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Effect of Cold Chain Infrastructure on Distribution Effectiveness of Heat-Sensitive Pharmaceuticals: A Case of Rwanda Medical Supply Ltd

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[1;2;3]Master of Science in Procurement and Supply Chain Management of the University of Kigali as a Proceducural Requirement to Conduct Research

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Abstract: This study assessed the effect of cold chain infrastructure on the distribution effectiveness of heat-sensitive pharmaceuticals at Rwanda Medical Supply Ltd (RMS). Specifically, it examined the effects of cold chain equipment reliability, personnel competence, adequacy and implementation of Standard Operating Procedures (SOPs), and temperature monitoring systems on distribution effectiveness. The study was grounded in Supply Chain Management and Systems theories and adopted a mixed-methods descriptive and correlational research design. Data were collected from a stratified random sample of 109 RMS employees involved in cold chain operations using structured questionnaires and were analysed using descriptive statistics, Pearson correlation, and multiple linear regression. The findings showed that the four cold chain infrastructure variables jointly explained 45.5% of the variation in distribution effectiveness ($R^2 = 0.455$, $p < 0.001$). Regression results revealed that SOP adequacy and implementation ($B = 0.453$, $p < 0.001$) and equipment reliability ($B = 0.249$, $p = 0.019$) had statistically significant positive effects on distribution effectiveness. In contrast, personnel competence and temperature monitoring systems did not show statistically significant independent effects in the multivariate model, despite their bivariate relationships with distribution effectiveness. The findings also identified important weaknesses in last-mile temperature surveillance, particularly the limited availability of data loggers during distribution. The study concluded that RMS maintains a functional central cold chain system, but distribution effectiveness is constrained by gaps in last-mile monitoring and inconsistent procedural implementation. It recommends strengthening preventive equipment maintenance, expanding temperature-monitoring devices to last-mile distribution, and improving compliance with simplified and standardized SOPs across distribution points.

Keywords: *Cold Chain Infrastructure, Equipment Reliability, Personnel Competence, Standard Operating Procedures, Temperature Monitoring Systems, Distribution Effectiveness.*

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I. INTRODUCTION

Heat-sensitive pharmaceuticals such as vaccines, insulin, and biologics require continuous temperature control to preserve their quality, safety, and effectiveness. Their successful distribution therefore depends on reliable cold chain infrastructure throughout storage and transportation.

Cold chain infrastructure includes reliable equipment, competent personnel, effective Standard Operating Procedures (SOPs), and temperature monitoring systems. Refrigerators, cold rooms, insulated containers, data loggers, GPS sensors, and alarm systems help maintain required conditions, while trained personnel and clear procedures support correct handling and timely corrective action.

Distribution effectiveness goes beyond delivering medicines physically. It involves maintaining product integrity, ensuring timely delivery, preventing stock-outs, reducing wastage, and ensuring that medicines reach health facilities in the required condition and quantity. Weak cold chain systems can lead to temperature excursions, product degradation, financial loss, and risks to patient safety.

In many low- and middle-income countries, cold chain systems continue to face challenges such as unreliable power supply, inadequate maintenance, limited monitoring devices,

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weak personnel competence, and inconsistent application of procedures. Last-mile distribution is particularly vulnerable because temperature-sensitive products often pass through multiple handling and transport points.

In Rwanda, Rwanda Medical Supply Ltd (RMS) is responsible for procuring, storing, and distributing health commodities through its central and regional warehouse network. Although RMS has invested in cold rooms, refrigerators, monitoring systems, and SOPs, limited empirical evidence exists on how these cold chain infrastructure components influence the distribution effectiveness of heat-sensitive pharmaceuticals. This study therefore examined the effects of equipment reliability, personnel competence, SOP adequacy and implementation, and temperature monitoring systems on distribution effectiveness at RMS.

II. LITERATURE REVIEW

Cold chain infrastructure is essential for maintaining the quality, safety, and effectiveness of heat-sensitive pharmaceuticals throughout storage and distribution. This study focuses on four main dimensions: equipment reliability, personnel competence, Standard Operating Procedures (SOPs), and temperature monitoring systems, with distribution effectiveness as the outcome variable.

- *Cold Chain Equipment Reliability*

Reliable cold chain equipment includes cold rooms, refrigerators, freezers, refrigerated vehicles, and cold boxes. Equipment functionality, maintenance, calibration, qualification, and validation are important because failures can cause temperature excursions and product degradation. Studies in Africa have shown that ageing equipment, poor maintenance, power interruptions, and non-validated transport systems weaken cold chain performance.

- *Personnel Competence*

Personnel competence refers to the knowledge, skills, attitudes, and practical ability required to handle, store, transport, and monitor temperature-sensitive pharmaceuticals correctly. Previous studies have shown that inadequate training, weak practical skills, and limited understanding of corrective actions increase the risk of cold chain failures. Regular refresher training, competency assessment, mentoring, and knowledge transfer are therefore important for maintaining effective cold chain operations.

- *Standard Operating Procedures*

SOPs provide written guidance for ensuring consistency, regulatory compliance, and reduction of human error in cold chain operations. Their effectiveness depends not only on availability but also on clarity, accessibility, relevance, implementation, supervision, and staff adherence. Studies have shown that SOPs may exist formally but remain poorly implemented because of weak supervision, inadequate resources, limited awareness, and overly technical language.

- *Temperature Monitoring Systems*

Temperature monitoring systems provide visibility and early detection of temperature deviations. Modern systems include digital data loggers, remote monitoring devices, IoT systems, GPS-enabled sensors, and automated alerts. These technologies improve continuous monitoring and support timely corrective action. However, their effectiveness depends on staff ability to interpret data, respond to alarms, and implement corrective and preventive actions.

- *Distribution Effectiveness*

Distribution effectiveness refers to the ability to deliver heat-sensitive pharmaceuticals in the right condition, at the right time, and in the required quantities. It includes product quality preservation, order fulfilment, control of temperature excursions, reduction of wastage, documentation compliance, and service reliability.

- *Theoretical Review*

The study was guided by Supply Chain Management Theory and Systems Theory. Supply Chain Management Theory emphasizes integration, coordination, reliability, and responsiveness across procurement, storage, transportation, and distribution activities.

Systems Theory views cold chain infrastructure as an interconnected system in which equipment, personnel, procedures, and monitoring mechanisms work together. Failure in one component can affect the performance of the entire distribution system.

- *Research Gap*

Most previous studies have examined cold chain equipment, staff competence, SOPs, or monitoring systems separately. Limited evidence exists on their combined effect on distribution effectiveness, particularly within Rwanda's public pharmaceutical supply chain. This study therefore addresses the gap by examining these four dimensions together at Rwanda Medical Supply Ltd.

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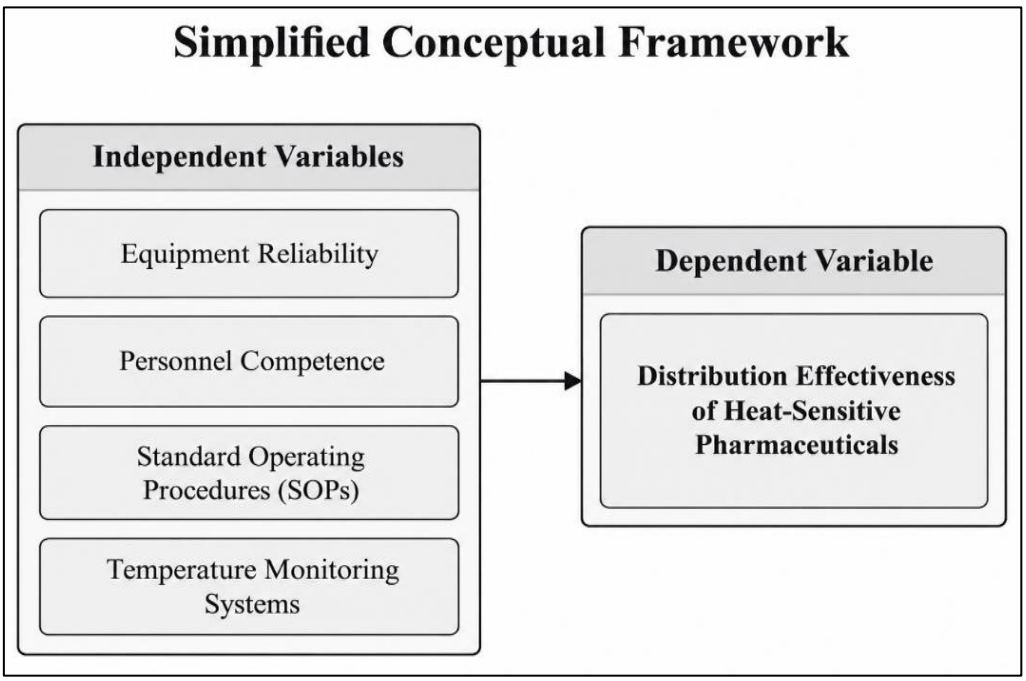


Fig 1 Simplified Conceptual Framework

III. METHODOLOGY

The study adopted a descriptive and exploratory research design using both quantitative and qualitative approaches to assess the effect of cold chain infrastructure on the distribution effectiveness of heat-sensitive pharmaceuticals at Rwanda Medical Supply Ltd. Quantitative data were collected through structured questionnaires, while open-ended questions were used to obtain qualitative insights.

The study population consisted of RMS staff directly involved in storage and distribution activities, including warehouse personnel, quality assurance staff, and drivers from the central and regional warehouses. A total population of 150 employees was considered, from which a sample of 109 respondents was determined using Yamane's formula at a 95% confidence level and 5% margin of error. Stratified random sampling was used to ensure proportional representation of staff from the central and regional warehouses.

Data were collected using a structured self-administered electronic questionnaire consisting of demographic questions, Likert-scale items, and open-ended questions. The questionnaire measured equipment reliability, personnel competence, SOP adequacy and implementation, temperature monitoring systems, and distribution effectiveness.

After collection, data were coded, cleaned, and analysed using IBM SPSS Statistics Version 27. Descriptive statistics, including frequencies, percentages, means, and standard deviations, were used to summarize the data. Pearson correlation was applied to examine relationships between variables, while multiple linear regression was used to determine the combined and individual effects of the four cold chain infrastructure variables on distribution effectiveness. Qualitative responses were analysed using content and thematic analysis.

Ethical clearance was obtained from the University of Kigali, and administrative authorization was obtained from RMS. Respondents participated voluntarily, and confidentiality and anonymity were maintained throughout the study.

IV. FINDINGS AND DISCUSSION

The findings indicate that cold chain infrastructure at Rwanda Medical Supply Ltd was generally well established, although notable operational weaknesses remained, particularly in personnel confidence during last-mile handling and the use of temperature data loggers during transportation.

Table 1 Summary of Descriptive Findings

Variable	Key Indicator	Mean	Std. Dev.
Equipment Reliability	Preventive maintenance performed consistently	4.23	0.728
Personnel Competence	Regular mandatory cold-chain/GSDP training	4.35	0.865
SOP Adequacy and Implementation	SOPs are comprehensive and easy to follow	4.56	0.630
Temperature Monitoring	Real-time monitoring provides accurate readings	4.59	0.748
Distribution Effectiveness	Orders delivered on time under correct temperature conditions	4.48	0.715

Source: Field Research, 2026

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Equipment reliability was rated positively, particularly preventive maintenance (M = 4.23) and annual calibration of data loggers (M = 4.21). However, access to qualified technicians recorded the lowest equipment score (M = 4.05), suggesting some differences in technical support across RMS facilities.

Personnel competence produced mixed findings. Regular training was highly rated (M = 4.35), but staff confidence in ice-pack conditioning and cool-box packing recorded only M = 3.00. This indicates a gap between receiving training and confidently applying cold-chain procedures during last-mile distribution.

SOP adequacy and implementation received particularly strong ratings. SOP comprehensiveness recorded M = 4.56, while staff adherence recorded M = 4.39. These findings suggest that clear and consistently applied procedures form an important component of RMS cold-chain operations.

Temperature monitoring showed the greatest contrast. Real-time monitoring systems were rated highly (M = 4.59), whereas the use of data loggers during last-mile transportation recorded only M = 2.98. This identifies last-mile temperature surveillance as a significant operational weakness.

Distribution effectiveness was generally rated highly, with on-time delivery under correct temperature conditions recording M = 4.48, while product potency preservation and minimal product wastage both recorded M = 4.28.

Table 2 Correlation, Regression and Hypothesis Results

Variable	Pearson r	B	β	p-value	Decision
Equipment Reliability	0.558	0.249	0.221	0.019	H_{01} Rejected
Personnel Competence	0.382	-0.006	-0.005	0.953	H_{02} Not Rejected
SOP Adequacy & Implementation	0.658	0.453	0.440	<0.001	H_{03} Rejected
Temperature Monitoring Systems	0.527	0.118	0.123	0.221	H_{04} Not Rejected

Source: Field Research, 2026

All four independent variables had positive and statistically significant bivariate correlations with distribution effectiveness. SOP adequacy and implementation showed the strongest relationship ($r = 0.658$, $p < 0.001$), followed by equipment reliability ($r = 0.558$), temperature monitoring ($r = 0.527$), and personnel competence ($r = 0.382$).

In the multiple regression model, SOP adequacy and implementation had the strongest significant independent effect on distribution effectiveness ($B = 0.453$, $\beta = 0.440$, $p < 0.001$). This indicates that clear, relevant, and consistently implemented procedures are especially important in maintaining effective pharmaceutical distribution.

Equipment reliability also had a positive and statistically significant effect ($B = 0.249$, $\beta = 0.221$, $p = 0.019$). This finding supports the importance of preventive maintenance, calibration, equipment qualification, and timely technical support in maintaining the integrity of heat-sensitive pharmaceuticals.

Although personnel competence was positively correlated with distribution effectiveness, it did not remain statistically significant in the multivariate model ($B = -0.006$, $p = 0.953$). This suggests that personnel competence may contribute through its interaction with equipment, SOPs, and other operational systems rather than through a strong independent effect.

Similarly, temperature monitoring systems showed a significant bivariate relationship but no significant independent regression effect ($B = 0.118$, $\beta = 0.123$, $p = 0.221$). The descriptive findings nevertheless revealed an important practical weakness in the limited use of data loggers during last-mile transportation.

V. CONCLUSION AND RECOMMENDATIONS

➢ *Conclusion*

- Equipment Reliability: Equipment reliability had a positive and significant effect on distribution effectiveness ($\beta = 0.221$, $p = 0.019$). Reliable and well-maintained cold chain equipment therefore supports effective pharmaceutical distribution.
- Personnel Competence: Personnel competence did not have a statistically significant independent effect ($\beta = -0.005$, $p = 0.953$), although it remained operationally important within the wider cold chain system.
- SOP Adequacy and Implementation: SOP adequacy and implementation had the strongest significant effect on distribution effectiveness ($\beta = 0.440$, $p < 0.001$). This confirms the importance of clear and consistently applied procedures.
- Temperature Monitoring Systems: Temperature monitoring did not have a significant independent effect ($\beta = 0.123$, $p = 0.221$), although it remains important, especially for last-mile distribution.

Overall, cold chain infrastructure significantly influenced the distribution effectiveness of heat-sensitive pharmaceuticals at RMS, with SOP implementation and equipment reliability emerging as the main significant determinants.

➢ *Recommendations*

- SOPs: RMS should strengthen SOP implementation and staff adherence across all cold chain activities.
- Equipment: Preventive maintenance should be improved and ageing equipment replaced where necessary.

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- Temperature Monitoring: RMS should strengthen continuous temperature monitoring, especially during transportation and last-mile delivery.
- Personnel Competence: Regular refresher training should be provided on cold chain handling and temperature excursion response.

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