Guidelines and Standard Operating Procedures (SOPs)
Sinovac Vaccine (CoronaVac)
Target Audience

- All the concerned national, provincial & district health authorities and health care workers who are involved in the COVID-19 vaccine operations, establishment, and management of COVID-19 Vaccination Counters both at public and private health facilities.

Objective of this document

- To provide guidance on Sinovac COVID-19 Vaccine (CoronaVac) storage, handling, administration and safe disposal along with recommendations for vaccine recipients. Vaccination should not be considered as an alternate for wearing a mask, physical distancing and observing other SOPs for COVID-19 prevention.

Vaccine Basic Information

- CoronaVac manufactured by Sinovac Biotech Ltd. is an inactivated virus COVID-19 vaccine.
- Active ingredient: Inactivated SARS-CoV-2 Virus (CZ02 strain).
- Adjuvant: Aluminum hydroxide.
- Excipients: Disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride.
- CoronaVac is a milky-white suspension. Stratified precipitate may form which can be dispersed by shaking.

Vaccine Dose

- Two doses should be administered by intramuscular injection in the deltoid region of the upper arm.
- The second dose should be given 28 days after the first dose.
- Each vial (syringe) contains 0.5 mL of single dose containing 600S8U of inactivated SARS-CoV-2 virus as antigen.

Who should receive CoronaVac:

- Individuals who are 12 years of age and above.
- Vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19, including obesity, cardiovascular disease, respiratory disease and diabetes.
- Pregnant women and those who are breastfeeding
Who should NOT receive CoronaVac:

- People with history of allergic reaction to CoronaVac or other inactivated vaccine, or any component of CoronaVac (active or inactive ingredients, or any material used in the process).
- Previous severe allergic reactions to the vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.).
- People with severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.).

Shelf life

- The expiry date of vaccine is indicated on the label and packaging
- The shelf life is 12 months

Vaccine Storage

- Store in a refrigerator (+2°C to +8°C).
- Do not freeze. Protect from light.
- The outside refrigerator (room) temperature should not be more than (+25°C).

Pre-Vaccination Phase

- Designated Nurse/Skilled Immunization Staff/Vaccinator/ Doctor should administer the vaccine
- The CVC staff should have prior training on vaccine handling, cold chain, Infection Prevention Protocols, Reporting Tools / MIS and Adverse Events Following Immunization

Vaccination Phase

Administration

- Precautions
  - CoronaVac for intramuscular (IM) injection only, in the deltoid muscle.
  - The vaccine should be inspected visually prior to administration and discarded if particulate matter or differences in the described appearance are observed.
  - Contraindications, warnings and precautions to injection must be checked prior to administering the study injection.
- This vaccine is strictly prohibited by intravascular injection. There are no data yet on the safety and efficacy of this vaccine by subcutaneous or intra-dermal injection.
- Before use, check whether the packaging container, label, appearance, and expiration date meet the requirements. It should not be used under following circumstances: damage or crack, spots, stains, scratches on the outer surface of the vaccine container, unclear label, expired vaccine, or abnormal appearance.
- Adequate treatment provisions, including epinephrine injection and emergency treatment, should be available for immediate use. Individuals should be observed for at least 30 minutes on site after vaccination.
- Avoid exposing CoronaVac to the disinfectant during use.
- Do not freeze. It should be administered immediately after opening the vial.
- Avoid contact with vaccine fluid when opening.
- The vaccine does not contain any preservative
- To facilitate the traceability of the vaccine, the name and the batch number of the administered product must be recorded for each recipient

**Steps**
- Wear mask and observe COVID-19 SOPs
- Greet the client
- Complete verification process in the National Immunization Management System (NIMS)
- Take consent. Since vaccine may be administered to both walk-in and previously registered patients, consent should be worded accordingly, e.g “I agree to receive this COVID-19 vaccine because I have registered myself in the system” or “I agree to receive this COVID-19 vaccine to avail walk-in vaccination facility”. (Annex)
- Expose site (deltoid of non-dominant arm) for administration
- Explain the procedure and inform that some pain on giving injection, discomfort at the site of injection or fever after the injection, may happen
- Take vaccine vial out of the vaccine carrier
- Open the vial by removing plastic cover/cap
- Take out 22G-25G 0.5ml syringe and remove needle cap
- Discard the needle and syringe in safety box
- Insert the syringe needle through the top rubber pad of vaccine vial
- Draw 0.5ml of diluted vaccine from the vial
- Inject intra muscularly at the site of injection at an angle of 90° (right angle) following “No-touch technique”

**During vaccination, do NOT**
- Touch the rubber pad of vaccine vial (causes contamination and result in AEFI)
- Recap needle of syringes (can cause needle stick injuries)
Post Vaccination Phase

**Vaccine Related Wastage and Disposal Guideline**

- Syringes, needles, and empty vaccine vials should be placed in an FDA-approved sharps container. Such containers are made from rigid, puncture-proof plastic and prevent injury and spread of infectious waste.
- Never discard needles or other sharp objects in the trash or loose into the bio-hazardous waste box/container.
- Remaining doses of vaccine is not hazardous and does not contain any viral material. Leftover doses of vaccine, may be disposed off in accordance with state regulation requirements for non-hazardous pharmaceuticals.
- After administration of vaccine, remove gloves and perform hand hygiene. Gloves may be discarded in a regular bin if they are not overtly contaminated. If there is bleeding, contaminated gloves should be discarded in biohazardous waste bin.

**General Measures Post Vaccination**

- Complete entry in the NIMS
- Send the client for observation area for 30 minutes
- After 30 minutes if no acute adverse events are experienced by the client, explain the next steps on follow up visit for second dose and to report to health facility/1166 helpline if any adverse event is experienced

**Adverse Events Following Immunization (AEFI)**

According to the grading standard of adverse reaction incidence from Council for International Organizations of Medical Sciences (CIOMS), i.e. very common (10%), common (1%-10%), uncommon (0.1%-1%), rare (0.01%-0.11%) and very rare (<0.01%). All adverse reactions are summarized and described as follows:

**Local adverse reaction at injection site**

- Very common: pain.
- Common: swelling, pruritus, erythema, induration.
- Uncommon: burn at injection site.

**Systemic adverse reactions**

Very common: headache, fatigue
Common: myalgia, nausea, diarrhea, arthralgia, cough, chills, pruritus, loss of appetite, rhinorrhea, sore throat, nasal congestion, abdominal pain

Uncommon: vomiting, hypersensitivity, fever, tremor, flushing, edema, dizziness, drowsiness

Rare: muscle spasms, eyelid edema, nose bleeds/epistaxis, abdominal distension, constipation, hyposmia, hot flashes, hiccup, conjunctival congestion

Severity of adverse reactions

- The severity of adverse reactions observed in these clinical trials is mainly Grade 1 (mild), the incidence rate of adverse reactions for Grade 3 and the above was 1.31%.
- Grade 3 and above adverse reactions include pain at injection site, cough, fever, headache, sore throat, abdominal pain, dizziness and drowsiness.

Serious adverse event (SAE)

- No serious adverse event related to vaccination was identified

Vaccination should not be considered an alternate for:

- Wearing a mask
- Physical distancing
- Observing other SOPs for COVID-19 prevention

The Ministry acknowledges the contribution of Mr Syed Shamim Raza in updating the guidelines

For more information, please contact:

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