



Psychogenic illness following vaccination: exploratory study of mass vaccination against pandemic influenza A (H1N1) in 2009 in South Korea

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Purpose: Adverse events during mass vaccination campaigns have had a profoundly negative impact on vaccine coverage rates. The objective of the study was to identify the characteristics of reported psychogenic illness cases following mass vaccination that needed further interventions of the national immunization program.

Materials and Methods: We collected documents that were submitted to the Korea Centers for Disease Control and Prevention for vaccine injury compensation, and analyzed cases of psychogenic illness following pandemic influenza A (H1N1) vaccination in 2009 which were confirmed by the Korean Advisory Committee on Vaccine Injury Compensation.

Results: During the 2009-2010 influenza season, 13 million Koreans were vaccinated against pandemic influenza. Of 28 reported psychogenic illness cases following immunization, 25 were vaccinated through school-located mass immunization. Significant numbers of them were female adolescents (68%) or had underlying vulnerable conditions or emotional life stressors (36%). They required lengthy hospitalization (median, 7 days) and high medical costs (median, US \$1,582 per case).

Conclusion: Health authorities and organizers of future mass vaccinations should be well aware of the possible occurrence of psychogenic illness, acknowledge their detailed characteristics, and take its economic burden into account to mitigate the risk of transmission of infectious diseases efficiently.

Keywords: Vaccination, Psychophysiological disorders, Hysteria, Students, Mass vaccination, Influenza vaccines

Introduction

Psychogenic illness following vaccination (PIV) is a syndrome that is a physiological reaction to a psychiatric stimulus related to anxiety about injections, and consists of a constellation of symptoms, such as dizziness, headache, hyperventilation, dyspnea, and nausea [1,2]. Previous reports suggested that it primarily affects adolescents in a school setting or in the early stages of mass immunization and usually develops within a day of vaccination [1,2]. A chain reaction following the index case may attract mass media attention and is promptly spread by the people who share similar beliefs about the vaccine and its safety [3].

School-located mass vaccination has been considered one of the major public health measures to immunize adolescents [4]. This strategy has been considered for selected vaccines (e.g., human papillomavirus and influenza vaccines) or in particular circum-

stances such as emergence of highly pathogenic infectious diseases and outbreaks of vaccine-preventable diseases [5]. However, in order to carry out a successful mass vaccination campaign using a school platform, it is necessary to understand and carefully prepare for possible occurrences of PIV. An inappropriate initial response to those individual PIV cases may result in clusters of subjects with anxiety, unnecessary medical intervention, large resource expenditures, and subsequent failure to achieve sufficient vaccine coverage, especially during a mass vaccination [2].

During the 2009-2010 influenza season, the impending threat of pandemic influenza urged Korean policy-makers to set strategies, such as prioritization of several groups including healthcare workers, schoolchildren, young children aged between 6 months and 6 years, pregnant women, military personnel, caregivers of young infants, persons living in social welfare facilities, persons with chronic medical conditions and the elderly [6]. Also, they implemented a mass vaccination campaign for military personnel and school children because it was an efficient measure to achieve high vaccination coverage within a short period of time. During the campaign, however, increased numbers of reports of adverse events following immunization (AEFIs) raised public concerns related to safety issues of novel vaccines and induced an increased number of PIV cases after school-located mass vaccination. Since the National Vaccine Injury Compensation System (NVICS) operated by Korea Centers for Disease Control and Prevention (KCDC) was started in 1995, PIV cases were reported following two nationwide mass vaccination campaigns: 27 cases following a mass vaccination campaign against huge measles outbreaks in 2000-2001 and 28 cases following a pandemic influenza vaccination campaign in 2009-2010 (unpublished, KCDC). There has been no PIV case which was not related with those two campaigns by 2015.

In our study, we investigated PIV cases related to the mass vaccination campaign against pandemic influenza during the 2009-2010 season from the NVICS data. We aimed to find demographic and clinical characteristics of PIV. In addition, we intended to demonstrate the economic burden of PIV on an individual and national level while describing its clinical course and healthcare seeking behaviours.

Materials and Methods

In South Korea, AEFIs are passively reported by physicians or patients through a web-based system. Serious AEFIs, clus-

tered AEFIs, any AEFI which raised public concerns or cases that claimed for compensation are investigated by the KCDC [7]. All requested cases are investigated primarily by the vaccine injury investigation team, and then reviewed by the Korean Advisory Committee on Vaccine Injury Compensation, which is composed of various experts including allergists, pediatricians, infectious disease specialists, lawyers, epidemiologists, and public health authorities [7]. The Korean government provides compensation to the injured people when the causal relationship with certain vaccines are approved by the committee. The requirement for a claim for compensation is a direct medical cost exceeding US \$270 (US \$1 = South Korean ₩1,100) [7]. In this study, only direct medical costs were considered for analysis.

We analyzed epidemiological features, clinical manifestations and treatments in the reports, which were concluded as psychogenic illness following monovalent 2009 pandemic influenza A (H1N1) vaccination. A vulnerable condition for PIV was defined as a prior resistance to vaccination or underlying personality or psychiatric disorder. A life stressor was defined as excessive sociological stress that might attribute to developing PIV, such as serious problems in child-parent relationships and school bullying. We focused on events relating to school-located mass vaccination, and analyzed PIV cases following school-located mass vaccination and cases following individual vaccination separately.

Ethics statement

This study is a review of compiled data from the NVICS, for which the KCDC did not require ethical review and approval.

Results

A total of 28 cases of psychogenic illness following pandemic influenza A (H1N1) vaccination claimed for vaccine injury compensation in 2009-2010. Their demographic and clinical characteristics were demonstrated in Table 1. Three were adults >30 years of age who were individually immunized in public health centers. All other cases were from school-located vaccination. School-based vaccination was associated with 3.7 PIV cases per 1,000,000 doses, in contrast to 0.5 PIV cases per 1,000,000 doses of individual vaccination.

Demographic and clinical characteristics of PIV in school-located vaccination

Among the 25 PIV cases in school-based vaccination, the ma-

Table 1. Demographic and clinical characteristics of psychogenic illness cases following immunization against pandemic influenza A (H1N1) in South Korea, 2009-2010

No.	Age (yr)	Sex	Symptoms	Onset of symptoms after vaccination	Duration of symptoms	Identified vulnerable condition (V) or stressors (S)	Diagnosis upon discharge from hospital
1	10	M	Paralysis, dyspnea, nausea, vomiting	15 min	2 days	-	Guillain-Barré syndrome suspect, conversion disorder suspect, vaccine adverse effect suspect
2	10	M	Weakness in the left leg	6 hr	12 days	-	Temporary synovitis suspect, vaccine adverse effect suspect
3	10	F	Tremors of arms	1 hr	68 days	-	Drug-induced tremor suspect, peripheral neuropathy suspect, acute cerebellar movement disorder suspect
4	11	M	Myalgia, dyspnea	6 hr	6 days	-	Hyperventilation, pain in limb
5	12	F	Tremors of the right leg, headache	5 min	7 days	-	Headache, unspecified abnormal involuntary movements
6	12	F	General weakness, dyspnea, headache, abdominal pain	15 min	3 days	-	Neuropathy
7	12	F	Paralysis, dyspnea, syncope, vomiting, tingling sensations	1 hr	3 days	-	Encephalopathy suspect, anaphylaxis suspect
8	12	F	General weakness, headache, chilling, fever	5 min	14 days ^{a)}	V	General weakness
9	13	F	Dyspnea, nausea, headache, tic movement	Immediate	11 days ^{a)}	S, V	Conversion disorder suspect, myoclonus suspect
10	13	F	Tingling sensations in extremities, paresthesia, general weakness	30 min	7 days	-	Other symptoms and signs involving general sensations and perceptions, Guillain-Barré syndrome suspect
11	14	F	Dyspnea, dizziness, headache, chest pain	6 hr	17 days	-	Acute pharyngitis
12	14	M	Headache, nausea, dyspnea, dizziness, abdominal discomfort	5 min	5 days	-	Hyperventilation
13	14	M	Headache, chest discomfort, dyspnea, tingling sensations in extremities	5 min	8 days ^{a)}	V	Guillain-Barré syndrome suspect, late-onset cerebellar ataxia
14	14	M	Paresthesia in extremities, weakness, dyspnea, abdominal and chest discomfort	57 min	10 days	-	Neuropathy
15	15	F	General weakness	5 min	9 days	V	Muscle weakness
16	15	F	Dizziness, headache, general weakness	10 min	18 days ^{a)}	V	Vaccine adverse effect
17	15	M	Headache, general weakness	On the day of vaccination	20 days	-	Vaccine adverse effect suspect, headache
18	15	F	Weakness in the both arms, decreased visual acuity	5 min	8 days	-	Visual disorder
19	16	F	Weakness in the both legs	30 min	7 days ^{a)}	-	Myelopathy suspect
20	16	M	Chilling, headache, dizziness, weakness in the both legs, myoclonus	5 min	4 days	V, S	Myelopathy suspect
21	16	F	Dyspnea, dizziness, chest pain, abdominal pain, hyperventilation	2 days	6 days	V	Hyperventilation
22	16	F	Syncope, dizziness, nausea, dyspnea, general weakness	30 min	10 days ^{a)}	V	Vaccine adverse effect
23	17	F	Palpitation, tachypnea, chest discomfort	30 min	7 days	V	Hyperventilation syndrome, vaccine adverse effect
24	17	F	Dyspnea, tingling sensations on both legs, myalgia, hyperventilation	30 min	21 days	-	Muscle weakness
25	17	F	Myalgia, general weakness, tingling sensations	6 hr	14 days	-	Myelopathy
26	33	F	General weakness, sweating, flushing, agitation	5 min	3 mo	-	Vaccine adverse effect suspect, somatization disorder suspect
27	46	F	Myalgia, tingling sensations, dyspnea	90 min	1 day	-	Vaccine adverse effect suspect
28	68	F	Headache, chilling, nausea, myalgia	1 day	6 days	-	Headache

^{a)}Duration of admission data was presented, rather than duration of symptoms, due to incomplete data.

Table 2. Summary of psychogenic illness cases following immunization against pandemic influenza A (H1N1) in South Korea, 2009-2010

	Psychogenic illness cases (male:female)	No. of doses administered	Median age (range, yr)	Time of symptom onset	Duration of symptoms median (range, day)	Identified vulnerable conditions or stressors
Mass vaccination						
Total	25 (8:17)	6,797,092 ^{a)}	14 (10–17)	Immediate–2 days	11.9 (2–68) ^{c)}	9
Elementary school	7 (3:4)	-	11 (10–12)	5 min–6 hr	14.4 (2–68) ^{c)}	0
Middle school	11 (5:6)	-	14 (13–16)	Immediate–6 hr	10.3 (5–20) ^{c)}	5
High school	7 (0:7)	-	16 (15–17)	30 min–2 days	10.3 (6–21) ^{c)}	4
Individual vaccination	3 (0:3)	6,199,891 ^{b)}	49 (33–68)	5 min, 1.5 hr, 1 day	5 days, 6 days, ≥5 mo	0

^{a)}This number includes mass immunizations in school (6,173,321 doses) and the military (623,771 doses).

^{b)}This number includes small numbers of group immunizations among healthcare workers.

^{c)}In some cases, duration of admission was presented instead of duration of symptoms due to incomplete data availability. Further details are shown in Table 1.

majority (68%, 17/25) was girls (Table 1). The median age of them was 14 years (range, 10 to 18 years). There were seven, eleven, and seven cases reported in elementary, middle and high schools, respectively (Table 2).

Their clinical presentations were variable: weakness (76%), headache (48%), dyspnea (44%), lightheadedness (36%), nausea (32%), myalgia (32%), paraesthesia (28%), abdominal discomfort (28%), chest pain (24%), tremor (20%), hyperventilation (16%), myoclonus (12%), and chills (8%) (Table 1). In two cases, the exact time of onset of symptoms and signs was not available as health records only described them as “immediate” and “on the day of vaccination,” respectively. The onset of symptoms and signs ranged from immediately to 2 days after vaccination, and 70% (16/23) occurred within 30 minutes. There were seven cases (30%) with onset after 1 hour. The median duration of symptoms and signs was 8 days, and most of them (80%, 20/25) lasted for <2 weeks (Table 2).

All cases presented clinical manifestations without identifiable neurological problems. The initial clinical impressions of them were varied: hyperventilation, Guillain-Barré syndrome suspect (five cases each); neurosis, conversion disorder (four cases each); peripheral neuropathy (three cases); psychogenic movement disorder and anxiety disorder (two cases each); and myelopathy, encephalopathy, late onset cerebellar ataxia, depressive disorder, somatization, tension type headache, upper respiratory infection, Tic disorder, central nervous system disorder and optic neuritis (one case each). Most of them underwent extensive tests, such as magnetic resonance imaging (MRI), cerebrospinal fluid analysis, electromyography and echocardiography, but all their test results were normal or unspecific. After thorough medical investigation, the final diagnoses of the cases upon discharge were also variable, such as vaccine adverse effects, Guillain-Barré

syndrome suspect, conversion disorder, depressive disorder, hyperventilation syndrome, somatization, and neurosis (Table 1). Their treatment mainly consisted of conservative management including hydration, pain control, and reassurance.

According to their medical records, nine (36%) had identified psychologically vulnerable conditions or significant life stressors (Table 1). Four cases were resistant to vaccination due to possible AEFIs, two cases had depressive disorder, two had apparent secondary gain, one had difficulty in school life due to bullying, and one had organic disease (mental retardation). Sixteen PIV cases had no definite underlying psychologically predisposing factors. PIV cases with vulnerable conditions or life stressors showed a shorter median time of symptom onset (7.5 minutes vs. 30 minutes) and longer median duration of hospitalization (10 days vs. 6.5 days) compared to those without any such conditions or stressors.

Behavioral patterns and medical cost of PIV in school-located vaccination

All of the PIV cases relating to school-vaccination were admitted to tertiary teaching hospitals, and over half of them (64%, 16/25) visited more than one hospital. One case visited four different hospitals because of the parents’ lack of confidence in healthcare personnel. Evaluations included MRI (68%, 17/25), nerve conduction study (36%, 9/25), and cerebrospinal fluid analysis (24%, 6/25). Hospitalization lasted for 7 days (median; range, 1 to 18 days). The median cost related to the use of healthcare facilities was US \$1,582 (range, US \$687 to US \$6,634) per person.

Characteristics of PIV cases who were vaccinated individually

Three PIV cases following individual vaccination against pandemic influenza A (H1N1) were reported for a claim for com-

compensation (Table 1). A 33-year-old woman developed general weakness, sweating, flushing, and agitation 5 minutes after vaccination, which lasted for 3 months. Laboratory and imaging studies could not reveal any organic disease and she was diagnosed with a vaccine adverse effect suspect or psychosomatization disorder suspect upon discharge from hospital. A 46-year-old woman presented myalgia, tingling sensation and dyspnea 90 minutes after vaccination, which lasted for 1 day. With no abnormal signs found in the brain and cervical MRI, she was diagnosed with a vaccine adverse effect suspect. A 68-year-old woman complained of a headache, chills, nausea and myalgia 1 day after vaccination, and her symptoms lasted for 6 days. Upon discharge from hospital, she was diagnosed with headache.

Discussion

Our study demonstrated that PIV occurred predominantly in adolescents during school-located mass vaccination, with more female adolescents being reported than male. This result is in accordance with previous studies regarding the vulnerability of adolescents to mass vaccination and the higher number of reports of PIV in females compared to males [1,2]. Also, a significant proportion of our subjects were in vulnerable conditions or had life stressors, which might have precipitated the PIV [8,9]. Moreover, South Korea is renowned for education fever and infamous for putting extraordinary sociopsychological pressure on students to achieve a higher position [10]. As the school examination period was near the time of the immunization campaign, academic stress might also have circumstantially affected the events.

Hospitalization of the PIV cases after school-located mass vaccination in this study lasted for 7 days and costed US \$1,582 per person. The economic burden of PIV per case is high considering that monovalent pandemic influenza vaccination during the campaign costed US \$22 (vaccine cost of US \$7 plus administration fee of US \$15), meaning that the medical cost per one PIV case is estimated to be the same as the cost of vaccinating 100 people. We can also compare this cost with that of an uncomplicated acute appendicitis operation (US \$256) or non-contrast-enhanced brain MRI (US \$184) in South Korea [11]. As many of the affected adolescents were tested with invasive and expensive procedures such as cerebrospinal analysis and MRI, the economic burden of PIV was significantly high. Considering the easy and frequent accessibility to healthcare facilities compared with other countries, healthcare-seek-

ing behavior could have affected the economic burden of PIV following vaccination in South Korea [12].

We acknowledge that several limitations exist in our study. Our analysis was only of those cases with claims for vaccine injury compensation, which may not represent the whole presentation of psychogenic illness related to the pandemic influenza vaccination in Korea, and therefore may have underestimated overall incidence. Also, we could not identify the risk factors of PIV. In order to determine whether or not a certain variable would be associated with an increased risk of PIV, the prevalence of each condition among non-PIV population should be known. Since relevant information could not be drawn from our data, only descriptive analysis was presented. In addition, the expense and duration of illness per case could have been overestimated because our cases might be selectively reported in order to meet the criteria for compensation claims. However, we initially aimed to evaluate cases that required further intervention at a national level and to estimate their economic burden. Therefore, we thought cases with expenses exceeding a certain amount were appropriate for analysis to measure the burden in order to emphasize the necessity for enhanced management of PIV during a mass vaccination campaign. Another limitation was that there was insufficient contextual information on PIV cases, such as the actual media attention received at that time and their impact on the immunization program.

However, to our knowledge, this is the first nationwide description of psychogenic illness following a mass vaccination campaign in South Korea. The data is reliable, because every case was initially investigated thoroughly by reviewing medical records to exclude true vaccine reactions and coincidental events by Epidemic Intelligence Service officers, followed by a review and validation by the Korean Advisory Committee on Vaccine Injury Compensation. In addition, we identified demographic and clinical characteristics of the cases. This data may be useful when setting future strategies for pandemic preparedness when mass vaccination is under consideration. Furthermore, we also presented information about the medical cost of PIV per person, demonstrating the estimate burden of illness at individual and national level.

School-located mass vaccination has proven to be a potent measure to maximize the vaccine coverage rate and to produce a prompt impact to interrupt the spread of infectious diseases [2,4,13-15]. Accordingly, for pandemic preparedness, mass vaccination has been suggested as one of the most powerful strategies [16,17]. However, the occurrence of mass psy-

chogenic illness has a potential to halt such intervention. Therefore, guidelines should be prepared and issued before initiating a mass vaccination campaign in a school setting.

There have been some suggestions from previous publications regarding the essential components of guidelines to mitigate the risk of PIV and its further spread. For example, administration of the vaccine in separate spaces and close observation, and reassurance before and after vaccination may be useful [2]. Those people with vulnerable conditions or life stressors who are more likely to develop PIV might need special attention. Also, it would be important to train healthcare personnel on identifying PIV and differentiating it from other illnesses like anaphylaxis, which require an immediate medical response. Prompt identification and labelling of an episode such as a mass psychogenic response, have also been suggested [3]. Furthermore, rapid risk communication as well as a long-term communication plan with the media should be established, considering its potential negative impact on public confidence in vaccination [1]. A prompt press release based on a transparent investigation and risk communication with academic society may help prevent the further spreading of the PIV to become mass PIV.

Human papillomavirus vaccines were introduced into the national immunization program for female adolescents in June 2016 in South Korea. The experience of PIV during the pandemic influenza vaccination campaign in 2009 provided legitimacy to exclude school-based immunization from the overall national immunization scheme. Also, to reduce the risk of PIV, long-term communication strategies, ranging from providing education materials for health teachers in schools to giving tips to healthcare providers about better communication skills regarding vaccines with adolescents and their parents, have been settled before the initiation of the program.

The findings of our study could serve as valuable information when setting guidelines for PIV during mass vaccinations. Although physicians in clinical practice would not refrain from conducting further investigations simply based on the characteristics listed in this study, organizers of immunization programs and health authorities may take these study results into consideration while preparing strategies for a successful immunization campaign.

Mass vaccination is a potent public health measure to interrupt transmission of an infectious disease in a short period of time, and to minimize the impact of a pandemic threat. However, before initiating the campaign, the possible risk of occurrence of PIV among adolescents should be considered

seriously. Its individual and national economic burden may be substantial and clustered PIV cases have the potential to interrupt the successful performance of the campaign, and even to play a role in losing public confidence in vaccination. Health authorities, immunization managers, and organizers of future mass vaccinations should be well aware of PIV and prepare risk communication strategies and tactics before the campaign.

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