



To provide an overview of the principles for the use of sedation as one of a range of measures to assist in the safe administration of COVID-19 vaccines.

This advice is intended to be general in nature, noting that some health services have developed, or are developing, procedural guidelines for vaccination under sedation for their context. Detailed clinical guidance should be developed collaboratively with input from anaesthetic groups, jurisdictional health services and relevant specialists.

Background

The process of administering a vaccine (i.e. giving an intramuscular injection) may cause severe anxiety in some individuals with anxiety disorders or needle-phobia, and/or may be difficult in certain individuals with behavioural disorders. A tiered approach initially using non-pharmacological measures may assist in facilitating vaccination. In patients where non-pharmacological techniques have failed, sedation may facilitate safe administration of vaccines in some special circumstances. Informed consent must be obtained prior to each dose from the patient themselves, or, where the patient does not have capacity to give consent, from the parent, guardian or substitute decision-maker. Sedation should not be used as a measure to enforce compliance with vaccination requirements.

Definitions

Sedation involves the administration of medication(s) to depress awareness and reduce responsiveness to external stimulation to varying degrees:

- **anxiolysis** involves administering a medication to reduce anxiety alone, where the patient is still able to respond verbally
- **conscious** sedation involves depression of consciousness, during which patients can still respond purposely to verbal commands or tactile stimulation and do not require any breathing support
- **deeper** sedation involves loss of consciousness, during which patients require breathing support.

Indications for sedation

In most cases, sedation should not be used as a first line option. Many individuals with anxiety or behavioural disorders can be safely vaccinated in the community using non-pharmacological techniques, such as a low-sensory stimulation environment, presence of comfort person/object, distraction with music, video or toys, relaxation techniques and cognitive behaviour therapy (for anxiety/needle-phobia).

Possible indications for sedation include people with severe anxiety or needle-phobia and developmental or behavioural disorders, where non-pharmacological measures to facilitate vaccination have been exhausted. The choice of sedative agent and the degree of sedation required will need to be determined on a case-by-case basis.

Safety of COVID-19 vaccines under sedation, including co-administration with other vaccines

ATAGI considers all COVID-19 vaccines currently registered in Australia to be safe and suitable for administration under sedation. Vaccines can be administered under any type of sedation (i.e. conscious or deeper sedation).

While there are no data on the safety of specific sedative agents given concurrently with any specific vaccine, there are also no theoretical safety concerns. There are no theoretical concerns regarding immunogenicity or effectiveness of COVID-19 vaccines if administered under various methods of sedation.

There are no concerns about the safety of COVID-19 vaccines if administered following use of various medications beyond the safety and risk of sedation itself.

COVID-19 vaccines can be co-administered with other vaccines if required, including influenza and routine childhood and adolescent vaccines (refer to ATAGI clinical guidance for COVID-19 vaccine providers).

There is limited evidence on the safety and effectiveness of co-administering COVID-19 vaccines at the same time as other vaccines. Providers need to balance the opportunistic need for co-administration with the benefits of giving the vaccines on separate visits.

There is the potential for an increase in mild to moderate adverse events when more than one vaccine is given at the same time. Co-administration or near administration (e.g. within days) with another vaccine may also make it challenging to attribute potential adverse events. Providers should ensure that parents/guardians of young children receiving COVID-19 vaccines are aware of the increased potential for local reactions.

Procedural sedation guidelines

There are no best practice guidelines currently available specifically for vaccination under sedation. There is one small retrospective study demonstrating that vaccination under sedation is an effective technique for a subset of paediatric patients.¹

ATAGI recommends that clinicians refer to the operational policies and guidelines of their local health service or facility regarding administration of vaccines under sedation. The choice of sedative agent(s) and degree of sedation (light vs deep) should be determined by the treating clinician, taking into account the patient's medical history, available resources, including a disability liaison officer service if available, and local procedural sedation guidelines.

Vaccines may also be administered opportunistically while patients are undergoing sedation for unrelated procedures.

Vaccination under sedation may not be available for all ages in all states and territories. ATAGI recommends that state and territory health departments and specialist immunisation services be consulted to review the available services in their jurisdiction and ensure that sedation for vaccination is accessible for patients who require it.

Post-vaccination observation

All patients who undergo sedation for vaccination require careful observation in the post-vaccination period, ensuring recovery from the sedative agents used and to detect any potential immediate adverse events relating to the vaccine (minimum 15 minutes observation). The period of observation varies depending on choice of sedative(s) and local procedural sedation guidelines.

Risks and benefits of opportunistic vaccination during sedation for an unrelated procedure

Opportunistic vaccination during an unrelated elective procedure undertaken under sedation or anaesthesia may be appropriate for some patients and should be strongly promoted when possible as it could avoid the need for a separate episode of sedation.

Opportunistic vaccination should only be considered during elective procedures where the patient is not acutely unwell.

Immunisation providers and the clinicians responsible for the procedure should be aware of the following:

- attribution of adverse events may be more challenging following vaccination during an unrelated procedure, for example, it may not be appropriate to provide COVID-19 vaccination during major surgery for an acutely ill patient
- overlapping adverse effects may increase discomfort for the patient (e.g. fever, muscle aches, joint pain after vaccination)
- the inflammatory responses and fever elicited by vaccines may interfere with the postoperative course.

Although surgery and anaesthesia are associated with transient (approximately 48 hours) immunomodulatory effects, these are not anticipated to interfere with an effective immune response to vaccination.²

References

1. Cheng, Daryl R., Sonja Elia, and Kirsten P. Perrett. "Immunizations under sedation at a paediatric hospital in Melbourne, Australia from 2012–2016." *Vaccine* 36.25 (2018): 3681-3685.
2. Siebert, J. N., et al. "Influence of anesthesia on immune responses and its effect on vaccination in children: review of evidence." *Pediatric Anesthesia* 17.5 (2007): 410-420.