AMA statement on vaccination for COVID-19

1. Introduction

The COVID-19 pandemic has presented rapidly evolving and significant challenges to health systems and economies worldwide.

To contain the spread of COVID-19, widespread lockdowns of businesses, schools and entire communities have been implemented, in addition to domestic and international travel restrictions and border closures.

Continuing outbreaks of COVID-19 worldwide and within Australia have demonstrated that while current public health advice, including social distancing, hand hygiene, mask wearing, and restrictions can control the virus to a degree, a COVID-19 vaccine(s) is the only measure that will potentially enable a return to 'normal' life. With more than 190 vaccines in development, the community should be optimistic about the prospects of an effective vaccine, although it needs to be understood that this is not guaranteed or that it may take longer to develop and roll out than the community might hope.

Even when a COVID-19 vaccine(s) becomes available, some degree of social distancing or other containment measures may still be required, depending on the efficacy of the vaccine(s) and how quickly it can be rolled out.

2. COVID-19 vaccine safety

For any vaccine roll-out to be successful, it must gain and maintain the trust and confidence of the community.

Potential COVID-19 vaccines must be proven safe and effective through proper (although expedited) research and testing before they are accredited and made available to the community. In many cases the rapid development of potential vaccine candidates has been made possible by utilising earlier work from SARS-CoV-1 and MERS CoV vaccine development, the adaption of production processes from existing vaccines or vaccine candidates and leveraging

data from related vaccines[1]. This provides reassurance that while work has been rapid, corners are not being cut.

The AMA supports initiatives that improve the speed and efficiency of the Therapeutics Goods Administration (TGA) approval processes for COVID-19 vaccines. However, the TGA must still apply its usual rigour and criteria to assess their safety, quality and effectiveness. Given the speed of COVID-19 vaccine development, the role and supervision of the TGA will be critical to acceptance of a vaccine(s) by the community, as well as its ultimate performance in helping protect the community from this virus.

The approval of vaccines, particularly during their initial roll-out, may be restricted to specific patient cohorts based on the available trial data. This is an appropriate approach, recognising that as more data is gathered, the scope of approval can be expanded where shown that it is safe and effective to do so.

Comprehensive monitoring of COVID-19 vaccinations will be required, including both passive and active surveillance. This is a normal part of the oversight of vaccines in Australia and provides the community with reassurance that they are safe and effective. The TGA and other bodies involved in vaccine surveillance should be given additional resources, if required, to expand their capability and provide early insight into the performance of a COVID-19 vaccine(s) in Australia, including safety signals.

3. Planning and coordination

The efficient roll-out of a COVID-19 vaccine in Australia will require significant cooperation between the Commonwealth and the States/Territories, with strong guidance and input from industry and vaccine providers, including general practice. Arrangements should ensure a consistent approach across jurisdictions, with planning having regard for the need for access to the suite of potential vaccines, manufacturing capability, available distribution channels, regulatory arrangements and ongoing monitoring of take-up and safety.

As the primary vaccination provider in Australia, General Practitioners (GPs) should be represented at all levels of planning and coordination efforts.

4. COVID-19 vaccination allocation

During the early stages of roll-out, a COVID-19 vaccine(s) will need to be prioritised to certain groups. This reflects the reality that while demand for the vaccine(s) will be high, supply will be limited, at least in the short term. Trial data and the efficacy of a vaccine may also have implications for how a vaccine is prioritised.

[1] Krammer, F. SARS-CoV-2 vaccines in development. Nature (2020). https://doi.org/10.1038/s41586-020-2798-3

The US National Academies of Science, Engineering and Medicine (NASEM) has developed a consensus Framework for the Equitable Allocation of a COVID-19 Vaccine that outlines principles and criteria that should also be followed here. The fundamental principles that underpin this framework are:

Ethical Principles: Maximum Benefit, Equal Concern, and Mitigation of Health Inequities.
Procedural Principles: Fairness, Transparency, and Evidence-Base.

NASEM propose that the following risk-based criteria should be used to set general priorities among various population groups:

- risk of acquiring infection,
- risk of severe morbidity and mortality,
- risk of negative societal impact, and
- risk of transmitting infection to others.

5. Mandatory COVID-19 vaccination

In general, vaccines should only be given to individuals with appropriate consent. While the AMA has, on occasion, supported the linkage of vaccinations to the payment of Commonwealth benefits, this approach or any form of mandatory vaccination is not warranted in relation to COVID-19.

Instead, extensive efforts should be made to foster trust in the community and encourage voluntary uptake of a COVID-19 vaccination. This is particularly important for reassuring the public about vaccine safety, recognising that some people may have concerns about the rapid development of potential COVID-19 vaccines compared to the traditional vaccination development timeline[2].

6. COVID-19 vaccine providers

To assure the community of the safety of a COVID-19 vaccine(s), the administration of a COVID-19 vaccine needs to occur in a medically supervised environment. Best practice involves a vaccination being provided by a medical practitioner, or by an appropriately qualified nurse under the supervision of a medical practitioner.

Unless the technical requirements for the storage and administration of a COVID-19 vaccination make it unfeasible (in the short term or otherwise), the proven record of general practice means that it should be the primary vehicle for the delivery of a COVID-19 vaccine(s). GPs know their patients' medical history and can use this to triage them according to priority criteria, and provide education and trusted advice on whether a COVID-19 vaccination is appropriate for their circumstances.

[2] https://www.chiefscientist.gov.au/sites/default/files/2020-05/rrif-covid19-promising-vaccines.pdf

General practice has also demonstrated its capacity to reorganise its systems and processes to deal with challenges in health care delivery – something that has been shown throughout the COVID-19 pandemic. Depending on the type of vaccine(s) that is approved, the dosage regimen, and delivery system, general practice may require additional support as part of the roll-out. This may extend to training and education, vaccine storage equipment and more efficient distribution methods, including just-in-time delivery.

All COVID-19 vaccinations should be uploaded to the Australian Immunisation Register (AIR), with general practice having a demonstrated record of providing up-to-date and accurate information to the AIR. General practice should be appropriately funded to undertake this administrative function, which is not covered by Medicare funding.