Protocols for National Action to Respond to Adverse Events Following Immunisation

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Section 1: Introduction and background

Background

Immunisation is one of the most effective ways to protect individuals and the community from many common diseases. The low incidence of vaccine-preventable diseases in Australia is due to the effectiveness of our immunisation services and programs.

The National Immunisation Program was set up by the Commonwealth and state and territory governments in 1997. It provides free vaccines to eligible people to help reduce disease and improve national immunisation coverage rates.

Since routine immunisations were introduced in Australia in the 1950s, death or disability from many once-common infectious diseases have become rare (Australian Government Department of Health, 2018).

Vaccines used in national immunisation programs are extremely safe and effective. Nevertheless, few things are completely safe, and adverse reactions to vaccines can occur.

What is an adverse event following immunisation?

An adverse event following immunisation is defined as any unwanted or negative medical occurrence that happens after a person is immunised. The adverse event may be caused by the vaccine or it may be a coincidence (World Health Organization, 2014 (Revised March 2016)).

Most adverse events following immunisation are relatively minor, such as mild fever or redness at the site of the injection, and resolve quickly. Serious or severe events are extremely rare.

What is a safety signal?

A vaccine safety signal is information that indicates there may be a link between a vaccine and an event that was previously unknown or incompletely documented that could affect health (World Health Organization, 2019).

A vaccine safety signal may arise from:

- a previously unrecognised adverse event
- a change in the frequency or severity of a known adverse event
- identification of a new at-risk group for adverse events related to vaccine.

Purpose of the Protocols

These Protocols set out the process for ensuring timely, coordinated and appropriate responses to a vaccine safety signal by Commonwealth, state and territory officials responsible for immunisation safety.

Scope

The Protocols do not cover the detailed investigation and analysis that form an essential part of any response to vaccine safety signals; nor do they apply to the immediate management of an adverse event by clinicians such as doctors and nurses. They focus on the interaction between the Commonwealth, state and territory governments and guide communication and coordination of national program and regulatory responses to adverse events following immunisation.

Coordination

Activities under these Protocols will generally be communicated and coordinated through the Jurisdictional Immunisation Coordinators (JIC). Membership of the JIC includes senior officials from the Australian and state and territory government health departments with responsibility for

immunisation. The role of the committee is to share information and coordinate activities relating to immunisation at a national level.

Authority

The Protocols were endorsed by Commonwealth, state and territory government health departments through the Australian Health Protection Principal Committee (AHPPC) on 12 August 2020.

Section 2: Vaccine Safety Surveillance

What is vaccine safety surveillance?

Vaccine safety surveillance systems are designed to identify vaccine safety signals arising from adverse events following immunisation. Effective surveillance systems quickly identify significant safety signals, allowing prompt regulatory and program action to be taken to address the issue.

Australia's vaccine safety surveillance system

Australia has a comprehensive vaccine safety surveillance system in place to detect vaccine safety signals. It includes the following components:

- The Therapeutic Goods Administration (TGA[1]), which is responsible for ensuring the safety of vaccines used in Australia.
- The TGA monitors the international literature and is a member of international collaborations relating to immunisation to ensure it is aware of any safety issues reported in other countries.
- Companies that supply vaccines in Australia are required by law to report serious adverse events and any safety issues they become aware of to the TGA.
- Clinicians and individuals can report adverse events to the TGA or their state or territory health department. Many clinics provide information to consumers on how to report an adverse event following immunisation.
- Most states and territories have legislation requiring clinicians to report adverse events following immunisation to them. They share this information with the TGA.
- The Australian Government has funded AusVaxSafety, a system that allows GPs and clinics to proactively follow up with people receiving vaccines, their parents or carers, via text message to ask whether they, or their child, experienced a reaction following the vaccination. This system is increasing our knowledge about the more common minor adverse events and providing reassurance that vaccines are safe.

Identifying a safety signal

Identifying a safety signal can involve multiple steps. It may result from clinicians or patients reporting that they are seeing or experiencing something unusual, for example more children experiencing high fevers than usual following a vaccination; it may be a serious one-off event where there is a clear relationship to vaccination; or it could be a pattern of adverse event reporting identified through statistical data analysis.

Most states and territories collate and examine the data they receive on adverse events and the TGA collates the data nationally and analyses it to identify events or patterns that could constitute a safety signal. Once a signal is suspected, information is shared with the states and territories. The TGA is responsible for determining whether the signal requires further action.

[1] The TGA is part of the Australian Government Department of Health

In the event of a serious adverse event, the TGA will work with the relevant state or territory officials as well as the treating clinicians to collate the necessary information and determine whether the vaccine was the cause.

Section 3: Responding to a potential safety signal

A phased approach that includes ongoing risk assessment

These Protocols set out the approach to identify and respond to safety signals. They provide a phased approach designed to be responsive to the many different types of signals and ways in which they can present.

The Protocols include the following four phases:

- Phase 1: Investigate – this phase is initiated when a signal is suspected and covers the investigation processes required to determine whether there is a real signal that requires a response to manage the risks it poses
- Phase 2: Plan – this phase sets out the processes that are used to plan the actions that will be taken in response to an identified signal
- Phase 3: Act – this phase covers the implementation of actions to manage the identified risks
- Phase 4: Review – during this phase officials involved in the first three phases review the effectiveness of the Protocols.

Throughout the process the Australian Government will undertake continuous risk assessment to inform the need for national action as well as the urgency of the action.

While the four phases describe distinct processes, they will often need to be implemented in parallel. For example, if there is an urgent need to take a particular action, this may happen in parallel with continued investigation and planning.

It is also possible to exit the Protocols at any stage if the investigation and ongoing risk assessment indicate that national coordination is no longer required.

Figure 1: The four phases of responding to a potential safety signal

When are the Protocols initiated?

The Investigate phase may be initiated by the TGA in response to:

- adverse event reports made directly to the TGA
- a suspected signal found during routine data analysis
- a request from state or territory officials.

Not all potential signals will trigger the use of these Protocols. Many potential signals can be investigated and resolved without the need for intensive national communication and coordination such as set out in this document. The TGA's decision to initiate the Protocols will be informed by the need for national-level investigation, and the level of risk presented by the potential signal.

Phase 1: Investigate

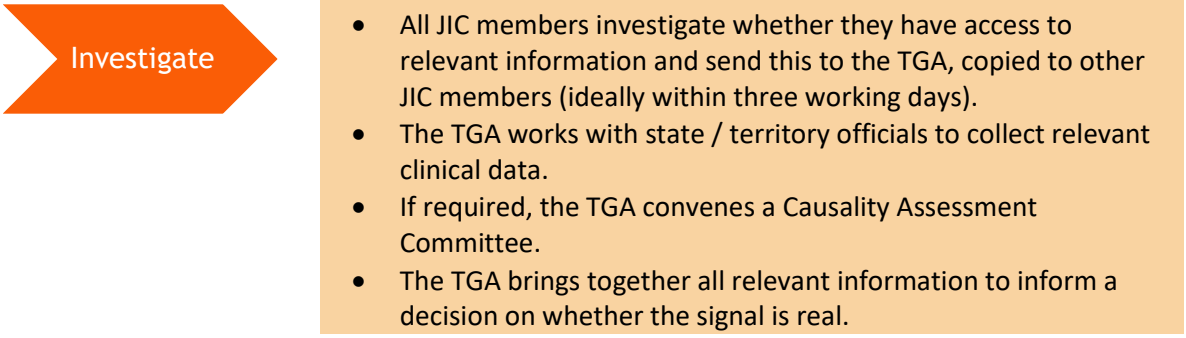
During the Investigate phase the TGA determines whether the suspected safety signal is real and makes an initial decision on how serious it is. The processes facilitate nationally coordinated communication to support gathering all relevant information as quickly as possible.

The TGA contacts the Jurisdictional Immunisation Coordinators (JIC) to initiate this phase. States and territories respond by investigating whether they have any relevant information (including early anecdotal information from clinics / clinicians) and send this to the TGA, copied to all other members.

The TGA works with state or territory officials and clinicians to collect relevant clinical information about the adverse event. If required, the TGA can convene a causality assessment committee. This committee consists of people with the necessary expertise (such as clinicians and epidemiologists) to determine whether the adverse event was likely to be caused by the vaccine and whether it meets the required criteria for causality.

The TGA is responsible for bringing together all the information, including both international and Australian data on adverse events, relevant clinical findings, and the findings of the causality assessment committee to inform a decision on whether a safety signal exists.

Figure 2: Summary of actions during the Investigate phase



Phase 2: Plan

During the Plan phase the Australian Government Department of Health (the Department), in consultation with the JIC, considers how to manage the safety issues that have been identified. The Department may also identify a need for further investigation and/or seek advice from relevant experts to ensure the planned actions will be effective.

Actions in the plan will generally fall into two categories:

- Regulatory responses – these will usually be implemented by the TGA as it is responsible for regulation of vaccines. Regulatory responses could include recalling a specific batch of a vaccine or cancelling approval of a particular type of vaccine
- Program responses – these may include communication activities to ensure the community and clinicians have any necessary information, or clinical education and training initiatives to address a problem relating to vaccine storage or administration.

The Department will consult closely with the JIC during the planning phase to agree a coordinated approach to communication and implementation at national, state and territory, and local levels.

The exception to this is if the need to act is urgent – in this case the JIC would be advised as soon as possible.

Figure 3: Summary of actions during the Plan phase

- TGA identifies that a safety signal exists and notifies the JIC.
- The Australian Government Department of Health assesses the information gathered during the Investigate phase and develops a plan for managing the identified safety issue in consultation with the JIC.
- Except in extremely urgent cases, the Department will provide advice to the JIC prior to taking any action or issuing public communication.

Phase 3: Act

During the Act phase the plan developed in Phase 2 is implemented. Any regulatory actions will be taken and there may be communication with clinicians and the community. Some actions may be longer term, such as changing training programs or revising policies and procedures. Particularly in the short-term, the situation will be monitored closely to assess the need for any further actions.

Figure 4: Summary of actions during the Act phase

- Regulatory action.
- Communication.
- Monitor the response, assess the need for any follow-up action, and implement follow-up action if required.

Phase 4: Review

The Review phase involves a simple review process to assess whether the Protocols were effective in guiding national communication and coordination and to consider whether the process could be improved. The JIC will undertake the review after Phases 1 and 2 and the immediate actions in Phase 3 have been completed.

The JIC as a whole will agree on any changes required to the Protocols. The revised Protocols will be provided to the AHPPC for endorsement.

Figure 5: Summary of actions during the Review Phase

- The Department puts the review process on the JIC agenda.
- Any revisions agreed by the JIC are provided to the AHPPC for endorsement.