





Protecting the Quality of Pharmaceuticals in Bangladesh

The International Rescue Committee implemented end-to-end traceability to protect the quality of health products and build patient trust.

Ensuring access to safe and effective health supplies requires quality assurance across the pharmaceutical value chain. International and national supply chain operators are responsible for maintaining quality from the place of manufacture until the product is in the hands of the client, which can be accomplished with traceability processes.

BACKGROUND

Since 2017, more than 700,000 Rohingya refugees have fled from Myanmar to Cox's Bazar in Bangladesh, joining hundreds of thousands who have been living in refugee camps and local Bangladeshi host communities. The refugees live in crowded, temporary shelters and rely heavily on humanitarian aid. This protracted situation prevents host communities from using arable land, which threatens their livelihoods. Both refugees and host community members, a total of 1.52 million individuals, have pressing and often unmet health care needs.

The International Rescue Committee's (IRC) health program in Bangladesh consists of four primary health care facilities, one basic emergency obstetric and newborn care center, 47 sexual and reproductive health clinics, and 13 referral hubs. The IRC also supports four government *upazila* (sub-district) health complexes.

PRACTICE

Ensuring quality in the health supply chain is a critical aspect of IRC's service provision. It uses end-to-end traceability of pharmaceutical products to ascertain the quality of all medicines that enter the supply chain in Bangladesh. In addition to complying with the International Organization for Standardization (ISO), IRC is committed to continuous learning through a systematized process based on field observations (Figure 1).

By following the steps in Figure 1, IRC helps prevent the distribution of counterfeit and sub-standard pharmaceutical products, which improves patient safety and builds trust in the health supply chain. Factors that enable end-to-end traceability include:

• Human resources: IRC develops and nurtures staff motivation and skills and provides competitive pay, benefits, and opportunities for advancement to attract and retain staff.



As country pharmacist for IRC's Bangladesh program, Shariful Islam has supported the QA system, including end-to-end traceability, to protect the quality of health supplies.

Location: Bangladesh

Organization: International Rescue Committee

Setting: Rohingya refugee camps and host communities

SCM practice area: Quality assurance (QA) and end-to-end traceability

HR cadres using this approach: Supply chain, pharmacy, and warehouse managers

This series of learning briefs focuses on health supply chain practices that humanitarian partners can implement to resolve common challenges and improve delivery of pharmaceutical and medical commodities.

Figure I. IRC's End-to-end Traceability Activities

discrepancies

a. Identification of	b. Verification of	c. Good
pharmaceutical	authenticity	record-keeping
productsEssential Drug ListCode numbers for easy traceability	 Prequalified distributors Rigorous QA (ISO 9001) Conformity of packaging, labels 	 Purchase order numbers Expiry dates Date of receipt Batch numbers Stock card numbers
d. Storage and	e. Distribution	f. Pharmacy and
 handling Storage in compliance with manufacturer's guidance Temperature controls Product tracing among regional warehouses and clinics 	 Appropriate containers Suitable vehicles Uninterrupted cold chain If outsourced, clear written agreements for compliance 	 dispensing to clients Pharmacy entry restrictions BIN and stock cards Quarantine zone established Patient's consumption tracing
g. Monitoring and tracking h. Reporting		
 Dedicated pharmacist to entire end-to-end tracea Quick identification of is 	o monitor bility process regulato	ng of adverse events to ry authorities, manufacturer

- **Training:** IRC provides tailored training and mentorship for specific staff, including members of the supply chain, fleet, warehouse, and health care units. It uses simulations and role-playing exercises to help staff understand how to apply traceability procedures.
- **Financial resources:** With a detailed checklist, IRC ensures budget allocation for traceability processes during its proposal design phase. IRC continuously looks for ways to improve cost-effectiveness and automate processes to reduce dependency on large amounts of funding for traceability. Most of the tools that IRC has developed to support traceability cost little or nothing.
- **Coordination and organizational learning:** IRC participates in the Health and Logistics Clusters and maintains a good rapport with national and international associations such as IAPHL, HCL, QUAMED, and the Pharmacy Council of Bangladesh to facilitate a learning environment that maximizes traceability and QA technical expertise and resources.

IRC's traceability process (Figure 1) was tested in 2022, when IRC Bangladesh had an incident during which the expiry date of secondary and tertiary packaging did not match the expiry date of the primary packaging. IRC immediately informed stakeholders and recalled all drugs by the manufacturer from field and site warehouses. The drugs were quarantined in the central warehouse and, after an internal review process conducted by the global and country management



PRACTICE AREA ESSENTIALS

End-to end traceability of health supplies

Traceability allows supply chain managers to track the history, application, use, and location of an item through recorded identification data, which can help ensure the quality of pharmaceuticals.

The supply chain manager needs to know:

- QA programs
- Visual inspection tools to detect substandard health products and inconsistencies
- Key activities for effective end-to-end traceability

Securing the pharmaceutical supply chain with full traceability

WHO Quality Assurance Policy for the Procurement of Essential Medicines and Other Health Products

The Supply Chain Manager's Handbook teams, IRC resolved the problem with the manufacturer. Thanks to the end-to-end traceability system, the product was recalled and sent back to the manufacturer.

IRC traces the movement of products from the manufacturer to the central warehouse to site warehouses and clinics. By reviewing each shipment's location, temperature, and other environmental data, IRC can identify potential problems and take action to resolve them. Product source and supplier authentication also help to validate products and prevent counterfeiting and tampering during transportation. Furthermore, IRC Bangladesh continuously monitors key indicators to prevent substandard products from reaching clients. IRC recently implemented the Integra enterprise resource planning system, which generates reports showing products that do not meet quality standards.

Key Lessons Learned

• Implementing an end-to-end traceability process requires significant investment in technology, training, and personnel, which is sometimes difficult to achieve. Organizations should plan sufficient funding for this purpose in every project; a QA checklist and a focus on prioritizing various initiatives can help.



IRC staff load a car with cold chain packs.

- Collaboration between stakeholders in the pharmaceutical supply chain is
 essential to implement QA and end-to-end traceability processes that meet organizational needs. This includes building
 and maintaining relationships with manufacturers, distributors, procurement units, warehouse and fleet staff, regulatory
 authorities, and health care providers.
- Training is important to ensure that staff members and other stakeholders understand the importance of traceability and how to apply procedures. Organizations should invest in continuous training programs tailored to the role of each member, including any non-technical staff who play a role in critical supply chain tasks such as maintaining a cold chain.

Traceability processes have helped IRC identify substandard products in the supply chain, enabling it to recall and prevent those products from reaching clinics and patients. This end-to-end product traceability practice demonstrates IRC's commitment to maintaining a rigorous QA system. In Cox's Bazar, the US Department of State's Bureau of Population, Refugees, and Migration is the leading funder of IRC's health program, including support for developing and maintaining most QA processes. USAID's Bureau for Humanitarian Assistance provided funding to strengthen the upazila health complexes in Cox's Bazar.

Building Capacity to Improve Pharmaceutical and Medical Commodity Management in Humanitarian and Disaster Settings Project



The Building Capacity to Improve Pharmaceutical and Medical Commodity Management in Humanitarian and Disaster Settings Project improves the capacity of people who manage health supply chains in humanitarian settings. It helps staff from international organizations and local NGOs to manage pharmaceutical and medical commodities by equipping them with training, guidance, resources, and follow-up support. JSI manages the project, which is funded by USAID's Bureau for Humanitarian Assistance.

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