# **COVID-19 Vaccine Strategy**

New Zealand

Dr Michael Tatley

Associate Professor

University of Otago/New Zealand Pharmacovigilance Centre





Te Whare Wánanga o Otágo

### Caveats

#### I am not a New Zealand Government Official

- New Zealand COVID-19 Strategy position references and vaccination details are extracted from publically available sources.
- The New Zealand COVID-19 Vaccine Safety Surveillance Strategy presented is a Framework proposal that is partly implemented.

This presentation reflects observations from The NZ Pharmacovigilance Centre at the University of Otago.





## Outline

- New Zealand COVID-19 Vaccine initiatives
- Proposal for COVID-19 Vaccine Safety Strategy for the Pacific
- IMSN role in ME analysis?





## New Zealand's COVID-19 Vaccine Strategy

#### Outcomes

- Supply of safe & effective COVID-19 vaccine
- Protect Maori, Pacific & other at risk population groups
- Full Cultural, Social, Economic recovery from COVID-19 Impacts
- NZ as a valued contributor to global wellbeing and the COVID-19 response
- NZ, Pacific & Global preparedness to respond to future disease outbreaks

### Work strands

- Global connection & contribution (vaccine development, distribution, use)
- Invest in research global contribution, builds relationships, supports early vaccine access
- Develop manufacturing ability (in case needed)
- Optimise regulatory approaches (ensure quality/safety, support research, enable manufacture)
- Use purchasing arrangements to secure supply & enhance resilience.

### Support WHO in equitable COVID-19 Vaccine distribution globally Includes focus in ensuring vaccine access for our Pacific Island partners





## New Zealand's COVID-19 Vaccine Strategy operational

### Funding allocated to

Domestic research Manufacturing capability International Research Collaboration GAVI assistance

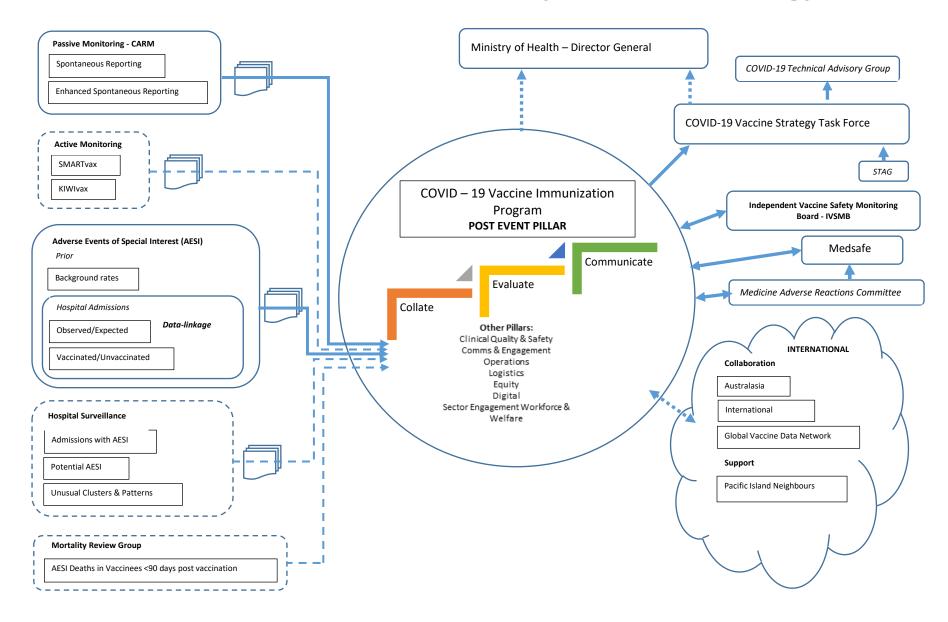
#### Organisational

COVID-19 Strategy Group COVID-19 Vaccine Strategy Task Force Scientific and Technical Advisory Group COVID-19 Vaccine Implementation Task Force *COVID Vaccine Pillars POST EVENT PILLAR* 





### NZ COVID-19 Vaccine Safety Surveillance Strategy



# COVID-19 Vaccine Monitoring in New Zealand

### Passive Monitoring

- CIR Adverse Event Module (20 minute observation window)
  - CARM COVID-19 Online Reporting (outside vaccination site)

#### CARM traditional

Online



- PMS software
- Hardcopy Reporting Card
- Email
- Telephone

- Standardized approach
- Rapid Easy entry
- Tickboxes





# What happens to reports of AEFI's to CARM?

Triaged

Serious Critical terms or events Hospitalization Life threatening Death Medically significant Persisting disability Congenital abnormality

Anaphylaxis Neurological event Bleeding clotting event Adverse Event of Special Interest

- Additional events added/data consistency check/'causality'
- Seek further information to clarify event reported
- Identify events of concern AESI's Patterns of events raising concern

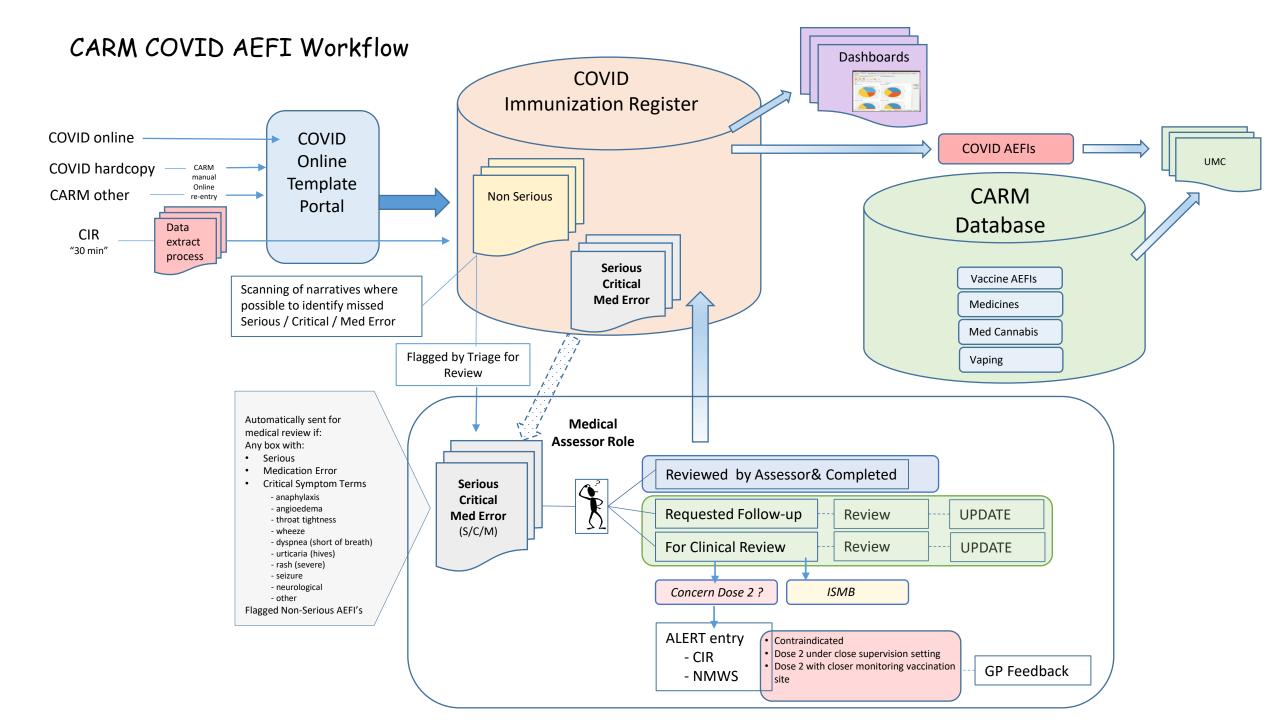
Unexpected events or Signals

#### Independent Safety Monitoring Board

Review Events of concern Review Safety data locally/globally Identify Vaccine Safety issues and risks to CVIP & Medsafe

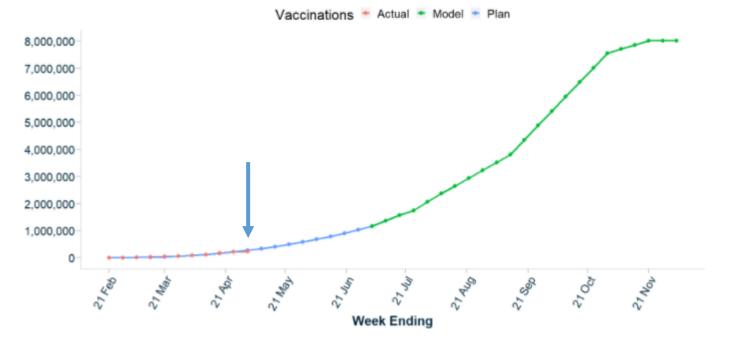






### Cumulative and Planned vaccination doses in New Zealand Pfizer Vaccine

# Cumulative planned and projected doses to December 2021



Dose 1	172 564	
Dose 2	60 024	
TOTAL	232 588	
	27 April 2021	

### Adverse events following Immunisation in New Zealand Pfizer Vaccine

AEFI reports received and vaccine doses administered, up to and including 27 March 2021

155 New AEFI reports since last update (151 new non-serious and 4 new serious)	0 No safety signals (potential safety issues) have been identified	55,143 Total doses administered (cumulative)
443 Total AEFI reports that were non-serious	14 Total AEFI reports that were serious	457 Total AEFI reports that were received (cumulative)

## **COVID-19 Medication Error**

### Principle

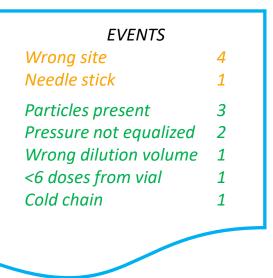
- CARM to receive reports resulting in HARM (i.e. reaches the patient)
- "Programme" manages
  - no Harm
  - near miss

Cold chain	
Quality	
Dilution	

= Immediate response by Operational Programme

### **Reporting options**









Strengthening Pharmacovigilance and Medicines Support Systems in the Pacific

# COVID 19 Vaccine safety Surveillance

Associate Professor Michael Tatley

University of Otago/New Zealand Pharmacovigilance Centre

July 2018





Te Whare Wánanga o Otág

# The Pacific region

### ..... Similarities with LMIC...

### • Little PV attention/activity in the South Pacific Region

3 countries PV training, 2 members of PIDM 21 (2002) & 27 reports

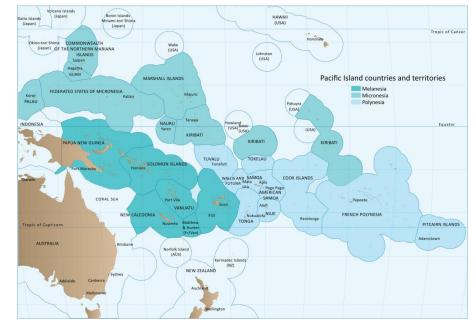
- Huge Area
- Population

11.9 million 10.13 million (PNG/F/Sol) 3.37 million (excl. PNG) 1.77 million (excl. PNG/F/Sol)

• GDP

US\$ 5,923(Avg) US\$ 4,274(Median)

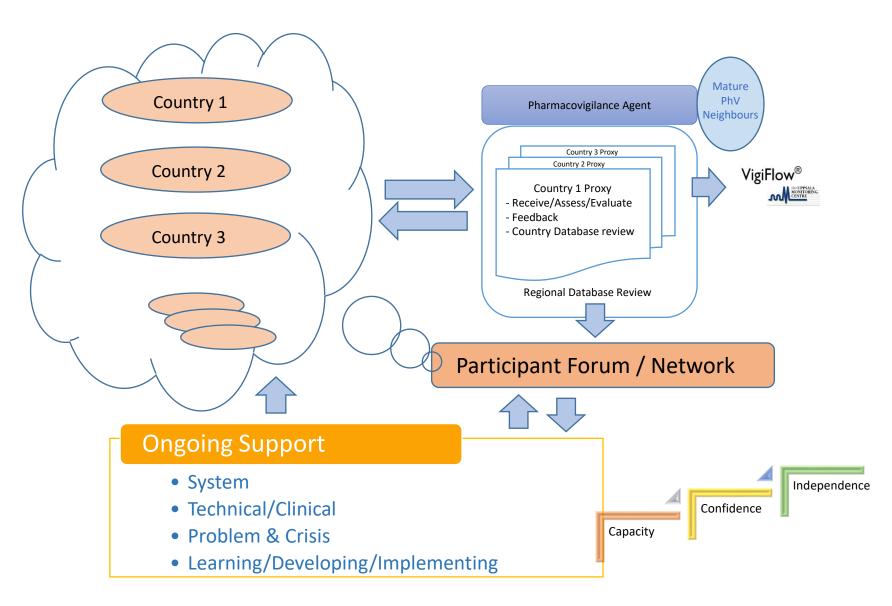
• Historical Affiliations & Independent







## **Operational Scenario**







### COVID-19 Medication Error Global Epidemiology Questions

### Coding Schema's?

- What coding schema's are being used if any by countries
  - NZ has developed a Pfizer-specific coding schema to support evaluation of reports

### Collation and review of ME reports from IMSN member countries?

Plans or possibilities to collate/analyze/describe IMSN member countries collective experiences



