Assessment of attitudes towards adverse events following immunization with oral poliovirus vaccine: a pilot study among high school students of Kinshasa, the Democratic Republic of Congo

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Objective: The aim of this study is to evaluate the reaction of students to adverse events following immunization in order to offer a baseline for developing a communication and risk management plan.

Method: This is a cross-sectional study conducted in Kinshasa. A survey was conducted between the third and the fourth rounds of Supplementary Immunization Activity. Nine hundred and fifty questionnaires were used and addressed students who attended this university from 1 to 10 June 2011.

Results: Completed questionnaires were received from 848 students, with 485 females (57.2%), 343 males (40.4%), and 20 unknown (2.4%); 46.9% of students were from the faculty of medicine and 24.7% was from the third graduate degree. From those who completed the questionnaire, 136 (16.4%) reported experiencing an adverse events following immunization. Concerning the attitude of students towards adverse events following immunization, 79 students (58.5%) did nothing; 54 (40.0%) opted for self-medication; 2 (1.5%) went to the hospital.

Conclusion: The main finding of our study is the low rate of people referring to health-care providers for vaccine-related problems, more specially for adverse events following immunization. A risk management plan should be focused in strategies to increase communication between population and health-care providers.

Keywords: Adverse events following immunization (AEFI), Oral poliovirus vaccine (OPV), Attitude, Student, Kinshasa, Democratic Republic of Congo, Africa

Highlights

- There was a poliomyelitis outbreak affecting even adults in Kinshasa, Democratic Republic of Congo.
- A supplementary immunization activity was organized.
- This study evaluates the attitude of students towards AEFI.

- The results shows that 136 (16.4%) reported experiencing an AEFI.
- A minority of student referring to health-care providers for AEFI.

Introduction

Immunization proved successful in eradicating small-pox in twentieth century.^{1–3} Since 1988, when the World Health Assembly launched the Global Polio Eradication Initiative, poliomyelitis has been the focus of eradication efforts.^{4,5} However, polio is still endemic in three countries (Afghanistan, Pakistan,

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Figure 1 Attitude of students towards AEFI.

and Nigeria) and there are still outbreaks in some developing countries.⁶ In 2010 and 2011, a larger outbreak of a poliomyelitis outbreak involving wild poliovirus type 1 (WPV1) had been reported in Central Africa. The particularity of this outbreaks an abnormal number of cases of acute flaccid paralysis (AFP) among adults reported in Congo-Brazzaville, a neighboring country of Democratic Republic of Congo (DRC). There were an estimated 554 cases of AFP from 20 September 2010 to 27 February 2011. The median age was 20 years and the case fatality rate was 40%.^{7–10} A total of 317 cases of AFP were confirmed as poliomyelitis.

In DRC, from 1 January 2011 to 21 July 2011 a total of 1198 specimens were analyzed from patients with AFP and WPV1 was confirmed for 71 patients. Kinshasa, the capital of the country, provided most of the cases of WPV seen in adults, with a total of 18 cases.¹¹

The Expanded Program on Immunization of DRC in collaboration with all stakeholders involved in polio eradication organized a Supplementary Immunization Activity targeting the entire population of Kinshasa. Oral poliovirus vaccine (OPV) was administered to all age groups in 4 rounds. In March 2011, monovalent OPV type 1 (mOPV1) was administered to 9 863 458 persons. In April, 10 091 567 persons received mOPV1. In May, bivalent OPV types 1 and 3 (biOPV) was administered to 9 724 982 persons and 10 206 785 persons received mOPV1 in June.¹² One of the main reasons for the decrease in immunization coverage during the third round was the spread of a rumor that OPV was responsible for an outbreak of

conjunctivitis, which occurred during the same period as the mass immunization campaign.

An Adverse Event Following Immunization (AEFI) is defined as ‘any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine’.¹³ According to this definition, conjunctivitis in this case may be considered as an AEFI. Unfortunately, when data were collected, informing communities about AEFI was not a part of immunization campaign strategy and the communication tool for AEFI was no yet effective at national scale. The decrease of participation in immunization activities due to this AEFI may be explained by the poor system of AEFI surveillance and management in DRC and the poor quality of communication between the Expanded Program on Immunization and the population. Study and analysis of population’s knowledge and attitude is a key for the elaboration of a risk management and communication plan. The aim of this study is to evaluate the reaction of students to AEFI in order to offer a baseline for developing such a plan for vaccine concern.

Patients and Methods

This is a cross-sectional study. The survey was conducted between the third and the fourth rounds of mass immunization campaigns for the general population. A questionnaire was performed including multiple choice questions. The questionnaire assessed knowledge related to adverse drug reactions, adherence in immunization, history of AEFI, and attitude

towards AEFI (see Appendix). Data were collected by students of the Université Simon Kimbangu in Kinshasa. The study was supervised by a staff member of the DRC National Pharmacovigilance Center and a staff member of the national representation of the World Health Organization.

The questionnaire addressed students who attended this university from the 1 to 10 June 2011. It was given only to those who accepted to participate in the survey. Students had to answer immediately and the questionnaire was given back once fulfilled. Most of the time student had just to answer 'Yes', 'No', or 'Unknown'. Students could answer regardless of whether or not they had participated in the mass immunization campaigns.

Ethical approval

Ethical clearance for this study was granted by the Central Office Health Zone of Kinshasa. Ethics or institutional review board approval was not requested for this investigation. Written informed consent was obtained from the subjects before the samples and patient data were collected. Confidentiality of data was maintained.

Data management

Students' responses were entered into a database created with an Excel table and analyzed using the Statistical Package for Social Sciences (SPSS) version 15.0 for Windows (SPSS, Inc., Chicago, IL, USA). Analysis was limited to descriptive statistics. Qualitative data were expressed in terms of frequency and percentage; for quantitative data, we used mean $\pm$ standard deviation.

Results

Completed questionnaires were received from 848 students. One hundred and two were excluded because of insufficient information giving on overall response rate of 8.3%. Sex distribution shows that

485 (57.2%) students were females, while 343 (40.4%) were males. The gender was unknown for 20 students. The male: female ratio was 1.4:1.0. The average age was 26.6 ± 3.8 years (ranging from 19 to 41 years old). In this cohort, 46.9% of students were from the faculty of medicine and 24.7% was from the third graduate degree (Table 1).

Overall, 839 (97.9%) of students answered that every drug has an adverse drug reaction (ADR) and 794 (93.6%) answered that vaccines are drugs. Concerning adherence to immunization, 774 students received OPV during the first round of the immunization campaign (91.3%), 797 in the second (94.0%), and 821 in the third (96.8%). From those who completed the questionnaire, 136 (16.4%) reported experiencing an AEFI (Table 2).

The attitude of students towards AEFI was analyzed for those who experienced any AEFI during one of these three rounds: 79 (58.5%) did nothing; 54 (40.0%) opted for self-medication; and 2 (1.5%) students went to the hospital (Figure 1).

Discussion

The main difficulty in the discussion was to find articles related to OPV AEFI for comparison. This illustrates how poor the pharmacovigilance systems are in low- and middle-income countries where OPV is still in use compared to the developed countries where OPV has been withdrawn and replaced with inactivated polio vaccine because of the risk of vaccine associated paralytic poliomyelitis.^{14,15} In a recent report, Nzolo *et al.* documented AEFI during the second round of this mass immunization campaign, but one of the weaknesses of their study was the lack of denominator, as in passive pharmacovigilance in general.¹² This article should be complementary and gives an idea of the proportion of students who experienced AEFI.

In our study, 136 students (16.4%) reported experiencing an AEFI. According to the World Health Organization, common minor vaccine reactions rate is less than 1%, but the rate may appear to be raised in certain situations, such as during mass campaigns.^{16,17} In our knowledge, this is the first study which reports the rate of adverse event following a mass immunization campaign in our country. Determination of rate is important for further evaluation of mass immunization campaigns.

According to our results, after experiencing any AEFI, 58.5% of students did not perform any action, 40% opted for self-medication, and less than 2% went to the hospital. This result illustrates the problem of under-reporting, which is the main weakness of passive surveillance.¹⁸ Management of AEFI by the population without the implication of health-care providers may be the base of development and spread

Table 1 Characteristics of participants

Characteristics	Frequency	Percentage
Gender		
Male	485	57.2
Female	343	40.4
Unknown	20	2.4
Education		
Medicine	398	46.9
Informatics	227	26.8
Economic sciences	96	11.3
Agronomy	127	15.0
Unknown	0	0
Degree		
1st degree	201	23.7
2nd degree	207	24.4
3rd degree	209	24.7
4th degree	109	12.9
5th degree	85	10.0
6th degree	37	4.3
Unknown	0	0

Table 2 Assessment of knowledge and participation in immunization

Questions/answers	Frequency	Percentage (%)
Every drug has an ADR		
Yes	830	97.9
No	15	1.8
Don't know	3	0.3
Vaccines are drugs		
Yes	794	93.6
No	45	5.3
Don't know	9	1.1
Did you get OPV during the first round?		
Yes	774	91.3
No	69	8.1
Don't know	5	0.6
Did you get OPV during the second round?		
Yes	797	94.0
No	41	4.8
Don't know	10	1.2
Did you get OPV during the third round?		
Yes	821	96.8
No	22	2.6
Don't know	5	0.6
Did you experience an AEFI?		
Yes	139	16.4
No	707	83.4
Don't know	2	0.2

of rumors.^{19,20} Therefore, waiting in health facilities for the return of patients for AEFI reporting after immunization should not be a good option for an AEFI surveillance system. Other strategies should be explored, such as active surveillance with trained Pharmacovigilance Center staff members, community-based reporting using trained member of communities, and patient's reporting. Nevertheless, an in-deep study of the population is needed to ensure that involvement of community and patients in AEFI reporting will not be an obstacle for the immunization system.

In our study group, 794 students answered that vaccines were drugs (93.6%) and for 839 students (97.9%), every drug has an ADR. Such evaluation is important before explaining that a vaccine can harm. This high level of knowledge could explain why the immunization coverage was the highest during the third round in this study group (96.8%), while the number of people accepting immunization was the lowest in the general population during the same period.¹² However, the survey was realized in urban area, among high students in Kinshasa. This is representative of neither the whole population of Kinshasa nor the population of the DRC, but gives us an idea about how knowledge can influence attitudes towards immunization. Nevertheless, this result suggests important questions such as if populations in the capital, where health facilities and health-care providers are accessible, do not refer for AEFIs what should be the attitude of the population in rural area where there is a decreased

accessibility because of distance and/or natural barriers.

One of the weaknesses of this study was the non-inclusion of opened or free questions. These questions could help us, for example, to understand the reason why some students did not receive OPV during the immunization campaigns and to have further information about AEFI description for those who experienced some and the type of self-medication used. Nevertheless, according to Nzolo *et al.* who published about AEFI report from students and pupils including those from USK during this period, it was found that the most common AEFI was headache, abdominal pain, fever, diarrhea, and asthenia.¹² Another weakness is that our rate is based on what people remember from their experience with vaccines. We cannot assess this experience and there is a real risk of underestimation, as some, for example, had to remember an experience they had 3 months ago. Nevertheless, these results remain important as they are the first in our country and they can serve as baseline for further assessment in our AEFI surveillance system.

Conclusion

The main finding of our study is the low rate of people referring to health-care providers for vaccine-related problems, more specially for AEFI. A risk management plan should be focused in strategies to increase communication between population and health-care providers. The content of communication has to take in account the knowledge of the population about ADR for drugs in general. Further

evaluation of the knowledge and attitudes of people is need with a greater and representative sampler, including rural area and analphabetic people, to determine which message should be shared with the population in a national scale.

Disclaimer Statements

Contributors LK, DBN, MP, NN, and GKM conceived the study; LK, DBN, MP, and GKM designed the study protocol; DBN and MP carried out the clinical assessment; LK, DBN, MP, MBE, NN, MNA, and MKG carried out analysis and interpretation of the data. DBN, MP, NN, LNY, KC, and NM drafted the manuscript; MBE and MNA critically revised the manuscript for intellectual content. All authors read

and approved the final manuscript. DBN and MNA are guarantors of the paper. The authors thank all students who participated in this study.

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Conflicts of interest No benefits in any form have been received or will be received from any commercial party related directly or indirectly to the subject of this article. The authors report no conflicts of interest.

Ethics approval A written consent was obtained from institutional authorities before addressing the students. Students' reporting of AEFIs was free. Ethics or IRB approval was not requested for this investigation.

Appendix

Questionnaire pour l'évaluation de la vaccination Dans le cadre de la réalisation d'un travail de fin d'étude

Date de naissance:/...../19.....	Sexe: M/...../F/...../
Faculté:	Promotion:

<p>1) Savez-vous que tout médicament possède un effet secondaire? OUI/...../NON/...../</p> <p>2) Donnez l'exemple de 3 médicaments avec chacun son effet secondaire</p> <table border="1"> <thead> <tr> <th>N°</th> <th>Médicaments</th> <th>Effets secondaires</th> </tr> </thead> <tbody> <tr><td>1)</td><td></td><td></td></tr> <tr><td>2)</td><td></td><td></td></tr> <tr><td>3)</td><td></td><td></td></tr> </tbody> </table> <p>3) Est-ce que le vaccin est un médicament? OUI/...../NON/...../</p> <p>4) Avez-vous pris le vaccin anti-poliomyélite lors de la première phase au mois de mars? OUI/...../NON/...../</p> <p>5) Avez-vous pris le vaccin anti-poliomyélite lors de la 2^{ème} phase au mois d'avril?</p>	N°	Médicaments	Effets secondaires	1)			2)			3)			<p>OUI/...../NON/...../</p> <p>6) Avez-vous pris le vaccin anti-poliomyélite lors de la 3^{ème} phase au mois de mai? OUI/...../NON/...../</p> <p>7) Avez-vous ressenti un effet secondaire après avoir été vacciné à l'une des phases ? OUI/...../NON/...../</p> <p>Si OUI, alors répondez aux questions ci-dessous</p> <p>8) Vous avez ressenti cet effet secondaire à quelle phase ? 1^{ère} phase 2^{ème} phase 3^{ème} phase</p> <p>9) Qu'avez-vous fait ?</p> <p>a) Je suis allé à l'hôpital</p> <p>b) J'ai informé un médecin ou un autre agent de santé</p> <p>c) J'ai pris moi-même un médicament</p> <p>d) Je n'ai rien fait</p>
N°	Médicaments	Effets secondaires											
1)													
2)													
3)													

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