P1- J10

Combining multi-jurisdictional data for vaccine safety investigations of rare adverse events

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Two Australian states have established an interstate data-sharing model with proven benefits for investigating rare adverse events of special interest whilst maintaining jurisdictional data privacy and integrity.

BACKGROUND

The COVID-19 pandemic has highlighted the necessity for rapid post-licensure vaccine safety investigations. These investigations are crucial for generating accurate risk-benefit analyses, thereby ensuring public safety and trust. The investigation of rare but serious Adverse Events of Special Interest (AESI) are not possible for small populations without adequate vaccination or adverse event data, particularly when disaggregating data by population demographics.

METHODS

Victoria (Vic) and West Australia (WA) have each established routine data-linkage between the Australian Immunisation Register and their respective hospitalisation and mortality data collections. A multi-jurisdictional combined analysis should be considered if the AESI meets all the following criteria:

1. The condition is rare, or the number of doses administered for the vaccine in question is too low to have generated statistical confidence in single jurisdictions alone.
2. Understanding of the diagnostic practices of the AESI between jurisdictions.
3. A power analysis determines that between the participating jurisdictions there is sufficient sample size.
4. The vaccine safety question is answerable with the data fields available.
5. The vaccine safety question is of mutual interest between the vaccine safety jurisdictions and the communities they serve.
6. The vaccine safety question falls within the existing public health surveillance agreements.

In the data-sharing model each state can generate de-identified data for an AESI, using agreed case definitions, data model, and analytical methods. It can be combined according to either of the below three strategies:

1. Meta-analysis strategy

Each jurisdiction completes an independent epidemiological analysis, with the final result combined using a meta-analysis approach with either a fixed- or random-effects model. This strategy is simplest and doesn't require sharing of individual-level data.

2. Pooled analysis strategy

Each jurisdiction producing a linelist of de-identified individual-level cases who meet the case definition, with their vaccine exposure status and other relevant fields (e.g. age group) depending on the condition under exploration. Each linelist should contain identical fields in the same format and the de-identified linelists are shared with one jurisdiction to pool the data and conduct the combined epidemiological analysis. This strategy allows for detailed disaggregated data analysis, even when one jurisdiction did not have enough data to generate a point estimate.

3. Cross-jurisdictional analysis strategy

A true distributed data model which allows the linkage of records for the same individual across different jurisdictions. This strategy is conducted as per the pooled analysis strategy, but with the addition of a unique identifier that is common between jurisdictions to connect them. The sharing of this line listed data may be arranged on a case-by-case basis or set up as an automatic repository of data on a shared secure platform. This strategy improves accuracy for datasets that capture people who live in border-towns where cross-border healthcare seeking is common.

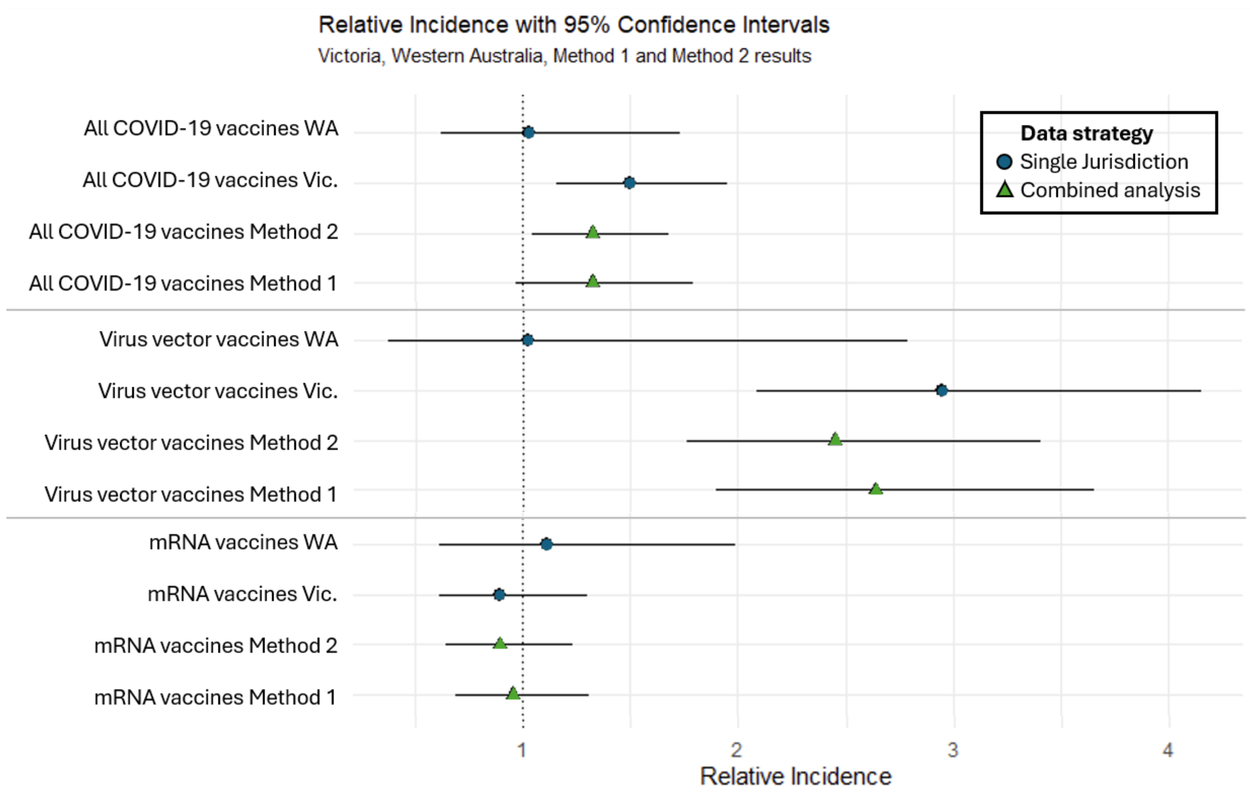
EXAMPLE: COVID-19 VACCINES & GUILLAIN BARRE SYNDROME

To demonstrate the utility of this data-sharing model, WA and Victoria combined data from a self-controlled case series, investigating the association between COVID-19 vaccines and Guillain-Barré syndrome (GBS).

Between 1-Jan-2021 to 30-Jun-2023 there were 401 GBS coded admissions in Victoria and 149 admissions in WA (ICD-10-AM code G61.0). Vic. found an increased relative incidence (RI) of GBS in the 42-days following AstraZeneca's COVID-19 Vaxzevria® vaccine. The increased incidence was also observed in WA however was insignificant due to small case numbers. Combined results:

- **1. Meta-analysis* strategy:** RI: 2.37, 95%CI: 1.69,3.31
  *fixed-effects chosen due to homogeneity of data capture and data analysis between states
- **2. Pooled strategy:** RI: 2.27, 95%CI:1.63,3.17
- **3. Cross-jurisdictional analysis:** Unable to be conducted due to ethics and data custodian constraints.

Both strategies tested confirmed the increased incidence following Vaxzevria®. Both strategies resulted in a decreased standard error and greater precision of the estimate compared to either state alone.



CONCLUSIONS

- This project represents successful co-investigation of rare AESI by two vaccine safety jurisdictions to generate more precise and timely estimates that can be used for benefit-risk analyses.
- Multi-jurisdictional collaborations are key to effectively investigate rare events rapidly and equitably in countries with relatively small populations.

FOR MORE INFORMATION ABOUT:

Vaccine Safety Health Link (Vic.)

Melbourne Children's — A world leader in child and adolescent health
The Royal Children's Hospital Melbourne
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Western Australia Vaccine Safety Service (WA)

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