

WHO/UNICEF JOINT STATEMENT

Temperature-sensitive health products in the Expanded Programme on Immunization cold chain

WHO and UNICEF joint statement encouraging greater health commodity supply chain convergence for temperature-sensitive pharmaceuticals where appropriate.

The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) reiterate the value of safe, feasible, and cost-effective integration of temperature-sensitive health products into Expanded Programme on Immunization (EPI) health supply chains. Past policies from both organizations have allowed the possibility of converging supply chains. **This statement provides further clarity by explicitly allowing convergence if feasible, cost-effective, and safe. This joint statement also supports the United Nations (UN) Commission on Life-Saving Commodities for Women and Children.** To that end, WHO and UNICEF:

1. Reiterate that safe, properly organized integration of temperature-sensitive pharmaceuticals is allowed when feasible and cost-effective.
2. Call on countries and partners to integrate temperature-sensitive pharmaceutical products into the vaccine cold chain where safe and feasible and to document integration experiences as evidence for future policies and guidance.
3. Recommend universal adoption of best storage and labeling practices as a precondition to integration to clearly distinguish non-vaccine products from vaccines and diluents.

OVERVIEW

Many pharmaceuticals must be kept in controlled temperatures to maintain potency during transport and storage. Challenges in maintaining this cold chain can damage or diminish access to lifesaving drugs. To ensure high-quality care, health systems must find ways to ensure that heat-sensitive drugs are managed within a temperature-controlled supply chain from manufacture, through procurement and internal logistic systems, to the point of use.

In fragile health care systems, such as those in developing countries, vaccine immunization programs often have the best, or only available, refrigerated cold-chain systems. Integrating other heat-sensitive health products into these systems can improve transport and storage, increasing access and saving lives. **WHO and UNICEF confirm that it is permissible to transport and store drugs in the vaccine cold chain, provided that best storage and labeling practices are adhered to at all times to clearly distinguish non-vaccine products from vaccines and diluents.**

BACKGROUND

When the global Expanded Programme on Immunization was launched 40 years ago, it focused on six childhood vaccines. Some of these vaccines had to be kept cold (2°C–8°C/35°C–46°F), making them one of only a handful of essential commodities that required a specific cold supply chain. Subsequently, the

Universal Child Immunization initiative, launched by UNICEF in the 1980s, initiated a sharp increase in country-level cold chain systems, which quickly became the backbone of national immunization programs. During the same decade, WHO, recognizing the importance of EPI and cold-chain best practice, disseminated early guidelines on cold-chain logistics.¹ Although not specifically focused on integration, these materials broadly supported the possibility that other temperature-sensitive health products might be stored in the vaccine cold chain.

Best practices evolved over time suggesting that vaccine cold chains managed by the EPI should be used exclusively for vaccines. This is partly because until recently, vaccines were the main essential health product that required cold chain transport in most developing countries. In addition, the EPI continues to operate largely independently from other health commodity supply chains. **Nevertheless, integration, if feasible and accomplished safely and efficiently, remains permissible.**

WHAT THE GUIDANCE SAYS

As noted, WHO and UNICEF guidance materials have included broad language suggesting that, if key provisions are met, other products may be safely stored in the vaccine cold chain. These provisions include: (1) maintaining good storage practices and (2) clear labeling and separation of non-vaccine products from vaccines and diluents at all times. For instance, the WHO 2014 Immunization in Practice manual states that “[i]

you are working] ... in an area with only one refrigerator and you need to store other heat-sensitive supplies such as drugs, ointments, serum and samples, be sure to label them clearly and keep them separate from vaccines and diluents.”²

In addition, in April 2014 the Strategic Advisory Group of Experts on Immunization endorsed a “Call to Action” developed by WHO’s Immunization Practices Advisory Committee.³ This document provides specific recommendations urging countries and the global community to strengthen immunization supply chains.⁴ One recommendation specifically advises increased efforts toward the convergence and integration of health commodity supply chains, including cold chains.

WHO/UNICEF RECOMMENDATIONS ON SAFE INTEGRATION

WHO and UNICEF reiterate that it is permissible to use the EPI cold chain for the storage of appropriate temperature-sensitive pharmaceuticals. In particular, WHO and UNICEF recommend the following:

Integration and documentation. Countries and partners are urged to consider integrating temperature-sensitive health products, particularly oxytocin, into national EPI cold chains, where safe and feasible. They are also urged to document experiences as evidence for future policies and guidance.

Safe storage and labeling. To keep non-vaccine products and vaccines and diluents safely distinct, leaders and health care workers must adopt solutions to quickly and clearly distinguish vaccines from other products, such as placing clear and unambiguous visual cues on external packaging.

FOR FURTHER INFORMATION

For further information, please contact:

Patrick Lydon, WHO, Geneva; lydonp@who.int

Benjamin Schreiber, UNICEF, New York; bschreiber@unicef.org

REFERENCES

- 1 WHO. *Logistics and Cold Chain for Primary Health Care*. Modules 1 to 25. WHO/EPI/LOG/84/modules 1 to 25. Geneva: WHO; 1984.
- 2 WHO. *Immunization in Practice: A Practical Guide for Health Staff*. WHO/IVB/04/06. Geneva: WHO; 2004.
- 3 WHO. Meeting of the Strategic Advisory Group of Experts on immunization, April 2014 – conclusions and recommendations. *Weekly Epidemiological Record*. 2014;89(21):221–236.
- 4 WHO Immunization Practices Advisory Committee. Immunization supply chain and logistics: a neglected but essential system for

EXAMPLE: ANSWERING THE OXYTOCIN CHALLENGE

Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the leading cause of maternal mortality worldwide. WHO has recommended oxytocin, a temperature-sensitive medicine, as the first-line choice for prevention and treatment of PPH.⁵ Over the next ten years universal access to this and similar medicines could avert an estimated 41 million PPH cases and save 1.4 million lives.⁶ For this reason, oxytocin is among 13 health products prioritized by the UN Commission on Life-Saving Commodities for Women and Children.

Because oxytocin degrades when exposed to prolonged heat, WHO and UNICEF have recommended that oxytocin-based products be kept refrigerated as much as possible.

Keeping oxytocin cool is a challenge, particularly in countries where daytime temperatures often exceed 30°C (86°F), electricity is unavailable or unreliable, and adequate cold-chain infrastructure is lacking. As a result, oxytocin is still often transported and stored outside of a temperature-controlled system, compromising its potency and shelf life.

Given these challenges, the UN Commission on Life-Saving Commodities for Women and Children has proposed transporting oxytocin within national EPI cold-chain infrastructures. Several countries, including Benin, Niger, Senegal, South Sudan, and Togo, have adopted this integrated approach, along with good storage and labeling practices.

WHO and UNICEF endorse the integration of oxytocin into the EPI cold chain in order to improve the availability of oxytocin that is not heat-damaged. Lessons learned from this experience can support integration of other drugs and products in the future.

national immunization programmes: a call-to-action for national programmes and the global community by the WHO Immunization Practices Advisory Committee, Geneva, Switzerland, March 2014. WHO/IVB/14.05. Geneva: WHO; 2014.

- 5 WHO. *Recommendations for the Prevention and Treatment of Postpartum Haemorrhage*. Geneva: WHO; 2012.
- 6 Seligman B, Liu X. *Economic Assessment of Interventions for Reducing Postpartum Haemorrhage in Developing Countries*. Bethesda, MD: Abt Associates Inc.; 2006.

World Health Organization

Expanded Programme on Immunization
20 Avenue Appia, 1121 Geneva 27
Switzerland
vaccines@who.int
www.who.int

United Nations Children’s Fund

3 United Nations Plaza
New York, NY 10017
USA
immunization@unicef.org
www.unicef.org