

Pioneering a Unified Platform for Comprehensive Vaccine Safety Assessment – The Global Vaccine Data Network (GVDN) Initiative

P3-S4

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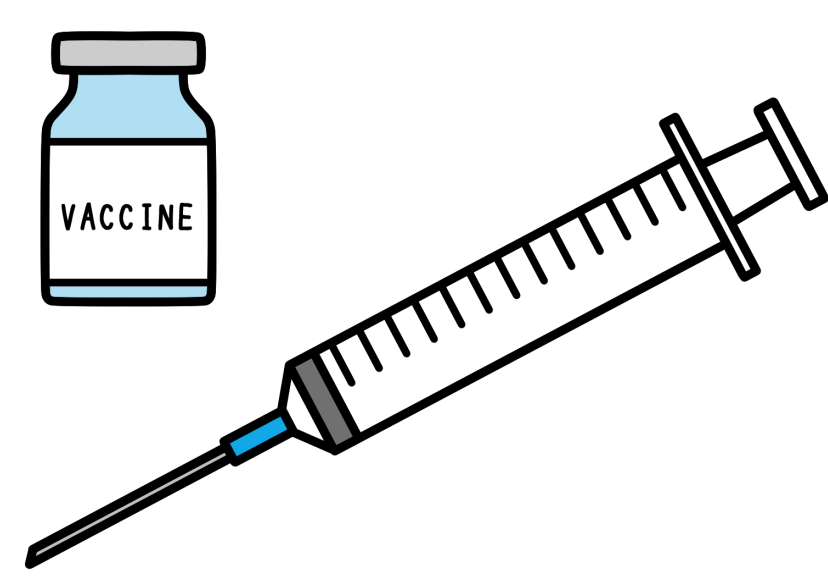
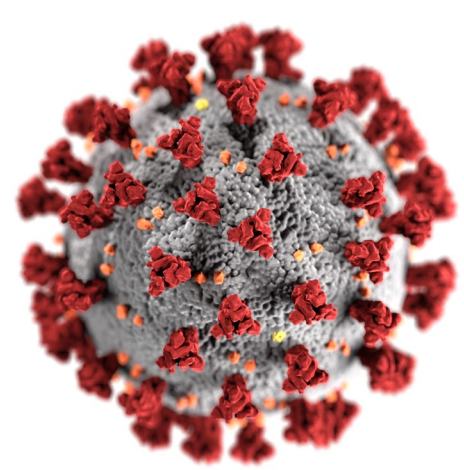
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- The Global Vaccine Data Network™ (GVDN®) has established a collaborative framework to globally assess vaccine safety, particularly focusing on rare adverse events.

- By utilising big data and combining both individual patient data analysis and site-level analysis results from diverse global sites, the GVDN enables comprehensive epidemiological studies to enhance evidence-based vaccine safety decisions and boost global vaccine confidence.

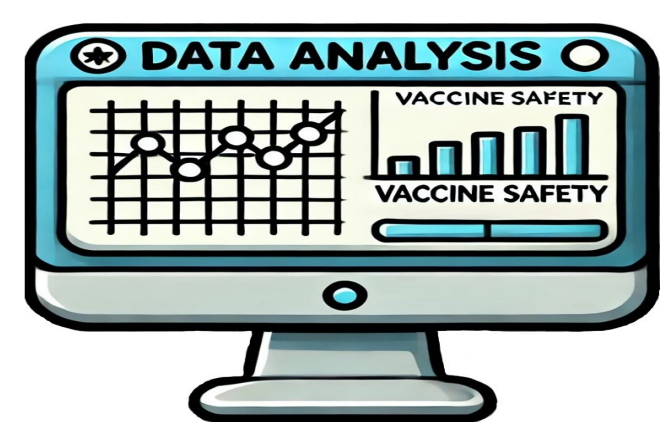
BACKGROUND

- Fragmented vaccine safety data globally hindered comprehensive assessment of outcomes and rare adverse events. In 2019, leaders in vaccinology and public health established the Global Vaccine Data Network (GVDN) to address this challenge through international collaboration.
- The use of big data from >100 millions of vaccinated individuals enables GVDN to characterise vaccine safety, promote evidence-based decisions and increase global vaccine confidence.
- This presentation outlines a pragmatic approach for conducting global epidemiological studies on COVID-19 vaccine safety within the GVDN framework.
- Adverse events of special interest (AESI) include Guillain-Barré syndrome, myocarditis and pericarditis, and vaccine-induced immune thrombotic thrombocytopenia.



DESCRIPTION

- Global Coordinating Centre (GCC):** Auckland UniServices Limited, New Zealand.
- Harmonised protocols:** Standardised statistical analysis plans across four AESIs to ensure methodological consistency while accommodating differences between AESIs.
- Data sharing and analysis:**
 - Common REDCap database for standardised data formatting across sites.
 - Minimal datasets template for sharing de-identified individual-level data for combined individual patient data (IPD) analysis.
 - Analysis results templates: Analysis results templates for sites that can only share site-level results.
- Analysis methods:**
 - Self-controlled case series (SCCS) efficiently uses data from cases only, assessing the relative incidence of AESI in post vaccination risk period.
 - Hierarchical modelling strategies to handle the complexities arising from non-convergence due to low case numbers.
- Flexibility:** Site-level analysis and IPD analysis are supported, with centrally developed analysis scripts.
- Meta-analysis:** GCC conducts a random effects meta-analysis to combine site-level and IPD analysis results.



OUTCOMES

- Participation included 20 countries/sites globally with data ranging from de-identified individual patient data (IPD) to aggregated site-level results.



- Pooled IPD and site-level results were meta-analysed.
- The study design accommodated varying event numbers per site, ensuring inclusivity and subgroup analysis for rare AESIs.
- Results finalisation is currently underway.



IMPACT and LESSONS

- Global collaborative efforts are crucial for studying rare post-vaccination events that single-centre studies cannot address.
- The GVDN serves as a model for global vaccine safety monitoring, aiding COVID-19 adverse event assessments and expanding to monitor other vaccines worldwide.
- Study design must accommodate variations between sites, including:
 - Time lags between event reporting and data availability.
 - Variability in size and available patient data.
 - Data confidentiality, consent, and suppression of small numbers.

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GLOBAL VACCINE DATA NETWORK

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