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The Importance of Indian Standards for Cold Chain Equipment in the context of immunization in India: Ensuring Quality, Efficiency, and Public Health

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Abstract
Indian Standards developed by the Bureau of Indian Standards (BIS) play a critical role in establishing uniform specifications and performance criteria for cold chain equipment used in Universal Immunization Programme (UIP). These standards ensure that Cold Boxes, Ice-Lined Refrigerators (ILRs), Deep Freezers (DF), Vaccine Carriers etc. meet the operational needs of healthcare settings, including those of remote and rural areas. This paper highlights the importance of adopting and enforcing Indian Standards for cold chain equipment in immunization programs, with a focus on improving vaccine efficacy, reducing wastage, and safeguarding public health.

Keywords: Bureau of Indian Standards (BIS), Universal Immunization Programme (UIP), Standardization, WHO PQS, vaccine Potency.

1. Introduction

India's Universal Immunization Programme (UIP) is one of the largest public health initiatives in the world, reaching approximately 2.7 crore new-borns and 3.04 crore pregnant women every year [1]. As one of the most cost-effective public health interventions, it has played a critical role in significantly reducing under-five mortality caused by vaccine-preventable diseases. Under UIP, vaccines are provided free of cost against 12 vaccine-preventable diseases, ensuring the potency and safety of vaccines is a public health priority.

Vaccines are highly sensitive biological products that gradually lose their potency—meaning their ability to provide protection against disease—over time **[**2**]**.This degradation occurs more rapidly when vaccines are exposed to temperatures outside their recommended storage range. Importantly, once potency is lost due to improper storage**,** it cannot be restored, even if the vaccine is later returned to the correct temperature.

A robust cold chain system is the backbone of vaccine delivery. It comprises a network of cold storage units, refrigerated transport, and temperature-monitoring devices that maintain vaccines within the

required +2°C to +8°C range throughout the supply chain [3]. In India, this system must operate across diverse terrains—from Himalayan villages to desert outposts and densely populated urban centers—often with limited access to reliable electricity and infrastructure.

2. Background:

2.1. Bureau of Indian Standards (BIS) [4]:

The Bureau of Indian Standards (BIS) is the National Standards Body of India, established under the BIS Act of 2016. Its primary role is to ensure the coordinated development of standardization, marking, and quality certification of goods, along with related matters. BIS contributes to the national economy by offering traceability and tangible benefits such as ensuring the availability of safe and reliable quality products, reducing health risks for consumers, encouraging exports and import substitution, and controlling the unnecessary proliferation of product varieties through its standardization, certification, and testing processes

2.1.1 What is a Standard?

A standard is a documented agreement that offers established solutions to recurring issues. It may include specifications, procedures, and guidelines designed to ensure that products, services, and systems are safe, consistent, and dependable [5].

2.1.2. Need for a Standard [6]:

Standards offer numerous benefits across various sectors. They can:

- Facilitate trade and commerce by ensuring uniformity
- Enhance process efficiency and effectiveness
- Support consistent performance and quality
- Simplify the comparison of products and services
- Safeguard health and safety
- Help conserve resources and minimize environmental impact
- Encourage innovation and technological advancement

2.2. How Standards are made [7]:

Standards are formulated by technical committees within Standards Developing Organizations (SDOs), which include representatives from a diverse range of stakeholders such as manufacturers, consumers, research and scientific institutions, academia, government departments and ministries, regulators, and testing laboratories. Nominated experts from these organizations draft standards based on proposals received from any stakeholder. The development follows established standardization practices and involves a consensus-driven process aimed at reaching a unified agreement.

2.3. What is an IS? [8]:

According to the BIS Act, 2016, any standard that is formulated and published by the Bureau of Indian Standards (BIS), the National Standards Body of India, in relation to a product, process, system, or service is recognized as an Indian Standard.

3. BIS Contribution in Strengthening of Cold Chain:

To address these challenges and promote reliability in cold chain operations, the Bureau of Indian Standards (BIS) has developed a suite of Indian Standards tailored to the requirements of cold chain equipment used in immunization. These standards provide technical specifications, performance bench-

marks, and safety criteria for vaccine refrigerators, cold boxes, and other equipment. They align with international guidelines, such as the WHO's Performance, Quality and Safety (PQS) specifications, while also considering India-specific operational needs [9].

Standardization ensures consistency in quality, facilitates centralized procurement for public health programs, and enables better monitoring and maintenance. As India continues to expand its immunization efforts—including new vaccines and campaigns like Mission Indradhanush [10]—the role of reliable, standards-compliant cold chain equipment becomes even more critical. This paper explores the significance of Indian Standards in supporting immunization logistics and sustaining vaccine efficacy across India's complex health delivery system.

4. Need for Standardization in Cold Chain Equipment

The Indian National Strategy for Standardisation (INSS), issued by the Ministry of Commerce & Industry, Government of India, recognizes standardisation as a vital component of the nation's quality infrastructure. It emphasizes the role of standards as a key enabler of economic activities across sectors. The strategy also highlights the need to build a robust and comprehensive ecosystem for standards development in India, incorporating global best practices and establishing responsive mechanisms to address standardisation challenges [11]. Regulatory compliance is essential in the cold chain Equipment, as it safeguards the safety, quality, and integrity of Vaccines throughout their journey from production to consumption [12].

A standardized cold chain is a cornerstone of effective immunization systems. In India, where millions of vaccine doses are transported and stored across varied geographic and climatic conditions, maintaining consistent quality and performance of cold chain equipment is crucial. Standardization ensures that equipment performs reliably under field conditions, safeguards vaccine potency, and supports efficient public health delivery.

4.1. Ensuring Vaccine Potency and Safety

Vaccines are highly sensitive biological products that must be stored and transported within a strict temperature range—typically between 2°C and 8°C for most vaccines, and as -15 °C **and** –20°C for others like oral polio vaccine (OPV)[13]. Non-standard equipment increases the risk of temperature excursions, leading to:

- Vaccine degradation or reduced potency.
- Increased vaccine wastage and cost burdens.
- Public health risks, including vaccine-preventable disease outbreaks.
- Loss of public trust in immunization programs.

Standardized cold chain equipment certified under Indian Standards [14] (e.g., IS 19106 for refrigerators {ILR}, IS 17547 for {DF} freezers) is tested to maintain these critical temperature ranges even in India's hot and humid climate zones.

4.2. Promoting Quality and Uniformity in Procurement

Government procurement for the Universal Immunization Programme (UIP) involves centralized purchasing of thousands of cold boxes, refrigerators, freezers, and vaccine carriers. Without standardized specifications:

- Equipment quality can vary across suppliers.
- Maintenance becomes inconsistent and costly.
- Field staff require training for multiple systems.

By enforcing BIS standards in procurement, quality and compatibility are assured. This leads to:

- Better inventory and service management.
- Simplified training for cold chain technicians.
- Greater accountability from manufacturers.

4.3. Enhancing Compatibility and Training

Standardization simplifies logistics by ensuring equipment compatibility [15] —whether it's fitting a specific size of ice pack into a Vaccine Carrier or cold box or using standard voltage ranges for refrigerators across different states. Standardization plays a crucial role in enhancing compatibility, interoperability, repeatability, and overall quality [16]

It also:

- Streamlines training programs for cold chain technicians and vaccine handlers.
- Reduces operational errors due to familiarity with standard equipment design.
- Improves outcomes of cold chain performance audits/assessments (e.g., WHO's Effective Vaccine Management assessments).

4.4. Supporting Innovation and Sustainability

BIS standards help drive:

- **Innovation**, by giving manufacturers a performance benchmark to meet or exceed (e.g., through solar direct-drive fridges or phase-change materials).
- **Sustainability**, by promoting the use of non-toxic refrigerants (e.g., R600a, R290) and eco-friendly insulation (e.g., cyclopentane over HFCs).
- **Energy efficiency**, especially critical in off-grid or power-deficient rural areas.

This aligns with India's National Action Plan on Climate Change (NAPCC) [17] and Sustainable Development Goals (SDGs), particularly in improving access to clean energy and health infrastructure.

4.5. Helps in promoting Make-in-India policy:

Indian standards for cold chain equipment are instrumental in advancing the "Make in India" initiative by promoting domestic manufacturing and decreasing dependence on imports. By providing clear guidelines and specifications, these standards ensure fair competition for local manufacturers, encourage innovation, and enhance the quality of home grown cold chain equipment. As a result, they support the growth of the domestic industry, generate employment and reinforce India's cold chain infrastructure [18].

5. Why BIS Standards Matter in Immunization:

5.1 Vaccine Integrity

Equipment certified to BIS-IS ensures stable temperature control across diverse Climatic conditions, preventing vaccine spoilage.

5.2 Alignment with Global Best Practices:

BIS standards integrate WHO PQS and EVM requirements, ensuring alignment with international Quality and safety guidelines.

5.3 Operational Consistency:

Uniform equipment standards simplify training, maintenance, and operation, as outlined in national manuals and job aid

It also helps in procurement of standard quality assured equipment ensuring safety and maintaining the potency of vaccine, as they are broadly aligned with International Standards.

6. Benefits of the Standards [19]:

Feature	Benefit
Temperature Control	Prevents cold chain breaches (2–8°C for vaccines; –15 to –25°C for freezers)
Quality Assurance	BIS standards guarantee that cold chain equipment adhere to specific quality criteria, reducing the risk of ineffective or harmful products.
Safety	By following BIS standards, manufacturers can ensure the safety of vaccines and equipment, thereby minimizing the risk of adverse reactions or contamination.
Environmental	Promotes use of ozone-friendly materials in insulation
Reliability	BIS certification instils confidence in healthcare professionals and the public by assuring that the products used in immunization programs are dependable and function as intended.
Standardization	BIS standards streamline the production process, ensuring consistent quality across various manufacturers of equipment.
Public Trust	Compliance with BIS standards fosters public trust in immunization programs, leading to increased participation and ultimately supporting disease prevention efforts.
Global Compliance	Facilitates WHO prequalification and vaccine export readiness
Regulatory Compliance	BIS standards are frequently harmonized with international standards, facilitating India's involvement in global immunization efforts and enhancing trade opportunities.
Reduced Risk of Counterfeits	BIS certification helps distinguish genuine products from counterfeit ones, safeguarding against potentially fake cold chain equipment.
Traceability	BIS standards enhance the tracking and traceability of the equipment, allowing for rapid identification and recall of any potentially problematic batches.

7. Conclusion:

The lack of standardization in cold chain equipment can compromise vaccine safety, disrupt immunization logistics, and undermine public health outcomes, -Potentially leading in loss of public trust. Indian Standards developed by the Bureau of Indian Standards (BIS) provide a technical and regulatory frame-

work to ensure consistency, reliability, and efficiency in cold chain infrastructure. Their adoption is essential for achieving immunization targets, minimizing vaccine wastage, and strengthening India's health system resilience.

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