

# Sudden death in the first and second years of life following immunization in the Republic of Korea, 1994-2011



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## BACKGROUND

Because the peak age for incidence of sudden deaths in infancy temporally coincides with the age of infant starting primary immunization, some have raised the question whether immunization is a risk factor for sudden death in infancy. Recent occurrence of two sudden deaths in infants in Korea renewed concerns about causal association between immunization and sudden deaths in infants.

## SETTING

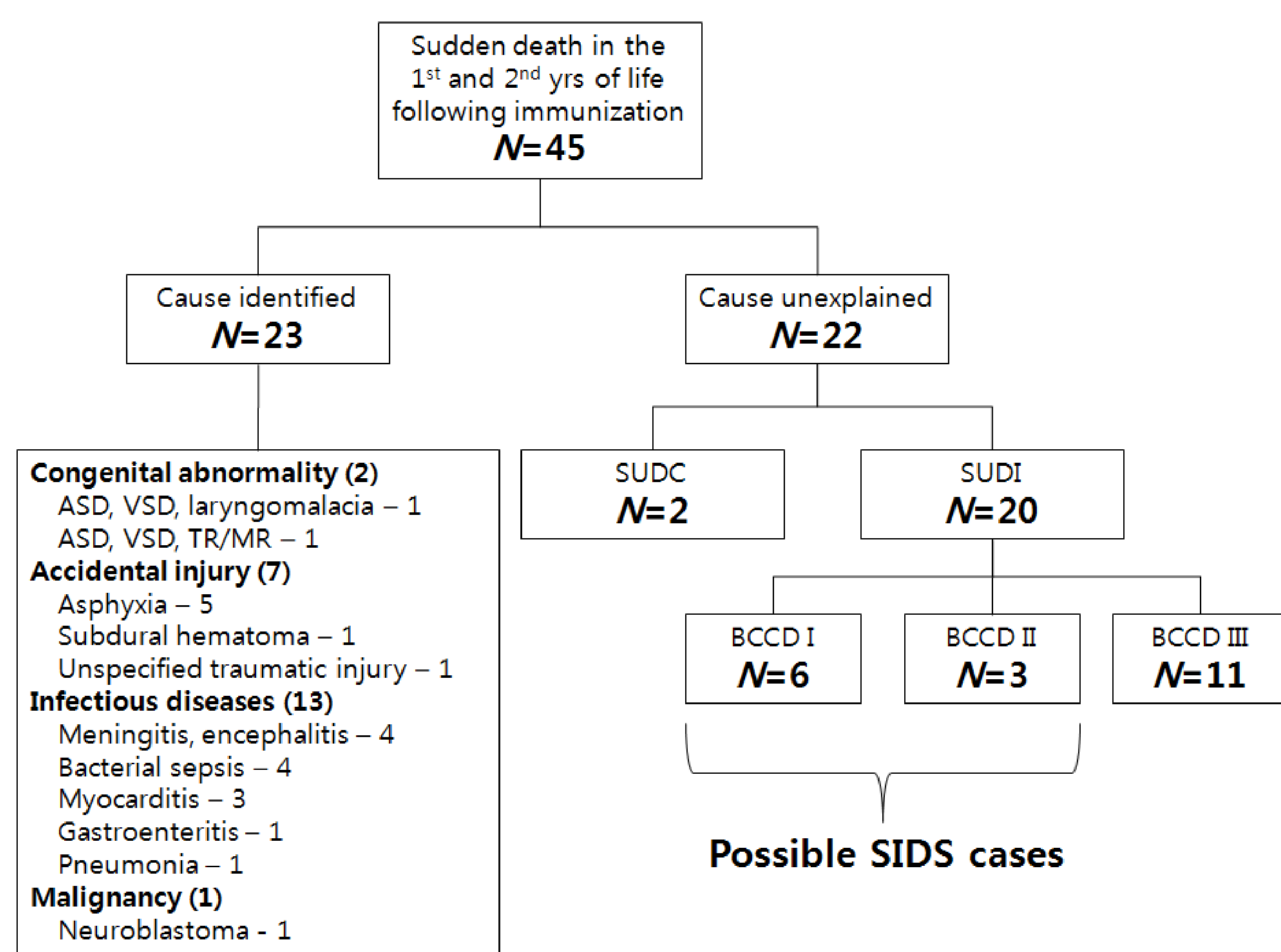
Retrospective review of data from Korean adverse events surveillance system and vaccine compensation programs.

## POPULATION

Republic of Korea, with annual birth cohort of approximately 450 thousand births and universal immunization coverage of more than 95% of target population.

## PROJECT DESCRIPTION

We classified the sudden death cases in the first two years of life into categories according to the presence of identified cause of deaths, then categorized the cases as sudden unexpected death in infancy (SUDI) if the deaths occurred the first year of life. Any SUDI case meeting Brighton Collaboration case definition (BCCD) of unexplained sudden death levels I or II were classified as sudden infant death syndrome (SIDS)



**Figure 1.** Schematic diagram to classify sudden death in the first and second years of life following immunization reported

	Cause identified				Cause unexplained			Total
	Congenital abnormality	Accidental injury	Infectious diseases	Malignancy	SUDI		SUDC	
					BCCD I/II	BCCD III		
Total N	2	7	13	1	9	11	2	45
Age, median (mo.)	3	4	6	-	4	3	18.5	4
Sex, M:F	1:1	4:3	8:5	1:0	4:5	8:3	1:1	27:18
Vaccines								
BCG			2					2
HepB		1	2		3	5		11
DTaP		2					2	4
JEV			1	1				2
MMR			1					1
VZV			1					1
Hib		1				1		2
H1N1		1	1					2
DTaP+IPV	2	1	3		2	2		10
DTaP+OPV			1		3	1		5
DTaP+IPV+HepB			1					1
DTaP+OPV+HepB					1			1
MMR+VZV		1						1
Hib+PCV						2		2

**Table 1.** Cases of sudden death in the first and second years of life following immunization by clinical syndromes reported in the Republic of Korea, 1994-2011

\* Abbreviations: SUDI, sudden unexpected death in infancy; SUDC, sudden unexpected death in childhood; BCCD, Brighton Collaboration Case Definition;  
 \* BCCD I/II under SUDI represents possible SIDS cases

	Hours				Unknown	Total
	0-6	6-24	24-72	≥72		
BCG		2				2
HepB	2	2		1	6	11
DTaP	1	3				4
JEV			1		1	2
MMR				1		1
VZV					1	1
Hib		1	1			2
H1N1			2			2
DTaP+IPV	1	5	2		2	10
DTaP+OPV	1	2	2			5
DTaP+IPV+HepB					1	1
DTaP+OPV+HepB		1				1
MMR+VZV					1	1
Hib+PCV					2	2
Total	5	16	8	2	14	45

**Table 2.** Cases of sudden deaths in the first and second years of life following immunization by interval from immunization to presentation in the Republic of Korea, 1994-2011

No.	Sex	Age (Mo)	Identified risk factors			
			Age	Sex	Low Bwt	Low SES
1	F	2	0			
2	F	3	0			
3	M	3	0	0		
4	M	4	0	0		
5	M	4	0	0		
6	M	2	0	0		
7	M	4	0	0		
8	M	4	0	0	0	
9	F	8			0	
10	M	1		0	0	
11	F	6				0
12	M	1		0		
13	M	1		0		
14	M	2	0	0	0	0

**Table 3** Case synopses of sudden unexplained deaths in the first and second years of life following immunization by identified risk factors for sudden infant death syndrome (SIDS) in the Republic of Korea, 1994-2011

## RESULTS/LESSONS LEARNED

From 1994 to 2011, a total of 45 cases of sudden deaths in the first two years of life following immunization were reported. The deaths with identified explanation were classified as follows: infectious diseases (n=13); accidental injuries (n=7); congenital abnormalities (n=2); and malignancy (n=1). Of 20 SUDI, nine were classified as SIDS. Hepatitis B vaccine (n=13) was the most frequent vaccine with temporal association with sudden deaths. Despite the implementation of universal immunization, only few sudden deaths were reported. Majority of deaths in infancy did not meet case definition for sudden infant death syndrome. Encouraging investigators to perform thorough investigation including postmortem autopsy and death scene examination may promote data comparability and provide guidance on decision making in vaccine safety monitoring and response system in Korea.