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	Vaccination Site Procedure	Next Revision [REVISION DATE]

STANDARD OPERATING PROCEDURE – END OF DAY CLOSURE PROCEDURE AT PRIMARY VACCINATION SITES

INSTITUTION	National Department of Health		
SECTION	COVID-19 Vaccine: Vaccine Site Closure Procedure		
OBJECTIVE	<ul style="list-style-type: none"> - To ensure that vaccination sites adhere to the minimum COVID-19 vaccination site closure protocols. - To outline duties and responsibilities of the personnel at vaccination sites. 		
SCOPE	- Vaccination site closure		
COMPILED BY		ORIGINAL DATE:	
AUTHORISED BY			
DEFINITIONS	<ul style="list-style-type: none"> - Ancillary items means the medical consumables needed to administer the COVID-19 vaccine and includes syringes, needles, cotton wool balls/swabs, etc. - Defaced vial means an empty COVID-19 vaccine vial of which the label is intentionally removed or clearly marked after administration to avoid an empty vial being reintroduced into the market and re-used. - Expiry date means the date up to which a medicine will retain the strength and other properties as stated on the label. - Mobile teams mean a vaccination team operating from mobile vehicles to provide outreach services, moving from place to place to provide vaccination services. Vaccines are transported in passive containers. No overnight storage or further distribution of vaccines is allowed. - Primary distribution site means a depot, sub-depot, wholesale pharmacy, or distributor which stores and distributes vaccines to vaccination sites and does not provide vaccination services to clients - Stock card means a paper-based tool used at vaccination sites to assist in monitoring vaccine usage - Stock issued means the vial count issued out of the main storage location (cold room/ fridge) to a vaccination site for use during the day at vaccination stations, or during outreach services. - Stock level means the vial count in the main storage location (cold room/ fridge) which is recorded by close of business daily for vaccines. - Stock lost means the vial count of any wastage due to for example breakage, expiry and pilferage - Stock received means the vial count delivered to the vaccination and/or distribution sites since the last daily update. - Stock Visibility System means a mobile application (SVS App) linked to a web management portal (SVS Web) used to monitor availability of medicines, vaccines and other health commodities. - Main storage location means the area in a vaccination site where bulk stock (vaccines, ancillary items, and medical equipment) is securely stored - Temporary outreach service: A place where vaccination services are provided on a temporary basis and linked to a primary vaccination site. Passive cold-chain containers are used, and vaccines are not stored on-site - Vaccination session means a period of time arranged for vaccinating vaccinees with the COVID-19 vaccine. 		

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	<ul style="list-style-type: none"> - Vaccination site means a health establishment or other site which is authorised to provide COVID-19 vaccination services to vaccinees.
ABBREVIATIONS	<ul style="list-style-type: none"> - EMS: Emergency Medical Services - EVDS: Electronic Vaccination Data System - IPC: Infection Prevention and Control - NDOH: National Department of Health - SAD: Supply, Allocation and Distribution - SVS: Stock Visibility System
POLICIES, REFERENCES, SOURCE MATERIAL	<ul style="list-style-type: none"> - Cold chain and Immunisation Operations Manual of 2015 - Drug Supply Management Policy/ Prescript (As applicable) - Pharmacy Act, 1974 (Act 53 of 1974) - Medicines and Related Substances Act, 1965 (Act 101 of 1965) - Good Pharmacy Practice rules published in terms of the Pharmacy Act, 1974 (Act 53 of 1974) - Provincial Nursing Act 33 of 2005 - Health Professions Act 56 of 1974 - National Health Act 61 of 2003 - National Environmental Management: Waste Act, 2008n (Act 59 of 2008) - National Environmental Management Act, 1998 (Act 107 of 1998) - Hazardous Substances Act, 1973 (Act 15 of 1973) - Standard Treatment Guidelines and Essential Medicines List for South Africa Primary Healthcare Level 2020 Edition
RELATED SOPs	<ul style="list-style-type: none"> - Vaccination process at vaccination site - Infection Control and Prevention - Cold chain management - Wastage management - SVS COVID-19 Training Guide
PRINCIPLES	<ul style="list-style-type: none"> - Closing the vaccination site is an integral part of holding a vaccination session and should be done properly. When closing the session any unused open COVID-19 vaccine vials must be dealt with according to the SOP for that specific vaccine. - To ensure ease of reporting and data standardisation, distribution and vaccination sites that are used during the COVID-19 vaccine roll out, and where vaccines are stored, are required to report their stock levels for the vaccines and related commodities through SVS. - The use of SVS by vaccination sites enable rapid remote access to the relevant planning data needed to monitor the availability of COVID-19 Vaccines and ancillary items, and support informed decision making and planning activities relating to the allocation and distribution of vaccines. - Through data provided by SVS, EVDS and other systems, planners will be able to ensure access to the correct quantities of vaccines for all eligible vaccine recipients at their chosen vaccination site. - The SVS application on the mobile device is enabled for data capturing offline/without network. If the mobile network signal is poor, stock updates can still be recorded on the device and then uploaded later when the signal is restored or the device is moved to an area with better signal. - Vaccination sites without mobile devices can also to download, install and self-enroll the desktop version of the SVS application to report using any windows computer with internet connectivity.

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	<ul style="list-style-type: none"> - For stock monitoring and planning purposes, only electronic stock updates on SVS or reporting via inbound API (at applicable sites) are allowed to enable rapid remote access of data. - Stock updates for vaccines must be done daily at the close of business every day. This includes current stock levels, stock expiry date, stock received, stock lost, stock issued, and stock transferred updates. - Stock updates for diluent and ancillary items must be done weekly by Friday, close of business. Private sector sites are not expected to report on ancillary items. - A site that is required to report on its stockholding will be deemed non-compliant to reporting if less than 100% of the Minimum Basket items assigned to the site formulary are reported on. - At any time, the balance on the stock card/SVS should reflect the quantity physically in stock. - Where non-reporting is due to technical challenges with the electronic equipment used or connectivity issues, the designated SVS COVID-19 champions must be informed. - Replenishment quantities allocated to each site will be determined by the NDOH based on the demand indicated on the EVDS system and informed by the vaccine stock available at the site. - Stock which is issued out on the SVS app during operating hours but is not used and is returned to the storage room (cold room/ fridge) must be captured as stock received back into storage at the end of the day to ensure it is included in the daily closing stock balance. - Where applicable, place doses for the next day in the fridge at the end of the vaccination session to thaw overnight. - Adhere to cold chain requirements during the return of unopened vaccine vials which remained unused at the end of the vaccination session. - An emergency trolley must be available and should include all emergency item medicines outlined in the Standard Treatment Guidelines. This emergency trolley must be checked twice daily by medical staff, of which once is at the end of the vaccination session. - Cleaning of the vaccination site should be performed frequently, at least twice daily with special attention to high touch surfaces. - The vaccination site managers should ensure that sufficient IPC items, vaccine administration equipment and consumables, and emergency tray equipment and consumables are available, and that COVID-19 vaccination protocols are observed at all times.
FUNCTIONAL ROLES AND RESPONSIBILITIES	<ul style="list-style-type: none"> - Site staff - Vaccine stock controller - Medical staff/ EMS
TOOLS/ MATERIALS/ EQUIPMENT	<ul style="list-style-type: none"> - SVS Android mobile device with SIM, OR - Windows computer with internet connectivity - Basic anaphylactic kit items - Medical equipment - Cleaning equipment/items
SAFETY WARNINGS	<ul style="list-style-type: none"> - N/A
MONITORING AND EVALUATION	
RECORD KEEPING	<ul style="list-style-type: none"> - <i>COVID-19 vaccine records shall be kept by the COVID-19 Vaccine Unit for a period of 5 years (e.g.)</i>

1.1. PROCEDURE:

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No	PROCEDURE	RESPONSIBLE
This Standard Operating Procedure (SOP) consists of the following sections: <ol style="list-style-type: none"> 1. Vaccine, diluent and ancillary stock levels update on SVS 2. Return of unopened vials by temporary outreach services and mobile teams to primary vaccination site 3. Disposal of partially used open vials 4. Replenishment of emergency trolley 5. Cleaning of vaccination site 6. Secure locking of vaccination site 		
1.	Vaccine, diluent and ancillary stock levels update on SVS	
1.1	Capture stock levels, expiry dates, stock received, stock lost, stock issued, and stock transferred for all vaccines on the SVS device daily at the end of the vaccination session using the SVS COVID-19 application. *NOTE: Stock updates for diluent and ancillary items must be done weekly by Friday, close of business. (Refer to the SVS COVID-19 Training Guide)	Vaccine champion
1.2	Capture additional fields required: <ul style="list-style-type: none"> - Stock received, - Stock lost, - Stock issued, and - Stock transferred. 	Vaccine champion
1.3	Review and monitor stock updates.	Vaccine champion SVS district and provincial champions, HOPS and vaccine roll-out coordinators.
1.4	Analyse and reconcile stock updates with vaccine usage.	Vaccine champion SAD Team at AMD, SVS champions, HOPS and vaccine roll-out coordinators.
2.	Return of unopened vials by temporary outreach services and mobile teams to primary vaccination site	
2.1	Open the cooler box and check the continuous temperature monitoring device for excursions below 2°C or above 8°C. If temperature excursion detected, follow temperature excursion procedure. If no temperature excursions detected return the vaccine to 2-8°C storage.	Vaccine champion
2.2	Count the unopened vaccine vials and write down the number on the tally sheet	Vaccine champion

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2.3	Calculate on the tally sheet the number of COVID-19 vaccines administered, number of vials received, opened, discarded, and returned, and submit the tally sheet to the first level supervisor.	Vaccine champion
2.4	Return unopened vials, vaccine carrier and coolant packs to the primary vaccination site/distribution point according to cold chain procedures. N.B.: Stock which is returned to the storage room (cold room/ fridge) at the primary vaccination/ distribution site must be captured as stock received back on the SVS app IF it was captured as issued out during operating hours on the SVS app.	Vaccine champion
2.5	Ensure that the required documents are completed to allow for correct reconciliation of vaccines transferred between temporary outreach services or mobile teams and primary sites. <i>(Refer to Annexure 1: Transferred vaccines reconciliation sheet)</i>	Vaccine champion
3.	Disposal of partially used open vials	
3.1	Check for opened vials with remaining doses. Check temperature records and dispose vial if 6 hours since reconstitution of the vaccine would have lapsed before it being administered.	Vaccine champion
3.2	Use a permanent black marker to deface the label on the empty vial, and empty vial packaging where applicable, before discarding. Alternatively remove the label of the empty vial, tear it in two and discard the label appropriately.	Vaccine champion
3.3	Safely dispose of the defaced vial in the designated disposal container or safety box, in accordance with regulation requirements.	Vaccine champion
3.4	Confirm disposal of vaccine: <ol style="list-style-type: none"> 1. Verbally to designated vaccine controller 2. Send email confirming disposal of vaccine to the designated vaccine controller. 	Vaccine champion
3.5	Capture quantity of disposed COVID-19 vaccine vials on SVS/ stock cards as stock issued.	Designated vaccine controller
3.6	Complete the of Waste Disposal Form. <i>(Refer to SOP: Waste Disposal of COVID-19 Vaccines)</i>	Designated vaccine controller
4.	Replenishment of emergency trolley	
	<i>The process below should be done twice daily, of which once is at the end of the vaccination session.</i>	
4.1	Check if the equipment and ancillary items listed on the Checklist for Emergency Trolley <i>(Refer to Annexure 2)</i> is available on the emergency trolley.	Designated HCP
4.2	Replenish the used equipment and ancillary items on the emergency trolley with stock from the vaccination site's main storage location before the commencement of the next vaccination session.	Designated HCP

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4.3	Check if the medication on the Checklist for Emergency Trolley (<i>Refer to Annexure 1</i>) is available. Also check the expiry dates of medication.	Designated HCP
4.4	Replenish the used and expired medication on the emergency trolley with medication from the store room.	Designated HCP
4.5	Pack medication according to FIFO/FEFO to ensure minimal wastage due to expired stock.	Designated HCP
4.6	Note medication which is close to expiry date on the <i>Medication Close to Expiry Sheet</i> .	Designated HCP
5.	Cleaning of the vaccination site	
5.1	Ensure the vaccination site has been cleaned and disinfected by cleaning staff according to National IPC requirements <i>(Refer to Annexure 3:-Daily Procedure Checklist):</i>	Vaccination site manager/ Cleaning Supervisor
5.1.1	Vaccination site is clean, and all surfaces are disinfected,	
5.1.2	Floors are cleaned and disinfected,	
5.1.3	Ablution facilities are cleaned.	
5.1.4	Hand sanitizer is available at each station for the next day's vaccination session.	
6.	Secure locking of the vaccination site	
6.1	Ensure the vaccination site has been securely closed and locked according to the prescribed security requirements (<i>Refer to SOP xx</i>).	Vaccination site manager/ Security Supervisor

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ANNEXURES	1. Drug Accountability Log List 2. Checklist for Emergency Trolley
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2. REVISION DATA

Revision No	Pages	Revision Details	Date	Approved

TRAINING REQUIRED

- Training to be conducted post SOP sign-off and prior to the effective date as per above
- Training to be administered to relevant responsible parties after each SOP revision

Trainees	Type of training

3. SOP AUTHORISED

	Name	Signature	Date
Compiled by			
Checked by			
Approved by			

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Annexure 1: Drug Accountability Log Sheet

Please insert

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Annexure 2: Checklist for Emergency Trolley

ELEMENT 148- Checklist for emergency trolley

Use the checklist below to check whether the emergency trolley is sufficiently stocked.

Scoring - In column for Score mark as follows:

Check if the equipment and medication is available. Also **check expiry date of medication. If medication are expired mark as 'N'**

Y (Yes) = available/functional; N (No) = not available/functional;

Item	Score
Laryngoscope set with adult blades	
Laryngoscope set with paediatric blades	
Spare bulbs for Laryngoscope	
Spare batteries for Laryngoscope	
Tracheal tubes - uncuffed (sizes 2.5 – 5.5mm) (minimum of 3 applicable sizes)	
Tracheal tubes - cuffed (sizes 3.0 - 8.5mm) (minimum of 3 applicable sizes)	
Penlight torch with spare batteries	
Water-soluble lubricant / lubricating jelly	
10 ml syringe	
Tape or equivalent to tie tube in place	
Tuning fork	
Patellar hammer	
Oropharyngeal airways	
Introducers for ET tubes or gum elastic bougie with adult stylets	
Introducers for ET tubes or gum elastic bougie with paediatric stylets	
Magill's forceps for adults	
Magill's forceps for paediatric	
Laryngeal masks – size 1 to 5	
Bag valve ventilation devices with oxygen reservoir & adult, paediatric & neonatal masks	
Oxygen delivery devices - partial rebreather masks, nebulizer masks, nasal prongs and T-piece	
Automatic External Defibrillator (AED)	
Cardiac arrest board	
I.V. cannulae: 14-24G and appropriate strapping	
Syringes:1-50ml	
Needles: 14-24G	
Sharps container	
I.V administration sets	
Stethoscope	
Pulse oximeter with adult & paediatric probes	
Non invasive electronic blood pressure monitoring device including paediatric & large adult cuff sizes	
Clinical thermometer	
Blood glucose testing machine, strips and spare batteries	

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Collection tubes for investigations	
Diagnostic Set and batteries including ophthalmic pieces(wall mounted or portable)	
Heavy duty scissors to cut clothing	
Paediatric Broselow tape	
Consumables for wound care (Gauze, bandages, cotton wools, plasters, eye patches, alcohol swabs and antiseptic solutions)	
Suture material - May be in vicinity or another cupboard (must be accessible)	
Urinary catheters and bags	
Nasogastric tubes and bags	
Medication stickers	
Emergency medicines (also check expiry dates)	
Activated Charcoal	
Angised 0.5 mg tabs or sublingual TNT	
Adrenaline	
Antihistamine	
Aspirin	
Atropine	
Beta stimulant nebulisation (eg salbutamol) and inhaler with spacer	
Calcium gluconate	
Anxiolytics	
Dextrose 50% IV	
Furosemide IV	
Hydrocortisone	
Insulin – short acting	
Ipratropium nebulisation and inhaler with spacer	
Lignocaine IV vials only not ampoules	
Magnesium Sulphate 50% 1 g in 2 ml amp	
Amlodipine	
Morphine - to be kept in locked scheduled meds cupboard	
Naloxone	
Thiamine	
Water for Injection	
IV Solutions	
0.9% NaCl	
10% Dextrose	
Appropriate paediatric solutions (e.g. half dextrose, Darrows, neonatalyte)	
Score	71
Percentage (Score/71)*100	%

Score calculation:

Y = 1; N = 0

Percentage obtained	Score
100%	Green
40-99%	Amber
<40%	Red

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Annexure 3: Site Checklist

Category	Specific item	Morning	Evening
Site Layout (as per initial layout)	Tables – Social distance applicable		
	Chairs – Social distance applicable		
	Clear way finding signage		
Site prep	Working hours of vaccination site displayed		
	Vaccination stations numbered / or direction available		
	All staff are wearing uniforms		
	All staff are wearing name tags		
	All staff allocated PPE		
Cleaning as per National IPC Manual	Vaccination site is clean, all surfaces disinfected		
	Floors cleaned and disinfected		
	Ablution facilities cleaned		
	Hand sanitizer available – at each station		
COVID-19 screening	COVID-19 screening register available		
	Clinical thermometer available for screening		
Administration	Appointment register updated		
IT system	Computers available at each vaccinator, switched on and functional		
	Computers available at each admin, switched on and functional		
	Vaccinator to login on their own account (EVDS)		
	Vaccinator to login out of their own account (EVDS)		
	Admin to login on their own account (EVDS)		
	Admin to login out of their own account (EVDS)		
	Device to record on the Stock Visibility System (SVS)		
	Update SVS		
Vaccine Cold chain compliance	Vaccine monitor identified to ensure integrity of the vaccine		
	Vaccine fridge has power, is switched on, and functional		
	Continuous temperature monitoring device available		
	Ample storage in fridge for vaccines		
	Temperature recorded twice daily		
	If temperature below 2°C and above 8°C, facility manager /responsible site pharmacist notified		
	Thaw vaccine if required (J&J and Pfizer if applicable)		

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Category	Specific item	Morning	Evening
Emergency trolley	Check Emergency trolley as per Ideal clinic list twice per day and replenish all items		
Consumables replenished	Needles (per vaccine type requirements)		
	Syringes (per vaccine type requirements)		
	Cotton Wool Balls		
	Diluent if applicable		
Healthcare waste	Health care Risk waste disposal - seal and remove to designated storage area		
	Health care risk waste containers and boxes replenished		
	Health care waste boxes/bags replenished		
Stationery	COVID-19 Screening Forms		
	Consent forms		
	Vaccination forms		
	Vaccination cards		
	Case reporting forms		
	Case investigation forms		
IEC material	Adverse events special interest forms		
	Fact sheets		
	Posters in place at relevant stations		
	Job aids at vaccinator station		