Republic of Sudan

Federal Ministry of Health

National Deployment and Vaccination Plan for COVID-19 Vaccines

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Executive summary

Sudan had received invitation to participate in the COVAX facility, the MOH expressed their willingness in participation in the COVAX Facility as part of the 57 AMC countries. Vaccine requested to cover the first 20% of the population without cost sharing with an overall objective initially to directly reduce the morbidity and mortality and maintenance of most critical essential services; then expansion will take place to reduce transmission and disruption of social and economic functions. Then will expand to cover additional 45-60% of the population using the window with cost sharing. The target population will be prioritized following SAGE recommendation and the developed scoring system. Health care workers, the workers dealing with the COVID patients' bodily secretions and aerosols and elderly with co-morbidity are considered as the top priority for the first wave vaccination.

The vaccination will be in form of 6 days campaign, using fixed, outreached, and temporal health facility, three persons will be per team. The AEFI committees at all levels will be activated. Community awareness and social mobilization plan will be implemented early as possible to ensure demand; on the other hand, a crisis communication plan will be in place.

COVID 19 surveillance system in Sudan will be updated to detect the immunization status.

Vaccine supply system will be prepared to ensure effective vaccine management at all levels

This plan rely on range of proven capabilities already in place in the immunization system, across the wider public sector, in implementing safe vaccination programs for the public. These include; highly experienced teams in the EPI and Health Emergency and disease Surveillance as well as in at the National Regulatory Authority, a reliable and trusted Cold Chain, qualified and trained healthcare workers who will administer the vaccine and experience in mobilizing significant operations and processes for previous mass immunization campaigns. These tried and trusted delivery mechanisms will be augmented by enhanced structures and processes to ensure the safe and efficient administration of vaccinations at a large scale. These include: Coordination and planning committees for COVID vaccination were created from MOH and partners, NITAG actively involved through all process of decision making and will support implementation. Fund raising process was started to cover the operation cost. ICT systems to enable the planning and scheduling of vaccinations, and to support the monitoring and evaluation of the success and effectiveness of the vaccination program

1. Introduction

1.1 Background

The Republic of the Sudan lies in Sub-Saharan Africa and the third largest country there, with a land area of 1,886,068 square kilometres (728,215 square miles) and has an estimated 2021 population of 49,248,148 (EPI population estimation). It has a coastal line along the Red Sea and shares borders with seven countries: Egypt, Eritrea, Ethiopia, South Sudan, the Central African Republic, Chad, and Libya. Sudan is a multiracial, multicultural nation distributed along 18 states and 189 localities of which three are completely closed because of conflict, lies in South Kordofan state.

Most of the Sudan's population is rural; with an urban population of 32.9% and 4% are pastoralists. There are 1,578,663 internally displaced people, and refugees from neighbouring countries amount to another 1,038,177 individuals, most of them are (south Sudanese refugees) out of camps. Currently, Sudan is witnessing a growing transformation towards urbanization. The population's growth rate is 2.4 % with a total fertility rate of 4.5 and the family size ranges from 5-6 members. Children less than 5 years old represent 15.2% of the total population amounting 7,990,627 under-five children and 1,726,831 infants, while those less than 18 years old represent 50.6%. About 46.5% of the population lives below the poverty line earning less than $1 a day, with 8% living in extreme poverty. Disparities between rural, semi-rural and urban areas are evident with a poverty rate of 67.4% in semi-rural and 64.8% in rural areas and 8% are nomads. The country ranks 165th on the Human Development Index (HDI). The adult literacy rate in Sudan is 69% and 45.2% among women aged 15-24 years. The primary education enrolment is 46%; with 82.2% of the cohort entering primary school completing primary education.

Decentralization was introduced in 1994 as a system of governance compatible with the needs of the multi-ethnic and multi-cultural society of Sudan. The system is founded upon a multi-tier government: National, state and locality governments (Districts) which are called localities.

The health system is formed of three tiers; Federal Ministry of Health (FMOH) is responsible for the development of national health policies, strategic plans, monitoring and evaluation of health system activities and external relations. There are 18 State Ministries of Health (SMOH); mainly responsible for interpretation and modifying of national policies to adapt the state situation. State level is the level of implementation of secondary and tertiary health care. The locality is the lower level and mainly responsible of implementation of health service and executing of operational plans, overall, there are 189 localities with only 3 localities completely inaccessible in South Kordofan state. Health services are provided by different entities. In addition to National & state ministries of health there are the police, military, universities, the private sector (both for profit and non-for-profit) and civil society. The health system suffered severe loss of human resources and uneven distribution.

The health services in Sudan facing many challenges:

1. Accessibility and equity: PHC services in Sudan covers around 60% of the population, weak referral system and no triaging system in place
2. Sudan being bordered with seven countries; with many entry points and ports distributed in 13 states bring the risk of cross border transmission of diseases
3. Human resources: Rapid and frequent turnover, migration of professionals is a major issue facing the health system in Sudan. For instance, 60% of physicians and 25% of pharmacists leave the country, low enumeration, and low morale (shortage and dependency on volunteers)
4. Absence of recent population census (last census was in 2008), continuous population movement between Sudan and neighbouring countries and between states including high influx of refugees (lack of cross notification).
5. Security closed areas in three localities in South Kordofan state
6. Community awareness and care seeking behaviour

The political situation has changed dramatically during the 2019, which witnessed the start of the protests, and the progressed into complete revolution. With the establishment of the transition government in August 2019.

Internally Displaced Persons (IPDs)

Armed conflict in Darfur has subsided but many parts of the region remain precarious because of the proliferation of arms and banditry. Government services, especially health, have been overloaded or stopped. The conflict damaged and destroyed infrastructure, seriously affected health service, and resulted in internal displacement of millions of people. Based on the micro-plans of Darfur states for 2020, there are around 1,578,663 persons (51,526 under 1-year children) living in 99 IDPs camps in 32 localities1. Routine immunization services in Darfur states are almost covering less than 25% of the target. Service provision depends mainly on acceleration campaigns that conducted in rounds by end of the year. Hence the risk of VPDs outbreak remains very high throughout the year due to low immunity. Establishing sustained routine immunization services and phasing out of the acceleration campaigns is on the top priorities of the EPI program in the coming five years.

Refugees

Sudan hosts one of the largest refugee populations in Africa. South Sudanese make up the majority. Many others fled violence and persecution in neighbouring countries, including Eritrea, the Central African Republic, Ethiopia, and Chad, but also the wars in Syria and Yemen pushed people to seek safety in Sudan. Most refugees live in out-of-camp settlements, host communities and urban areas, while others stay in 21 camps (9 at the East Sudan, 9 at White Nile State, 2 at East Darfur State and 1 at the Central Darfur State). Sudan continues to generously host and receive additional asylum-seekers. In total there are 1,056,326 individuals

[1] Darfur States 2019 Microplans

1.2 Coronavirus disease 2019

March 13th (week 11/2020) Sudan FMoH declared the first COVID-19 case, following this Sudan has passed through four stages the phase where there was no cases reported, then few sporadic cases at which all cases were linked to travel from cases coming from affected neighbouring countries to the community transmission. The current situation Sudan is passed through the community transmission and entering a high wave of the pandemic. Up to Sunday February 7th, 2021 a total of 50,003 suspected cases reported in Sudan of which 27,717 (55.4%) tested positive including 1835 associated deaths, CFR: 6.6%. Active cases signify 13.8% of the total confirmed cases

Figure (1): Distribution of confirmed COVID19 cases by epidemiological weeks- Sudan 2020-2021

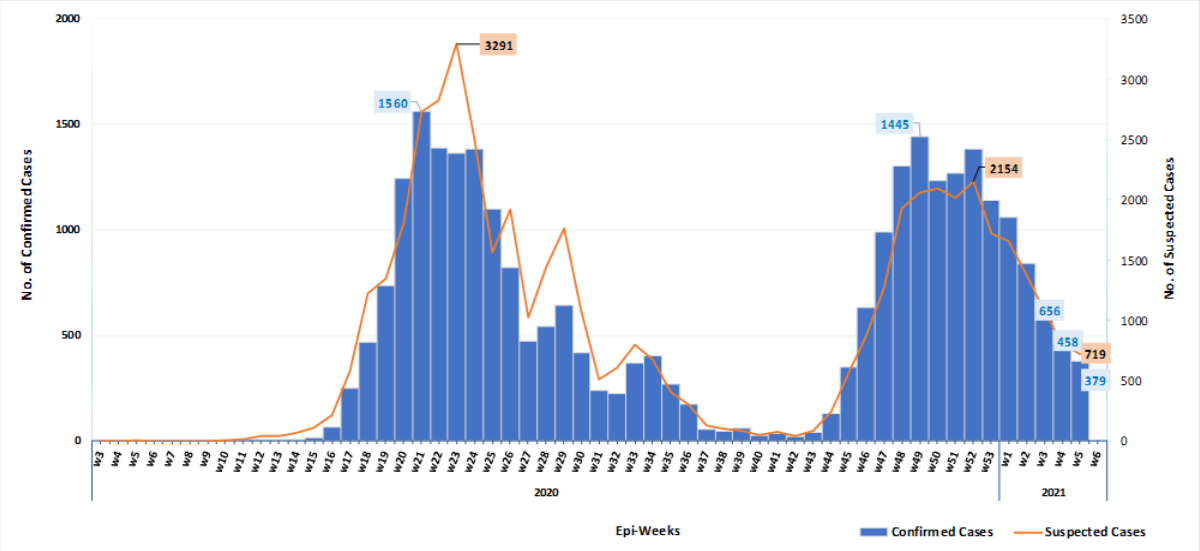


Table (1): Distribution of confirmed COVID-19 cases and deaths by states, Sudan 2021

State	Total Confirmed	Cumulative Deaths	CFR%
Khartoum	20106	811	4.0
Gezira	2335	335	14.3
Sinnar	502	62	12.4
River Nile	861	127	14.8
Kassala	381	42	11.0
Gedarif	664	86	13.0
Northern	617	76	12.3
Red Sea	718	69	9.6
White Nile	374	53	14.2
Blue Nile	49	3	6.1
North Kordofan	349	45	12.9
West Kordofan	194	7	3.6
South Kordofan	32	4	12.5
North Darfur	173	90	52.0
South Darfur	121	7	5.8
West Darfur	56	7	12.5
Central Darfur	7	3	42.9
East Darfur	32	8	25.0
Unknown	146	0	0.0
Total	**27717**	**1835**	**6.62**

Figure (2): Mapping of COVID-19 attack rates by states, Sudan 2020-2021

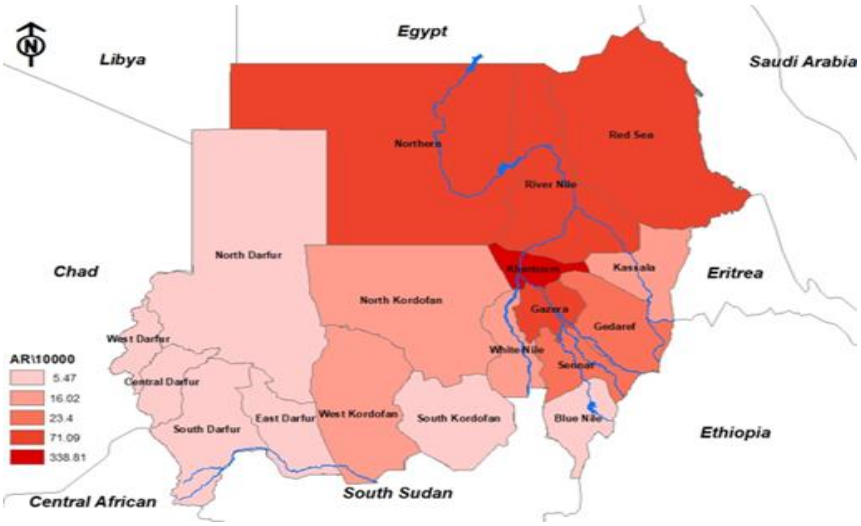
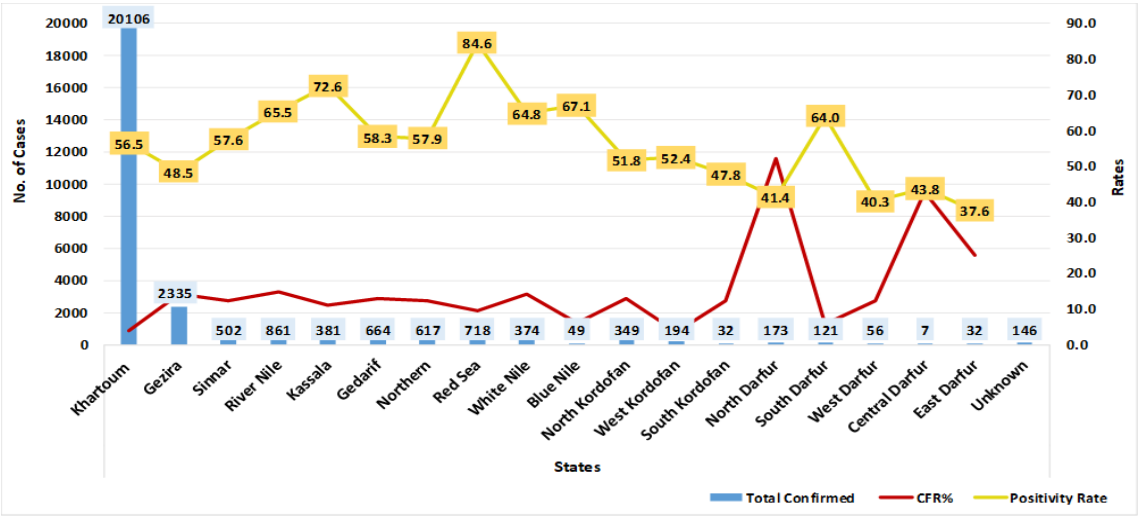


Figure (3): Distribution of COVID-19 confirmed cases, CFR and positivity rate by states up to 7 February, Sudan 2020-2021



Summary:

- Khartoum state represent 72.5% of Sudan total confirmed cases followed by Gezira state at 8.4%.
- Male patients represent 60% of confirmed cases and 70.1% of COVID-19 associated deaths.
- The “20-29.9” age group is the most affected signify 23.0% of confirmed cases, while 60.0% of deaths are among 60 years old and above.
- The highest CFR is 52.0% recorded in North Darfur, while the lowest CFR is 3.6% recorded in West Kordofan.

- Out of 1023 health staff tested for COVID-19 all over Sudan 77.0% was positive. Khartoum state represent 38.0% of the total tested health staff with a positivity of 95.3%

1.3 Impact of Coronavirus disease 2019 on Health System ad Services

Following confirmation of COVID-19 cases in Sudan 13 of March 2020, the government declared a national state of emergency to support and enhance the multi-sectoral response to COVID-19 outbreak Sudan's health systems have been confronted with rapidly increasing demand generated by the COVID-19 outbreak.. The health system was severely compromised due to overwhelming demand, resource diversion and closure of health facilities. Marked disruption of the health services followed by declining of uptake of essential services. Many factors contributed to this including the following:
Decrease of staff/health cadre working due to being under quarantine/isolation, and Mobility restrictions due to total lockdown followed by; widespread fear of contamination of beneficiaries to visit health facilities. The root causes of disruption was mainly due to the panic and fear of health care providers, closure of most of the private clinics and institutions, inadequate IPC at health facilities in terms of the structure and processes, unified guidance and conflicting commands (gap of team leaders as most of specialist and matron are above 60yrs), absent psychological support for health care providers, weak governance and accountability measures and logistical challenges

FMOH assessed the impacts of COVID-19 on access to Essential Health Services during the lockdown using WHO tool. The assessment revealed critical gaps in service availability, shortage of supplies and inadequate implementation of IPC measures. Substantial reductions in healthcare utilization were reported during the first half of 2020. Examples include over 8% reductions in DPT coverage, 20% reduction in tuberculosis detection rate and 25% reduction in Antenatal care.

COVID-19 socio-economic impacts

In Sudan, COVID 19 has a profound effect on the lives of everyone. Many families have lost loved ones, people have experienced loneliness and isolation and many people have lost their jobsas many of people in the big cities are prolong to the informal sectors and mechanisms such as the lockdown and movement restrictions impacted them harshly. The impact of the pandemic on society and on the economy has been extremely challenging. In the face of unprecedented economic fallout related to the COVID-19 pandemic, Sudan like other countries around the world is adopting expansionary fiscal and monetary policies to lessen the recessionary impact of mitigation measures.

The Sudanese Government has more limited fiscal space than many others, given its low tax effort and high cost of subsidies, which cannot be eased in the immediate future. The banking sector is already under stress with limited room for providing additional credit to businesses. The country further faces a binding foreign exchange constraint, which makes it difficult to import the needed commodities to provide the population with necessities, in the face of COVID 19 induced losses of income and production. The implementation of the needed expansionary policies is thus dependent on generous support of the International

community". This strongly amplified the impact of the disease on the health system and increases the mortality because of late care seeking

1.4 COVAX and COVID-19 vaccines

Sudan had received invitation to participate in the COVAX facility, the MOH expressed their willingness in participation in the COVAX Facility as part of the 57 AMC countries. The Technical Assistance Plan (TA) was submitted timely, approved budget was received in country, WHO and UNICEF are the two main partners to support Sudan in planning and implementation of the COVID vaccination as part of the TA plan. On other hand, many in country partners and donors showed their willingness to support; World Bank confirmed their readiness to support the operational cost, the cost sharing for extra doses and any more TA if needed.

Sudan submitted their vaccine request to the COVAX facility, showing their readiness, NITAG approval, the target groups, the vaccine characteristics preference, cold chain capacity and their regulatory process. The indemnity agreement was signed by the minister of Health and submitted to the COVAX facility. Sub technical committees formulated and drafted the National Vaccine Deployment Plan

The Government established the High-Level steering committee on COVID-19 Vaccination on October 22nd, 2020 to ensure the requisite oversight, agility and specialist input is available to support FMOH in the effective, efficient, and agile delivery of the COVID-19 Vaccination.

1.5 Governance and Decision-making process for COVID-19 vaccine introduction

Sudan has a very strong set of institutional arrangements to support good governance and most importantly, in respect of the safety of any vaccine. Sudan has a well-established and fully functional (NITAG) in place. The process of decision taking was went through all official and technical consultation as follows:

- The higher government officials participated in all COVAX consultation meetings
- Head of NITAG participated in all orientation sessions
- NITAG held two meetings, all available data, the overall opportunity in line with Sudan context and other countries experience were thoroughly discussed. Then NITAG recommended to the Minister of Health to accept Sudan participation in the COVAX facility
- Federal Ministry of Health formulated steering committee from all the director general and the directors of all related departments, revised the COVAX facility invitation and the NITAG recommendation and confirmed Sudan willingness of participation in the COVAX AMC facility
- National Technical Committee was formulated
- Subnational technical committees formulated covering all the pillars of the NVDP

The implementation of introduction of COVID 19 vaccine will rely in the normal way on the governance structures and statutory responsibilities of a range of existing bodies. However, to augment and support existing arrangements given the range of responsibilities, actors and the responsiveness that will be demanded as the vaccination and deployment take place. The COVAX National taskforce and the technical committees will not replace or displaced the existing roles and responsibilities but will be having an oversight role and avail a program management support.

2. Objectives

Sudan is on the phase of community transmission, as per SAGE recommendations the country will initially focus on direct reduction of morbidity and mortality and maintenance of most critical essential services; then expand to reduce transmission and disruption of social and economic functions. This will be achieved through vaccination of the 3% of the population to cover frontline healthcare workers (HCWs) in direct patient contact or who at risk of exposure to bodily fluids or aerosols and the elderly with co morbidity. The target of the 4% of the population will be proceeded by the first wave roll out of COVID vaccine. Followed by the 16 %of population based on the prioritization exercise, to maximize the benefit from the 20% from the COVAX facility, then will expand to cover 20-60% of the population using the window with cost sharing.

Plan stage	Initial rollout and ramp up		Open access
Vaccine availability	No of doses to cover 4% of the population	No of doses to cover 16 % of the population	≥ 20% -60% of population
Population to be vaccinated	Frontline HCWs all over Sudan and elderly with co-morbidities		
Delivery strategy	Vaccination centres		
Vaccine to be used	AstraZeneca		
Potential start date	March 2021		Depend on vaccine delivery

2.1 General objective:

To reduce mortality and morbidity from the COVID-19 pandemic through vaccination

2.2 Specific Objectives:

- To vaccinate at least 90% of the target population identified as high-risk groups
- To ensure continuation of essential services, including health services
- To reduce disruption of social and economic functions

2.3 Strategies

- Service delivery through fixed health facilities
- Special plans for the in-accessible areas, IDPs and refugees
- Ensure immunization safety and waste management
- Advocacy, Social mobilization, and communication for the COVID vaccination
- Adequate Vaccine supply and vaccine management
- Strong supportive supervision and campaign monitoring
- Ensure data quality and data accuracy
- Monitoring AEFI and post marketing surveillance
- Partnership and inter-sectoral coordination

3. Regulatory preparedness

National Medicines and Poisons Board (NMPB) is the National Regulatory Authority (NRA) of Sudan, which is responsible for the safety, efficacy and quality of human and veterinary medicines, medical devices and cosmetics. Regarding vaccines, the testing procedure requires sophisticated and complex analytical methods and equipment that should be managed by trained staff accordingly the NMPB relies on the WHO prequalified vaccines and no testing perform at the country level. The strategy and policy of registration of vaccines is to ensure quality, safety and efficacy that have been guaranteed by WHO prequalification program.

It's the first time for NMPB to face such an emergency case, that need introduction of vaccine which may not be WHO prequalified. In this case, the NMPB may rely on vaccines approved by stringent regulatory authorities (SRAs) or WHO emergency use listing (EUL) which is a procedure done by WHO and depend on risk assessment approach regarding quality, safety and efficacy of vaccines, however this is not highly recommended by NMPB, due to insufficiency in technical knowledge and experience in this area.

Objectives:

- To apply the fast track pathway for vaccine approval.
- To implement the fast track for importation.
- To ensure compliance of warehouses with good storage practices (GSP).
- To monitor safety, efficacy, and quality of vaccines post immunization. (vigilance and Post Marketing Surveillance (PMS)).

Requirement for registration:

A. Vaccine prequalified by the WHO:

1- According to WHO Expedited Procedure for Vaccine Registration the following forms should be submitted:
   I. Form 1a issued by the company.
   II. Form 1b from issued by WHO Vaccine Prequalification Office.

2- Submission of CTD dossier.

B- Vaccines listed under the EUL procedure:

1- Applicant from NRA
2- Site master file (SMF) for Drug Substances and inspection report(s) from the WHO inspection team showing compliance with GMP requirements.
3- Site master file (SMF) for Drug Product and compliance with GMP requirements.
4- Submission of CTD dossier.
5- The vaccine manufacturer must apply to NMPB with the following information:

Manufacturing quality data:

- Full characterization of cell banks according to WHO Technical Report Series (TRS) 978, and any subsequent updates.
- Full characterization of master and working seed organism(s), based on reference to the most appropriate WHO TRS.
- Process validation (based on quality risk assessment for the development stage) and demonstration of consistency of production at the production scale used for the lots to be distributed.
- Justified specifications for starting material, intermediates, and final products.
- Stability data for the vaccine produced at the scale produced for the lots to be supplied.

Non-clinical data and clinical data

A plan to monitor quality, safety and efficacy in the field and an undertaking to submit any new data to NMPB as soon as the new data are available

Labelling details:

As per the board regulation Arabic and English are the standard languages for the labelling and all required documents, in case of using any other languages official translation must be submitted and this to be endorsed by Sudan embassy in country of origin

- Summary of product characteristic (information for healthcare provider),
- Patient information leaflet
- Container labelling
- Any other instructional materials provided to the user.

Regulatory Preparedness for the AstraZeneca Vaccine as first wave:

The Minister of Health with the NRA confirmed country readiness to release EUA and an exceptional wavier for the AstraZeneca vaccine based on WHO EUL to ensure vaccine arrival, Communication was started with the customs official to prepare the importation permit. The Ministry of Health had signed the indemnity agreement as part B of the vaccine request and will proceed with signature of the required indemnity agreement with the manufacturer of the AstraZeneca after the release of WHO EUL. Written consent will be signed by the beneficiary.

4. Planning and coordination

Political commitment, country ownership and Policy issues

The Supreme Committee for the Corona Emergency in Sudan formulated March 2020, headed by member of the Sovereignty Council and all related ministers as members. The committee regularly updates the higher government officials and support decision making. The minister of Health is member and he supported and advocate for the COVID. Governmental commitment translated in term of the commitment of fulfilling the government requirement for country participation in the COVAX facility.

Under the guidance of the Minister of Health, Steering committee formulated for higher level guidance of the COVID vaccine introduction and vaccination, The committee involved representation from the concerned line ministries (Ministry of Education, Ministry of Social welfare, Ministry of Interior and Ministry of Endowment and Guidance), the private sector and higher management of the partners namely WHO, UNICEF and World Bank

The National Immunization Technical Advisory Group (NITAG), who was formulated in 2009, technically guides, advice and recommend the introduction of new vaccines into the country based on scientific evidence and according to the diseases burden and priorities. The role of the NITAG has been expanded and additional members were added to fulfil the requirement of the COVID vaccines. NITAG had recommended the introduction of COVID vaccine, participation in the COVAX facility, approved the prioritization criteria for the selection of the target population based on phased vaccine delivery and recommended the target population for the first wave.

Even though EPI in Sudan is well established and has an excellent experience in new vaccine introduction, but COVID vaccination is new experience in terms of the vaccine, target, vaccination post and demand. Ministry of health with its partners will conduct series of coordination and orientation session pre, during and post COVID vaccination.

National Technical Committee

Under guidance of the Primary Health Care directorate general, a national technical committee was formulated to follow on the planning and implementation of the introduction of the COVID vaccines. The committee was divided in 9 subcommittees with clear TORs, these are:

- Service delivery and identification of target populations
- Planning, coordination, and vaccine deployment planning
- Surveillance
- Monitoring and evaluation
- Vaccine safety monitoring; management of adverse events following immunization (AEFI) and injection safety
- Vaccine Supply chain and management of health care waste

- Vaccine acceptance and uptake (create and satisfy demand)
- Regulatory &post marketing surveillance
- Costing and funding

State COVID Vaccine Technical Committee

State COVID vaccine technical committee formulated headed by the state ministry of Health director general and membership of all line ministries, related departments, and partners.

Planning

Preparatory Activities:

Ministry of Health with WHO technical support organized two days planning workshop, members of the sub technical committees from MOH, NITAG, WHO and UNICEF were participated, the national vaccine deployment plan was drafted, covered all the components of the COVID vaccines deployment and vaccination, By end of the workshop the first draft of the plan formulated, the technical committees continued working until the development of the final NVDP.

Plans and micro-plans

The planning started at National level by identification of the target groups, agree on the vaccination strategies , vaccine to be used and date of vaccination, microplanning guidelines will be updated and shared with the subnational levels, Bottom up microplanning for the vaccination will begin at the state and locality levels, compiled at states to end up with the master national micro-plan for the campaign.
Human well-being and health equity will be highly considered during the micro planning process and mapping of sociodemographic groups who at significantly higher risk of severe disease or death (e.g. refugees, internally displaced persons, asylum seekers, population in conflict settings, incarcerated people, etc.) will be addressed; special plans and interventions will be prepared and implemented

Outlines of the activities:

- Conduct detailed situation analysis for COVID-19 outbreak in Sudan to support introduction of COVAX
- Establish coordination mechanism to manage COVID-19 deployment and vaccination operations at all levels
- Establish national steering committee for COVID-19 pandemic response
- Establish national technical committee for COVID-19 pandemic response
- Establish national technical subcommittee for COVID-19 emergency response
- Establish COVID technical committee at states level
- Establish COVID operation committee at localities level
- National level Coordination with stakeholders (medical association, policy, professional association, and line ministries)

- identification of target group
- Prioritization and identification of COVID vaccination subgroups within the targeted groups and priority states
- identification of service delivery strategy
- Establishment the pre - registration system
- Development of data management and use system
- Identification of priority states based on vaccines availability/risk/targets group/operation cost
- Development of micro-plans guidelines, tools and records etc.
- Identify logistic needs
- Inauguration of COVID vaccination services

Planning for the AstraZeneca vaccine as first wave:

- Prepare all the required documents for vaccine delivery and preparation of EUA with the NRA
- Registration of the identified target health workers defined as the frontline healthcare workers (HCWs) in direct patient contact roles or who risk exposure to bodily fluids or aerosols.
- Registration of elderly with co-morbidities
- Set the micro-plan for the vaccinations and prepare the vaccination sites
- Plan for preparation of waiting areas (at least for 20 minutes) and facilities for management of AEFI
- Plan for logistic and vaccine handling at central stores and daily distribution to the vaccination sites to ensure no stockout during the day
- Develop the schedule and map the target according to the planned sites
- Development of plans for TOT and cascade training, supervision plan
- Plan for management of any adverse event following immunization including the severe reactions

5. Service Delivery and Identification of the Target Population

There is range of proven capabilities already in place in the FMOH, the EPI, and across the public sector, in implementing safe vaccination programmes for the public. These include:

- Highly experienced teams in the FEPI as well as in at the National Regulatory Authority
- A reliable and trusted National Cold Chain,
- Qualified and trained healthcare workers who will administer the vaccine
- Experience in mobilizing significant operations and processes for previous mass immunization campaigns, and for swabbing, testing and tracing as part of our COVID-19 response.

These trusted delivery mechanisms will be augmented by ICT systems to enable the planning and scheduling of vaccinations, and to support the monitoring and evaluation of the success and effectiveness of the vaccination programme

Prioritizing the target population

Prioritizing the target population for COVID-19 vaccination is mandatory in the context of limited supply. Reference for prioritization of the target groups are:

- WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination issued on 14 September 2020
- WHO SAGE Roadmap for prioritizing uses of covid-19 vaccines in the context of limited supply issued on 13 November 2020
- The vaccination allocation sequencing approved by several Government

The decision making for selection and prioritization of the target population has passed through steps of analysis of the country COVID 19 surveillance data, revision of other countries experience consultation with all related health program and partners, the proposal was raised to NITAG for more scientific and transparent decision. Mortality, case fatality, and attack rates data used to guide constructing the scoring system. HCW and those working in direct care of known COVID-19`s patients are on the top priority for vaccinations. The scoring system for layered grading of identified populations, so group with higher risk will receive the vaccine before others with lower risk. Transparency regarding selection criteria and process is paramount and would be clearly communicated to authorities, community leaders and public.

Selection of target group:

Scoring system to stratify the community into priority groups for vaccination to optimize the coverage of at risk and reduce the total cost and logistics required. Factors weighed to produce the stratification score are:

1. Age (>45 years old 6.4 million)- form civil register – locality level data)
2. Presence of Comorbidities (included in the high-risk group for severe disease and increased mortality)- (form the Health Insurance database, referral clinics registry and voluntary declaration Using mobile based reporting tool.
3. Profession and probability level of exposure Location and social context in relation to hot covid-19 spread, institutionalized, refugee camps, and international workers.

The scoring system:

Factor	Specifics	Score	notes
Age	<45	0	**Shielding or frontlines?**
	45-60	20	
	>60	30	
Profession	HCW in "COVID-19 treatment centre"	100	○ Front liners at Hospitals and Covid 19 treatment centers ○ Health workers at high to very high risk of acquiring and transmitting infection ○ (HCWs) in direct patient contact roles (including vaccinators) or who risk exposure to bodily fluids or aerosols.) ○ Long-term care facilities ○ Outpatient ○ Home healthcare ○ Pharmacies ○ Public health
Co-morbidities	>1 co-morbidity	40	○ Severe Obesity ○ Diabetes ○ COP ○ Heart Condition ○ Chronic kidney ○ Cancer ○ Smoking ○ Solid Organ transplant ○ Sickle cell disease
	1 comorbidity	30	
	No co morbidity	0	
Location	Locality with high community transmission	10	○ Khartoum state, Aljazeera state ,red sea state ,algadarif
	Locality with low Community transmission	5	
	Locality with no documented C.T.	0	○

Table (2): The Scoring system for prioritization of the target population

Phase 1: very limited vaccine availability, 4 % of the population:

- Health workers (HCWs) in direct patient contact roles (including vaccinators) or who at risk of exposure to bodily fluids or aerosols. Estimated numbers of health care workers in Sudan is about 500.000 HCW in all states. Health workers in all settings (governmental and private) will be included in phase one
- Aged 45 and older with medical conditions and living at areas with high transmission or anticipated high transmission

Phase 2: (limited vaccine availability, for 4–20% of population.):

- Adults aged ≥45 years and older with medical conditions in the rest of the country. (hypertension and asthma) and at the rest of the country
- Key workers in essential jobs: teachers and school staff (examples may include preschool and primary school teachers because of the critical developmental stage of the children they teach, teachers of children where distance learning is very difficult or impossible).
- Other Key workers in essential jobs who cannot avoid a high risk of exposure to COVID-19(centers for public services, Transportation, Energy, Armed forces, bankers, etc.)
- Aged 16-45 years with medical conditions
- Aged 45 and older without co-morbidities
- Aged >18 years living /working in crowded accommodation where self-isolation and social distancing is difficult to maintain. (examples may include people living or working in detention facilities, incarcerated people, refugees, IDPs).

Phase 3 (moderate vaccine availability, for 21–50% of population:

- Pregnant women
- Lactating mothers
- Aged 18-45 years who did not have access to the vaccine in prior phases
- Children, adolescents up to 18 years

Target population for the first wave of vaccine rollout using AstraZeneca vaccine:

Sudan will follow the main purpose of the first wave that this allotted amount prioritized for the health worker at risk of direct contact with COVID 19 patients or who at risk of exposure to body fluids or aerosols, and the elderly with co morbidity (Severe Obesity, Diabetes, COP, Heart Condition, Chronic kidney, Cancer, Smoking, Solid Organ transplant and Sickle cell disease)

Service delivery strategy for the 4% of the target population:

The vaccination will be 6 days as a national campaign, health facility based using fixed and outreached strategies.

The health workers vaccination: based on the facilities the plan will managed, in big facilities like a tertiary or secondary hospital, temporal vaccination sites will be arranged .Number of teams will be based on the targets and the campaign days. The PHC workers including the vaccinators will be linked to the vaccination sites arranged for the elderly with comorbidities in their catchment areas.

The elderly with co-morbidity will be vaccinated at the health facility in their catchment area.

The vaccination team will be composed of three persons; vaccinator, register and social mobilizer.

Outlines of the activities:

Identify the target population, Prioritization and support obtaining accurate estimate:

- Selection of target group
- validation of data with relevant sectors
- Construct and apply a scoring system

Registration

- Developing mechanism for registration
- Developing and piloting the tool for registration
- Assigning personnel for registration and train them

Training of the personnel

Development of the training guidelines for the vaccination, for the health workers and supervisors to include but not limited to:

- COVID 19 disease and prevention strategies
- Target population
- COVID vaccine administration (dose, injection site etc.)
- Social mobilization (Main messages)
- Recording and reporting of the vaccination
- AEFI and their field management
- Vaccine management.
- Injection safety including safe disposal of the waste
- Monitoring and evaluation

Cascade training will be adopted firstly by conduction of a TOT training at the national level for states' trainers using the updated field guide/manual with WHO and UNICEF support. TOT at state levels will conducted for the locality trainers followed by a series of training sessions for providers two weeks before the campaign with a close supervision from national, WHO and UNICEF staff. A list and number of the health workers that will be involved in the vaccination will prepared by each state for all their levels to be included in the training plan of each state.

Establishing a new delivery platform(ensure continuity of routine immunization services)

- Develop criteria of health setting to deliver services
- Scaleup other platforms delivering health services

IPC measures

- Developing and distributing IPC guideline for COVID19 vaccination
- Development and approval of the guideline
- Print the guideline
- Distribute the guideline
- Designing, Printing and Distributing IPC Posters
- Assessing the IPC standards in the vaccination sites

Setting standards for the vaccination site

- Formulating assessment team
- Conduction of assessment
- Developing improvement plan
- Implementing improvement plan
- Quantification of the IPC Supply

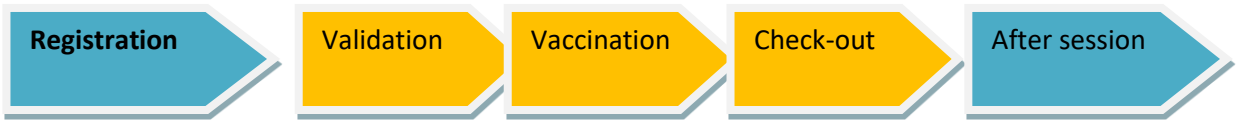
Supervision

- Developing supervision tool
- Selection of supervisors
- Conduction of supervision

6. Monitoring and evaluation

Establishing a digitalized information system for all activities will be carried out and used through all process of COVID vaccination. The system will include the registration of targeted group prior to implementation of vaccination, verification of data after generating from its sources and categorization will be done. Vaccination, documentation and observation and reminder for second dose will be addressed. Follow up meetings will be conducted with other COVID-19 core committees to monitor the progress of committees work and completion to set all needed indicators of COVID vaccination. System development with all requirements will be closely monitored and tested prior to implementation of vaccination. Training to all who will be using this system will be provided at national level to ensure quality of delivering the vaccination service. Printing materials (vaccination cards which will be provided to the beneficiaries and supervision forms) will be secured.

Vaccination process:



Procedure outside vaccination site	Inside vaccination site			Procedure outside vaccination site
Vaccination request and preliminary information including informed consent	Registration, verification of vaccination eligibility	preparation and vaccination	Resting phase, documentation	observation and reminder for second dose

Vaccination uptake will be assessed in an ongoing manner to track the implementation of the vaccination program and acceptance of the vaccination in the populations targeted in line with the prioritization framework. Monitoring of the uptake by population group will be done where it is possible to obtain denominator data (e.g. census data for different age groups). Analysis will be carried out on uptake by demographic characteristics, such as gender, age, area of residence, workplace settings for HCWs (University hospital groups, hospitals, and primary care sites).

COVID vaccine coverage will be reported through the system at the service delivery site directly to the HUB center at FEPI and regular feedback will be maintained. Supportive

supervision visits using special checklist will be performed regularly and according to the supervision plan.

The COVID vaccine introduction monitoring will be through:

- Monitoring the immunization coverage of the vaccine.
- Drop-out rate (first dose of COVID and the second dose).
- Wastage rate
- Adverse Events Following Immunization (AEFI).

Outlines of the activities:

Establishment of one system for all activities

- Identify the requirements/needs to develop the system.
- Identify the infrastructure necessary for the system.
- Identify the specifications and Quantities required to develop the system.
- Development of the software system
- Provision of desktop computers
- provision of internet connects and network for 6 months

Preparation of vaccination materials

- Designing vaccination card, registration, and supervision forms
- Printing vaccination card, registration, and supervision forms
- Distribution vaccination card, registration, and supervision forms

Staff Training at the all levels

- TOT of state core team at National level on the M&E system
- Training of reporters (registration of vaccine recipient)
- Training of technical support staff

Selection and definition of M&E indicators

- Meetings with COVID19 sub-committees to identify indicators
- Prepare an indicator master list for COVID vaccine introduction
- Review meeting for approval of indicators.
- Development and update of checklists, registers, and reports

Carrying out Supervision of the components of the system

- Meeting to define the schedule and modality of supervision based on the requirements of the system
- Develop supervision Guideline.
- Develop the supervision check list.
- Training of supervisors and data entry on the supervision of the system

- Data collection
- Data entry and analysis

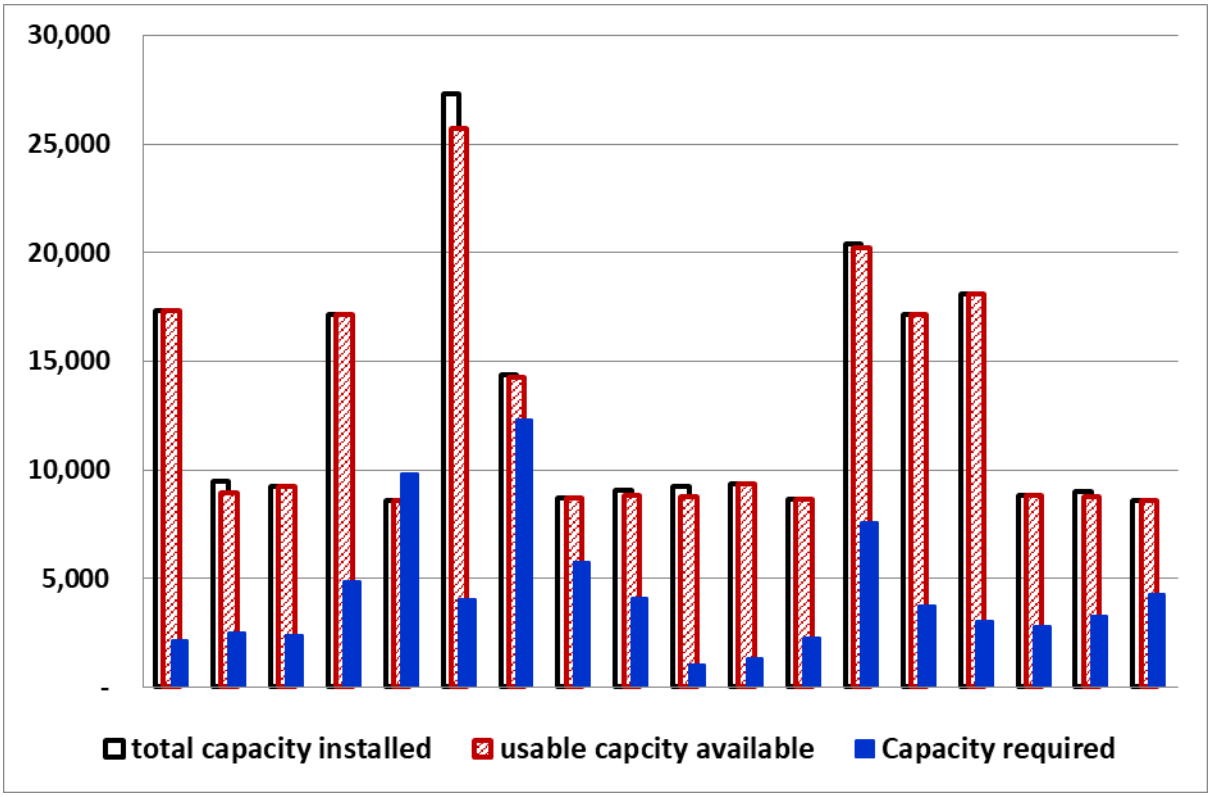
Follow up Meetings

- Weekly M&E committee meeting.
- Monthly COVID subcommittees follow up meetings.
- Post implementation Review meeting.

7. Vaccine Supply chain and Waste Management

Sudan has an immunization supply chain that consists of the national store, 18 State stores, 183 locality stores and 2,421 service points. The Cold Chain capacity at the national and states levels are adequate for regular vaccines including campaigns with free space available in both +2 to + 8 and -20 at national and sub-national levels. Cold Chain capacity at national level is 283,000 liters and the fig below show clearly that all states has good free cold chain capacity at +2 to +8 and -20.

Fig (4): showing the total cold chain capacity, usable part, and the capacity required to keep the current vaccines and pipeline up to 2021

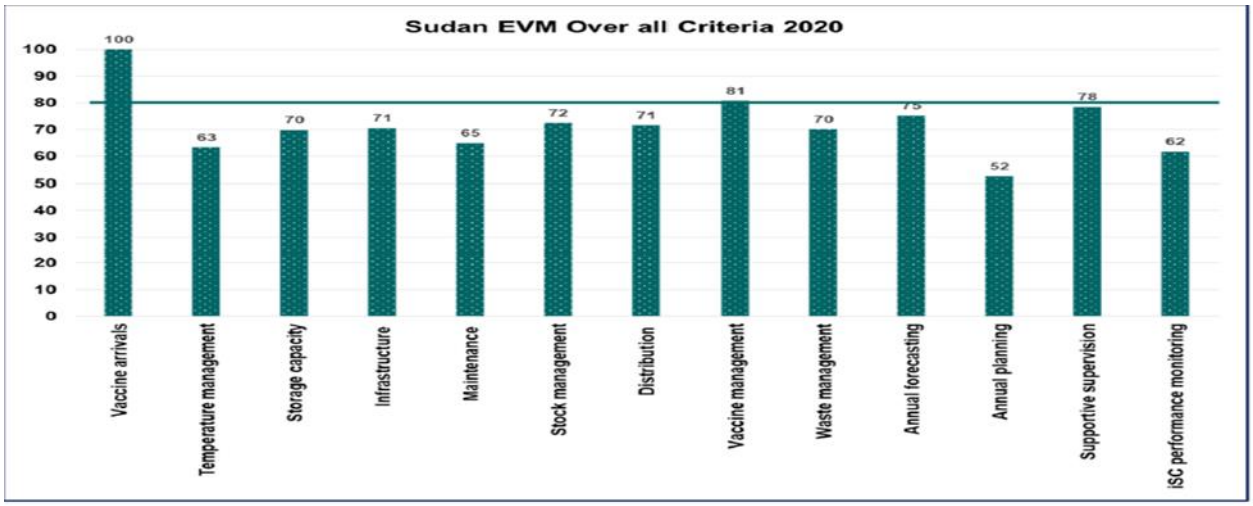


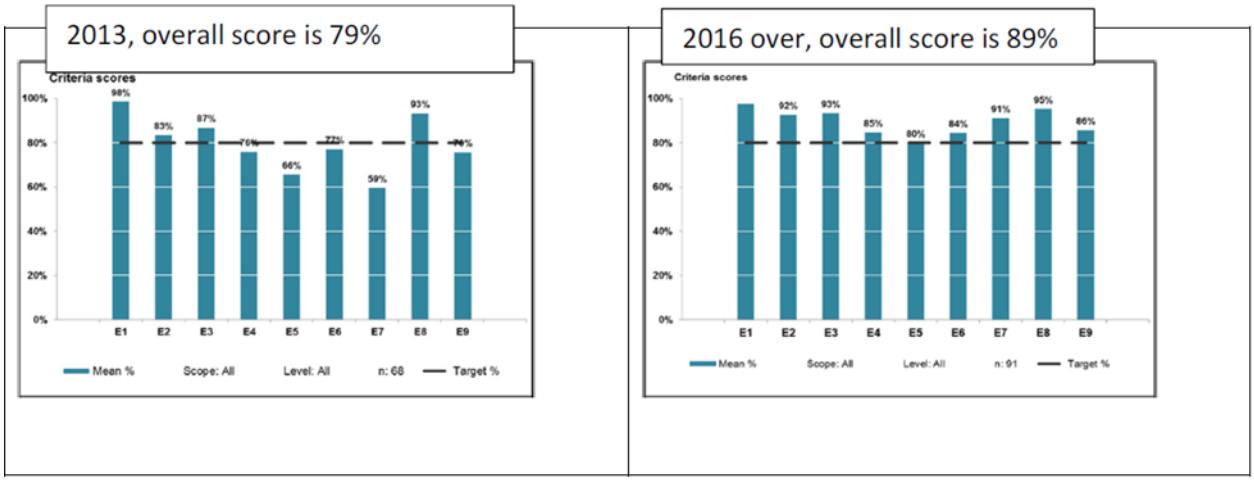
The programme has strong history of achievement on Effective Vaccine Management (EVM) during the last ten years as shown in fig 2 and 3 below. The most recent EVM assessment was conducted February-March 2020 using EVM2.0. The result of the most recent EVM assessment shows some week areas in the new and old criteria; reason for low performance includes the high turnover in immunization technical staff and mid-level management, massive leadership changes during the current political transition and low implementation of the previous EVM improvement plans. In addition to what was mentioned also the EVM2.0 is more comprehensive and covers more technical and performance indicators.

FMoH and partner has increasingly invested in strengthening the supply chain in term of equipment, buildings and human resource capacity building through EVM Improvement Plan (EVM-IP).

EVM-IP has been developed based in the finding of the EVM 2020, Based on the EVM process, a workshop was conducted to discuss the finding and to prepare the EVM-IP for implementation. The new EVM-IP addresses the key identified gap areas and will be translated into multiyear implementation plan.

Fig (5): EVM 2.0 result 2020





Cold Chain capacity:

Based on the comprehensive Cold Chain Equipment Inventory that was conducted in 2016 and updated twice in 2018 and 2021, there is one National cold store with total capacity of 283,000 liters in 2 to 8C and 20,000 liters in the range of -20 C. The table below show the available cold store at the National level as updated January 2021.

Table 3: National level cold store (Cold and freezer rooms) in the Central Vaccine Store				
Central Vaccine Store	Year of installation	Refrigerant gas	Status	Net vaccine storage capacity (in litres)
Cold-room 1	2016	R22a	Functioning	60,000
Cold-room 2	2016	R22a	Functioning	60,000
Cold-room 3	2016	R22a	Functioning	40,000
Cold-room 4	2015	R22a	Functioning	72,000
Cold-room 5	2014	R404a	Functioning	25,000
Cold-room 6	2007	R22a	Functioning	10,000
Cold-room 7	2014	R134a	Functioning	10,000
Cold-room 8	2002	R134a	Functioning	6,000
Total				283,000
Freezer-room	2021	R404a	functioning	10,000
Freezer-room	2014	R404a	functioning	10,000
Table shows the detail of the freezers in National store this Store.				
	Quantity	Year of installation	Refrigerant gas	Status
TFW 800- Dometic/B Medical	8	2016	R134a	functioning
TFW 800 Electrolux	5	2014	R134a	functioning
TFW791 Electrolux	1	2002	R134a	functioning
Chest freezer Ocean	4	2005	R134a	functioning
Source: Updated CCE Inventory and gap analysis- (recent update 2021)				

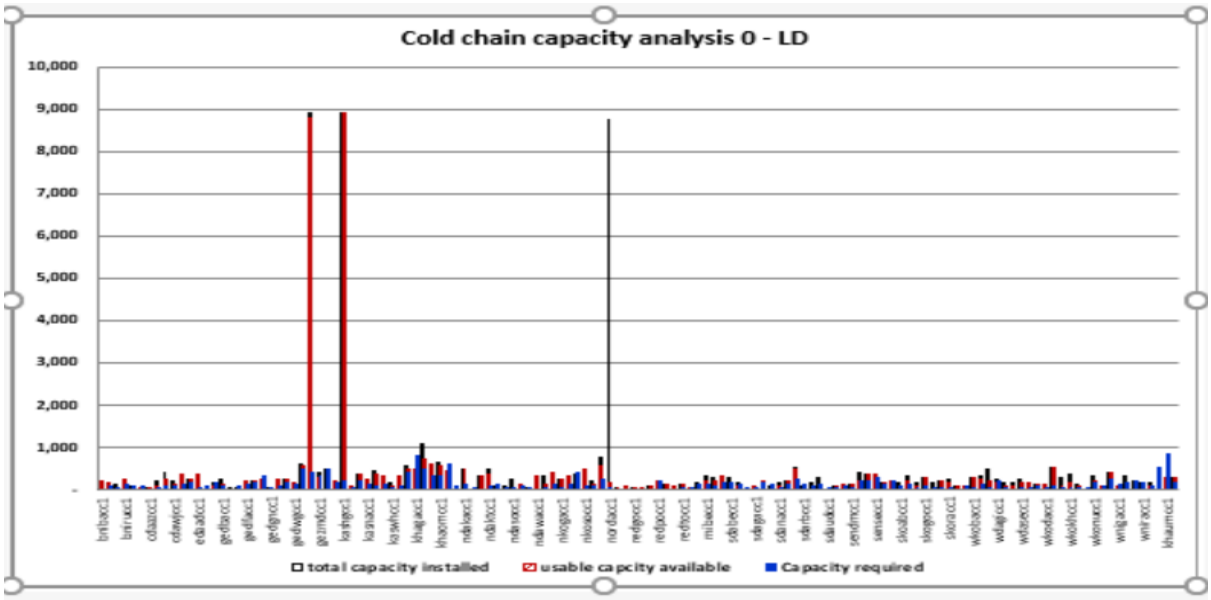
At the state levels (Sub-National) there are 18 stores one in each state with adequate capacity in all states except Gazira state (see table two). One large cold room of 40 cubic meter has been deployed to Gazira state to overcome the issue of the storage capacity and will be installed in the next month. Two states cold chain building needs rehabilitation (Namely Khartoum and Gezira) to install additional vaccine storage capacity.

Table 4: available and gap vaccine storage capacity by states:

State	Location	Number of equipment				Available capacity		Gap/ excess lit	
		Refrigerators	Freezers	Cold Rooms	Freezer Rooms	2-8 degree C	below 0 degree C	2-8 degree C	below 0 degree C
Blue Nile	Damazine	2	0	2		17143	2733	2167.5	95.6
Central Darfur	Zalingi	22	13	1		8936	2236	2493.6	110
East Darfur	Eldeain	10	7	1		9962	1118	2373.4	104.7
Gedarif	Gedarif	0	0	2		17143	639	4873.9	215
Gezira	Madani	0	0	1		8571	847	(-) 9858.8	434.9
Kassala	Kassala	16	0	3		25714	1050	4033.6	178
Khartoum	Khartoum	2	2	1		14334	891	12337.8	544.3
North Darfur	El Fasher	2	2	1	1	8760	9956	5775.7	254.8
North Kordofan	El Obaid	7	5	1		8892	1101	4105.4	181.1
Northen	Dongola	13	8	1		8796	865	1049.5	46.3
Red Sea	Port Suda	8	0	1		8679	736	1306.3	57.6
River Nile	Atbra	1	0	1		8571	842	2255.9	99.5
South Darfur	Nyala	5	4	2		17394	1980	7575.9	334.2
Sinnar	Sinnar	0	0	2		17143	789	3724.1	164.3
South Kordofan	Kadugli	17	8	2		18129	2094	3032.4	133.8
West Darfur	Genina	5	2	1		8924	1250	2817.3	124.3
West Kordofan	El Fula	6	6	1		8907	843	3259.9	143.8
White Nile	Rabak	0	0	1		8571	1215	4259.8	187.9

Source: Updated CCE Inventory and gap analysis- (recent update 2021)

At locality level there is 186 locality level cold store and the analysis of the gap is shown in the figure below.



At services delivery level there is 2,622 fixed sites with cold chain equipment that will be used in the COVID vaccination sites to keep COVID vaccines that need to be kept in the range +2 to +8 C (refer to table one for number of facilities and cold stores by states.)

Table 5: Vaccine stores at different levels by states.

State	State vaccine stores	Locality vaccine stores	Health facilities	Total facilities
Blue Nile	1	7	55	63
Central Darfur	1	7	34	42
East Darfur	1	9	54	64
Gedarif	1	12	169	182

Gezira	1	8	220	229
Kassala	1	11	102	114
Khartoum	1	7	538	546
North Darfur	1	18	138	157
North Kordofan	1	8	203	212
Northern	1	7	60	68
Red Sea	1	10	67	78
River Nile	1	7	100	108
South Darfur	1	21	145	167
South Kordofan	1	13	84	98
Sinnar	1	7	133	141
East Darfur	1	8	114	123
West Kordofan	1	14	119	134
White Nile	1	9	86	96
	18	183	2,421	2,622

Vaccine ordering and shipment plan:

As soon as the national deployment plan approved, UNICEF country office will coordinate with the national government and supply division. The country will prepare the vaccine request and complete receiving advice and once the sale order is raised for vaccines and the Purchase order are available, the team will start coordinating to receive the vaccines. Shipments size will be coordinated to manage the maximum volume to receive at once and the capacity of receiving teams to receive, unpack and store the arrived vaccines, shipment arrival schedule will be designed to allow timely and effective management of the arriving vaccines. The first 3.396 million doses from AstraZeneca will be received in three equal lots and with interval of one week between each shipment and the other.

As per the standard procedures, the country will require certificate of origin and corticate analysis before vaccine arrived in country. There are two logistic offices who will handle vaccines receiving process. Once vaccines become ready, the Pre-Advice for shipment should be shared with clearance officers for safely procedures. EPI cold chain will be part of the loop in preparation to receive the vaccine. vaccines will be monitored through the cold chain through controlled cold chain system and with temperature monitoring devices. Reports on vaccine utilization and balance will be shared in daily basis with states and levels for review and advice.

Human Resource:

The country will capitalize in the current infrastructure and human resources available in immunization supply chain to manage the deployment of vaccines coming through COVAX facility. This will include the first deployment of 3,396,000 doses from AstraZeneca and possible other deployment including from Pfizer. The management will include from the entry point up to the beneficiaries; this include logistic, vaccine management component and vaccine transportation from the Central cold through supply chain.

The country has 10 supply and logistic officers at the national level managed by the national cold chain manager and 3 assistants one as deputy manager who oversees the zonal coordinators, maintenance and dry store management personnel, one monitoring specialist and supply receiving and dispatch coordinator. At sub national level at all states there one cold chain manger assisted by cold chain technicians (average of three in all states). At localities level, the cold chain is managed by the locality operation officers assisted by cold chain technician while at the service point, vaccine management is part of vaccinators' responsibilities.

All staff dealing with cold chain and vaccine management at the national, subnational are trained on Effective vaccine management and most of the locality level staff are trained. Due to the high turnover and management changes, there is need to conduct periodic training to train the new staff as soon as they joined the programme. The country is currently planning to conduct back to back sessions to train 60 cold chain officers on vaccine and cold chain handling at the national level and planning to rollout the training to the locality and down to the service points. It's agreed that sessions on COVID vaccines management will be part of the training that will take place in March 2021. Ministry of health also planning to conduct Mid-Level Management (MLM) training using the new modules and COVID vaccines will be covered as part of the MLM and all other EPI related trainings.

For the first shipment of 3,396,000 doses from AstraZeneca, federal ministry of health will train 30 supply and logistician officers, 1,035 service providers and four administrative teams from the first targeted states.

Cold Chain Human resource advanced training:

To ensure proper management of all type of COVID vaccines and in anticipation Pfizer vaccine may be deployed at any time through COVAX, the FMoH with support from UNICEF and WHO will ensure that four cold chain officers and logisticians will be trained and assigned to manage and coordinate the UCC and all vaccines that require Ultra-Cold Chain. Guidelines for receiving, storing and distribution of Pfizer vaccine is under development. The staff who will manage the vaccination at the outreach sites will be trained in how to handle the vaccine through the supply points from the time they receive, store and thaw it in the refrigerators from +2 to+8, and safely deliver it to beneficiary before discard point and take care of the thawed and others in temperature +2 to +8. The guidelines for vaccine management at the outreach site are currently under development will focus on minimizing wastage rate. The staff will also be trained in orientation, immunization safety, vaccine use and discard points and how to monitor post vaccination adverse events follow-up and reporting.

Vaccine logistic

Refrigerated vehicle will be used in all vaccine movement within the country from airport to the National Central Cold store and then to the states cold chain in the targeted states. Vaccine will be distributed directly from the state level cold store to the selected vaccination sites in the targeted states. At the state level cold chain, vaccine will be kept in cold rooms,

Gazira state will install cold room before vaccine arrival to overcome the storage gap in state cold chain at health facility level, vaccine refrigerators will be used to keep the AstraZeneca vaccine in the normal temperature range of +2 to +8 C. All vaccines will be transported in controlled temperature from +2 to +8 C in passive containers using conditioned icepacks and then loaded in refrigerated trucks. The Cold boxes that will be used to transport the vaccines most be supplied with continuous temperature monitoring devices through the supply chain and all staff will be trained on how to read them and take appropriate e actions if the vaccine reached discard point at any time through the supply chain.

To reduce vaccine wastage for both system and operational wastage, proper vaccine management training will be conducted for all involved to ensure everyone through supply chain will carry out his/her role and responsibilities. The first batch will include training of 1,065 staff and four management teams. The supply and logistic plans are developed to ensure that there is zero system's vaccine wastage and to adhere to the minimum accepted level of vaccine utilization wastage rate. Reverse cold chain will be considered to prevent single dose wastage; vaccine will be transferred back to the states' and central store if remain after completing the course of the campaign. Cold chain equipment are available at all levels, health facilities with gap in capacity will receive additional space from the equipment already brought by UNICEF and Health System strengthening. CCEOP equipment will arrive late in March and will be used for the second and upcoming COVAX vaccine shipments. The Passive containers are available at all supply level with adequate quantities to meet the anticipated need with buffer stock already available at national level. Back -up generators are available at national and state cold store to avoid any risk in temperature range well in advance.

Vaccines for fixed sites will include outreach quantities and will be transported and managed at the health facility cold chain while mobile teams will take vaccines for up to five days.

To ensure enough space for possible supply of COVID vaccines that require special temperature range, Ultra-Cold Chain capacity is readily available in country in two locations, namely the Institute of Endemic Diseases, University of Khartoum which has 2 ultra-cold chain freezers ready for the use. Additional two ultra-cold chain equipment are available in the National Public Health Lab. The total free capacity available for the first Pfizer small wave in the two locations is 3,452liters. The Federal Ministry of Health also considering installation of three Ultra Cold Chain that received last year for National Lab but were not installed, the installation site will be in National EPI Cold Store within period of two weeks. It's worthy to mention that one private company has reviewed the ultra-cold chain need and they are working to support provision of 4,000 liters of ultra-cold chain equipment and possible installation support to prepare for possible deployment of vaccines that require -70C.

Two standby generators are available in the two locations and ready to use to ensure stable and continued electricity supply for the UCC. Additional two generators were released to the national cold store in preparation to install the new units. The UCC will be kept monitored 24/7 to maintain controlled temperature level and ensure that the electricity supply and the ambient temperature will allow attaining and maintaining the required ultra-freezing level.

The country is also planning to use the dry ice. Two suppliers are assessed to provide the needed dry ice and found to be having adequate capacity for production of around 50 kg and they agree also in principle to prioritize the vaccination need during the first wave. The FMoH still to calculate the need for the dry ice and agree with suppliers with obligated contracts. Once the guideline for calculation has become available for countries, FMoH will come with the need for dry ice. FMoH agreed with the supplier to train the FMoH key relevant staff on dry ice management and use.

Outreach vaccination sites arrangement for Pfizer vaccine (if supplied):

The 10 selected outreach sites are all equipped with well-functioning Ice-Lined refrigerators/freezers (ILRs). Additional ILRs are available at the national cold store to be installed if storage capacity expansion is required. The 10 outreach vaccination sites will be staffed and arranged as follow:

1. The selected sites should have functioning cold chain with adequate free space available to accommodate the Pfizer vaccine supplies required to be kept at the level of the selected facilities (if needed additional ILR will be deployed to the site from the national cold store). No passive cold boxes will be used to store vaccine in the outreach site.
2. All refrigerators will be equipped with temperature monitoring devices with outside display screen to monitor the temperature;
3. In immunization site, vaccine will be received based on the expected number of beneficiaries for the specific day and vials will be thawed only when beneficiaries are available to reduce the chance of vaccine wastage
4. Vaccine will be transported in manufacturer secondary packing after replacing the dry ice at the UCC central unit. Refrigerated vehicles will be used in all vaccine transportation stages. Refrigerated vehicles will be equipped with temperature monitoring devices to monitor the temperature
5. PPEs to deal with the dry ice will be supplied with adequate quantities to all vaccination sites
6. The outreach immunization site will have screening and reception compartment with security enforcement. In this section, the targeted individuals will be screened to ensure their eligibility, medically checked for vital signs, receive orientation on vaccination and then registered and sign the consent.
7. After signing consent, the eligible individuals will be assigned to immunization desk to get the vaccine and immunization card.
8. After vaccination, the vaccinated individuals stay for at least 20 minutes;
9. The vaccination site will have emergency unit to deal with any case of reaction and anaphylactic shock.
10. If some vials are remaining from the specific day supply, it will be kept in the ILRs and clearly labeled to be used in the next day. All diluted vials will be used only for six hours and the arrangement of beneficiaries will focus in minimizing the risk.
11. All sites will follow waste safety and management and monitoring adverse events following immunization.

For other immunization consumables, the government will cover the needed cost and could borrow supplies and replenish it once procurement completed. FMoH will use UNICEF procurement services to bring in injection and safety related supplies.

PPEs for Health workers involved:

Currently there is stock of PPEs for routine immunization and continuity of PHC service delivery. The country will supply all selected health facilities and others with adequate PPEs including face mask, sanitizers and other necessary PPEs, meanwhile sale orders for full need will be raised as soon as fund transfer is completed to replenish the depleted supply stock, for other future rounds PPEs need will be secured well in advance to ensure safety and timely implementation. Other injection safety supplies including soap, water, printing, and others will be outsourced from local market for fast track process.

Waste management:

Based on the previous experiences from campaigns where injections are the delivery modality, the country will use the standard pre-qualified injection supplies through UNICEF system, this also include procurement of safety boxes. Reuse protection syringes will be used without recapping and used syringes will kept in standard safety boxes (there is syringes arriving for routine and YF campaign that are arriving, and the country will borrow and compensate later before the campaign date in June 2021. Other safety supplies such as cotton, sub, PPEs, sanitizers are all locally procured supplies and will be ordered from the local market. once the day end, the supply officers will collect the used syringes in the safety boxes and other injection safety supplies and will burn them according to the panned method of treatment and will be documented for future planning.

8. Vaccine safety monitoring; management of Adverse Events Following Immunization (AEFI) and Injection Safety

Sudan has a well-established AEFI surveillance since 2005 that at the beginning started as pilot and then scaled up to full system to report AEFI from all vaccination fixed sites in 2011. The AEFI is backed up with the causality assessment committee that formed in 2013, consist of all relevant members and main stakeholders. The establishment was based on WHO guidelines, with participation of WHO, CO, RO and HQ offices in the training and review of the reporting format. In the context of COVID 19 and due to the novelty of the COVID 19 vaccines, and to ensure effective monitoring and management of COVID-19 vaccine safety issues and the required resources in terms of tools, techniques, techniques and guidance, the Ministry of Health has formed a national sub-committee/working group consisting of all vaccine safety stakeholders as part of the national COVAX introduction technical committee to develop the detailed operational plan in relation to NDVP. This plan defines what is meant by pharmacovigilance preparedness, and provides guidance for preparedness, planning and implementation. It also includes section of the safety communication. The safety communication part of the plan describes the expected factors that influence people's perceptions of vaccine safety, communication needs and solutions.

Table (6):Observed and Estimated AEFI reporting for Sudan based on JRF data (2015-2019).

Year	AEFI reported as per JRF data
2015	480
2,016	187
2017	269
2,018	120
2019	1,076

As showed on the above table over the last 5 years, Sudan has well established AEFI system and reports regularly through well-defined system of command. The notification system is the immediate one. The moment the case notifies to the health facility AEFI focal point, and then reports through the channels (HF, locality, and state to the federal EPI) within 24 hours.

Serious AEFI immunization reported, adequately investigated, and classified from 2016 to 2019 were 13, 15,9 and 23 respectively. Showing reasonable capacity which can be strengthened to detect AEFI for COVID-19 vaccines including signals.

For COVID-19 The AEFI surveillance materials will be updated with in context of theCOVID-19 vaccines and the training protocols for serious AEFI will be updated with insurance of the standard measures for dealing with anaphylactic shock or reaction.

Vaccine Safety

The COVID-19 vaccine in general and specific for AstraZeneca. will be kept in the recommended temperature and, as the vaccine has no VVM the other measures of vaccine safety will be vigorously managed and supervised. Starting with the vaccine management once reached the country and transportation from the airport to the central cold chain. Then based on EPI vaccine storage and transportation system the COVID-19 vaccine will be handled with the standard measures to up to the immunization sites. The preparation of the session including the thawing prior to dilution, standard vaccine reconstitution method, appropriate dose, injection site, and route of injection will be highly considered during the training of the vaccinators. In addition, injection safety practices using the safety boxes for the collection and disposal of used syringes and the appropriate medical Waste Management will be strongly implemented**.** The vaccination centre will be designed to accommodate waiting area that expect the beneficiaries to wait after vaccination for 20 minutes to be observed on anaphylactic or reaction and to be treated accordingly**.** Although the vaccination centre will be part of the health facility, still all needed medical supply and medicines (epinephrine) needed for anaphylactic shock on hand very close to the vaccination post.

Essential element of pharmacovigilance is post-licensure surveillance of AEFI, which involves.

- Update of causality assessment committees in the light of COVID-19 vaccines. (More engagement of relevant specialist such as adult medicine) and ensure will be hold on standby.
- Update of guidelines management anaphylactic shock protocol
- Strengthening the AEFI reporting and investigation system
    - Orientation of Physician and Specialist through Scientific forums.
    - Key messages will be developed and disseminated through the vaccinators and will make sure each vaccinee left the vaccination centre with a clear guidance on how to self-report on AEFI.
    - Training of AEFI surveillance officers at all levels on Covid-19 AEFI reporting and AEFI management and injection safety
    - Using hotline for reporting, the number of “4545” it’s the national hotline that currently in use to report the Adverse Drug Reaction. The reporting of COVID 19 vaccines AEFI system will be enhanced through using this hotline after training of the staff working in the call centre.
    - Active AEFI surveillance will be implemented using the existing COVID 19 call centre to follow the vaccinees on a regular basis up to 1 year.
    - An efficient communication mechanism about COVID-19 vaccines between different stakeholders including the beneficiaries will be in place to ensure

that people are fully aware about vaccine safety issues and can report any concerns.

- Strengthening investigating serious AEFI and clusters of AEFI

9. Advocacy, Communication & Social Mobilization

The goal of advocacy and communication is to engage and educate leaders and communities to help them understand, support and demand COVID 19 vaccination services. It also helps planners, managers, and service providers to understand and work better with communities at all levels.

An advocacy, communication, and social mobilization (ACSM) plan will facilitate empowerment of target communities to access accurate and timely information, resulting in greater public awareness and acceptance of vaccination. However, all the services should be offered in observance of the COVID-19 pandemic IPC guidelines currently used in the country. Planning for communication or engagement activity should start at the national level, after political commitment and consensus on the core programmatic aspects of COVID 19 vaccination are agreed upon. This planning should include four critical components which are:

1. Establishing national, provincial, district, and sub district advocacy, communication, and social mobilization subcommittees
2. Developing a communication plan
3. Preparing for management of communication issues (crisis communication)
4. Monitoring and evaluation of communications activities.

Advocacy and communication strategies for COVID 19 vaccination at all levels will be informed by human centered approaches as guided by the EPI policy documents.

Vaccine Acceptance and Uptake (create and satisfy demand)

High acceptance and demand of any new vaccine requires careful and strategic planning. The vaccine acceptance and demand generation interventions aim to ensure high levels of vaccine acceptability and uptake among frontline healthcare workers. This will be achieved through a multitude of interventions pre, during and post the vaccination process.

The main activities include:

- Risk communication and Community Engagement
- Generation of behavioral and social data on vaccine demand and uptake
- Securing high-level political and trusted influencers support
- Capacity building at national and sub-national level
- Risk communication interventions and monitoring and evaluation

Risk communication and Community Engagement

Risk communication and community engagement places communities in an active role for the demand and acceptance of the COVID-19 vaccine by providing factual, timely and appropriately contextualized information about the COVID-19 vaccine.

The prime purpose of risk communication during this COVID-19 pandemic.:

- To ensure that everyone at risk for the disease is informed about risk reduction including how to reduce the risk of spreading COVID-19,
- How to take personal protective and preventive measures,
- What to do when someone is suspected of having the disease,
- Engage the communities as partners in the planning and providing mechanism for feedback and feed forward,

Importantly, the deployment of vaccines in a situation of limited supply creates the need for setting and gaining public acceptance for clear priorities

Generation of behavioral and social data on vaccine demand and uptake

Evidence needs to be generated to inform accurate planning, which will be done through carrying out surveys, assessments, or other forms of rapid data collection activities. In addition, rumor tracking, management and reporting will be conducted on a regular basis to combat spread of misinformation among frontline healthcare workers, which will start from the onset of the vaccination process and continue throughout.

Securing high-level political and trusted influencers support

High level political support from trusted influencers is crucial for adequate implementation of planned interventions during all phases and among all levels. Hence, key pillars within the community should be included in planning and training to gain their understanding and support for the vaccine. Planned initiatives include a launch ceremony in the form of a video recording of the first case of a vaccination subject from the influencer group that will be shared broadly on social media and mass media platforms. Stakeholders and frontline healthcare worker groups will be mapped and identified to be engaged in a proper manner, and Trust Committees will be formulated within the health sector.

Capacity building at national and sub-national level

Ensuring health workers have positive experiences as early beneficiaries of COVID-19 vaccine is crucial, given their influential role as vaccinators, advocates, and change agents in the community, including communication skills training to support them in dealing with misinformation and vaccine hesitancy. Previous researches have demonstrated that healthcare workers can offer interventions to increase vaccination.

The capacity building needs for the frontline healthcare workers will be identified in order to assess the levels of their acceptability, satisfaction and uptake of the vaccine, as well as their abilities to convey the information among their peers and the community at a later stage. Accordingly, these needs and gaps will be integrated into the training tools development and adaptation

As the first vaccine recipients and as vaccinators, health workers must be equipped with the technical capacity and confidence to deliver the vaccines and communicate and engage with the community. Healthcare workers require capacity building in advance of the vaccine rollout. They will need decision-making and job aids to support them in prioritizing eligible

vaccine recipients. Having tailored messaging to reach diverse community contexts, enhanced skills in listening, interpersonal communications and community dialogue will help to equip healthcare workers to hold difficult conversations both in the face of demand from those not eligible to receive the vaccine in the first phases, and those who are hesitant about receiving the vaccine. Listening and collating early experiences, concerns, successes, etc. from healthcare workers will help inform ongoing vaccine delivery. To ensure broader reach of adequate and correct information around the vaccine, messages will be developed, tested, approved and produced throughout the vaccine introduction and implementation process. These messages will be shared through a variety of channels including a website, call center and social media platforms.

Risk communication interventions and monitoring and evaluation

There will be a crisis communication plan in place prior to the introduction of the vaccine if serious misinformation, rumors or any other crisis like (AEFIs) occur. The plan is a part of the overall crisis communication plan. The aim is to investigate and manage the crisis so that it does not negatively affect the programme. This plan will be implemented by a steering committee to address all crisis or misinformation that is anticipated with the introduction of COVID vaccine. A dedicated spokesperson from the steering committee will be responsible for communicating to the public.

10. Surveillance

The national sentinel surveillance includes 1817 reporting sites which roughly represents 30% of all health facilities present in the country. As for community-based surveillance, it is functioning in 15 out of 18 states. Furthermore, there is Event Based Surveillance with an incident tracking reporting system incorporated to it.

Since the report of the first case of COVID-19 , COVID-19 added to group A notifiable diseases and utilized all its existing systems to detect cases; furthermore, sentinel sites were instructed to start zero reporting of COVID-19. Active surveillance has been initiated and Community Based Surveillance activities were expanded. Nevertheless, the surveillance system is facing different challenges including communication irregularity, incompleteness of data, poor contact tracing and under-reporting due to different factors related to health seeking behavior, testing capacity, human and financial resources.

General Objective:

To provide necessary surveillance information within the existing system required for guiding the implementation and adjustment of the COVID-19 vaccination program.

Specific Objectives:

- To update existing COVID-19 surveillance plan
- To estimate vaccine effectiveness (VE) and impact of vaccination through epidemiological studies
- To describe long-term immunity, duration of immunity, and need for booster doses if required
- To address reporting requirements from a global perspective on VE and impact.

Strategies:

- Update the surveillance guidelines, SOPs registration and reporting forms to include checking the vaccination status
- Training and orientation directed towards staff
- Supervision of sentinel sites and teams
- Early detection of cases and contact tracing
- Epidemiological studies
- Reporting and data sharing

The above strategies will be implemented through updating the national plan and including molecular surveillance activities and consequently updating data collection forms. Furthermore, community-based surveillance will be expanded to states affected by COVID-19 in addition to provision of technical support to national, state, and rapid response teams at locality level which includes training and planned supervision. The monitoring of surveillance activities will be through daily and weekly reports in addition to scheduled virtual monthly review meetings with states. Moreover, to assess the vaccine effectiveness epidemiological

studies including observational and serological studies will be conducted once vaccination has been rolled out. Human resources needed to support the surveillance system will be incentivized accordingly.

Outlines of the activities:

Planning and management

- Update the COVID-19 national surveillance plan
- Update of states & Localities COVID-19 surveillance plan
- Conduct molecular surveillance activities
- Expand CBS for COVID-19 affected States including revitalization of the Community Rapid Response Teams (CRRT) focusing on rural, remote, and underserved communities
- Support operational costs (transport and airtime) of RRTs in COVID-19 affected States to support alert verification, investigation, contact tracing and initiation of initial control measures
- Rent vehicles for the RRTs

Training and orientation

- Develop training plan for COVID-19 surveillance
- Training of Trainers (TOT) - Federal & States
- Training of Trainers (TOT) - Localities
- Training of RRT
- Orientation sessions for community level through media outlets
- Orientation sessions for all other health cadre

Supplies& Logistics

- Assessment and evaluation of supplies needed (PPE, Disinfectants, Communication materials and Investigation kits)
- Provision and Distribution of supplies for Call centres, RRT, Surveillance officers, IPC personnel

Printing of materials

- Revise and update surveillance records and collection forms (investigation forms, lab request form and registration form), and develop vaccination card
- Print and distribute the surveillance forms

Monitoring and Evaluation

- Daily and weekly reporting
- Updating and Printing of the supervisory check list
- Supportive planned supervision to all sentinel sites (at least once per site)
- Monthly assessment of overall surveillance implementation activities
- Conduction of epidemiological studies to assess vaccine effectiveness

- Virtual monthly review meeting with states

Human resources

- Provision of Incentives to support staff at call centres, HEEC officers and RRTs (24/7 service)
- Deploy surveillance officers to the isolation centers
- Support contact tracing of COVID-19 cases

11. Costing and funding

Background

Sudan faces economic crisis manifested by devaluation of local currency and decrease in its purchasing power, high inflation rate and rapid unpredictable increase in prices.

This situation has been exacerbated by the unprecedented economic fallout related to the COVID-19 pandemic. Sudan like other countries is adopting expansionary fiscal and monetary policies to lessen the recessionary impact of mitigation measures.
The fiscal space is very limited given the low tax effort and high cost of subsidies, which cannot be eased in the immediate future. The country further faces a binding foreign exchange constraint (official rate I USD = 55 SDG while market rate is 390 SDG), which makes it difficult to import the needed commodities to provide the population with necessities, in the face of COVID 19 induced losses of income and production.

Outlines of the activities:

- Mapping all partners that involve in supporting national response to COVID-19
- Advocacy meetings to mobilize domestic resources including with the private sector
- Include COVID vaccine program costs (vaccine, operating costs, HR and capital costs) in government budgetary and other planning documents approved by the appropriate authority; in addition, include appropriation or allocation (from MOF/treasury) in the cash planning as an additional means to ensure that financing is readily available.
- Conduct\complete Vaccine Introduction Readiness Assessment using integrated VIRAT tool
- Supportive financial supervision to follow preparations and implementation of execution of the planned budget
- Conduct risk mapping analysis to identify possible risks that may hinder execution of the planned budget (devaluation of the local currency; increased inflation; fuel crisis; approvals and fund disbursement; etc.) and implement the appropriate risk mitigation measures

Costing of the NVDP

NVDP is being costed using COVID-19 Vaccine Introduction and Deployment Costing (CVIC) Tool (version 1.0).

Priority interventions were selected guided by WHO/UNICEF guidance on developing a national deployment and vaccination plan for COVID-19 vaccines. Unit costs were calculated based on recent experiences of EPI programme using the official exchange rate (I USD = 55 SDG).

Below table shows the total cost for HI 2021 (this is initial calculation using CVIC Tool and subject to be updated based on feedback of CVIC HQ team). The estimated operational cost

(not including vaccines) is about 3.5 m USD (will be updated once CVIC completed and reviewed).

Vaccines (and customs clearance) - demand-based calculation	$ 18,388,286
Vaccine-related supplies	$ 298,215
Indemnity fund	$ 124,778
Central costs	$ 2,024,852
International logistics	$ 53,255
Domestic logistics - Cold Chain	$ 17,987,410
Domestic logistics - Security	$ 4,680
Delivery (last mile) - results-based	$ -
Delivery (last mile) - input-based (Medium Variant)	$ 6,002,655
Total	**44,884,130**

Partners mapping was conducted to identify all donors and stakeholders who are supporting implementation of COVID-19 National Response Plan. Below table shows the contribution of different stakeholders in the response plan

Stakeholder/partner	**Areas of work/support**	**Estimated cost USD**
Government of Sudan		
WHO	Leadership and Coordination, Point of Entry, Surveillance and Risk Assessment, Laboratory, Case Management, Infection Prevention and Control (IPC), Risk Communication and Community Engagement, Rapid Response Team (RRT), and Isolation centres	7,500,000 (not include the cost of testing kits)
UNICEF	Current Support: Risk Communication and Community Engagement, Laboratory and infection control aspect Potential support: WASH component in the Isolation centres, procurement of medicine, capacity building activities,	8,900,000
UNFPA	Supplies and consumables	
WB	Support implementation of NVDP	
UNDP	Procurement of medical equipment. PPEs and supplies	
Italian Cooperation	Incentives for Health workforce	100,000€
Domestic donation (Private companies	Laboratory, Case Management, Infection Prevention and Control (IPC), Risk Communication and Community Engagement,	$2,000,000 Plus in-kind donation

Sudanese business men federation, Sudanese exporters chamber, telecom-companies	Rapid Response Team (RRT), and Isolation centres	
Qatar	Emergency medicines, Ambulance	
UAE	Emergency medicine	
King Sulman Relief Centre	Emergency medications IV flowed	1,600,000$
China	In kind (testing kits, PPEs, medicines)	
CSOs		
CDC Africa	Laboratory (training & kit for testing)	
DFID/FCDO	Testing kits, PPEs	300,000
Korea	In kind (testing kits, PPEs, medicines)	
EU	Construction of isolation centres, ambulances, training, medical equipment, and operational cost	20,000,000
Gavi		1,200,000
The Global Fund		1,600,000
UNAMID		1,900,000

Government requested the World Bank to cover the cost implementation of the NVDP (operational cost), and the WB confirmed their readiness to cover the operational cost.

FMOH is working with Ministry of Finance to include COVID vaccine program costs (vaccine, operating costs, HR and capital costs) in government budgetary and other planning documents to be approved by the cabinet as an additional means to ensure that financing is readily available. Moreover, FMOH supported by WHO and UNICEF is advocating other donors and partners including bilateral to secure additional amounts of vaccines and support implementation of NVDP. There is a plan to engage private sector, NGOs and other national stakeholders in the process.

Risk mapping and analysis to identify possible risks that may hinder execution of the planned budget (devaluation of the local currency; increased inflation; fuel crisis; approvals and fund disbursement; etc.) is planned to be conducted before start of implementation of NVDP. Accordingly, appropriate risk mitigation measures will be adopted.

12. Vaccination of the Special Population

Sudan hosts one of the largest refugee populations in Africa. as of December 2020, the Sudan hosts over 1 million refugees. South Sudanese make up the majority. Many others fled violence and persecution in neighboring countries, including Eritrea, the Central African Republic, Ethiopia, and Chad, but also the wars in Syria and Yemen pushed people to seek safety in Sudan. Most refugees live in out-of-camp settlements, host communities and urban areas, while others stay in 21 camps (9 at the East Sudan, 9 at White Nile State, 2 at East Darfur State and 1 at the Central Darfur State).Sudan continues to generously host and receive additional asylum-seekers

Inter-tribal clashes in Central African Republic (CAR) have been ongoing since September 2019 and led refugees from CAR to flee to safety in Sudan. The situation along the CAR-Sudan border remains tense and extremely volatile. UNHCR has revised its 2020 planning figure for CAR refugee arrivals to 20,000 individuals by end of 2020. generously host and receive additional asylum-seekers.

Beginning of November 2020, UNHCR has recorded an influx of asylum seekers at border entry points in East Sudan from Ethiopia, after military confrontations in the Tigray region in northern Ethiopia. UNHCR's teams at the border areas of the eastern Sudanese states of Kassala and Gedaref are working with the Sudanese Commissioner of Refugees (CoR), local authorities and partners to monitor and respond to the situation, as well mobilizing resources to provide life-saving assistance services to the new arrivals. Inter-agency coordination and contingency response planning is well underway. currently, more than 60,000 Ethiopian refugees are settles in the 4 camps in Gedarif and Kassala states

Humanitarian situation

Congested camps, poor sanitation and limited access to safe water are further challenges affecting the health of the refugees. The El Nino phenomenon has already impacted the area with significant increase in Malaria cases occurring outside of the rainy season.

In White Nile, however, the situation regarding space in the camps is more critical as new arrivals have passed through reception centers and being relocated to new established camps. There is a backlog of refugees waiting at the reception centers in East Sudan border with Ethiopia for relocation and there is a desperate need to expand existing sites along with services to meet the needs of the unanticipated new arrival caseload, as well as avoid deterioration of basic service standards for refugees already living in the increasingly overcrowded sites.

COVID-19 Among IDPs, Refugees, Migrants and Returnees-Based on weekly received data from WHO field offices 2020-2021

Since May 2019 WHO-EMRO has requested detailed separate reporting for COVID-19 among IDPs, Refugees, Migrants and Returnees in Sudan EWARS seven states. The collected data reflects the state activities regarding; types of implemented COVID-19 activities

(Coordination, Surveillance IPC and case management) and investigation of COVID-19 rumors circulating at camp's level

Five states reported COVID-19 confirmed cases at camps during 2020-2021; South Darfur reported 45 cases of which eleven are reported during 2021 and majority of the cases were from Gereida and Otash camps. East Darfur state reported a total of nine confirmed COVID-19 cases mainly from Kario and Alfords's south Sudanese refugee's camps, three cases reported in January 2021. Each of North Darfur and White Nile states reported seven confirmed cases during 2020 and no confirmed cases during 2021. Since the beginning of the Ethiopian refugees' influx to Eastern Sudan; Gadarif states reported a total of 6 confirmed cases including one associated death since week 52/2020 distributed at the three settlements within the state.

Sudan will request COVID vaccines through the humanitarian Buffer as part of the country allocations

The IDPs will be considered and prioritized as part of the overall national population, using the scoring system based on all the risk factors for them

Objectives of the vaccination:

- Ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings

Reaching high risk groups in inaccessible and underserved areas

High impact of the COVID vaccination can be achieved only through reaching all prioritized individuals regardless of the geographical and social location. The marginalized individuals are more likely to be not vaccinated through the identified services delivery strategies, because neither the health service nor the communication mechanisms reach their communities. Therefore, a context specific strategy will be developed to vaccinate target health workers and elderly with comorbidity in hard to reach, urban slum and migrant groups during the coming nationwide COVID vaccine campaign. The strategy will use the micro-plans data to identify and cover the most marginalized community. Context specific communication strategy tailored to meet the informational need of the vulnerable group would also be part of the strategy. Outreach and mobile strategy through dedicated vaccination team will be initiated to reach individuals