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= Abstract =

Analysis of The Adverse Events Following Immunization of the
National Compensation Program and the
Surveillance System in Korea, 1995 2000

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Purpose : To describe the characteristics of the claims for compensation and the methodology of investigations concerning adverse events following immunization(AEFI) and epidemiologic characteristics of the AEFI. From these results, to give a suggestion for improving AEFI surveillance system, consequently to stabilize National Immunization Program.

Methods : Totally 61 cases were reported to the National Compensation Program and surveillance system of AEFI from 1995 to 2000. Documents from National Compensation Program, medical records and epidemiologic investigation reports of the cases were collected and analyzed.

Results : The number of reported cases was 12 in 1995, 3 in 1996, 12 in 1998, 5 in 1999, and 29 in 2000, respectively. That of deaths was 24(39.3%) and 16 cases among them were autopsied(66.7%). That of claims for compensation was 36 and 17 cases among them were compensated(47.2%). The proportion of claim was lower in 1999 2000 than in 1995 1998, but proportion of compensation increased. Although proportion of investigation was lower in 1999 2000 than in 1995 1998, cases which were not epidemiologically investigated, decreased. The epidemiologic investigation launched within 24 hours after report increased from 25% in 1995 1998 to 48.3% in 1999 2000. Among reported cases, the num-

ber of boys was 31(50.8%), and 75.4% of subjects were from 2 months to 24 months old. 78.4% of adverse events occurred within one week after immunization.

Conclusion : We can find that surveillance system of AEFI and quality of epidemiologic investigation has been somewhat improved. But, it seems that severe cases were more frequently reported than moderate or mild cases, and reporting rate was lower than that of other developed countries. We could not identify the detailed epidemiologic characteristics of AEFI due to these limitation of data. To achieve the stabilization of National Immunization Program, reporting rate and the quality of investigation should be improved.

Key Words : Adverse event following immunization, Surveillance, Case Investigation

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1995 12 , 1996 3 , 1998 12 , 1999 5 , 2000 29 61 1997 24 (39.3%) , 16 (66.7%) (Table 1). 49 (80.3%) , 36 (59.0%)

3 , 1995 1996 가 15 1998 가 1998 7 (58.3%) , 1999 4 (80.0%) , 2000 23 (79.3%) , 1998 8 (66.7%) , 1999 3 (60.0%) , 2000 10 (34.5%) . 1997 가 (Table 1).

1995 가 1998 가 가, 3 1999 가

2 . 가 1995 2000 36 17 (47.2%)

Table 1. The Reported Cases of Adverse Events Following Immunization, 1995 2000

Year	No. of reports	Death(%)	Autopsy(%) [*]	Epidemiologic investigation(%)	Claim for compensation(%)
1995	12	4(33.3)	2(50.0)	12(100.0)	12(100.0)
1996	3	-	-	3(100.0)	3(100.0)
1997	-	-	-	-	-
1998	12	5(41.7)	3(60.0)	7(58.3)	8(66.7)
1999	5	2(40.0)	2(100.0)	4(80.0)	3(60.0)
2000	29	13(44.8)	9(69.2)	23(79.3)	10(34.5)
Total	61	24(39.3)	16(66.7)	49(80.3)	36(59.0)

^{*}The denominator of proportion is the number of death

1995 41.7%, 1996 0.0%, 1998 62.5%, 1999 66.7%, 2000 50.0% . 1995 가 3 가 13 (76.5%) 1 , 2 , 1 가 60% (Table 2). 36 (DTaP) 가 17 (47.2%) 가 8 (22.2%), 8 (22.2%) 17 (DTaP) 가 11 64.8%가 6 75%가 B , MMR (Table 3). 3 21 9 4 (44.4%) 가 4 2 1 . 1994 15 7 1996-1998 , B , DTaP 가 1999 2000 가 1994 6 6 (100.0%), 1995 1998 17 15 (88.2%), 1999 2000 38 15 (76.3%) , 1994 5 (83.3%), 1995 1998 4 (26.6%), 1999 2000 8 (53.3%) 가 1994 6 6 (100.0%), 1995 1998 17 14 (82.4%), 1999 2000 38 29 (76.3%) 1994 50%, 1996 1998 50%, 1999 2000 75%

Table 2. The Proportion of the Compensated Among Reported Cases, 1995 2000

Year	No. of claims	No. of compensated*	Proportion of compensated(%)
1995	12	5	41.7
1996	3	-	0.0
1997	-	-	-
1998	8	5	62.5
1999	3	2	66.7
2000	10	5	50.0
Total	36	17	47.2

*Three of those is partially awarded because their parents refused examinations necessary to explain the adverse events(e.g. autopsy)

1994 6 6 (100.0%), 1995 1998 17 15 (88.2%), 1999 2000 38 15 (76.3%) , 1994 5 (83.3%), 1995 1998 4 (26.6%), 1999 2000 8 (53.3%) 가 1994 6 6 (100.0%), 1995 1998 17 14 (82.4%), 1999 2000 38 29 (76.3%) 1994 50%, 1996 1998 50%, 1999 2000 75%

Table 3. The Distribution of Reported Cases by Vaccine and Adverse Events

Type of vaccines and adverse events	No. of reported	No. of claimed	No. of compensated
Vaccines*			
BCG	9	7	0
BCG/HBV	1	1	0
HBV	3	2	0
DTaP	6	3	2
DTaP/Polio	21	12	9
DTaP/Polio/HBV	3	2	0
DTaP/Polio/HiB	4	0	0
MMR	3	1	0
JE	9	6	4
JE/HiB	1	1	1
JE/KHF	1	1	1
Adverse events			
Death	21	9	4
Anaphylactic shock	4	4	4
Sudden infant death syndrome	4	2	0
Aspiration	3	0	0
Acute pericarditis and myocarditis	1	1	0
Intestinal obstruction	1	0	0
Fluid-electrolyte Imbalance	1	0	0
Dehydration and congenital malformation	1	0	0
Septic shock	1	0	0
Unknown	5	2	0
Nervous system	20	17	13
Encephalitis	7	6	4
Encephalopathy	4	4	3
Seizure	3	3	3
Febrile conversion	3	1	0
Transverse myelitis	2	2	2
Sciatic nerve neuropathy	1	1	1
The others	20	10	0
BCG lymphadenitis	7	7	0
Local adverse reaction	4	2	0
Generalized rash	3	0	0
Anaphylactoid reaction	1	0	0
Subcutaneous petechia	1	0	0
Thrombocytopenia	1	0	0
pericarditis	1	0	0
hepatitis	1	0	0
Pneumococcal pneumonia	1	1	0
Total	61	36	17

*BCG : Bacille calmette-guerin vaccine, HBV : hepatitis B virus, DTaP : diphtheria-tetanus-acellular pertusis, Polio : oral poliovirus, HiB : *haemophilus influenza* type b, MMR : measles-mumps-rubella, JE : japanese encephalitis, KHF : Korean hemorrhagic fever

Table 4. The Cause of Death by Autopsy

Cause of death	Autopsy					
	Yes			No		
	No. of reported	No. of claimed	No. of compensated	No. of reported	No. of claimed	No. of compensated
Anaphylactic shock	4	4	4	-	-	-
Sudden infant death syndrome	4	2	0	-	-	-
Aspiration	2	0	-	1	0	-
Acute pericarditis and myocarditis	1	1	0	-	-	-
Intestinal obstruction	1	-	-	-	-	-
Fluid-electrolyte imbalance	1	-	-	-	-	-
Dehydration and congenital malformation	-	-	-	1	0	-
Septic shock	1	-	-	-	-	-
Unknown	1	-	-	4	2	0
Total	15	7	4	6	2	0

(Table 5).
 가 29 47.5
 % 17 (27.9 %), 9
 1 가 16 (37.2 (14.8%), 4 (6.6%)
 %), 2 가 2 (4.7%), 3 5 가 4 (9.3 24 가 31 (50.8%)
 %), 6 30 가 8 (18.6%) , 30 가 , 78.4%가
 13 (30.2%) . 1 (Table 8).
 가 1995 1999 14.3%
 1999 2000 48.3% 가 (Table 6).
 11 가 7 (63.6%) 11 4 (36.4%),
 11 (40.7%), 2 가 2 (7.4%), 3 5 가 1 (10.0%), (BCG) 10
 3 (11.1%), 6 30 가 7 (25.9%), 30 . B 9 (90.0%) 가
 4 (14.8%) . 1 가 1995 28 3 , DTaP/Polio
 1999 25% 가 18 (64.3%), 10 (35.7%)
 1999 2000 43.5% 가 1 .
 (Table 7). , (BCG) 12
 4 . . B DTaP/
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 31 (50.8%), 30 (49.2%) . , (MMR) 12 24
 가 75.4 DTaP/Polio 24
 % DTaP/ 1 , B , DTaP,
 Polio 21 34.4% , MMR
 (BCG) 9 , 9 14.8% . 24

Table 5. The Characteristics of Vaccines, Claims for Compensation, Epidemiologic Investigations by Period

Vaccines, compensation, and epidemiology investigation	Period		
	1994(%)	1995 1998(%)	1999 2000(%)
Vaccines*			
BCG	-	6(35.3)	3(7.9)
BCG/HBV	-	1(5.9)	-
HBV	-	1(5.9)	2(5.3)
DTaP	-	-	6(15.8)
DTaP/Polio	-	6(35.3)	15(39.5)
DTaP/Polio/HBV	-	1(5.9)	2(5.3)
DTaP/Polio/HiB	-	1(5.9)	3(7.9)
MMR	-	-	3(7.9)
JE	4(66.7)	1(5.9)	4(10.5)
JE/HiB	1(16.7)	-	-
JE/KHF	1(16.7)	-	-
Total	6(100.0)	17(100.0)	38(100.0)
Compensation among claimed cases			
Compensated	2(33.3)	4(26.7)	8(53.3)
Partially compensated	3(50.0)	-	-
Rejected	1(16.7)	10(73.3)	7(46.6)
Total	6(100.0)	15(100.0)	15(100.0)
Epidemiologic investigation			
Yes	6(100.0)	14(82.4)	29(76.3)
No	0(0.0)	3(17.6)	9(23.7)
Total	6(100.0)	17(100.0)	38(100.0)

*BCG : Bacille calmette-guerin vaccine, HBV : hepatitis B virus, DTaP : diphtheria-tetanus-acellular pertussis, Polio : oral poliovirus, HiB : *haemophilus influenza* type b, MMR : measles-mumps-rubella, JE :japanese encephalitis, KHF : Korean hemorrhagic fever

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(Table 9).

21 DTaP/Polio 가 10
47.6%
가 8 (40.0%) 가

Table 6. Interval between Onset of Symptoms and Reporting Time

Interval	No. of reports(%)	Periods	
		1995 1998 (%)	1999 2000 (%)
1 day	16(37.2)	2(14.3)	14(48.3)
2 days	2(4.7)	1(7.1)	1(3.4)
3 5 days	4(9.3)	-	4(13.8)
6 30 days	8(18.6)	2(14.3)	6(20.7)
>30 days	13(30.2)	9(64.3)	4(13.8)
Total	43(100.0)	14(100.0)	29(100.0)

Table 7. Interval between Reporting Time and Start of Investigations

Interval	No. of reports(%)	Periods	
		1995 1998 (%)	1999 2000 (%)
1 day	11(40.7)	1(25.0)	10(43.5)
2 days	2(7.4)	-	2(8.7)
3 5 days	3(11.1)	-	3(13.0)
6 30 days	7(25.9)	1(25.0)	6(26.1)
>30 days	4(14.8)	2(50.0)	2(8.7)
Total	27(100.0)	4(100.0)	23(100.0)

7 (35.0%)
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(Table 10).

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Table 8. The Characteristics of Reported Cases

Characteristics	No. of reports	Percent total(%)		
Sex	Male	31	50.8	
	Female	30	49.2	
Age	0 < 1 month	2	3.3	
	1 < 2 months	3	4.9	
	2 < 12 months	35	57.4	
	12 < 24 month	11	18.0	
	2 < 4 year	2	3.3	
	4 < 7 year	4	6.6	
	7 < 15 year	4	6.6	
Vaccine*	BCG	9	14.8	
	BCG/HBV	1	1.6	
	HBV	3	4.9	
	DTaP	6	9.8	
	DTaP/Polio	21	34.4	
	DTaP/Polio/HBV	3	4.9	
	DTaP/Polio/HiB	4	6.6	
	MMR	3	4.9	
	JE	9	14.8	
	JE/HiB	1	1.6	
	JE/KHF	1	1.6	
	Place of vaccination	School	4	6.6
		Hospital	9	14.8
Public health center		29	47.5	
Private clinic		17	27.9	
Unknown		2	3.3	
Interval between immunization and symptom onset	24 hours	31	50.8	
	1 week	17	27.9	
	1 month	7	11.5	
	6 months	5	8.2	
	1 year	1	1.6	
Total	61	100.0		

* BCG : Bacille calmette-guerin vaccine, HBV : hepatitis B virus, DTaP : diphtheria-tetanus-acellular pertusis, Polio : oral poliovirus, HiB : *haemophilus influenza* type b, MMR : measles-mumps-rubella, JE : japanese encephalitis, KHF : Korean hemorrhagic fever

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 (hypotensive hyporesponsive episodes)

Table 9. Characteristics of Reported Cases by Type of Vaccines

Characteristics	Type of vaccines [†]						Total	
	JE	BCG	HBV	DTaP/Polio	DTaP	MMR		
Sex	Male	4(36.4)	1(10.0)	3(100.0)	18(64.3)	3(50.0)	2(66.7)	31(50.8)
	Female	7(63.6)	9(90.0)	-	10(35.7)	3(50.0)	1(33.3)	30(49.2)
Age	0 <1 month	-	2(20.0)	-	-	-	-	2(3.3)
	1 <2 months	-	2(20.0)	1(33.3)	-	-	-	3(4.9)
	2 <12 months	-	6(60.0)	1(33.3)	28(100.0)	-	-	35(57.4)
	12 <24 months	3(27.3)	-	-	-	6(100.0)	2(66.7)	11(18.0)
	2 <7 years	4(36.4)	-	1(33.3)	-	-	1(33.3)	6(9.9)
	7 <15 years	4(36.4)	-	-	-	-	-	4(6.6)
	Interval [†]	24 hours	4(36.4)	3(30.0)	1(33.3)	18(64.3)	4(66.7)	1(33.3)
	1 week	3(27.3)	-	2(66.7)	8(28.6)	2(33.3)	2(66.7)	17(27.9)
	1 month	4(36.4)	1(10.0)	-	2(7.1)	-	-	7(11.5)
	6 months	-	5(50.0)	-	-	-	-	5(8.2)
	1 year	-	1(10.0)	-	-	-	-	1(1.6)
Total		11(100.0)	10(100.0)	3(100.0)	28(100.0)	6(100.0)	3(100.0)	61(100.0)

^{*}JE :japanese encephalitis, BCG :Bacille calmette-guerin vaccine, HBV :hepatitis B virus, DTaP :diphtheria-tetanus-acellular pertusis, Polio :oral poliovirus, MMR :measles-mumps-rubella

[†] Interval between immunization and symptom onset

1 가 18), 50% 가 3 , 가 가 1 VAERS 58%가 20), 2%, 12.3% 19), 16 4 가 , , , 가 가 21), 22), 2 12 57.4%, 12 24 18% 가 14 (66.7%), 가 7 (33.3%) 가 2 2 12 80%가 , 63.7%가 1 가 3

Table 10. Adverse Events by Vaccines

Adverse events	No. of reports	Vaccines*										
		BCG	BCG/ HBV	HBV	DTaP/ Polio	DTaP/ Polio/ HBV	DTaP/ Polio/ HiB	DTaP	MMR	JE	JE/ HiB	JE/ KHF
Death	21	2	0	2	10	2	3	0	0	2	0	0
Anaphylactic shock	4	-	-	-	2	-	-	-	-	2	-	-
Sudden infant death syndrome	4	-	-	-	1	1	2	-	-	-	-	-
Aspiration	3	-	-	1	2	-	-	-	-	-	-	-
Acute pericarditis and myocarditis	1	-	-	-	1	-	-	-	-	-	-	-
Intestinal obstruction	1	-	-	-	1	-	-	-	-	-	-	-
Fluid-electrolyte Inbalance	1	-	-	-	1	-	-	-	-	-	-	-
Dehydration and congenital malformation	1	-	-	-	1	-	-	-	-	-	-	-
Septic shock	1	-	-	-	-	-	1	-	-	-	-	-
Unknown	5	2	-	1	1	1	-	-	-	-	-	-
Nervous system	20	0	0	0	8	0	0	2	1	7	1	1
Encephalitis	7	-	-	-	-	-	-	1	-	4	1	1
Encephalopathy	4	-	-	-	2	-	-	1	1	-	-	-
Seizure	3	-	-	-	3	-	-	-	-	-	-	-
Febrile conversion	3	-	-	-	1	-	-	-	-	2	-	-
Transverse myelitis	2	-	-	-	1	-	-	-	-	1	-	-
Sciatic nerve neuropathy	1	-	-	-	1	-	-	-	-	-	-	-
The others												
BCG lymphadenitis	7	6	1	-	-	-	-	-	-	-	-	-
Local adverse reaction	4	-	-	1	-	-	-	3	-	-	-	-
Generalized rash	3	-	-	-	2	-	-	-	1	-	-	-
Anaphylactoid reaction	1	-	-	-	-	-	-	1	-	-	-	-
Subcutaneous petechia	1	-	-	-	1	-	-	-	-	-	-	-
Thrombocytopenia	1	-	-	-	-	-	-	-	1	-	-	-
Pericarditis	1	-	-	-	-	1	-	-	-	-	-	-
Hepatitis	1	-	-	-	-	-	1	-	-	-	-	-
Pneumococcal pneumonia	1	1	-	-	-	-	-	-	-	-	-	-
	61	9	1	3	21	3	4	6	3	9	1	1

*BCG : Bacille calmette-guerin vaccine, HBV : hepatitis B virus, DTaP : diphtheria-tetanus-acellular pertusis, Polio : oral poliovirus, HiB : *haemophilus influenzae* type b, MMR : measles-mumps-rubella, JE : japanese encephalitis, KHF : Korean hemorrhagic fever

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55.7%
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14.6%, 10% ²⁸⁾
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sive hyporesponsive episodes) DTaP
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가 1999 2000 76.3%
1995 1998
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1999 2000 9

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1999 2000 43.5%

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3 , 1998 12 , 1999 5 , 2000 29
61 , 24 (39.3%) ,
16 (66.7%)
가 36 (59.0%)
17 (47.2%)
가 49 (80.3%)
가
1995 1998 17 15 (88.2%),
1999 2000 38 15 (76.3%)
가 가
26.6% 1999 2000 53.3% 가 .

가
1995 1998 17 14 (82.4%), 1999
2000 38 29 (76.3%)
가

1 가 1995 1998
25% 1999
43.5% 가
21 가 14
(66.7%), 가 7 (33.3%) 가 2

2 24 가 75.4%
78.4%가

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