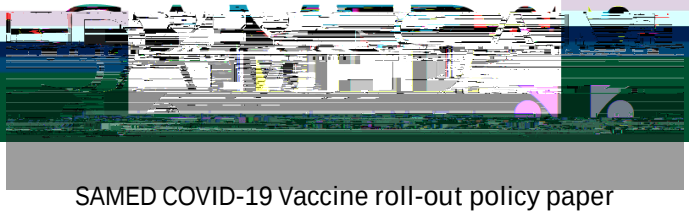

SAMED COVID-19 Vaccine roll-out policy paper

As the spread of the coronavirus COVID-19 continues to impact the health of people and the economy of South Africa, the South African Medical Technology Industry Association (SAMED) and its members are working to support efforts against the pandemic including the rollout of the COVID-19 vaccine(s). We are committed to collaborating with all stakeholders in support of the need to contain and combat the COVID-19 pandemic.

This policy paper draws on best practices and global learnings and is likely to evolve with the progression of the pandemic.

Contents:

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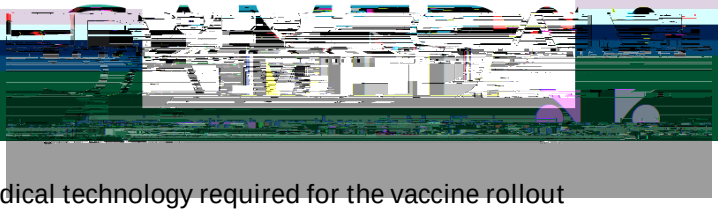


1. Ancillary medical technology required for the vaccine rollout

The following is a list of possible ancillary medical technology that may be required:
Personal Protective Equipment (PPE) ie gowns, overshoes, gloves, masks and face s

Stage	Type	Device	Description	Relevance
Preparation	Safety	Needle	18.G 1.5in	N/A
Preparation	Safety	Needle	18G 1.5in	N/A
Preparation	Conventional	Needle	18G 1in	N/A
Preparation	Conventional	Syringe	10ml LS	N/A
Preparation	Conventional	Syringe	10ml ET	N/A
Preparation	Conventional	Syringe	10ml LL	N/A
Administration	Dose Sparing	Combo	0.25-1ml 23G 1in	Adults
Administration	Dose Sparing	Combo	0.25-1ml 25G 1in	Children
Administration	Dose Sparing	Combo	0.25-1ml 25G 5/8in	Babies
Administration	RUP (reuse prevention)	Combo	0.5ml 23G 1in/0.5ml 24G 3/4in	Adults
Administration	RUP	Combo	0.5ml 25G 1in, 0.5ml 25G 5/8in, 0.5ml 25G 5/8in, 0.5ml 25G 5/8in, 0.05ml 27G 3/8in, 0.1ml 27G 3/8in, 2ml 23G 1in LS	Children
Administration	Conventional	Needle	23G 1in	Adults
Administration	Conventional	Needle	25G 1in	Children
Administration	Conventional	Needle	25G 5/8in	Babies
Administration	Safety	Needle	23G 1in	Adults
Administration	Safety	Needle	25G 1in	Children
Administration	Safety	Needle	25G 5/8in	Babies
Administration	Conventional	Syringe	1ml LS, 2ml LS	N/A
Skin Preparation	Alcohol Swabs	Swabs	Alcohol Swabs	N/A

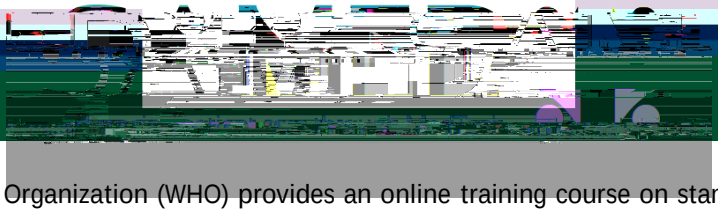
Dose sparing technology should be considered.
Given the potential local manufacture of vaccines, pre-filled syringes also need to be considered for future delivery.
Some of the available technologies for each stage are outlined in the table below.

b) Ensure safe vaccination delivery

Providing additional and refresher training for vaccinators on the importance of safe injection practices will be especially important to ensure vaccination safety. Additional injections will also increase the quantities of safe injection supplies needed. Budgeting for these additional supplies, including infection protection control measures, to ensure their timely availability is an important step in the planning process. Other vaccination sites and healthcare workers could be used to assist with the vaccinations, for example pharmacies and corporate clinics with existing trained staff and protocols for cleaning and sanitising will assist the vaccination procedure.

c) Safeguard injection safety

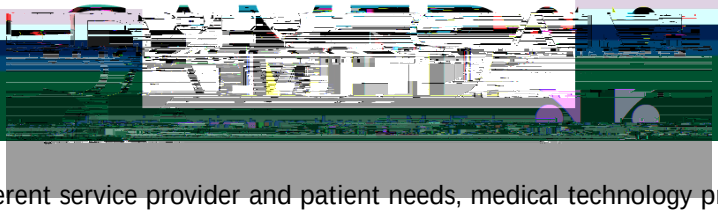
Injection safety is the safe handling of all injection equipment, routine monitoring of the availability and use of safe injection equipment, and correct disposal of contaminated injection equipment. Sharps and, more specifically, needles are considered the most hazardous category of healthcare waste for health workers and the community at large if they are not properly handled and disposed of. Waste management of biohazardous materials i.e. following universal precautions for handling of sharps as well as disposal of biohazardous materials at vaccine administration clinics/sites is critical. Certified / approved waste removal companies must be engaged for this destruction process. Needlestick injuries can easily occur and carry a high potential for infection, including hepatitis B and hepatitis C, HIV and sepsis. To prevent risk of infection to the community and to health workers, the safe disposal of used needles and syringes is a critical component of any immunization programme. To prevent risk of infection to patients, community and to health workers, safe injection practices are vital. Proper injection technique, the use of safety devices and the safe disposal of used needles and syringes are fundamental components of any immunization programme. An adequate supply of safety boxes and their proper disposal must be assured.



The World Health Organization (WHO) provides an online training course on standard precautions for injection safety that could serve as a timely refresher for those administering injections in the context of COVID-19. In addition to the traditional injection safety recommendations, in the context of COVID-19, vaccinators should perform hand hygiene after each recipient, with soap and water or hand sanitizer containing 60–80% alcohol to help prevent the spread of COVID-19.

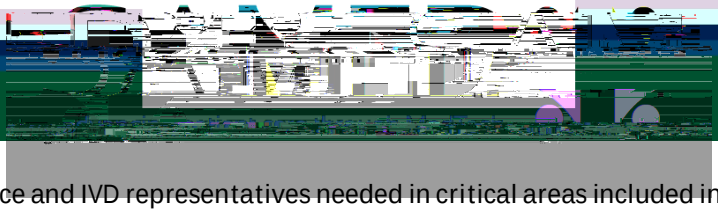
d) Cold chain equipment considerations

It is recommended that the National Department of Health (NDoH) consider an Inventory and Gap Analysis Tool for assessing vaccine volumes and corresponding cold chain capacity per catchment area. Identifying surge capacity: (i) assess and map available cold chain capacities according to c g0ET(d)o5



To meet different service provider and patient needs, medical technology procurement contracts should not be exclusive, but should allow for participation of multiple supplier models and types where feasible.

Tendering processes should not be implemented in a way that artificially controls the number of competing organisations. This principle should be reflected in limits to the size and duration of



7. Medical device and IVD representatives needed in critical areas included in phase 1 of the Covid vaccination rollout

Healthcare workers, the elderly, other front-line essential workers (including medical device representatives needed in theatre / surgery and healthcare facilities to support treatment of patients) and those with comorbidities should be the first recipients of the vaccine. Ideally, the most vulnerable to the least should be vaccinated in a systematic rollout over the subsequent months following the receipt of vaccine stock. Healthcare workers and other essential workers should get their vaccine through workplaces. For the elderly, strategies to vaccinate them will include deploying nurses and other qualified medical staff to offer vaccination at pension points, in communities and primary healthcare centres where people with chronic illnesses like diabetes and hypertension get their medication. Mass immunisation strategies in rural areas would have to be developed at district level in recurrent rollout programmes. Using existing networks, such as private pharmacies, makes sense for broader distribution.

SAMED recommends that medical technology industry company representatives that perform critical functions be included in the initial phases based on their direct risk of exposure and to ensure continuity of patient care throughout the healthcare system. These personnel, often referred to as 'Company Representatives in the Clinical Environment' (CRICE) are required, among others, to:

Be present in patient care settings to provide technical support concerning the safe and effective application of surgical products and technologies.

Support procedures/equipment/technology in the operating room or procedural suite and are required to be present during urgent, non-elective procedures (e.g. trauma, transplant, cardiac treatment) and other medically necessary procedures (e.g. joint replacement, cancer treatment, dialysis etc).

Be involved in the remote calibration or adjustment of medical devices (for example, pacemakers, laser technology) to the surgeons' and manufacturers' specifications.

Service or repair critical medical devices and equipment (including diagnostics).