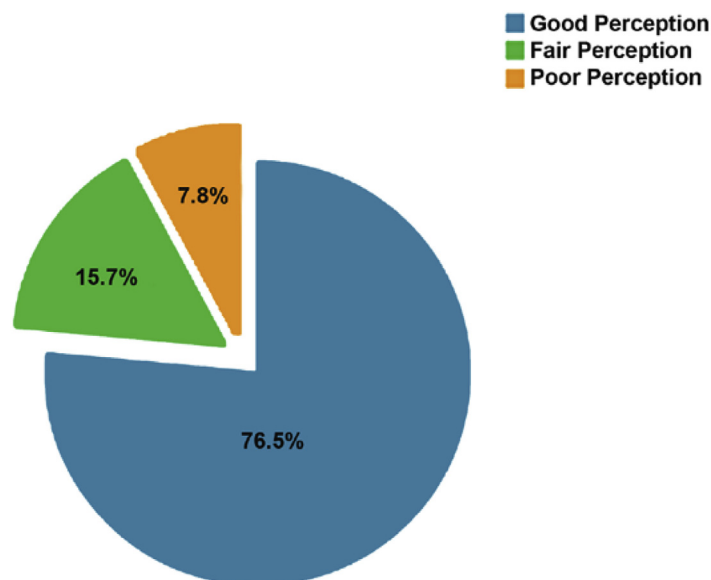


Fig. 4. Perception and knowledge level of health care professionals toward AEFI.

A Mann-Whitney U test was run to determine if there were differences in perception and knowledge score between “Being trained about AEFI” and “Not being trained about AEFI” group. Distributions of the perception and knowledge score in the two groups were similar as assessed by visual inspection. Median knowledge scores for “Being trained about AEFI” (5) and “Not being trained about AEFI” (5) were not statistically different, $U = 1254,5$, $z = 0.860$, $p = .390$.

When they were asked about the factors that incite them to report, 32,4% (33/102) of them replied that the primary cause would be the health condition of the child, 8,8% (9/102) said that parents concerns would be a reason for reporting. Some other replies were; all the cases we observe are a good reason for reporting (7,8%), feeling responsible for reporting (2%), repeated cases of the event (2%), serious events (7,8%), to decrease the consequences of AEFI (1%), to prevent the occurrence of AEFI in the future (3,9%), the improvement of vaccine quality (1%), the enhance vaccine safety (2,9%), to incite training (2%), to incite studies on this sector (2%), and a few replied that they would report only reactions that were considered really AEFI (1%).

The majority of the child consultancy physicians acknowledged that it was their responsibility to report an AEFI (78,6%, 22/28), while 25% (3/12) of the pediatricians, 68,8% (11/16) of the family physicians, 83,8% (31/37) of the vaccinators and 77,8% (7/9) of the nurses felt responsible for reporting. Difference in proportions was tested using Fisher exact test $p = .001$. Almost all the pediatricians and family physicians pretended that AEFI reporting was not part of their job and delegated it to the child consultancy department.

Majority of the respondents (88,23%, 90/102) believed that enhancing AEFI surveillance could increase vaccine safety. A high percentage of the respondents (84/102, 82,35%) responded that they thought the event was not related to the vaccine and for this reason they did not report. Most of the child consultancy physicians updated themselves every year about adverse events following immunization; 20/28 (71,4%). Only a few pediatricians get updated information about AEFI every year; 7/12 (58,3%) compared with other occupational groups like family physicians; 14/16 (87,5%), vaccination nurses; 25/37 (67,5%) and general nurses; 6/9 (66,7%). This demonstrated the lack of interest of pediatricians toward adverse events following immunization due to their belief that this is not part of their responsibility.

Some of the health workers said that they usually discuss about AEFI in their work setting with other colleagues, especially about policies of reporting.

4.5.1. Barriers to reporting

Table 2 summarizes the reasons for not reporting.

Table 2. Proportion and frequency of health professionals reporting the following motivations for not reporting and AEFI.

Reasons for not reporting	Frequency	Reasons for not reporting	Frequency
I am not aware of AEFI reporting procedure	8(7,8%)	Fear that the consequences might fall on me	2(2%)
I have not observed any AEFI	45(44,1%)	Lack of belief that the event was related to vaccination	17(16,7%)
Neglected	14(13,7%)	Lack of knowledge about adverse events following immunization	3(2,9%)
Lack of interest	1(1%)	The event was not considered serious enough to be reported	2(2%)
Lack of availability of AEFI reporting form	10(9,8%)	Decrease of AEFI events during the last years	3(2,9%)

Although 99% (1001/102) of the respondents replied that they knew what was an AEFI and they would readily recognize an AEFI, several of them did not have a clear definition of what is considered an AEFI.

Another barrier to reporting is not having a clear definition of what was reportable. While some other health professionals stated that serious adverse events were referred to the Mother Teresa Hospital for a specialized treatment and this was considered as a reported AEFI. Thus underreporting might be explained by the different perceptions of HW's about what constitutes an AEFI and what are the reportable AEFIs.

Although only a few respondents responded that the fear of the consequences might impede them to report an AEFI, more of them declared that there have been cases when they referred cases with AEFI to tertiary health care hospitals and got feedback charging on them and blaming accuses from parents and even from other health care workers. Especially consultancy physicians declared they are not protected and blamed regardless of the reason of AEFI. Nevertheless, the main reason for not reporting was because a respondent thought he or she had not observed an AEFI (44,1%). Univariate analysis identified two variables significantly associated with not reporting; profession type and work setting. There was no statistically significant difference between years of experience categories and the proportion of health professionals having ever reported an AEFI ($\chi^2(4) = .533, p = .970$). Thus the number of years they have worked in that profession did not influence on the practice of reporting AEFI. The age was not a factor which influenced the attitudes of HW in reporting AEFI ($\chi^2(3) = 4.349, p = .226$).

4.5.2. Preferred method of reporting

The preferred method of reporting is through paper form. The preferred way of reporting was; "through a printed reporting form" (58,8%), followed by the respondents who preferred all the possible ways of reporting (23,52%) like email, reporting form, through a internet based system, through an application in smart phone and through short message (SMS). The smart phone application was preferred by 13,75% of the respondents. When asked whether internet might facilitate reporting, 82/102 (80,4%) of the respondents answered "yes". Some of the health workers suggested the construction of an electronic system linked to their workplace which would allow an automatic submission and reporting of AEFI.

4.5.3. Vaccine resistant groups

When asked about whether there have been vaccination refusals or hesitate to vaccinate, almost all the respondents replied "YES" and completed the reply

declaring that the most vaccine resistant groups were parents who were health care providers (mainly physicians), parents from religious groups and parents who had a previous history of AEFI with the elder child. Health workers noticed that most of the refusals more often occurred for certain vaccines, like MMR, DTP and Pentavalent vaccine. Generally a low level of education among the parents is one of the main factors influencing parent's perception about AEFI. This kind of group were influenced by information for AEFI in media, internet, anti-vaccination TV programs and other parents incorrectly informing them about links between vaccination and AEFI and even from other health care providers who due to the lack of information, made false declarations about AEFI.

4.6. Knowledge about AEFI surveillance system

This is the section with the lowest score among health care professionals. There were a total of 10 questions to evaluate the knowledge of health care workers about stakeholders involved in AEFI surveillance system. The results are represented in Fig. 5.

A Kruskal-Wallis H test was run to determine if there were differences in knowledge score about AEFI surveillance system between health care professionals. Distributions of knowledge score about AEFI surveillance system were not similar for all groups, as assessed by visual inspection of a box plot. The distributions of this score were statistically significantly different between groups, $\chi^2(4) = 17.740$, $p = .001$. Subsequently, pair wise comparisons were performed using Dunn's (1964) procedure. A Bonferroni correction for multiple comparisons was made with statistical significance accepted at the $p < .01$ level. This post hoc

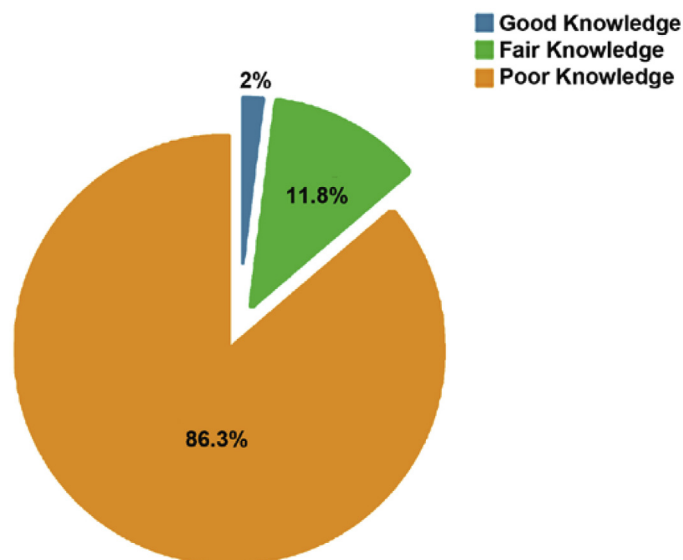


Fig. 5. Knowledge level of health care professionals about AEFI surveillance system.

analysis revealed statistically significant differences in knowledge score about AEFI surveillance system between consultancy nurses (mean rank = 40,91) and consultancy physicians (mean rank = 68,82) ($p < .001$) but no differences were noted between other groups.

A very small proportion of the respondents (2/102, 2%) had “Good Knowledge” level about the stakeholders involved in AEFI surveillance. Most of them (86,3%, 88/102) had “Poor knowledge” level.

Although the majority of the respondents did know that data about AEFI are analyzed (91/102, 89,2%) almost half of them (39/91, 42,85%) did not know who analyzed the data.

Although 51/102(50%) of them claimed that they did know who was responsible for investigation of events following immunization,most of them did not feel themselves as part of investigation procedure.

Although 58/102 (56,86%) of them reported that they have been in contact with National Immunization Program(NIP), only half of them (29/102, 28,43%) knew where was it settled. Most of the respondents confused the role of NIP and Pharmacovigilance sector and were not able to differentiate whether they had been visited by one or the other previously.

It is observed a lack of feedback information and communication between vaccine stakeholders. 70/102 (68,6%) of the respondents claimed that they did not receive any feedback information after they have reported for an AEFI.

4.7. Training

Although almost all of the respondents pretended to have knowledge about AEFI (99%, 101/102) most of them cited that they got this knowledge from daily literature textbooks (28,3%, 32/102), university studies (25,7%, 29/102), conferences and seminars (15,9%, 18/102), colleagues (3,5%, 4/102), and from vaccination schedule itself (5,3%, 6/102) and internet (3,5%, 4/102). Only 17,7% (20/102) of them stated that they got the knowledge about AEFI from training programs. However the respondents who reported to have got knowledge about AEFI from training programs had better knowledge level than those reporting other fonts of information. 21,88% (7/13) of the respondents with “Good knowledge” level reported to have gained knowledge about AEFI in trainings while 62,85% (22/35) of the participants categorized as “Poor knowledge” level cited that they got knowledge about AEFI during studies and literature. This difference could be explained in part by the incentives and awareness given during trainings programs and seminars. Nevertheless, having a previous AEFI training did not significantly influence the knowledge level on AEFI, $\chi^2(2) = 5.249$, $p = .072$ (Table 3).

Table 3. Relation between training and knowledge level.

	Knowledge level			Total
	Poor Knowledge	Fair Knowledge	Good Knowledge	
No Training	28 40,00%	36 51,43%	6 8,57%	70 100,00%
Training	7 21,88%	18 56,25%	7 21,88%	32 100,00%
Total	35 34,31%	54 52,94%	13 12,75%	102 100,00%

Majority of the respondents did not have any training about AEFI (68,6%, 70/102). Although 31,37% (32/102) of the respondents cited to have got a previous training about AEFI, only 37,5%(12/32) of them recalled when they got this training. 62,5% (20/30) could not recall when they might have been trained. The ones who recalled the last training claimed that it has been more than two years ago and a few of them stated that they got training from colleagues with more experience in the field. A fewer proportion of respondents claimed to have been trained about causality assessment (8,8%) and the way of reporting an AEFI (26,47%).

Majority of the respondents were ready to learn more about adverse events following immunization and requested periodic training (every year) and updated information about AEFI information (93,13%, 95/102).

5. Discussion

The mean of total scores in percentage was 54,1% ($\pm 13,8$). The mean percentage score of the section regarding practice and attitude toward AEFI was 67% ($\pm 20,24$), while the mean percentage score of perception and knowledge about AEFI was 74,2% ($\pm 16,2$). The section which got the lowest score was knowledge about AEFI system which got 27,8% ($\pm 17,7$). This suggests that although health care professionals have a good perception about AEFI they do not have as much as good practice of reporting and they do not have good knowledge about AEFI surveillance process and stakeholders involved in vaccine safety. This influences their attitude toward surveillance and reporting of AEFI. A positive and encouraging finding from our study is that almost all of the health workers were conscious that reporting AEFI increases vaccine safety. The good perception levels of healthcare workers indicate the good will of them to do reporting of adverse events following immunization. A few respondents stated that the motivation they did not report until that moment was because of fear that the consequences might fall on them. Lack of motivation and staff anxiety influences negatively to AEFI

surveillance and reporting. It should also be noticed that in a few rural health posts the role of pediatrician was covered by family physician who treats health problems of adults and children. In these areas the family physician was unaware of AEFI surveillance and believed that this was the responsibility of vaccination nurses. However there were no difference in knowledge level between urban and rural areas indicating that work setting do not influence the knowledge about AEFI. The difference between the proportion of health workers who reasserted that they have encountered an AEFI during their practice and those who stated to have reported an AEFI suggests that AEFI reporting is neglected.

Generally stating health staff out of the child consultancy setting was unaware and not interested about surveillance and reporting of AEFI. They thought this was part of staff which carried vaccination. This is an indicator to enhance awareness through vaccination training. Some of the respondents declared that reporting AEFI was not part of their clinical responsibilities. This emphasizes the need of sensitizing the health care workers on AEFI surveillance.

Poor knowledge level might be explained also by the type of font of information used to get knowledge. Textbooks and university graduation developed many years ago might not be an optimal font of information as they are not updated with the new information about AEFI. There was no statistically significant correlation between years of experience and knowledge about AEFI, although it is supposed that as the years of experience increase, the practice and knowledge level increase proportionally. This might be explained partially by the fact that AEFI surveillance system is relatively new in Albania and although there has passed about 14 years since its inception, health staff are still unaware about this system. Moreover some of the respondents were insecure about the definition of AEFI and what should be and not be reported. This leads to insufficient and inconsistent information about AEFI and impossibility to deal correctly with patients who refuse vaccination. When they were asked about any serious event they have encountered during their work most of them replied: edema, abscess, fever, cyanosis, generalized urticaries, lipotimia, pallor and fretfulness. Serious symptoms such as convulsions/seizures and encephalopathy/encephalitis were not cited. This suggests lack of knowledge about AEFI and underreporting of such symptoms. Because the frequency of occurrence of serious AEFI is low it is easy for them to be under-reported or missed completely. Although the preferred method of reporting was AEFI reporting form, most of the health workers declared that they contact through phone with care takers of children and solve the situation. This also indicates an underreporting situation. 68,6% of the respondents claimed that they did not get feedback information. This demonstrates a lack of communication between vaccine safety stakeholders. A majority of the respondents (68,6%) stated that they did not get any training about AEFI but almost all of them were ready to learn more about

AEFI surveillance. This shows interest from them to get more knowledge and report AEFI.

Although 52,6% of the responders preferred the paper form of reporting, an electronic based report would reduce the time needed to fulfill an AEFI reporting form, increase the accuracy and quality of reporting using as data entry methods like pre-defined terms in checklists might ascertain relevant information. However such predefined terms might be a font of bias as they focus on specific symptoms and signs and probably excluding unexpected cases. The lack of internet in various rural areas and lack of knowledge of health workers about internet usage might be an obstacle for implementing this method of reporting. Report completeness is critical to the validity of AEFI reports [13]. However the transfer from a paper/ telephone way of reporting to a completely web-based should be done with caution as the reports derived from HW who are familiar with the paper form but not familiar with internet might be lost.

For subject having an AEFI that come to medical attention, careful medical evaluation is required to confirm the diagnosis, assess the probability that vaccine caused the AEFI and assess the safety of future immunizations [14]. Assessing the possibility of future immunizations is particularly very challenging as there is a lack of scientific data regarding the risk of recurrence of AEFI. Another group of patients who need expert medical advice are patients with underlying medical conditions that may alter the risk of an adverse event and/or lead to reduced vaccine effectiveness [15]. Such specialized clinical services for patients with previous AEFI or possible contraindications to immunization have been established in several locations and the experience of other countries like Australia, Italy and the United Kingdom has demonstrated that a systematic approach to patients with previous AEFI history is associated with high acceptance of re immunization [16, 17, 18]. These specialized services are helpful also to educate public and physicians about vaccine adverse events [16]. Trained staff is especially important during immunization campaigns.

Training of health care workers is very important. According to WHO immunization safety surveillance needs to include training of all health workers at all levels in order to enable appropriate response at all levels in the system [19]. The focus on training is put also in a study by Bedford et al. (2005), who specifies that health professionals engaged in vaccination need to be trained so that they are able to provide accurate and up to date information about the diseases and vaccines to their patients, ensure that their practice is safe and effective and also give a high standard of care [1]. In a study by Hutchinson et al. (2007) it was found that the familiarity of health workers with the AEFI surveillance system was dependent on training in AEFI [6]. Training was associated with higher reporting rates amongst health workers, especially nurses. Although training is essential for health care

providers, only 35% of 26 studied European Union countries had developed a training program or manual for nurses on prevention, identification and treatment of AEFI [20].

93,13% of the respondents answered they need training about AEFI. This is an encouraging result showing the will of them to conduct AEFI surveillance and points out the importance of communication between public health authorities and health care providers.

The fact that the majority of respondents had an AEFI reporting form in their setting is an encouraging result. Availability of AEFI reporting forms at the immunization centers significantly influences the reporting as it represents the basic tool essential in carrying out AEFI surveillance. In a ten month prospective study by Doodoo et al. (2007) in Ghana, it was noted a six hundred percent increase in AEFI reporting rate following training, monitory visits and provision of AEFI reporting forms [4]. Human capacity development is central to address multiple vaccine safety issues. Reporting AEFI cases must always be encouraged but improved capacity in terms of know-how should also be accompanied by the development of an infrastructure that supports ongoing monitoring of the safe use of vaccines [21]. WHO (2011) asserts that as the AEFI cases are not reported for a long period of time, health workers lose interest or forget about appropriate procedures to manage AEFI cases [22].

6. Conclusions

From this study we could conclude that even if an AEFI would be detected there are a few barriers to reporting. However, despite the barriers of reporting, under-reporting might be attributed to the less reactive vaccines during the last years. This decreases the awareness of health workers toward reporting AEFIs as they do not need to use frequently the reporting form. Although the number of health care professionals who fear of personal consequences is low, this might be a factor which contributes to poor perception on AEFI surveillance.

Strengthening reporting systems by increasing healthcare provider participation and knowledge about AEFI can enhance surveillance efforts during real-time events, like mass immunization in a pandemic.

Another very important practice to be implemented in daily work practice of health workers is the screening of children for possible contra-indications prior to the immunization. This will minimize the risk of serious adverse reactions and prevent any further complications which would enhance the negative impact on immunization program.

The findings from this study are aimed to be used as a base to enhance vaccine safety surveillance by healthcare authorities and immunization authorities. Based

on the results from this study we have developed some recommendations like follows:

- It is necessary to develop training programs. Staff at all levels should be trained in diagnosing, treating and reporting of AEFIs in order to avoid underreporting and increase public trust on vaccination [1]. Beside the passive surveillance, active surveillance with trained staff to conduct pharmacovigilance might be implemented. Proper training modules might prevent a substantial number of AEFI which result from immunization errors.
- Developing educational programs. Studies demonstrate that educational programs can have a significant impact on health professional behavior toward reporting of AEFI [10]. Appropriate case ascertainment improves specificity and lowers the operating costs of surveillance systems [3]. This kind of programs might be integrated within the system of continuous educational programs for health care workers and coordinated with national immunization program activities. It might be thought to include them also to the university study programs. Educational programs in pre-natal consulting to increase pregnant women's awareness about child care are also important.
- Building feedback systems to give information on AEFI result have also resulted in increased reporting rate of AEFI [10]. A two-way flow of information between health care providers and public health authorities might improve the quality and interpretation of data.
- Another way to increase the reporting of ADRs is through the promotion and implementation of patient self-reporting. Their role is complementary to that of health providers and this has been confirmed in various studies [2].
- It is important also to find and build mechanisms to fade barriers of reporting adverse events following immunization. The provisions should take in consideration every barrier and prevent it to continue be an obstacle for reporting.
- To address the reasons of under-reporting, AEFI reporting guidelines should be made available in the form of booklets and posters in different locations inside the health care facilities. This form would be very productive as it would serve as a constant reminder for the health workers.
- Mentorship programs between new health workers and experienced health workers also should be included in the manuals of AEFI policies. This mentorship programs will help to remind and alert the health workers of the importance of AEFI reporting.

The surveillance system and its methods for reporting should be “user friendly” in order for all the health workers be easy to access in different work settings [23].

The questionnaire used for collecting data of this study was a completed set of questions which tested all points and aspects regarding knowledge of health workers about surveillance and reporting of adverse events following immunization. Other questionnaires with different questions might be as well used to study the same objective. However there are a core of questions which are necessary to conduct studies like this. In every study of this type it is important to evaluate; the knowledge about AEFI from a medical point of view, knowledge about the AEFI surveillance system, practice and perceptions about AEFI reporting, questions about training.

6.1. Limitations and strengths of the study

Despite visiting all the health centers of the district of Tirana, we did not interview the health workers working in private health settings like private maternity hospitals. In the last years there is a tendency of Albanian mothers to give birth to their children at the private Hospitals where the infant is vaccinated with the first two vaccines administered within 24 hours after birth. Although all the private hospitals and private maternity clinics are supplied with vaccines from National Immunization Program, they do sometimes advice and administer to the child other brands of the specified vaccine. Health workers working at the private sector have different perceptions and attitudes toward reporting adverse events following immunization.

Another group of health workers who have not been interviewed are those who work at tertiary care facilities like hospitals. A minor number of vaccines with serious AEFI might seek for treatment in hospitals or might be referred by primary health care workers to the hospitals. Therefore physicians working at these facilities are responsible too for reporting AEFI. Other limitation includes recall bias. For this reason some questions were re-phrased and repeated in the questionnaire.

The questionnaire is conducted through interviews conducted face to face, not giving the possibility to the respondents to complete in clusters the questionnaire and give the same responses. Although the study was conducted only in the district of Tirana, the results might be generalized for all the country as the reporting policy and practices are the same in all districts of Albania.

Declarations

Author contribution statement

Irsida Mehmeti: Performed the experiments; Wrote the paper.

Erida Nelaj: Performed the experiments.

Artan Simaku: Analyzed and interpreted the data.

Eugena Tomini: Contributed reagents, materials, analysis tools or data.

Silva Bino: Conceived and designed the experiments.

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Competing interest statement

The authors declare the following conflict of interests: Silva Bino, Erida Nelaj, Artan Simaku and Eugena Tomini; work for the National Institute of Public Health which is the technical and advisory organ of the Ministry of Health about public health issues and supervises the health centers used for the purpose of this study. However, the interview was performed by Miss Irsida Mehmeti, who is not part of the National Institute of Public Health.

Additional information

No additional information is available for this paper.

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