



A Systematic Review Of Active Vaccine Surveillance Studies: Focused On The Vaccine Safety Datalink

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BACKGROUND

- Vaccine active surveillance system is important to detect potential adverse events after the introduction of the vaccine.
- Many countries operate the active monitoring surveillance system and we reviewed Vaccine Safety Datalink (VSD) that is collaborative project between Centers for Disease Control and Prevention and health management organizations.
- This project has begun 30 years ago from 1990 until now, and various studies have been conducted using the VSD data.

OBJECTIVE

- To review and categorize the published literature to describe the characteristics of the studies using VSD database.
- To identify possible study in vaccine active surveillance system such as VSD.

METHODS

- Inclusion criteria**
 - Data source: VSD webpage, EMBASE and Medline
- Exclusion criteria**
 - Not original papers
 - Not use VSD database
 - Not related to vaccine, vaccine preventable disease, adverse events
- Data abstraction**
 - Two reviewers were independently reviewed
- Classification**
 - Description: incidence, coverage and pattern
 - Analysis: safety, effectiveness and factor
 - Methodology: study design and statistical method
 - Database: DB construction, linkage and validity
 - If records are duplicated each classification, we counted by dividing the number of each in the tables.

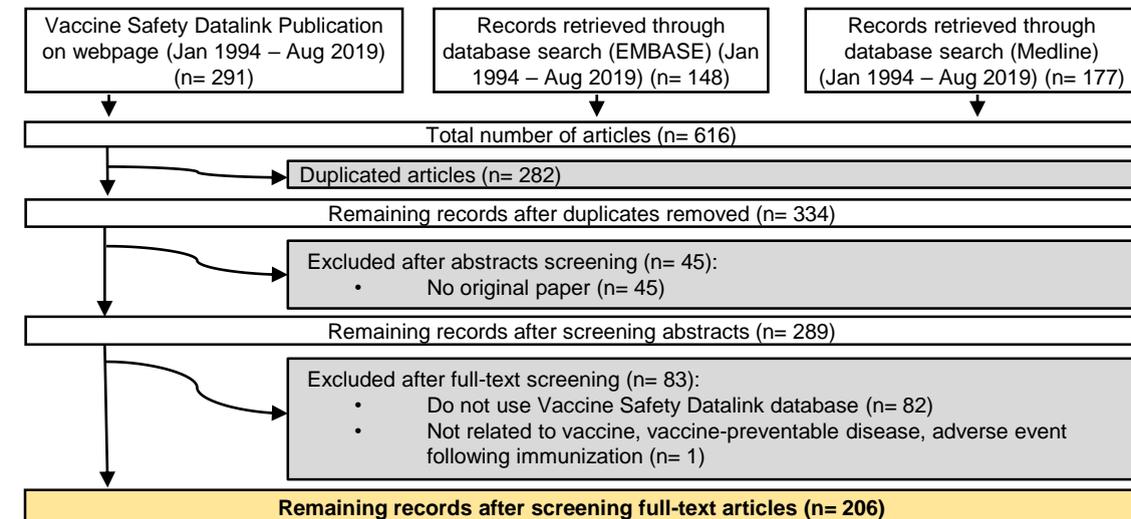


Figure 1. Flow diagram of the study selection

Table 1. Summary Characteristics of VSD studies

Study Characteristics	N (%)
Total	221 (100.0)
Descriptive studies	43 (19.5)
Incidence of disease (VPD or AEFI)	21 (9.3)
Coverage	21 (9.3)
Pattern	3 (1.3)
Analytic studies	134 (60.6)
Safety	125 (55.3)
Effectiveness	3 (1.3)
Factors related to vaccination	10 (4.4)
Methodology studies	22 (10.0)
Study design	6 (2.7)
Statistical methodology	17 (7.5)
Database studies	22 (10.0)
Database construction	7 (3.1)
Database linkage	3 (1.3)
Database validity	14 (6.2)

- From 334 studies, total of 206 studies were included.
- The majority was analytical study (n=134, 60.6%).
- 43 studies (19.5%) were classified into descriptive study such as incidence of diseases (n=21, 9.3%) and vaccine coverage (n=21, 9.3%). Others were categorized as methodological studies (n=22, 10%) and study on VSD database studies (n=22, 10%).
- Vaccine safety studies were focused mainly on influenza (n=54, 43.2%), followed by HBV, pneumococcal, DTaP/DTP and MMR.

Results

Table 2. Top 5 the type of vaccines studied for the safety studies

Vaccinated	N (%)
Total	125 (100.0)
Influenza	54 (43.2)
Hepatitis B virus	23 (18.4)
Pneumococcal	22 (17.6)
DTaP/DTP	19 (15.2)
MMR	18 (14.4)

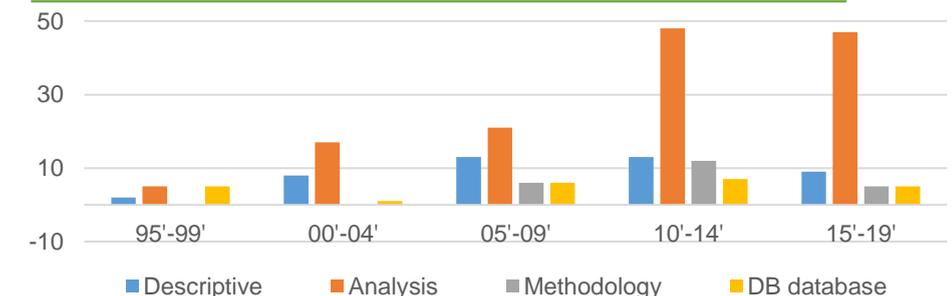


Figure 2. Type of studies conducted every 5 year

Strengths & Limitations

- The VSD system is a good model that emerged in the early days of a vaccine active surveillance system and is a well-established pioneering model.
- We reviewed all the results using the VSD database, and it is meaningful to classify the research results by type.
- Studies that do not use the term 'Vaccine Safety Datalink' cannot be identified.
- There are other good systems, but there is a limitation that not all vaccine active surveillance systems have been seen, and it is difficult to apply them uniformly because each country has different data collection methods.

Discussions & Conclusion

- In the early stages of construction, it became a set-up study, and analysis studies are being used a lot recently.
- Methodology studies are also progressing, and research on the database it self seems to be doing well through VSD system.
- The reason why influenza studies a lot was used due to the H1N1 issue, and If such an issue arises, it could be confirmed that the vaccine active surveillance system can quickly cope and utilize it.
- It plays an essential role in making evidence.

Acknowledgement

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