

TEMPERATURE-SENSITIVE HEALTH PRODUCTS IN THE EXPANDED PROGRAMME ON IMMUNIZATION COLD CHAIN: INTERIM UPDATE ON COVID-19 RESPONSE, 15 May 2020

WHO and UNICEF joint statement encouraging greater health commodity supply chain integration for temperature-sensitive pharmaceuticals where appropriate: updated to provide interim guidance for COVID-19 response

Due to the global circulation of the virus causing COVID-19 and the current pandemic, the World Health Organization (WHO) and the Global Polio Eradication Initiative (GPEI) have released interim guidance on both routine and supplemental immunization activities. Both the pandemic and the response have had a significant impact on countries' cold chain systems, requiring flexibility and agility to deliver comprehensive health services and manage surplus vaccine stores and other cold chain commodities.

The WHO and United Nations Children's Fund (UNICEF), reiterate the value of safe, feasible, and cost-effective integration of temperature-sensitive health products into the Expanded Programme on Immunization (EPI) health supply chains. This interim guidance provides further clarity by highlighting integration as a practical solution and provides reference to planning tools to design and implement an integrated cold chain.

To that end, WHO and UNICEF:

1. Reiterate that safely and properly organized integration of temperature-sensitive pharmaceuticals should be considered, including but not limited to COVID-19 diagnostics and therapeutics, oxytocin, insulin and HIV diagnostic kits and treatments requiring refrigeration at 2-8°C and do not pose any risk when integrated with vaccine products.
2. Recommend careful assessment of existing cold chain capacity, supply chain system design, policies and vaccine stock inventory prior to integration of non-vaccine products in the vaccine cold chain system to guide prioritization and decision-making.
3. Recommend general adoption of best storage and handling practices including proper labeling and segregation 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 medicines. To ensure high-quality care, health systems must

find ways to ensure that heat-sensitive medicines are managed within a temperature-controlled supply chain from the manufacturer, through the entire supply chain, to the point of use.

In May 2015, WHO and UNICEF published a joint statementⁱ permitting for the integration of other health commodities into the vaccine cold chain system if feasible and accomplished in a safe and efficient manner. This statement remains valid and is updated to cover additional health commodities including medicines, laboratory reagents and test kits used for COVID-19, provided that best storage and labeling practices are always adhered to clearly distinguish non-vaccine products from vaccines and diluents.

Countries need to ensure that their cold chain system is sufficiently flexible to manage

fluctuations due to logistical restrictions caused by COVID-19 and the additional demands placed on cold chain storage capacity from COVID-19 therapeutics and diagnostics, catch up of routine immunization and supplemental immunization activities, in addition to other cold chain items utilized to deliver essential health services.

This new joint statement serves as interim guidance. As the COVID-19 pandemic is constantly evolving, this statement will be reviewed and updated to provide further guidance, as necessary.

BACKGROUND:

On 11 March 2020, WHO declared that COVID-19 can be characterized as a pandemicⁱⁱ. Since then many countries have adapted stricter measures to control the spread of the disease in the communities. On 24 March 2020, GPEI and specifically the Polio Oversight Board recommended suspending all polio campaigns whilst the COVID-19 pandemic is still activeⁱⁱⁱ. On 26 March 2020, WHO also released interim guidance^{iv} recommending to countries to temporarily cease supplemental immunization activities where the risks outweigh the benefits and to institute appropriate measures when

implementing routine immunization to prevent the spread of COVID-19. Some countries have also set up sub-national labs to support testing for the virus that causes COVID-19. The test kits, reagents and other lab supplies that require cold storage may likely use the existing national and sub-national cold chain facilities and equipment to accommodate this surge. The stockpile of unused campaign vaccines, the disrupted delivery schedules and the need to store other heat-sensitive health commodities, including COVID-19 diagnostic and therapeutic products, significantly challenge the existing cold chain capacity and alter the supply and stock balances.

WHO-UNICEF GUIDANCE:

The 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.

In April 2014, the Strategic Advisory Group of Experts (SAGE)^v on Immunization endorsed the recommendation of the WHO's Immunization Practices Advisory Committee (IPAC) to increase efforts toward the convergence and integration

of health commodity supply chains, including cold chains^{vi}. The 2014 version of the WHO Immunization in Practice manual^{vii} also provides specific examples on how to safely apply the integration of other heat-sensitive health commodities in the vaccine refrigerator at the health center. Further, the WHO guidance on storage and transport of time- and temperature-sensitive pharmaceutical products can be found in the WHO Technical Report Series, No. 961, 2011, Annex 9.^{viii}

In the context of the COVID-19 pandemic, the guidance is further expanded to integrate the storage and transport of temperature-sensitive COVID-19 therapeutics, laboratory reagents and

test kits in the vaccine cold chain system. **However, EPI refrigerators and vaccine carriers should NEVER be used for the storage of COVID-19 laboratory specimens or samples.** Regardless of the demand for COVID-19 confirmatory testing, which may entail temporary storage of specimens in a cold chain

prior to transport for testing in reference laboratories, it is critical that this recommendation is respected. **Care must be exercised to prevent contamination of vaccines and other pharmaceutical and laboratory products.**^{ix}

WHO AND UNICEF RECOMMENDATIONS ON SAFE INTEGRATION:

As greater demands are placed on cold chain systems in countries, it is necessary to re-emphasize that

1. it is permissible to use the EPI/vaccine cold chain system for the storage and

2. transport of appropriate temperature-sensitive pharmaceuticals,
3. the WHO and UNICEF guidance on safe integration must be followed to ensure the quality and potency of all health products in the shared storage space, and
4. the decision to integrate should be guided by a cold chain capacity assessment and integration plan.

In particular, WHO and UNICEF recommend the following:

COLD CHAIN CAPACITY ASSESSMENT AND FORECASTING

- When planning for future expansion of cold chain capacity, countries are advised to consider including an additional 25% to 30% storage space - depending on the usual forecast and planned supply chain interval - for surge capacity in times of emergency. This should be clearly reflected and aligned with cold chain contingency plan and health emergency preparedness plan.
- Countries should maintain an updated list of all potential facilities (public and/or private) with functional cold chain equipment to ensure surge capacity and maintain updated cold chain inventories, particularly in the context of COVID-19 pandemic.
- Countries are encouraged to use data from latest assessments, such as the WHO-UNICEF Effective Vaccine Management (EVM), Cold Chain Equipment Optimization Platform (CCEOP), applicable system design analysis or cold chain mapping exercises, to determine their existing cold chain capacity and the feasibility of

integrating storage of vaccines and appropriate non-vaccine products in the EPI cold chain system. In the absence of these, a rapid assessment should be conducted to ensure compliance with vaccine storage temperature requirements.

- To understand the total storage volume required, countries can use the existing WHO-UNICEF EPI Logistic Forecasting Tool^x and WHO COVID-19 Essential Supplies Forecasting Tool (ESFT)^{xi}.
- If the existing capacity is not sufficient to accommodate all appropriate temperature-sensitive health products or if the required storage temperatures are outside the usual ranges used for storing vaccines, countries are advised to explore options to manage surplus stock, such as:
 - prioritizing items to be stored in the EPI cold chain (vaccines should be prioritized).
 - adjusting distribution frequency based on cold chain capacity and utilization rate

- using any available and functional WHO prequalified cold chain equipment^{xii}

- commissioning of private cold chain facility where the temperature can be maintained to safely store the products

INTEGRATION AND DOCUMENTATION

- Countries are urged to consider integrating temperature-sensitive health products, including but not limited to COVID-19 diagnostics and therapeutics, oxytocin, insulin and HIV diagnostic kits and treatments requiring refrigeration, into the national EPI cold chain system (including storage and transportation), where safe and feasible.
- Integration should not be limited to physical storage but should extend to recording, reporting, and monitoring of all supplies using the same EPI cold chain equipment/ facility to ensure proper management.
- Countries are advised to develop an integration plan and to consider

updating relevant policies and standard operating procedures (SOPs) to ensure the efficiency and sustainability of the approach.

- Ensure that systems for supervising staff, monitoring temperatures and maintaining cold chain equipment are in place given the increased value (both monetary and breadth of health needs being met) of products being stored jointly, especially with the possible stockpiling of vaccines due to disrupted service delivery and programme activities.
- Countries are encouraged to document experiences and best practices as evidence for future policies and guidance.

SAFETY CONSIDERATIONS

- To keep non-vaccine products and vaccines and diluents safely separated, each product should be allocated with a dedicated, labelled space within the shared cold chain equipment.
- If allotting dedicated space for each product is not feasible due to limited storage capacity, 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 the external packaging.
- Countries should consider modifying vaccine receipt and distribution

schedules where and when required to avoid excess burden on the cold chain.

- Before a country integrates non-vaccine products into the EPI supply chain, all staff handling products in the supply chain need to be trained on the updated SOPs and safety guidelines to ensure smooth integration and mitigate against products being mistaken for one another.
- In case staff are repurposed for COVID-19 surge capacity, countries are advised to use available innovative learning materials to ensure that staff responsible for managing cold chain gain basic knowledge on supply chain management and the management of temperature sensitive health products.

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- 3 GPEI: Summary of urgent country and regional recommendations from the Polio Oversight Board meeting of March 24, 2020
- 4 Guiding principles for immunization activities during the COVID-19 pandemic, Interim guidance, 26 March 2020
- 5 WHO. Meeting of the Strategic Advisory Group of Experts on immunization, April 2014 – conclusions and recommendations. Weekly Epidemiological Record. 2014;89(21):221–236.
- 6 WHO Immunization Practices Advisory Committee. Immunization supply chain and logistics: a neglected but essential system for 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.
- 7 WHO. Immunization in Practice: A Practical Guide for Health Staff. WHO/IVB/04/06. Geneva: WHO; 2004.
- 8 WHO Technical Report Series, No. 961, (2011), Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products. Geneva: WHO; 2011
- 9 WHO COVID-19 Guidance: Laboratory Testing for 2019-nCoV in Humans <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>
- 10 EPI Logistics Forecasting Tool https://www.who.int/immunization/programmes_systems/supply_chain/resources/tools/en/index3.html
- 11 WHO COVID-19 Essential Supplies Forecasting Tool <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items>
- 12 WHO Performance, Quality and Safety Catalogue. https://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/