Queensland Health

Guide for Informed Consent of Children & Young People for COVID-19 Vaccinations

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This guideline is designed to support Hospital and Health Services (HHSs) vaccination clinicians with information about informed consent for COVID-19 vaccines in young people (ages 12-17 years) and children (ages 5-11 years). In this guideline, the term "child" or "children" refers to patients aged 5 to 11 years old and "young person" or "young people" refers to patients aged 12 to 17 years old.

Prior to COVID-19 vaccination occurring, valid consent must be obtained from one of the following:

- The child or young person who is deemed a Mature Minor or "Gillick competent"
- A Parent who themselves have capacity
- Carers able to produce a court order to prove legal authority to consent on behalf of the child or young person
- Legal guardian (for example under a child protection order made under the *Child Protection Act 1999* or other order made under the *Adoption Act 2009*)
- An order made by the Supreme Court of Queensland or the Family Court of Australia).

For consent to be valid, it must be voluntary and fully informed, and vaccination providers must provide sufficient information about the vaccine, its risks and benefits, common reactions to vaccinations and the more serious, but rare side effects or inherent risks of the COVID-19 vaccines. Sufficient time should be provided for the child, young person or parent/legal guardian (as applicable) to ask questions for further information. The Commonwealth Department of Health has prepared resources for patients online here, with more information specific to adolescents available here. Queensland Health has developed a parent/legal guardian information sheet for children available here which should be provided in printed form.

In Queensland Health, the QCVMS system allows for paperless informed consent for consumers aged 12 years and over. Young people who do not have capacity to provide consent and all children (aged 5-11 years) must be accompanied by a parent/legal guardian (as applicable) to provide consent or provide a pre-signed valid paper consent form that has been completed by the parent/legal guardian (as applicable) at the time of vaccination.

Paper based forms for adults and young people are also available here for use in ICT downtime. Any use of these forms is to be subject to local HHS governance of clinical records and any data retention policies.

What is informed consent?

The Queensland Health Guide to Informed Decision-making in Health Care Sections 3 and 4.7 provide useful references. Additionally, the Queensland Health Guidance on Age of Consent for Vaccinations is a useful reference for the application of Mature Minor (or Gillick) Competence in Queensland. In Queensland,

- individuals under the age of 18 years can consent to health care where they have been assessed as having sufficient capacity to do so (i.e. when the child or young person is Gillick competent)
- there is no fixed lower limit below 18 years of age at which children or young persons are deemed to be able to consent to health care (i.e. Gillick Competent)

- individuals aged under 11 years will require a parent/legal guardian/other person to provide consent
- individuals aged 12 to 15 years will generally require a parent/legal guardian/other person to provide consent
- in most cases, individuals over 16 years of age would likely be assessed to have capacity to consent for vaccination. However, this will depend on the understanding, intelligence and maturity of the young person.

The clinician providing the vaccination makes this assessment and needs to be satisfied that the young person has sufficient understanding and intelligence to:

- fully comprehend the proposed treatment and has legal capacity to give consent
- discuss the vaccination including its risks and benefits
- provide their verbal consent, freely and voluntarily, (that can be recorded in the QCVMS system by the clinician), prior to administering the vaccine.

If a clinician cannot assess capacity or does not think the young person has capacity, the clinician should seek advice from a more experienced clinician or defer the vaccination that day and refer the individual to an appropriate service and document this decision.

How to assess capacity to consent to vaccination?

To establish that a young person has capacity to consent to COVID-19 vaccination, the health practitioner must carry out an assessment to show the patient has sufficient understanding, intelligence and maturity to appreciate the nature, consequences and risks of the vaccination, and the alternatives, including the consequences of not receiving the vaccination.

When assessing a young person's capacity, the following issues should be considered (see *Consent to Treatment of Children Circular from the Chief Health Officer* Issue No 23 December 2006):

- the age, attitude and maturity of the young person, including their physical and emotional development
- the young person's level of intelligence and education
- the young person's social circumstances and social history
- the nature of the young person's condition
- the complexity of the health care, including the need for follow up and supervision after the health care
- the seriousness of the risks associated with the health care
- the consequences if the young person does not have the health care
- where the consequences of receiving the healthcare include death or permanent disability, that the young person understands the permanence of death or disability and the profound nature of the decision he or she is making.

The more complex the health care or more serious the consequences, the stronger the evidence of the young person's capacity to consent to the specific health care will need to be. In the case of vaccinations, it is not complex health care with a rare risk of serious consequences, so the threshold of evidence of the young person's capacity to consent to the specific health care will be lower compared to the evidence of capacity required for some other types of health care (such as in situ contraceptive devices and surgical procedures).

The health practitioner should document in QCVMS when they assess a young person as a Mature Minor/Gillick competent with capacity to provide consent to COVID-19 vaccination and any details which influenced their decision as to whether the young person has capacity.

Do parents or guardians need to be present at the time of vaccination?

Considerations for Young people (ages 12-17 years)

If valid consent has not been obtained in writing prior to attending a vaccination appointment and the young person is not a Mature Minor, then a parent or legal guardian (as applicable) needs to be present to provide consent and for vaccination to proceed.

In situations where parents or legal guardians have given advance consent to the vaccination it is still good clinical practice to encourage the parent/legal guardian or an adult that is familiar to the child (for example a relative, close family friend, carer or teacher) to attend with the young person. The reasons for this include:

- confirming the child or young person's identity
- providing additional clinical history or medical information about the child or young person
- reassuring and supporting the child or young person
- providing supervision after the vaccination during any observation periods.
- providing the opportunity for the parent/legal guardian to ask questions about the child or young person's vaccination for further information

Considerations for Children (ages 5-11 years)

In the case of children, in most cases, the parent/legal guardian providing consent will attend the vaccination appointment with the child. Written consent signed by the parent or legal guardian is required for each vaccination episode in children.

In situations where parents or legal guardians have given advance consent to the vaccination, it is required that the parent/legal guardian or an adult who is familiar to the child (for example a relative, close family friend, carer or teacher) must attend the vaccination episode with the child.

General Considerations

In circumstances where the parent or legal guardian does not attend with the child or young person, and the health practitioner has concerns that consent given in advance may not be valid, the vaccination should be postponed until the validity of the informed consent has been confirmed.

In cases of young people who do not have capacity to consent for themselves, if there was valid consent provided by parent or guardian for their first dose appointment and this can be checked or is documented in their QCVMS record, there is no specific requirement for documented consent to be provided for their second dose appointment if not accompanied by a parent or guardian, as this is a two dose vaccination schedule and the Consent Form requires a parent/legal guardian to consent to the recommended doses of the COVID-19 vaccination. Clinical discretion should be used in situations where the health status of the young person has changed since the previous dose. This does not apply to children, where documented consent is required for all doses.

Even if a young person may have capacity to consent on their own, it is good practice to encourage them to consider seeking the involvement of a parent/legal guardian or other adult of their choosing before reaching a decision. This may:

- provide the adult with appropriate information (including any necessary supervision arrangements and possible adverse effects) so they might support the young person in their decision and during the health care
- give the adult the opportunity to provide information that the young person may not be aware of (for example, details of previous medical conditions and relevant family history) and to have questions answered in advance
- allow the adult the opportunity to attend when the health care (for example, vaccination) is provided with the agreement of the patient.

If a child or young person does not wish to involve a parent or other adult, the reasons for this should be explored.

Where a child or young person does not have capacity to give consent, this does not reduce the significance of their involvement in decision-making, and health practitioners should communicate with the child or young person and involve them as much as possible in decisions about their care.

First Nations arrangement considerations in consenting for children's vaccinations

Torres Strait Islander people considerations

Torres Strait Islander people can apply for legal recognition of Alian Kastom (Torres Strait Islander) child rearing practice under the *Meriba Omasker Kaziw Kazipa (Torres Strait Islander Traditional Child Rearing Practice) Act 2020 (Qld)*. This requires an application to be made to the Commissioner for a Cultural Recognition Order to enable a permanent transfer of parentage from the biological parents to the cultural parents. See here for more information and please engage with the Indigenous Hospital Liaison Officers (IHLOs) for guidance and for cultural protocols.

Other informal kinship arrangements

There may be situations, particularly in rural and remote First Nations communities, where a child is accompanied to a vaccination service by an adult who is not their parent or legal guardian. In these situations, it is strongly encouraged that the accompanying adult makes all attempts to obtain all relevant medical history as well as a pre-signed consent form from the child's parent or legal guardian prior to attending for vaccination.

If this is not possible, all reasonable attempts should be made by the vaccination clinic staff to contact the parent or legal guardian of the child to obtain verbal consent for the vaccination.

To obtain consent, in a situation where there is an informal kinship arrangement and all reasonable attempts have been made to obtain consent to treatment from a parent or legal guardian, in the best interests of the child, the clinicians should confirm that the person is in a role exercising parental responsibility for the minor by assessing:

- is there a longstanding pre-existing care relationship between the minor and the person?

- do the parents of the minor consent to the person being the kinship carer?
- is the person within the child's extended family?
- do they hold a Medicare card for the minor?
- Do they possess sufficient knowledge of the child's medical history, in particular relating to immunisation history, cardiac history and allergies?
- whether under Aboriginal tradition or Torres Strait Islander custom that the person would be regarded as the parent of the minor by liaising with the Indigenous Hospital Liaison Officers (IHLOs)?
- If, through the relevant cultural authority, that the person is accepted by the community as the child's 'kin' based on the traditions, observances, customs and beliefs of a particular community or group?

If the clinician is able to satisfy themselves of the above, then they may accept that person to consent for the child. It would be necessary for each HHS to develop their own pathways for clinicians to follow if undertaking this assessment, including whether escalation of individual cases to the HHS delegate is necessary (for example the Executive Director of Medical Services).

All consideration and information relied on by the clinician must be recorded in the medical record including that the consent was obtained based on kinship being recognised.

It is important to recognise that as with any group of people, there is a wide range of individual variations and the needs of individuals will have to be assessed on a case-by-case basis. Indigenous Health Workers in the community or IHLOs are able to assist health practitioners in the process of obtaining informed consent from Aboriginal and Torres Strait Islander patients.

Children's Health Queensland's Informed Consent Policy (CHQ-POL-24702) is a valuable resource on the cultural considerations in obtaining consent for children whose communities have kinship arrangements.

Escalation of concerns surrounding consent

In a small number of cases, there may be questions surrounding the validity of the consent provided. Some examples where this situation could arise include where there is concern that a parent does not have sufficient capacity to provide consent themselves, the child or young person presents for vaccination unaccompanied, or the adult or relative (non-parents) accompanying the child are not established legal guardians. In instances like these, it is prudent for each HHS to have a local procedure for escalation of consent concerns by the vaccination staff. This should include a pathway for potential approval to proceed with the vaccination if deemed appropriate by the relevant HHS delegate (such as the Executive Director Medical Services). This is particularly important for consumers who are located in remote and rural areas or who have travelled significant distances to obtain vaccinations.

It is important that the vaccination environment is considered in these situations. A child and accompanying adult who attend a vaccination clinic suggests a higher willingness to receive vaccination (and understanding of vaccinations) than in settings where home visits initiated by a HHS are conducted. Caution should be applied in the latter (or similar) settings to ensure the health literacy of consent providers is adequately assessed and their cultural safety is maintained. Importantly, caution should be used to ensure the decision is free from pressure and consent is given voluntarily.

Deferral of vaccination

If a child or young person presents to a vaccination location with a valid consent form or is a Mature Minor and has capacity to consent to the vaccination, however does not receive a vaccination, please document that reason into the clinician's comment section of QCVMS. Reasons could include, but not limited to:

- clinical assessment showed the patient is currently unwell and it is recommended to postpone vaccination until after this illness has passed;
- prior significant allergic reaction to the vaccine or its components and the child, young person or their parent/legal guardian was advised that they should seek further advice from their family doctor; or
- refused to proceed with the vaccination when it was offered.

Young people and children subject to child protection orders

For children or young people who are subject to child protection orders and/or placed in out of home care, please see this immunisation policy from the Department of Child Safety in relation to specific consent requirements. Additional guidance is available here. **Please note that Mature Minors under care are still able to consent to their own vaccination regardless of child protection orders.**

The Child Protection Act 1999 (Section 97) authorises delegated officers to make immunisation arrangements for **children and young people who are in the custody or guardianship of** the chief executive (Child Safety). To authorise immunisation for a child subject to a custody order, a COVID-19 Vaccination Consent for Young Person (12-17 years) form or COVID-19 Vaccination Consent for Child (5-11 years) form is to be signed by the Child Safety manager.

Additionally, **approved carers and care services of children and young people subject to orders granting guardianship** to the chief executive (Child Safety), are authorised to provide consent for immunisations, although it is always preferable to gain the parents' consent to immunisation when they retain guardianship. The carer must supply or produce a copy of the *Authority to Care – Guardianship to the Chief Executive form* if requested by the vaccination provider.

Mature Minors who decline vaccination

A child or young person who has capacity to consent to health care can also decline health care. In this situation a vaccination provider should:

- explore carefully the reasons for the child or young person declining to give consent
- encourage the child or young person to involve a parent/legal guardian or other adult before reaching a decision
- explore the reasons why they do not wish to involve a parent/legal guardian or other adult (in some circumstances, the health practitioner may need to consider overruling a child or young person and involve a parent/legal guardian in the decision-making process, for example, if there are child protection concerns)
- consider whether alternative health care might be acceptable
- consider involving other members of the multidisciplinary team, an independent advocate or a named or designated doctor for child protection, if their involvement would help with the decision-making process

- consider obtaining a second opinion about the young person's capacity if there is any doubt
- document the details of the above discussions in QCVMS
- remember that to be valid, consent must be informed, voluntary and free from any pressure by health practitioners, parents or others.

Remember, that where there is significant risk from a child or young person declining to consent to health care, it is advisable to seek advice from a senior medical practitioner. Ultimately, however, a court may override a child or young person's decision and the first and paramount consideration will always be the welfare, wellbeing and best interests of the child or young person.

If there is disagreement between the wishes of a child or young person, and their parent or guardian, it is appropriate to consider seeking a second opinion from a senior, experienced, medical practitioner or obtaining legal advice or a court ruling if the disagreement cannot be resolved through discussion and consensus.

Relevant Documentation

Please note that any use of the forms below are to be subject to local HHS governance of clinical records and any data retention policies.

Considerations for young people (ages 12-17 years)

Young people in this cohort may be Mature Minors/Gillick competent. This means that a young person may be able to give consent for vaccination. This is dependent on the individual young person.

The following forms are available for use:

- A Queensland Health COVID-19 Vaccination Consent for Young Person (12-17 years) form that can be scanned into ieMR (SW9500) e.g. inpatient settings
- A Queensland Health ICT downtime form (SW9500) including pre-screening and health professional attestation statement (for use in genuine ICT downtime situations).
- ATAGI Pfizer information sheets

Considerations for Children (ages 5-11 years)

Children in this cohort cannot be Mature Minors/Gillick competent. This means that a child cannot give consent for vaccination.

The following forms are available for use:

- A Queensland Health consent form that can be scanned into ieMR (SW9519) e.g. for all vaccination clinics and inpatient settings
- A Queensland Health ICT downtime form (SW9520) including pre-screening and health professional attestation statement (for use in genuine ICT Downtime situations only)
- Queensland Health Parent/legal guardian information sheet (SWPI9475)
- ATAGI Pfizer COVID-19 vaccine for children aged 5 to 11: information for parents and guardians which is a detailed document including information on what to expect after vaccination and covid-19 testing after vaccination.