

COVID-19 Vaccine Safety Interest Group (CVSIG)

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Recommendations for Global Implementation of Safe
COVID-19 Immunization Practices



Introduction

In late 2019, the first cases of a novel human coronavirus disease 2019 (COVID-19)* were reported in Wuhan, Hubei Province, China.

Caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)*, this public health concern was recognized in January 2020, by the World Health Organization (WHO) naming this highly-contagious, rapidly-spreading outbreak under the acronym COVID-19, and two months later, COVID-19 was declared a pandemic.¹

In early 2020, worldwide measures were put in place to stop the spread of the virus. Social distancing, masking, proper hand hygiene and travel restrictions were enacted. Rather quickly, stay-at-home lockdown rulings were enforced worldwide. The need for a vaccine was evident. With unprecedented multinational collaboration and expedited development, the first human trials of a vaccine to protect against COVID-19 began in March 2020.^{2,3}

During the fall of 2020, as the world waited in anticipation for the emergency use/conditional marketing authorization of COVID-19 vaccines, members of the **International Medication Safety Network (IMSND)** began to discuss safety issues that might impact global immunization roll out efforts with regard to the knowledge on vaccination errors already gathered by the IMSND and its members.⁴

With the goal of sharing experience and learning from member countries to address COVID-19 vaccine safety issues, the IMSND Executive Committee formed the **IMSND COVID-19 Vaccine Safety Interest Group (CVSIG)** in February 2021. The two primary objectives of the initiative were to address issues encountered by members during global vaccine rollout and to create a guiding document of experience-based safety recommendations.

International Medication Safety Network

The International Medication Safety Network (IMSND) is an international network of safe medication practice centers established with the aim of improving patient safety. This is achieved by operating medication error reporting programmes and producing guidance to minimize preventable harms from medicine use in practice. IMSND promotes safer medication practice to improve patient safety internationally.

For more information: www.intmedsafe.net/about/





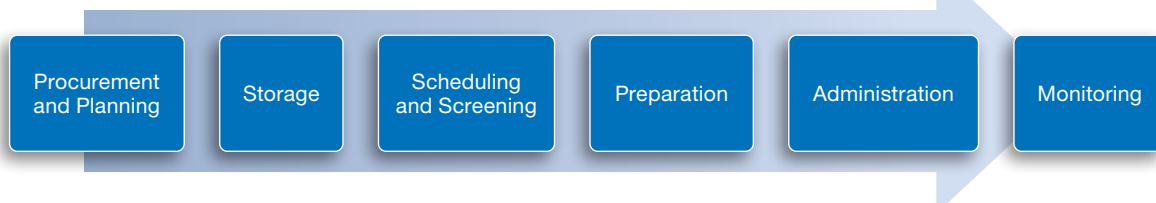
Building a Response to the Different Types of Vaccine-Related Errors

In a series of CVSIG meetings in mid-2021, as vaccination campaigns rolled out, IMSNI members shared firsthand experience with a variety of risks, near-misses, errors[^], and adverse events following immunization with COVID-19 vaccines⁵. These included issues with screening (e.g., wrong age, patients with contraindicated conditions), storage (e.g., inappropriate storage temperature, confusion and mis-selection resulting from storage near other vaccines or monoclonal antibodies), preparation (e.g., serial errors for vaccines needing a two-step reconstitution process, diluent errors including incorrect diluent volume or no dilution, dosing errors including wrong dose, no dose, expired dose), administration (e.g., shoulder injury related to vaccine administration, wrong time interval for second dose or third dose, syringe and/or needle malfunction or misuse leading to underdose, wrong vaccine, wrong drug, wrong route of administration, accidental exposure), and monitoring (e.g., missed second or third doses). IMSNI members also provided a pharmacovigilance overview of adverse events following immunization reported with COVID-19 vaccines.

In addition, the approach to errors has evolved over the course of COVID-19 vaccination campaigns (for example, intervals between doses, authorized ages, authorized doses, and recommended vaccines).

The following safety recommendations were developed based on the collective experience and learning from IMSNI member countries and should be considered for implementation in global COVID-19 immunization efforts. The recommendations shared below follow the vaccine use process and address errors occurring during each stage.

VACCINE USE PROCESS



While these safety recommendations are targeted for the COVID-19 global immunization campaign, many will also apply to the prevention of errors in other vaccination efforts.

References

- * Officially named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) by the International Committee on Taxonomy of Viruses (ICTV)
- [^] A vaccine error is any preventable event that may cause or lead to inappropriate use of the vaccine or patient harm. Centers for Disease Control and Prevention. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-A>
- 1. Centers for Disease Control and Prevention, COVID-19 Timeline www.cdc.gov/museum/timeline/covid19.html, accessed 12/28/21
- 2. National Institutes of Health U.S. National Library of Medicine, ClinicalTrials.gov, accessed 12/28/21
- 3. World Health Organization International Clinical Trials Registry Platform (ICTRP) www.who.int/clinical-trials-registry-platform, accessed 12/28/21
- 4. International Medication Safety Network (IMSNI) Position Statement on Safer Design of Vaccines Packaging and Labelling 2015 <https://www.intmedsafe.net/imsn-advocacy/imsn-advocacy-for-vaccine-safety/2015-imsn-position-statement-on-safer-design-of-vaccines-packaging-and-labelling/>
- 5. Aggregated analysis by CVSIG members; see full list of CVSIG presenters in the Acknowledgements and Disclosures section of this document



Procurement and Planning

- Communicate the quantity of vaccine to be delivered and its approximate arrival time to the receiving staff to ensure the facility is prepared (e.g., staff and storage space) to accept the shipment
- When preparing for vaccination clinics, ensure adequate vaccine doses and vaccine preparation and administration supplies (e.g., diluent, syringes, antiseptic, adhesive bandages, vaccination cards) are available based on the anticipated number of people to be vaccinated
- Follow a first in, first out inventory management method for vaccines and plan for end of clinic doses to minimize vaccine waste
- Communicate who is eligible to receive vaccines in a clear, well-defined, and widely-available vaccine roll out plan and guidance document

Storage

- Plan for appropriate storage of vaccines taking into consideration the volume of inventory to be kept on hand, the required storage temperature(s) and equipment and transportation needs
- Ensure consistent maintenance of cold chain storage units (e.g., refrigerators and freezers)
 - Monitor and record storage temperatures daily
 - For refrigerator or freezer storage, check and record the minimum and maximum temperatures at the start of each day and check the current temperature each time vaccines are accessed
 - Consider use of remote cold chain storage temperature monitoring with temperature excursion alerts
 - Identify personnel responsible to remotely monitor devices and those who should receive emergency notification should equipment fail
 - Provide maintenance of remote monitoring systems, as appropriate
 - Take appropriate action anytime vaccine storage temperatures are out of range
- Maintain proper storage conditions for vaccines during transportation and distribution including minimization of product movement within containers
- Store vaccines in a manner that avoids confusion with other medications, other vaccines, or other concentrations of the same brand vaccine
- Store each batch of the same vaccine according to validity date



Scheduling and Screening

- During appointment booking, screen patients for vaccine eligibility based on contraindications, patient age, time/interval between doses, and prior vaccinations
- When multiple vaccine doses are required to achieve immunity, ensure patients are appropriately scheduled to receive subsequent doses
- Use multilingual communication, interpreters, and translators, as appropriate when communicating with patients
- Where possible, ensure appropriate facilities for neuro-disability (e.g., mental health and intellectual disability) patients
- When utilizing online vaccine appointment scheduling, provide alternative options for those unable to use or access the online system
- Consider site location and weather conditions when booking appointments
- Prioritize vulnerable patients in the queue

Preparation and Administration

- Train vaccinators on how to prepare (as required) each dose, including how to use vials, prefilled syringes, and/or syringes and safety needles and on how vaccines must be administered including the approved route of administration, dose(s), risk for shoulder injury related to vaccine administration and how to prevent it
- Provide both didactic and practical training of staff prior to them showing up for vaccination duties; once at the vaccination site, provide direct, on the job observations of preparation, as appropriate, and administrations prior to allowing immunization staff to work independently
- When possible, have different staff to prepare and label vaccines from those who will administer vaccines

Preparation

- Establish a separate, clean, organized, distraction minimized area for vaccine preparation
- When multiple brands of vaccines are in use, restrict to one brand/vaccine type available at each vaccination site, when possible
 - If unable to restrict to one brand/vaccine type per location, provide segregated workspaces for each vaccine type
- When a vaccine requires dilution, apply a label to the vial to indicate that the diluent has been added and include the date of expiry (beyond-use date)



- Segregate diluted vaccine vials from those that have not been diluted
- Label each syringe filled with a dose of vaccine drawn from a multi-dose vial, with at a minimum, the name of the vaccine, dose, lot number, and time and date of expiry (beyond-use date), except if they are being prepared and administered immediately thereafter
- During preparation, follow a workflow that supports timely identification of errors
 - For example, working with only one vial at a time, withdraw all doses from the vial and verify the number of filled syringes matches the quantity expected before preparing the next vial of vaccine
 - Store all syringes from one vial together; do not mix syringes from multiple, different vials
 - When possible, have a second person perform a check of the preparation process
- Implement a process that supports easy recognition of patients who may have received a wrong dose/vaccine/diluent or no vaccine
- When possible, have manufacturers provide vaccines in a ready-to-administer form

Administration

- When patients arrive to be vaccinated, identify the patient, and requested vaccine
- Review COVID-19 vaccine eligibility based on vaccine type/brand, patient age, time/interval between doses, and prior vaccinations
- Ensure the patient flow is clearly marked and communicated, and verify that patients understand how to follow the process from intake/waiting room through vaccination administration and monitoring room
- Prior to administration, conduct a visual check of the syringe containing the vaccine to be administered to ensure it contains vaccine (and does not contain only air)
- When possible, involve the patient by asking them to review the information on the labeled syringe or vial as an extra check prior to administration
- Document vaccine administration at the time of administration



Monitoring and Follow Up

- Require vaccination locations to define and follow guidelines to manage medical emergencies
- Have medications and supplies available in vaccine site locations to treat medical emergencies such as an anaphylactic reaction
 - Ensure medications and supplies intended to treat medical emergencies are stored in a manner that avoids confusion with vaccines and vaccine supplies
- Complete a site risk assessment to proactively identify potential clinical and non-clinical risks
- Provide guidance for the management of preparation and/or administration errors
- Educate patients, family members, and/or caregivers on vaccines, adverse events following immunization and when to seek medical advice
 - Use multilingual communication, interpreters, translators, and use of pictograms, as appropriate when interacting with patients
- Communicate with patients and encourage them to complete the vaccination schedule
- When possible, consider use of a patient-facing app to consult with a physician or schedule an appointment
- As appropriate, provide the patient with documented proof of vaccination, including vaccine type, name, lot number, expiration date, date of vaccination, location of vaccination
 - When possible, consider use of a patient-facing app to store vaccine status which can be used as a “passport to travel” or for other vaccine-required activities and to provide contact tracing to prevent disease spread
- Consider use of SMS (short message service) text messaging to facilitate patient monitoring
- Ensure vaccinators and/or health professionals in vaccination sites are trained in adverse events following immunization (AEFI) management including detecting AEFI, identifying AEFI, reporting AEFI, investigating AEFI and treating patients
- When administering vaccines treat adverse events following immunization as a priority
- Provide training to healthcare practitioners to help them identify potential adverse events following immunization
- Provide a variety of pathways for patients, healthcare practitioners, and those working in emergency care centers to report adverse events following immunization and errors related to use of vaccines
- Include specific patient characteristics, for example, race, age, ethnicity, whether a patient belongs to a specialty population such as indigenous people or those from remote populations, when completing safety reports for vaccines
- Provide additional training in signal detection for those who are analyzing adverse events following immunization
 - Strengthen the pharmacovigilance system to be able to handle the monitoring of adverse events following immunization



Moving Forward

- Promoting packaging vaccines in prefilled unit-dose syringes as a global standard
- Addressing issues related to COVID-19 vaccine safety for pediatrics as COVID-19 vaccines are being authorized for use in more countries
- Addressing risks during overlapping COVID-19 immunizations and other immunization campaigns
- IMSN involvement in review of a globally standardized schema and pathways for adverse events following immunization reporting

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