*Disaster Medicine and Public Health Preparedness*

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# Pandemic Incident Management for Vaccine Safety Challenges: Victoria's Alert Advisory Group Experience

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**Brief Report**

**Cite this article:** Clothier HJ, Wolthuizen M, Laemmle-Ruff I, Lewis G, Radkowski C, Buttery J and Crawford N (2024). Pandemic Incident Management for Vaccine Safety Challenges: Victoria's Alert Advisory Group Experience. *Disaster Medicine and Public Health Preparedness*, **18**, e137, 1–5
https://doi.org/10.1017/dmp.2024.100

Received: 27 December 2023
Accepted: 19 April 2024

**Keywords:**
biosecurity; vaccine safety; immunization; surveillance; incident control; pandemic

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**Abstract**

Safe vaccines are critical for biosecurity protection, yet adverse events—rightly or wrongly attributed to immunization—potentially cause rapid loss of confidence, reduced vaccine uptake, and resurgence of preventable disease. Effective vaccine safety incident management is essential to provide assessment and lead appropriate actions to ensure vaccination programs are safe and mitigate unwarranted crisis escalation that could damage vaccine programs and the effective control of vaccine preventable disease outbreaks or pandemics. Incident management systems (IMS) are used globally to direct emergency management response, particularly for natural disasters of fire, flood, and storm. Public health is equally an emergency response and can therefore benefit from these command control constructs. While examples of IMS for outbreak response and mass immunization logistics exist, there is little to no information on their use in vaccine safety. We describe Australia's vaccine safety Alert Advisory Group establishment in Victoria during the COVID-19 pandemic and onward embedding into routine practice, anticipant of new vaccines, and the next biosecurity threat.

Safe vaccines are critical for biosecurity protection with adverse events, rightly or wrongly attributed to immunization, potentially causing rapid loss of confidence, reduced vaccine uptake, and diminished ability to effectively manage biosecurity threats.[1] COVID-19 vaccination was rightly planned as high-volume rapid delivery programs to combat the pandemic.[2] Such new vaccine implementations at scale inevitably bring challenges demanding preprepared capability to take action to ensure safety and maintain confidence in immunization.

Incident management systems (IMS) are used globally to direct emergency management response, particularly for natural disasters of fire, flood, and storm.[3,4] Public health is equally an emergency response and can therefore benefit from these command control constructs.[5]

The Department of Health of Australia's second largest state, Victoria (population approximately 6.5 million),[6] in anticipation of a COVID-19 pandemic vaccine, established a structured escalation pathway called an "Alert Advisory Group" (AAG) modeled on Australia's emergency interservice incident management system (AIIMS).[3] This ensured the state was primed to rapidly respond to safety challenges, provide assessment, lead actions to ensure program safety, and mitigate unwarranted crisis escalation that could damage the vaccination response critical to halt the pandemic.

We describe the vaccine safety AAG incident management structure, its use during the pandemic, and onward embedding into routine practice, anticipant of new vaccines and the next biosecurity threat.

## Victoria's Vaccine Safety Surveillance Landscape

Victoria has comprehensive robust vaccine safety services through Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC), established in 2007.[7,8] SAEFVIC provides intelligence informing national program policy with integrated clinical services for review of serious adverse events and clinical advice to individuals. During COVID, these clinical services were expanded to a state-wide network of specialist immunization services (VicSIS clinics) for both adult and pediatric vaccinees.[9]

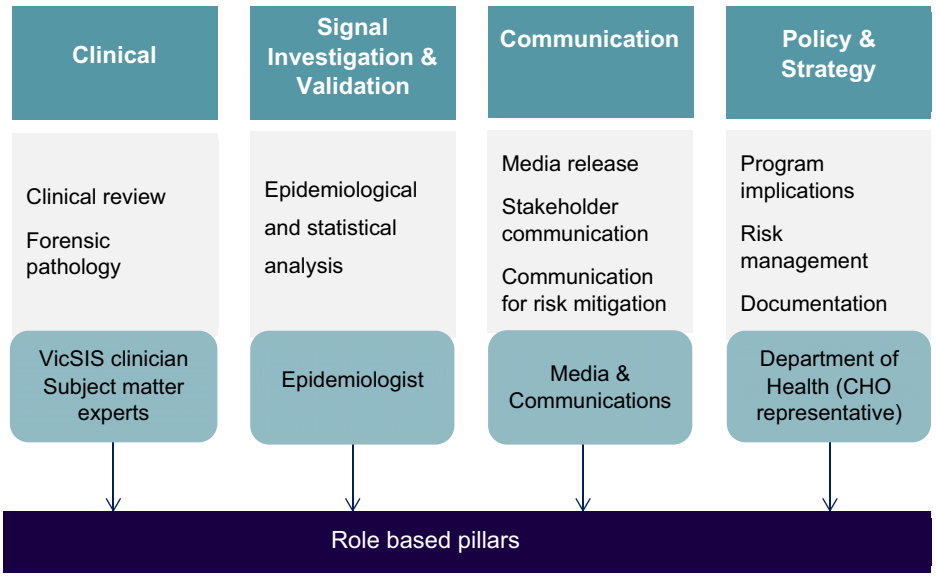


**Figure 1.** The four-pillar structure of Victoria's Alert Advisory Group.

SAEFVIC surveillance comprises multifaceted data interrogation systems to effectively detect, validate, and investigate vaccine safety signals.[8,10,11] The state-level system partners with the national AusVaxSafety post vaccination active surveillance survey that supports vaccinees from participating sites to report adverse events via automated responses on days 3, 8, and 42 post-vaccination.[12] This integrated program of surveillance provides assurance that vaccines are as safe as possible; however, inevitably alerts or challenges will arise, real or spurious. To maintain confidence in immunization, it is important that these challenges can be rigorously and transparently addressed.[1,13]

## Methods

### *Alert Advisory Group (AAG) Structure*

The AAG comprises four foundation role-responsibility pillars representing key stakeholders across actionable themes: clinical, epidemiology, policy, and communications (Figure 1). The roles were not designated to individuals but purposely maintained as expertise-based with a cascading roster to ensure each domain could be consistently represented. The AAG was not an alternative to clinical care or a causality assessment but was tasked to provide rapid assessment of the safety concern, determine the real or perceived risk to the vaccination program and/or risk of consequent vaccine hesitancy in the community, and initiate mitigation strategies as required.

Terms of reference were purposed to ensure (1) department oversight of vaccine safety incident and management, (2) subject matter expertise for informed decision-making, (3) informed stakeholders, (4) identify and mitigate spurious alerts from causing unwarranted alarm, and (5) documentation of process and action outcomes.

Terms of reference were approved by June 2020 in anticipation of the COVID-19 vaccine rollout, which in Australia commenced 8 months later, in February 2021. The aim was to coordinate and not duplicate, particularly as other jurisdictions around Australia established similar processes during the COVID-19 pandemic, with the national regulator (TGA) a standing invite to all AAGs and weekly information sharing via TGA-convened virtual meetings, thus maintaining state and national visibility across vaccine safety concerns. All AAGs were in confidence, with standard confidentiality agreements in place.

### *Triggers and Activation*

An alert was broadly defined as any issue that could cause risk of harm to individuals or confidence in immunization programs. This was intentionally broad to be inclusive and best prepared for the unknown.

Alert triggers were anticipated to arise through international networks, existing surveillance systems intended to capture reports of serious adverse events following immunization (AEFI), surveillance signal detections, and media (including social media).[14] While any cause for concern could trigger an AAG, 5 specific events were predefined: (1) an acute clinical event leading to an intensive care unit admission, life threat, or death, (2) a significant increase in reporting trend above background rate expectation, (3) a media story generating attention that may damage the program, (4) a national or international AEFI issue of concern, and (5) cold chain breach or vaccination error (with vaccine administered to multiple people).

An AAG could be activated by a representative of any one of the four pillars and, during the COVID response, was facilitated by a single point of contact (dubbed "the bat phone") at the Victorian Vaccine Control Centre (VVCC). On receiving a call, the VVCC would schedule an AAG accessing a rostered contact list to ensure each role was appropriately filled and the AAG convened in a timely manner.

### *AAG Activations*

The first AAG activation occurred 3 weeks into the COVID-19 vaccination program for a serious AEFI, which, on review, was


https://doi.org/10.1017/dmp.2024.100

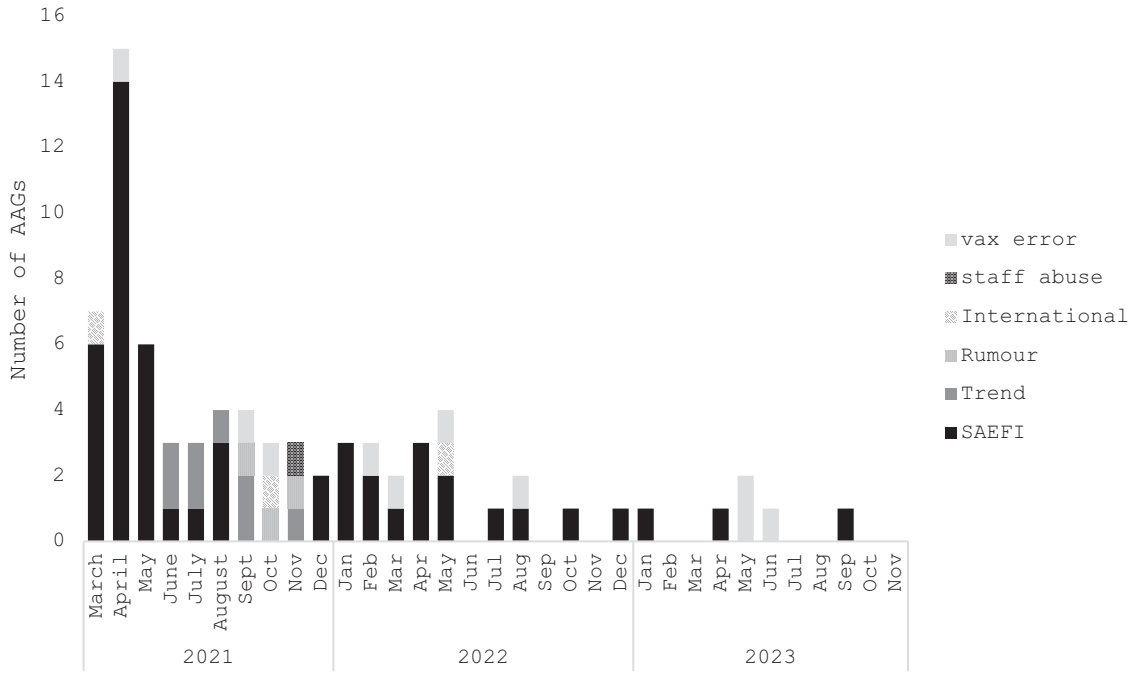


**Figure 2.** Alert Advisory Group meetings by topic, month and year, Victoria 2021–Nov 2023.

considered not associated with vaccination and de-escalated. Shortly thereafter, on March 18, 2021, the second AAG was convened as concerns were raised internationally of blood clots following AstraZeneca vaccination, with European Medical Agency (EMA) and Australian Technical Advisory Group for Immunisation (ATAGI) statements released on March 19, 2021.[15,16]

From February 2021 to November 2023, Victoria convened 73 AAGs (54 in the first 12 months, 71 (97%) related to COVID-19 vaccines). Review of reasons for AAG activation provides insight to the safety challenges arising. Most common (n=51, 70%) were individual serious AEFI followed by 10 (14%) vaccination error events, 8 (11%) potential safety signals, 3 each for media rumors and international scares, and 1 AAG considered abusive behavior toward immunization staff and the impact on their psychological well-being (Figure 2).

Reason for convening AAGs changed over time as the COVID-19 vaccination program matured. The first 3 months were mostly individual serious AEFI—at that time any death triggered an AAG, and as the program initially focused on aged care facilities this was not an uncommon coincidental event.[17] In addition, this period included the first local cases of thrombosis with thrombocytopenia syndrome (TTS).[18] The next 6 months were mixed, with surveillance trend triggers, in particular myocarditis and pericarditis[19] (June 10, 2021 AAG), and rumors, including malicious social media hoaxes fabricating death of 2 youth.[20] From 2022 onward, AAGs mostly responded to individual unusual serious AEFI that were not listed in product information and large-scale vaccination error events, with frequency declining to approximately bimonthly (Figure 2).

The one AAG convened to address increasing abuse experienced by immunization staff from persons demanding access to specific vaccine brands (which, at that time, were restricted to target groups as a means to manage limited supply) demonstrates the flexibility of AAGs to address varied vaccine safety challenges.

### *De-escalations and Escalations*

A key AAG objective was to determine risk and initial steps for mitigation, loosely as a binary response of de-escalate or escalate. De-escalations primarily comprised media holding lines in readiness to respond to community concern if they arose. Escalations saw formation of incident management team (IMT), with the four pillars of the AAG forming the base IMT structure with additional stakeholders and subject matter experts brought in as appropriate.

Specific IMTs were established for ongoing review and management of TTS, myocarditis and pericarditis, and two vaccination administration error events involving over 1000 and 600 vaccine recipients, respectively.

One example of an AAG escalation was in response to a large-scale vaccine error event, whereby vaccine had been administered past its use-by thaw date, impacting over 600 vaccinations. Thaw expiry dates were a specific complexity for mRNA vaccines because vaccines originally stored at -70 degrees Celsius could be thawed and kept at +2 to +8 Celsius in standard vaccine refrigerators for up to 28 days prior to use, requiring diligent record keeping and checking of dates.[21] In this incident, the timing from thaw to use was not in question; therefore, there was minimal increased risk of adverse events, but rather the efficacy of vaccine administered could not be assured, as storage was outside of the manufacturer's requirements.[21] A series of IMTs were held, with a broad range of stakeholders including community representation, to lead the process of open disclosure to those potentially impacted[22] and determine vaccination pathways and track activities through to closure of the event. The structured IMTs facilitated capture of lessons learned. These were incorporated into vaccination error guidelines adopted nationally,[23] vaccine error document templates, and an online eLearning module (available through the Melbourne Vaccination Education Centre (MVEC)) on vaccine error prevention, management, and open disclosure.[24]


https://doi.org/10.1017/dmp.2024.100

### Business As Usual

Victoria's AAG process demonstrated good planning and preparedness, flexibility to different triggers and reasons for an alert, and provided responsive and timely escalation and coordinated communication. AAGs ensured a supportive environment for reporting and escalating incidents, facilitated a direct link between clinicians and vaccine safety public health teams, provided effective incident management, and directed long-term outcomes to improve safety. These attributes were considered as key lessons learned and, therefore, the AAG was embedded into routine vaccine safety surveillance systems.[11] With the VVCC disbanded following the peak of the COVID-19 crisis, central coordination was transferred to SAEFVIC as Victoria's Vaccine Safety Surveillance Service in mid-2023, in partnership with the Department of Health, maintaining the four-pillar role profiles. Following this transfer of coordination, AAGs have been convened for serious AEFI and vaccine error events, including one, on request, supporting another jurisdiction with large-scale vaccination error events.[25] Two AAGs have been held for vaccines other than COVID-19; one each for a serious AEFI and a vaccine error event.

## Discussion

Incident management systems for civilian emergency response were developed in the 1970's in response to communication breakdowns and inefficient coordination in the management of large wildfire events.[26] In the United States, incident control systems are part of the National Response Framework that provides guidance for national responses to all types of disasters and emergencies.[4] In Australia—and especially Victoria as a high bushfire-risk state—these concepts are ensconced in the Australasian Inter-Service Incident Management System (AIIMS), providing the operational backbone of the Emergency Services State Control Centre.[3,27] Threats to public health are deemed a Class 2 emergency and, as such, fall under the same emergency management constructs.[5,28] However, there is a dearth of literature on how AIIMS has been applied in the infectious disease control setting. One exception is the clear articulation of the value of incident control for outbreak response "after action reviews," particularly during the COVID-19 outbreak response by Dalton et al.[29] The benefits of a coordinated response with clear leadership go beyond management of the incident itself but also to the protection of the mental well-being of the response personnel. While there are international examples of incident management used for logistics of mass vaccination campaigns,[30,31] this article is, to the authors' best knowledge, the first description of IMS used for vaccine safety signal events in either a pandemic or routine setting.

The flexibility and simplicity of the IMS's adaptability to different crisis settings is both commendable and a sound recognition of the intent.[26] The robust processes are complimentary to support future rapid deployment intended by the global Mission for 100 Day Vaccines for biosecurity threats.[32] Likewise, these processes anticipate new vaccines, such as respiratory syncytial virus vaccine, that will target important populations, including pregnant women and the elderly.[33] As clinical trials are logistically and economically limited in sample size and population heterogeneity,[34] the necessity for postmarketing surveillance systems to have capability not only to detect rare adverse events but also effectively respond to vaccine safety challenges is ever more the future for which we must prepare.[35]

## Conclusion

Victoria's AAG escalation strategy using emergency incident management structures ensures a robust and well-prepared vaccination program able to rapidly assess and respond appropriately to escalate or de-escalate emergent vaccine safety challenges. This structure helped maintain confidence in the COVID-vaccine pandemic response and establish a framework for future vaccine safety challenges to biosecurity management.

**Acknowledgments.** The authors would like to acknowledge the Victorian Department of Health COVID-19 response teams and SAEFVIC and MVEC staff for their work in supporting vaccine safety in Victoria. We especially acknowledge both the state Victoria Vaccine Control Centre and National Vaccine Operations Centre for the secretarial coordination of AAGs throughout the pandemic response. Thank you also to our VicSIS, AusVaxSafety, and Global Vaccine Data Network colleagues. SAEFVIC at the Murdoch Childrens Research Institute is supported by funding from the Department of Health Victoria.

**Author contribution.** Concept, design, and establishment of AAGs: HC, MW, JB, NC. Incident Management leadership: HC, MW, JB, NW. Data management and analysis: HC. Evaluation and embedding into routine practice: all authors. Writing of the manuscript: HC. Review and editing of the manuscript: all authors.

**Competing interest.** The authors have no conflicts of interest to declare.

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