6th Pharmacoepidemiology Research Network Symposium

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ABSTRACTS

COVID-19 Vaccines: U.S. Centers for Disease Control and Prevention safety monitoring activities

Julianne Gee

U.S. Centers for Disease Control and Prevention

COVID-19 vaccines are powerful tools to reduce the burden of COVID-19 disease and its serious complications, including hospitalization and death. Three vaccines are currently authorized or approved for use in the United States. Recommendations range from vaccinating children as young as 5 years of age to giving booster doses to adults ≥ 65 years of age. In all, over 420 million Americans have been vaccinated. Monitoring vaccine safety is a priority for the Centers for Disease Control and Prevention (CDC); safety monitoring has been the most intense and comprehensive in U.S. history, using established systems such as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD), as well as newly created systems such as v-safe and the v-safe pregnancy registry. Monitoring efforts have rapidly characterized the safety profiles of COVID-19 vaccines and confirmed that the majority of reported side effects are mild and transient with most reported adverse events being non-serious. Since the inception of the COVID-19 vaccination program, CDC systems have detected and/or rigorously evaluated several serious adverse events including anaphylaxis, thrombosis with thrombocytopenia syndrome, Guillain-Barré syndrome, and myocarditis. Follow-up of confirmed myocarditis cases following COVID-19 vaccination to assess long-term outcomes is in progress. The CDC has funded the Global Vaccine Data Network, a multinational research consortium consisting of 22 data partners in 18 countries, to evaluate the safety of COVID-19 vaccines. In addition, the CDC is involved in multiple efforts globally, providing technical assistance for COVID-19 vaccine safety monitoring and exchanging information with international partners. As COVID-19 vaccine recommendations expand to include lower ages and additional vaccinations are administered in the United States and worldwide, the CDC and its international partners continue to ensure that vaccine safety is a priority and remain vigilant in vaccine safety monitoring efforts.

m-Health based detection of Adverse Events Following Immunisations: Does this improve vaccine pharmacovigilance?

Michael Gold

University of Adelaide and Women's and Children's Health Network, Adelaide, Australia

Post-licensure surveillance of Adverse Events Following Immunisations (AEFIs) is essential for vaccine pharmacovigilance. Passive reporting of AEFIs is the primary mechanism of surveillance. However, in 2019, 44% of 191 countries globally did not meet the required indicator of ≥ 10 AEFI reports per 100,000 surviving infants. The COVID-19 pandemic and rapid vaccine roll-out has demonstrated the necessity for robust vaccine pharmacovigilance and in some jurisdictions strengthening of AEFI surveillance has occurred. However, enhancing passive surveillance through additional strategies, such as the use of m-Health, cohort event monitoring, and sentinel surveillance have also been used. In the USA and Australia SMS-based surveillance has been widely implemented through V-Safe and Ausvaxsafety, however, the utility of these mechanisms of surveillance requires further evaluation. In 2018, the Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) randomised control trial investigated the feasibility and acceptability of SMS based surveillance and the findings of this trial inform the use of m-Health for AEFI surveillance.

A global vaccine data network – now a reality

Helen Petousis-Harris

University of Auckland

Assessment of adverse events following immunization (AEFI) that have a delayed onset or diagnosis, occur beyond clinical trial study follow-up, are rare or occur among subpopulations are often beyond the scope of initial clinical programmes. This makes robust post authorisation studies critical. However, rare events require very large study populations, and are often beyond the ability of single countries. Isolated multinational collaborations have successfully generated information on some vaccines, but sustainable cost-effective infrastructure and capacity building are needed for both timely hypothesis testing and to assess new vaccines. COVID-19 has highlighted the importance of such systems.

The Global Vaccine Data Network (GVDN) was established in 2019, initially as a network of over 16 sites in 14 countries, and now includes over 21 sites across over 18 countries. All have demonstrated capacity in vaccine safety studies either independently or as collaborators. The consortium is supported by a coordinating centre based at the University of Auckland in New Zealand.

In response to COVID-19 the GVDN received a United States Centers for Disease Control grant to undertake a programme of safety activities. These activities include the establishment of background rates of adverse events of special interest, observed over expected assessments, association studies, genomic studies, and outputs aimed at assisting with vaccine confidence.

The capacity currently exists globally to assess vaccine safety across a network of geographically diverse sites including populations of hundreds of millions. Developing this capacity further will be critical to the assessment of COVID-19 vaccines and other newly introduced vaccines in the future.

New Zealand pharmacovigilance for Comirnaty vaccine

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Introduction

The COVID-19 pandemic has resulted in the unprecedented development of vaccines designed to reduce the severity of infection, hospitalisations and deaths. Whilst the production of these vaccines has been rapid, the approvals for use in various countries have been based on good quality clinical trial data, albeit at an earlier stage than usual. As for all medicines, information from safety in clinical trials only partly describes the full safety profile and post-market safety monitoring is required.

In addition, for the COVID-19 vaccines fears regarding the 'new' technology used to produce the vaccines and the rapid development have fuelled vaccine hesitancy. Therefore, a robust safety monitoring system is essential in helping to address these fears.

This presentation will outline the safety monitoring system in New Zealand for the COVID-19 vaccines and some of the outcomes of this monitoring. This work is the result of a collaboration between the Centre for Adverse Reactions Monitoring (CARM), Medsafe, and the COVID-19 Vaccine and Immunisation Programme (CVIP).

Safety Monitoring Overview

We will describe how we have leveraged new technologies and systems available in the Ministry. For example:

- Integration of reports from the COVID Immunisation Register (CIR) and webform on the CARM website into a new vaccine safety monitoring database
- Use of Qlik dashboards to visualise data for reported adverse events
- Use of data linkage between the CIR and other datasets
- Post Vaccine Symptom Check (an active monitoring system).

We will also describe the process for detecting, investigating and communicating safety signals.

What does the safety profile look like?

We will provide a summary of the safety profile confirmed for New Zealand to date for Comirnaty.

We have had a fantastic response to calls for reporting to CARM through the passive reporting system, with an average reporting rate of 4.8 reports per 1,000 vaccinations.

A number of safety signals have been investigated and continue to be closely monitored. Myocarditis/pericarditis was added to the Comirnaty data sheet and we will provide more information on this side effect to vaccination.

Near real time detection of COVID-19 vaccine safety signals in New Zealand with Rapid Cycle Analysis (RCA)

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Initial safety and efficacy profiles of vaccines are identified through clinical trials. However, there is an inherent limitation because the number of participants is limited, which may mean that rare adverse reactions are not identified. Following approval of a drug, post-market surveillance is crucial to ensure adequate safety and to raise awareness of any potential rare adverse reactions.

Using the National Minimum Data Set (NMDS), the rates of adverse events of special interest (AESIs) that occur in people who have received the Pfizer COVID-19 vaccine are compared to background rate data from the SAFE study led by Associate Professor Helen Petousis-Harris. If the rate of adverse events among vaccinated people is higher than among the comparison group, the vaccine may be associated with an adverse event. Certain adverse reactions that occur following vaccination with the Pfizer COVID-19 vaccine have also been observed in people who develop COVID-19. This affects the ability to obtain accurate statistics on an adverse reaction attributed to the vaccine, especially in countries with high levels of COVID-19 infection, where many cases may be undetected. However, New Zealand is in a unique position to get accurate measurements on the safety profile of the Pfizer vaccine because we are among a small number of countries with low levels of COVID-19 infection.

Rapid Cycle Analysis allows for near real time detection of AESIs by calculating the relative risk (RR) at a specific point in time from observed and expected rates with specific risk windows. To do this effectively, criteria used to measure these AESIs must be individualised. For example, the onset time of a particular disease could influence the risk window, or a subset of the population might be at higher risk. This presentation outlines the process implemented by Medsafe and the COVID-19 Vaccine and Immunisation Programme for near-real-time signal detection of AESIs following COVID-19 vaccines, to support vaccine safety monitoring for the New Zealand population.

Engaging communities in conversations about COVID-19, vaccines, and community immunity

Karyn Maclennan

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Pharmacoepidemiology Research Network, University of Otago, Dunedin

More than ever, rangatahi (youth), whānau, and communities need access to culturally relevant, accessible and engaging information about medicines that is grounded in science, not mis- or disinformation. This is imperative in enabling young people and their whānau to have confident conversations and make informed decisions about their use of medicines, and in building greater capacity to actively participate in addressing health issues in their communities and in society more generally.

Framed by an overarching waka and wayfinding analogy, we have collated and created an engaging suite of resources through which young people and their whānau have journeyed into the science of medicines. Each paddle of our waka steers to a different part of this journey:

Discover – where medicines come from

Create – making medicines

Explore – how medicines work

Protect – how to use medicines safely

Imagine – what the future holds

Removing barriers to accessibility, we have taken these hands-on, interactive, visual and story-telling resources/activities to settings of everyday life for our target audience. Travelling to schools, marae, community hubs, and festivals, we have engaged over 3,500 people across Otago/Southland in the last 10 months, igniting conversations and creating a welcoming, accessible, and engaging environment to discover and explore the science and significance of medicines.

Amidst a global pandemic in which vaccines play a vital role, generating conversations and enabling informed decision making about COVID-19 vaccination is a timely imperative. Our community engagement relating to COVID-19 vaccination (including Corona-Bowling/COVID Kerplunk community immunity

challenges and touchscreen delivery of multi-layered content about SARS-CoV-2 and COVID-19) has been hugely valued and appreciated by our communities.

This work is ongoing and has highlighted: the importance of kanohi-ki-te-kanohi (face-to-face) engagement with our communities, and a huge appetite to learn about medicines – no te whitiwhiti kōrero, i mohio ai (it is through shared conversation, that I understand).

Cutaneous adverse reactions to the Pfizer/BiONTech COVID-19 vaccine in New Zealand

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Acknowledgements: Rhiannon Braund[3], Michael Tatley[4]

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The introduction of vaccination is a significant step towards controlling the global COVID-19 pandemic. Adverse reactions to the vaccine, including cutaneous manifestations, can be a barrier to vaccination. We present a case series of 18 patients who have been referred to the dermatology department of a New Zealand public hospital since April 2021, with cutaneous manifestations following their vaccination and diagnosed as likely vaccine reactions by dermatologists. The range of reactions included urticaria, pitryriasiform eruptions, local erythematous plaque, leukocytoclastic vasculitis, and flares of pre-existing psoriasis, contact dermatitis and reactivation of herpes zoster. Cutaneous adverse reactions are uncommon and are generally not contraindications to future vaccination.

Remdesivir and renal injury: interpreting global case safety reports in the context of COVID-19 infection

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Background
The safety profile of remdesivir, conditionally approved for COVID-19, was limited at its 2020 introduction. Reports of suspected adverse drug reactions are collected in VigiBase, the WHO Global Database of Individual Case Safety Reports (ICSRs). A previous VigiBase study, employing a COVID-19 indication-focused disproportionality analysis to minimize confounding from underlying polysymptomatic disease, provided a descriptive analysis of COVID-19 ICSR data for remdesivir. Disproportionate renal outcomes for remdesivir were noted. Renal injury had been demonstrated in preclinical animal studies.

Aim
Using the COVID-19 indication-focused disproportionality analysis, to ascertain the effect of potential confounders on the adjusted reporting odds ratio (aROR) for remdesivir and renal conditions.

Methods
A composite renal outcome was defined based on MedDRA Higher Level Grouping Terms (HLGT) Nephropathies, Renal disorders (excl nephropathies) and Urolithiases. From the descriptive analysis an aROR was calculated and potential confounders identified for remdesivir and the renal outcome. Five sensitivity analyses were undertaken.

Results
From the descriptive analysis, 5299 reports for remdesivir were entered into VigiBase during 2020, with 74% from the Americas. In 1089 (21%) data indicated severe/critical disease. Co-reported medicines peaked during the first 3 days of remdesivir treatment several with known nephrotoxicity. Remdesivir monotherapy was recorded in 37.5% of reports suggesting incomplete data. Based on these

observations, adjustment was made for covariates including COVID-19 and/or nephrotoxic co-medications and the overall aROR for the selected HLGTs was 2.9, confidence interval 2.3–3.6. In the present study the results of the five sensitivity analyses exploring confounding by disease severity, potential data quality issues and country specific reporting patterns, suggest that the results are robust, with a final aROR between 2.5 and 3.6.

Conclusion

Disproportionality analysis using a VigiBase background of reports for medicines only when they were indicated for COVID-19 infection led to a more conservative estimate of the aROR (2.9) compared with a previously published value for acute renal failure of 20.3 which had used, as background data in VigiBase, other medicines used to treat COVID-19 but without restriction to the COVID-19 indication. Our sensitivity analyses based on the potential confounders showed that they did not impact the aROR.

Medicine access equity – the people behind the numbers

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[1] *Te Pātaka Whaioranga, Pharmac*

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In 2019, Te Pātaka Whaioranga, Pharmac published its discussion document *Achieving medicine access equity in Aotearoa New Zealand – towards a theory of change*. Equitable use and access is a strategic priority for Pharmac and it has an established work programme to support this priority. This work contributes to Pharmac's objectives for Te Whaioranga – its Māori responsiveness strategy, and its Pacific responsiveness strategy. Sandy's presentation will provide an overview of Pharmac's work including their data analytic approaches for insights on access to medicines. Professor Norris' presentation will provide the lived experience of people facing barriers to access medicines.

Professor Norris and her team from the University of Otago's Division of Health Sciences were awarded funding in 2020 through the Health Research Council of New Zealand's new Health Delivery Research Investment round to investigate issues around access to medicines. This project, a collaboration between Pharmac and researchers, aims to explore lived experience, understandings, and views of accessing medicines. Many pharmacoepidemiological studies have found inequity in medicines utilisation, with Māori, Pacific, and people living in areas of high socio-economic deprivation using fewer medicines than expected. The *Access to Medicines: Exploring Lived Experience to Inform Policies and Programs* study attempts to understand some of the reasons for these differences in utilisation by exploring the lived experience of people facing inequities. The study aims to recruit 27 households (7 Māori, 7 Pacific, 6 former refugee, and 7 Pakeha households living in poverty) and follow them for 12 months, talking with them about their lives and their experiences of seeking healthcare and medicines.

Understanding lived experience can shed light on the realities that shape inequitable access to, and utilisation of, medicines and complement the findings of quantitative studies.

Long-acting bronchodilators and risk of acute coronary syndrome in people with chronic obstructive pulmonary disease

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Background
Chronic obstructive pulmonary disease (COPD) and coronary heart disease are leading causes of health loss and death, and there is concern that long-acting bronchodilator drugs (long-acting muscarinic antagonists [LAMAs] and long-acting beta$_2$-agonists [LABAs]) may further increase the already high risk of coronary events in people with COPD. In a recent case–control study nested within a national cohort of people who commenced long-acting bronchodilator therapy for COPD, we found that current use of LAMA and LABA dual therapy (concomitant use of a LAMA and a LABA) was associated with a higher risk of acute coronary syndrome (ACS) when compared with current use of LAMA therapy (LAMA alone). However, we did not have information about several important predictors of cardiovascular disease and so were unable to rule out some residual confounding by underlying cardiovascular risk.

Aim
To estimate the risk of ACS in current users of LAMA and LABA dual therapy relative to current users of LAMA therapy.

Methods
We undertook a nested case-control study using linked data from the PREDICT Cardiovascular Disease Cohort, regional laboratories, and the Ministry of Health's National Collections. The underlying cohort (n=29,993) consisted of people aged 45–84 years who had undergone cardiovascular risk assessment in primary care and had commenced long-acting bronchodilator therapy for COPD between 2006 and 2016. Cases were cohort members diagnosed with fatal or non-fatal ACS after cohort entry (date of first long-acting bronchodilator dispensing). We used risk set sampling to randomly select up to 10 controls (n=13,550) from the cohort for each

case (n=1490), matching by date of birth, sex, date of cohort entry, and COPD severity. Conditional logistic regression was used to estimate odd ratios and 95% confidence intervals (95% CI).

Results

Relative to current use of LAMA therapy, the adjusted odds ratio for current use of LAMA and LABA dual therapy was 1.72 (95% CI 1.28–2.31). Current users of LABA therapy and LAMA therapy had comparable risks (adjusted OR 1.06; [95% CI: 0.82–1.37]).

Conclusion

Given the relatively modest patient-relevant benefits of using two versus one long-acting bronchodilator, these findings have important implications for clinical decisions about the potential benefit/harm ratio of COPD treatment intensification.

SSRI and SNRI antidepressants in late pregnancy and risk of postpartum haemorrhage

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Background

Serotonin release from platelets promotes clot formation. Antidepressants that inhibit serotonin transporters, such as selective serotonin reuptake inhibitors (SSRIs) and serotonin noradrenaline reuptake inhibitors (SNRIs), can impair platelet function by reducing the amount of serotonin taken up and stored within the platelets, resulting in prolonged bleeding. Most evidence supports an increased risk of postpartum bleeding following exposure to SSRI/SNRI antidepressants in late pregnancy. SNRIs appear to carry a higher risk than SSRIs, but little is known about the risk of specific SSRIs.

Aims

To assess the association between SSRI/SNRI use in late pregnancy and 1) any postpartum haemorrhage, and 2) severity of postpartum haemorrhage.

Methods

Members of the New Zealand Pregnancy Cohort whose pregnancy ended in delivery (n=621,742) were linked with their dispensing records in the Pharmaceutical Collection to determine antidepressant exposure in late pregnancy. Exposure was defined as having received a dispensed supply of antidepressant sufficient for use within the last 30 days of pregnancy. Diagnostic and procedure codes in the National Minimum Dataset were used to identify pregnancies complicated by postpartum haemorrhage within 6 weeks of delivery, and those who received a blood transfusion during the same admission (a proxy for haemorrhage severity).

Results

Unpublished findings will be discussed during the presentation.

Paracetamol overdose in New Zealand

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Background

Paracetamol poisoning is reported as one of the top reasons for calls to the National Poisons Centre in New Zealand. It is also reported to be one of the leading causes of drug overdose in cases reported to the hospital in developed countries. Paracetamol overdose occurs mainly due to intentional self-harm or accidental overdose. Our study focuses on highlighting the prevalence of paracetamol overdose between the years 1995 to 2018 and the predominant cause across all the District Health Boards in New Zealand.

Aims

- To study the frequency and cause of paracetamol overdose in New Zealand
- To evaluate the frequency and occurrence of paracetamol poisoning across gender and age groups in New Zealand and to raise public awareness on paracetamol overdose.

Methods

The study is a retrospective descriptive study with data obtained from the Ministry of Health, New Zealand, of all reports received from all the District Health Boards of publicly funded hospitalisations due to paracetamol from 2007 to 2018

Results

Poisoning by paracetamol (4-AP derivative) accounted for an average of 21% of hospital admissions due to poisoning by medicaments over the 23-year period reviewed (1995–2018). A higher percentage of paracetamol poisoning was caused by intentional self-harm (79%) while 16% of cases were caused by accidental overdose. Paracetamol poisoning was higher in females (73%) compared to males (27%). The highest level of paracetamol poisoning was seen in the age group 15–19 years (29%) followed by the 20–24 years age group (15%).

Conclusion

Our study shows that in New Zealand, paracetamol poisoning contributes significantly to both the annual percentage of poisoning by medicines, and hospital admissions. Our study also shows that the majority of cases of paracetamol poisoning are caused by intentional self-harm and this occurs 3 times more in females than males with the age group 15–24 years mostly involved. Our study thus shows the need for urgent measures to be taken to reduce the occurrence of paracetamol poisoning. A focus on age and gender specific strategies can be effective in reducing paracetamol poisoning.

Investigating patterns of cholinesterase inhibitor utilisation in New Zealanders with Parkinson's disease: a nationwide study using linked administrative data

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Background

Parkinson's disease (PD) is a progressive neurodegenerative disorder affecting approximately 12,000 New Zealanders. Cognitive changes, ranging from mild impairment to dementia, are common in individuals with PD. Like other dementias, symptoms of PD dementia are treated with cholinesterase inhibitors. Previous New Zealand studies have examined trends in the utilisation of cholinesterase inhibitors, however patterns of their use in PD are unknown.

Aims

To describe patterns of cholinesterase inhibitor utilisation in PD in New Zealand.

Methods

All community dispensings for cholinesterase inhibitors were extracted from the Pharmaceutical Collection between 1 January 2011 and 31 December 2019. The probability of a PD diagnosis was determined through Bayesian modelling using national and local datasets.

Results

Cholinesterase inhibitors were dispensed to 24,575 individuals in the 9-year study period, of these, based on our Bayesian model 1,629 (7%) were estimated as having PD and represented 9% of the total PD cases estimated during this period. For those with PD dispensed a cholinesterase inhibitor 69% were male, 90% were New Zealand European, 4% were Asian, 3% were Māori and 2% were Pasifika. The mean age when starting cholinesterase inhibitor treatment was 76 years (SD 8 years) and the mean duration of treatment was 18 months (SD 20 months). Ninety-seven percent of those with PD had been dispensed donepezil compared to 10% for rivastigmine.

Conclusions

We estimate that 9% of those with PD are treated with cholinesterase inhibitors. The prevalence of PD dementia is approximately 30%, with a lifetime risk of dementia in PD approaching 50%, indicating low use of cholinesterase inhibitors in PD dementia. Rivastigmine is the only cholinesterase inhibitor approved for treatment of PD dementia, however donepezil is far more widely used. In New Zealand rivastigmine requires special authority which may contribute to its under use.

Randomised controlled trial of removing prescription charges: preliminary findings of the FreeMeds Study

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Background
Prescription charges prevent many people from accessing the medicines they need to maintain or improve their health. In New Zealand, where most people pay $5 per prescription item, Māori and Pacific peoples, those living in most deprived areas and those with chronic health conditions are the most likely to report that cost prevents them from accessing medicines. This may lead to poorer health outcomes and increased use of more expensive publicly funded care, such as hospitalisations.

Aims
To evaluate the effect of removing prescription charges on health outcomes and health care utilisation patterns of people living in high deprivation areas with high health needs.

Methods
We recruited participants living in areas of high socio-economic deprivation (NZDep 7-10) with high health needs (i.e. who either took medicines for diabetes, had COPD, or who took anti-psychotic medication). They were randomised to either the intervention group or the control group. The study paid for all $5 prescription charges for those in the intervention group from 1 February 2020 to 31 January 2021. Participants in the control group received usual care.

The primary outcome was hospital bed-days. Secondary outcomes were: all-cause and diabetes/mental health-specific hospitalisations, prescription medicines dispensed (number and type), deaths, emergency department visits, and quality of life as measured by EQ-5D-5L.

Results

We recruited 1,054 participants, of whom 47% were Māori.

Analysis is ongoing. Preliminary results will be presented at the meeting.

Conclusions

Being unable to afford prescription medicines is only one of many factors that influence adherence to medicines, but removing prescription charges would be relatively simple and in New Zealand would be inexpensive compared to other policy changes. This RCT will help identify the extent of the impact of a simple intervention to improve access to medicines on health outcomes and health service utilisation.