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# CLINICAL GOVERNANCE REQUIREMENTS FOR COVID-19 VACCINATION CLINICS AT RACF

The following outlines the clinical governance requirements and accountabilities for COVID-19 vaccination clinics at residential aged care facilities (RACF). The RACF and the immunisation provider each have clinical governance accountabilities related to the vaccination activity over three phases:

- Preparation for the vaccine clinic
- The clinic
- Conclusion of each clinic and post clinic

## Preparation for the vaccine clinic

Activity	RACF
<b>Clinical Lead</b>	<ul style="list-style-type: none"> <li>• RACF must establish a Clinical Lead (eg Registered Nurse) who is responsible for managing the vaccine program at the site (both dose administrations) including:               <ul style="list-style-type: none"> <li>• to liaise with the PHN and the immunisation provider (the vaccine team)</li> <li>• formally signing off on all logistics and arrangements</li> <li>• formally authorising dose requirements (lists of residents and staff)</li> <li>• meet the immunisation provider upon arrival for local orientation and support clinic set up</li> <li>• formally authorising suitability of residents for a vaccine on the day and ensuring consent has been confirmed for all participating residents</li> <li>• liaise with the immunisation provider on the day</li> <li>• receives a formal clinical handover from the immunisation provider at the conclusion of each clinic day and assumes responsibility for all residents prior to the departure of the vaccination team</li> </ul> </li> <li>• RACF will advise the PHN and the immunisation provider supplier the name and contact details for this Clinical Lead.</li> </ul>



## Preparation for the vaccine clinic cont.

Activity	RACF
<p><b>Clinical review for suitability to receive the vaccine prior to vaccination day</b></p>	<p><b>Residents</b></p> <ul style="list-style-type: none"> <li>RACFs are accountable to review all residents and determine there are any concerns in relation suitability to receive the vaccine. Where there are concerns in relation to resident suitability for the vaccine, RACFs should consult with GPs. GPs may provide a phone assessment or may review the resident personally. GP advice should be documented in the resident care notes.               <ul style="list-style-type: none"> <li>Assessing an individual's suitability to receive the vaccine, is a precursor to the resident or their representative making informed consent decision to receive or decline the vaccine.</li> <li>The clinical review outcomes for all residents must be provided to the the immunisation provider (refer template Vaccination patient list).</li> </ul> </li> <li>In accordance with ATAGI advice, the only people who are not suitable to receive the vaccine are those with:               <ul style="list-style-type: none"> <li>anaphylaxis to a previous dose of the same COVID-19 vaccine, or</li> <li>anaphylaxis after exposure to any component of a COVID-19 vaccine including to polyethylene glycol (PEG)</li> </ul> </li> <li>Immunisation providers should be alert to residents that have <b>a bleeding disorder</b> or are taking <b>a blood-thinning medication (anticoagulant)</b>.</li> </ul> <p><b>Workers</b></p> <ul style="list-style-type: none"> <li>Workers may wish to engage with their GP or other health professionals to discuss risks and benefits of vaccine, and their clinical suitability to receive the vaccine, to inform their decision on whether to receive the vaccine.</li> <li>RACF will be responsible for confirming workers' intention to participate (or not) in the vaccination program.</li> </ul>
<p><b>Consent</b></p>	<ul style="list-style-type: none"> <li>RACF is responsible for facilitating, seeking and recording informed consent for all residents assessed as suitable to receive the vaccine including residents that:               <ul style="list-style-type: none"> <li>have a substitute decision maker</li> <li>do not have a substitute decision maker</li> </ul> </li> <li>A consent package including a consent form template and relevant information are available to support this activity (refer - Consent package).</li> <li>Evidence of residents' consent must be made available to the immunisation provider on the day.</li> </ul>

## Preparation for the vaccine clinic cont.

Activity	RACF
<b>Worker participation</b>	<ul style="list-style-type: none"> <li>RACF will be responsible for confirming workers' intention to participate (or not) in the vaccination program.</li> </ul>
<b>Establishing dose requirements</b>	<ul style="list-style-type: none"> <li>RACF compiles a list of dose requirements which specifies all consenting residents identified as suitable for vaccination and staff intending to participate (refer template - Vaccination patient list). Include a contingency of additional doses, equivalent to five percent of those residents that haven't consented prior. These additional doses can be used for people who decide to participate on the day.               <ul style="list-style-type: none"> <li>Dose requirements are to be authorised by the Clinical Lead responsible for overseeing the vaccination program.</li> </ul> </li> <li>The dose requirements are sent to the immunisation provider and informs the number of doses that will be brought to the site on the day for residents and workers.</li> <li>The COVID vaccine for RACF residents and staff does not need to be prescribed by a GP.</li> </ul>
<b>Site readiness</b>	<ul style="list-style-type: none"> <li>RACF is responsible for ensuring the site is prepared in a manner that is appropriate and supports an efficient and safe vaccine clinic. The site must comply with the readiness requirements for COVID-19 vaccination clinics at residential aged care facilities (refer checklist - Clinic site requirements). This includes               <ul style="list-style-type: none"> <li>Physical environment</li> <li>Infrastructure</li> <li>Workforce</li> <li>Technology</li> </ul> </li> <li>The RACF should engage with the PHN for assistance on meeting the Clinic site requirements.</li> <li>The RACF should ensure it:               <ul style="list-style-type: none"> <li>Has safe resident identification process especially where residents are unable to state their own name and date of birth</li> <li>It is well stocked in diagnostic equipment, Sphigmomanometers, oxygen saturation monitors, hand sanitizer, disinfectant wipes and other consumables</li> <li>Has PPE in stock to address any local state / territory health authority requirements</li> </ul> </li> <li>The RACF should ensure it has basic diagnostic capability to ensure suitability of residents on the day and to manage adverse events including oxygen.</li> <li>The RACF will need to engage with the immunisation provider supplier to confirm site readiness compliance.</li> </ul>



## Preparation for the vaccine clinic cont.

Activity	RACF
<p><b>Planning for vaccine clinic support</b></p>	<ul style="list-style-type: none"> <li>• Each RACF should ensure they have plans and processes in place to manage and support resident participation in the clinic in an efficient, safe and appropriate manner; and prevent and manage violence or aggression in the clinic.</li> <li>• Each RACF should ensure they will have an adequate number of appropriately qualified staff, who are familiar with and are known to the residents, rostered to support the vaccine event. This may include the need to source additional capability (eg clinical skills) or capacity, to ensure clinical safety including to facilitate and support resident flow through the clinic.</li> <li>• RACF should ensure processes and appropriate numbers of trained/qualified staff are in place to monitor residents, and identify, manage and report adverse events.               <ul style="list-style-type: none"> <li>• RACF may wish to have a Registered Nurse on duty following the departure of the vaccination workforce, to manage post vaccination side effects such as fever and pain.</li> </ul> </li> <li>• RACF should have in place clear escalation processes, systems and contact details for residents with adverse events.</li> </ul>
Activity	Immunisation provider
<p><b>Site readiness</b></p>	<ul style="list-style-type: none"> <li>• Immunisation provider must be satisfied that the clinic site complies the readiness requirements for COVID-19 vaccination clinics at residential aged care facilities; and the site requirements for the release of the Pfizer vaccine (where vaccine).</li> </ul>



## The Clinic

Activity	RACF
<b>Support clinic set up</b>	<ul style="list-style-type: none"> <li>The RACF Clinical Lead must be onsite to meet the immunisation provider upon arrival, to provide local orientation and support clinic commencement.</li> </ul>
<b>Resident preparation</b>	<ul style="list-style-type: none"> <li>RACF clinical staff should assess residents registered for a vaccine on the day.                             <ul style="list-style-type: none"> <li>If a resident develops an acute medical issue on the day of vaccination, a discussion with the resident's normal medical provider should be required to determine the suitability for vaccination.</li> </ul> </li> <li>On arrival, the RACF should provide the vaccine workforce with a list of residents who will be receiving the vaccine.                             <ul style="list-style-type: none"> <li>The sign off sheet should record that all residents on the list have been assessed as suitable to receive the vaccine on the date of vaccination day.</li> <li>The sign off sheet <b>must be authorised by the Clinical Lead</b> who is responsible for managing the vaccine program at the site.</li> </ul> </li> <li>The RACF should ensure that only residents assessed as suitable and recorded on the list are presented for vaccination (noting some individuals may change their mind and decide not to receive the vaccine on the day).</li> <li>The RACF will prepare the residents for the vaccination clinic, together with their consent form and any information about:                             <ul style="list-style-type: none"> <li>the resident's medical conditions, allergies, bleeding disorders or immunocompromise (i.e. weakened immune system)</li> <li>any medications the resident is taking</li> <li>any reactions the resident has had to any vaccine in the past</li> <li>for each resident, any communication, cultural or behavioural factors that are relevant to the vaccination process</li> <li>whether a support person is required to be with the resident at time of vaccination</li> </ul> </li> </ul>
<b>Staff participation</b>	<ul style="list-style-type: none"> <li>The RACF will provide the vaccine workforce with a list of workers that will be vaccinated on the day.</li> </ul>
<b>Clinic management</b>	<ul style="list-style-type: none"> <li>The RACF is responsible for the efficient and safe movement of residents through the clinic.</li> <li>Use of PPE in line with local state health authority requirements.</li> </ul>



## The Clinic cont.

Activity	RACF
<b>Resident monitoring post vaccination</b>	<ul style="list-style-type: none"> <li>RACF is clinically responsible for residents that have received the vaccine, once released from the immunisation provider's 15 minute post vaccination observation (i.e. the clinic may still be operating)</li> <li>RACF are responsible for ensuring appropriately trained/qualified staff actively monitor residents, to identify, manage, document and report adverse events.</li> </ul>
Activity	Immunisation provider
<b>Site readiness</b>	<ul style="list-style-type: none"> <li>The immunisation provider will receive a local orientation from the RACF Clinical Lead.</li> <li>The immunisation provider is responsible for ensuring adequate number of appropriately qualified staff are present to deliver the vaccine clinic in an efficient and safe manner.</li> </ul>
<b>Resident preparation</b>	<ul style="list-style-type: none"> <li>The immunisation provider should satisfy themselves that residents are suitable to receive the vaccine, including through a screening process.</li> <li>The immunisation provider must be satisfied on the day that informed consent has been given for all residents receiving the vaccine through sighting appropriate evidence (preferably the standardised consent form).</li> </ul>
<b>RACF Workers</b>	<ul style="list-style-type: none"> <li>The immunisation provider will:                             <ul style="list-style-type: none"> <li>screen workers registered for a vaccine, on the day of the clinic and confirm the worker's suitability (or otherwise) to receive the vaccine.</li> <li>Obtain consent from workers</li> </ul> </li> </ul>
<b>Reporting</b>	<ul style="list-style-type: none"> <li>The immunisation provider is responsible for reporting vaccinations to the AIR</li> </ul>
<b>Monitoring and reporting adverse events</b>	<ul style="list-style-type: none"> <li>The immunisation provider is responsible for monitoring residents for adverse events in the post vaccination observation period (15 minute, or 30 minutes in some limited cases) and reporting adverse events that occur in the post vaccination observation period.</li> </ul>



## The conclusion of the Clinic

Activity	RACF
<b>Clinic closure and hand over</b>	<ul style="list-style-type: none"> <li>At the conclusion of each clinic day, the immunisation provider and the RACF will have a formal clinical handover, which is attended by the RACF Clinical Lead, with the RACF assuming clinical responsibility of all residents prior to the departure of the vaccination team. This may include a signed verification handover.</li> <li>RACF may wish to have a Registered Nurse on duty following the departure of the vaccination workforce, to manage post vaccination side effects such as fever and pain.</li> <li>In the event of an adverse outcome, the RACF will enact relevant escalation process and pathways (refer separate guidance materials).</li> </ul>
<b>Resident records</b>	<ul style="list-style-type: none"> <li>Record vaccination in resident records</li> </ul>
<b>Records of worker vaccination</b>	<ul style="list-style-type: none"> <li>Make a record of staff who have received the vaccination, have declined the vaccination or for another reason have not been vaccinated (e.g. contraindication)</li> </ul>
Activity	Immunisation provider
<b>Clinic closure and hand over</b>	<ul style="list-style-type: none"> <li>At the conclusion of each clinic day, the immunisation provider and the RACF will have a formal clinical handover, which is attended by the RACF Clinical Lead and agreed to prior to the departure of the vaccination team. This may include a signed verification handover.</li> </ul>

