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The Role of Pharmacy Professionals in Improving Cold Chain Management and Storage Safety of Temperature-Sensitive Medications

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ABSTRACT: Cold chain management is a core responsibility of pharmacy professionals, whose training and oversight ensure that temperature-sensitive medications—vaccines,

insulin, biologics, blood products, and certain antibiotics—retain their potency from manufacturer to patient. Pharmacists establish and enforce storage protocols, monitor refrigeration equipment with calibrated data loggers and continuous temperature tracking, and respond to excursions with documented, evidence-based corrective actions. Beyond infrastructure, they serve as the institutional memory for stability data and manufacturer specifications, interpreting whether a brief deviation compromises a product or whether it can be safely returned to inventory. This judgment directly affects patient safety, therapeutic outcomes, and the financial cost of avoidable waste.Pharmacists also function as educators and system designers who translate cold chain requirements into everyday practice. They train technicians, delivery staff, and clinical colleagues on proper handling, minimize door openings, arrange stock for first-expiry-first-out rotation, and design contingency plans for power outages or equipment failure. In resource-limited settings, pharmacy professionals are often the ones adapting protocols to unreliable electricity, using validated cold boxes and phase-change materials where refrigeration cannot be guaranteed. Through documentation, auditing, and participation in quality improvement, they convert cold chain management from a passive storage task into an active safety system—one whose failures are usually silent and whose successes go unnoticed until a vaccine or biologic performs exactly as it should.

INTRODUCTION

The cold chain is the controlled sequence of storage, handling, and transport events that protects temperature-sensitive medicines from manufacture to administration. Its purpose is not merely logistical; it is therapeutic. A vaccine, insulin product, monoclonal antibody, or advanced therapy that has been exposed to inappropriate temperatures may lose potency, undergo irreversible physical or chemical degradation, or become unsafe for use even when its external appearance is unchanged. The World Health Organization's model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products therefore treats cold chain management as a quality-critical activity requiring defined responsibilities, validated equipment, documented monitoring, and trained personnel [1]. Within this system, pharmacy professionals are not peripheral operators but central accountable professionals. They receive, store, dispense, monitor, investigate deviations, train staff, and counsel patients, and they are uniquely placed to connect pharmaceutical science with day-to-day storage safety [1].

The importance of this role has increased as the range of thermolabile medicines has expanded. Community and hospital pharmacies now manage not only conventional vaccines and insulin but also biosimilars, monoclonal antibodies, ultra-low-temperature biologicals, and cell and gene therapies. Each product category brings specific temperature limits, handling requirements, and excursion-management rules. At the same time, inspections continue to identify basic failures in daily practice, including missed temperature recordings, overstocked refrigerators, incorrect probe placement, and failure to escalate out-of-range readings. These failures show that cold chain safety depends less on the existence of guidelines than on whether pharmacy professionals translate those guidelines into routine, auditable practice [1].

Regulatory and Quality Frameworks Governing Cold Chain Practice

Cold chain practice is structured by international, regional, and national requirements that define what constitutes acceptable storage and distribution. The World Health Organization's good distribution practices provide a global reference for maintaining product quality throughout the supply chain and for managing temperature-sensitive products according to defined conditions [2]. The United States Pharmacopeia General Chapter <1079> addresses good storage and distribution practices for drug products and reinforces the need for documented temperature control, monitoring, and deviation management [3]. In Europe, guidelines on good distribution practice for medicinal products for human use establish expectations for quality systems, personnel, premises, equipment, documentation, and temperature control during storage and transport [4]. In the United States, FDA regulations under 21 CFR Parts 211 and 203 impose current good manufacturing practice and prescription drug distribution requirements that apply to refrigerated and otherwise temperature-sensitive products [5].

These frameworks converge on several principles that directly shape pharmacy practice. Storage conditions must be defined and justified; monitoring must be frequent, documented, and reviewed; excursions must be investigated rather than merely

recorded; personnel must be trained and competent; and records must be retained and available for inspection. The pharmacist is the professional within the pharmacy who converts these expectations into standard operating procedures, training programmes, equipment qualification schedules, and audit systems. Regulatory compliance is therefore not achieved by purchasing a data logger or displaying a thermometer. It is achieved when a coherent quality system exists in which monitoring data are reviewed by a named person, deviations are escalated, corrective actions are implemented, and records demonstrate that the system has worked [5].

Professional accountability reinforces legal obligation. Regulatory inspections have identified medicine storage failures as professional standards failures, not merely housekeeping deficiencies. The General Pharmaceutical Council reported in 2025 that 86 pharmacies failed a storage standard, with nearly one in twenty unable to demonstrate appropriate refrigeration of medicines [6]. The findings included failure to record maximum and minimum temperatures daily, recording out-of-range temperatures without informing the pharmacist, overstocked refrigerators, medicines pushed against the back wall or into ice compartments, and the use of uncalibrated or mercury-based thermometers [6]. These are not abstract regulatory issues. They are practical failures of professional governance, and they demonstrate why the pharmacist-in-charge must establish clear responsibility, visible leadership, and a culture in which every staff member understands when and how to escalate a cold chain concern [6].

The Expanding Landscape of Temperature-Sensitive Medications

Temperature-sensitive medications are not a single homogeneous group. They include products stored at controlled room temperature, under refrigeration, frozen, ultra-low temperature, and cryogenic conditions. A pharmacist must distinguish among these categories and apply the correct storage condition to each product. The integrative literature on thermolabile medicines emphasizes that pharmacists have a direct role in therapeutic safety through correct storage, stability awareness, and patient counselling, particularly as more products require strict temperature control [7]. Table 1 summarizes the principal storage categories encountered in pharmacy practice.

Table 1. Principal storage categories for temperature-sensitive medications

Storage category	Typical temperature range	Representative products	Key risks
Controlled room temperature	20–25 °C, sometimes 15–30 °C	Many oral solids and some inhalers	Heat degradation and humidity damage
Refrigerated	2–8 °C	Most vaccines, insulin, monoclonal antibodies, biosimilars	Freezing damage and excursions above 8 °C
Frozen	−25 °C to −15 °C	Certain vaccines and selected biological intermediates	Loss of cold chain and repeated freeze–thaw cycles
Ultra-low temperature	−86 °C to −40 °C	Cell therapies, selected gene therapies, specialized biologicals	Equipment failure and cryogenic hazards
Cryogenic	Below −150 °C, often vapor-phase liquid nitrogen	CAR-T cell products and other advanced therapies	Handling safety and inventory complexity

The refrigerated category is the most familiar in community and hospital pharmacy, but it is also the category in which routine failures are frequently documented. Overstocking reduces air circulation, products placed at the back of a refrigerator may freeze, and door storage exposes medicines to repeated temperature fluctuation. The pharmacist must therefore treat refrigerator capacity as a quality constraint, not merely a space constraint. The growing number of temperature-sensitive products dispensed in community settings means that cold chain competence is no longer confined to vaccine-handling pharmacies. It is a general professional requirement [7].

Training, Competency, and the Human Dimension of Cold Chain Safety

Technology and infrastructure are necessary but insufficient conditions for cold chain safety. The human element—knowledge, skill, and conscientious practice—is equally determinative. A cross-sectional assessment of vaccine cold chain handlers found an average knowledge score of 62.42% and an average practice score of 65.33%, both below the 80% target set by the Effective

Vaccine Management framework, and concluded that training has a measurable effect on both knowledge and practice, particularly when multiple training modalities are combined [8]. The implication is clear: cold chain competence cannot be assumed from professional qualification alone. It must be deliberately developed, assessed, and refreshed [8].

The pharmacist's role in training is both didactic and supervisory. Effective training is role-based and mapped to standard operating procedures. Not every member of staff needs the same depth of knowledge, but every person who handles temperature-sensitive products must understand the storage requirements of those products, the signs of an excursion, and the escalation pathway. A role-based curriculum should cover the relevant storage ranges, pack-out and shipping procedures, temperature monitoring and documentation, and the actions to take when a deviation occurs. The pharmacist should deliver or oversee the training, assess competence through observation and questioning, and provide refresher training at defined intervals. Competency assessment should include practical demonstration of temperature recording, interpretation of monitoring data, and correct execution of excursion procedures. Without this human dimension, even well-designed equipment and written procedures can fail at the point of daily practice [8].

Cold Chain Safety in Resource-Limited and Low- and Middle-Income Settings

In low- and middle-income countries, cold chain challenges are compounded by structural constraints. A narrative review of vaccine cold chain distribution in developing countries identified persistent problems including unreliable electricity supply, inadequate storage and transport capacity, long distribution routes, limited funding for maintenance, fragmented governance, and shortages of trained personnel [9]. These factors contribute to temperature excursions, vaccine wastage, and stock-outs, particularly in remote and underserved settings. Climate-related events can also damage refrigeration systems, and contingency arrangements for power outages or equipment failure are often weak [9].

In these settings, the pharmacist's role must be adapted to the available resources. Innovations such as solar direct-drive refrigeration, real-time temperature monitoring, electronic logistics management information systems, and drone-enabled last-mile delivery have shown potential, but many remain pilot-based and donor-dependent [9]. The pharmacist can contribute by advocating for context-appropriate technology, developing low-resource monitoring protocols that prioritize the most critical products, and training staff in contingency procedures for power outages and equipment failure. The principle of proportionate risk management is essential. Where continuous electronic monitoring is not feasible, the pharmacist must design a system of manual checks, physical indicators, and clearly defined escalation pathways that provide the greatest possible protection with the resources available [9].

Core Responsibilities of Pharmacy Professionals Across the Cold Chain Lifecycle

The pharmacist's responsibility begins at receipt. Incoming shipments of temperature-sensitive products must be inspected for evidence of temperature excursion during transit, and the pharmacist must verify that shipping conditions were appropriate before accepting the goods. National cold chain guidelines emphasize that receiving procedures should include verification of temperature indicators or data loggers, confirmation that the product temperature is within the labeled range, and documentation of any discrepancy before the product is released into inventory [10]. A product that cannot be shown to have been maintained within its required temperature range during transit cannot be assumed to be fit for use [10].

Once a product is accepted, the physical environment of storage becomes the determinant of its integrity. The pharmacist must ensure that refrigerators, freezers, and controlled-temperature rooms are appropriate for the products stored, are qualified before use, and are maintained in a state of validated control. Storage safety is also a matter of inventory discipline. Overstocked refrigerators impede air circulation and create temperature gradients that can compromise products at the rear or in corners. The pharmacist must establish stock levels consistent with the capacity of the storage unit, implement first-expiry-first-out rotation, and ensure that products are not stored in locations where they are exposed to freezing or excessive heat. Products should remain in their original packaging where possible, both to protect them from light and to preserve lot and expiry information. The pharmacist's judgment about what belongs in the refrigerator, how much of it belongs there, and how it should be arranged is an exercise of professional expertise with direct consequences for product quality [10].

Temperature Monitoring and the Management of Excursions

Temperature monitoring has evolved from manual twice-daily readings of minimum and maximum thermometers to continuous digital surveillance with real-time alerts. Each modality has a role, and the pharmacist must select the approach that

is proportionate to the risk associated with the products stored and the resources of the practice setting. Table 2 compares the principal monitoring approaches.

Table 2. Approaches to temperature monitoring in pharmacy practice

Approach	Typical method	Advantages	Limitations
Manual min–max logging	Alcohol or electronic min–max thermometer with twice-daily recording	Low cost, simple, suitable for low-risk ambient storage	Provides only interval extremes and relies on staff diligence
Portable data loggers	USB or Bluetooth loggers placed in storage units and downloaded periodically	Time–temperature history and suitability for mapping and transport	Data may be reviewed retrospectively unless integrated
Continuous wired or wireless systems	Sensors connected to a central monitoring platform with alarms and remote access	Real-time alerts, automated records, and suitability for high-risk products	Capital and maintenance costs and need for validation
IoT-enabled real-time loggers	Cellular or network-connected devices with cloud dashboards	Remote visibility, predictive analytics, and inventory integration	Dependence on connectivity and data governance considerations

Manual monitoring remains acceptable for controlled room temperature storage in many community pharmacies, and guidance commonly recommends recording minimum and maximum temperatures twice daily with the identity of the reviewer documented. However, for refrigerated vaccines, biologics, and advanced therapies, continuous monitoring is increasingly regarded as the standard of care because it captures excursions that occur between manual readings and provides the evidence needed for deviation investigations. The pharmacist must ensure that whatever system is used is calibrated, that alarms are functional, and that data are retained for the required period [10].

A temperature excursion is not simply an inconvenience to be noted in a logbook. It is a quality event that requires investigation and a documented disposition decision. Written procedures must describe the actions to be taken when storage conditions deviate from the labeled range, and all excursions must be investigated with an evidence-based decision about the affected stock [11]. The investigation should establish the magnitude and duration of the excursion, the products affected, the stage of the cold chain at which the event occurred, and whether the product's stability data permit continued use. The pharmacist must be notified promptly, must initiate the deviation record, and must decide whether the product can be released, quarantined pending manufacturer consultation, or discarded. The decision cannot be based on a generic rule alone; it must be product-specific and informed by the manufacturer's stability data and, where necessary, by a formal stability assessment. Table 3 outlines a structured approach to excursion management.

Table 3. Structured response to a cold chain excursion

Step	Action	Responsible professional
Detect and secure	Identify the affected storage unit, prevent further dispensing, and isolate affected stock	Designated cold chain lead or pharmacist
Document	Record time, duration, temperature range, products affected, and preserve monitoring data	Pharmacist or trained technician
Assess	Determine whether the excursion falls within stability data and consult the manufacturer if necessary	Pharmacist
Decide disposition	Release, quarantine, or discard and document the rationale	Pharmacist

Correct and prevent	Identify root cause, implement corrective action, and review the procedure if needed	Pharmacist-in-charge or quality lead
Learn	Share findings with staff and update training where relevant	Pharmacist-in-charge

The final step—learning—is often neglected. An excursion that is investigated and closed without changes to practice is a missed opportunity. The pharmacist should treat each deviation as a signal about the robustness of the system and should use accumulated data to identify patterns, such as recurrent door-opening problems, equipment aging, or gaps in staff knowledge.

Biologics, Biosimilars, and Advanced Therapies: Special Storage Challenges

The composition of pharmacy inventories has changed substantially in recent years. Biosimilars and innovative therapies have introduced a growing number of temperature-sensitive products with specific handling requirements. Monoclonal antibodies and their biosimilars generally require storage at 2–8 °C, and their protein structure is vulnerable to degradation under temperature stress, compromising stability and efficacy [12]. For some products, stability data permit limited excursions. Unopened vials of a bevacizumab biosimilar, for example, remained stable for 72 hours at 25 °C when protected from light, while opened vials could be stored for up to 60 days at 2–8 °C, but such allowances are product-specific and cannot be generalized [13].

At the more demanding end of the spectrum, cell and gene therapies require ultra-low temperature freezers operating between −86 °C and −40 °C, and some chimeric antigen receptor T-cell products arrive cryopreserved in vapor-phase liquid nitrogen at approximately −180 °C. A national survey of French hospital pharmacists highlighted the practical difficulties of ultra-low-temperature storage, including equipment availability, monitoring, and workflow adaptation [14]. These products introduce not only temperature complexity but also handling hazards, including cryogenic burns and asphyxiation risk, and they demand redundant cooling systems and validated monitoring that exceed the requirements of conventional refrigerated storage. Purpose-built cold chain facilities for cell and gene therapies therefore emphasize redundancy, alarm systems, chain-of-identity documentation, and trained personnel [15]. The pharmacist's role in this environment extends beyond temperature logging to the design of fail-safe storage architectures and the coordination of chain-of-identity and chain-of-custody requirements [15].

Storage Facility Design, Equipment Qualification, and Temperature Mapping

Once a product is accepted into the pharmacy, the physical environment of storage becomes the determinant of its integrity. The pharmacist must ensure that refrigerators, freezers, and controlled-temperature rooms are appropriate for the products stored, are qualified before use, and are maintained in a state of validated control. Calibration and validation of pharmaceutical refrigerators are central to this process, because an uncalibrated device may provide reassuring readings while failing to maintain the required range [16]. Temperature mapping is a related requirement. Calibrated data loggers are placed throughout the storage unit to measure temperature distribution over a defined period, identifying warm and cold spots and confirming that the unit can maintain the required range under representative load and door-opening conditions [17]. Mapping should be performed before initial use, after significant modifications, and on a risk-based schedule thereafter [17].

Equipment qualification extends beyond mapping to include verification of alarms, calibration of sensors and monitoring devices, and documentation of maintenance and repair history. The pharmacist is responsible for ensuring that these activities occur and that the resulting records are available for inspection. A qualified refrigerator is not merely one that has been mapped; it is one whose performance is continuously demonstrated through monitoring, maintenance, and review. Incorrectly positioned probes, thermometers with low batteries, and uncalibrated devices are common inspection findings, and they illustrate what happens when equipment qualification is treated as a one-time event rather than as a continuing responsibility [17].

Technology, Data, and Digital Transformation of Cold Chain Oversight

The digital transformation of cold chain management has created new possibilities for pharmacist oversight. IoT-enabled data loggers transmit temperature and humidity data in real time to cloud platforms, allowing pharmacists to monitor storage conditions remotely and to receive alerts when parameters drift outside acceptable limits. These systems can integrate with inventory management platforms, linking temperature data to specific lots and enabling faster identification of affected stock during an excursion. Blockchain-based architectures have been proposed to enhance traceability and integrity across the pharmaceutical supply chain, combining environmental sensors, edge computing, and distributed ledger storage to create

tamper-resistant records of cold chain conditions [18]. Related work on blockchain and temperature-setting approaches for temperature-sensitive medicines emphasizes secure supply chain records and controlled environmental data [19].

For the pharmacist, these technologies are not ends in themselves. Their value lies in the quality of the decisions they enable. A real-time alert is useful only if there is a clear procedure for responding to it, a designated person who is accountable, and a documented record of the response. The pharmacist must therefore approach digital tools as components of a quality system, not as substitutes for professional judgment. The selection of a monitoring platform should be based on its fitness for the specific products and settings, its validation status, and its capacity to generate records that satisfy regulatory requirements. Monitoring data constitute quality records, and they must be retained for the period specified by regulation and organizational policy. The identity of the person reviewing the data must be documented, and the audit trail must be secure against alteration. The pharmacy remains responsible for the completeness and accuracy of its cold chain records even when cloud-based platforms are used [19].

Logistics, Cost, and Proactive Temperature Management

Cold chain management is also a logistics and economic activity. The integrity of temperature-sensitive medicines depends on packaging, shipping configurations, transport validation, and coordination among manufacturers, distributors, wholesalers, and pharmacy receiving teams [20]. Each transfer between organizations creates a potential break in the chain, and the pharmacist must ensure that receiving procedures are robust enough to detect and respond to transit excursions. The economic consequences of failure are substantial. Temperature excursions can destroy product value, disrupt inventory, delay treatment, and increase replacement costs, and the true cost of an excursion includes not only the discarded product but also the operational and clinical consequences of stock unavailability [21].

A proactive approach to temperature management shifts attention from retrospective investigation to prevention. This includes risk assessment of storage and transport processes, selection of appropriate packaging and monitoring devices, validation of shipping routes, and use of data to predict and prevent excursions before they result in product loss [22]. For the pharmacist, proactive management means reviewing monitoring data for trends rather than waiting for an alarm, planning storage capacity before introducing new products, and ensuring that contingency arrangements exist for power outages, equipment failure, and extreme weather. The pharmacist's role in logistics is therefore not limited to accepting deliveries. It includes participating in the design of the cold chain that supplies the pharmacy and advocating for resources that reduce the risk of temperature-related loss [23].

Auditing, Continuous Quality Improvement, and the Learning Pharmacy

Cold chain safety is not achieved once and then maintained automatically. It requires a cycle of audit, feedback, and improvement. Audits should examine the structure of cold chain management, including equipment, procedures, and training records; the process of storage and monitoring, including temperature records, excursion investigations, and stock rotation; and the outcomes, including product wastage, compliance rates, and inspection findings. A pharmacist-led strengthening of vaccine cold chain management in primary health centers reported improvements in transport temperature compliance from 90% to 100%, reductions in delivery delays from 60% to 0%, increases in staff competency from 20% to 100%, and a 47% reduction in vaccine wastage [23]. These results were not attributable to a single intervention but to a systematic approach that combined training, monitoring, and accountability. The pharmacist was the common factor across these interventions, providing the technical leadership and quality oversight that made improvement possible [23].

To manage cold chain safety effectively, pharmacists need meaningful indicators. Table 4 proposes a set of indicators that can be used to monitor performance and identify areas for improvement.

Table 4. Suggested key performance indicators for pharmacy cold chain management

Indicator	What it measures	Target direction
Percentage of required temperature readings completed	Monitoring compliance	Increase toward 100%
Percentage of excursions investigated within defined timeframe	Responsiveness of deviation management	Increase toward 100%

Percentage of staff with current cold chain competency assessment	Workforce readiness	100%
Rate of product wastage attributable to cold chain failure	Outcome quality	Decrease
Time from alarm to pharmacist notification	Escalation efficiency	Decrease
Percentage of storage units with current qualification and calibration	Equipment assurance	100%

These indicators should be reviewed at regular intervals and used to inform training, resource allocation, and procedural revision. The pharmacist's role is to ensure that the indicators are meaningful, that the data are reliable, and that the review process leads to action rather than to passive documentation [23].

Standard Operating Procedures and Practical Storage Safety

Standard operating procedures are the practical expression of the pharmacist's accountability. They should define who is responsible for temperature monitoring, how often readings are taken, how alarms are handled, how excursions are investigated, how products are received, how stock is rotated, and how records are retained. The Ontario College of Pharmacists' cold chain guideline provides a useful model of written expectations for refrigeration, monitoring, documentation, and excursion management in pharmacy practice [24]. The NHS standard operating procedure for fridge monitoring and cold chain standards similarly illustrates how ward and clinic storage can be governed by defined procedures, designated responsibilities, and escalation pathways [25]. The pharmacist-in-charge must ensure that procedures are current, accessible, understood by staff, and reviewed after incidents or changes in equipment or product range [25].

Practical storage safety also depends on simple disciplines that are easy to overlook. Refrigerators should not be overfilled. Products should not be stored in doors, vegetable bins, or against cooling vents. Diluents should be managed according to product-specific requirements rather than assumed to require refrigeration. Thermometers and probes should be correctly positioned, and alarms should be tested. Staff should know how to reset a thermometer, recognize a failing device, and report an out-of-range reading immediately. These are not minor administrative details. They are the daily practices through which the cold chain either holds or breaks [25].

CONCLUSION

The cold chain is a chain of professional decisions as much as a chain of equipment and logistics. Pharmacy professionals are the individuals best equipped to make those decisions well: they understand the science of stability, they are trained in quality systems, they are accountable to regulatory and professional standards, and they are present at every point where a temperature-sensitive medicine is received, stored, dispensed, and explained to a patient. The role of the pharmacist in cold chain management therefore extends far beyond the act of recording a temperature. It encompasses the design of storage systems, the qualification of equipment, the training and supervision of staff, the investigation of excursions, the use of data to drive improvement, and the creation of a culture in which the integrity of temperature-sensitive medicines is treated as a non-negotiable professional obligation.

The evidence reviewed here shows that cold chain failures remain common and costly and that they are frequently rooted in human and organizational factors rather than in unavoidable technical limitations. It also shows that pharmacist-led interventions can produce measurable improvements in compliance, competency, and product wastage. The challenge for the profession is to translate these findings into sustained practice: to ensure that every pharmacy has a designated cold chain lead, a current standard operating procedure, a validated monitoring system, a trained workforce, and an audit cycle that closes the loop between detection and improvement. If pharmacy professionals embrace this responsibility fully, they can significantly reduce the burden of temperature-related medicine loss and, more importantly, protect the therapeutic efficacy and safety of the medicines on which patients depend.

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