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

Addendum to policy brief

5 April 2022

World Health Organization

Background

This document serves to update the policy brief *Injection safety in the context of coronavirus disease (COVID-19) vaccination*[1] (IS Policy Brief), with additional guidance. The IS Policy Brief remains valid and highlights the overall importance of reinforcing injection safety in the context of the pandemic, especially considering the significant resulting increase in the number of injections being administered worldwide.

This Addendum confirms that substituting syringes with re-use prevention features (RUP) for auto-disable (AD) syringes may exceptionally be necessary to address shortages of 0.3 ml AD syringes. In addition to the shortages of this specialty size, this Addendum to the IS Policy Brief further acknowledges compounding factors that will exacerbate availability challenges of AD syringes for some COVID-19 vaccines. In particular, some dosing regimens now call for non-standard dose volumes that do not correspond to any existing size of AD syringes.

This document provides additional guidance to complement the IS Policy Brief, on the use of RUP syringes in the event of non-availability of suitable AD syringes for administering various COVID-19 vaccines. Using appropriate, fit-for-purpose alternatives is a recognized practice in the interim management of shortages or non-availability. In keeping with that principle, this guidance does not intend to replace long-standing policies on the use of AD syringes in immunization programmes. It also reinforces specific details needed in training for immunization providers on the different performance features of RUP syringes. Finally, it responds to requests to identify supportive actions for industry partners, international development partners and donors to support the resolution of this shortage. The two key elements that this document addresses include:

- Guidance on the selection of safety syringes for recommended dose volumes for which AD syringes do not exist; and
- Training considerations that are not typical to immunization programmes.

The approach to developing this Addendum included a review of the original policy brief and the corresponding resources; a review of recently released vaccine dose volume recommendations relative to available AD syringes with corresponding volumes; and consultation with and consideration of feedback from injection safety experts from the COVAX[1] partnership. Two virtual consultations with these experts identified key points to be addressed. The elements described in this document were then reviewed and agreed upon by the experts.

In the event of changes in vaccine dose volumes, supply of AD syringes, or other areas that impact safe injection of COVID-19 vaccines, this document will be reassessed and updated.

Shortages and dose volumes that do not correspond to existing auto-disable (AD) syringe options

Current examples where AD syringes are either in short supply or unavailable in a corresponding size include the situations described below.

- The Pfizer-BioNTech vaccine (Comirnaty) dosing for adult and adolescent administration is 0.3 ml[2], but there are shortages of this size of AD syringe.
- The dosing for Pfizer-BioNTech vaccine (Comirnaty) for children ages 5-11 years is 0.2 ml[2]. A rapid market review showed no sources of 0.2 ml AD syringes.

[1] https://www.who.int/initiatives/act-accelerator/covax

- The recommended booster dose for Moderna is 0.25 ml for adults >18 years[3], but there is only one WHO prequalified manufacturer of a 0.25 ml AD syringe[4].
- It is possible that shortages will persist and that additional dosing regimens will emerge that do not correspond to existing AD syringe sizes.

Specification recommendations for reuse-prevention (RUP) syringes

In cases where appropriate AD syringes are either in shortage or do not exist, national vaccination programmes may temporarily use suitable low-volume RUP syringes that can correctly and safely administer the required dose for each vaccine, until supply of appropriate sized AD syringes is established and increased to meet demand. It is important to note that RUP syringes are graduated, flexible-dose syringes. In selecting the appropriate RUP syringes, graduation marks must correspond to the dose volume, e.g., a 0.25 ml dose must be delivered with a syringe that has graduation marks of 0.05 ml. Also, immunization providers must be made aware of and trained on the need to use the graduation marks in drawing the correct dose volume.

The preferred characteristics below (Table 1) reflect the preference to use an RUP syringe that most closely matches the performance features of AD syringes.

Table 1. Preferred characteristics of RUP syringes to be used as a temporary alternative to AD syringes

Equipment	Remarks
Auto-disable (AD syringes)	Equipment of choice for vaccination
Re-use prevention (RUP) syringes	Temporary use when AD is not available
Preferred specification of RUP as a temporary alternative to AD syringes	• Volume: 1-2 ml syringe with RUP feature • Graduation: 0.05 - 0.1ml graduation • Needle type: Fixed needle • Needle size: per vaccine requirements e.g., 23G -25G × 1" (0.5-0.6- × 25 mm) for intramuscular injection • Dead space: lowest dead space possible (e.g., equivalent to ISO7886-3)

Staff training recommendations

It is essential that health workers are familiar with the COVID-19 vaccine product they are administering and receive clear guidance and training on the delivery of safe injections. In addition to the seven steps for safe injections[5], immunization providers should receive specific reinforcement on using a graduated, flexible-dose syringe versus fixed-dose AD syringes. National programmes will need to assess the level of training required for this, noting that in certain contexts immunization providers may lack training in the use of graduated, flexible-dose syringes. For those products with non-standard volumes, it is critical that the provider be aware of the volume of the specific vaccine to be administered and if an RUP syringe is being used, that they are also trained on the differences of how these syringes are used.

Calls for action

There is an explicit need for critical actions by the following key stakeholders (Table 2), to make sure that all injections are safe injections, particularly in the context of the ongoing pandemic.

Table 2. Calls for actions to key stakeholders

Stakeholders	Action
Industry partners	• Prioritize standard dose volumes in vaccine development • Scale up or initiate production of 0.2 ml, 0.25 ml and 0.3 ml AD syringes • Scale up production of 1ml/2ml RUP syringes with appropriate graduation marks for vaccine delivery
International development partners	• Support the introduction of messaging and training • Ensure that vaccines are bundled with corresponding quantities of appropriate AD/RUP syringes, including to the facility level
Donors	• Ensure that vaccines are provided with appropriate AD/RUP syringes • Support the procurement of suitable administration devices.

Resources

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.

References

1. Injection safety in the context of coronavirus disease (COVID-19) vaccination. Geneva: World Health Organization; 2021. (Injection safety in the context of coronavirus disease (COVID-19) vaccination (who.int), accessed 2 March 2022).
2. WHO interim recommendations on the use of the Pfizer – BioNTech BNT162b2 vaccine against Covid-19. Geneva: World Health Organization; 2022 (Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing (who.int), accessed 3 March 2022).
3. Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19. Geneva: World Health Organization; 2022. (Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (who.int), accessed 3 March 2022).
4. WHO list of Prequalified Devices and Equipment. Geneva: World Health Organization; 2021. (IMD_Products_Catalogue_20200420_V0_.pdf (who.int), accessed 3 March 2022).
5. Make Smart Injection Choices. Geneva: World Health Organization; 2017. (https://www.who.int/infection-prevention/tools/injections/IS_HealthCareProviders_Leaflet.pdf, accessed 3 March 2022).

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