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Health
REPUBLIC OF SOUTH AFRICA

COVID-19 VACCINATION GUIDE
VACCINATION OF CHILDREN 5 – 11 YEARS
MARCH 2023

This document provides guidance on administration of COVID-19 vaccination to children 5 – 11 years of age. It is designed to form an annexure to the "*COVID-19 Vaccine Implementation Guide and Toolkit*" and will be used to update COVID-19 vaccination training materials to cover vaccination of this age group.

Children who are at risk of developing severe disease will be offered COVID-19 vaccination consisting of two doses of monovalent Comirnaty® paediatric vaccine administered with an minimum interval of 21 days between the two doses.

CLINICAL CONSIDERATIONS

Which children are eligible to be vaccinated?

Only children who are at risk of developing severe COVID-19 disease are elligible to be vaccinated. The disease states which place children at risk of developing severe disease are shown the table below, and all children with these diseases or conditions should be offered vaccination.

Disease state	Comment
Respiratory disease	Including those with poorly controlled asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, cystic fibrosis, ciliary dyskinesias, bronchopulmonary dysplasia, bronchiectasis, previous tuberculosis
Chronic heart conditions	Haemodynamically significant congenital and acquired heart disease, or less severe heart disease with other comorbidity. This includes: • Single ventricle patients or those palliated with a Fontan (Total Cavopulmonary Connection) circulation • Those with chronic cyanosis (oxygen saturations <85% persistently) • Patients with cardiomyopathy requiring medication • Patients with congenital heart disease on medication to improve heart function • Patients with pulmonary hypertension (high blood pressure in the lungs) requiring medication
Chronic conditions of the kidney, liver or digestive system	Including those associated with congenital malformations of the organs, metabolic disorders and neoplasms, and conditions such as severe gastro-oesophageal reflux that may

	predispose to respiratory infection as well as renal and liver failure
Chronic neurological disease	This includes those with: • Neuro-disability and/or neuromuscular disease that may occur as a result of conditions such as cerebral palsy, autism, epilepsy and muscular dystrophy • Hereditary and degenerative disease of the nervous system or muscles, other conditions associated with hypoventilation • Severe or profound multiple learning disabilities (PMLD), Down's syndrome, those on the learning disability register • Neoplasm of the brain
Endocrine disorders	Including diabetes mellitus, Addison's and hypopituitary syndrome
Immunosuppression	• Immunosuppression due to disease or treatment, including: - Those undergoing chemotherapy or radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients • Genetic disorders affecting the immune system (e.g., deficiencies of IRAK-4 or NEML, complement disorder, SCID) • Those with haematological malignancy, including leukaemia and lymphoma • Those receiving immunosuppressive or immunomodulating biological therapy including transplant patients • Those treated with or likely to be treated with high or moderate dose corticosteroids • Those receiving any dose of non-biological oral immune modulating drugs e.g., methotrexate, azathioprine, 6-mercaptopurine or mycophenolate • Those with auto-immune diseases who may require long term immunosuppressive treatments. • Those living with Human Immunodeficiency Virus infection. • Children who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy
Asplenia or dysfunction on the spleen	Including hereditary spherocytosis, homozygous sickle cell disease and thalassemia major
Serious genetic abnormalities that affect a number of systems	Including mitochondrial disease and chromosomal abnormalities

Additional clinical considerations

- Children with a history of myocarditis or pericarditis:
    - If history is prior to COVID-19 vaccination, may be vaccinated after the episode of myocarditis or pericarditis has completely resolved.

    - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Comirnaty® paediatric vaccine for children 5 through 11 years of age. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved.
- Comirnaty® paediatric vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.

Contraindications

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine.

Precaution

History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine have a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

SERVICE DELIVERY PLATFORM

The majority of children who will be eligible for COVID-19 vaccination have long-term health conditions which require them to attend health services on a regular basis. Within the public sector many of these children are managed at hospital level (central, tertiary, regional and district hospitals), although a substantial portion (primarily children with HIV infection) are managed at Primary Health Care facilities. Any facility providing vaccination must be registered as a vaccination on the Master Facility List (MFL). The facility may be a primary vaccination or outreach site.

COVID-19 vaccination for children will be introduced in a phased approach, broadly following the phases outlined below:

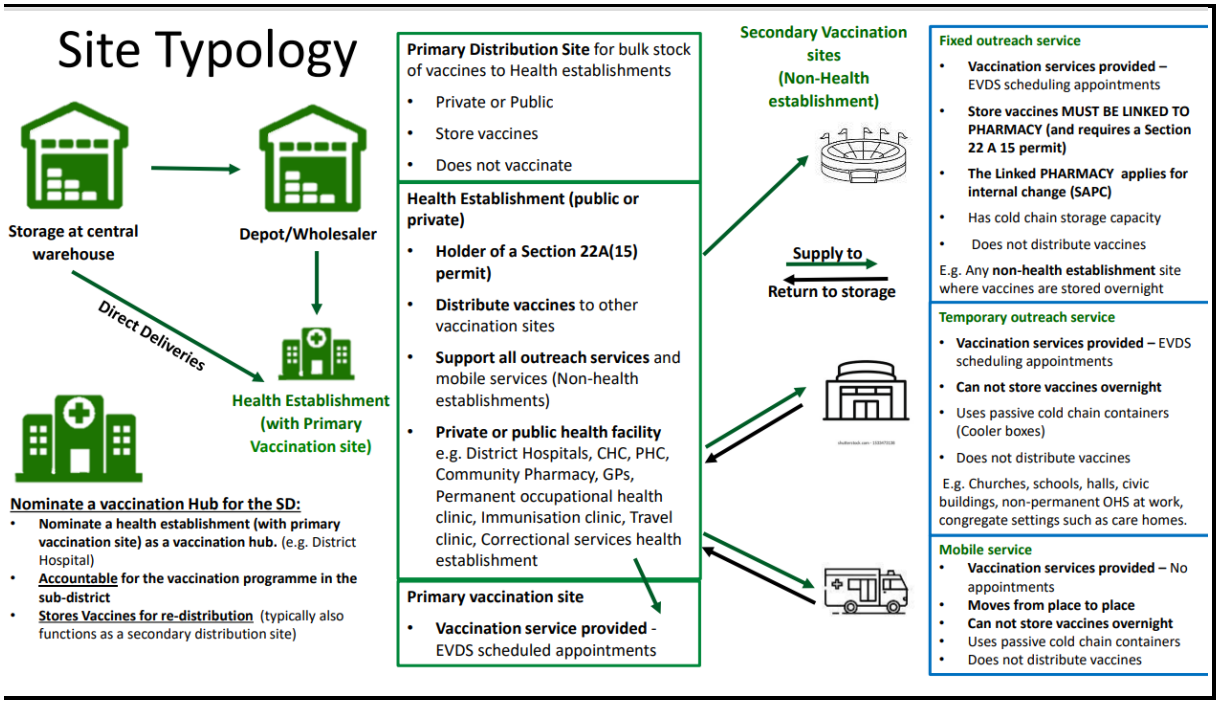
- Phase I: Introduction in a limited number of central and tertiary hospitals in each province
- Phase II: Expansion to all tertiary and regional hospitals.

- Phase III: Expansion to sufficient hospitals to ensure that there is a least one site per district.
- Phase IV: Expansion to Primary Health Care facilities – in most cases through outreach from exising sites.

COVID-19 vaccination for children 5 to 11 years will not initially be available in the private sector. Children who receive care within the private sector will be accommodated in the public sector. Re-imbursement mechanisms for COVID-19 vaccinations administered in the private sector are currently being reviewed, and provision of vaccination of children 5 – 11 years old will be included in any future reimbursement processes.

VACCINE DISTRIBUTION

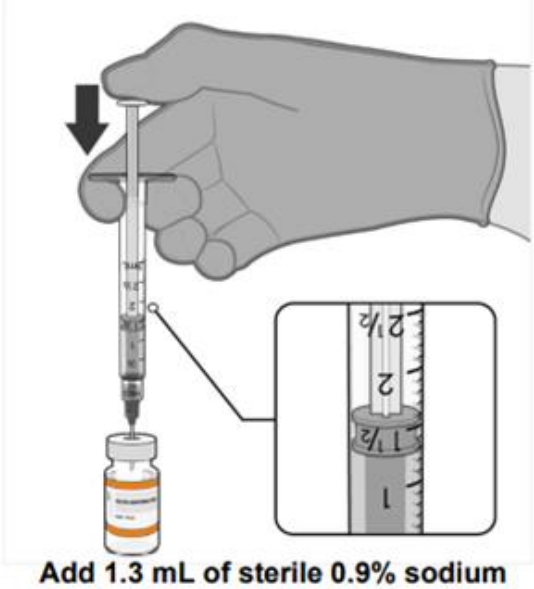
- The Comirnaty® paediatric vaccine® will be distributed within the current COVID-19 vaccine distribution model, from BIOVAC
- The vaccine will be distributed to the public sector only free of charge. From April 2023, private sector providers will be able to access the Comirnaty® peadiatric vaccine through a service level agreement with the relevant provincial departments of health.
- All sites storing the vaccines require a Section 22A(15) permit
- Orders must be placed on the Control Tower using NHPVS. Cut-off time is Wednesday at 22h00 for delivery the following week
- The minimum order quantity is 10 vials per shipper, and therefore the minimum order quantity is 10 vials per site.

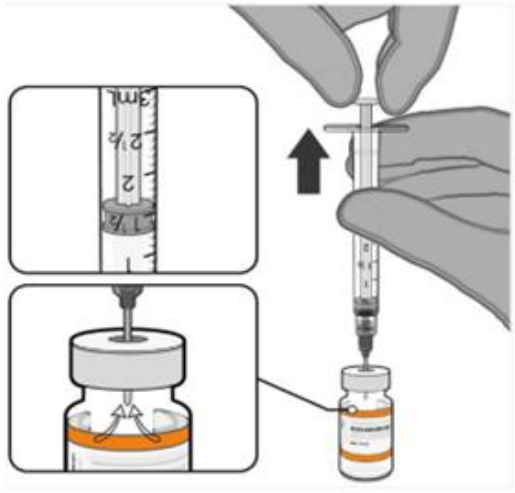


STEP-WISE GUIDE TO VACCINE ADMINISTRATION

STEP 1. DILUTION AND PREPARATION OF VACCINE

Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION	
 ✓ Orange plastic cap and label with orange border.	Verify that the vial of Comirnaty® peadiatric vaccine has an orange plastic cap and a label with an orange border and states “Children 5y to < 12y.”
Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION	
 Store in the refrigerator for up to 10 weeks prior to use.	Thaw vial(s) of Comirnaty® paediatric vaccine before use either by: • Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC]. • A carton of **10 vials** may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks. • Allowing vial(s) to sit at room temperature [up to 25ºC] for 30 minutes.

Before dilution	
 Gently × 10	• Before dilution, mix by inverting vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
 Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.	• Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper • Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.

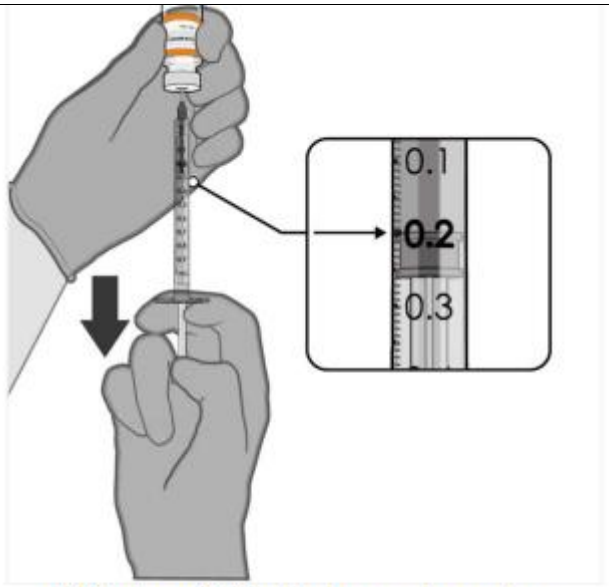
<table>
<tr><td> 
Pull back plunger to 1.3 mL to remove air from vial.</td><td>• Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe</td></tr>
<tr><td colspan="2">After dilution</td></tr>
<tr><td> 
Gently × 10</td><td>• Gently invert the vial containing the Comirnaty® paediatric vaccine 10 times to mix.
• Do not shake.
• Inspect the vaccine in the vial.
• The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter</td></tr>
<tr><td> 
Record the date and time of dilution.
Use within 12 hours after dilution.</td><td>• Record the date and time of dilution on the vial label.
• Store between 2°C to 8°C
• Discard any unused vaccine 12 hours after dilution, or at the end of the immunisation session whichever occurs first</td></tr>
</table>

STEP 2: PREPARATION FOR VACCINATION

- Confirm that the child 5 through 11 years of age is eligible to be vaccinated (see above).
- Register the child on the EVDS (see details below) or on a paper form (see Annexure A).
- Consent should be recorded on a consent form, and should be stored in the child's medical records at the facility.

STEP 3: ADMINISTER THE VACCINE

- Ensure that the vaccine vial has been correctly prepared and stored.
- Draw up the correct dose (Primary Series: 0.2 mL of the monovalent vaccine, 2 doses 21 days apart).

Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border - WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 **Withdraw 0.2 mL dose of vaccine.**	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Comirnaty® peadiatric vaccine preferentially using a low dead-volume syringe and/or needle. • Each dose must contain 0.2 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. • Administer immediately

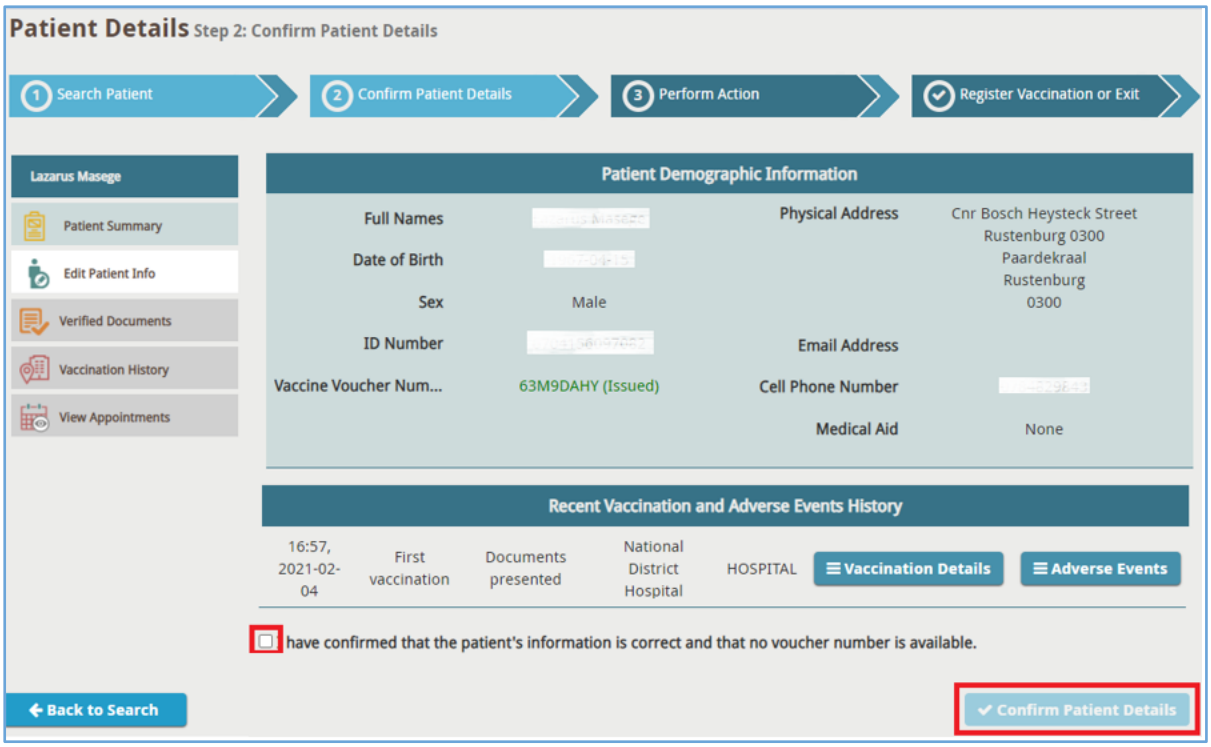
- Administer the vaccine.
  - Administer Comirnaty® peadiatric vaccine by intramuscular (IM) injection)
  - The deltoid muscle is the preferred injection site. The Vastus lateralis muscle in the anterolateral thigh can also be used.
  - Needle gauge and length: Use a 22-25 gauge, 1 inch

STEP 4: RECORD THE VACCINATION

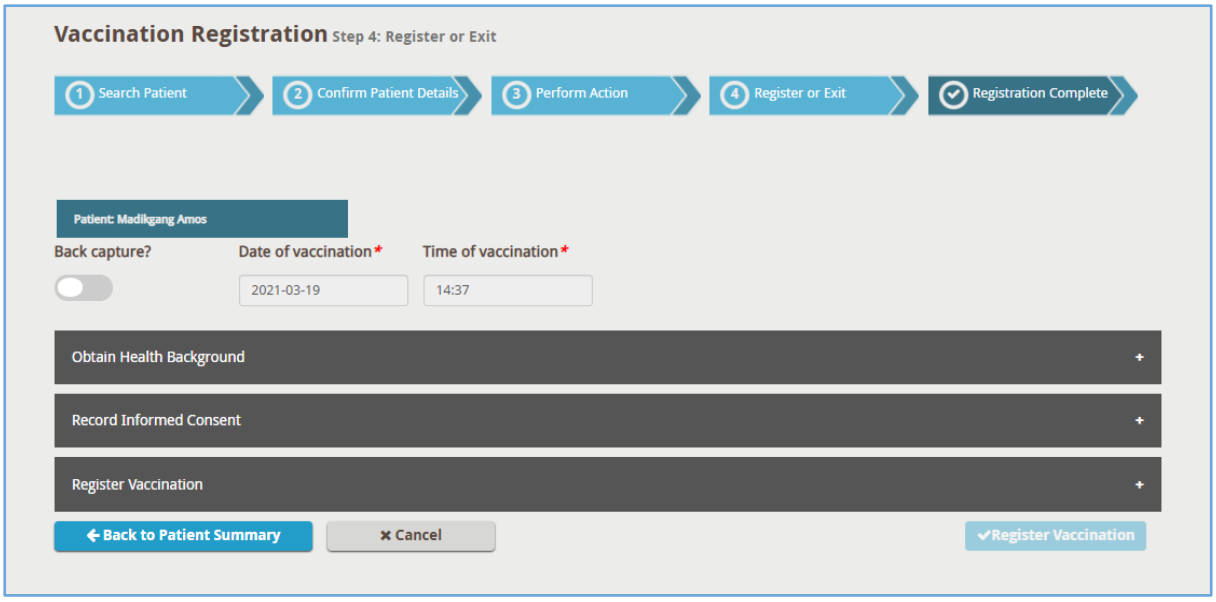
- COVID-19 vaccination providers must document vaccine administration in the Electronic Vaccination Data System (EVDS) at the time of administration or on a paper form. If a paper form is used, the record must be back captured into EVDS within 24 hours.
- Parent/gaurdian/caregiver's consent must be recorded on a paper consent form and this must be filed with the child's health record.
- Proof of identity:
    - **Child: A birth certificate must be presented.**
    - Adult: An identity document must be provided by the accompanying adult (parent/gaurdian/caregiver). This may be a South African ID number, a foreign passport number, a Section 22 (asylum seeker) permit number, a Section 24 (legal refugee) permit number or a refugee identification number.

Recording the vaccination on the EVDS

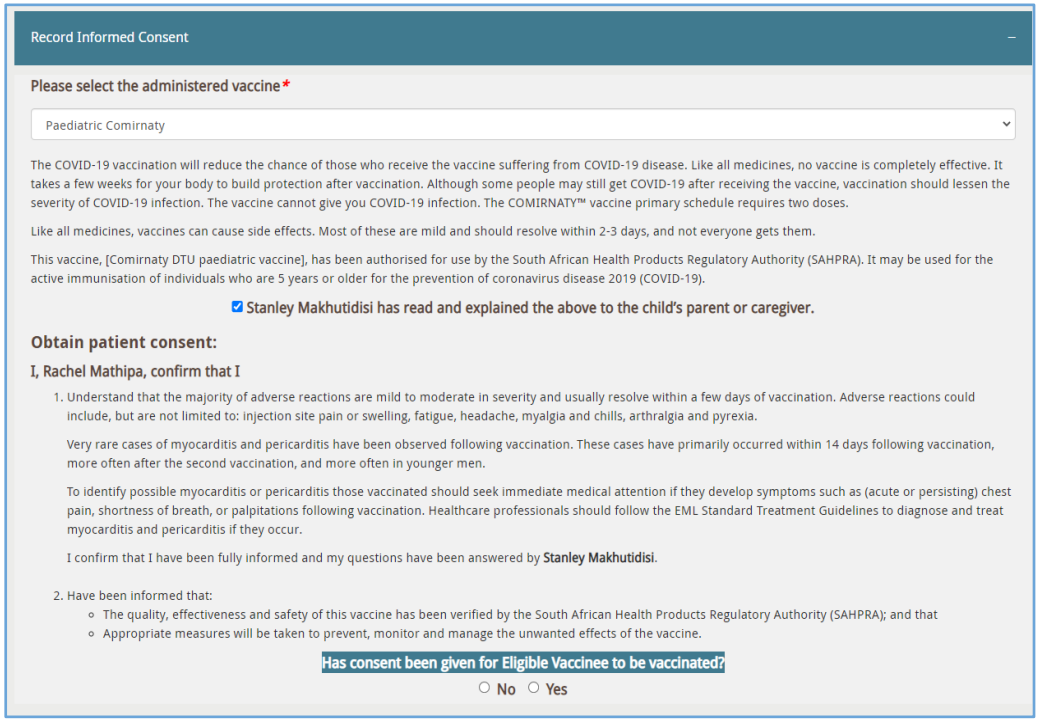
- Both the parent/gaurdian/caregivers' and the childs' details, including identity numbers, must be recorded on the EVDS. EVDS will link the child and the adult.
- Search for the child on the EVDS.
- Search for the caregiver/guardian of the child by using the identity document number presented by the accompanying adult.
- Confirm both individuals' details, click on the record to continue and confirm that the information presented is correct. Edit the information if it is not correct.



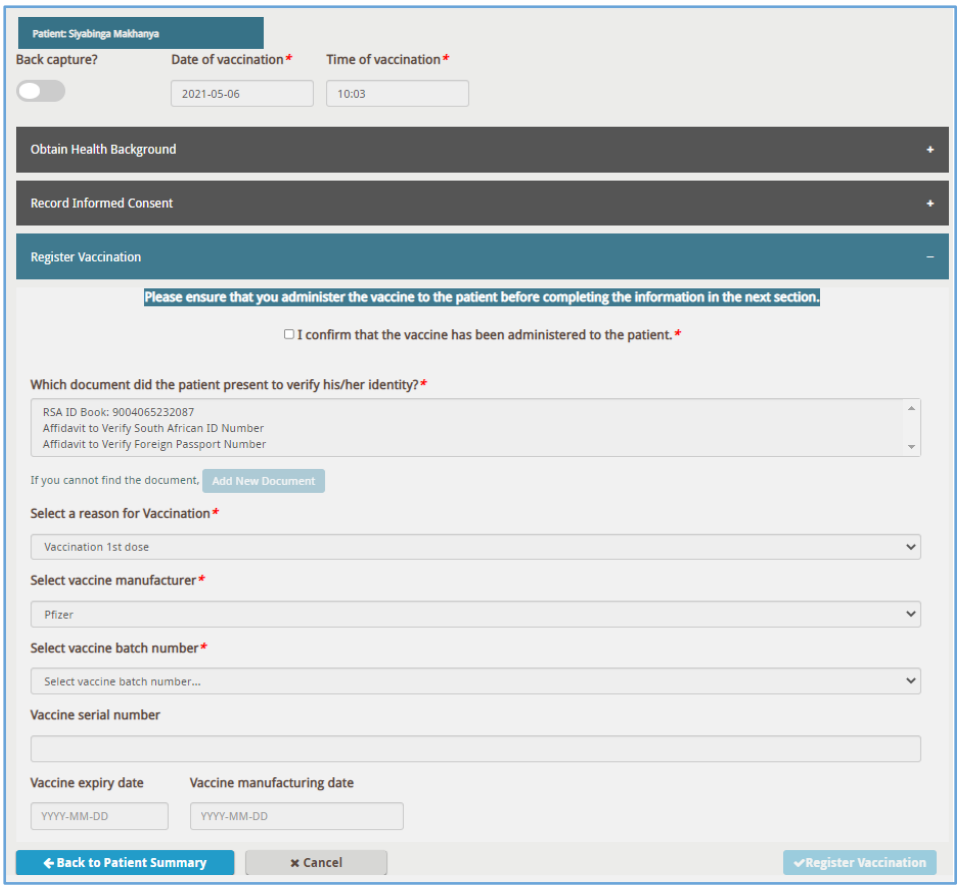
- Identity documents:
  - Select *Verified documents* on the left to add an identity document. Ensure that the child and adult's documents are be listed here.
  - Add a new identity document by clicking on *Add* and select the type of document from the list provided. Enter the identification number printed on the document .
- Select the **Patient Summary** to confirm vaccine eligibility
- Click on the *Register Vaccination* button at the bottom
- EVDS will initiate the registration process and you will now capture the patient's health background, consent and vaccine information.
- Complete the EVDS health background screen.



- Complete the EVDS consent screen using the information on the paper consent form.



- Register the vaccination **AFTER** you have administered the vaccine
  - Check that all items are complete and select **Paediatric Comirnaty.**
  - Enter the vaccine batch number, serial number (if available) and vaccine expiry date.
  - Click on the *Register Vaccination* button at the bottom right.



- The child or careigver should also be provided with a vaccination record card, which includes the following information: date of vaccination, product name/manufacturer, lot number, and name and location of the administering clinic and healthcare professional. The vaccinator must sign the vaccination record card.

STEP 5: OBSERVE THE CHILD FOLLOWING VACCINATION

- Procedures for observation are outlined in Chapter 7 of the COVID-19 Vaccine Implementation Guide and and Toolkit

- Vaccination providers should oberve patients after vaccination to monitor for allergic reactions and syncope:

    - 30 minutes for persons with:
        - An allergy-related contraindication to a different type of COVID-19 vaccine
        - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
        - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
    - 15 minutes: All other persons

- Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.

- Have a written protocol to manage medical emergencies following vaccination. Recommendations, including equipment and medications can be found in Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination

- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

STEP 6: MANAGE AND REPORT ADVERSE EVENTS

Adverse events following immunisation should be managed and reported as outlined in the *"COVID-19 Vaccine Implementation Guide and Toolkit"* (Chapter 8: Vaccine Safety Surveillance).

Adverse events following immunisation can be be recorded on:

- MedSafety app
- At any health facility
- National Health Hotline (0800 299 999)

Which adverse events should be recorded?

Vaccine administration errors (whether associated with an adverse event [AE] or not)

Serious AEs (irrespective of attribution to vaccination)

- Multisystem inflammatory syndrome (MIS) in adults or children - Adverse event of special interest
- Cases of myocarditis (for mRNA vaccines) – Adverse event of special interest
- Cases of pericarditis (for mRNA vaccines) – Adverse event of special interest
- Cases of COVID-19 that result in hospitalization or death

Any additional adverse events following immunisation of concern

Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.

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COVID-19 VACCINATION
RECORD OF ADMINISTRATION OF PAEDIATRIC DOSE (5-11 years old)

DETAILS OF VACCINEE (CHILD)

All personal particulars like names, surname, date of birth should be official particulars that appear on the child's birth certificate.

First Name/s																
Surname																
Date of birth	Y	Y	Y	Y	M	M	D	D								
Gender (tick one)	Male			Female												
ID number																
Address																
Is the child a member of a medical aid scheme? (tick one)	No		Yes		If yes, please provide medical aid details below											
Medical Aid Scheme																
Medical Aid Number																
Dependent Code																

DETAILS OF PARENT/GUARDIAN

All personal particulars like names, surname, date of birth should be official particulars that appear on the persons ID or passport

First Name/s																
Surname																
Date of birth	Y	Y	Y	Y	M	M	D	D								
Gender (tick one)	Male			Female												
ID number																
Relationship to child																
Address																
Mobile number																
Email																

DETAILS OF VACCINATION SITE

To be completed by the Vaccinator

Vaccination site UID																
Vaccination site name																
District																

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PRE-VACCINATION QUESTIONS

To be completed by the Vaccinator

Is the child sick today?	Yes		No	
Has the child received any other COVID-19 vaccine at any time?	Yes		No	
- If yes, which vaccine?				
- Date of administration				
Has the child ever had an anaphylactic reaction or other severe symptoms after receiving another vaccination or injection (a shot given intravenously, intramuscularly, or subcutaneously)? If Yes, please describe the symptoms	Yes		No	
Does the child have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication? If Yes, please describe the reaction from the symptom list below:	Yes		No	
- Trouble breathing	Yes		No	
- Broke out in hives	Yes		No	
- Facial or tongue swelling	Yes		No	
- Low blood pressure	Yes		No	
Does the child have any chronic conditions?	Yes		No	

VACCINE INFORMATION

To be completed by the Vaccinator

Vaccine name															
Vaccine manufacturer															
Batch no:															
Expiry date	Y	Y	Y	Y	M	M	D	D							
Dose (tick one)	First dose				Second dose				Other dose						

ADVERSE EVENTS FOLLOWING IMMUNISATION

To be completed by the Vaccinator

Did any adverse event occur?	No		Yes											
If yes, was it recorded on the AEFI system?	No		Yes											

VACCINATOR DETAILS

To be completed by the Vaccinator

First Name/s															
Surname															
ID number															
Job Title															
Professional body	SANC			HPSCA											
Registration no:															
Mobile number															
Signature															
Date:	Y	Y	Y	Y	M	M	D	D							