COVID-19 Vaccine Programme Implementation Updates 2023

23rd and 27th March 2023

Contents

- Why is COVID-19 vaccination still important?
- Key programmatic updates
  - Integration into routine health services
  - Updated schedules
  - Vaccination of children 5 – 11 years old
- Update on Vaccination site selection and permits
- Update on effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines
- Vaccine Safety Surveillance and COVID-19 No Fault Compensation

How does COVID-19 affect you?

- COVID-19 infection could have no symptoms, mild symptoms but some COVID-19 can be **severe, result in hospitalisation or death**
- The **elderly and persons with underlying medical conditions** are more likely to get very sick from COVID-19
- COVID-19 can **damage many different organs and systems** in your body
- The **complication of COVID-19 infection could result in long COVID**, that result in new, returning or ongoing health problems lasting weeks or months
- You can get **long COVID even if you had no symptoms or mild illness** during COVID-19 infection

Why is it still important to get vaccinated against COVID-19 ?

- COVID-19 vaccination protects against severe disease, hospitalisation and death
- COVID-19 vaccination reduces the risk of developing long COVID, even if you have a breakthrough infection
- Vaccines are safe and effective

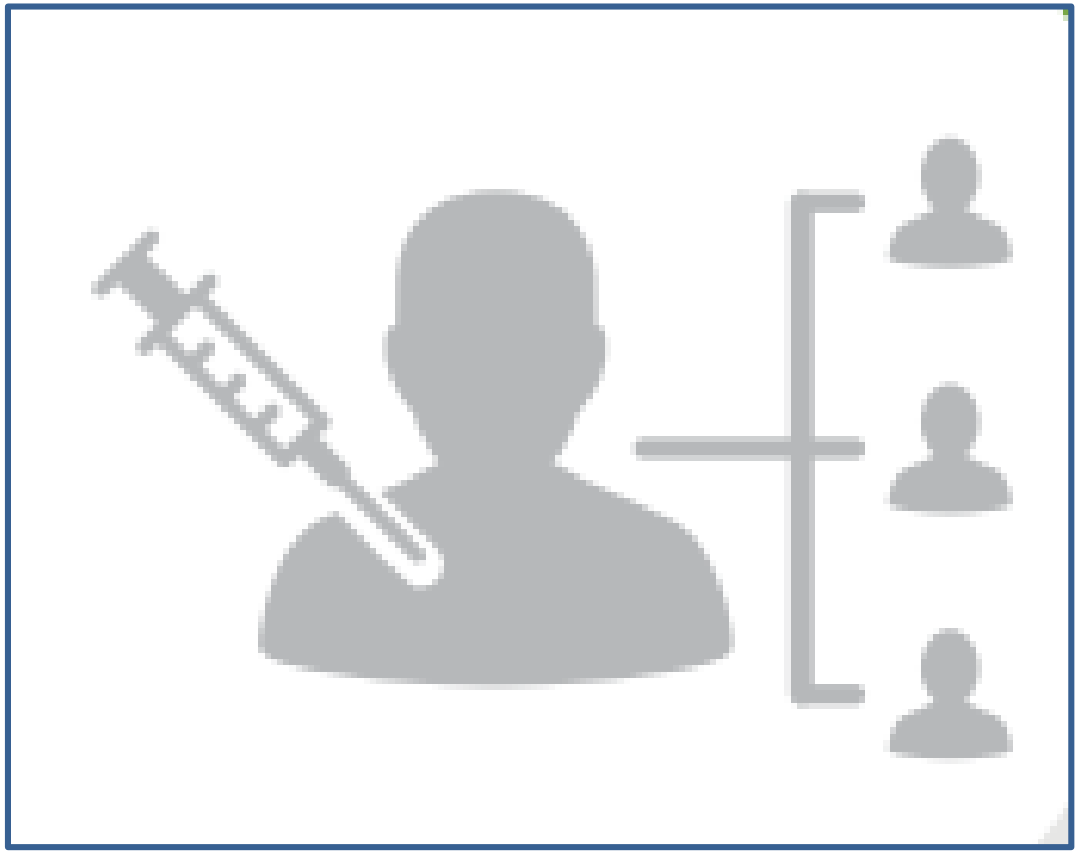
Why do you need a booster?

- Viruses change and mutate over time. COVID-19 has mutated resulting in different variants of concern
- Vaccine protection wains over time and boosters are required to optimise the protection against COVID-19
- Heterologous boosting further enhance the immune response, providing greater protection

Vaccination programme updates

- Integration of services

- Updated adult vaccination schedule



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Phila
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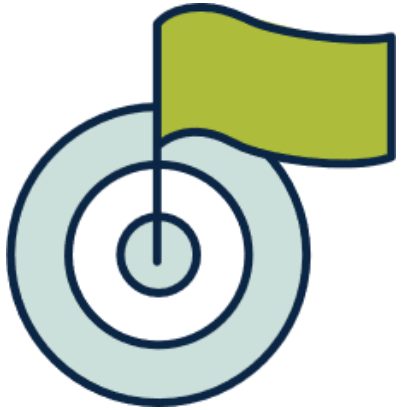
2030 NDP

Integration Framework



Integration of vaccinations against preventable diseases into routine health services from both strategic management and operational perspectives

Provide recommendations on the integrated management structure at a National, Provincial and District level

Provide guidance on the functional integration of vaccine services within routine health services at service delivery interface using the integrated clinical services management platform

Integrated Vaccine Services

INTEGRATED VACCINE SERVICES REFERS TO…

The provision of vaccine services **within the service delivery platform**; clinics, community healthcare centres, mobile services and outreach points

Where practically feasible, the vaccine should be offered at point of service in the same consultation room

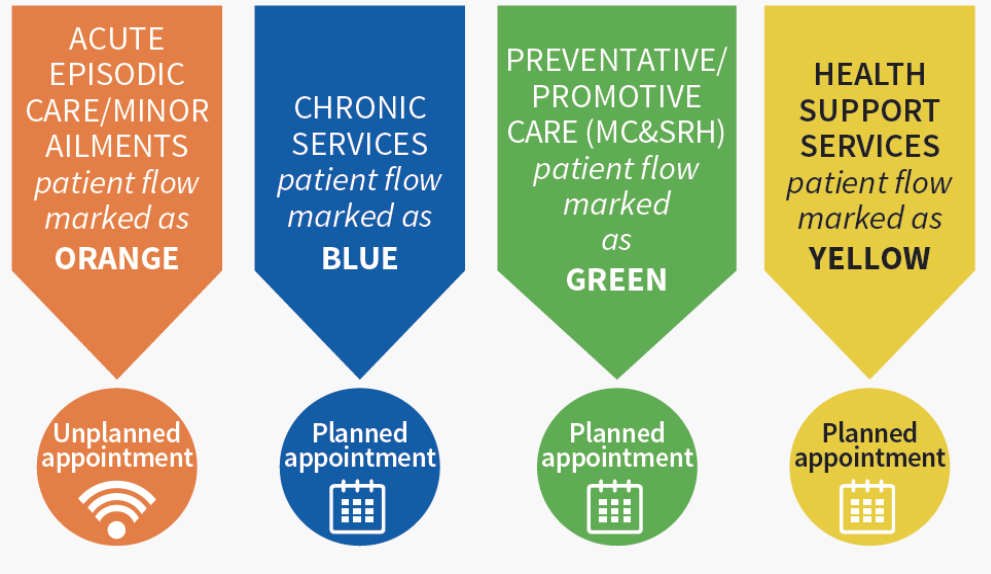
During consultations across all services patients should be offered the relevant vaccines for their age group and risk classification as an opt in service

Recommendation 3: Functional Integration

An incremental approach to integration of vaccine services within primary healthcare services is recommended.

Each facility **will tailor-make the recommendations** based on its unique attributes as a one size fit all solution is not feasible.

Services delivered for vaccine preventable diseases should be delivered within the streams of care as proposed by the **Integrated Clinical Services Model**



Update – Adult COVID-19 vaccination schedule Circular 1 of 2023

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Persons 50y and older

SCHEDULE FOR PERSON 50 YEARS AND OLDER: Updated 30 January 2023								
Primary Schedule	**Booster doses**							
One dose								
COVID-19 vaccine Janssen®	Minimum of 60 day interval	COVID-19 vaccine Janssen® **OR** Comirnaty® Vaccine	Minimum of 90 day interval	COVID-19 vaccine Janssen® **OR** Comirnaty® Vaccine	Minimum of 120 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®	Minimum of 180 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®

OR

SCHEDULE FOR PERSON 50 YEARS AND OLDER: Updated 30 January 2023								
Primary Schedule			**Boosteroses**					
First dose		**Second dose**						
Comirnaty® Vaccine	Minimum of 21 day interval	Comirnaty® Vaccine	Minimum of 90 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®	Minimum of 120 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®	Minimum of 180 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®

Persons 18y - 49y

SCHEDULE FOR ADULTS 18 – 49 YEARS: Updated 30 January 2023						
Primary Schedule **One dose**	**Booster doses**					
COVID-19 vaccine Janssen®	Minimum of 60 day interval	COVID-19 vaccine Janssen® **OR** Comirnaty® Vaccine	Minimum of 90 day interval	COVID-19 vaccine Janssen® **OR** Comirnaty® Vaccine	Minimum of 180 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®

OR

SCHEDULE FOR ADULTS 18 – 49 YEARS: Updated 30 January 2023						
Primary Schedule			**Booster doses**			
First dose		**Second dose**				
Comirnaty® Vaccine	Minimum of 21 day interval	Comirnaty® Vaccine	Minimum of 90 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®	Minimum of 180 day interval	Comirnaty® Vaccine **OR** COVID-19 vaccine Janssen®

Immunocompromised adults

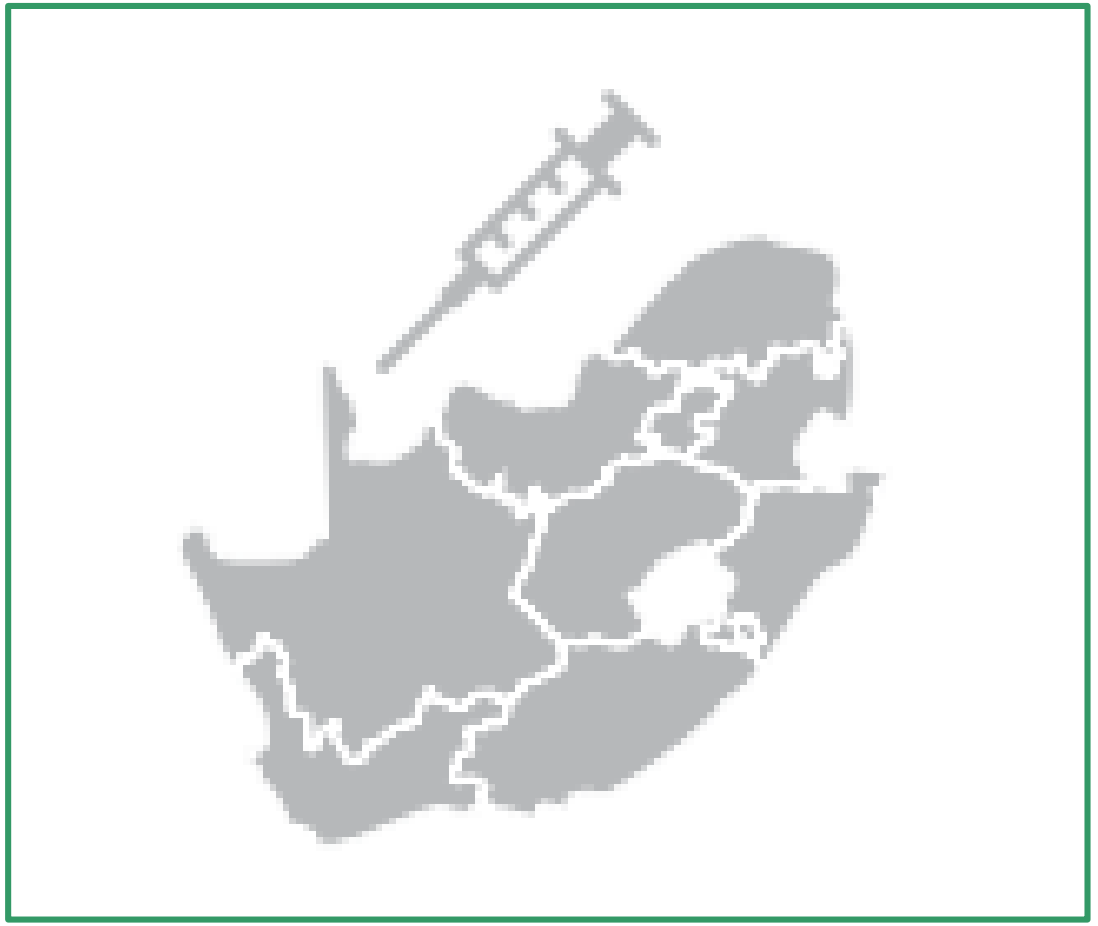
- Adults who are registered as immunocompromised on the EVDS are eligible to receive the additional booster doses providing that 180 days has elapsed from their previous dose
- In future, immunocompromised adults will be eligible to receive the standard age-appropriate schedule

Adolescents (12 – 17 years old)

SCHEDULE FOR ADOLESCENTS 12 – 17 YEARS: Updated 23 February 2022		
Primary Schedule		
First dose		**Second dose**
Comirnaty® Vaccine	Minimum of 21 day interval	Comirnaty® Vaccine

Update on Vaccination Site selection and permits

Ms Marione Schönfeldt
Pharmaceutical Policy Specialist



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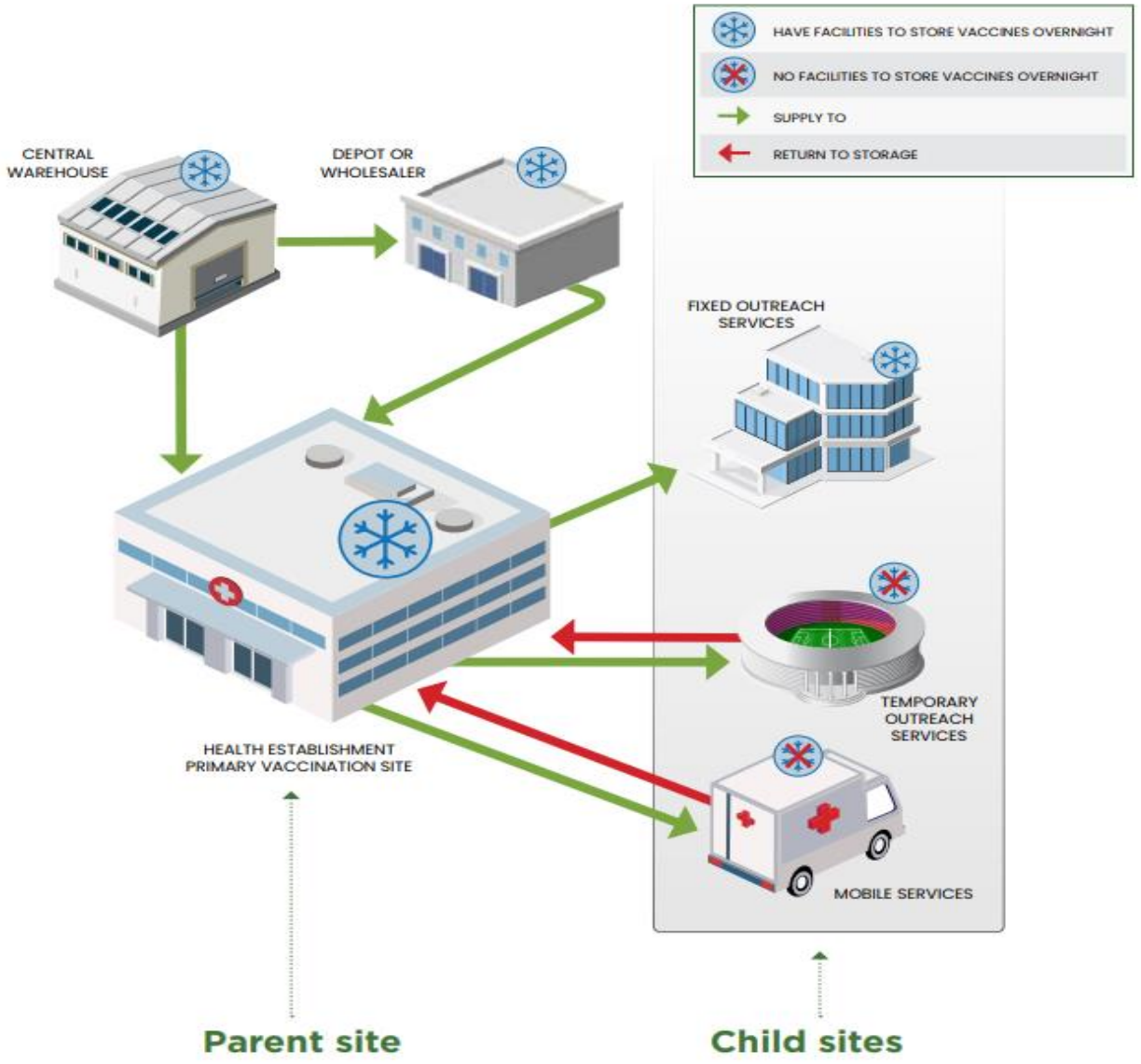
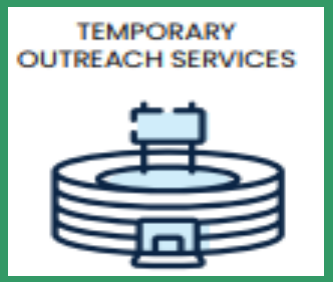
Types of vaccination sites



- **Identify** a health establishment (primary vaccination site) this should now include CHCs and PHCs
- The Sub-district is **accountable** for the vaccination programme
- **Vaccines may be stored for re-distribution**
- **For further guidance on** setting up your vaccination hub, consult NDoH

It is important that you have a **service delivery model** which is correctly set-up/linked on the MFL

Outreach sites reminder

Service	Definition	Characteristics
	A non-health establishment set up on a semi-permanent basis with a permit, and equipped with the required equipment to store vaccines overnight.	• Fixed outreach sites cannot exist without a primary site • Not all community sites are on MFL, some may need to be manually added • Requires its own s22A(15) permit • Cannot host its own outreach sites
	A facility where vaccination services are provided on a temporary basis, does not store vaccines overnight and is linked to a primary vaccination facility	• Sites are added to MFL by Facility Representative but vaccine services are not activated • Operates under primary vaccination site's s22A permit • Cannot store vaccines overnight
	A facility where vaccination services are provided on a temporary basis. The site does not store vaccines overnight and is linked to a primary vaccination facility. Vaccines are administered to clients by a team of vaccinators moving from place to place.	• Sites are added to MFL by Facility Representative but vaccine services are not activated. • Operates under primary sites permit. • Cannot store vaccines overnight.

Update on Section 22A15 permits

- **Section 22A(15) permit for active vaccination sites will be extended for an additional 2 years**
- A new permit will be issued to you in terms of Section 22A(15) the Medicines and Related Substances Act, 101 of 1965 and will be ready for download from the SAPC web-site
- To download the permit, click on the link **"https://ndoh.permits.e2.co.za/applications/permitsearch"** and enter your MFL IUD in the appropriate slot.
- Alternatively, visit the website of the South African Pharmacy Council at www.sapc.za.org.
- Go to the COVID-19 link,
- Click on link next to, **"Search for approved COVID-19 Vaccination Sites",**
- Enter the site name in the search box - **Enter the MFL IUD to download the permit**
- For enquiries email: **covidpermits@health.gov.za** quoting your MFL IUD, Facility Name and Query Type on the subject line

Vaccine distribution and availability – Private sector

- From the **1st of April 2023, vaccines will only be distributed to public sector** health facilities
- The private sector will access the vaccine from the provincial departments of health through designated health facilities, leveraging existing or new **Service Level Agreements (SLA) between the provincial department of health and the private service providers**
- The province will provide **vaccines free of charge** to the private provider, as per the provincial SLA
- COVID-19 vaccination for children 5 to 11 years will be available in the public sector and in the private sector through SLAs. **Children who receive care within the private sector will be accommodated in the public sector**

Cost reimbursement model update

- COVID-19 vaccines will be provided at zero value to private service providers
- The **Supply and Distribution Agreements will be concluded**, and the department will no longer reimburse private providers for vaccine or vaccine administration costs associated with the vaccination of uninsured persons after the **31st March 2023**
- COVID-19 vaccines and administration costs will remain a **prescribed minimum benefit** for insured patients, with the price of the COVID-19 vaccine Janssen® and Comirnaty® (Pfizer) vaccines cost R0,00.
- This will allow private providers to continue to claim for the vaccine administration cost.
- From the 1st April 2023, the **vaccine administration cost will be fixed at R100** (inclusive of VAT) per dose in both the public and private sectors.

Cost reimbursement model update

Summary of changes

1. **Uninsured clients accessing vaccination in the public sector will be vaccinated free of charge**
2. **Insured clients vaccinated in the private sector will receive the service free of charge** as the vaccine will be provided free of charge, and the medical scheme (PMB) will reimburse the vaccine administration fee
3. **Insured clients accessing the service in the public sector will receive the service free** of charge. Where capacity exists, the administration fee can be claimed from the patient's medical scheme
4. **Uninsured clients accessing vaccination in the private sector will be required to pay the vaccine administration cost of R100**. The provincial or national department of health will not reimburse private providers for administering the vaccine.

Cost reimbursement model update

Summary of changes

5. **Active vaccination sites in the private sector will receive a credit against their account for unused COVID-19 vaccine doses remaining at the end of March 2023**. The usable vaccine stock on hand recorded on the Stock Visibility System (SVS) will be used to determine the credit where applicable
6. **The cash collection by distributors will conclude once** all the claims for vaccinations up to the 31st March 2023 have been processed. This will further allow the distributors to complete the associated cash collection activities before the end of their contracts on the 30th June 2023

Effective vaccine management, cold chain, logistics, and distribution of COVID-19 vaccines

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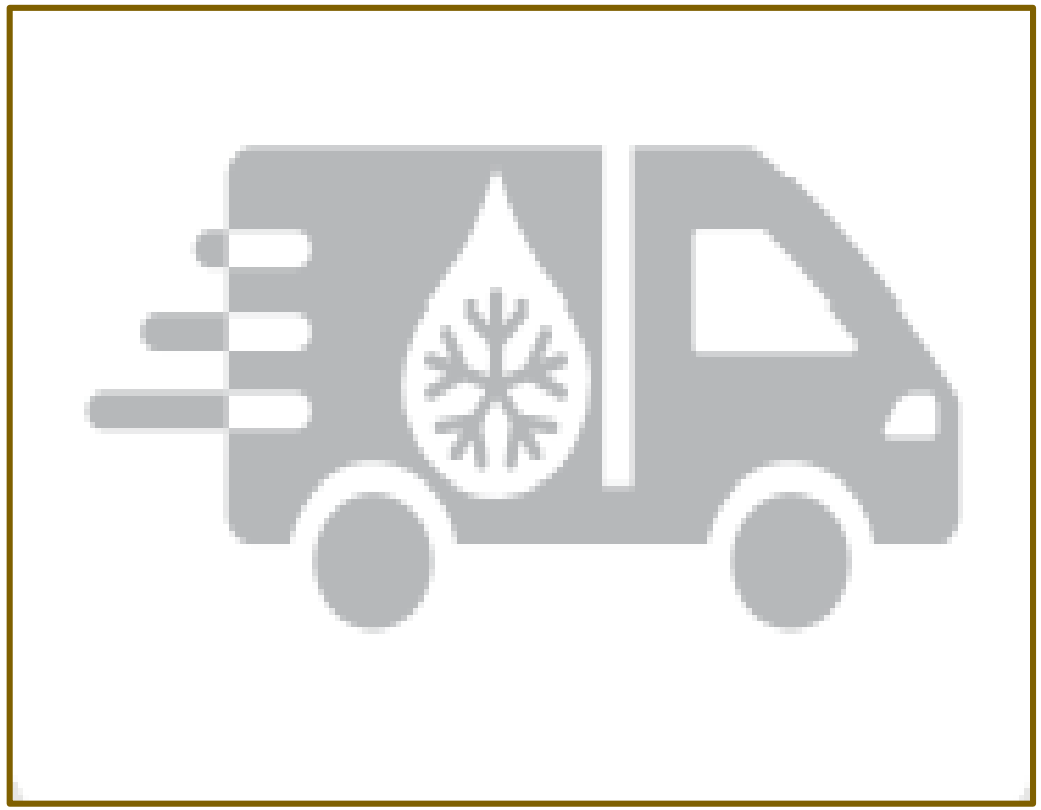
Ms Monsenique Botha (SVS)
USAID Global Health Supply Chain Program – Technical Assistance



SVS Covid-19 Basic Principles

Only sites storing the Covid-19 vaccine overnight must use this instance of SVS.

Reporting Frequency

- **Daily Reporting** must be completed for all Covid-19 vaccines before 23:45.

Capturing Fields

- Each time data is submitted **ALL** capturing fields must be recorded.
- All data must be recorded as **VIALS** and **NOT DOSES**

Only the last update per item for the day will be recognized as the update for the day.

Successful synching *after updates is required for sites to reflect as compliant.*

All Covid-19 vaccines *on the site's SVS formulary must be reported on including those where stock is not held at the time.*

$$\text{Current Stock Level} = (\text{OB} + \text{R}) - (\text{I} + \text{T} + \text{L})$$

For **SKIPPED REPORTING DAYS**, end-users should update data for all the days missed on the day of capture (days missed + day of capture) This will ensure the stock always balances back to what was received from the supplier/distributor.

SVS is NOT a transactional system. Users should not use it to update multiple transactions (issues, receipts, losses etc.) as they occur during the course of the day.

All **PARTIALLY USED VIALS CANNOT** be used after 6 hours of the first vial puncture and are therefore **considered as issued** and should be counted under '***Stock Issued***'.

SVS Covid-19 Data Capturing Fields: Reporting Definitions

Current Stock Level	Vial count in the freezer/refrigerator at the end of reporting cycle daily
Expiry Date*	Date up to which the stock item will retain its strength and other properties *(The expiry date of the vaccines that expire first must be used)*
Stock Received	Vial count delivered since the last daily update *(This includes stock received from the Distributor, Primary Distribution Sites & Primary Vaccination Sites & does **not** include Stock Returned from Outreach Sites.)*
Stock Lost	Vial count of any wastage due to breakage, expiry, missing inventory etc. *(In the case of vaccines, this does **not** include wastage due to partially used vials)*
Stock Issued	Vial count issued out of the freezer/refrigerator or bulk storage area for use during the day at a vaccination stations on site or during outreach services *(In the case of vaccines, partially used vials should be counted as stock issued)*
Stock Transferred	Vial count sent to another vaccination site or primary distribution site

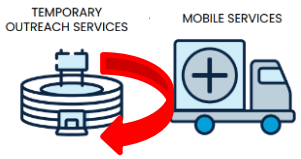
** See the Covid-19 Vaccination Guide for more information.*

Know the Difference

Stock Received

Stock received from supplier/ distributor / depot / primary distribution sites / primary vaccination site

Vials **not** doses



Does **not** include vials returned from outreach services

VS

Stock Returned

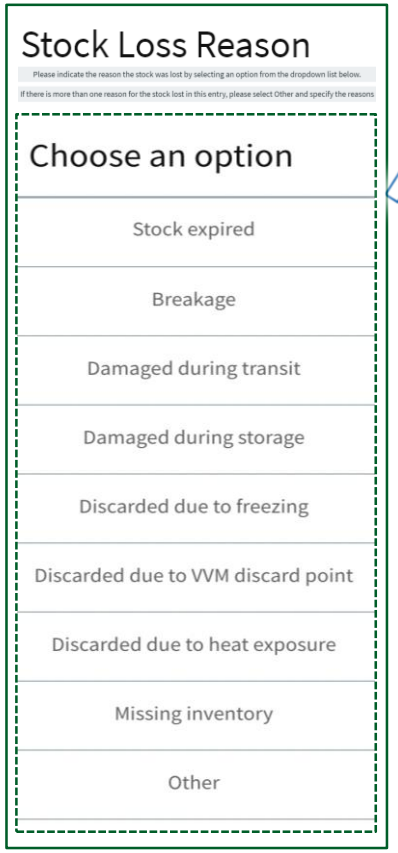
NOT an SVS field

Unused stock returned from outreach services

Must be deducted from the total “Stock Issued” for the day

Know the Difference

Stock Lost



- Full vials wasted due to breakage, expiry, missing inventory, temperature excursions, etc.
- Vials **not** doses
- Does **not** include partially used vials

vs

Stock Issued

- Stock used during the day at vaccination stations or outreach services
- Vials **not** doses
- Includes partially used vials (“opened” vials)

vs

Stock Transferred

- Stock sent to another primary vaccination* or distribution site** & not to outreach services
- Vials **not** doses

***Primary vaccination site:** A place at a health establishment where vaccination services may be provided*

****Primary distribution site:** A depot, sub-depot, wholesale pharmacy, or distributor which stores and distributes vaccines to vaccination sites and does not provide vaccination services to clients*

Maintaining Data Integrity

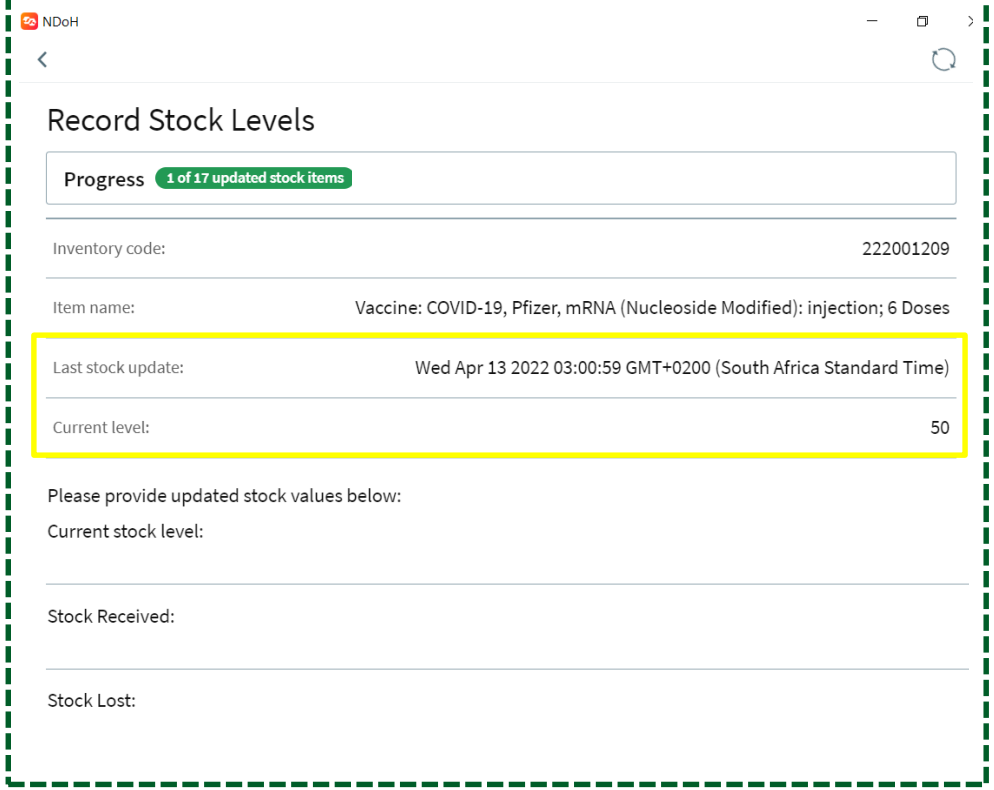
$$\boldsymbol{Current\ Stock\ Level = (OB + R) - (I + T + L)}$$

- *Opening Balance (**OB**)*
- *Stock Received (**R**)**
- *Stock Issued (**I**)**
- *Stock Transferred (**T**)**
- *Stock Lost (**L**)**

For each of these, capture **the total of all events that occur during the day/week as per reporting requirements.*

***The last updated stock levels for the day will reflect the day's closing balance and become the next day's/week's opening balance*

*Opening Balance (**OB**):*



Strengthening Opportunities

DO	DON'T
1. Reporting Consistency on SVS Covid-19	
✓ Update ALL vaccines on formulary daily	X Update one vaccine only or skip reporting days
2. SVS Covid-19 Data Variances	
✓ Update the totals of all events that occur during the day for all the capturing fields accurately	X Omit transactions and capturing fields
✓ One update per day	X Duplicate updates or capturing fields
✓ Only the last update per item for the day will be recognized as the update for the day	X Update daily capturing fields cumulatively over time
	X Update multiple times per day
✓ Update data for all the days missed on the day of capture (days missed + day of capture)	X Update incorrectly after skipped reporting day/s X Make multiple updates per day to account for skipped reporting day/s
✓ Capture partially used vials as "Stock Issued"	X Capture partially used vials/wasted doses as "Stock Lost"
✓ Capture the earliest occurring expiry dates of all batches according to the storage conditions and guidelines	X Capture stock expiry date as per manufacturer's expiry date once vaccines have moved to a different temperature range

Inaccurate data entries for the **Covid-19 vaccines** can only be corrected for the day in question and not for past reporting cycles.

Stock levels cannot be captured retrospectively on SVS Covid-19.
Once the updating window is missed, the previous day's updates cannot be made individually.

Integration of COVID-19 Vaccine Reporting on SVS

What fields stays the same?

- Current Stock Level
- Stock Lost
  - Stock Lost Reasons
- Expiry Date

What changes?

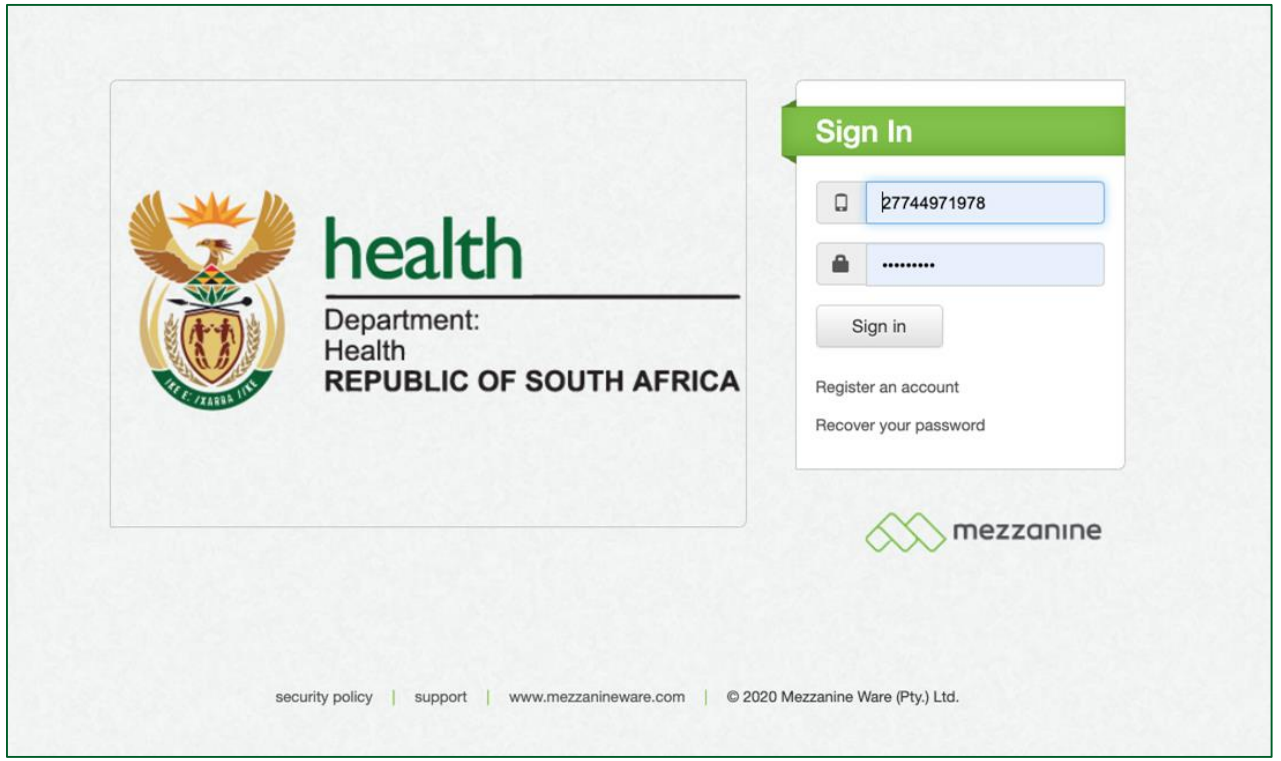
- Reduced reporting frequency
- Reporting of COVID-19 Vaccines will migrate to NDoH SVS with medicines
- Removal of “Stock Issued”, “Stock Transferred”, and “Stock Received” fields
- Inclusion of Enhanced Expiry Date functionality
  - Monitoring of expiry dates at various temperature ranges
  - Highlights stock at risk of expiry
  - Maximum allowable expiry date feature

COVID-19 SVS Web Portal Access

Managers in the public (**National**, **Provincial** and **District** level) and private sector can login on the SVS Covid-19 web portal to monitor site performance (reporting compliance) and stock availability (identify stockouts) daily and weekly.

To login and access data:

- Contact the SVS NDoH project manager (PM) **requesting access** through your provincial SVS champion or group lead;
- Complete and return a signed **confidentiality agreement** to the NDoH SVS PM;
- The registered users will receive a **SMS and/or email with user access credentials** to access the web portal.



https://covid19vaccinesza.app

Understanding vaccine wastage

Vaccine wastage occurs in most vaccination programmes and is influenced by various factors that could be specific to the vaccine or the vaccinator. The wastage is divided into two categories i.e. **wastage in open vials and wastage in unopened vials.**

Wastage in unopened vaccine vials is unacceptable and is mainly due to poor stock control practices, poor cold chain or logistics processes. This type of wastage must be eliminated as it is considered avoidable.

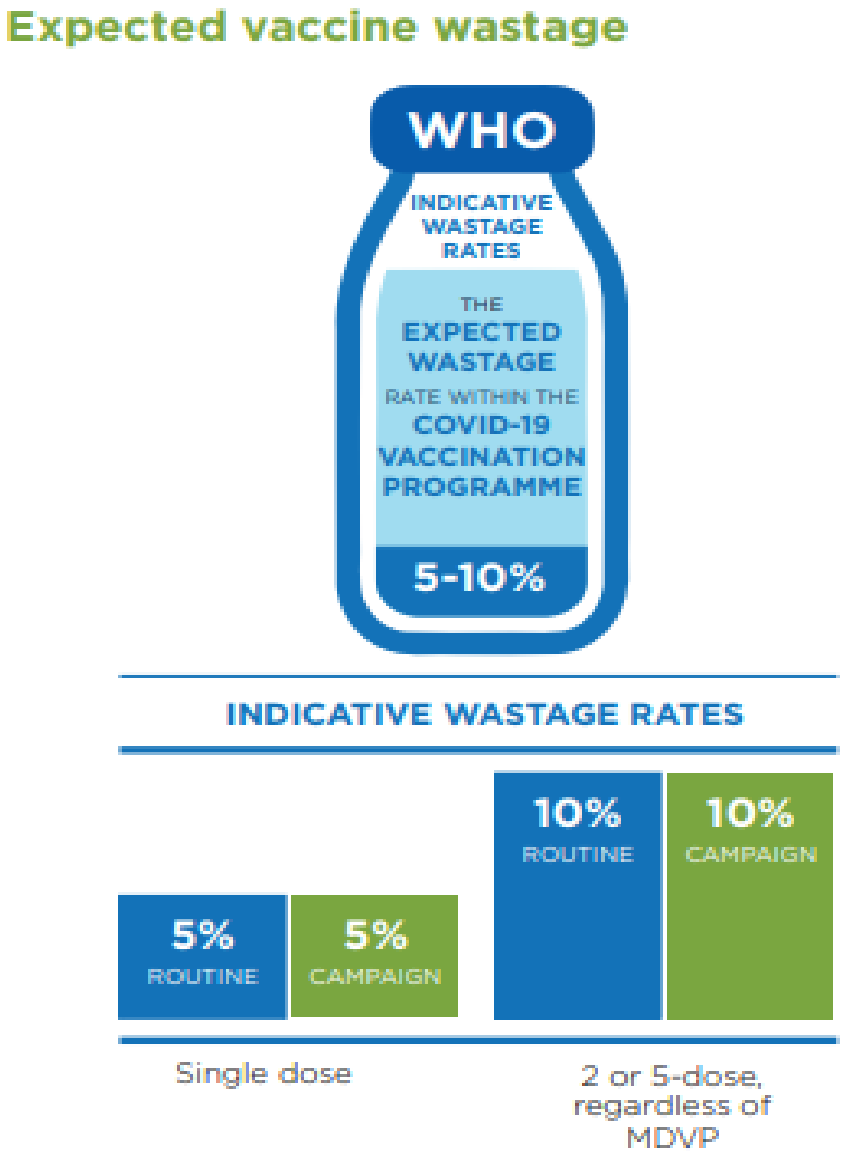
- Expiry
- VVM Indication
- Heat Exposure
- Freezing
- Breakage
- Missing Inventory
- Theft
- Discarded unused vials after outreach

Wastage in opened vaccine vials usually occurs at the service delivery level and might be considered unavoidable and somewhat acceptable if the wastage occurred while preventing missed immunisation opportunities. This type of wastage can never be eliminated but can be reduced over time.

- Remaining doses at end of session
- Unable to draw indicated number of doses
- Poor reconstitution practices
- Submergence of opened vials
- Patient reaction

Understanding vaccine wastage

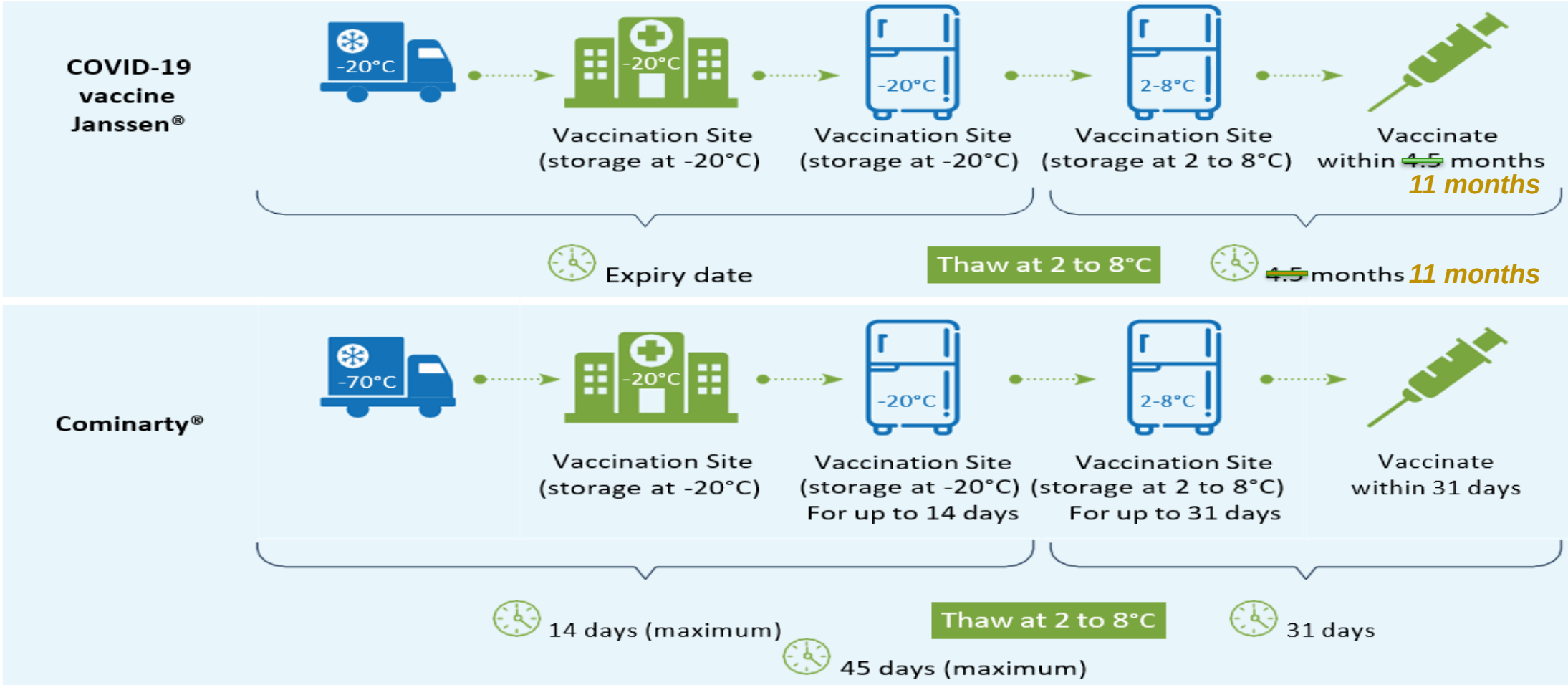
- Vaccine wastage occurs in most vaccination programmes
- **However, the question remains if vaccine wastage can be reduced, and if so, how?**
- Vaccine wastage is defined as the number of vaccines doses discarded, lost, damaged, or destroyed during the storage, distribution, and use of a vaccine
- A well-managed immunisation supply chain reduces the cost of the immunisation programme while improving efficiencies without compromising the quality of the services provided or immunisation coverage



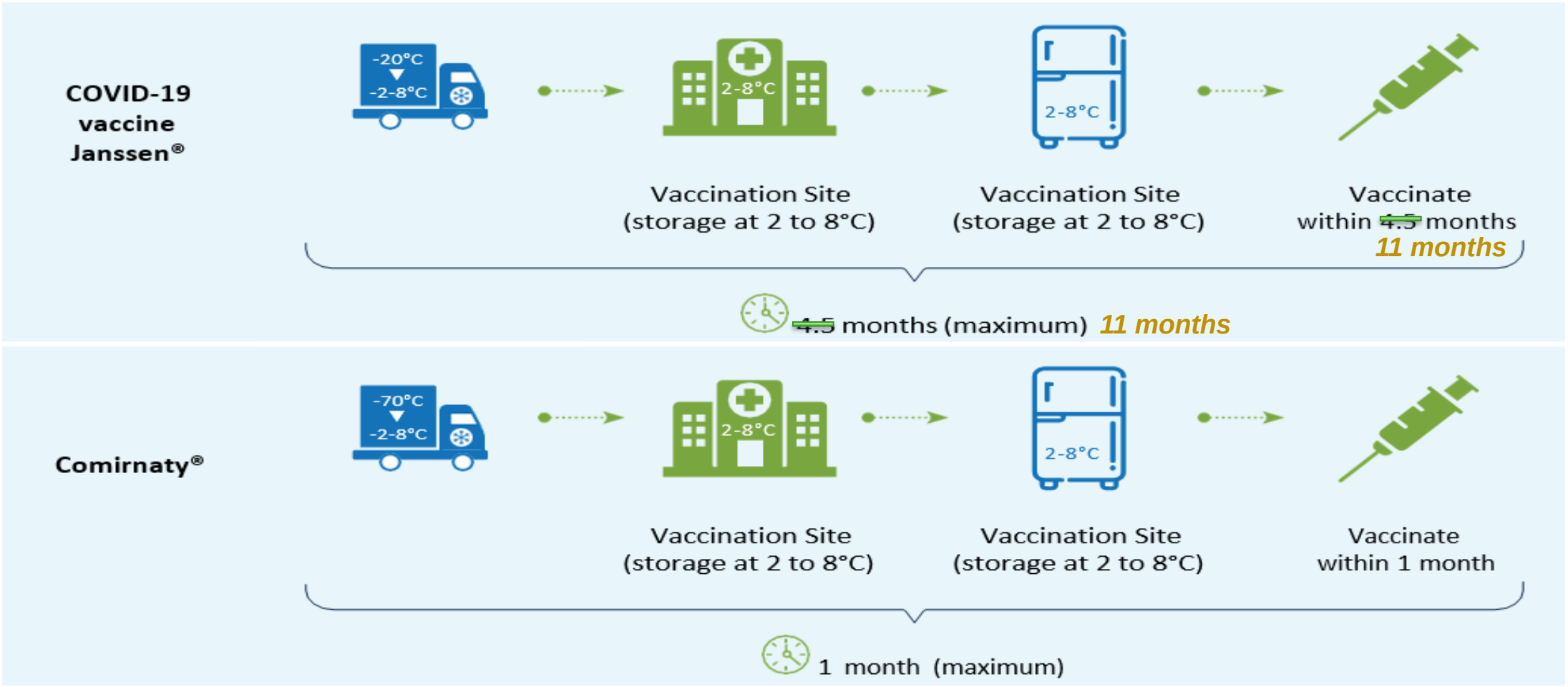
Vaccine wastage vs. missed opportunities

- Vaccination sites should minimize wastage where possible. However, any intervention to **reduce vaccine wastage should not result in lower immunisation coverage** or contribute to missed opportunities for vaccination
- The **risk of vaccine wastage should always be weighed against the benefits of vaccination**, which include a reduction in healthcare costs and maintaining high levels of vaccination coverage
- Various strategies could be implemented to reduce vaccine wastage in open vials like planning the immunisation session or scheduling vaccine recipients, however **during a period of decreased demand it is essential to open a vial for use even if the ideal number of vaccines recipients are not at the vaccination site**
- **This will ensure high levels of immunisation coverage while reducing the risk of the vaccine expiring in vaccination sites**

Primary Vaccination Site -20°C Storage - Reminder



Primary Vaccination Site 2° to 8°C Storage - Reminder



Transferring Pfizer Comirnaty Vaccine between temperature Ranges - Reminder

Storage at **-60-80°C**

Manufacturer's expiry date on the carton **A**

45 days **NOT** exceeding **A**

Expiry date **B** at **-15-25°C**

Can be stored for **14** days

Expiry date **C** at **2-8°C**

Can be stored for **31** days

Expiry date **C** at **2-8°C**

Can be stored for **31** days

31 days **NOT** exceeding **A**

The expiry date on the outer tray orthe vaccine vial must be updated when the vaccine tray or vial is moved to the next temperature range and the original expiry date must be **made unreadable**

Transferring Janssen Vaccine between temperature Ranges - Reminder

Storage at

-15-25°C

Manufacturer's expiry date on the carton A

11 months

~~4.5~~ months **NOT** exceeding A

Expiry date B at

2-8°C

Can be stored for ~~4.5~~ **months**

11 months

The expiry date on the outer tray orthe vaccine vial must be updated when the vaccine tray or vial is moved to the next temperature range and the original expiry date must be **made unreadable**

Distribution of Comirnaty® 5-11y vaccine

- 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

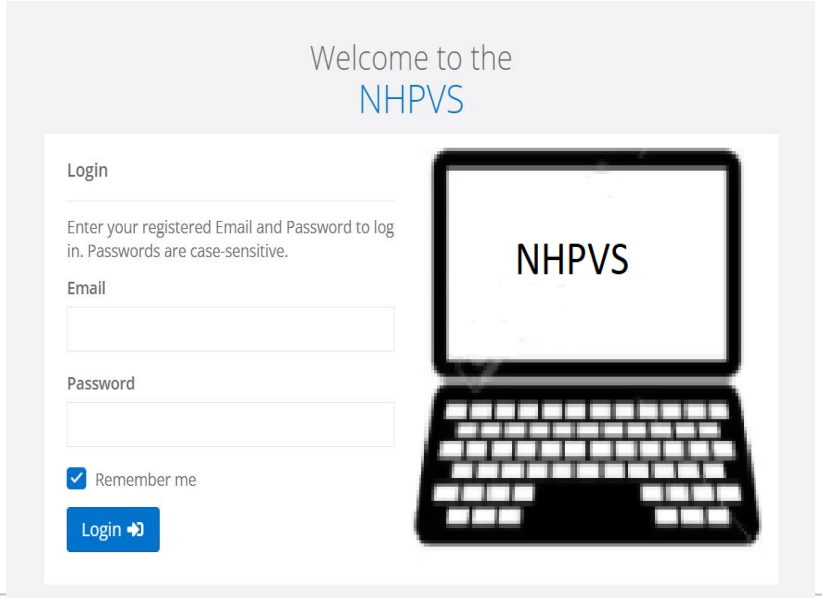
Vaccine Purchase Orders

NHPVS system is a web-based platform for placing orders for COVID-19 vaccines.
Orders weekly cut-off is Wednesdays at 22H00 for delivery the following week Tuesday to Friday
Benefits of NHPVS includes:

- It is a secure web-based platform where a full history of order submissions are maintained;
- It is a simple platform that processes orders effectively;
- It removes the need for orders to be sent via email, phone etc.

- Access the NHPVS secure website: **https://nhpvs.summx.co.za**

- Provincial Primary and Distribution site representatives Log on with email address and password that has been shared COVID-19 Vaccine Control Tower Team



Introduction: Pfizer Comirnaty® vaccine in 5-11y old population

Dr Lesley Bamford
Specialist: Child, Youth and School Health
National Department of Health

Children eligible for vaccination?

- 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

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 dyskinesiasbronchopulmonary 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

Children eligible for vaccination?

Disease state	Comment
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

Children eligible for vaccination?

Disease state	Comment
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

Children eligible for vaccination?

Disease state	Comment
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

Who should refer children for vaccination?

- Any clinician can refer a child for vaccination to a site that offers Comirnaty 5-11y old vaccination
- EVDS will not require specific details of the clinician

Service delivery model – 5-11y COVID-19 vaccination

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

- 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.
- 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.

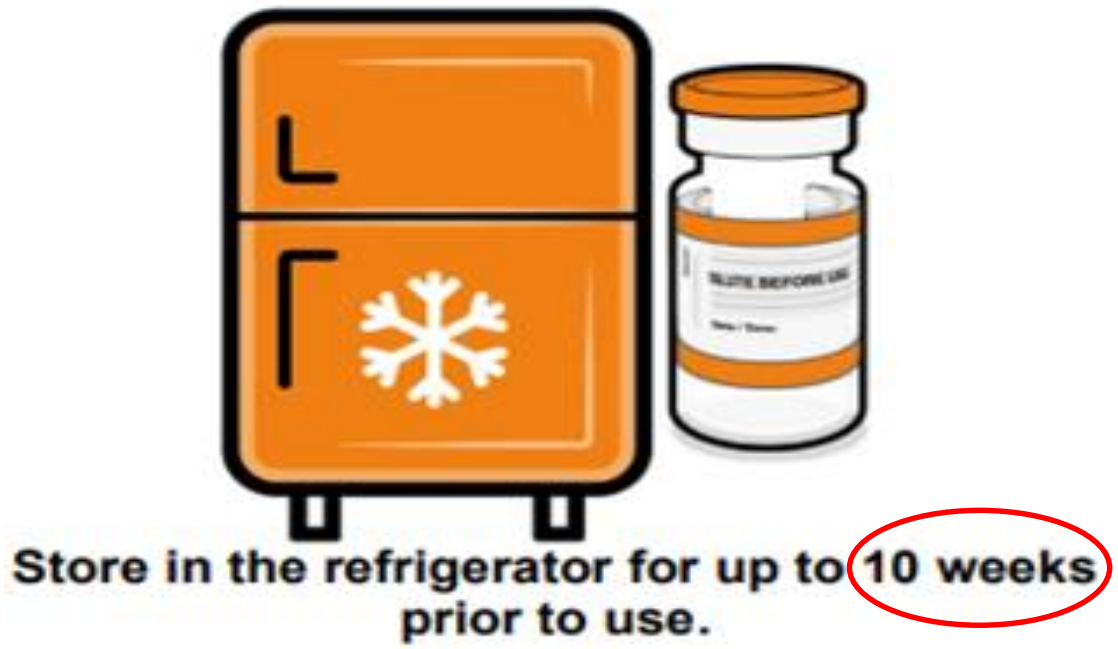
Phase IV: Expansion to Primary Health Care facilities – in most cases through outreach from exising sites

Comirnaty 5-11y vaccine presentation

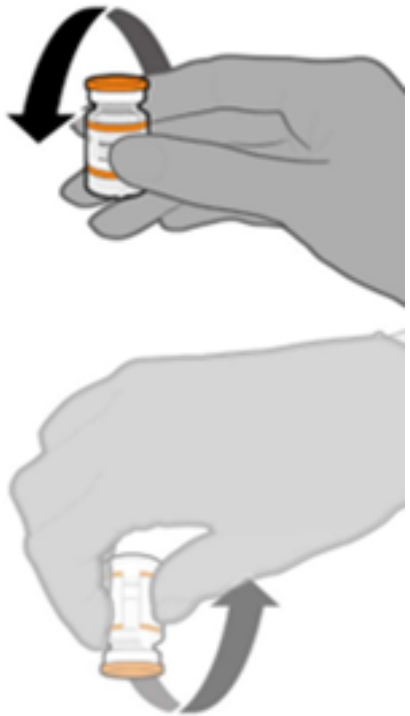
Dilution and preparation of vaccine

Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION	
	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.”

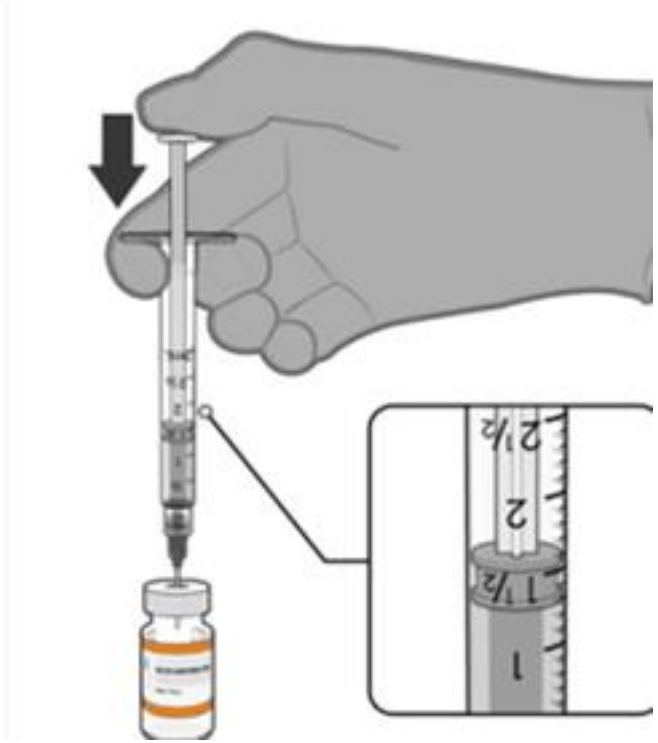
Dilution and preparation of vaccine

Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION	
	Thaw vial(s) of Comirnaty® paediatric vaccine before use either by: • Vaccines are distributed at -70ºC • 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 [2ºC to 8ºC] for up to **10 weeks**.

Dilution and preparation of vaccine

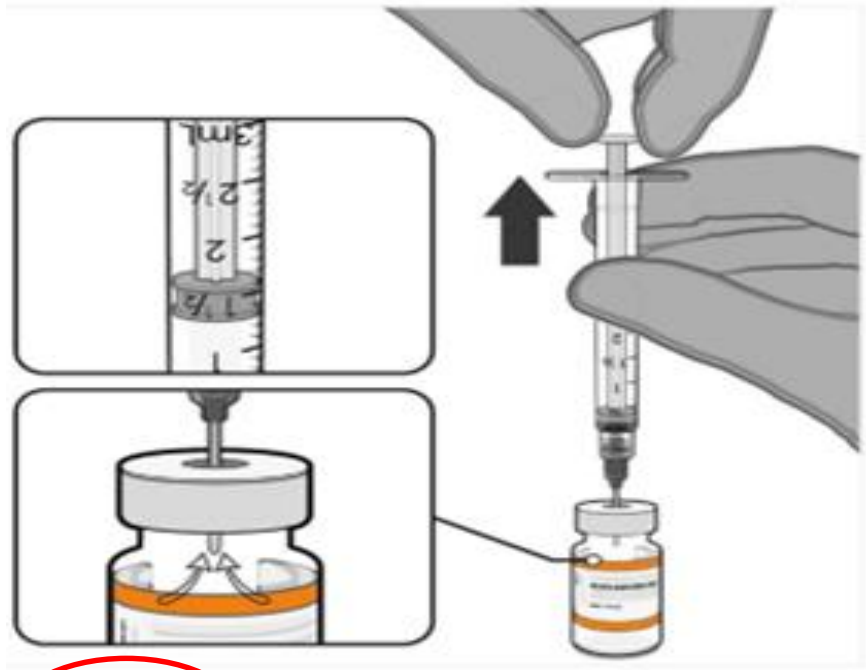
Before dilution	
	• Before dilution, mix by inverting vaccine vial gently 10 times. • Do not shake. • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.

Dilution and preparation of vaccine



- 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

Dilution and preparation of vaccine



- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe

After dilution

- 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

After dilution

Record the date and time of dilution.
Use within 12 hours after dilution.

- 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

Administration of COVID-19 Vaccines

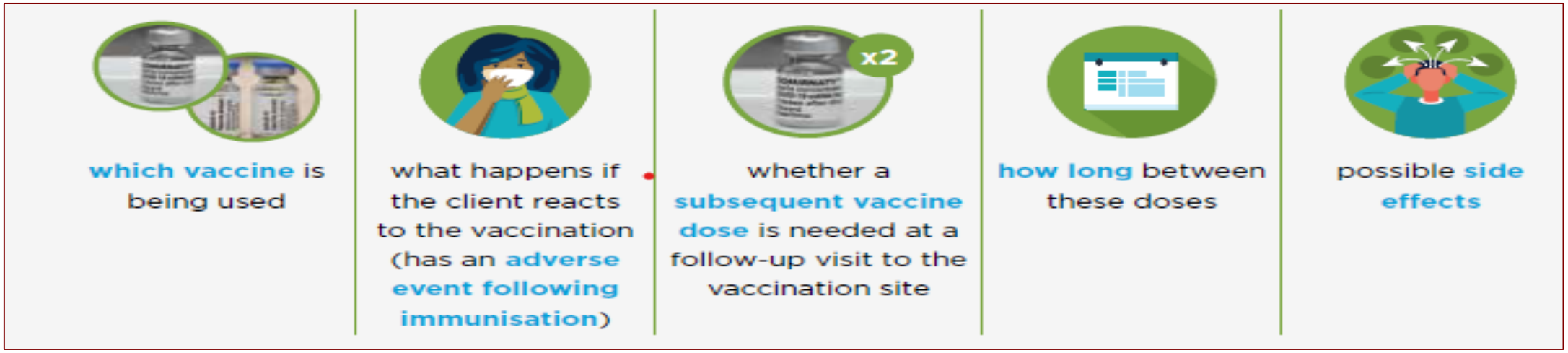
Dr Lesley Bamford
Specialist: Child, Youth and School Health
National Department of Health

Informed consent – 5-11y old Comirnaty vaccination

Obtain informed consent

- The vaccinator council the parent/guardian or care-giver accompanying the child:

No vaccine has 100% efficacy



To receive their COVID-19 vaccination, the parent/guardian or care-giver accompanying the child must sign a paper consent form that will be recorded on EVDS **digitally** or, if they agree for the child to be vaccinated

Preparation of vaccines 5-11y old Comirnaty vaccination

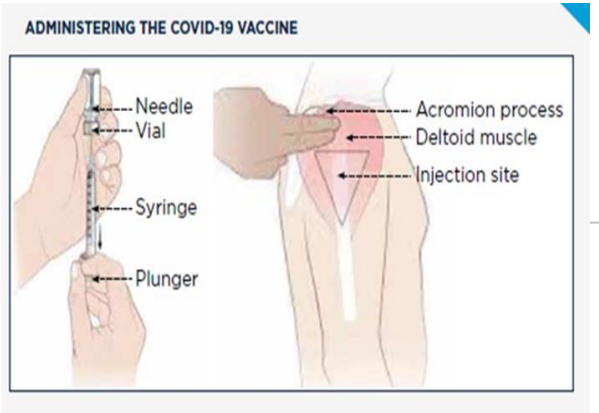
- Keep vaccine vials in a passive container, and protected from light
- Always maintain cold chain
- Prepare each vaccine according to the manufacturer's instructions
- **Do not pre-draw vaccines**
- **Do not leave the needle and syringe in a vial**
- **Do not turn clients away because they are not enough for opening a new vial**
- Open vaccine vials should be discarded after twelve hours

Vaccine administration process 5-11y old Comirnaty vaccination

- Always **disinfect hands before** starting with this procedure
- Before opening a vial, **confirm that the vaccine has not expired and that the orange vial "COMIRNATY for 5-11y olds" indicated on the vial**
- **Clean the rubber stopper** of the vial with a cotton swab moistened with clean water, before each withdrawal from the vial
- **Draw up the required dose** (see vaccine-specific instructions) using a sterile needle and syringe.
- Follow the "**one needle, one syringe, one time**" policy
- Expose the **arm completely** from shoulder to elbow

Vaccine administration process 5-11y old Comirnaty vaccination

- Identify the injection site which is 3-5cm below the acromion process
- Clean skin with cotton wool moistened with water, not an alcohol swab
- **Do not soak the cotton balls/swabs in water and leave for the day**
- **Administer 0,2ml of Pfizer Comirnaty 5-11y vaccine** into the deltoid muscle of the non-dominant arm
- Inject the vaccine by holding the syringe firmly between thumb and forefinger and inserting the needle into the densest portion of the muscle at a 90° angle
- **Do not administer COVID-19 vaccines intravenously or subcutaneously.**

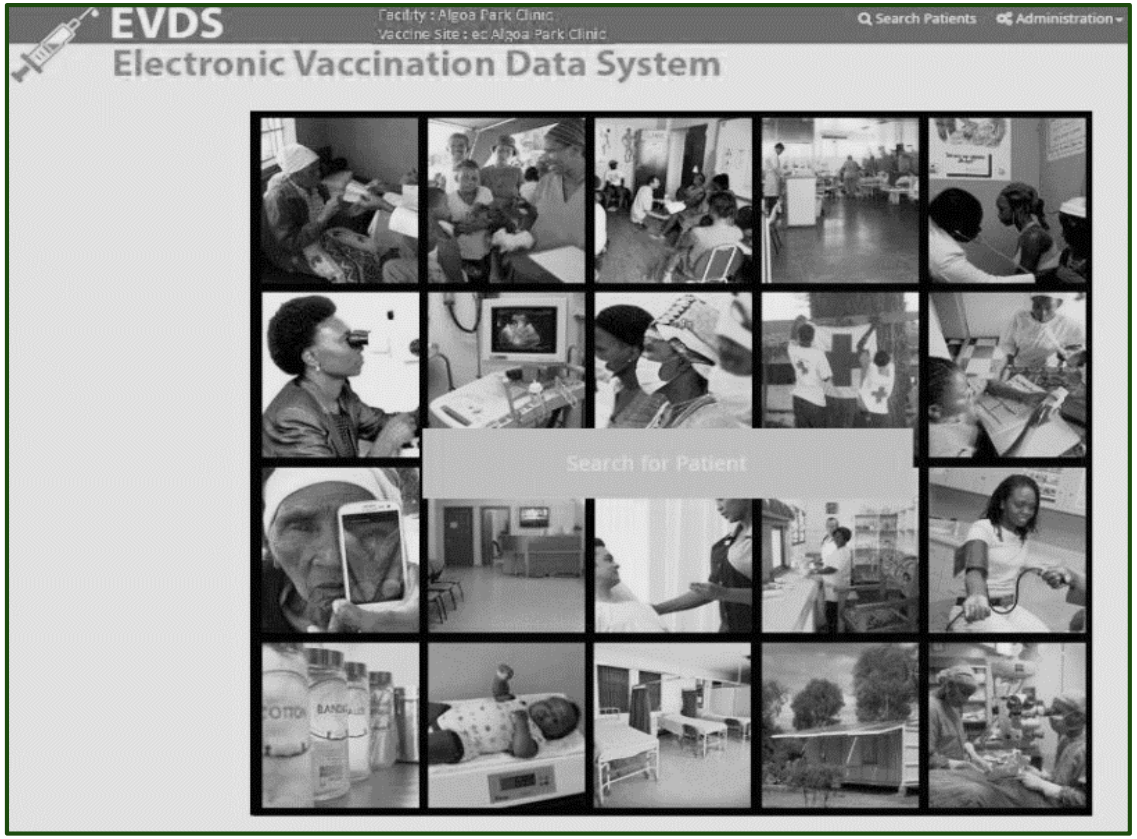


Vaccine administration process

- Inject the vaccine **slowly and remove needle quickly**
- **Apply gentle pressure** with sterile gauze or cotton ball
- **Do not rub the site** as this interferes with the absorption of the vaccine
- **Discard needle and syringe as one** (without disconnecting or re-capping) into the sharps container
- **Disinfect your hands** and make the client comfortable

Recording the vaccination on the EVDS

Ms Alka Larkan



Recording the 5-11y Comirnaty vaccination on EVDS

- COVID-19 vaccination providers must document vaccine administration on the Electronic Vaccination Data System (EVDS) at the time of administering the dose. If a paper form is used, the record must be back captured into EVDS within 24 hours.
- If a paper form is used, the record must be back captured into EVDS within 24 hours or as soon as the system is available. **Paper forms must be kept in a secure location** at the facility
- Parent/gaurdian/caregiver's consent must be recorded on a paper consent form and this must be filed with the child's health record. **Accompanying adult** in these slides refers to the parent/gaurdian/caregiver who accompanies the child

Recording the 5-11y Comirnaty vaccination on EVDS

Proof of identity source documents

- **Child**: A **birth certificate must be presented** by the accompanying adult.
- **Adult**: An **identity document must be provided** by the accompanying adult. 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.

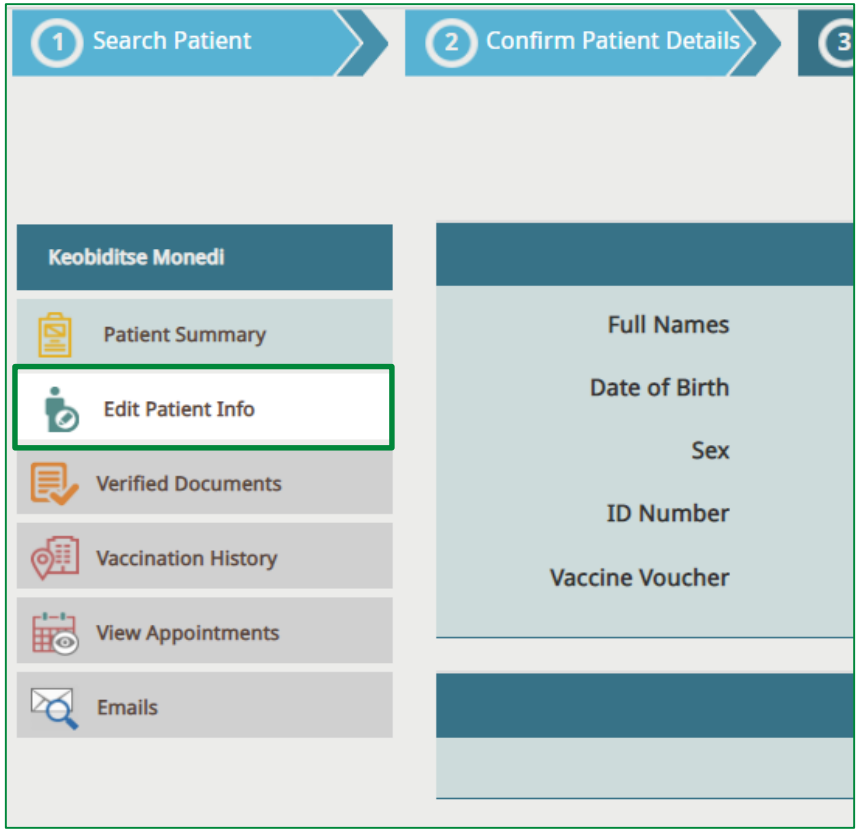
Recording the 5-11y Comirnaty vaccination on EVDS

1. Search for the Vaccinee
2. Confirm/Update Vaccinee Details
3. Verify Documents
4. Register or Back-capture a Vaccination
5. Register an Adverse Event

Recording the 5-11y Comirnaty vaccination on EVDS

Search for the Vaccinee and Confirm/Update their Details

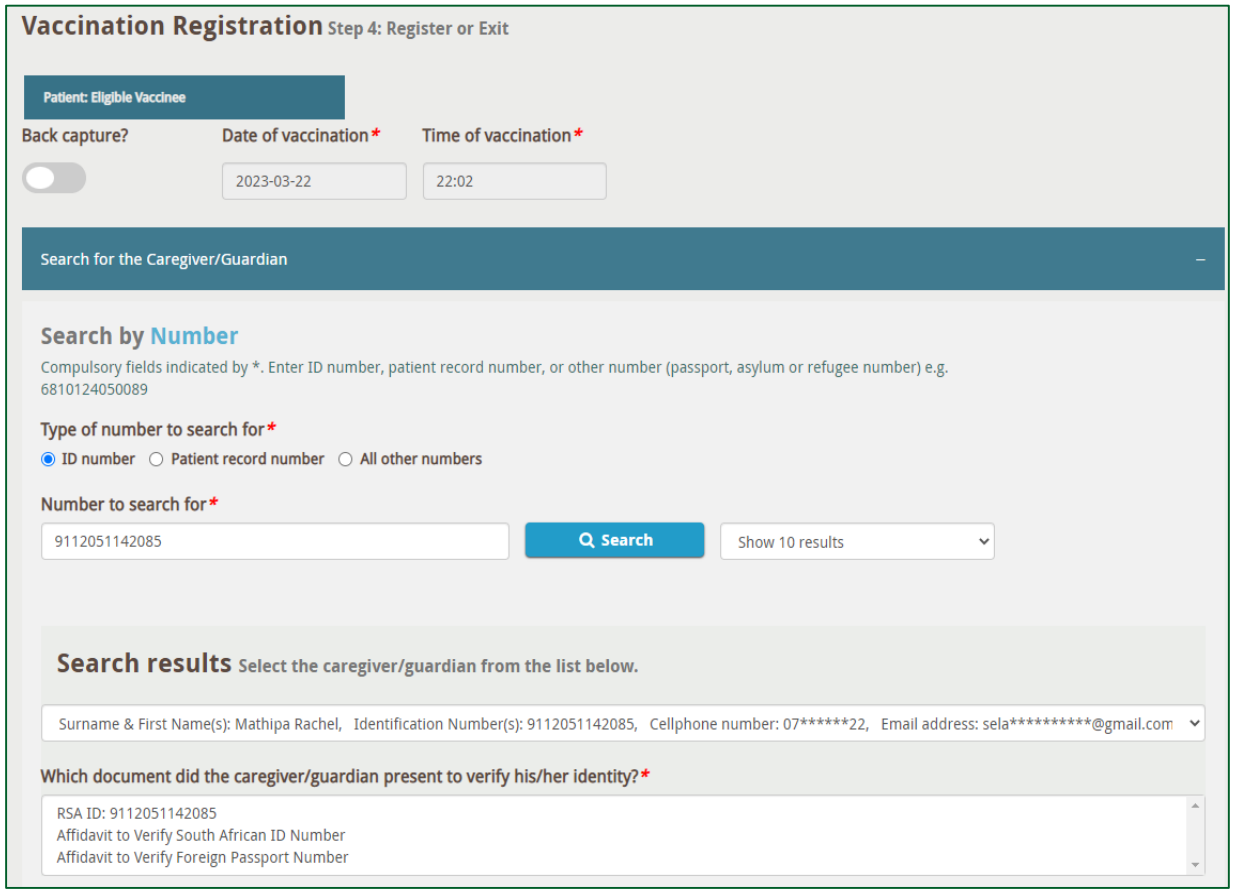
- Search for the child on the EVDS and click on the search result.
- Click on the *Edit Patient Info* button.
- Confirm the vaccinee's details.
- Edit the information if it is not correct.



Recording the 5-11y Comirnaty vaccination on EVDS

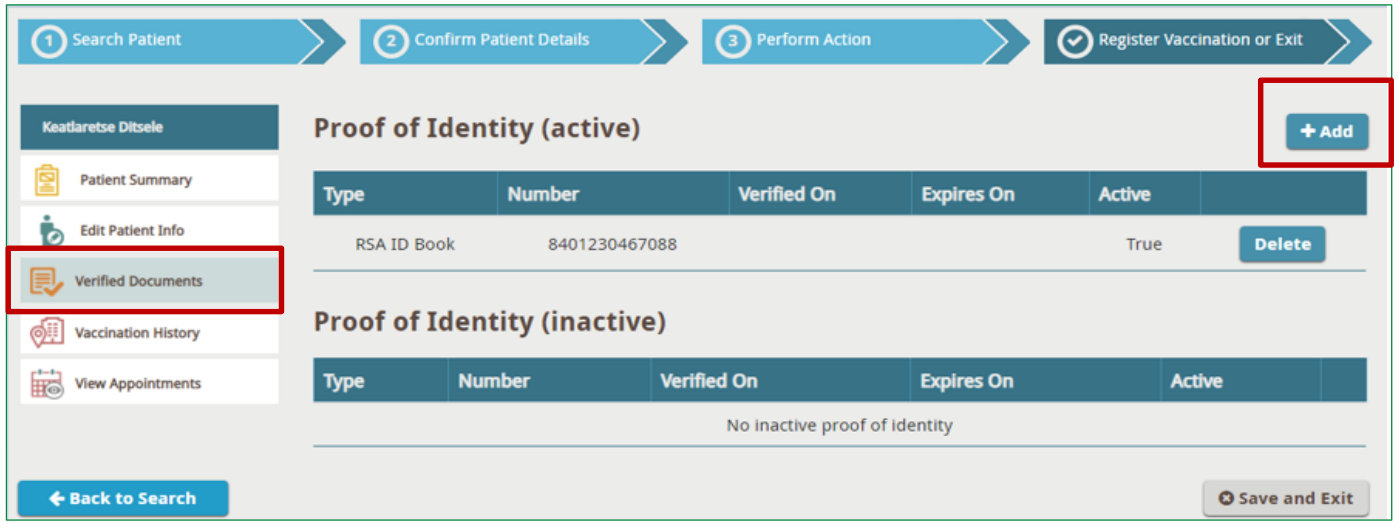
Link the accompanying adult to the child (vaccinee)

- Search for the caregiver/guardian of the child by using the identity document number presented by the accompanying adult.
- Select caregiver/guardian from the search results.
- Select the type of document presented by the accompanying adult.



Recording the 5-11y Comirnaty vaccination on EVDS

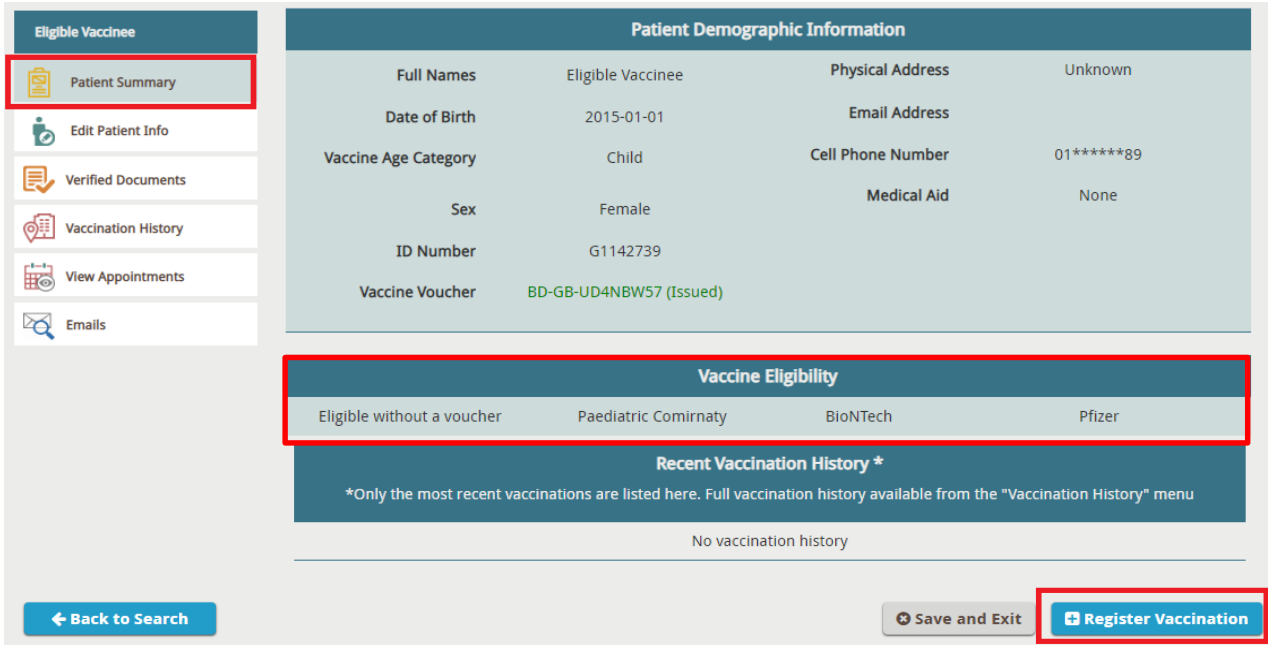
Verifying Documents



- The *Verified Documents* tab on the left side of the screen displays identification documents linked to the vaccinee's record.
- Ensure that both **the child and adults'** documents are listed here.
- Click on the *Add* button on the right of the screen to enter a new document. There can only be one identity document added at a time.

Recording the 5-11y Comirnaty vaccination on EVDS

Begin vaccination registration

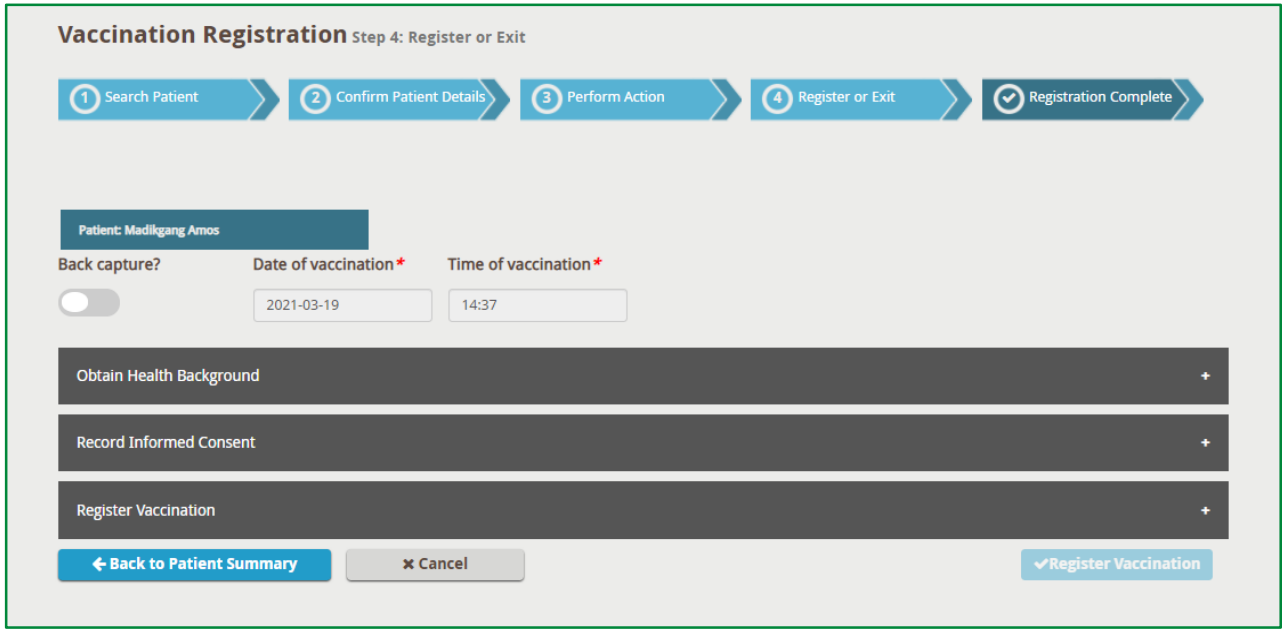


- Select the **Patient Summary** tab on the left hand side
- Confirm vaccine eligibility
- Click on the *Register Vaccination* button at the bottom
- EVDS will initiate the registration process and you will now capture the patient's health background, consent and vaccine information.

Recording the 5-11y Comirnaty vaccination on EVDS

Health Background

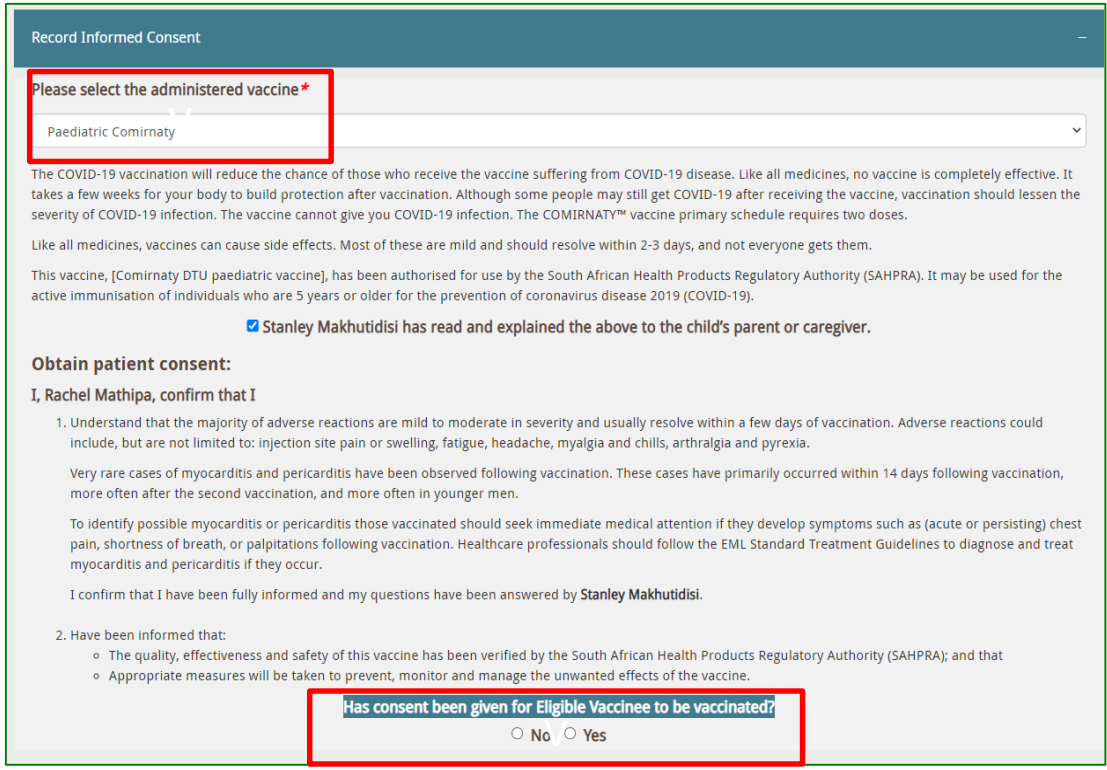
- Add the date and time of the vaccination. **This must be the date of the vaccination**
- Click on *Obtain Health Background*
- Capture the vaccinee's health background by asking and completing answers to all of the questions displayed.
- Once all of the questions have been answered, select the *Yes* checkbox to continue.



Recording the 5-11y Comirnaty vaccination on EVDS

Record consent

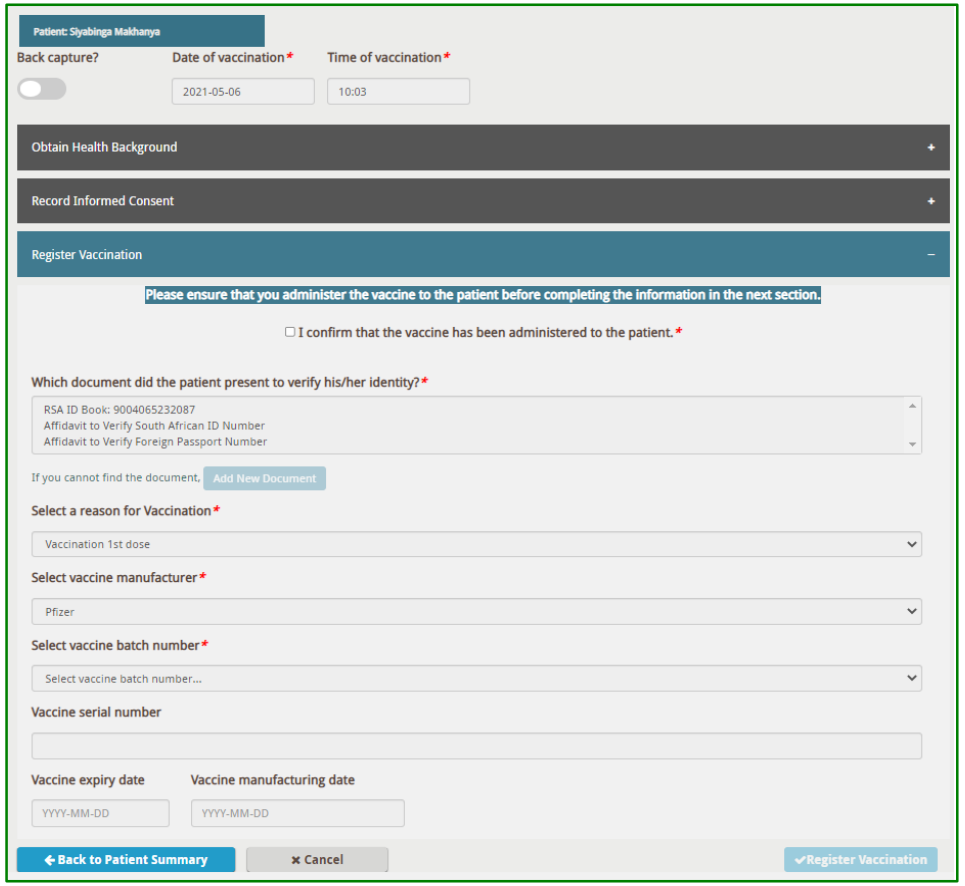
- Consent for a child under 12 is provided by the parent/guardian/caregiver
- Consent must be captured from the paper consent form
- Select the type of vaccine that will be administered to the vaccinee
- This will be listed as **Paediatric Comirnaty**
- Note that the consent is provided for the **Eligible Vaccinee**, i.e. the child



Recording the 5-11y Comirnaty vaccination on EVDS

Register the Vaccination

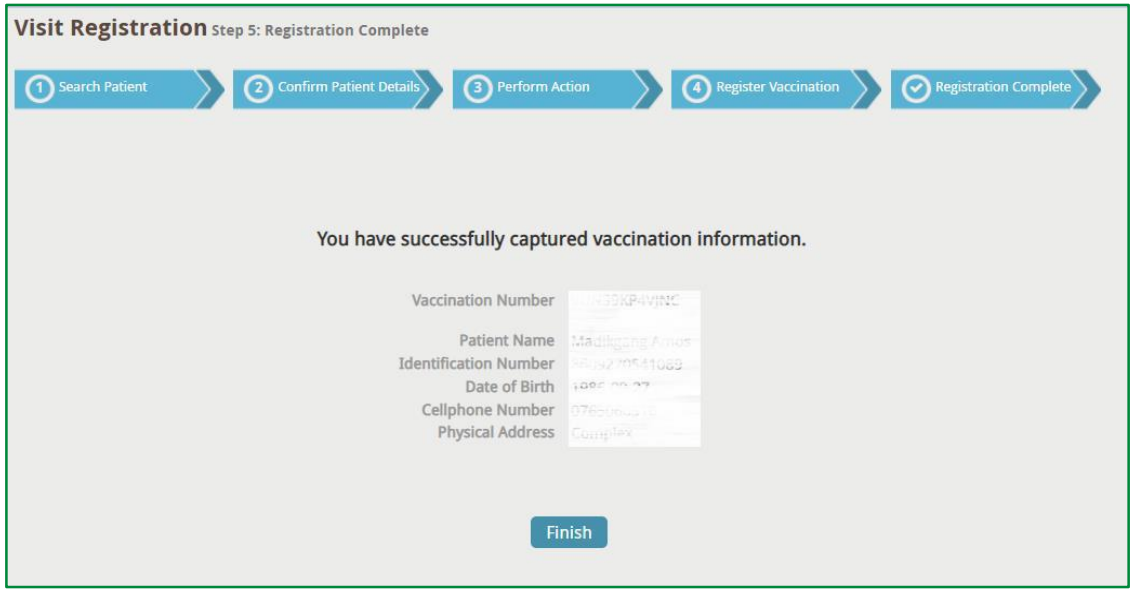
- **AFTER** you have administered the vaccine select the “I confirm that the vaccine has been administered to the vaccinee” checkbox.
- Select the type of identification document presented (this should be a birth certificate).
- Select whether this is the first vaccination or the second vaccination
- 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.



Recording the 5-11y Comirnaty vaccination on EVDS

Finish Registration

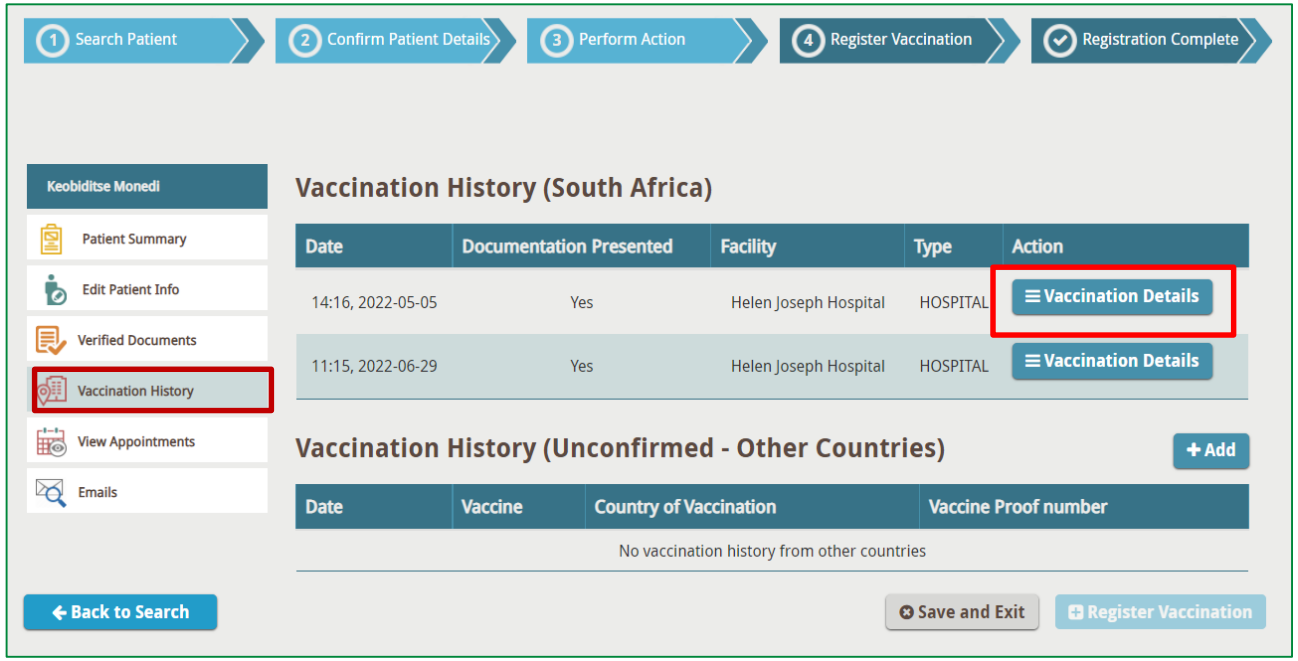
- A page is displayed with a summary of the vaccinee details as well as the unique vaccination number.
- The child or careigver should also be provided with a vaccination record card, which includes the following information: date of vaccination, product name/manufacturer, lot number, and name and location of the administering clinic and healthcare professional. The vaccinator must sign the vaccination record card.



Recording the 5-11y Comirnaty vaccination on EVDS

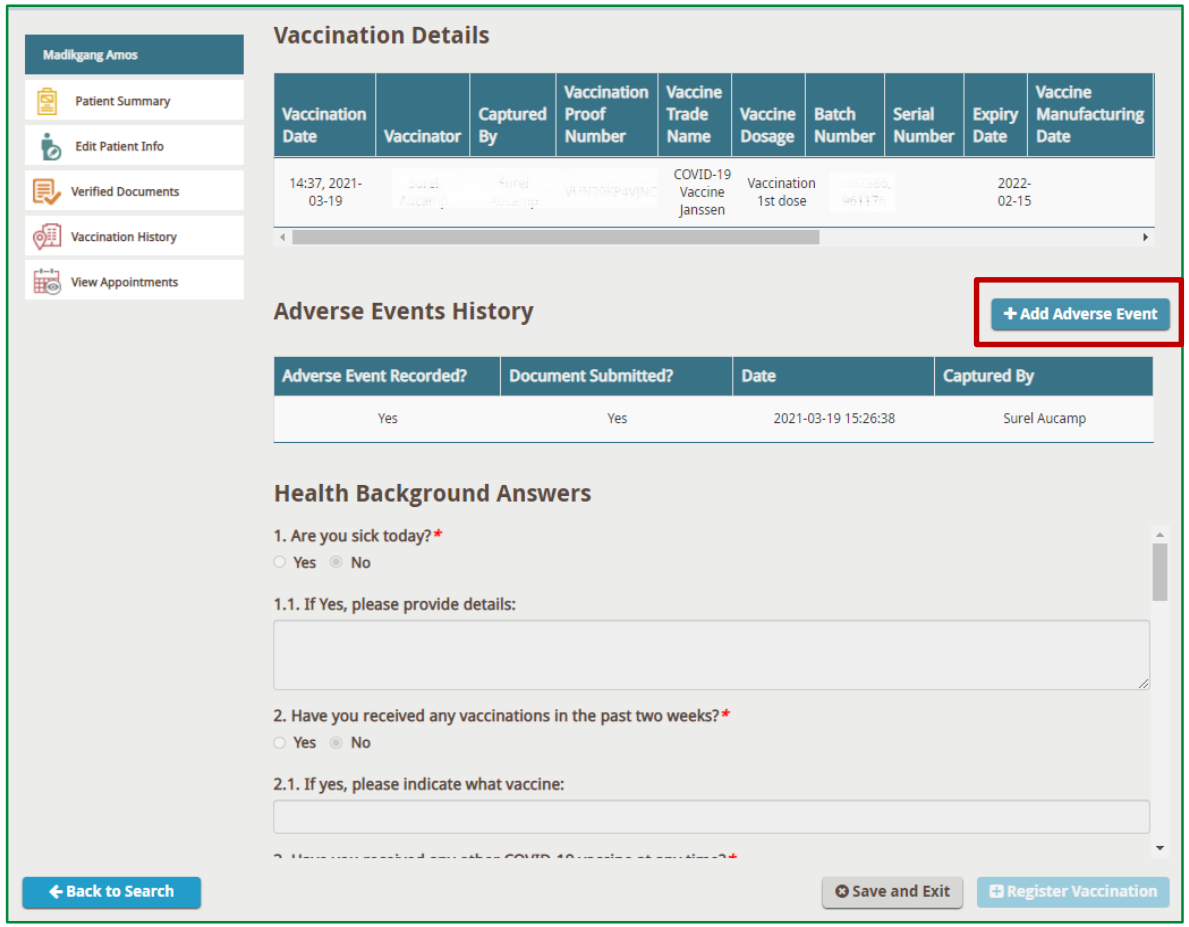
To view and update vaccination History

- This tab provides a list of all vaccinations administered
- Click on the *Vaccination Details* button if you wish to check the details for a specific vaccination
- This is also where you can add an Adverse Event Following Immunisation



Recording the 5-11y Comirnaty vaccination on EVDS

- Add an **Adverse Event Following Immunisation (AEFI)** associated with a vaccination by clicking on the *Add Adverse Events* button to the right, below the Vaccination Details
- Complete the details of the adverse event and select *Add*
- If the adverse event occurs after recording the vaccination, search for the patient and select the *Vaccination History* tab on the left, and then follow the previous step



Vaccine Safety Surveillance and COVID-19 No Fault Compensation

Ms Marione Schönfeldt
Pharmaceutical Policy Specialist

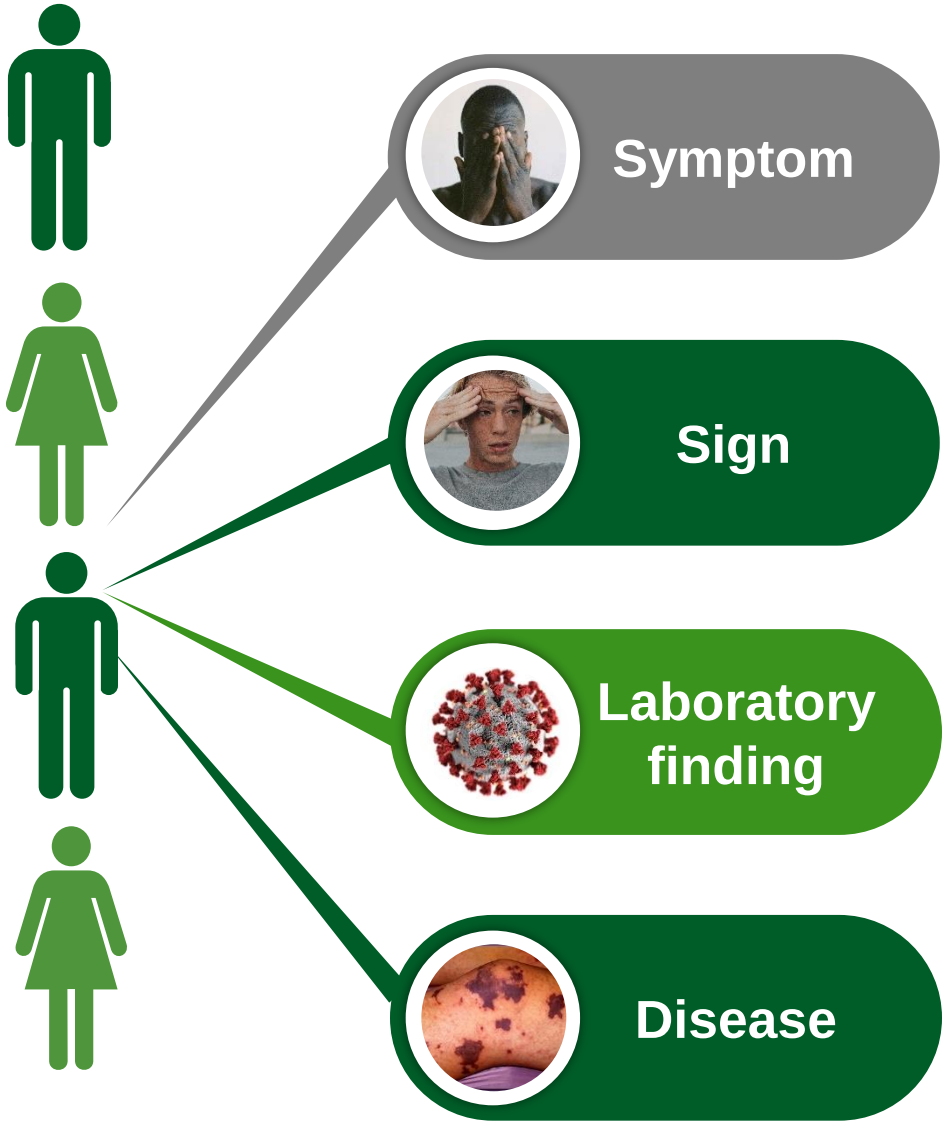
What is an adverse EVENT following immunisation (AEFI)?

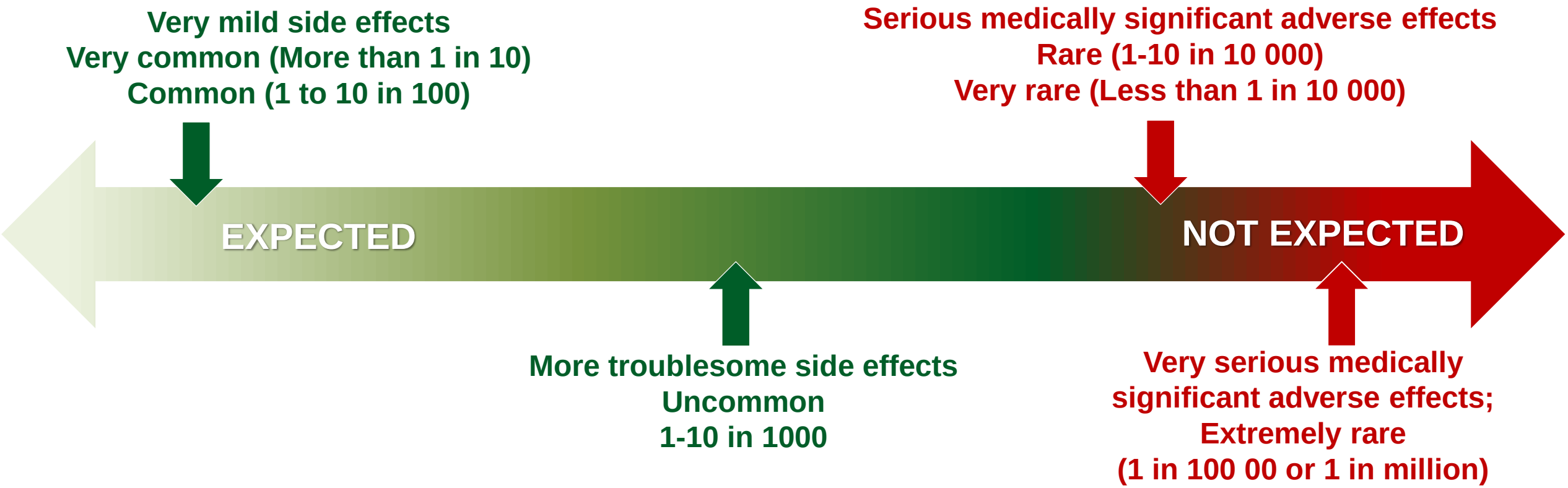
Temporal relationship

TIME

Investigate causal relationship

Some adverse events may be vaccine-related
NEED INVESTIGATION AND ASSESSMENT!!





MINOR EVENTS

- Do **not** pose a **potential risk**
- Usually occur **within a few hours** of vaccination
- **Resolve** after short period of time
- **Self-limiting**, hardly requiring treatment
- **Local** and **systemic** reactions
- Part of the **immune response**
- Other **vaccine components** can trigger reactions
- **Inform** and **assure** vaccine recipients about events

SEVERE EVENTS

Non-serious

- Usually do not result in long-term problems
- Can be disabling
- Are rarely life threatening

Serious events

- Result in death
- Require inpatient hospitalisation
- Life threatening
- Result in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically important events

Electronic reporting: Med Safety App

Med Safety App

- **Mobile** application – free download
- Available for **Android** and **iOS** devices
- **Electronic reporting** of
- Adverse drug reactions (**ADRs**) for medicines
- Adverse events following immunisation (**AEFI**)
- Can be used by both **healthcare professionals** and the **public**
  → minimise under-reporting
- Replaces the need for paper forms → strengthens **data quality**

Keep you up-to-date with information → **Drug safety news**

Can function **offline** without internet connection

http://medsafety.sahpra.org.za/

REPUBLIC OF SOUTH AFRICA

2030 NDP

SAHPRA Microsite: http://aefi-reporting.sahpra.org.za/

SAHPRA
South African Health Products Regulatory Authority

- Introduction
- Definitions
- How to report AEFIs
- Doses administered
- AEFIs reported
- Frequently reported AEFIs
- Serious AEFIs
- Causality assessment
- FAQ's
- More information

Adverse events following immunisation (AEFI) for COVID-19 vaccines

Introduction

This page provides information on reports of adverse events following immunisation (AEFIs) associated with COVID-19 vaccine administration. All medicines, including vaccines, can cause side effects. In the case of vaccines, side effects or adverse events that occur after vaccine administration are known as AEFIs. However, the benefits of COVID-19 vaccination outweighs the risks. COVID-19 vaccines have proven to prevent severe form of disease, hospitalisation and death.

An AEFI is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease. Most adverse events for COVID-19 vaccines are non-serious and mild, and resolve within the first 2-3 days after vaccination. For example, mild headache, pain and redness at the injection site, slight fever, etc. Not all suspected adverse events, whether minor or serious, are caused by the vaccine. It is possible that the timing of the suspected adverse event may be coincidental to the vaccination.

AEFIs are grouped into five categories, which are:

- Vaccine product-related reaction
- Vaccine quality defect-related reaction
- Immunisation error-related reaction
- Immunisation anxiety-related reaction
- Coincidental event

Disclaimer

It is important to note that the adverse events following immunisation (AEFIs) reported on this site have not been assessed for causality (unless specified), and therefore, the events may not necessarily have a causal relationship with the administration of the vaccines.

Close

The Sisonke Phase 3b clinical trial was a real-world study to monitor the effectiveness and safety of the COVID-19 Vaccine Janssen amongst healthcare workers. The Sisonke study commenced on 17 February 2021 and was completed 17 May 2021, after vaccinating 495 829 vaccine recipients including, 479 768 healthcare

Health facility

Med Safety App

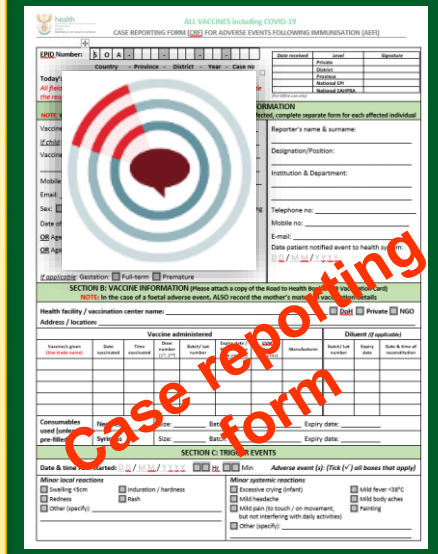
COVID-19 Hotline
0800 029 999

MILD/MINOR EVENTS

Expected

COVID-19 VACCINE SIDE EFFECTS

Self-limiting and/or can be managed



Case reporting form

SEVERE EVENTS

Not expected

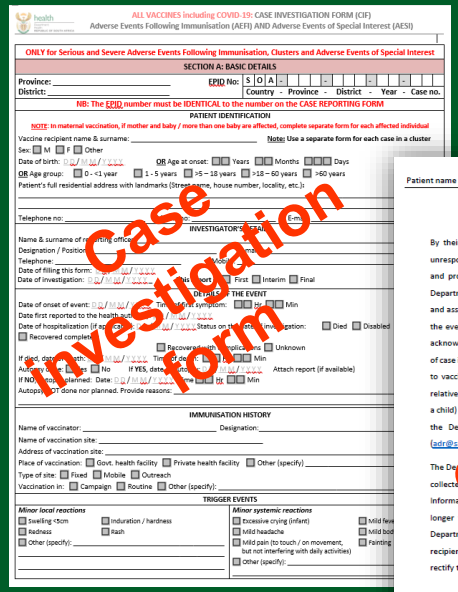
Serious events

Investigated

- Result in death
- Require inpatient hospitalisation
- Life threatening
- Result in persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Medically important event or reaction

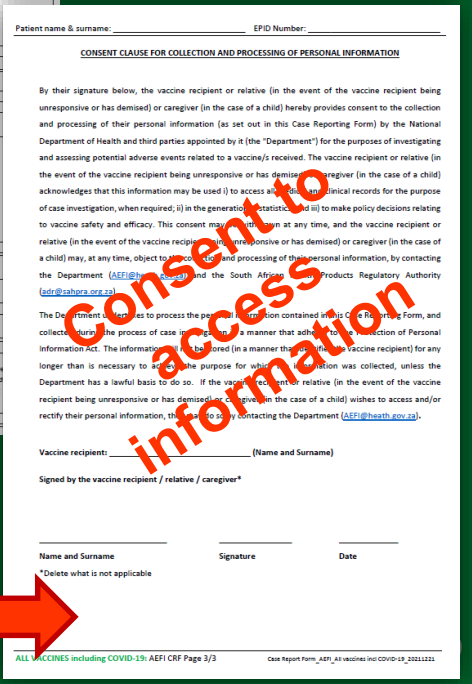
Non-serious events

- Need clinical management
- Usually do not result in long-term problems



Case investigation form

Already included in case reporting form and Med Safety App



Consent to access information

By reporting side effects and adverse events you can help provide more information on the safety of the vaccines

Prerequisites for AEFI causality assessment

1

Case investigation completed

CRF and CIF completed, with case investigation completed

2

Specific diagnosis

There must be a specific "diagnosis" (clinical sign, abnormal laboratory finding, symptom and/or disease) which is being investigated for and association with immunisation

Essential evidence:

- Personal details
- Vaccine administered
- AEFI experienced
- Dates of events
- Clinical notes
- Laboratory results
- Co-existing conditions
- Other medicines taken
- Previous allergies
- Autopsy report

3

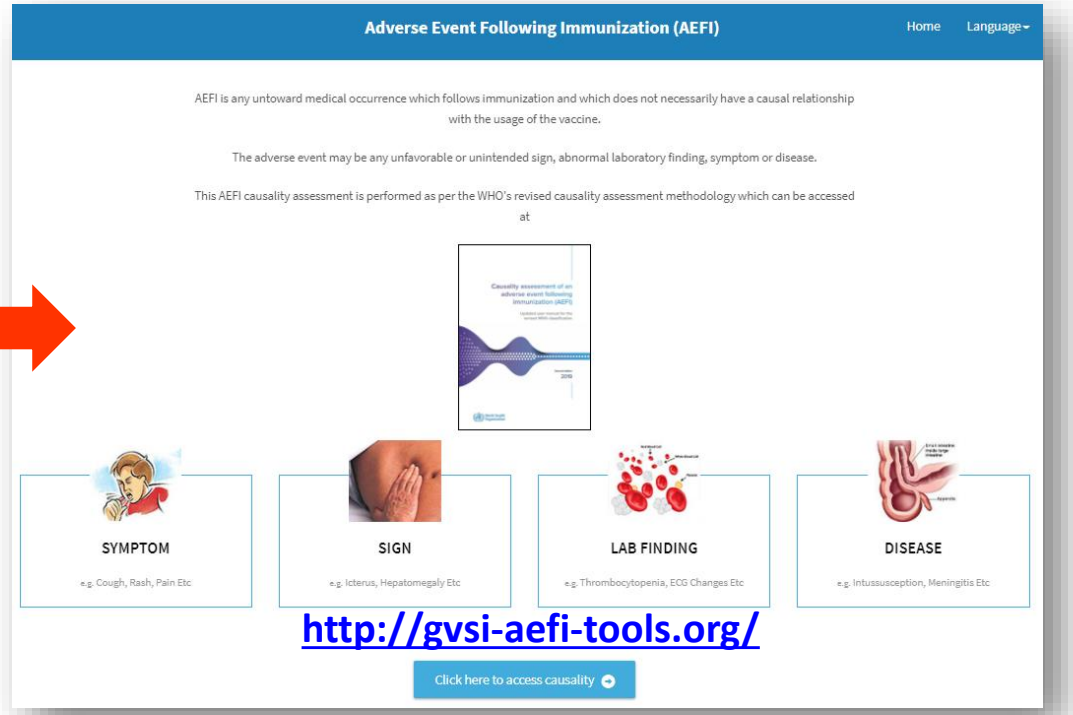
Details and evidence

All details of the case should be available at the time of assessment, including supporting documentation (clinical notes, laboratory results, autopsy report, etc.)

National Immunisation Safety Expert Committee (NISEC)

Causality assessment

- **Non-statutory, standing, ministerial-appointed, advisory** committee of **independent experts**
- **Review** and **assess** cases of adverse events reported to NDoH and SAHPRA
- Use WHO methodology for **causality assessment**
  - Determine the likelihood that the event might have
    been caused by the vaccine received
  - Classify the cases in terms of causal association
- **Monitoring** reported AEFI data for **potential signals** of previously unrecognised vaccine-related adverse events
- Provide **independent**, **scientific advice** and **recommendations** to NDoH and SAHPRA



Provincial AEFI Committees

Pre-liminary causality assessment

Systematic review of data about the AEFI case

Eligibility of the case?
Patient identifier, vaccine, valid diagnosis

Strong evidence for other causes?
Medical history, clinical examination, investigations (e.g. autopsy, laboratory, reports)

Known causal association with the vaccine?
Product-related, biological plausibility, quality defect, immunisation error, stress-related response

Did the event happen within the time window?
E.g. anaphylaxis mostly within first hour

Strong evidence against a causal association?
Published literature, Cochrane and systematic reviews

Are there any other qualifying factors?
Pre-existing conditions, past occurrence, background rates, medication, risk factors

Causality assessment classification

Consistent with causal association to immunisation

A1
Vaccine product-related reaction

Individual's response to inherent properties of vaccine, even when vaccine has been prepared, handled and administered correctly

A2
Vaccine quality defect-related reaction

Caused or precipitated by vaccine, due to one/ more quality defects of the product, including its administration device, provided by manufacturer

A3
Immunisation error-related reaction

Caused by inappropriate vaccine handling, prescribing or administration

A4
Immunisation stress-related response

Arising from anxiety about the immunisation and fear of injection e.g. fainting

Causality assessment classification

Inconsistent with causal association to the immunisation

C
Coincidental event

An event that happens after vaccination but is not caused by the vaccine or vaccination process

Event caused by something other than the vaccine product, immunisation error or immunisation anxiety

Implications for COVID-19

- **Potential comorbidities** → especially in elderly e.g. hypertension, diabetes, heart disease
- Coincidental events can occur in **healthy individuals** without comorbidities
- **Newly** acquired or diagnosed **illness**
- **Spontaneous** occurrence of an event without known risk factors
- Other **exposures** to drugs or toxins prior to event
- Surgical or other **trauma** leading to a **complications**
- Estimate **population-based background rates**
  - Pre-specified adverse events of special interest
  - Mortality per age group / disease

Causality assessment classification

Indeterminate

Potential signal and maybe considered for investigation

B1 Indeterminate

Temporal relationship is consistent but insufficient definite evidence for vaccine causing the event

Causality can change when additional information becomes available either about the same case or about similar cases

B2 Indeterminate

Conflicting trends or inconsistency with causal association to immunisation

Causality assessment classification

Unclassifiable

Ineligible for causality assessment

Amount of information available is so limited that the assessment cannot be initiated

<u>Example</u>: No vaccine name; no valid diagnosis; no identifiable vaccinee

Unclassifiable case

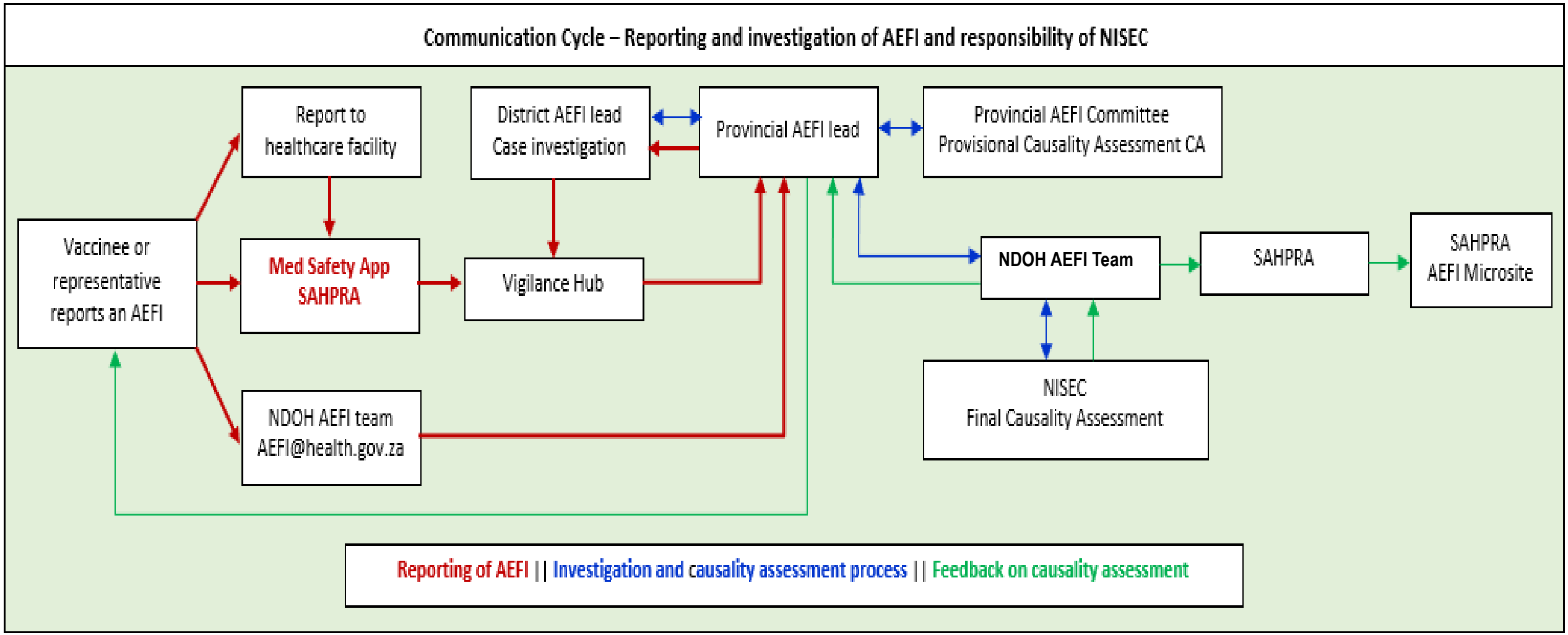
Able to initiate an assessment, but during the process, discover that some key elements are unavailable to permit a logical classification

<u>Example:</u> No laboratory results

Example: Ineligible case

- Reporter details: Unknown
- Province: Unknown
- Patient name: Private
- Date of birth: Unknown
- Age: 75 years
- Sex: Female
- Reaction onset: 14 days
- Outcome: Death

Communication cycle for AEFI



No fault Compensation Scheme

Private and Public sector

HEALTH CARE PROVIDER:

Vaccination

Data captured on the Electronic Vaccine Data System (EVDS)

a. Vaccine data

b. Provider data

Provincial / District AEFI teams

National Department of Health

National Immunisation Expert Committee –

INJURY ALLEGED

1. Notify AEFI COVID-19 process
2. Report AEFI on case reporting form / MedSafety app
3. Investigate Severe AEFI or AEFI with Serious outcomes
4. Collect all relevant medical records required
5. Analyse case at the provincial level

NISEC causality assessment

NISEC asses all severe AEFI or AEFI with serious outcome

Serious events to be compensated e.g. including

a) Death

b) Permanent physical or mental disability

c) Temporary physical or mental disability

Move to administrator

From current AEFI process

Administrator

CAUSALITY ESTABLISHED

- **Administration unit contacts patient or representative**

1. Establishes eligibility
2. Confirm personal information
3. Validate vaccination
4. Evaluate timely reporting
5. Describe injury from causality assessment

Serious events including:

a) Death
b) Permanent physical or mental disability
c) Temporary physical or mental disability

- Case manage the claim
- Contact claimant when required

Responsibility of the Scheme administrator

- Secretariat to adjudication and appeal committees
- Validate eligibility
- Check completeness of documentation
- Feedback cycle with claimant/representative
- Finalise agenda and supporting documents
- Convenes adjudication panel and appeal panel as required

Move to Adjudication process

From Administration process

Administrator

ADJUDICATION

- Adjudication panel meets
- Define injury
- Determine temporary or permanent disability using compensation table
- Recommend compensation or death benefit for family

APPROVAL OF COMPENSATION OFFERED TO VACCINE INJURED PERSON : HOD OF NDOH

Vaccine injured person
Accept the compensation
OR
Vaccine injured person reject the compensation

APPEAL

Secretariat arranges appeal
Appeal panel meets
Review decision and decide

Compensation

ADMINISTRATON

1. Feedback to claimant/representative
2. Accepted vs rejected
3. Award (Compensation table)
4. Verify claimant bank details
5. Process payment in the NODH-
6. Make payment
7. Compile summary report
8. Minutes of Adjudication/ Appeal panel
9. Periodic reports and statistics on the adjudication /appeal panel processes

Questions ?