Injection safety in the context of coronavirus disease (COVID-19) vaccination

Policy brief

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World Health Organization

Objective, approach and target audience

The number of injections given worldwide each year has nearly doubled with the advent of immunizations for COVID-19. Injections, whether for prevention or therapeutic treatments, are the most commonly performed invasive medical procedure and as such, have associated risks. Past failures around the world to ensure the safety of injections, including practices such as reuse of syringes and needles, led to significant morbidity and mortality (1). WHO has developed policy, guidance and implementation resources to promote safe injection practices and considerable progress has been made over time (2,3,4). With the magnitude of injections increasing at an unprecedented rate (5), proactive measures to avoid risk are critical to the success of immunization initiatives and to the continuity of other health services.

This policy brief synthesizes WHO guidance and policy in the context of the extraordinary increase in global injections resulting from COVID-19 immunization campaigns. It recalls injection safety progress, recommendations and practices and highlights the need to actively reinforce and integrate these areas into immunization campaigns and into efforts to ensure continuity of other health services. It also calls attention to information on specialized syringes for certain COVID-19 vaccines and solutions for possible supply shortages.

This document is a resource for ministries of health including immunization programmes, national medicine regulatory authorities, and procurement authorities. Information on shortages is provided for ministries of health as well as for industry and trade associations. Provision of training information targets civil society and government entities engaged in training of medical staff.

Injection safety: “First, do no harm”

Injection safety has been a cornerstone of immunization programmes for decades and significant investments and progress have been made in eliminating the dangerous practice of the reuse of syringes and needles. Injection safety relies on the fundamental premise that healthy people seeking immunizations should not be subjected to any unnecessary risk related to injection practice (6). It has been reinforced by multiple United Nations agency joint statements starting in 1999 with the introduction of auto-disable (7) (AD) syringes, updated policies from WHO in 2016 (2), and updated implementation tools in 2017 (3).

In the context of COVID-19 vaccination campaigns, injection safety needs to be reinforced and rigorously applied to protect patients, health workers, and communities (8). The unprecedented number of vaccinations worldwide is far beyond any prior immunization effort, including the 6.8 billion doses of COVID-19 vaccines already administered in the first year of their availability, as well as the number that are still urgently needed (5).

WHO is highlighting this issue in the context of COVID-19 vaccinations as evidence shows that injection safety has not been universally implemented, despite many years of progress (4). Estimating the additional disease burden from unsafe practices is complex given the number of possible scenarios for immunization coverage; however, failing to ensure safe practice would clearly increase that risk (9). Progress must continue and cannot go backwards in the pandemic.

Changing environment of a pandemic and forecasting syringe supplies

WHO estimates recognized that over 16 billion injections are given annually around the world. Prior to COVID-19, approximately 5-10% were for vaccinations and other preventive services (10, 11). However, some scenarios for COVID-19 vaccination target 7 billion people (with two doses each) by the end of 2023 (12), which would require an additional 5.6 billion units annually. Narrowing the question to AD syringes, the global demand in 2021 has already surpassed 4.5 billion for all vaccination, and the sustained demand could be from 4 to 7-fold the typical annual demand for AD syringes.

Increased injection safety risks, including shortages and lack of trained staff

Shortages

Supply of vaccines in early 2021 has been constrained and syringe availability has been adequate to date to match that supply. However, the expected increase in supply is significant and shortages of syringes are a potential risk.

- While figures vary, current capacity to supply AD syringes is estimated at 6 billion annually (13). Based on the above scenario, a shortage of more than 1 billion per year could occur if manufacturing capacity is not increased to match the demand for COVID-19 vaccination plus routine immunizations programmes. The impact on countries that have policies requiring AD syringes for immunization could be significant, especially for low- and middle-income countries.
- Increases or repurposing global production capacity of syringes would require clear estimates and enough time to ramp up capacity, with a need to start at least 6 months in advance of need.
- According to both WHO and the World Trade Organization, avoiding the market chaos caused by export bans, hoarding, parallel trade and abusive pricing, will also be critical to ensure that syringes reach the points of care together with the vaccines (14).
- Avoiding syringe supply shortages and implementing safe practices should be reinforced; however, any suspected health care-associated outbreak should be immediately investigated including a review of infection prevention and control practices to identify the source, including potential lapses in injection safety practices. Guidance on infection prevention and control are available from WHO and other sources (15, 16).

Staff training

The demand for immunization providers will continue to stress health systems in countries around the world. Estimates are changing, but current informal methods for calculating additional staff needs show that a conservative increase in the number required will be at least 250 000 additional health workers (17).

- Newly trained health workers will need specific reinforcement of training in safe injection practices to avoid unsafe practices (for example, reuse, recapping, poor waste management, including sharps' disposal).
- For existing health workers, training support for injection safety remains critical as they are at increased risk, including for needle-stick injuries.

Core elements of injection safety applied to COVID-19 immunization campaigns

The WHO Global Campaign on Injection Safety (3) recognizes core principles including training, a sufficient supply and efficient distribution of syringes, use of AD syringes for immunization and reuse prevention syringes for curative injections, community awareness, and appropriate management of sharps' waste. The campaign reinforces the original principles that all injections should be safe and not pose a risk to the patient, the health worker or the community, including waste management activities.

As COVID-19 vaccination campaigns roll-out and, particularly, as the supply of vaccine increases, all core areas of injection safety need attention, including an urgent focus on staff training and the supply chain to reduce risks of both unsafe practices and shortages. Supplies, such as sharps disposal containers should also be in place along with plans for appropriate disposal of sharps waste.

Special sizes of AD syringes

While normally available AD syringes can be used for most COVID-19 vaccines, some require a special 0.3 ml size, which has a more limited supply. In situations where normal supply of AD syringes are not sufficient, please refer to the WHO list of Prequalified Devices and Equipment (18) for information on alternative products that also have the safety features of AD syringes. It is also important to refer to the vaccine product sheets concerning the recommended syringe sizes and details for each of the vaccines (19). The sheets contain information on syringe types and characteristics.

It is very important, especially for the 0.3 mL syringes, to be aware that substituting other syringe sizes can reduce the number of doses that can be aspirated from each vial. Training materials are available for vaccines where syringes with a low dead space design are recommended, along with options in the event of constrained syringe supply (20). If prequalified 0.3mL AD syringes are not available (18), exceptionally consider prequalified 1mL or 2mL RUP syringes that meet the following requirements:

- • Dead space of syringe and needle combination: ≤ 0.035mL
- • Graduation: ≤ 0.1 mL increments
- • Needle: 23G x 1" (0.60 x 25 mm)
- • Preferred packaging configuration: Co-packaged needle and syringe
- • Prioritization of needles: 1. Fixed needle 2. Safety luer needle 3. Standard luer needle

Calls for action

There is clear need for critical actions by the following key players, to make sure that all injections are safe injections, particularly in the context of the ongoing pandemic.

- Governments and national programmes will need to:
  - plan procurement and delivery of the right syringes in advance to ensure prompt use of the COVID-19 vaccine;
  - ensure that systems are set up to prevent syringe reuse by reinforcing WHO guidelines, as well as other infection prevention and control practices for safe vaccination delivery, including systems for appropriate sharps' waste management;
  - support health workers with training, especially new workers who may be brought in to support campaigns.
- Industry partners will need to:
  - ensure investment in nationally relevant end-to-end supply chain functions for syringes, ranging from forecasting, production, procurement through delivery to health care facilities, including appropriate sharps' waste management;
  - maintain political conversations to avoid disruptive policies, such as export restrictions that can create short supply.
- International development partners will need to:
  - engage with the COVAX Facility and others to ensure transparency, fairness and an equitable supply of syringes.
  - ensure that vaccines are bundled with corresponding quantities of appropriate syringes.

Resources

The resources provided in this document are examples of the ongoing work in injection safety. For additional resources on injection safety programmes and policies, please refer to the *Injection Safety* home page: https://www.who.int/teams/integrated-health-services/infection-prevention-control/injection-safety.

For additional information on WHO prequalified injection devices, sharps' disposal and related equipment, please refer to: https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/index.aspx.

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