

Joint Policy Statement¹

Promoting the exclusive use of injection safety devices for all immunization activities

WHO and UNICEF strongly recommend the systematic and exclusive use of auto-disable (AD) syringes for the delivery of vaccines and reuse prevention syringes (RUP) for the reconstitution of vaccines during routine immunization services and mass vaccination campaigns.

This policy statement, which replaces the 1999 WHO/UNICEF/UNFPA joint policy statement on this subject, further re-affirms that:

- Auto-disable syringes, vaccines and safety boxes continue to be supplied as a “bundle” ; and
- UNICEF will not procure standard disposable syringes for any immunization activities, including syringes used for reconstitution.

In addition, WHO and UNICEF:

Urge countries to:

- Develop a strategy for the exclusive procurement, training and education of health workers on the use of AD syringes and reuse prevention syringes for vaccine delivery and reconstitution, as well as their effective disposal and waste management;
- Evaluate the feasibility of adopting injection devices with sharps injury protection (SIP) technologies for vaccines; and
- Transition by 2020, to the exclusive procurement and use of AD syringes for vaccine administration and reuse prevention syringes for vaccine reconstitution that meet WHO quality standards.

Urge donors and development partners to:

- Exclusively fund vaccines bundled with WHO prequalified AD syringes and reuse prevention syringes for vaccine delivery and reconstitution, and sharps safety boxes for sharps disposal.
- Support health -worker- training in the use of AD syringes and reuse prevention syringes for all immunization activities.

Urge manufacturers to:

Further develop and improve affordability of AD and RUP syringes and sharps injury protection (AD/SIP) technologies for both delivery and reconstitution devices.

Context

WHO, UNICEF and partners – including the Safe Injection Global Network (SIGN), have been working together for

more than two decades to promote safe injection practices with policy makers and programme managers, in making sterile injection equipment widely available, and in

¹ This joint policy statement revises and replaces the *WHO-UNICEF-UNFPA policy statement on the use of auto-disable syringes in immunization services*. WHO/V&B/99.2. It is issued by the World Health Organization, Geneva, Switzerland (Department of Immunization, Vaccines and Biologicals and the Department for Essential Medicines and Health Products), the United Nations Children's Fund (UNICEF Programme Division, New York, USA and UNICEF Supply Division, Copenhagen, Denmark).

educating health workers on the critical importance of using only sterile injection devices.

In 1999, the release of a WHO/UNICEF/UNFPA Joint Statement on injection safety ([WHO/N&B/99.25](#)) facilitated the initial push towards the exclusive use of auto-disable (AD) syringes for vaccinations, encouraging countries and the market to shift towards safer injection technologies and devices with the goal of phasing out regular disposable syringes. AD syringes have an internal mechanism that blocks the barrel after a single use. This re-use prevention feature safeguards from multiple use of the same device and thus, the potential transmission of life-threatening infections.

In 2006, UNICEF issued further instructions concerning Re-Use Prevention (RUP) syringes with a built-in safety mechanism preventing re-use towards enhancing injection safety targeting 2ml, 5ml and 10ml syringes for the reconstitution of vaccines. Within two years, the use of regular disposable reconstitution syringes began to be phased out in favour of the RUP syringes, nevertheless progress has been slower than desired.

Today, the majority of countries worldwide have switched from regular disposable syringes to AD syringes for delivering vaccines. In addition, several partners have played a key role in funding and market shaping to promote and ensure greater availability and affordability of WHO prequalified AD syringes. While important progress has been made, the spotlight is now on unsafe vaccine reconstitution practices, using disposable syringes, which continue to be reported in many countries.

Problem statement

The use of regular disposable syringes to reconstitute vaccines is considered an improper and unsafe practice, yet it still occurs in some countries.

In 2016, it was estimated that over 65% of countries² continue to use, purchase and procure regular disposable syringes despite the following:

- (i) Global recommendations to switch to the exclusive use of these technologies have repeatedly been made by the international immunization community, including the 2015 global campaign on injection safety and WHO's call for worldwide exclusive use of re-use prevention syringes (WHO, 2015)

- (ii) Re-use prevention reconstitution syringes that are WHO pre-qualified and meet performance, quality and safety (PQS) standards are widely available for procurement on the global market.

Evidence-based policy

WHO and UNICEF are issuing this revised 2019 Joint Statement to re-iterate the recommendation to immunisation programmes to systematically and exclusively use AD syringes and reuse prevention syringes for all delivery and reconstitution of vaccines, in routine immunization services and mass vaccination campaigns.

This policy decision is based on sufficient evidence that the said technology is fit for purpose for all national immunization programmes.

Evidence on acceptability, safety, performance and systems fit

A field study in Indonesia, conducted by UNICEF in 2007, evaluated the acceptability, safety, and performance of introducing RUP syringes for reconstitution of freeze-dried vaccine and concluded that the overall immunization systems effectiveness would be improved from the widespread use of this technology³. The key findings indicated that RUP syringes: (i) were well received by health workers and easy to use, or learn how to use – especially in cases where AD syringes for delivery were already in use (the technology is similar); (ii) improved injection safety by preventing reuse of reconstitution syringes and improved health worker satisfaction because of the added measures of safety compared to regular disposable syringes; (iii) fit easily into country vaccine supply chains without burdening the system; (iv) are highly acceptable for use in both routine immunization and campaign settings; and (v) are intuitive technologies, but will require specific training as a key factor to ensure successful and sustained introduction. The study further demonstrated that hands-on training, demonstrations and user practice with two or three actual syringes and vaccine vials are essential to ensure successful introduction of RUP syringes for freeze-dried vaccine reconstitution in field immunization settings.

Supply and pricing

In 2016, UNICEF supplied AD syringes for 91 countries and was offered over 500 million 5ml and 2ml RUP syringes. A review by UNICEF of the global supply situation indicates that the market is healthy, with enough WHO prequalified manufacturers to meet demand should all countries

² Based on countries that procure their syringes through UNICEF.

transition to the use of RUP syringes for vaccine reconstitution.

In terms of pricing, an RUP syringe costs slightly more than a disposable syringe. However, the marginal price premium for this technology against its cheaper disposable alternative is more than offset by the risks averted in terms of safety⁴.

Future supply and market and potential pricing trends

If the demand from countries were to grow in the future, evidence on potential pricing trends suggest that the unit price could drop to similar price levels as AD syringes.

Safe disposal

The transition from disposable to RUP syringes for vaccine reconstitution would not add additional waste for disposal. In line with the bundling policy, sufficient sharps safety boxes would be supplied with the relevant quantity of syringes for safe and effective sharps disposal.

References

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⁴ Auto-Disable (AD) and Re-Use Prevention (RUP) Syringes and Safety Boxes - current price data
https://www.unicef.org/supply/index_62309.html