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 90º (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
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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.
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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: