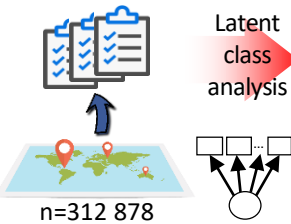


# Safety profiles of mRNA COVID-19 vaccines using World Health Organization global scale database (VigiBase) : A latent class analysis

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ICSRs following mRNA COVID19 vaccines with serious AE



ICSR; individual case safety report, AE; adverse event,  
\* Median (quantile 1 - quantile 3)

System organ class	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5
Cardiac					
Gastrointestinal					
Infectious					
Injury, procedure					
Musculoskeletal					
Nervous system					
Respiratory					
Skin					
Vascular					
0% Estimated probabilities of serious AEs 100%					

Cluster 1

**Infection AEs**  
(43,606/ 13.9%)

**1. Frequently reported AEs:**  
COVID-19 (67.4%), Vaccination failure (46.6%)

**2. Gender:** Female (53.1%)

**3. Age group:** ≥ 75 years (21.4%)

**4. Time to onset\*:** 85.5 days (16-149.5 days)

Cluster 2

**Cardiac AEs**  
(43,606/ 13.9%)

**1. Frequently reported AEs :**  
Myocarditis (25.0%), Pericarditis (14.7%)

**2. Gender:** Male (59.7%)

**3. Age group:** 12~17 years (5.3%)

**4. Time to onset\*:** 4 days (1-17 days)

Cluster 3

**Respiratory/vascular AEs**  
(43,606/ 13.9%)

**1. Frequently reported AEs :**  
Dyspnoea (27.1%), Pulmonary embolism (14.8%)

**2. Gender:** Female (58.2%)

**3. Age group:** ≥ 75 years (17.3%)

**4. Time to onset\*:** 4 days (1-17.5 days)

Cluster 4

**Systemic AEs**  
(25,529/ 8.2%)

**1. Frequently reported AEs:**  
Headache (43.8%), Nausea (31.5%)

**2. Gender:** Female (69.5%)

**3. Age group:** 18~44 years (34.2%)

**4. Time to onset\*:** 1 days (0-9 days)

Cluster 5

**Systemic AEs**  
(150,561/ 48.1%)

**1. Frequently reported AEs:**  
Headache (16.9%), Pyrexia (12.6%)

**2. Gender:** Female (63.4%)

**3. Age group:** 18~44 years (30.9%)

**4. Time to onset\*:** 2 days (1-12.5 days)

**Conclusion** Using latent class analysis (LCA), we found five clusters of serious AEs following mRNA COVID-19 vaccines. Each cluster was distinguished by potential factors such as age, gender, region, and time-to-onset. These findings could contribute to enhancing understanding of safety profiles, and establishing management strategies for serious AE of special interests following mRNA COVID-19 vaccination.