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Controlled Price, Risk Evaluation and Storage and Delivery of Cold Chain Medicines in Homecare pharmacy Services

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Abstract
The rise in homecare pharmaceutical services has seen the rise in the demand of cold chain delivery of temperature-sensitive drugs such as insulin, monoclonal antibodies, and vaccines. The present paper assesses compliance risks and logistical risks related to the homecare traceability and stocks of those drugs. The assessment of the risk was applied following a systematic approach with references to WHO recommendations of the GDP and national regulations, in which 22 homecare pharmacies providers in Egypt and Southeast Asia were audited. The temperature data loggers were used to monitor 120 deliveries and it was found that 31 percent of them had temperature excursions greater than 15 minutes taken out of the 2-8 degree C range. The root cause analysis found some of the following problems: inadequate packaging, slow handoffs, and a lack of real time temperature monitoring. Also, forty eight percent of the providers had no formal SOPs governing cold chain breach. The research advises that cold chain providers should be mandatorily certified, IoT-based temperature monitors should be adopted and the regulatory provisions to be tightened to improve the compliance and ensure the safety of patients.

Keywords: ***cold chain logistics, homecare pharmacy, regulatory compliance, temperature sensitive medications, WHO GDP and risk assessment.***

1. Introduction

1.1 Several advances in the treatment of patients are being made in the medical industry

The popularization of the homecare pharmacy provision has transformed how patients consume their drugs and access them. Given current trends in the global healthcare system towards the model of more personalized and patient-centered care, homecare pharmacy services have become prominent, especially in the area of chronic conditions as well as palliative care. The use of cold chain medicines or temperature sensitive pharmaceuticals such as insulin, monoclonal antibodies, vaccines, and biologic therapies is one of the important trends in this evolution. Such medications need to be regulated in terms of temperature through the supply chain all the way to the patients so that they stay efficacious and safe.

The growing prevalence of chronic diseases like diabetes, autoimmune and cancer disorders has fuelled the growing demand of these life saving drugs. The convenience and independence that the homecare environment provides are seen and used to the advantage of patients, particularly during the need of long-term medication schedules or complicated medication regimens. Nonetheless, this movement has also raised up serious concerns on the safe storage and distribution of such drugs, since they are very sensitive to anything that might upset their temperature limits.(1)

1.2 These Temperature-Sensitive commodities are distractible to thermal excursions in the course of transportation and storage

Thermal excursions are especially sensitive in cold chain medicines, since they can happen when temperature of the product falls outside the range of ideal temperature. The norms of many cold chain products should lie within the 2-8 range, and even a minor fluctuation can severely tamper with the pharmaceutical value of the drug. A number of stages of the cold chain can develop thermal excursion: storage, handling, transportation. Any point of the distribution chain starting with warehouses, to pharmacies, all the way to the homes of patients is posed with a threat of temperature deviations, especially in cases where the process of delivery is not closely managed.

One of the most important stages of cold chain medicines is delivery process since glass medicines seek to be in the environment and logistics which are hard to be observed immediately. The basic reasons that may lead tothermal excursions are low levels of packing insulation, delays in handovers of various delivery crews, and incapable transportation conditions. Although the packaging might be suitable and can solve the problem of the

desired temperature at the beginning, putting the product into very adverse environmental conditions or ineffective transportation logistics might eventually lead a product to exceed its temperature limit, rendering it unsafe and ineffective. This is an alarming situation especially considering the fact that most of these drugs are life-saving drugs which require the observance of temperature in the strictest form.(2)

1.3 There is an inconsistency in the provision of regulatory oversight and risk mitigation strategies in most parts

Regulatory framework and risk management approaches to cold chain logistics in homecare pharmacy services are inconsistent within various jurisdictions as a challenge, even though the importance of cold chain logistics in homecare pharmacy services is increasing. In most countries, the storage, transportation, and delivery of medicines in the cold chain does not enjoy uniformity in terms of requirements. Although some regulations like the Good Distribution Practice (GDP) by the World Health Organization (WHO) exist to give a framework in which the integrity of cold chain medicines can be assured, the regulations are not applied equally in all areas or even countries.

The facilities needed to sustain a good cold chain could be non-existent in other regions especially those considered low-resource types and this is where there could be very large holes in the regulatory system. This may lead to erratic training of the logistics providers, poor temperature recording and nonexistence of standard operating procedures (SOPs) on dealing with the violations of the cold chain. Furthermore, unless the gaps are tightly controlled through effective enforcement procedures, they might cause significant hazards to patients, such as the provision of ineffective drugs or drugs that are hazardous because they were stored improperly or transported.

1.4 This paper will conduct an evaluation of regulatory compliance as well as represent any critical risks in home delivery of cold chain medicines

The subject of the investigation is to carry out a regulatory assessment of homecare pharmacy services that manage the storage and delivery of cold chain drugs and therefore the logistic risks that may jeopardize the safety and efficacy of temperature sensitive drugs. The study will highlight some of the major threats faced in the management of the cold chain including homecare pharmacy service providers in 22 geographical locations covering parts of Egypt and Southeast Asia. The analysis of the collected data gathered by the monitoring of the temperature excursions during 120 deliveries will help reveal the existence of any systematic problems, including inadequate insulation of packaging, postponed handoff, and absence of real-time tracking.(3)

Moreover, the study shall identify the regulatory loopholes existing in the homecare service delivery of cold chain drug and the best practice that would enhance better adherence to the national and international regulations. It will always recommend the use of IoT-based temperature monitors, design of mandatory certification programs that must be undertaken by cold chain logistics providers, and introduce stricter enforcement of regulatory frameworks by the country drug authorities. These measures are very important and must be bolstered to help in making sure that cold chain medicines are reliable and can provide such security to guard patient safety by ruling out the possibility of treatment failure because of inappropriate storage conditions.

Overall, this research aims at giving an entire picture of the regulatory issues and risks of instituting home delivery of cold chain medicines. The research undertaken to help improve the quality and safety of homecare pharmaceutical services to both the team providing it and the patients it serves in areas where cold chain medicines are essential in continued health management by analyzing the current practices, mapping the gaps, and suggesting the appropriate solutions.

2. Material and methods

2.1 Design of the Study: Risk Evaluation and Regulatory assessment was performed on WHO GDP Guidelines

The paper presents the study that has used risk assessment and regulatory audit design to examine storage and delivery processes of cold chain medicines in homecare pharmacies. The work has been informed by the Good Distribution Practice guidelines of World Health Organization (WHO GDP), the outcome of which is to ensure the quality and integrity of the pharmaceutical products along the supply chain. These recommendations adjust to different elements of temperature control, packaging, storing and transportation, so that medications are always maintained in the conditions that are needed to maintain their effectiveness and safety.(4)

The risk assessment framework applied in this research was organized in such a way that it pointed out the possible weaknesses in the cold chain logistic process, starting at the storage centres down to the point of delivery to the

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homes of the patients. One of the most important aspects was to estimate the regulatory conformity to the WHO GDP parameters and particular dangers presented by the failure to adhere to these procedures. This audit was also meant to identify some of the most serious logistical issues which could arise including temperature deviations, poor packaging, and absence of real time monitoring. Such a strategy did not only offer some insight on the operational issues encountered by homecare pharmacy services but also served to indicate potential sources of possible improvement so that patient safety could be improved.

2.2 Locations and Subjects: 22 Participants in Homecare pharmacy services audited in Egypt and Southeast Asia

The study unfolded on the basis of 22 homecare pharmacy service provider- service providers who had operations in Egypt and Southeast Asia. These areas were chosen due to the increased use of homecare pharmacy services in these areas, and the multiplicity of the healthcare infrastructures. The availability of a high or low infrastructure, access to technology facilities and implementation of regulations are different in those regions, presenting a distinctive logistics challenge to homecare pharmacy providers.

The 22 organizations providing homecare pharmacy services represent a wide array that included organizations in the public and the private sector, and that included a very broad array of services (management of chronic conditions (e.g., diabetes, cancer, autoimmune diseases) to end-of-life treatment). These providers were sampled using purposive sampling method so that a representative cross section of the various regions of homecare pharmacy services can be sampled. Providers delivering temperature-sensitive drugs were targeted using the study, including insulin, monoclonal antibodies, and vaccines, which, in most cases, are required to meet strict cold chain challenges.(5)

The data was collected during 6 months and each of the providers was audited relative to their cold chain practice. The points to be audited were not brought to the attention of the providers in order to prevent any prejudice on their workflow. The cross-regional analysis of regulatory compliance and logistics practices involving cold chain medicines was possible because of the heterogeneity of the dataset, which involved several regions and areas.

2.3 Data Collection Instruments: Structured Audit Checklist, Data Loggers and Review of SOP Documentation

A structured audit checklist, data loggers, and review of Standard Operating Procedures (SOPs) documentation, were the three major tools used in the process of data collection.

Structured Audit Checklist: It was a detailed audit checklist which was developed on the basis of WHO GDP advice and domestic regulatory needs. The question list in the checklist was of considerable variety, encompassing such issues as the sufficiency of the storage conditions, compliance to temperature controls, and the availability of official guidelines on dealing with temperature variations. The checklist was prepared to determine whether established procedures were being exercised by each homecare provider or not and whether or not deviations of standard practice are exhibited.

Temperature Data recorders: Temperature recording instruments were used to record the temperature situations during the delivering procedures. The 120 delivery items were tracked on the basis of the data loggers that enabled the recording of temperature excursion during the transportation of these items. The data loggers were programmed to measure temperatures at intervals that were regular and they captured the changes as it differed with the 2-8 o C range which is considered to be critical. This enabled accurate examination of the degree of temperature excursions that occurred during delivery phase which is a key moment when the integrity of cold chain medicines ought to be maintained.(6)

Documentation review of SOPs: The review of the SOPs of individual providers that dealt with cold chain management was also studied. The SOP review established whether the providers had written procedures on how they were to handle cold chain breaches, including the actions to follow in case of temperature deviations or any packaging problems. Especial emphasis was to be put on how these SOPs could be written and how they could be enforced and how absence of written guidelines or compliance with such guidelines may cause yet more risks of mishandling of cold chain products.

2.4 Measures of Evaluation: The frequency of temperature deviation, Adherence to GDP protocols, existence of SOP, and documentation of Logistics

Multiple common assessment measures were applied to evaluate the general performance and conformity of the homecare providers in the handling cold chain medicines:

Temperature Deviation Frequency: A focus area in this regard was the frequency and duration of a temperature deviation because even deviations beyond the required 2-8 is an area that is subjected to potential degradation of the medication. The variables of the study entailed measurement of degree of temperature excursions that took place during the 120 deliveries along with the occurrence of excursions exceeding 15 minutes which is the limit at which serious attention should be paid.

WHO GDP Protocol compliance: Compliance with WHO GDP protocols was measured as per the responses involved in the audit checklists. This involved assessing how the provider would adhere to the temperature monitoring standards, storage compliance, packaging standards and existence of required documentation to drive its compliance.

SOP Presence: The availability and the quality of a SOP in relation to cold chain handling was rated. This measure offered an understanding concerning whether homecare pharmacy providers established clear specifications regarding dealing with risks of temperature sensitive medications, as well as how effective provided operations were.

Logistics Documentation: The research also considered the logistics paperwork regarding every delivery. This involved the checking of temperatures records, tracking of shipments and schedules of delivery to make sure there was a good number of records in the distribution process.(7)

These evaluation metrics were subsequently used to determine the risk factors and come up with recommendations that can lead to enhanced regulatory compliance and logistical practices within the scope of the homecare pharmacy sector.

3. The regulatory Risk Assessment Framework

3.1 Built by following the WHO GDP principles and the national regulations of cold chain

The Regulatory Risk Assessment Framework that was used in this research has been created on the basis of the World Health Organization Good Distribution Practice (WHO GDP) as well as cold chain regulations within the countries/regions that had been studied. These guidelines were developed by WHO GDP (globally accepted practices) and describe best industry practices in regard to the distribution, storage and transportation of pharmaceutical products, especially those that insist on strict temperature control. These instructions have highlighted the importance of product integrity throughout product distribution chain by establishing standards on storage facilities, means of transportation, and modes of handling, as well as supervision policies.

Along with the international WHO standards on GDP, the framework was supplemented by guidelines in national regulations of cold chain that are also implemented in Egypt and Southeast Asia. Such regulations are usually formulated to accommodate the logistical issues and even infrastructure constraints that exist in these territories. In other cases, national guidance can be more explicit in regards to requirements on the operation of transportation of temperature-sensitive medications, roles of logistics providers and what should be done in case of temperature breaches. The two principles of WHO GDP in combination to that of homecare pharmacy services assessing compliance with regulations presented a detailed and locally friendly plan to evaluate the level of compliance with various regulations.

3.2 Provider Storage, Transport and Breach Management Adherence Measures

The framework of risk assessment paid special attention to the compliance with the protocols associated with manipulations of the cold chain breakage in terms of storage, transport, and management. All these factors play an imperative role in making sure that cold chain medicines are effective and safe.(8)

Storage Protocols: The structure examined whether the homecare pharmacy providers stored their pharmacists according to the WHO GDP recommendations on storage conditions. This involved how the storage facilities could sustain a set range of 2-8 Celsius environment, existence of temperature monitoring equipment and provision of backup power units in case of the equipment failure. The audit ensured that these providers had regular temperature checks and temperature logs kept to ensure compliance and trace.

Transport Protocols: Transport protocols were considered in the study as per GDP guidelines where transportation procedures were reviewed from the perspective of ensuring that cold chain medicines were safe in transit. This amounted to checking on whether insulated packaging has been used, whether vehicles had been fitted with temperature monitoring systems and whether vehicles had been well maintained to prevent changes in temperature. It also checked the management of delivery timelines because when transportation is delayed, there is also the chance of temperature skyrocketing.

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Breach Management Protocols: This is perhaps the most important part of the regulatory risk assessment as regards the evaluation of how the providers handled breach of the cold chain. The framework evaluated the presence of formal SOPs (Standard Operating Procedure) of dealing with temperature deviations among the providers. This was in terms of the strength of compliance on whether there were guidelines on the possible identification of a breach, investigation on the root cause and taking of appropriate actions. The researchers as well looked into the existence of any escalation processes to notify the senior employees or outside agencies concerning an increased temperature that might affect the quality of medications. To effectively remove the possible cases of harm put upon patients, the breach management is of utmost importance as it portrays the ability to handle the cases of temperature excursions promptly and adequately.(9)

3.3 Contained Validation of Training, Documentations, Packaging Procedures and Escalation Systems

There was also the comprehensive check up of training programs, documentation procedures, packaging requirements and the escalation procedures to be followed as part of the framework to cover the overall process of providing regulatory adherence.

Training Programs: Training of staff on cold chain management was one of the key parts of the assessment that have been verified. This involved the assurance to provide sufficient training on cold teaching to all the relevant personnel as well to the personnel involved in the storage, handling and delivery. The model evaluated formalization of training programs, their periodic update and the expertise of staff in execution of cold chain procedures. Another way of preventing cold chain breach is proper training to reduce human error because human error is a major cause of cold chain interference.

Documentation Practices: The other risk assessment framework in question concerned the quality of documentation as handed by the providers. This should be well documented to ensure that it meets the regulatory standards and offer traceability in cases of a breach. The analysis estimated whether the providers maintained elaborate records of temperature monitoring, details of shipment and incidences of breaches. The adequacy and the accuracy of these records were also evaluated as lacking the appropriate information or records that were not accurate might deter the identification of the issues and emergence of the actions to control it.

Packaging Standards: Packaging as the solutions to secure cold chain medicines during storage and transportation was also one of the major concentrations. The framework was used to confirm that, providers were competent with the guidelines on insulation packaging as stipulated by WHO GDP, and that the packaging materials were sufficient to compromise the desired temperature range. This comprised an inspection into whether cooling gels, refrigerants, and temperature indicators were applied in the most suitable methods to ensure the authenticity of temperature-sensitive drugs during transportation.(10)

Escalation Mechanisms: The last one was the existence of escalation mechanisms based on how the cold chain breaches were handled. Such mechanisms are aimed at assuring that in the case of a temperature excursion, the matter is presented in real time to the corresponding people and any necessary measures are taken as soon as possible. The framework assessed the existence of formal escape routes by the providers such as the use of breaches in notifying the top management, regulatory bodies and customers. Proper escalation mechanisms also provide that cold chain-related issues are addressed adequately and quickly in order to prevent any possible negativity on the level of patient safety.

4. Operation Shortcomings and Logistical Blemishes

4.1 lame Thermal Packaging and Inability to Apply Validated Cold Boxes in several Occasions

The thermal packaging associated with the transportation of the cold chain medicines was very poor and it was found to be one of the greatest logistical gaps during this study. Thermal packaging plays a paramount role in keeping temperature-sensitive drugs like insulin, monoclonal antibodies, and vaccines at a temperature of 2- 8 o C in transit. The source of packaging is the initial defense point against changes in temperatures especially in transit where outside conditions may change vastly.

Although the sufficient insulation is recognised as an important aspect, in spite of this several cases of insufficient thermal packaging were recorded among the 22 homecare pharmacy providers audited in Egypt and Southeast Asia. Cold chain medicines were in most instances transported in containers that were not well insulated, and therefore such containers could not sustain the desired temperature throughout the delivery process. Some of the providers employed simpler insulated packaging but the material was usually not enough to help in sustaining the

stability of temperature given a long delivery period. The fact that they do not employ valid cold boxes and best insulation materials enhanced both the risk of temperature excursions and a reduction in the safety and effectiveness of the drugs they were delivering.(11)

There was also a failure to always use validated cold boxes; those that are particularly designated to offer constant temperature during the transportation procedure. Such boxes have machines that help in adjusting temperatures and refrigerants which help in preserving the cold chain. Nevertheless, most of the providers made use of generic packaging solutions that did not confer the key features, which increased risks of temperature sensitive medication delivery even further.

4.2 Scarce Utilization of Real-Time Temperature Control or Alert System during Transportation

One of the serious operation flaws that was found was that little use of real time temperature monitoring or alert systems when in transit was used. The real-time monitoring feature enables constant monitoring of the temperature surrounding the delivery hence supplying useful information to make sure that the medicine stays in the defined temperature level. Unless there are real-time supervisions, any thermal excursions experienced during transportation could not be identified and the medicines remained vulnerable to adverse temperature changes.

Their research found that the IoT-based temperature loggers or real-time temperature tracking device, which has the ability to generate continuous data about the temperature of cold chain products during delivery system, was used by a small proportion of providers. Temperature monitoring was in the majority of a manual operation (paper reports) or random, and no notifications were sent to the proactive response that something could occur during the transportation and may disturb the temperature. Consequently, the occurrence of deviation was recognized with a serious time lag, which allowed the subjects to stay longer in the unpleasant environment(12)

The absence of real-time warning also implied that the couriers and pharmacy providers were most of the time unable to know deviations related to temperatures until after the particular deliveries were done. Such slow reaction to the violations decreased the capacity of timely correction, i.e., of moving the medications into a properly controlled temperature-wise environment or returning the shipment. The inability to establish proactive temperature alerting systems therefore caused high chances of degradation of medicines and undermined the integrity of cold chain medicines.

4.3 Lapse in Handoff Between Caregiver and Courier Bettered the Risk of Thermal Excursions

The other gap in this operation that was found to be critical was failure to conduct handoff between the courier and the caregiver, as delays augmented chances of thermal excursion. The last stage of the cold chain is delivering the medicine to a patient at home which has its distinctive issues because usually they switch the drugs with the one inside the reference vehicle to the person taking care of the patient or to the patient itself. The transfer process plays a critical role in ensuring quality of the cold chain since any delay or malpractices during this step may make the medicines vulnerable to adverse temperature variations.

The survey concluded that there were several cases where delays had taken place in the process of handing over when the couriers reached the home of the patient yet fail to transfer the drug to the caregiver or the patient promptly. These delays were as a result of many reasons among them being communication failures, care giver availability, and failures in scheduling. Consequently, drugs, which were first kept in sufficient temperature in transportation became parked in the courier vehicle or outside the patient household to last a long, and more time, thus, causing temperature excursions.(13)

Besides, the inadequate scheduling systems and the arrangement of delivery services and caregivers created a scenario when medications were left more time than needed outside the house, facing the temperatures of the outside environment, which may interfere with their effectiveness. On other occasions, the drugs were given to the wrong caretaker or kept in places that guarantee control of temperature, which is in this case inadequately ventilated storage rooms. All these by-the-way delays and hand off errors increased thermal excursion possibilities considerably and also made it harder to trace and monitor cold chain right up to the final delivery phases.

The research indicated that proper couriers to caregivers handoff is needed to ensure that cold chain medicines are preserved. Standardization of the hand-off process, better communication between logistic providers and care givers and clear practices of managing the deliveries may help alleviate the danger that may be posed by the delays and minimize the chances of the breakdown of the package during this stage of the delivery.

5. Results

5.1 One-third of the Tracked Deliveries Experienced Temperatures Deviations of 2-8 Degrees C.

Throughout the audit of 120 carried-out deliveries, 31 percent of the deliveries had temperature excursion that was past the critical 2-8 o C levels for over 15 minutes. Such observation is alarming since the exposure to unsuitable temperatures even during short time intervals will invalidate the effectiveness and safety of cold chain drug products, including insulin, monoclonal antibodies, and vaccines. The temperature changes identified in these shipments portrays that the gaps between gap in packaging and transportation procedures followed by most homecare pharmacy providers are vast. The root cause analysis pointed out at the inadequate insulation of packaging, late handoffs, and the absence of real-time tracking as some of the contributing factors to those breaches. This has highlighted the need to have improved temperature monitoring and verified cold boxes to enable delivery of medicines that are within the required temperature in the course of transportation.(14)

5.2: 48 percent of Providers had no Formal SOPs to use in resolving the Breaches of Cold Chain

The second most interesting discovery of this research is the fact that 48 percent of audited homecare pharmacy providers did not have any formal Standard Operating Procedures (SOPs) of how they managed cold chain breaches. SOPs play a vital role because it would give a methodical way of detecting, reporting, and taking an action against deviation in temperature. The fact that none of the providers used formal SOPs implies the inability of almost half of them to pay enough attention to the consequences of temperature excursions, exposing patients to inefficient or contaminated drugs.

In cases where the SOPs were implemented, they were usually incomplete or were not frequently updated so that the staffs could not adopt standard procedures in cases where breach had taken place. The managing of cold chain breaches has this hole, which should be filled with thorough and universal procedures in all providers, as well as procedures on how to analyze the root cause, what corrective measures are to be taken, and how communication is set up in case of an incident and with authorities.

5.3 36 percent of the Providers Applied the Use of Real-Time Tracking Systems or Post-Delivery Temperature Logs

Another factor identified by the study, only 36 percent of the audited providers utilized real time monitoring of the temperatures or kept the temperatures logs after the delivery. Real-time tracking is the factor that can help to guarantee the compliance with cold chain requirements by means of timely discovery of temperature shifts and timely intervention in the course of delivery. The low implementation of these technologies suggests that a large proportion of the providers continue to use outdated or manual monitoring of temperature that are at best inaccurate and lack the timeliness to detect a deviation in the temperature.(15)

The fact is that providers that used real-time tracking systems were in a better position to monitor the changes in temperature and manage the situation, which decreased the chances of damage to medication. Relating to the fact that most providers do not have real-time tracking and post-delivery logs, there is a great need of improvement in this matter. The use of such technologies would facilitate the ability of cold chain medicines to remain in the temperature range needed and enhance general compliance with the WHO GDP recommendations.

Table 1: Key Results Summary

Metric	Percentage
Deliveries with Temperature Deviations (>15 mins)	31
Providers Lacking Formal SOPs	48
Providers Using Real-Time Tracking Systems	36

Figure 1: Key Results From Cold Chain Delivery Audit

6. Conclusion

6.1 There are regulatory and operation gaps in storage and delivery of cold chain medicines in a homecare environment

This research study shows great regulatory and practical gaps with relation to how cold chain medicines are stored and delivered in homecare pharmacy services. The development of homecare services has resulted in additional dependence on the cold chain logistics, especially when it comes to critical medications like insulin, monoclonal antibodies and vaccines, where adherence to the temperature recommendations becomes crucial. Nevertheless, the findings of this audit have shown that the problem of compliance with the Good Distribution Practice (GDP) standards, namely, the issue of temperature regulation and breaches management, continues to place numerous providers in a difficult position.

The biggest concern found was the fact that 31 percent of the deliveries that were tracked could not sustain the necessary range of 2-8 C of temperature longer than 15 minutes. This is the failure that can be associated, first of all, with the poor packaging, the absence of temperature monitoring, and weak handoffs that reveal the important defects in the operations. Moreover, 48 percent of providers have no formal SOPs regarding breaches of cold chains, which is an indication of system failure. Lack of protocols to remedy a deviation in temperatures exposes the providers to high chances of delivering contaminated drugs, which could cause a failure in the therapeutic intentions and poor patient outcomes.

There exists an inconsistent regulatory framework to be applied to homecare pharmacy services and its implementation varies among jurisdictions. These problems are compounded by the absence of standardized approaches in cold chain logistics and transportation practice, and it is hard to guarantee the successful delivery of temperature-sensitive medications. One of the key recommendations shown in the audit outcome is that there is urgent need to improve the regulation of the sector and ensure that it abides more consistently by a set of standards regardless of regions where the establishments are located.

6.2 Certification, More Investigation and Imposing IoT-based Monitoring Would Be a Necessity

Since cold chain integrity is very vital, this research study reveals the importance of creating a mandatory certification of all cold chain logistics suppliers who are involved in homecare pharmacy services. The certification will help providers work according to all the needed standards of temperature control, packaging, transportation, and management of breach. It is important that homecare pharmacy provide services of high level of quality control especially those dealing with temperature sensitive products by assigning certification demands.

Additionally, there is the need to have a more robust regulation force. Regulatory agencies need to do more surveillance and make sure distributors of homecare products follow national and international cold chain requirements as well as following WHO GDP standards. It is expected to supplement this enforcement with regular auditing and inspection of the cold chain practices to support the continuous compliance and timely correction of its shortcomings once they are detected. Enforcement would offer a direct guideline to be used by the providers, diversity of practices will be limited and there will be minimal risk.

Moreover, to eliminate the lack of real-time monitoring, which is observed in most of the providers audited, it would be crucial to implement Internet of Things (IoT)-based system of temperature monitoring. Just a third of the care-givers used real-time monitoring technology in the study and most of them lacked any records of post-

delivery temperatures. The use of IoT-based monitoring systems would enable real-time continuous data on the fluctuations of temperature, which would enable the providers to identify departures by any small margin in the specified range of 2-8oC degree, which can be corrected before the medication is supplied to the patients. These technologies do not only help increase patient safety but also leave a valuable record of temperature compliance which is the key to regulatory transparency and accountability.

6.3 Integrity of Cold Chain Is Essential to Maintain Efficacy of Drugs and protect Patient Outcome

The integrity of the cold chain is an essential parameter to the effectiveness and safety of temperature sensitive medicines. Perhaps most importantly (as shown in this research), thermal excursions, or even short term excursions out of the preferred temperature range, can jeopardise the stability and efficacy of drugs. In the cases of medicines such as insulin and monoclonal antibodies, the instability in temperature will result in the deterioration of the chemical properties making the medication weaker or even toxic.

To protect the patient outcomes, it is thereby important to ensure cold chain integrity. Compromised cold chain conditions may also bring about therapeutic failure, exacerbating the conditions of the affected patients or even resulting in the cases of adverse reactions to medications. The effects of such failures are especially devastating in vulnerable cohorts, as is the case of patients needing life-saving biologics or vaccines.

The results of the present study highlight the necessity to develop an entire process of cold chain management that should be incorporated into the homecare pharmacy services as well. It is not merely enhancing the logistics and packaging but also on the real-time temperature control and the creation of effective SOPs to handle cold chain lacks. By having a proper regulatory framework, training possibilities, and technological applications, the providers will be able to heavily mitigate the threat of degradation of medication and enhance the safety of patients. Finally, the homecare pharmacy services should focus on the importance of the cold chain to ensure that they serve patients better in terms of ensuring that they offer safe, and effective and reliable treatments.

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Conflicts of interest

The authors have no conflicts of interest to declare

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