Pharmacophore

ISSN-2229-5402

Journal home page: http://www.pharmacophorejournal.com

PREDICTING VACCINE COLD-CHAIN FAILURE USING TEMPERATURE STREAMS, PACKAGING, ROUTE, AND EXCURSION HISTORY

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ARTICLE INFO

Received:
05 February 2026
Received in revised form:
16 April 2026
Accepted:
19 April 2026
Available online:
28 April 2026

Keywords: Vaccine cold chain, Predictive analytics, Temperature excursion, Machine learning, IoT monitoring, Phase-change materials

ABSTRACT

Vaccines can lose potency when exposed to temperatures outside their specified storage range, and cold-chain failures may compromise immunization programs even if discovered only after delivery. Most monitoring systems react after a temperature threshold has already been crossed, limiting opportunities for re-cooling, rerouting, or shipment replacement before product integrity is threatened. To address this, a predictive machine learning model is proposed to estimate the probability of vaccine cold-chain failure before an excursion occurs, integrating streaming temperature data, packaging insulation characteristics, route conditions, and the shipment or container's excursion history. Using a gradient-boosted classification framework applied to historical shipment records and continuously updated sensor feeds, the model considers features such as temperature trends, variability, packaging configuration, phase-change material properties, expected route exposure, and prior excursion severity. By identifying shipments whose thermal conditions are becoming unstable before formal failure thresholds are crossed, the model can support targeted interventions, including expedited transfer, additional cooling at hand-off points, or pre-release quality review. Predictive cold-chain analytics have the potential to shift vaccine logistics from retrospective excursion documentation to proactive risk management, reducing wastage, enhancing supply-chain resilience, and safeguarding the integrity of vaccination programs.

To Cite This Article: Boateng S, Mensah K, Asante K, Owusu L. Predicting Vaccine Cold-Chain Failure Using Temperature Streams, Packaging, Route, and Excursion History. Pharmacophore. 2026;17(2):112-22. https://doi.org/10.51847/v4xboYLxhw

Introduction

Vaccines are vulnerable to both heat and freezing damage, and reviews of cold-chain practice show that freezing remains a persistent risk rather than a fully resolved operational problem [1]. Field studies of vaccine distribution have also shown that cold-chain adaptability can determine whether new vaccines can be introduced without creating avoidable product losses [2]. The economic and public health consequences of cold-chain failure are therefore not limited to a single shipment; they can affect coverage, trust, and the reliability of immunization programs. A predictive model for cold-chain failure must begin from this product-integrity premise, treating every temperature deviation as a potential signal of future risk rather than only as a retrospective compliance event.

Cold-chain monitoring has evolved from periodic checks and chemical indicators toward data loggers, cloud-connected sensors, and IoT-enabled platforms [3]. Experimental and field work on vaccine temperature monitoring shows that internal vial or container temperatures may respond differently from simple environmental measurements, which complicates reliance on fixed thresholds alone [4]. Even when real-time systems generate alerts, many are configured to notify personnel only after a limit has been breached, so the alert is primarily reactive rather than preventive [5]. A predictive model should therefore transform monitoring data into a forward-looking estimate of excursion probability while there is still time to intervene.

The growing availability of sensor, packaging, route, and logistics data creates an opportunity to model failure risk before it becomes visible as a threshold violation. Pharmaceutical temperature excursion programs already emphasize structured handling of excursion records and quality decisions [6], while big-data approaches to cold-chain transportation have proposed

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early warning systems for pharmaceutical logistics [7]. Related cold-chain studies in food and perishable supply chains show that machine learning can use temperature histories, environmental variables, and routing context to anticipate thermal instability [8, 9]. These developments support a model-oriented approach in which vaccine cold-chain monitoring is treated as a dynamic prediction problem rather than a passive recording process.

This manuscript specifies a predictive model that combines real-time temperature stream features, packaging characteristics, route parameters, and excursion history to estimate the probability of an impending cold-chain failure. Packaging and thermal configuration are central because insulated containers, coolant preparation, and phase-change materials shape the buffer between external stress and internal product temperature [4]. Route and exposure features are also essential because journey duration, transport conditions, and regional climate influence the thermal load experienced by a shipment [10]. The proposed model is therefore designed to produce a continuously updated risk score that can guide proactive logistics action before a damaging excursion occurs.

Background

Vaccine Cold-Chain Requirements and Failure Modes

Vaccine cold-chain requirements are defined by the need to keep products within specified temperature ranges from storage through final delivery, because potency can be compromised by excessive heat, freezing, or repeated thermal stress [1]. Cold-chain studies during vaccine introduction have shown that infrastructure, packing practice, and handling procedures can shape whether temperature control remains stable under field conditions [2]. Work on cold water pack preparation further demonstrates that even seemingly routine cooling practices may expose vaccine vials to temperatures that differ from intended storage assumptions [4]. These failure modes make the prediction task clinically and operationally important, because a model must capture not only obvious overheating but also freezing risk and cumulative instability.

Sensor Technology and Real-Time Temperature Data Streams

Modern cold-chain monitoring increasingly uses IoT sensors, data loggers, and integrated digital platforms to generate continuous or near-continuous temperature observations during storage and transport [3]. Simulated vaccine transport studies show that time- and temperature-controlled data can reveal patterns that would be missed by sparse manual checks [5]. Deep learning work on vaccine refrigeration systems illustrates how high-frequency temperature streams can be used to detect anomalous thermal behavior on constrained devices [11]. For predictive modeling, these streams must be converted into stable features that represent recent level, direction, variability, and acceleration without overwhelming the model with redundant time points.

The Role of Packaging and Phase-Change Materials

Packaging determines how external thermal stress is filtered before it reaches the vaccine payload, so model inputs should represent insulation type, container geometry, coolant mass, and phase-change material behavior. Reviews of vaccine cold-chain management emphasize that cold storage and packaging technologies are central to maintaining viable temperatures across diverse distribution contexts [12]. Temperature-controlled container modeling has shown that cold energy storage systems can be represented through predictive temperature models, indicating that package thermal characteristics can be learned as part of a risk architecture. In the proposed vaccine model, these variables would act as predictors of thermal buffer capacity and susceptibility to future excursion.

Route, Duration, and Environmental Exposure

Route characteristics influence cold-chain risk because transport mode, travel duration, ambient climate, stops, and hand-offs determine the thermal stress imposed on the package. Thermal mapping of pharmaceutical transport routes has been used to construct route-level risk scores, showing that geography and route structure can be converted into predictive variables [10]. Real-time temperature prediction based on cooling dynamics also indicates that remaining journey conditions can be linked to the expected internal temperature trajectory [8]. A vaccine failure model should therefore incorporate planned route duration, expected external temperatures, seasonal exposure, and operational complexity rather than relying only on the container's current internal temperature.

Machine Learning in Cold-Chain and Logistics

Machine learning has already been explored for cold-chain prediction in pharmaceutical and adjacent perishable logistics, although direct vaccine-specific models remain less developed. A pharmaceutical cold-chain study using big data proposed early warning logic for transportation risk [7], and a later hybrid outlier detection case study showed how abnormal pharmaceutical cold-chain patterns can be identified from operational data [13]. Food and agricultural cold-chain studies have used neural networks, ensemble models, and hybrid architectures to forecast temperature conditions during transport [14-16]. These studies suggest that vaccine cold-chain failure can be approached as a supervised risk prediction problem, provided that model design remains aligned with pharmaceutical quality requirements rather than simply optimizing generic forecasting performance.

Model Development Overview

High-Level Prediction Framework

For an active vaccine shipment, the proposed model ingests recent temperature history from the logger or IoT platform, packaging metadata, planned route information, and historical excursion data for the shipment lane or reusable container. The output is a dynamic failure risk score that reflects the probability of a future temperature excursion under the currently observed conditions, similar in spirit to early warning approaches proposed for pharmaceutical cold-chain transportation [7]. The framework treats each update as a new decision point, allowing risk to rise or fall as the shipment moves through different transport stages. This design extends retrospective excursion management programs [6] into a predictive decision layer that could support intervention before formal breach confirmation.

Figure 1 presents the proposed predictive cold-chain failure architecture, showing how streaming temperature evidence, packaging resilience, route exposure, and excursion history are transformed into an interpretable risk score for proactive logistics and quality action.

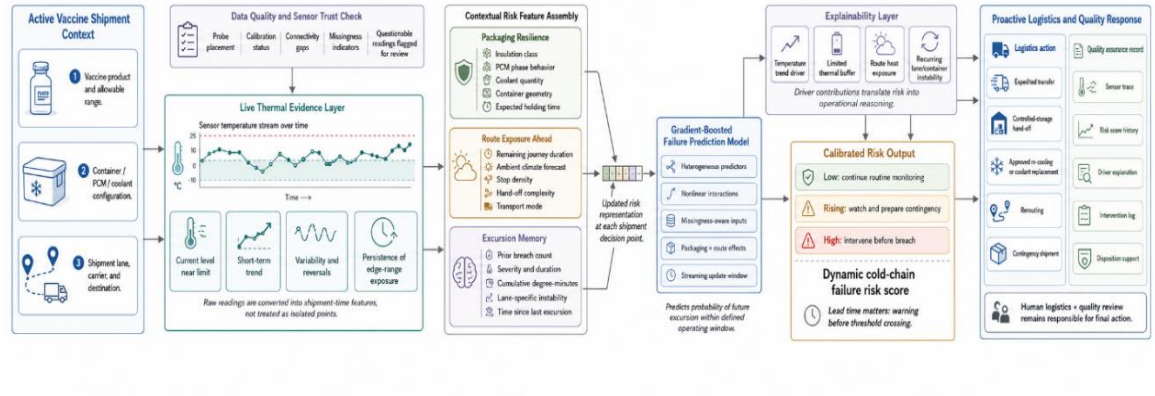

Figure 1. Predictive cold-chain failure architecture for vaccine shipments using temperature streams, packaging resilience, route exposure, and excursion history.

Core Input Features

Core temperature features would include moving average, short-term variability, maximum and minimum slopes, recent reversals, and persistence near the edge of the acceptable range. Packaging features would encode container type, insulation properties, coolant pack configuration, and PCM characteristics, reflecting evidence that cooling preparation and container thermal behavior influence product temperature stability [4]. Route features would describe expected duration, mode of transport, climate exposure, stop density, and hand-off complexity, consistent with route-level risk scoring in pharmaceutical transport [10]. Excursion history would capture prior breach count, duration, severity, cumulative degree-minutes outside range, and time since last excursion, drawing on the structured logic of temperature excursion management and quality review [6, 17].

Design Principles

The model should be real-time, continuously updated, interpretable, and designed to trigger graduated logistics responses rather than a single binary alarm. IoT-enabled vaccine cold-chain frameworks show how temperature data, device identity, and logistics information can be connected into a broader monitoring architecture [3], while blockchain-oriented vaccine tracking approaches illustrate the value of reliable digital shipment records [18]. Interpretability is essential because quality and logistics teams must understand whether a risk score is being driven by temperature trend, packaging weakness, route exposure, or repeated historical instability. The model should therefore support operational trust by pairing risk estimation with clear driver explanations and auditable data provenance.

Data Sources and Feature Engineering

Temperature Logs and Field Data Collection

Temperature logs would be extracted from logger files, IoT dashboards, or cloud-connected sensors and transformed into regular shipment-time intervals for modeling. Vaccine transport simulations demonstrate that time-temperature data can be collected under controlled scenarios to study cold-chain behavior [5], while deep learning work on refrigeration monitoring shows that streaming data can be processed for anomaly-oriented inference [11]. Each shipment interval would be labeled according to whether the shipment remained stable or later experienced a temperature excursion, using quality rules from established excursion management practice [6]. Feature engineering would avoid treating each raw measurement as independent and would instead summarize recent thermal behavior in a way that preserves trend, variability, and proximity to limits.

Encoding Packaging and Route Information

Packaging variables would be encoded as categorical and continuous predictors, including insulation class, container dimensions, PCM or coolant type, coolant quantity, pack preparation method, and expected thermal holding behavior. Studies of vaccine vial temperatures under different cooling preparations indicate that pack handling can materially influence the internal thermal environment [4], and broader vaccine cold-storage reviews reinforce the relevance of container and cooling technology selection [12]. Route plans would be converted into model features such as expected journey duration, transport mode, route thermal exposure, season, stop frequency, and hand-off intensity, building on thermal mapping approaches for pharmaceutical transport routes [10]. These engineered features would allow the model to learn interactions between packaging resilience and the environmental stress imposed by the planned route.

Constructing Excursion History Features

Excursion history features would summarize prior thermal failures associated with a reusable container, shipping lane, packaging configuration, facility, or logistics provider. Pharmaceutical excursion management frameworks emphasize that excursion duration, severity, product exposure, and disposition decisions must be captured systematically for quality assurance [6, 19]. Tier-based approaches for temperature excursion management further suggest that historical breach characteristics can be organized into risk-relevant categories rather than treated as isolated incidents [17]. In the proposed model, prior excursion count, recency, cumulative exposure, and repeated route-specific instability would modify future risk because they may indicate stressed packaging, recurring handling weaknesses, or environmental conditions not fully represented in the route plan.

Table 1 defines the proposed input domains and shows how each feature group contributes distinct operational meaning to vaccine cold-chain failure prediction.

Table 1. Model input domains, feature logic, and operational meaning for predicting vaccine cold-chain failure

Input domain	Representative engineered features	What the feature domain captures	Expected relationship to future failure risk	Operational interpretation	Potential data-quality concerns
Streaming temperature behavior	Moving average, temperature slope, short-term variability, maximum and minimum recent values, reversals, persistence near range limits	Current thermal stability of the shipment and whether conditions are drifting toward unsafe exposure	Rising trends, repeated reversals, high variability, or persistent edge-range exposure may indicate loss of thermal control before a formal excursion	Identifies shipments that appear stable by threshold status but are becoming thermally fragile	Sensor placement error, logger delay, calibration problems, intermittent connectivity, irregular sampling intervals
Proximity to product-specific limits	Distance from upper and lower allowable range, time spent near boundary, rate of approach to heat or freezing threshold	How close the shipment is to a breach relative to product requirements	Smaller distance to either heat or freezing boundary increases near-term risk, especially when paired with continued adverse trend	Distinguishes overheating risk from freezing risk and supports product-specific monitoring logic	Incorrect product temperature range, wrong vaccine profile assigned to shipment, missing product metadata
Packaging and thermal-buffer capacity	Container type, insulation class, coolant quantity, PCM type, expected holding time, container age, pack preparation method	The capacity of the packaging system to absorb future thermal stress	Lower insulation performance, depleted coolant, inadequate PCM behavior, or unsuitable pack preparation may increase susceptibility to future excursions	Helps determine whether the problem is likely caused by package weakness rather than current ambient exposure alone	Incomplete packaging records, unrecorded pack preparation deviations, aging reusable containers, inconsistent PCM conditioning
Route and environmental exposure	Remaining journey duration, ambient temperature forecast, transport mode, season, stop frequency, hand-off count, route thermal-risk score	The external stress that the shipment is expected to encounter before delivery	Longer exposure, hot or freezing climate zones, dense hand-offs, and high-risk lanes increase predicted failure probability	Supports rerouting, expedited transfer, or preventive intervention at planned hand-off points	Inaccurate route plan, unexpected delays, missing carrier data, unreliable weather or ambient exposure estimates
Shipment status and milestone timing	Current transport stage, time since dispatch, time until next controlled-storage point, dwell time at transfer node	Where the shipment is in the logistics process and whether intervention is still feasible	Risk may rise during loading, unloading, long dwell periods, last-mile delivery, or delayed transfer stages	Converts risk prediction into time-sensitive operational action rather than a static alert	Poor milestone synchronization, delayed status updates, manual entry errors, inconsistent time zones

Excursion history and repeated instability	Prior breach count, breach severity, breach duration, cumulative degree-minutes outside range, time since last excursion, lane/container recurrence	Whether similar shipments, containers, lanes, or providers have shown repeated thermal instability	Frequent, severe, recent, or recurring excursions suggest structural vulnerability and may raise baseline risk	Identifies problematic routes, reusable containers, or logistics practices requiring preventive review	Incomplete historical records, inconsistent excursion definitions, missing linkage between container, carrier, lane, and product
Facility and handling context	Origin and destination facility, storage hand-off quality, staff handling patterns, loading/unloading procedure indicators	Human and site-level contributors to cold-chain reliability	Facilities or hand-off points associated with repeated instability may increase risk even when package and route appear acceptable	Supports targeted training, standard operating procedure review, or facility-level corrective action	Sparse facility metadata, underreported handling deviations, confounding by route or product mix
Data reliability and missingness	Missingness flags, sensor signal gaps, duplicate readings, abnormal flatlines, calibration status, probe location confidence	Whether the model should trust the input evidence fully or route it for human review	Poor data reliability may increase uncertainty and require conservative monitoring even when the numeric risk score is moderate	Prevents false reassurance from incomplete or unreliable sensor evidence	Missing calibration records, sensor malfunction, connectivity loss, unverified logger placement

Predictive Model Architecture

Model Choice – Gradient-Boosted Trees

A gradient-boosted tree architecture is appropriate for this conceptual model because vaccine cold-chain risk data are likely to combine continuous time-series summaries, categorical packaging descriptors, route variables, missing fields, and nonlinear interactions. Hybrid pharmaceutical cold-chain outlier detection illustrates the need for models that can handle irregular operational patterns without assuming that all shipments follow a single smooth trajectory [13]. Related cold-chain prediction work using ensemble and neural approaches shows that nonlinear relationships among temperature, environment, and logistics variables can be informative for risk estimation [15, 16, 20]. Gradient boosting would therefore provide a practical architecture for integrating heterogeneous predictors while remaining compatible with post-hoc interpretability methods needed by quality and logistics teams.

Input Feature Vector and Pre-processing

At each prediction update, the input vector would combine recent temperature summaries, encoded packaging variables, route exposure indicators, shipment status, and excursion history. Time-series prediction studies in cold supply chains show that raw temperature histories often need transformation into model-ready representations that capture recent dynamics and expected future conditions [8, 9, 14]. Missing historical fields for new containers or newly introduced lanes would be handled using explicit missingness indicators and conservative default categories rather than silent imputation, because the absence of prior history may itself be operationally meaningful. Pre-processing would also normalize timing, align sensor records with route milestones, and flag questionable observations when sensor reliability or placement could distort the measured thermal profile [21, 22]. **Figure 2** illustrates how raw cold-chain shipment information is transformed into a model-ready input representation by combining recent temperature dynamics, packaging variables, route exposure indicators, shipment status, excursion history, missingness flags, timing alignment, and sensor-quality checks.

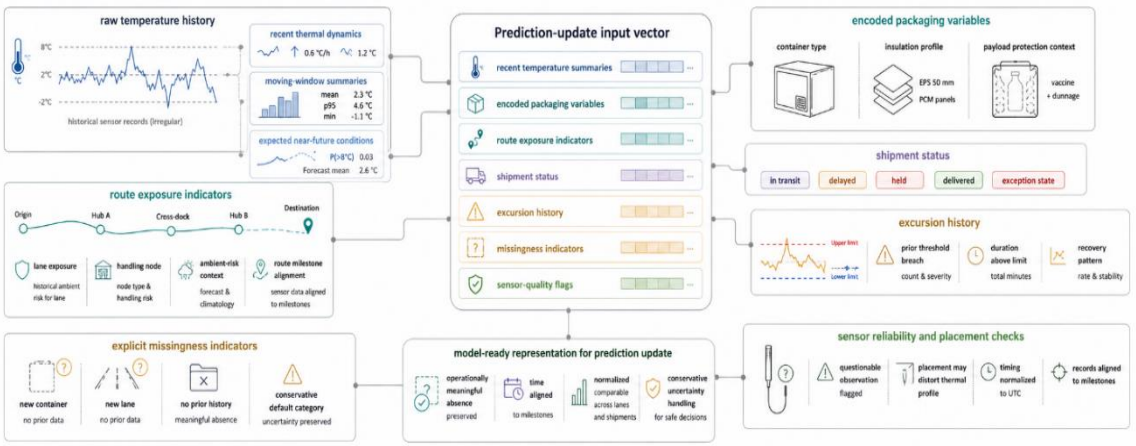

Figure 2. Model-ready input representation for cold-chain prediction updates.

Output: Excursion Risk Score

The model output would be a calibrated probability that the shipment will exceed the allowed temperature range within a defined future operating window, accompanied by an alert threshold chosen according to quality and logistics tolerance. Pharmaceutical temperature excursion programs show that excursion decisions require structured interpretation rather than a purely automated pass-fail label [6], so the risk score should support human review and graduated intervention. Mean kinetic temperature evaluations indicate that exposure interpretation may depend on the pattern and duration of thermal stress rather than a single instantaneous value [23]. The risk score would therefore be used as a decision aid that prioritizes shipments for action, while final product disposition would remain governed by quality procedures and regulatory expectations.

Handling Temporal and Spatial Variability in Cold-Chain Data

Temporal Dynamics and Streaming Predictions

The model would refresh its prediction as new temperature readings arrive, using a sliding window to summarize recent thermal level, trend, variability, and proximity to excursion limits. Real-time temperature prediction in cold supply chains has shown that thermal trajectories can be modeled dynamically rather than treated as isolated observations [8]. Machine learning studies on cold-chain break detection further suggest that sequential patterns may indicate instability before a threshold breach is formally observed [24]. In vaccine distribution, this temporal design would allow the risk score to evolve as the package passes through storage, loading, transit, unloading, and last-mile delivery conditions.

Accounting for Environmental Variation along the Route

Environmental variation would be represented through route-linked exposure features, including forecasted ambient temperature, expected climate zones, route duration, and the thermal stress associated with planned stops or transfers. Thermal mapping of pharmaceutical transport routes supports the use of route-specific risk indicators because the same container may behave differently under different regional and seasonal conditions [10]. Cold-chain transport prediction using data mining also shows that route and condition data can be transformed into predictive representations for transport stability [25]. The model would therefore treat the remaining route as a changing exposure profile rather than as a static shipment attribute.

Table 2 shows the key route-linked environmental exposure features used to represent changing thermal risk conditions during pharmaceutical transport.

Table 2. Route-Linked Environmental Exposure Features for Dynamic Cold-Chain Risk Modeling

Feature Category	Variable	Description	Data Source	Effect on Thermal Risk
Ambient conditions	Forecasted ambient temperature	Expected external temperature along each segment of the route	Meteorological forecasting systems	Higher temperatures increase risk of heat excursion and degradation
Climate context	Climate zone classification	Regional climatic classification (e.g., temperate, tropical, arid)	Geographic climate databases	Determines baseline thermal stress profile of transport environment
Temporal exposure	Route duration	Total and segment-level transit time	Logistics tracking systems (GPS, TMS)	Longer durations increase cumulative exposure to temperature variability
Handling events	Planned stops and transfers	Scheduled warehouse stops, customs checks, or vehicle changes	Supply chain management systems	Increases risk due to repeated container opening and environmental transitions
Route geography	Elevation and terrain profile	Altitude changes and terrain-related climate shifts	GIS mapping systems	Affects local temperature and pressure-related thermal dynamics
Seasonal context	Seasonal period	Time of year during shipment (e.g., winter/summer)	Shipment scheduling data	Modulates overall ambient exposure intensity across the route

Learning from Heterogeneous Packaging and Product Types

The model would use packaging variables as grouping and interaction features so that different insulated shippers, PCM combinations, coolant configurations, and payload conditions could have distinct risk profiles. Vaccine cold-chain technology reviews emphasize that storage and transport systems differ in their thermal performance, operational suitability, and vulnerability to implementation errors [12]. Temperature-controlled container prediction using cold energy storage systems further indicates that package-specific thermal behavior can be learned from operational temperature patterns. This heterogeneity matters because a route that is safe for one container configuration may be high risk for another with lower thermal buffer or different phase-change behavior.

Model Interpretability and Proactive Logistics Decisions

Explaining Excursion Risk to Logistics Managers

Model interpretability would translate the risk score into driver contributions that logistics and quality personnel can understand, such as a rising internal temperature trend, an unusually stressful route forecast, or a packaging configuration with

limited remaining thermal buffer. Pharmaceutical excursion management practice requires transparent evaluation of exposure circumstances, because quality decisions depend on why and how the deviation occurred rather than only on the existence of an alert [6]. Industry recommendations on temperature cycling studies also show that excursion support requires scientifically interpretable evidence about product and package behavior under thermal stress [26]. A model explanation layer would therefore make the prediction actionable by identifying which modifiable conditions are contributing most strongly to risk.

From Alert to Action: Intervention Recommendations

A high-risk prediction should trigger operational recommendations that correspond to the dominant risk drivers, such as accelerating delivery, transferring the shipment to controlled storage, replacing coolant at an approved hand-off point, or initiating a contingency shipment. IoT-enabled vaccine cold-chain frameworks support this kind of response because sensor streams can be connected to logistics workflows and decision systems [3]. Blockchain-based vaccine tracking approaches further suggest that digital shipment records can preserve intervention history and strengthen accountability across hand-offs [18]. The model would not replace quality disposition, but it could prioritize the shipments most likely to benefit from immediate preventive action.

Integration Into Vaccine Distribution & Quality Assurance

Embedding in Logistics Command Centers

The predictive model would be embedded in a supply-chain visibility platform where active shipments are displayed according to dynamic risk rather than only current temperature status. Cold-chain IoT frameworks describe how monitoring devices, communication infrastructure, and management platforms can be integrated into vaccine distribution operations [3]. Risk prediction work for pharmaceutical transportation similarly supports the use of early warning systems as part of operational command structures [7]. In this setting, logistics managers could review a risk heat map of shipments, inspect the main drivers of risk, and coordinate preventive actions across carriers, warehouses, and receiving facilities.

Supporting Quality and Regulatory Compliance

Predictive risk scores, sensor records, route context, and intervention logs should be stored as part of the shipment's digital quality record. Comprehensive pharmaceutical temperature excursion programs emphasize the need to document excursion context, evaluation logic, and disposition decisions in a structured manner [6]. Mean kinetic temperature evaluation studies show that exposure interpretation may require more than a simple maximum or minimum temperature reading, especially when duration and pattern of exposure influence risk interpretation [23]. A predictive system would therefore support regulatory compliance by preserving evidence that the organization monitored risk proactively and responded according to defined quality procedures.

Evaluation Strategy

Prediction Accuracy and Lead Time

The evaluation strategy should assess whether the model distinguishes shipments that will later experience an excursion from those that remain within range, while also examining whether warnings occur early enough to support operational action. Because excursions may be relatively uncommon compared with stable shipments, evaluation should include methods suitable for imbalanced classification rather than relying on a single aggregate measure [13]. Cold-chain break detection studies show that models should be judged not only by event identification but also by whether they identify meaningful precursors to instability [24]. In this manuscript, performance would be described conceptually through classification quality, calibration, and practical advance-warning usefulness rather than through fabricated numerical results.

Temporal and Geographical Validation

Validation should test whether the model generalizes across seasons, geographic regions, transport lanes, and logistics partners that were not dominant in model development. Route-based pharmaceutical thermal mapping demonstrates that risk patterns can vary across transport contexts, making geographical validation essential for a model intended for broad deployment [10]. Agricultural and food cold-chain prediction studies using environmental and route features also show that models trained under one set of conditions may require careful evaluation when applied to different temperature regimes or operational settings [15, 16]. Temporal validation would therefore examine whether the model remains reliable when weather, route congestion, packaging use patterns, and demand cycles change.

Operational Impact

Operational evaluation should examine whether model-informed interventions are expected to reduce excursions, vaccine wastage, preventable quality holds, and emergency logistics responses without creating excessive false alarms. Machine learning-based temperature management in perishable supply chains illustrates how predictive models can be connected to safety and quality control decisions rather than used only for retrospective analytics. Digital twin approaches to shelf-life and loss mitigation further suggest that predictive cold-chain systems can support adaptive supply-chain decisions when data streams are linked to operational actions. For vaccine logistics, the strongest evaluation would combine predictive validity with evidence that the model changes decisions in ways that preserve product integrity.

Table 3 provides a deployment-oriented evaluation and governance framework for determining whether predictive cold-chain analytics are accurate, timely, interpretable, auditable, and operationally useful.

Table 3. Evaluation and governance framework for deployment-ready predictive cold-chain analytics

Evaluation or governance dimension	Core question	Recommended assessment approach	Why it matters for vaccine cold-chain use	Evidence or decision artifact produced	Failure mode if neglected
Discrimination	Can the model distinguish shipments that later fail from shipments that remain stable?	Evaluate event classification using metrics suitable for imbalanced data, including sensitivity, specificity, precision-recall behavior, and false-alarm burden	Cold-chain excursions may be uncommon, so high overall accuracy can hide poor detection of true failures	Performance report stratified by route, product, package type, and season	Model appears accurate but misses the most operationally important failures
Calibration	Does the predicted probability correspond to observed failure frequency?	Compare predicted risk bands against observed excursion rates; recalibrate across time, geography, and packaging configurations	A risk score must be interpretable as probability-like evidence for quality and logistics prioritization	Calibration plot, risk-band table, threshold justification memo	Teams overreact to inflated scores or ignore understated risk
Lead-time usefulness	Does the warning occur early enough for intervention?	Measure time between high-risk prediction and threshold breach; classify warnings by actionable lead-time windows	The model's value depends on preventing failure, not merely predicting it shortly before or after breach	Lead-time distribution by route stage and intervention opportunity	Alerts arrive too late for re-cooling, rerouting, or controlled-storage transfer
Freezing versus heat-risk sensitivity	Can the model identify both overheating and freezing risk?	Evaluate upper-limit and lower-limit breach prediction separately; examine driver explanations for both failure types	Vaccines may be harmed by heat or freezing, and packaging interventions may affect each differently	Separate heat-risk and freezing-risk validation summaries	Model becomes biased toward visible heat excursions while missing freeze damage risk
Generalizability across routes and seasons	Does the model remain reliable across changing geographic and climatic conditions?	Use temporal validation, geographic holdout validation, seasonal stress testing, and new-lane monitoring	Route exposure and climate strongly influence cold-chain stability	Regional validation report and deployment boundary statement	Model performs well on familiar lanes but fails in new climates or seasonal extremes
Packaging and product heterogeneity	Does the model handle different shippers, PCM systems, and vaccine requirements?	Stratify performance by packaging configuration, product temperature range, coolant preparation, and container age	A route safe for one container may be unsafe for another thermal configuration	Package-specific performance and recalibration matrix	Generic risk estimates obscure package-specific vulnerabilities
Explanation reliability	Are driver explanations stable, plausible, and useful to logistics and quality teams?	Review feature contribution patterns for representative high-risk shipments; compare explanations with known operational events	Users need to know whether risk is driven by temperature trend, route stress, packaging weakness, or prior instability	Explanation audit log and case-review summaries	Staff receive risk scores without knowing what action is appropriate
Human-in-the-loop governance	Are model outputs used as decision support rather than automated product disposition?	Define escalation pathways, role responsibilities, override rules, and quality-review requirements	Vaccine disposition requires structured quality judgment and documentation	Standard operating procedure for model-informed intervention	Automated or poorly documented decisions create regulatory and safety risk

Data provenance and auditability	Can the organization reconstruct why a shipment was flagged and what action followed?	Store sensor traces, route context, model version, risk-score history, explanations, and intervention records	Cold-chain decisions must be defensible and traceable across logistics and quality systems	Digital shipment quality record	Preventive actions cannot be justified during quality review or inspection
Drift monitoring	Does model performance degrade as products, routes, climate, sensors, or packaging change?	Monitor prediction distributions, calibration drift, false-alert trends, missed events, and packaging-route interaction shifts	Cold-chain networks evolve, and static models may become unreliable over time	Drift dashboard summary, recalibration trigger report, model-change log	Old model logic persists after operational conditions change
Intervention impact	Does the model improve real-world cold-chain outcomes?	Compare excursion rates, wastage, emergency replacements, quality holds, and intervention timeliness before and after deployment	Predictive analytics should improve product integrity and logistics resilience, not only produce scores	Operational impact evaluation report	Model adds alert burden without reducing preventable cold-chain failures
Equity and global health suitability	Can the model support both high-resource and constrained distribution settings?	Evaluate performance under intermittent connectivity, sparse route metadata, varied infrastructure, and last-mile delivery constraints	Vaccine programs often operate across diverse infrastructure conditions	Context-of-use assessment and minimum-data deployment guidance	Model benefits only data-rich routes while leaving fragile distribution settings unsupported

Limitations

Sensor Reliability and Data Gaps

The model would depend on the reliability, calibration, placement, and connectivity of temperature sensors, so poor sensor data could lead to misleading risk estimates. Studies of medicine cold-chain storage conformity and personnel practices show that operational behavior and storage conditions can vary across facilities, which may introduce data gaps or inconsistent records [22]. Temperature variation studies in pharmaceutical storage settings also indicate that local practices and infrastructure can affect the quality of temperature evidence available for decision-making [21]. The model should therefore include data-quality checks, missingness indicators, and procedures for human review when the input stream is incomplete or questionable.

Generalizability across Different Vaccine Products and Packaging Innovations

A model trained on current vaccine products, packaging systems, route structures, and handling practices may need recalibration when new products, new temperature requirements, or new thermal protection technologies are introduced. Vaccine cold-chain management reviews emphasize that storage technology and distribution practice continue to evolve, which can change the relationship between packaging features and excursion risk [12]. Temperature cycling and excursion support studies also show that product-package behavior under stress must be evaluated scientifically rather than assumed to remain constant across configurations [26]. Generalizability should therefore be treated as an ongoing validation requirement, especially when reusable containers age, PCM formulations change, or distribution networks expand into new climates.

Conclusion

A predictive model for vaccine cold-chain failure would shift temperature management from retrospective excursion documentation to forward-looking risk estimation. By combining streaming temperature behavior, packaging characteristics, route exposure, and excursion history, the system could identify shipments whose thermal stability is becoming fragile before a breach is confirmed. The model would function as a decision-support layer rather than as a replacement for quality procedures. Its value would lie in helping teams act earlier, focus attention on the most vulnerable shipments, and preserve vaccine integrity across complex distribution networks.

The principal strength of the proposed approach is its integration of multiple risk domains that are often reviewed separately. Temperature streams describe what is happening now, packaging features describe the shipment's thermal resilience, route features describe the stress still ahead, and excursion history describes whether similar systems have failed before. Interpretable driver contributions would make the risk score more useful for logistics managers and quality personnel. Integration into

existing cold-chain platforms would also allow the model to support routine monitoring rather than requiring a separate analytical workflow.

Important challenges remain before such a model could be used confidently in operational vaccine distribution. Sensor failures, intermittent connectivity, incorrect probe placement, and inconsistent shipment records could weaken prediction quality. Model drift may also occur as packaging technologies, vaccine products, transportation networks, and climate exposure patterns change. Prospective validation in real logistics settings would be needed to confirm that predictions are timely, understandable, and operationally useful.

Future progress will require collaboration among vaccine manufacturers, logistics providers, packaging engineers, data-platform vendors, regulators, and global health agencies. Shared benchmark data and common validation protocols would help distinguish models that merely describe past excursions from those that support reliable preventive action. Pilot deployments should focus on transparent decision support, auditable quality records, and measurable operational learning. Predictive cold-chain safeguards could become a practical component of resilient immunization systems when technical modeling is paired with disciplined logistics governance.

Acknowledgments: None

Conflict of interest: None

Financial support: None

Ethics statement: None

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