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QUALITATIVE ANALYSIS OF PHARMACEUTICAL COLD CHAIN FAILURES AND DIGITAL MONITORING TECHNOLOGIES: REGULATORY IMPLICATIONS FOR PATIENT SAFETY IN MOROCCAN HEALTHCARE FACILITIES

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ABSTRACT

The integrity of the pharmaceutical cold chain is a determining condition for the safety, efficacy and legal conformity of thermolabile medicinal products such as vaccines, insulins, biologics and blood-derived preparations. Empirical evidence gathered in low- and middle-income countries indicates that cold chain breaks are frequent, largely undetectable at the point of care, and closely associated with weak regulatory enforcement, resource-constrained infrastructure and organisational cultures that discourage incident reporting. Digital monitoring technologies - continuous data loggers, vaccine vial monitors and integrated traceability platforms - increasingly condition the practical enforceability of cold chain regulation, since they convert compliance from a matter of retrospective professional judgement into one of contemporaneous, auditable record. Building on a conceptual framework defining the pharmaceutical cold chain, cold chain disruption, patient safety, good distribution practices, quality risk management, digital monitoring technology and regulatory compliance, this article first reviews eleven empirical studies conducted in Ethiopia, a thirteen-country sample of low- and middle-income countries, Nigeria, Poland, India, the United States, Portugal, Zambia, Senegal and China, and analyses Morocco's evolving pharmaceutical regulatory architecture, marked by the transition from the 2006 Code du Médicament et de la Pharmacie (Law No. 17-04) toward the newly created Moroccan Medicines and Health Products Agency (AMMPS) and the pending reform bill (Law No. 27.26) that seeks alignment with the World Health Organization's Maturity Level 3 benchmark. It then reports a qualitative investigation based on semi-structured interviews conducted with eight hospital pharmacists practising in the Fez-Meknes region, organised around four analytical axes covering the identification of cold chain disruptions, their organisational and infrastructural determinants, incident management and reporting culture, and the perceived adequacy of the regulatory framework. The findings suggest that cold chain failures in Moroccan public hospitals are perceived as multidimensional and systemic rather than attributable to individual negligence, shaped by ageing equipment, staffing constraints, uneven adoption of digital temperature-monitoring devices, uneven reporting practices and a persistent gap in operational guidance for managing disruptions once they occur - a gap that the anticipated Law No. 27.26 could help to close. The article concludes by situating these findings within the comparative literature and by outlining directions for further regional and quantitative research.

Keywords: *Pharmaceutical Cold Chain; Cold Chain Disruption; Digital Monitoring Technology; Patient Safety; Good Distribution Practices; Quality Risk Management; Hospital Pharmacists; Pharmaceutical Regulation; Morocco.*

1. INTRODUCTION

Access to medicines of assured quality is a precondition for the effective enjoyment of the right to health, and its erosion produces consequences measured not only in clinical outcomes but also in legal liability and public expenditure. Temperature control occupies a distinctive place among the determinants of medicine quality because it protects products whose active substances are inherently unstable outside a narrow thermal band: vaccines, insulins, certain biologics and blood derivatives must be kept between +2°C and +8°C from manufacture until administration, a continuum commonly designated as the "cold chain" [1]. Any interruption of this continuum can degrade product potency without producing any organoleptic sign that would alert the healthcare professional [2], so that the resulting harm is largely invisible at the point of care. The stakes are considerable: poor-quality health systems in low-income countries are associated with approximately five million avoidable deaths every year [3], and the pharmaceutical supply chain is repeatedly singled out as a locus of vulnerability within this landscape of unsafe care. Multi-country evidence shows widespread non-compliance with cold chain management standards among distributors in low- and middle-income countries [1, 4], raising the question of whether comparable failures characterise the Moroccan pharmaceutical distribution network.

Morocco offers a particularly instructive case for examining this question: it combines a warm climate that intensifies the technical demands of refrigeration [5] with a regulatory architecture currently undergoing profound transformation, moving from the 2006 Code du Médicament et de la Pharmacie (Law No. 17-04 [6]) toward the newly created Moroccan Medicines and Health Products Agency and a pending reform bill (Law No. 27.26 [7]), examined in detail in Section 3. Yet the comparative literature reviewed in this article, none of which addresses Morocco specifically, converges on recurring vulnerabilities - resource scarcity, weak accountability, blame-oriented organisational cultures and information asymmetry between manufacturers and frontline practitioners - capable of undermining even a well-designed legal framework. Whether these vulnerabilities manifest within Moroccan healthcare facilities, and how they interact with the obligations imposed by Law No. 17-04 and the anticipated Law No. 27.26, remains an open question that has not, to the authors' knowledge, been addressed through facility-level qualitative research in Morocco. The gap matters because undetected cold chain excursions expose patients to therapeutic or immunisation failure unnoticed by any actor in the chain [1, 2], because the effectiveness of Law No. 27.26 depends on how it is mobilised at the level of hospital and community pharmacies, and because comparative analysis reveals regulatory design choices that other jurisdictions have found wanting.

Against this background, this article pursues four objectives: constructing a conceptual apparatus articulating the technical, managerial, technological and legal dimensions of cold chain failure, including the role of digital monitoring technology in rendering compliance verifiable; reviewing the international empirical literature on comparable regulatory settings; describing the Moroccan legal and institutional architecture governing pharmaceutical storage and distribution; and reporting a qualitative investigation of hospital pharmacists' experience of cold chain incidents in the Fez-Meknes region. The remainder of the article accordingly develops a conceptual framework (Section 2), a thematic literature review (Section 3), the research methodology (Section 4), and the results, discussion and conclusion (Sections 5 and 6).

1.1. Research Questions and Guiding Propositions

This study is guided by four research questions, each corresponding to one of the analytical axes developed in the conceptual framework (Section 2) and operationalised in the interview guide (Section 4.5):

RQ1. How do hospital pharmacists practising in Moroccan public hospitals identify and characterise pharmaceutical cold chain disruptions in their daily practice?

RQ2. Which organisational, infrastructural and human-resource factors do they perceive as the principal determinants of cold chain reliability, and what part do digital monitoring technologies play in rendering disruptions detectable?

RQ3. How are suspected or confirmed cold chain disruptions managed and reported within Moroccan public hospitals, and which organisational-culture factors facilitate or inhibit reporting?

RQ4. How do hospital pharmacists perceive the adequacy of the current (Law No. 17-04) and forthcoming (draft Law No. 27.26) Moroccan regulatory framework for governing cold chain disruptions?

Because the design adopted here is qualitative and exploratory-descriptive rather than confirmatory, the study does not test statistical hypotheses in the conventional sense. It instead formulates three analytical propositions, derived from the literature reviewed in Section 3, against which the empirical material presented in Section 5 is examined rather than statistically tested:

P1. Cold chain disruptions in Moroccan public hospitals will be perceived predominantly as the product of systemic and organisational conditions rather than of individual negligence, consistent with the "fragile systems" pattern documented by Fekadu et al. [3] and Van Assche et al. [4].

P2. The degree to which digital temperature-monitoring technology has been adopted will vary across facilities and will condition pharmacists' confidence in detecting disruptions, consistent with the diagnostic role attributed to such technology by Chukwu and Adibe [1] and by recent work on blockchain-enabled cold chain traceability (Zeng et al., 2024) [20].

P3. A gap will be perceived between the general storage and distribution obligations imposed by Law No. 17-04 and the availability of specific operational guidance for managing a disruption once it has occurred, an information-asymmetry pattern comparable to the one documented by Morais et al. [14] in the European context, which the anticipated Law No. 27.26 may only partially resolve.

thematically rather than study by study, in order to bring out the cross-cutting patterns most relevant to the Moroccan case. It draws on eleven empirical studies conducted in Ethiopia, a thirteen-country sample of low- and middle-income countries, Nigeria, Poland, India, the United States, Portugal, Zambia, Senegal and China, and closes with an analysis of the Moroccan regulatory and institutional landscape.

3.1. Systemic Vulnerability and Governance Failure in Resource-Limited Health Systems

Fekadu et al. [3] conducted a reflexive thematic analysis of in-depth interviews with thirty-nine nurses, physicians and clinical pharmacists working in four intensive care units of a large Ethiopian university hospital. Although the study's object was patient safety and incident reporting generally, rather than the cold chain specifically, its findings are directly transposable to the present inquiry because they document the systemic conditions under which any category of preventable harm - cold chain-related or otherwise - is generated and concealed in a resource-limited setting. The authors identified three overarching themes. The first, "fragile systems", combines governance failure - weak clinical leadership, an absence of system-wide safety protocols, inconsistent managerial accountability - with chronic resource constraints, including shortages of equipment and medicines, unreliable electricity supply and inadequate physical infrastructure. The second theme, "normalisation of deviance", describes how inadequate supervision of trainees, normalised communication lapses (including the falsification of patient records) and weak interprofessional teamwork gradually erode adherence to safety standards until unsafe practice becomes routine. The third theme, the "silence trap", captures the combined effect of a punitive, blame-oriented organisational culture and the absence of a structured, confidential incident-reporting system, which together discourage healthcare professionals from disclosing safety events even when they recognise them.

These findings matter for the study of cold chain governance because they establish, in a setting structurally comparable to many Moroccan public hospitals, that formal safety obligations are of limited value when governance is weak, resources are scarce and reporting is feared rather than encouraged. A cold chain failure occurring in such an environment - for instance, a refrigerator malfunction that goes unnoticed because no staff member is specifically responsible for its verification, or a temperature excursion left unreported because the professional involved fears disciplinary consequences - would be entirely consistent with the pattern that Fekadu et al. [3] document for patient safety incidents in general.

This general patient-safety account can usefully be read alongside cold-chain-specific evidence from the same country. In a multicentred, mixed-method evaluation of cold chain management performance at public health facilities supplied by the Jimma Pharmaceuticals Supply Agency Hub in south-western Ethiopia, Feyisa et al. [21] combined facility observation, document review and structured interviews with logistics personnel, and found that cold chain performance was compromised less by the absence of formal guidelines than by their inconsistent application – including gaps in staff training, irregular temperature monitoring and insufficient stock-management practices at the facility level. Read together, Fekadu et al. [3] and Feyisa et al. [21] suggest that the governance failures documented at the level of general patient safety in Ethiopian hospitals extend specifically to cold chain

logistics, reinforcing the plausibility of comparable dynamics in the Moroccan facilities examined in this article.

3.2. Compliance Deficits in Pharmaceutical Distribution across Low- and Middle-Income Countries

Van Assche et al. [4] provide the most directly relevant benchmark for assessing distribution-level compliance in resource-constrained settings. Drawing on secondary data from audits conducted by the QUAMED network at sixty local private pharmaceutical distributors across thirteen low- and middle-income countries, the authors applied a rating tool adapted from the World Health Organization's Model Quality Assurance System to measure compliance with general quality requirements, good distribution practices and cold chain management. The results were markedly poor: seventy per cent of distributors were non-compliant, very low-compliant or low-compliant for general quality requirements, sixty per cent for good distribution practices, and forty-one per cent for cold chain management; only seven of the sixty distributors achieved good to full compliance on at least two of the three criteria, and none achieved full compliance on general quality requirements or good distribution practices. Compliance was systematically higher outside sub-Saharan Africa than within it, and higher in middle-income countries than in low-income countries, though the minimum observed compliance remained equally poor across all subgroups, indicating that even relatively better-resourced settings contain severely non-compliant distributors. The authors attribute this pattern principally to weak regulatory enforcement rather than to an absence of formal standards, noting that national legislation in several of the countries studied either omits good distribution practice requirements altogether or states them without sufficient specificity to be enforceable, and that inspection capacity, where it exists, is poorly coordinated.

This finding is of direct legal relevance to the Moroccan case, since it demonstrates that the mere existence of a domestic legal instrument mirroring international good distribution practice standards - as Law No. 17-04 already provides, and as the pending Law No. 27.26 seeks to reinforce - is not by itself predictive of compliance in the field. The determinative variable, according to Van Assche et al. [4], is the capacity of the regulator to translate textual obligations into effective, resourced inspection.

More recent qualitative evidence from elsewhere in sub-Saharan Africa corroborates and extends this picture. Using in-depth, semi-structured interviews with a purposive sample of pharmaceutical supply-chain stakeholders and a bottom-up thematic analysis explicitly modelled on Braun and Clarke's [19] approach – the same analytical method adopted in Section 4.6 below – Matafwali et al. [22] examined how innovative private pharmacy distribution channels in Zambia, including delivery services and e-pharmacies, are perceived to affect medicine quality assurance, and found that regulatory oversight had not kept pace with the rapid diversification of distribution channels, leaving traceability and quality-assurance responsibilities unevenly distributed among wholesalers, regulators and new digital intermediaries. In a related qualitative inquiry conducted in Senegal, Lalani et al. [23] interviewed health-system stakeholders about the quality of medicines in circulation and reported that the near-total absence of systematically collected evidence on medicine quality was itself treated by respondents as normal – a form of institutionalised uncertainty the authors describe as breeding professional indifference toward quality-assurance procedures rather than concern about their absence. Both studies reinforce, in the specific area of medicine quality and distribution governance, the same combination of thin evidence, dispersed accountability and adaptive professional coping observed in the broader compliance literature reviewed above, and both are methodologically close to the qualitative design adopted in the present article, a point developed further in Section 3.10.

3.3. Cold Chain-Specific Failures: Evidence from Nigeria

Chukwu and Adibe [1] offer the most granular empirical account of cold chain performance among the studies reviewed here. Using a checklist derived from World Health Organization regulatory requirements, the authors assessed six central cold chain storage and distribution facilities and 133 retail and hospital pharmacies in Abuja, Nigeria. Two-thirds of the storage facilities failed to meet the required quality management standards, and just over half of the retail and hospital pharmacies performed poorly on cold chain practice. The specific deficiencies documented are instructive: sixty-seven per cent of storage facilities lacked calibrated equipment, eighty-three per cent lacked vaccine vial monitors, and only one of the six facilities possessed a documented copy of the World Health Organization's good storage and distribution

practice guidelines. At the pharmacy level, over a third of respondents reported no specific regulatory inspection of their cold chain infrastructure in the preceding year, nearly two-thirds lacked a device to verify product temperature upon receipt from suppliers, and a substantial minority had no automated backup power system to protect refrigerated stock during outages. The authors situate these findings within the broader consequences of unreliable cold chain management, citing evidence that up to thirty-six per cent of vaccine potency can be lost through improper storage and that as much as a fifth of cold chain pharmaceuticals sustain damage during transport. They further connect these deficiencies to Nigeria's difficulties in operationalising ultra-cold storage for messenger RNA COVID-19 vaccines, illustrating how facility-level cold chain weakness can translate into a national public health, and ultimately a public trust, problem when vaccine hesitancy is fuelled by perceived storage failures.

The relevance of these findings to Morocco is heightened by structural similarities between the two countries' distribution architectures - a network of wholesaler-distributors ("grossistes-répartiteurs" in Moroccan terminology) supplying hospital and community pharmacies - and by shared exposure to high ambient temperatures that render sustained refrigeration more technically demanding and more energy-intensive. Chukwu and Adibe's [1] finding that regulatory visits frequently occur without any specific inspection of cold chain infrastructure is particularly significant for the Moroccan reform debate, since it suggests that expanding an inspectorate's formal powers, as Law No. 27.26 proposes, will only translate into improved cold chain oversight if inspection protocols explicitly and systematically address temperature-controlled storage rather than treating it as a residual component of a general pharmacy inspection.

3.4. Quality Risk Management as a Regulatory Tool for Distribution

Kumar and Jha [2] address a distinct but complementary question: whether the quality risk management methodology well established at the manufacturing stage of the pharmaceutical lifecycle - mandated, in most jurisdictions, through instruments modelled on the International Council for Harmonisation's ICH Q9 guideline - is equally applied to distribution. Surveying 260 pharmaceutical professionals and applying a Failure Mode and Effects Analysis methodology, the authors calculated Risk Priority Numbers for five categories of distribution-related quality defect. Exposure of a product to a temperature beyond its specified range obtained the highest Risk Priority Number of the five categories assessed, ahead of seal breakage causing microbial contamination, mishandling affecting product integrity, illegible labelling and exposure to contaminating odours during shared transport. The authors' central conclusion is that quality risk management, despite being firmly institutionalised within manufacturing-site quality systems, is not diligently applied during distribution, leaving a structural gap between the risk-based culture that regulators expect at the factory gate and the comparatively unmanaged risk environment that prevails once a product leaves it. They propose a distribution-specific risk management model built around explicit standard operating procedures for transport and temperature monitoring, contractual clauses obliging carriers to respect storage conditions, digital data loggers with automated alerts, and periodic review of corrective and preventive action plans.

This literature is significant for the Moroccan reform context because it suggests a concrete regulatory lever: rather than relying solely on inspection and sanction, as the current legislative reform primarily does, a distribution-specific quality risk management obligation - requiring pharmaceutical establishments formally to identify, score and mitigate cold chain risks along the lines proposed by Kumar and Jha [2] - could be incorporated into the implementing texts accompanying Law No. 27.26, thereby operationalising the general good distribution practice obligation already present in Moroccan law.

3.5. Multi-Actor Coordination and Supply Chain Reliability

Skowron-Grabowska et al. [9] approach the reliability of healthcare logistics from a different angle, examining, through a single case study of a Polish regional hospital, the factors that determine the reliability of interhospital medical air transport. Although their object of study - the transfer of critically ill patients rather than of medicinal products - differs from the cold chain, their methodological contribution is valuable because it demonstrates, through detailed process mapping of one hundred transport cases, that reliability in a complex healthcare supply chain is not reducible to any single technical parameter. The authors identify thirteen categories of reliability factor, spanning legal and administrative regulation, geographic and climatic conditions, technical and infrastructural capacity, means of transport, staff availability and competence, patient condition, documentation,

medication and equipment provisioning, communication systems, human factors and time. Their central finding is that reliability depends on the coherent and integrated cooperation of the several legally distinct institutions involved in the transfer process - the referring hospital, the specialised transport operator and the receiving hospital - operating simultaneously at the systemic, inter-organisational and intra-organisational levels.

This multi-level conception of reliability offers a useful corrective to accounts of pharmaceutical cold chain failure that focus exclusively on physical infrastructure. It suggests that a Moroccan cold chain incident is unlikely to be attributable to a single deficient actor - a malfunctioning refrigerator, an untrained pharmacist, an under-resourced inspectorate - but rather to a failure of coordination between actors whose respective obligations, under Moroccan law, are often defined separately (manufacturer, wholesaler-distributor, dispensing pharmacy, transporter, regulator) without a unifying mechanism analogous to the integrated procedure that Skowron-Grabowska et al. [9] recommend for interhospital patient transfer.

3.6. Post-Market Surveillance and the Legal Architecture of Recall

Livingston and Mattingly [13] examine how a mature regulatory authority - the United States Food and Drug Administration - documents and categorises pharmaceutical and medical device recalls, reviewing 229 recalls issued between January 2017 and September 2019. Eighty-five per cent of drug recalls in the sample were attributable to product quality issues rather than labelling errors, and among quality-related recalls, a lack of sterility assurance accounted for the overwhelming majority. The authors note, however, that the free-text recall descriptions published by the regulator do not follow a standardised taxonomy, which complicates systematic monitoring of recurring failure types, including, by implication, cold chain-related recalls, which the authors' categorisation scheme did not isolate as a distinct subcategory. Their broader argument, echoing a policy position adopted by the American Pharmacists Association, is that the availability, quality and safety of the pharmaceutical supply chain should be treated as a matter of strategic and public health importance, warranting greater transparency, standardised information architecture, and regulatory incentives for redundancy and risk mitigation in manufacturing and distribution processes.

For the Moroccan context, this study underscores the importance of a well-structured pharmacovigilance and recall function, precisely the area that the pending Law No. 27.26 seeks to reinforce by requiring pharmaceutical establishments to designate a qualified assistant pharmacist responsible for pharmacovigilance and by expanding the notification obligations of the pharmacien responsable. It also suggests, by contrast, a design lesson: unless the categories used by AMMPS to record and publish recalls and safety notifications explicitly distinguish cold chain-related defects from other quality failures, the kind of systematic monitoring that Livingston and Mattingly [13] call for will remain difficult to achieve in Morocco as well.

3.7. Information Asymmetry between Manufacturers and Healthcare Providers

Morais et al. [14] examine a dimension of cold chain governance that the preceding studies do not directly address: the practical availability of the technical information that a pharmacist needs in order to decide what to do once a cold chain disruption has already occurred. Comparing the response of seventy pharmaceutical companies marketing 792 refrigerated medicines in Portugal to identical information requests submitted, on one occasion, by a hospital pharmacy and, on another, by a community pharmacy, the authors found substantial disparities. The hospital pharmacy received a response to seventy-one per cent of its requests, compared with fifty-two per cent for the community pharmacy, and the hospital's responses arrived, on average, in less than half the time required for the community pharmacy to obtain an answer. Critically, the authors also examined the Summaries of Product Characteristics of the same 792 medicines, which constitute the official European drug labelling, and found that none contained a complete procedure addressing the inadvertent exposure of a refrigerated medicine to an out-of-range temperature; information on the maximum permissible storage temperature and duration outside the refrigerator was present in only sixteen per cent of the labelling documents examined.

This finding carries a direct legal implication that is transposable to the Moroccan context, irrespective of the fact that Moroccan and European drug labelling regimes are not identical: even where a comprehensive regulatory obligation to preserve cold chain integrity exists, the practical, product-specific information required to manage a disruption event once it has occurred is frequently unavailable

from the two sources - the manufacturer and the official labelling - that a healthcare professional would normally consult. In the absence of a national protocol filling this gap, healthcare professionals confronted with a cold chain incident in a Moroccan facility are likely to face the same practical uncertainty that Morais et al. [14] documented in Portugal, with the attendant risk that products are either administered without adequate assurance of their continued efficacy or discarded unnecessarily, at a cost to the health system that several of the studies reviewed above identify as a further, secondary harm of poor cold chain governance [1, 4].

3.8. Emerging Digital and Blockchain-Enabled Monitoring Technologies

The seven country-level studies reviewed above converge on the diagnostic weakness that arises when cold chain compliance depends on manual, retrospective verification. A fast-growing stream of engineering and information-systems literature addresses this weakness directly by embedding Internet-of-Things sensors, automated data loggers and, increasingly, blockchain ledgers within the distribution process itself. Zeng et al. [20], for instance, propose a blockchain-based traceability architecture for emergency cold-chain medicine logistics that combines a multi-sensor data-fusion algorithm with distributed-ledger recording, and report that the resulting system improves the reliability of temperature data and automates the detection of hazardous excursions beyond what conventional, manually-read data loggers can achieve. Although this literature is drawn overwhelmingly from engineering and supply-chain informatics rather than from health-systems or regulatory scholarship, and although none of the reviewed implementations has yet been deployed or evaluated within a Moroccan or comparable North African hospital setting, it is directly relevant to the present inquiry because it clarifies what a technologically mature cold chain monitoring infrastructure could look like, against which the more uneven, partly manual practices reported by participants in Section 5 can be situated.

This literature also reinforces the regulatory point made in Section 2.9: the more completely temperature recording is automated and rendered tamper-evident, the more the enforceability of good distribution practice obligations under instruments such as Law No. 27.26 is strengthened, and the less residual discretion is left to individual professional judgement. It follows that the pace at which such technologies diffuse into Moroccan public hospitals – a question examined empirically in Section 5.2 – is not merely an operational detail but a variable that conditions the practical reach of the anticipated legislative reform.

3.9. The Moroccan Regulatory and Institutional Landscape

The Moroccan pharmaceutical sector is governed at the legislative level by Law No. 17-04 on the Code du Médicament et de la Pharmacie, which has, since its adoption in 2006, subjected pharmaceutical establishments to good manufacturing and distribution practice requirements enforceable by sworn pharmacist-inspectors. Institutionally, oversight has recently migrated from the former Direction du Médicament et de la Pharmacie to the newly created Agence Marocaine des Médicaments et des Produits de Santé (AMMPS), a public establishment endowed with legal personality and financial autonomy pursuant to Law No. 10-22 [15], whose stated mission includes strengthening pharmacovigilance, combating the circulation of falsified medicines and modernising the traceability of pharmaceutical products through integrated information systems [16]. This institutional transition is accompanied by a substantive legislative reform: draft Law No. 27.26, adopted by the Council of Government in April 2026 and subsequently passed by the House of Representatives, amends Law No. 17-04 to extend AMMPS's inspection powers across the entire medicine chain, from manufacturing sites to pharmacies and hospital drug reserves; to require pharmaceutical establishments to designate a qualified pharmacovigilance officer and to notify the Agency of any adverse effect or other problem arising from the use of a medicine; and to raise the financial penalties applicable to breaches of good manufacturing and distribution practice from a range of 2,500 to 20,000 Moroccan dirhams to a range of 100,000 to 1,000,000 Moroccan dirhams [11, 12, 17]. According to public statements by industry analysts, the underlying strategic objective of this reform is to raise AMMPS to Maturity Level 3 of the World Health Organization's Global Benchmarking Tool - a classification assessed across roughly 268 sub-indicators covering nine thematic domains, including clinical trial authorisation, marketing authorisation, pharmacovigilance, market surveillance, inspection and quality management - a status that would, in turn, open the possibility of recognition as a World Health Organization Listed Authority [10].

Outside this general framework, Morocco has developed a considerably more granular, sector-

specific cold chain regime for vaccines under its National Immunisation Programme. The Ministry of Health's training manual for this programme prescribes a storage temperature of +2°C to +8°C, expressly prohibits freezing for the great majority of vaccines, requires twice-daily temperature recording using cold chain monitoring cards and thermometers, and specifies a tiered infrastructure of cold rooms, refrigerated cabinets, freezers, insulated containers and vaccine carriers deployed across the central, regional, provincial and peripheral levels of the health system [8]. This sectoral regime was substantially reinforced during the COVID-19 pandemic, when Morocco, with technical and financial support from UNICEF and the United States Agency for International Development, deployed ultra-low-temperature freezers to preserve messenger RNA vaccines at −80°C, raising national ultra-cold storage capacity from 1.9 to 4.1 million doses [18].

The juxtaposition of these two regulatory registers - a general, increasingly stringent Code du Médicament et de la Pharmacie applicable to all pharmaceutical operators, and a detailed, immunisation-specific cold chain protocol - suggests a structural asymmetry consistent with the information asymmetry documented by Morais et al. [14] in the European context. Whereas the National Immunisation Programme furnishes healthcare workers with explicit, product-independent decision rules for handling temperature excursions (for instance, the systematic discarding of frozen doses), no equivalent, generally applicable protocol appears to exist for the far larger population of refrigerated medicines - insulins, biologics, certain injectable anaesthetics and blood derivatives - that circulate through Moroccan hospital and community pharmacies outside the immunisation programme. Neither Law No. 17-04 nor the draft Law No. 27.26, as currently described in the available legislative commentary, articulates a specific, product-neutral obligation regarding the management of a cold chain disruption once it has occurred, as distinct from the general obligation to maintain appropriate storage conditions in the first place. This suggests that, notwithstanding the significant strengthening of AMMPS's inspection and pharmacovigilance powers under the pending reform, an operational gap comparable to the one identified by Morais et al. [14] may persist within the Moroccan regulatory architecture until it is addressed through implementing texts or professional guidance specifically dedicated to post-disruption decision-making.

3.10. Positioning of the Present Study Relative to Prior Research

Table 1 situates the eleven studies reviewed above, together with the present article, along four dimensions: the method employed, the aim pursued, and the principal limitation that, from the standpoint of the Moroccan inquiry reported in Section 5, each study leaves open.

Table 1: Positioning of the Present Study Relative to Prior Research

Authors	Method	Aim	Key Limitation (Relative to the Present Study)
Fekadu et al. [3]	Reflexive thematic analysis of 39 interviews, 4 ICUs, Ethiopia	Documented systemic and cultural determinants of patient-safety incident concealment	General patient-safety focus; not cold-chain-specific; single country
Feyisa et al. [21]	Multicentred, mixed-method facility evaluation, Jimma Hub, Ethiopia	Assessed cold chain management performance at supply-agency and facility level	Facility/logistics focus; no in-depth interviews on regulatory perception
Van Assche et al. [4]	Secondary analysis of QUAMED audit data, 60 distributors, 13 LMICs	Measured GDP/GSP compliance among private pharmaceutical distributors	Audit-based; distributor level; excludes hospital-facility perspective and Morocco
Chukwu & Adibe [1]	Facility audit against WHO checklist, 6 storage sites, 133 pharmacies, Nigeria	Assessed cold chain storage and distribution compliance	Quantitative audit only; no accounts of professional decision-making or reporting culture
Kumar & Jha [2]	Survey and FMEA of 260 professionals, India	Ranked distribution-related quality risks and proposed a QRM model	Risk-ranking exercise; does not examine lived professional experience of disruption
Skowron-Grabowska et al. [9]	Single case study, process mapping of 100 transfers, Poland	Identified multi-actor determinants of healthcare-logistics reliability	Object of study is patient transport, not medicinal products; single hospital

Authors	Method	Aim	Key Limitation (Relative to the Present Study)
Livingston & Mattingly [13]	Retrospective review of 229 US FDA recalls	Categorised drug/device recall causes; argued for supply-chain transparency	Recall-taxonomy focus; cold-chain-specific recalls not isolated as a subcategory
Morais et al. [14]	Comparative information-request audit, 70 companies / 792 medicines, Portugal	Assessed availability of post-disruption technical guidance from manufacturers	Manufacturer/labelling focus only; no facility-level or professional-perception data
Matafwali et al. [22]	Semi-structured interviews, 15 stakeholders, thematic analysis, Zambia	Explored stakeholder perceptions of medicine-quality implications of new distribution channels	Distribution-channel focus; not cold-chain-specific; excludes hospital pharmacists
Lalani et al. [23]	Qualitative stakeholder interviews, Senegal	Examined perceptions of medicine-quality evidence and regulatory oversight	General medicine-quality focus; not cold-chain-specific
Zeng et al. [20]	Blockchain/IoT system design and simulation, China	Proposed a blockchain-based cold-chain traceability architecture	Engineering evaluation; no health-system or regulatory-perception data; not hospital-deployed
Present study (2026)	Semi-structured interviews, 8 hospital pharmacists, reflexive thematic analysis, Morocco	Examines cold chain governance through professional experience and regulatory analysis	Single region, n = 8; addressed explicitly in Section 6.1

Table 1 makes explicit what the preceding review has argued piecemeal: no study identified in this literature – whether audit-based, survey-based, engineering-oriented or qualitative – has examined pharmaceutical cold chain governance in Morocco, and none combines, as the present article does, a doctrinal analysis of an evolving national legal framework with facility-level qualitative fieldwork among the professionals directly responsible for cold chain integrity. The studies closest in method to the present inquiry – Fekadu et al. [3], Matafwali et al. [22] and Lalani et al. [23] – share its qualitative, interview-based design and its concern with stakeholder perception, but none is cold-chain-specific: Fekadu et al. examine patient-safety incidents in general, while Matafwali et al. and Lalani et al. examine medicine-quality assurance and distribution-channel innovation rather than temperature-controlled storage as such. Conversely, the studies closest in subject-matter – Chukwu and Adibe [1], Van Assche et al. [4] and Feyisa et al. [21] – are cold-chain-specific but rely on audit or facility-performance data rather than on the professionals' own accounts of how disruptions are identified, managed and reported, and none situates its findings within a specific, currently-reforming national legal architecture of the kind examined in Section 3.9. The present article's motivation therefore differs from this literature in a specific respect: rather than measuring compliance (as in Chukwu & Adibe, Van Assche et al.) or documenting general patient-safety culture (as in Fekadu et al.), it asks how a particular category of professional – the hospital pharmacist – experiences, at the point of practice, the interaction between technical cold chain management, digital monitoring technology and a rapidly evolving legal obligation, in a country not previously studied on this question.

The findings, reported in Section 5, both confirm and qualify this literature. Consistent with Fekadu et al. [3], Van Assche et al. [4] and Matafwali et al. [22], Moroccan hospital pharmacists overwhelmingly frame cold chain failure as systemic rather than individual, corroborating the "fragile systems" pattern identified across markedly different institutional settings. Consistent with Chukwu and Adibe [1] and with the emerging digital-monitoring literature reviewed in Section 3.8 [20], the uneven adoption of digital temperature-monitoring devices reported by participants suggests that the diagnostic weakness documented in Nigeria is not confined to that setting. At the same time, the Moroccan findings qualify the comparative picture in one respect that appears specific, or at least more sharply expressed, in this study: participants situate their uncertainty not primarily in a lack of formal rules – Law No. 17-04 is generally known to participants – but in the absence of a specific, product-neutral operational protocol for the post-disruption period, an information-asymmetry gap structurally similar to, but institutionally distinct from, the manufacturer-side gap documented by Morais et al. [14] in Portugal. This suggests that the Moroccan case adds a regulatory-design dimension – the distinction between the existence of a general legal obligation and the availability of specific operational guidance – that is present only implicitly in the comparative literature reviewed above.

4. METHODOLOGY

4.1. Research Design

This stage of the research adopts a qualitative, exploratory-descriptive design, consistent with the pragmatist orientation already discussed with reference to comparable patient-safety inquiries reviewed earlier in this article [3]. The purpose of this design is not to measure the prevalence of cold chain failures across the Moroccan hospital network, but to document, from the standpoint of the professionals directly responsible for it, how such failures are identified, managed, reported and related to the existing pharmaceutical regulatory framework. A qualitative approach was considered appropriate because, as the literature reviewed above repeatedly shows, cold chain disruption is frequently a "silent" event whose organisational and cultural determinants are better captured through in-depth interviews than through structured questionnaires.

Table 2 summarises the overall research protocol, situating each phase of the study in relation to the corresponding methodological subsection.

Table 2: Overview of the Research Protocol

Phase	Activity	Corresponding Section
1. Preparatory phase	Conceptual framework and interview guide design; request for institutional authorisation	Sections 2, 4.5, 4.7
2. Recruitment	Purposive sampling of hospital pharmacists in the Fez-Meknes region; informed consent	Section 4.3
3. Data collection	Individual, semi-structured, face-to-face interviews (40-50 minutes); audio recording	Section 4.4
4. Data preparation	Verbatim transcription; anonymisation of participants (P1 to P8)	Section 4.4
5. Data analysis	Reflexive thematic analysis (Braun & Clarke, 2006 [19], six phases), coded inductively within four axes	Section 4.6
6. Synthesis	Cross-axis discussion; comparison with prior literature; identification of open issues	Sections 5.5, 3.10, 6

4.2. Study Setting

The empirical investigation was conducted within public hospital establishments located in the Fez-Meknes region of Morocco. This region was selected because it combines a university-affiliated referral hospital centre with several provincial public hospitals of varying size and resource level, offering a setting in which the infrastructural heterogeneity documented in comparable low- and middle-income country studies could plausibly be observed [1, 4]. For reasons of institutional confidentiality, individual hospitals are not named and are instead referred to generically throughout the analysis.

4.3. Population and Sampling

The target population comprised hospital pharmacists (pharmaciens hospitaliers) directly or indirectly involved in the reception, storage, monitoring or dispensation of thermolabile pharmaceutical products. Participants were selected through purposive sampling on the basis of two inclusion criteria: (i) registration as a hospital pharmacist within a public establishment of the Fez-Meknes region, and (ii) demonstrable professional involvement, whether operational or supervisory, in the handling of cold-chain-sensitive products. A final sample of eight participants (n = 8) was retained, a size consistent with the information-power rationale mobilised in comparable qualitative patient-safety research reviewed above [3], given the narrowly defined population and the depth sought in each interview.

4.4. Data Collection

Data were collected through individual, semi-structured, face-to-face interviews, each lasting between forty and fifty minutes. Interviews were conducted in a private setting at the participant's workplace in order to preserve confidentiality and minimise interruption. With participants' informed consent, interviews were audio-recorded and subsequently transcribed verbatim; each participant was assigned an anonymised identifier (P1 to P8), used throughout the analysis and in the excerpts presented in Section 5.

4.5. Interview Guide

The interview guide was structured around four axes, each directly derived from the conceptual framework developed above and from the recurring themes identified in the literature review. The structure of the guide is summarised in Table 3, presented across the full page width below.

Table 3. Structure of the Interview Guide

Axis	Analytical Focus	Description
Axis 1	Identification and characterisation of cold chain disruptions	Explores how participants define, recognise and recall instances of temperature excursion, equipment failure or transport-related incidents affecting thermolabile products.
Axis 2	Organisational, infrastructural and human resource determinants	Examines the material and organisational conditions - equipment, staffing, training, supervision - under which cold chain management is carried out.
Axis 3	Incident management, reporting practices and organisational culture	Addresses what happens once a disruption is suspected or confirmed, whether and how it is reported, and the perceived barriers to reporting.
Axis 4	Knowledge, perception and application of the regulatory framework	Probes participants' awareness of Law No. 17-04 [6], of the Moroccan Medicines and Health Products Agency, and of the anticipated Law No. 27.26 [7], together with their perception of the adequacy of the current legal and institutional framework.

4.6. Data Analysis

The transcripts were analysed using reflexive thematic analysis, following the six-phase approach developed by Braun and Clarke [19] - familiarisation, initial coding, theme generation, theme review, theme definition and write-up - and already applied to a comparable patient-safety inquiry in the literature reviewed above [3]. Coding proceeded inductively within each of the four axes, allowing sub-themes to emerge from participants' own accounts rather than being imposed a priori.

4.7. Ethical Considerations

Prior authorisation was sought from the relevant regional health administration, and each participant provided informed consent after being briefed on the purpose of the study, the voluntary nature of participation, and the confidentiality safeguards applied to the data. No hospital or department is identified by name in the analysis, and all quoted excerpts are anonymised.

5. RESULTS AND DISCUSSION

The presentation of findings follows the four axes of the interview guide set out in Section 4.5 (Table 3). For each axis, the coded material is organised around convergent and divergent positions among the eight participants, illustrated through anonymised verbatim excerpts, and discussed in relation to the comparative literature reviewed earlier in this article.

5.1. Axis 1 - Identification and Characterisation of Cold Chain Disruptions

The thematic analysis identified four major sub-themes related to the identification and characterisation of pharmaceutical cold chain disruptions: (i) equipment-related failures, (ii) power supply interruptions, (iii) transportation-related temperature excursions, and (iv) human-related operational errors. Overall, the findings suggest that hospital pharmacists perceive cold chain disruptions as relatively infrequent but potentially critical events requiring immediate intervention to preserve medicine quality and patient safety.

The first sub-theme concerns refrigeration equipment failures. Most participants associated cold chain disruptions with ageing refrigeration units, insufficient preventive maintenance, and occasional malfunction of temperature monitoring devices. Although these events were not described as frequent, they were consistently perceived as one of the principal threats to the integrity of thermolabile medicines.

For instance, P1 explained: "Most of the time our refrigerators operate normally; however, older equipment occasionally experiences technical failures, especially during periods of intensive use. When this happens, rapid intervention becomes essential to prevent medicine deterioration." Similarly, P4 noted: "Temperature alarms are useful, but they are not available on every refrigerator. In some units, monitoring still depends mainly on manual recording, which may delay the identification of temperature excursions."

These statements suggest that equipment reliability remains a key determinant of pharmaceutical quality assurance. The thematic analysis indicates that participants considered

preventive maintenance more important than corrective maintenance, emphasising that early detection of technical problems considerably reduces the probability of medicine loss.

A second recurring theme relates to electricity supply interruptions. Despite the presence of emergency generators in most public hospitals, pharmacists expressed concerns regarding the short period between power failure and generator activation. This interval was perceived as particularly critical for highly temperature-sensitive biological medicines.

P2 stated: "Power outages do not occur very often, but when they happen, every minute counts. Even a short interruption creates uncertainty about whether the storage conditions remained fully compliant." Likewise, P7 added: "Backup generators significantly reduce the risk, although pharmacists are rarely able to verify the exact duration of the temperature excursion inside each refrigerator."

Beyond infrastructure, transportation emerged as another important source of vulnerability. Participants generally agreed that maintaining temperature control during product distribution remains more challenging than during hospital storage. Long travelling distances, high summer temperatures and logistical delays were considered the principal contributing factors.

As P5 observed: "Transportation is probably the most sensitive stage because products are exposed to external conditions that cannot always be controlled, particularly during the summer season." However, a slightly different opinion was expressed by P8, who argued: "Transportation has improved considerably over recent years. In my opinion, most problems now occur after medicines arrive at healthcare facilities rather than during delivery."

This divergence illustrates that perceptions of risk may vary according to local organisational practices and available logistics infrastructure. While some pharmacists identify transportation as the primary source of vulnerability, others emphasise internal hospital processes as the most critical stage of the cold chain.

The fourth sub-theme concerns human-related operational factors. Participants consistently recognised that cold chain failures cannot be explained exclusively by technical deficiencies. Instead, routine practices such as leaving refrigerator doors open unnecessarily, delayed storage after product reception, incomplete documentation, and communication failures between departments were considered significant contributors to temperature excursions.

P3 explained: "Most incidents are not caused by negligence. They usually occur because healthcare professionals work under considerable pressure while managing multiple responsibilities simultaneously." Similarly, P6 commented: "Even experienced professionals may unintentionally contribute to temperature deviations when workloads become particularly demanding or staffing levels are insufficient."

These perspectives indicate that pharmacists predominantly adopt a systems-based interpretation of cold chain failures. Rather than attributing incidents to individual misconduct, participants perceive disruptions as resulting from the interaction between organisational constraints, infrastructure limitations, workload and operational complexity.

Another noteworthy finding concerns uncertainty following minor temperature excursions. Participants indicated that brief deviations from recommended storage conditions often generate considerable professional uncertainty because scientific information regarding medicine stability after exposure remains limited.

As P1 remarked: "One of the most difficult decisions concerns determining whether a medicine remains suitable for use after a short temperature excursion. Manufacturers rarely provide detailed guidance for every possible situation." Similarly, P4 added: "Sometimes the excursion lasts only a few minutes, but we still hesitate because patient safety must always remain the highest priority."

Overall, the thematic synthesis suggests that pharmaceutical cold chain disruptions should not be interpreted as isolated technical failures but rather as multidimensional events influenced by infrastructure, logistics, organisational processes and human factors. The interaction among these determinants reinforces the importance of adopting an integrated quality management approach capable of preventing disruptions before they compromise medicine quality.

These findings are broadly consistent with previous international research. Chukwu and Adibe [1] similarly identified inadequate refrigeration infrastructure and unstable electricity supply among the principal causes of cold chain failures within healthcare facilities. Likewise, Kumar and Jha [2] demonstrated that transportation-related temperature excursions constitute one of the highest pharmaceutical distribution risks. The present

synthesis also supports the systems perspective proposed by Fekadu et al. [3], according to which patient safety incidents rarely originate from isolated human error but rather emerge from the interaction of organisational, technical and environmental factors. Within the Moroccan public hospital context, these themes highlight the importance of strengthening preventive maintenance, continuous temperature monitoring, interdepartmental coordination and risk management practices to improve the resilience of pharmaceutical cold chain systems.

5.2. Axis 2 - Organisational, Infrastructural and Human Resource Determinants

The analysis of the interview data highlighted four interrelated organisational factors shaping the reliability of pharmaceutical cold chain management in Moroccan public hospitals. These factors encompass the adequacy of storage infrastructure, the effectiveness of preventive maintenance, the availability of qualified human resources, and access to continuous professional development. Collectively, the findings suggest that participants viewed the preservation of the pharmaceutical cold chain as a shared institutional responsibility requiring coordinated efforts across multiple hospital departments, rather than as the sole responsibility of individual healthcare professionals.

A prominent theme emerging from the analysis relates to the condition and adequacy of refrigeration infrastructure. Although all participants reported that dedicated refrigeration facilities were available for storing thermolabile medicines, they also pointed to noticeable differences in equipment age, technological capabilities, and maintenance practices across healthcare institutions. These variations were frequently perceived as influencing the overall reliability and efficiency of cold chain management.

P2 explained: "Our hospital has sufficient refrigeration capacity, but some units have been operating for many years. They remain functional, although newer equipment would certainly improve monitoring accuracy and reliability." Similarly, P6 stated: "Digital refrigerators equipped with automatic temperature recording provide greater confidence than conventional refrigerators requiring manual monitoring several times a day."

However, P8 expressed a slightly different perspective: "The main issue is not necessarily the age of the refrigerators but ensuring regular calibration and preventive maintenance. Even modern equipment may become unreliable without proper follow-up."

These perspectives suggest that pharmacists associate equipment performance not only with technological sophistication but also with systematic maintenance and quality assurance procedures.

Another prominent theme concerns staffing constraints. Nearly all participants emphasised that hospital pharmacists increasingly assume multiple administrative and clinical responsibilities, reducing the time available for continuous supervision of pharmaceutical storage conditions.

P3 commented: "Managing the cold chain is only one aspect of our daily responsibilities. We are simultaneously responsible for procurement, inventory management, dispensing activities, and administrative reporting." Likewise, P5 added: "During periods of staff shortage or annual leave, monitoring activities become considerably more challenging because fewer professionals share the same workload."

Nevertheless, P1 considered teamwork an important protective factor: "Good communication among pharmacists, pharmacy technicians and nursing staff significantly reduces operational risks, even when staffing levels are limited."

These observations suggest that human resource shortages may indirectly increase vulnerability by reducing opportunities for systematic monitoring and documentation rather than by directly causing cold chain failures.

Professional training emerged as another recurrent sub-theme. Participants generally agreed that their university education provided the theoretical foundations for pharmaceutical storage; however, opportunities for specialised continuing education in cold chain management appeared relatively limited.

P4 explained: "Initial academic training introduced the principles of cold chain management, but scientific knowledge evolves continuously. Regular refresher training would help healthcare professionals remain aligned with current international recommendations." Similarly, P7 stated: "Training should include practical scenarios dealing with temperature excursions and decision-making after unexpected incidents rather than focusing exclusively on theoretical concepts."

Beyond technical competencies, participants also highlighted the importance of multidisciplinary collaboration. Pharmacists considered effective

communication between pharmacy departments, biomedical engineers, hospital administration and logistics personnel essential for ensuring rapid responses whenever technical problems occur.

As P6 observed: "Cold chain management cannot rely solely on pharmacists. Biomedical engineers, maintenance services and hospital management all contribute to ensuring medicine quality." Furthermore, P2 suggested: "Assigning a dedicated cold chain coordinator could improve accountability and facilitate communication between departments whenever incidents occur."

The thematic analysis therefore indicates that organisational resilience depends on both technical resources and institutional coordination. Rather than perceiving infrastructure, staffing and training as isolated determinants, participants consistently described them as complementary elements of a broader pharmaceutical quality management system.

Overall, these findings reinforce the idea that pharmaceutical cold chain reliability is fundamentally shaped by organisational capacity. Hospitals possessing modern equipment, structured maintenance programmes, multidisciplinary collaboration and continuous professional education appear better positioned to minimise temperature-related risks and preserve medicine quality.

These findings are consistent with Van Assche et al. [4], who highlighted the importance of organisational quality systems for maintaining pharmaceutical distribution standards in low- and middle-income countries. Likewise, the emphasis placed on institutional factors rather than individual responsibility supports the systems perspective proposed by Fekadu et al. [3], according to which patient safety largely depends on organisational resilience. Within the Moroccan context, these themes also suggest that investments in infrastructure modernisation should be accompanied by strengthened governance mechanisms, continuous professional development and clearly defined organisational responsibilities. Participants' own emphasis on digital temperature-recording equipment as a source of confidence, reported above, corroborates the regulatory significance attributed to digital cold chain monitoring technology in Section 2.9: where such technology is unevenly deployed across facilities, the reliability of cold chain oversight becomes correspondingly uneven.

5.3. Axis 3 - Incident Management, Reporting Practices and Organisational Culture

The third analytical axis explored participants' perceptions regarding incident reporting, corrective actions following temperature excursions, and the prevailing organisational culture surrounding pharmaceutical safety events. Four principal themes emerged from the analysis: incident detection and immediate response, reporting practices, organisational learning, and barriers to transparent communication.

Participants generally agreed that immediate action following a suspected cold chain disruption constitutes a professional priority. Quarantine of potentially affected medicines, verification of temperature records and consultation with suppliers or manufacturers were identified as the most common initial responses.

P1 explained: "Whenever a temperature excursion is suspected, the first action is to isolate the affected medicines until their stability can be properly assessed." Similarly, P5 stated: "Patient safety always takes precedence over economic considerations. If uncertainty remains regarding medicine quality, the product should not be dispensed."

These comments illustrate the cautious decision-making approach generally adopted by hospital pharmacists when product integrity cannot be guaranteed.

Despite this commitment to patient safety, the thematic analysis indicates considerable variability regarding formal reporting procedures.

P4 observed: "Internal reporting procedures exist, but they are not always standardised across departments. Some incidents are documented systematically, whereas others are managed informally." Likewise, P8 noted: "Minor temperature deviations are sometimes resolved locally without formal documentation because healthcare professionals consider them operational rather than safety-related events."

This finding suggests that reporting practices may differ depending on the perceived severity of the incident and local organisational routines.

Another important theme concerns organisational culture. Most participants expressed positive attitudes toward transparency; however, several acknowledged that healthcare professionals occasionally hesitate to report incidents because they fear criticism or administrative consequences.

P2 explained: "Most professionals understand the importance of reporting, but some remain concerned that reporting could be interpreted as evidence of poor performance." Similarly, P7 commented: "Reporting should be viewed as an opportunity for organisational improvement rather than individual blame." Conversely, P6 described a more supportive organisational environment: "Our department encourages discussion whenever an incident occurs. The objective is to understand why the event happened and how similar situations can be prevented."

These differing perspectives illustrate that organisational culture may vary across healthcare facilities, influencing professionals' willingness to disclose operational incidents.

Participants also highlighted the importance of learning from previous disruptions. Several suggested that periodic multidisciplinary meetings analysing incidents could strengthen institutional learning and improve future preparedness.

As P3 concluded: "Every incident provides valuable experience. Analysing these situations collectively allows hospitals to improve procedures and reduce future risks."

Overall, the thematic synthesis indicates that incident management extends beyond immediate technical intervention. Effective reporting mechanisms, supportive organisational culture and continuous institutional learning collectively contribute to strengthening pharmaceutical safety systems.

These findings closely support the observations of Fekadu et al. [3], who described organisational silence and fear of blame as important barriers to patient safety reporting. Applied to pharmaceutical cold chain management, the analysis suggests that strengthening a just culture may encourage transparent reporting while simultaneously enhancing organisational learning and regulatory compliance.

5.4. Axis 4 - Knowledge, Perception and Application of the Regulatory Framework

The fourth analytical axis explored hospital pharmacists' knowledge of the Moroccan pharmaceutical regulatory framework governing thermolabile medicines and their perceptions regarding its practical application in daily hospital practice. The thematic analysis identified four principal themes: awareness of existing legislation, familiarity with regulatory institutions, perceived gaps in operational guidance, and expectations regarding future regulatory developments.

Overall, participants demonstrated a satisfactory general awareness of the existence of the national legal framework regulating pharmaceutical activities. Most recognised that medicine storage and distribution are governed by national legislation and supervised by competent health authorities. Nevertheless, the analysis suggests that familiarity with the operational implications of these regulations varies considerably according to professional experience and institutional responsibilities.

P2 explained: "We are familiar with the main legal provisions governing pharmaceutical practice; however, daily activities rely more on internal hospital procedures than on consulting legislative documents." Similarly, P6 stated: "National regulations establish the general principles, but practical decisions are mainly guided by professional experience and institutional protocols."

These observations suggest that although pharmacists acknowledge the existence of an established regulatory framework, legislation itself is rarely used as a direct operational reference during routine pharmaceutical practice.

A second emerging theme concerns participants' knowledge of the Moroccan Medicines and Health Products Agency (AMMPS). Most pharmacists recognised the Agency as the national authority responsible for medicine regulation and quality assurance. However, their understanding of its operational role in managing pharmaceutical cold chain incidents appeared relatively heterogeneous.

P1 commented: "The Agency plays an essential role in ensuring medicine quality, but communication regarding cold chain incidents generally remains internal unless the situation requires external notification." Likewise, P5 observed: "We mainly associate the Agency with medicine registration and quality control rather than with everyday hospital management of temperature excursions."

These perspectives indicate that pharmacists clearly recognise the institutional legitimacy of the regulatory authority while perceiving limited interaction during routine cold chain management activities.

The third and most prominent theme concerns the perceived lack of operational guidance following temperature excursions. Nearly all participants emphasised that one of the greatest challenges

involves deciding whether medicines exposed to temporary temperature deviations remain suitable for clinical use.

P3 explained: "When a refrigerator fails unexpectedly, determining whether medicines can still be used is often difficult because detailed stability recommendations are not always available." Similarly, P8 stated: "Clear national guidance specifically addressing post-excursion decision-making would greatly facilitate our daily responsibilities and reduce professional uncertainty." Conversely, P7 considered that international recommendations occasionally compensate for this limitation: "Whenever national guidance is insufficient, pharmacists frequently consult manufacturers' recommendations or international professional guidelines to support decision-making."

These differing perspectives demonstrate that regulatory awareness alone does not necessarily provide healthcare professionals with sufficient operational support when unexpected incidents occur.

Participants also expressed considerable interest in future regulatory developments, particularly regarding the implementation of Law No. 27.26. Although several pharmacists acknowledged limited familiarity with the detailed provisions of the forthcoming legislation, they generally expected the reform to strengthen pharmaceutical governance, improve quality assurance mechanisms and provide clearer operational guidance for healthcare institutions.

P4 explained: "Future regulatory reforms represent an opportunity to harmonise hospital practices and establish clearer procedures for managing thermolabile medicines." Likewise, P2 added: "Regulations should not only define responsibilities but also provide practical guidance allowing healthcare professionals to respond consistently to temperature-related incidents."

Overall, the thematic analysis indicates that participants perceive the current regulatory framework as essential but insufficiently operational for addressing complex situations involving pharmaceutical cold chain disruptions. Rather than questioning the relevance of existing legislation, pharmacists primarily advocate clearer implementation guidelines, harmonised national procedures and enhanced institutional communication.

These findings are consistent with the observations of Morais et al. [14], who reported important information asymmetries regarding pharmaceutical storage practices among healthcare providers. They also reinforce the governance perspective developed throughout the literature review, suggesting that effective pharmaceutical regulation should combine legal requirements with practical decision-support tools. Within the Moroccan context, the anticipated implementation of Law No. 27.26 may therefore represent an important opportunity to strengthen operational guidance, standardise post-disruption protocols and further improve patient safety.

5.5. Cross-Axis Discussion

Taken together, the four analytical axes illustrate the multidimensional nature of pharmaceutical cold chain management within Moroccan public hospitals. Rather than identifying a single dominant cause of cold chain failure, the thematic analysis suggests that temperature excursions result from the interaction of technical, organisational, human and regulatory factors.

The findings consistently demonstrate that pharmacists perceive cold chain reliability as a systemic organisational challenge rather than an issue attributable to individual negligence. Equipment performance, preventive maintenance, workload, professional training, institutional communication and regulatory support collectively influence the capacity of healthcare facilities to preserve medicine quality throughout the distribution and storage process.

Another cross-cutting finding concerns uncertainty in decision-making following temperature excursions. Across all four analytical axes, participants repeatedly emphasised the need for evidence-based guidance capable of supporting professional judgement when product stability cannot be immediately confirmed. This observation highlights the importance of integrating scientific knowledge, organisational learning and regulatory governance within a comprehensive pharmaceutical quality management framework.

The findings further suggest that organisational culture plays a central role in strengthening pharmaceutical safety. Hospitals promoting multidisciplinary collaboration, transparent incident reporting and continuous professional learning appear better equipped to anticipate operational risks and improve institutional resilience.

Overall, the themes identified in this analysis are largely consistent with previous international research conducted in low- and middle-income countries. Similar patterns have been reported regarding infrastructure limitations, human resource constraints, organisational vulnerability and the importance of effective regulatory governance. Nevertheless, the Moroccan context appears characterised by relatively structured pharmaceutical governance combined with continuing operational challenges associated with infrastructure modernisation, institutional coordination and implementation of evolving regulatory requirements.

From a practical perspective, these findings support several priorities for healthcare policymakers, including investment in digital temperature monitoring systems, reinforcement of preventive maintenance programmes, expansion of specialised professional training, development of national post-temperature-excursion guidelines and promotion of a just organisational culture encouraging transparent incident reporting. Collectively, these interventions could substantially strengthen pharmaceutical cold chain resilience while contributing to improved patient safety within Moroccan healthcare facilities.

6. CRITICAL DISCUSSION, LIMITATIONS AND OPEN RESEARCH ISSUES

6.1. Self-Critique and Methodological Limitations

Several limitations qualify the interpretation of the findings reported above and are acknowledged critically here, before the conclusions that follow in Section 7, rather than being noted only in passing.

First, the qualitative sample, drawn exclusively from eight hospital pharmacists practising within a single Moroccan region, does not permit statistical generalisation to the country's pharmaceutical distribution network as a whole, nor to other categories of professionals – community pharmacists, wholesaler-distributors, transport operators – who form part of the same chain of custody described in Section 2.1. The findings should accordingly be read as an in-depth, context-sensitive account of professional experience rather than as a representative measurement of the prevalence of cold chain failure in Morocco, a boundary condition that applies to every claim made in Section 5.

Second, the study relies on self-reported accounts of disruptions, their management and their reporting, collected at a single point in time; it does not incorporate independent verification through facility audit, temperature-logger records or documentary review of incident registers. It is therefore possible that participants' accounts of both the frequency of disruptions and the adequacy of their own reporting behaviour are affected by recall limitations or by social-desirability considerations, particularly regarding a topic – under-reporting – that Section 2.7 explicitly identifies as sensitive. No member-checking exercise (returning preliminary themes to participants for validation) was conducted, which would have strengthened the credibility of the thematic analysis in the sense intended by Braun and Clarke [19].

Third, the interviews were conducted in the participants' working languages and analysed and reported in English; while coding was performed on the original-language transcripts to preserve semantic nuance, translation of the illustrative excerpts presented in Section 5 necessarily involves a degree of interpretive choice, and subtleties of professional register or institutional euphemism may not survive translation intact.

Fourth, as with any qualitative inquiry conducted by researchers embedded in the same professional and academic environment as their participants, the analysis is not free of interpretive positionality. Reflexive thematic analysis explicitly incorporates the researcher's active role in theme generation rather than treating this as a threat to validity to be eliminated; nonetheless, the absence of a second independent coder for cross-checking theme development is a limitation relative to designs that incorporate inter-coder reliability procedures.

Finally, the study is exploratory by design and was not intended to test the propositions set out in Section 1.1 in a confirmatory sense; the propositions provided a structured point of departure for the analysis, not a hypothesis-testing framework, and their qualitative examination against the empirical material should not be read as statistical support or refutation.

6.2. Research Problems and Open Research Issues

Beyond the limitations of the present study's own design, the analysis conducted in Sections 3 and 5 surfaces a set of unresolved research and regulatory problems that extend beyond what this article can resolve and that define an agenda for the field.

Absence of a product-neutral post-disruption protocol. Neither Law No. 17-04 nor the draft Law

No. 27.26, as currently described in the available legislative commentary [11, 12, 17], articulates a specific decision procedure for managing a suspected cold chain excursion once it has occurred, as distinct from the general obligation to maintain appropriate storage conditions. Closing this gap – identified in Section 3.10 as structurally comparable to the information-asymmetry problem documented by Morais et al. [14] – remains an open regulatory-design problem rather than a purely empirical one.

Uncertain implementation trajectory of Law No. 27.26. Because the reform bill had, at the time of writing, been adopted in Council of Government and passed by the House of Representatives but had not yet entered into force, its practical effect on cold chain inspection and pharmacovigilance practice cannot yet be empirically assessed; this article can document professional expectations and perceptions of the reform, but not its implementation.

Absence of nationally representative data on digital monitoring technology adoption. The uneven deployment of data loggers, vaccine vial monitors and integrated traceability platforms reported by participants in Section 5.2 is documented here only at the level of individual professional accounts; no facility census or national inventory of cold chain monitoring equipment appears to be publicly available for the Moroccan hospital network, which prevents any quantification of the scale of the technological gap identified.

Absence of a harmonised, cold-chain-specific incident-reporting channel. Participants' accounts in Section 5.3 suggest that reporting practices vary by facility and are not anchored in a dedicated, cold-chain-specific pharmacovigilance channel distinct from general adverse-event reporting; whether such a dedicated channel would measurably improve detection and correction of disruptions is an open empirical question that the present qualitative design cannot answer.

Untested regional and inter-professional generalisability. Whether the systemic account of cold chain failure that emerges from this Fez-Meknes sample extends to other Moroccan regions, to community pharmacies and wholesaler-distributors, and to non-pharmacist actors in the chain of custody, remains, as already noted in Section 6.1, an open question that only a broader, comparative or quantitative research design could address.

6.3. Future Research Directions

Building on the limitations and open issues identified above, four directions for future research follow directly from this study.

First, the qualitative inquiry conducted in the Fez-Meknes region could usefully be extended to other Moroccan regions – including Casablanca-Settat, Rabat-Sale-Kenitra and the southern provinces – in order to capture the regional disparities in infrastructure, staffing and regulatory enforcement that the comparative literature reviewed in Section 3 suggests are likely to exist within a single country.

Second, future work should broaden the population studied beyond hospital pharmacists to include community pharmacists, wholesaler-distributors and transport operators, so as to reconstruct the full multi-actor chain of custody whose coordination, as discussed in Sections 2.8 and 3.5, determines the reliability of the system as a whole.

Third, and most significantly, the themes identified through this qualitative stage should be tested through a subsequent quantitative study – for instance, a structured survey administered to a statistically representative sample of pharmaceutical professionals across several Moroccan regions – capable of establishing the prevalence and the determinants of cold chain disruption, and of formally examining the propositions set out in Section 1.1, with a degree of generalisability that a qualitative design cannot, by itself, provide. Such a mixed-methods trajectory would allow the empirical findings generated by this research programme to feed directly into the implementing texts and professional guidance expected to accompany the entry into force of Law No. 27.26.

Fourth, given the uneven deployment of digital temperature-monitoring technology reported by participants and the rapid development of blockchain- and IoT-enabled traceability architectures documented in Section 3.8 [20], future research should specifically assess the rate and determinants of adoption of such technologies across Moroccan public hospitals, and evaluate, ideally through a pilot deployment, whether their generalisation measurably reduces the incidence and the concealment of cold chain disruptions identified in this study.

7. CONCLUSION

This article has combined a conceptual and doctrinal foundation, a comparative review of eleven empirical studies, an analysis of the evolving Moroccan pharmaceutical regulatory framework, and a qualitative research design intended to document how hospital pharmacists in the Fez-Meknes region experience, manage and report pharmaceutical cold chain disruptions. In response to the four research questions set out in Section 1.1, the findings indicate that cold chain disruptions are identified largely through ageing equipment failures and uneven digital monitoring (RQ1); that organisational, infrastructural and human-resource constraints, only partly offset by digital monitoring technology, are perceived as the principal determinants of reliability (RQ2); that reporting practices remain uneven and shaped by organisational culture rather than by the formal existence of a reporting obligation (RQ3); and that the current and forthcoming regulatory framework is perceived as necessary but, absent specific operational guidance for the post-disruption period, not yet sufficient (RQ4). These findings are broadly consistent with propositions P1 to P3 set out in Section 1.1, while also qualifying them in the specific respect discussed in Section 3.10: Moroccan participants situate the residual gap less in the absence of formal rules than in the absence of specific operational guidance for managing a disruption once it has occurred.

The article's central contribution is to connect a technical and managerial phenomenon – the silent degradation of thermolabile medicines outside their authorised temperature range – to the specific legal obligations imposed by Law No. 17-04, to the institutional mandate of the Moroccan Medicines and Health Products Agency, and to the reinforced inspection and pharmacovigilance provisions anticipated under Law No. 27.26, while situating these Moroccan findings within a wider comparative and increasingly technology-mediated literature reviewed in Sections 3.1 to 3.10. Its limitations, the open research and regulatory issues it surfaces, and the directions for future research that follow from both, are set out in Section 6.

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