

Original Research Article

Assessment of the effect of cold chain infrastructure on insulin storage and distribution in Anambra State, Nigeria

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Sent for review: 6 June 2026

Revised accepted: 16 September 2026

Abstract

Purpose: To assess cold chain infrastructure and its influence on insulin storage and distribution across some selected facilities in Anambra State, Nigeria.

Methods: This study adopted a cross-sectional design and employed a purposive sampling technique to select 27 facilities across 11 Local Government Areas (LGAs) in the State. The facilities selected included hospitals and pharmacies where insulin is actively stored and/or dispensed to patients. Elitech RC-5 digital data loggers and a structured questionnaire were used to obtain temperature and cold chain handling data from the facilities.

Results: The findings revealed that there was a high level of deviation from the recommended storage temperature as recorded by the facilities, and that none of the facilities achieved adequate cold chain performance, while 92.59 and 7.41 % of facilities were classified as poor and marginal, respectively. The results also showed that the majority of facilities recorded very high temperature excursions, and that the overall monitoring outcomes revealed that only 22.81 % of the time of monitoring fully complied with the recommended temperature range.

Conclusion: The widespread inefficiencies in cold chain have been highlighted and the need for urgent policy and regulatory interventions has been proposed.

Keywords: Cold chain management, Cold chain performance, Healthcare infrastructure, Insulin storage, Temperature data logger, Temperature monitoring

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Tropical Journal of Pharmaceutical Research is indexed by Scopus, Chemical Abstracts, Embase, Index Copernicus, EBSCO, African Index Medicus, JournalSeek, Directory of Open Access Journals (DOAJ), African Journal Online, Bioline International, Open-J-Gate and Pharmacy Abstracts

INTRODUCTION

The management of cold chain constitutes an essential factor of modern healthcare delivery systems, essential in the handling of biopharmaceutical products that are sensitive to temperature. These include vaccines, insulin and other biologics. Under controlled temperatures, the management of cold chain involves a series of coordinated activities starting from the point of manufacture and continuing through storage,

transportation and distribution to the end user. The crucial requirement for maintaining the World Health Organisation (WHO) recommended temperature range of 2 – 8 °C inclusive for most insulin formulations is to maintain product integrity to ensure therapeutic efficacy and patient safety [1,2]. So if there is a break anywhere in the chain, then the insulin product may not work or may even become unusable.

The complexity of cold chain systems has grown with the increasing demand for temperature-sensitive pharmaceuticals, due to the increase in the number and diversity of products that need controlled environments, and from the expansion of distribution networks through which these products must be delivered effectively across different locations [3-6]. Therefore, the infrastructure, including refrigerators and temperature control monitoring devices, trained and experienced staff, and logistics and information systems with continuous monitoring and quick response to temperature excursions, are key factors in the effective management of the cold chain [7,8]. When infrastructure, personnel, logistics and information systems function effectively, there is a significant improvement in health outcomes and the healthcare delivery system.

Insulin, a medication for individuals living with diabetes mellitus, is vulnerable to temperature fluctuations, and as a peptide hormone, it is highly sensitive to both heat and freezing conditions, which can affect its potency [9-11]. As a result of the high prevalence of diabetes in resource-limited settings, like Nigeria, it has become a public health priority to ensure the availability of effective insulin products. The insulin products are often transported under very high temperatures and may be stored for a long time in facilities that lack adequate monitoring systems, which may compromise their quality before they reach patients, thereby leading to poor glycemic control, high risk of complications, and even high cost of healthcare delivery [12-14]. While private and public facilities in Anambra State are engaged in healthcare delivery, and insulin products are available in hospitals, pharmacies, patent stores, and even in open markets, the effect of cold chain system on insulin storage and distribution is underexplored, creating a significant gap. There is, however, a strong demand to evaluate the performance of cold chain infrastructure and practices in the context of insulin storage and distribution and the extent of temperature control, frequency and severity of temperature excursions and the monitoring system effectiveness. These are essential for identifying weaknesses in the supply chain.

The current study assessed the cold chain infrastructure and evaluates its influence on insulin storage and distribution in Anambra State, Nigeria. Furthermore, the study examines temperature control patterns across the selected facilities, evaluates the monitoring practices and compliance levels, and identifies the challenges affecting cold chain performance.

EXPERIMENTAL

Study design and setting

The study used a cross-sectional survey approach to collect data from different facilities in selected Local Government Areas (LGAs), and it also involved field-based monitoring of temperature conditions from August, 2024 to February, 2025.

The study was conducted in eleven (11) Local Government Areas (LGAs) of Anambra State, Nigeria, which is one of the five South-Eastern States with tropical climatic conditions and relatively high temperatures. Nine of the selected LGAs were urban while two (2) were suburban.

Study population and sampling of facilities

The study population comprises hospitals and pharmacies where insulin is stored and distributed across the LGAs of Anambra State. Purposive sampling was used to collect a total of 27 facilities across the study area, consisting of 19 hospitals and 8 pharmacies where insulin was actively stored and dispensed to patients.

Materials

The study used temperature data loggers deployed in insulin storage units at each selected facility to record the temperature readings at 3-minute intervals over 30 - days period. The study assessed refrigerators used for insulin storage and considered the National grid electricity (Enugu Electricity Distribution Company (EEDC), backup generators, and solar power systems as the energy sources. Additional materials included in this study were data recording sheets for documenting observations and protective casings for data loggers. A structured questionnaire was designed to collect data from cold chain personnel.

Data collection procedure

This study combined field-based temperature monitoring and facility-level assessments to collect data at each facility. The digital temperature data logger (Elitech RC-5) was installed in the refrigerators for at least 30 days at each facility and positioned in a way that the actual storage conditions of insulin would be reflected.

Furthermore, a structured questionnaire was distributed at each facility to gather information on refrigeration, backup power supply and

equipment to monitor temperature, regular checks of temperature and staff training on cold chain.

Measurement of cold chain performance

Assessment of the cold chain performance in the study was done using temperature-based indicators, which were derived from continuously monitoring the insulin storage conditions across the sampled facilities. The evaluation was based on compliance with the WHO-recommended storage temperature range of 2 - 8 °C.

Temperature metrics

The temperature metrics used for each facility included the mean temperature (°C), standard deviation of temperature, minimum temperature, and maximum temperature. The primary measure of cold chain performance, which is the percentage of time that insulin was stored within the recommended temperature range (2-8 °C), was calculated using Eq 1.

$$\text{Percentage Compliance} = \frac{n}{N} \times 100 \dots\dots\dots (1)$$

where n stands for the number of readings within 2 - 8 °C, and N is the total number of readings [26].

Temperature excursion

Temperature excursions were defined as any recorded temperature that falls outside the range 2 - 8 °C; these were categorised and quantified as the number of excursions, which denotes the number of temperatures outside the recommended range, and total excursion duration (hours), which represents the cumulative time during which temperatures remained outside the acceptable range. Temperature excursions were classified into two categories, namely minor deviations indicating slight departures from the recommended range with limited impact, and major deviations denoting significant departures.

Recovery time

The recovery time is the time taken to return to the recommended temperature range, 2 - 8 °C following an excursion, measured for each facility.

Cold chain performance classification

Facilities were categorized based on the percentage of time during which the recorded

temperatures remained within the recommended temperature range 2 - 8 °C:

- Adequate cold chain, if insulin was stored within 2 - 8 °C for at least 95% of the total monitoring period.
- Marginal cold chain if insulin was maintained within 2 - 8 °C for 80 % to 94 % of the monitoring period.
- Poor cold chain if the insulin was stored within 2 - 8 °C for less than 80% of the monitoring period.

However, this classification framework helped to identify the facilities that had a satisfactory performance and those that require immediate intervention.

Data analysis

Data analysis was carried out using R statistical software, version 4.5.2. The data results were presented using descriptive statistics, including mean, standard deviation, percentages, and bar charts.

RESULTS

Facility and distribution locations

All the facilities have functional refrigerators. About 25.90 % of the facilities have temperature monitoring devices connected to the refrigerator. Frequency of temperature checks according to respondents shows that 31.82 % maintain their temperature monitoring chart once per day, 13.64 % never maintain the chart, 45.45 % twice per day, while 9.09% did not know. About the training of cold chain personnel, 25 % of the staff had their last training 6 – 12 months ago, 5 % had theirs 13 – 18 months ago, 40 % had their last training more than 2 years ago, while 30 % were never trained.

Figure 1 displays the distribution of power sources used by the surveyed healthcare facilities. The majority (39.13 %) of facilities relied on a combination of national grid electricity and generators, while 26.09 % depended only on the national grid, with 17.39 % using a combination of solar and generators and 8.69 % relying exclusively on solar energy. Only 4.35 % of facilities utilized all three sources (national grid, generator, and solar), while another 4.35% depended only on generators. The findings indicated that most facilities relied on multiple power sources to ensure continuity of electricity supply for maintaining the insulin cold chain, according to respondents.

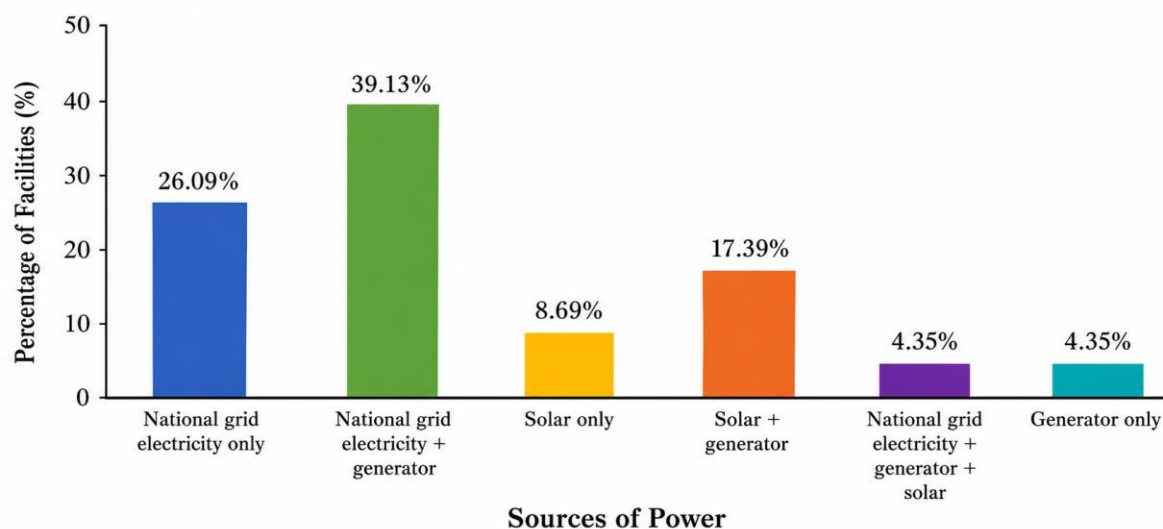


Figure 1: Sources of power for healthcare facilities

Table 1 presents a summary of 27 facilities, including hospitals and pharmacies, across 11 Local Government areas of Anambra State. A total of sixteen (16) were from urban areas, 10 from suburban areas, and one (1) from rural area. A total of 19 were hospitals, while eight (8) were pharmacies. It was observed that insulin was stored more in hospitals than in pharmacies.

Cold chain analysis

Table 2 presents the temperature performance of insulin storage across 27 sampled facilities in different Local Government Areas in Anambra State. The findings revealed variations in the storage temperature of insulin, with almost all the facilities deviating substantially from the recommended storage temperature range of 2 - 8 °C.

Table 1: Samples collected

Facility code	Type Of Facility	Type of Settlement	Local Govt. Of Facility
FC-1	Pharmacy	Urban	Awka South
FC-2	Teaching Hosp.	Urban	Awka South
FC-3	Hospital	Urban	Awka South
FC-4	Hospital	Suburban	Anaocha
FC-5	Hospital	Urban	Idemili South
FC-6	Teaching Hosp.	Urban	Nnewi North
FC-7	Hospital	Suburban	Nnewi North
FC-8	Hospital	Suburban	Nnewi North
FC-9	Hospital	Rural	Nnewi South
FC-10	Hospital	Suburban	Aguata
FC-11	Hospital	Urban	Aguata
FC-12	Pharmacy	Urban	Aguata
FC-13	Hospital	Urban	Idemili North
FC-14	Hospital	Urban	Onitsha North
FC-15	Hospital	Urban	Onitsha South
FC-16	Hospital	Urban	Onitsha South
FC-17	Pharmacy	Suburban	Orumba South
FC-18	Pharmacy	Suburban	Orumba South
FC-19	Hospital	Suburban	Idemili North
FC-20	Hospital	Suburban	Njikoka
FC-21	Pharmacy	Urban	Awka South
FC-22	Hospital	Urban	Awka South
FC-23	Hospital	Suburban	Njikoka
FC-24	Pharmacy	Urban	Awka South
FC-25	Pharmacy	Urban	Aguata
FC-26	Pharmacy	Urban	Onitsha North
FC-27	Hospital	Suburban	Njikoka

The results showed that Facility 18 had the highest mean storage temperature (30.78 °C), followed by Facility 17 (30.17 °C), while the lowest mean storage temperature was recorded by Facility 16 (-4.79 °C). Furthermore, a larger variation in storage temperature was observed in Facility 07 (SD = 12.91 °C), followed by Facility 01 (SD = 10.37 °C). In addition, the maximum storage temperature was recorded as 45.9 °C obtained in Facility 07, while the minimum storage temperature of -14.6 °C was observed in Facility 24.

The findings of this study also revealed that the proportion of time during which insulin was stored within the recommended storage temperature, 2-8 °C was very low. The highest percentage of time during which insulin was within the recommended temperature range was 93.88 %, recorded in Facility 13 in Idemili North, followed by Facility 03 in Awka South (84.36 %), Facilities 04 (Anaocha), 17 and 18 (Orumba South), and 25 (Aguata), which recorded 0 % compliance. The results indicated that the majority of the facilities recorded percentage compliance below 80 %, while none of the facilities met the threshold for adequate cold chain performance ≥ 95 %.

The results revealed a frequent occurrence of temperature excursions across facilities, with the highest number of excursions (227) recorded by Facility 01 (Awka South), followed by Facility 03 (Awka South), which recorded 175 excursions, while the lowest number of excursions of 1 was recorded in Facilities 04 (Anaocha), 17 and 18 (Orumba South), and 25 (Aguata). Furthermore, the results showed that the majority of facilities recorded a total duration of excursions exceeding 500 hours, and that the time taken to return insulin to a safe temperature varied across the facilities, with Facility 21 (Awka South) experiencing the highest recovery time of 247.98 hours, followed by Facility 12 (218.35 hours) in Aguata.

Distribution of cold chain performance

The overall distribution of cold chain performance across the 27 sampled facilities indicated a predominant failure in maintaining appropriate insulin storage conditions within the study area. The results also showed that none of the facilities (0 %) achieved an adequate cold chain status, which is the recommended temperature (2 - 8 °C), and that 25 facilities (92.59 %) were categorized as having poor cold chain performance, indicating that insulin was stored

within the acceptable temperature range for less than 80 % of the storage time, while only 2 facilities (7.41 %) were classified as marginal, meaning they maintained acceptable temperature conditions for between 80% and 94 % of the storage time.

Figure 2 presents the distribution of cold chain performance across the LGAs, revealing a consistently poor cold chain performance across different LGAs in the State. The results revealed that the mean percentage of time insulin was stored within the recommended temperature range (2 - 8 °C) varied based on the number of facilities accessed across the LGAs. The results revealed that despite Idemili North recording the highest compliance level (47.49 %), followed by Onitsha North (33.11 %), Nnewi South (31.61 %), and Awka South (30.83 %), all still fall significantly below the acceptable threshold of 95 %.

Other LGAs, however, performed very badly, with 0 % compliance for Anaocha, Orumba South and 11.19 % for Aguata, 10.64 % for Onitsha South, 7.32 % for Idemili South and 18.59 % for Njikoka, all showing very low compliance. The results showed that in majority of the LGAs, the cold chain status was generally low, which indicated that there were significant temperature control shortcomings. Figure 2 shows the cold chain performance by LGA.

Monitoring and operational performance

Table 3 presents the frequency and outcomes of temperature monitoring across the 27 sampled facilities, revealing variation across facilities. The results showed that Facility 13 (93.88 %, 15835 observations), Facility 03 (84.36%, 25946 observations), and Facility 22 (61.00 %, 10247 observations) were the only facilities that demonstrated higher compliance with the recommended temperature range (2 - 8 °C). The results further revealed that Facility 04 (100 %, 15854 observations), Facility 17 (100 %, 16298 observations), Facility 25 (100 %, 19658 observations), and Facility 18 (99.9 %, 16298 observations) were facilities that showed major deviations from the recommended temperature range, while Facilities 04, 17, and 25 recorded 0% compliance, indicating severe cold chain failure. Furthermore, Facilities 26 (25.24 %), 14 (24.37 %), 23 (23.57 %), and 22 (23.31 %) showed minor deviations, which can be corrected compared to other facilities. Figure 3 is a visualisation of temperature monitoring outcomes at the facilities in Anambra State.

Table 2: Summary of temperature characteristics by facility

Facility Code	LGA	Mean±SD (°C)	Temp Min (°C)	Temp Max (°C)	Temp % Time within 2–8 °C	No. of Excursions	Total Excursion (hrs)	Time Taken to Cool (hrs)	Insulin Status	Chain Status
F01	Awka South	16.24 ± 10.37	-3.3	34.4	22.01	227	658.55	1.6		Poor
F02	Awka South	13.83 ± 3.82	4.5	31.6	3.59	44	789.08	126		Poor
F03	Awka South	6.79 ± 2.44	3.6	31.1	84.36	175	240.55	0.85		Marginal
F04	Anaocha	21.05 ± 3.79	12	33	0	1	792.65	NA		Poor
F05	Idemili South	13.76 ± 4.17	-2.3	31.4	7.32	28	909.3	0.45		Poor
F06	Nnewi North	10.32 ± 5.82	-3	31.2	3.51	13	718.5	0.45		Poor
F07	Nnewi North	10.78 ± 12.91	2.9	45.9	29	69	517.9	4.65		Poor
F08	Nnewi North	11.27 ± 3.98	2.9	32.3	24.81	165	1009.35	28.6		Poor
F09	Nnewi South	8.87 ± 4.3	-1.3	32.3	31.61	131	509.05	4		Poor
F10	Aguata	14.86 ± 8.16	-3.5	32.6	15.38	62	690.25	0.55		Poor
F11	Aguata	11.5 ± 6.35	-5.1	31.2	25.37	90	608.95	5.15		Poor
F12	Aguata	18.28 ± 5.6	5.8	34.8	4.01	11	780.85	218.35		Poor
F13	Idemili North	5.42 ± 1.82	-0.9	31	93.88	97	51.55	0.45		Marginal
F14	Onitsha North	1.68 ± 4.08	-5.3	33.1	34.52	164	550.35	0.75		Poor
F15	Onitsha South	-0.65 ± 7.19	-12.5	31.9	18.91	91	795.14	0.2		Poor
F16	Onitsha South	-4.79 ± 2.48	-8.6	30.9	2.36	8	842.4	0.2		Poor
F17	Orumba South	30.17 ± 0.84	19.5	35.8	0	1	814.85	NA		Poor
F18	Orumba South	30.78 ± 2.29	8.9	35.7	0	1	814.2	NA		Poor
F19	Idemili North	16.39 ± 4.07	6.8	27.2	1.11	10	833	17.25		Poor
F20	Njikoka	11.45 ± 2.73	4.9	32.9	10.37	33	796.5	2.6		Poor
F21	Awka South	18.57 ± 5.7	6	35.8	1.29	4	972	247.95		Poor
F22	Awka South	8.34 ± 1.88	6	31.9	61	132	329.06	1		Poor
F23	Njikoka	8.03 ± 6.03	-3	30.5	44.69	98	650.85	0.3		Poor
F24	Awka South	18.77 ± 10.34	-14.6	35	12.73	72	858.25	20.55		Poor
F25	Aguata	28.84 ± 1.59	14.1	33.4	0	1	982.85	NA		Poor
F26	Onitsha North	9.33 ± 3.54	-1.1	32.9	31.7	69	638.9	104.75		Poor
F27	Njikoka	12.69 ± 1.99	5.9	33.6	0.72	2	877.45	13.15		Poor

Note: Under Cold Chain Status, Adequate represents $\geq 95\%$ of the time within 2-8°C, Marginal stands for 80-94%, and Poor is for $< 80\%$ of the time within 2-8°C

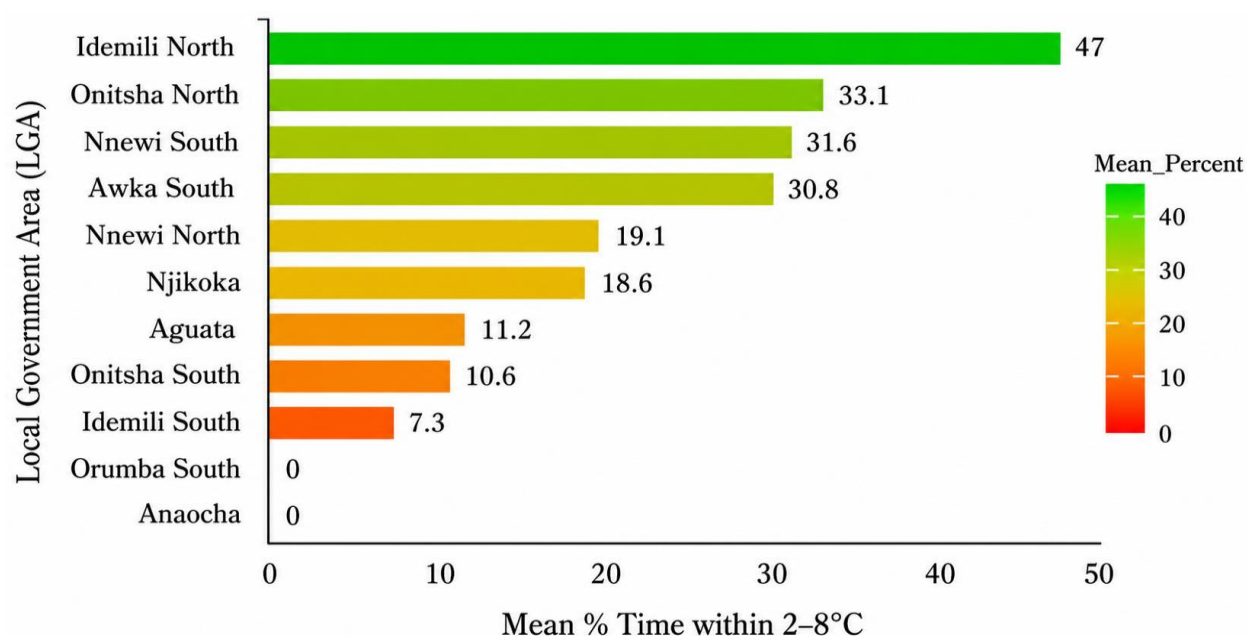


Figure 2: Cold chain performance by LGA

Table 3: Levels of compliance and deviations at 100 % hourly frequency of temperature monitoring by facility

Facility Code	Fully compliant (2–8°C)	Major deviations recorded	Minor deviations corrected
FC01	3718 (22.01%)	11152 (66.03%)	2020 (11.96%)
FC02	587 (3.59%)	13711 (83.78%)	2067 (12.63%)
FC03	25946 (84.36%)	1562 (5.08%)	3250 (10.57%)
FC04	0 (0.00%)	15854 (100.0%)	0 (0.00%)
FC05	1437 (7.32%)	16810 (85.66%)	1377 (7.02%)
FC06	522 (3.51%)	11608 (77.94%)	2763 (18.55%)
FC07	4232 (29.00%)	9565 (65.55%)	794 (5.44%)
FC08	6660 (24.81%)	15389 (57.32%)	4799 (17.87%)
FC09	4707 (31.61%)	7149 (48.02%)	3033 (20.37%)
FC10	2509 (15.38%)	11990 (73.49%)	1816 (11.13%)
FC11	4140 (25.37%)	9308 (57.03%)	2872 (17.60%)
FC12	653 (4.01%)	14464 (88.89%)	1154 (7.09%)
FC13	15835 (93.88%)	426 (2.53%)	606 (3.59%)
FC14	5804 (34.52%)	6911 (41.11%)	4097 (24.37%)
FC15	3708 (18.91%)	13334 (68.01%)	2565 (13.08%)
FC16	407 (2.36%)	16570 (96.02%)	279 (1.62%)
FC17	0 (0.00%)	16298 (100.0%)	0 (0.00%)
FC18	0 (0.00%)	16268 (99.9%)	17 (0.1%)
FC19	187 (1.11%)	15661 (92.95%)	1000 (5.94%)
FC20	1844 (10.37%)	12748 (71.72%)	3183 (17.91%)
FC21	255 (1.29%)	18682 (94.85%)	759 (3.85%)
FC22	10247 (61.00%)	2636 (15.69%)	3915 (23.31%)
FC23	10517 (44.69%)	7471 (31.74%)	5547 (23.57%)
FC24	2504 (12.73%)	15741 (80.03%)	1425 (7.24%)
FC25	0 (0.00%)	19658 (100.0%)	0 (0.00%)
FC26	5931 (31.70%)	8057 (43.06%)	4722 (25.24%)
FC27	127 (0.72%)	17454 (98.74%)	96 (0.54%)

Figure 3 summarises the overall temperature monitoring outcomes across the facilities studied. The results indicated that 22.81 % (112477 observations) of the recorded temperatures were within the recommended temperature range of 2 – 8 °C, while majority of the temperatures recorded (66.21 %, 326477 observations) fell

slightly outside the recommended storage range, which was later corrected within a short period, and 10.98 % (54156 observations) of the observed temperatures deviated significantly from the recommended range, indicating major temperature excursions.

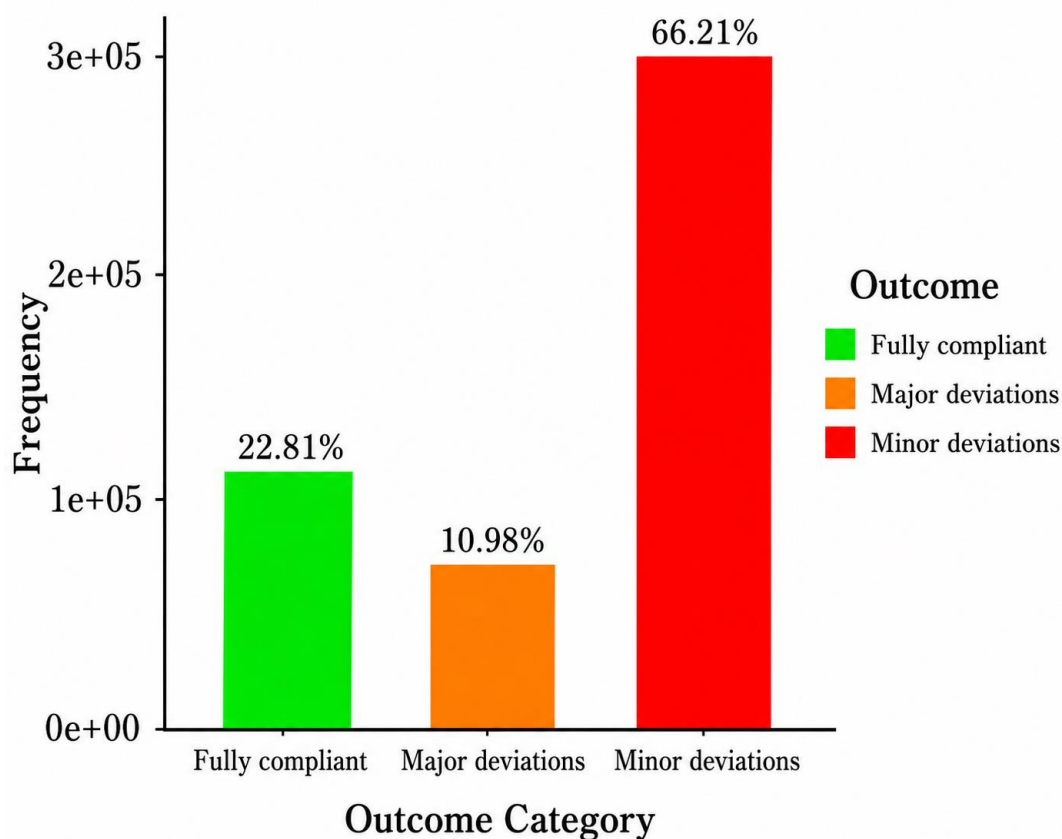


Figure 3: Overall monitoring outcomes of insulin storage

However, from these findings, a total of 77.19 % (i.e., 66.21 + 10.98 %) of temperatures recorded were outside the acceptance range, demonstrating a large spread of instability in the storage conditions of insulin and underscoring persistent challenges in maintaining cold storage conditions. Figure 4 shows the overall cold chain monitoring outcomes for insulin in Anambra State.

DISCUSSION

Cold chain management is a specialised area of biopharmaceutical product management that begins when a biopharmaceutical product is manufactured, stored and moves through the distribution chain until it reaches the end user at the time of administration. It is responsible for the storage temperature of these products. Cold chain management is vital for preserving the quality, potency, and therapeutic efficacy of biopharmaceuticals. In resource-limited settings like Anambra State, Nigeria, concerns about biopharmaceuticals such as insulin quality are heightened by weak regulatory systems and limited product stability evidence. This highlights the need for a systematic assessment of insulin quality and cold chain management practices to ensure therapeutic efficacy [27].

The findings of this study revealed significant deficiencies in cold chain management across facilities in Anambra State. The results showed a very low compliance with the recommended storage temperature range and indicated that none of the facilities achieved adequate cold chain performance. These results align with the reports of Al-Worafi and Yen et al. [15, 16] on the challenges of infrastructure and supply chain complexities and inefficiencies as factors that compromise pharmaceutical storage systems in developing countries.

This current study was in contrast with the study done in Rwanda by Ngirimanzi *et al.* [17], where 22 (56.0 %) had refrigerator conformity with cold chain storage requirements. In the current study, it was observed that the cold chain performance from the different Local government areas sampled showed 47.49 °C as the highest temperature attained and 0 °C as the lowest temperature attained, also contradicting the study done by Ngirimanzi *et al.* [17], with the highest temperature as 21.4 °C and lowest temperature as – 3.4 °C.

In Tanzania, 48.5% of the health facilities sampled did not comply with the temperature

requirement recommended by the World Health Organization [18]; this was in contrast with the current study, which had 92.59 % non-conformity with the temperature requirement. Also, the study done in Ghana by Agyekum [19] revealed that 26.2 % of the sampled facilities did not comply with the temperature requirement.

The high prevalence of poor cold chain status suggests a widespread problem, more than just a problem within individual facilities; factors such as poor electricity supply, poor refrigeration systems, and lack of adoption of advanced technologies in temperature monitoring may be contributing. Temperatures were monitored for at least 30 days, but the high percentage of temperature excursions indicated that there was not a strong connection between monitoring and corrective action, which is a significant disconnect between monitoring and action. In tropical countries like Nigeria, power supply is unreliable and facilities for insulin maintenance are not readily available; maintaining cold chain is very challenging, as evident in the outcome of this current study. The results of this study were similar to the study conducted by Feyisa et al. [20], who found that the lack of proper records, inadequate storage and infrastructure challenges, including unstable power, are the factors that adversely affected performance. The failure of some of the refrigerators or the inability to reach the ideal temperature for insulin storage in refrigerators may have been due to an inconsistent power supply, which was noted in this study [21].

Moreover, the percentage of temperatures outside the acceptable range highlighted the instability of storage conditions, indicating that the insulin was not stored in extreme conditions for a long time, but rather in short-term fluctuations, as evidenced by the high percentage of minor deviations, which can affect its potency, and the very few major deviations, suggesting that the insulin was not stored in extreme conditions for a long period of time. Again, the wide-ranging differences between facilities and Local Government Areas highlighted the infrastructure and resources available. The results obtained in this current study have revealed that monitoring cold chain compliance is essential in the maintenance of insulin quality and other thermolabile products [23], to ensure that the integrity of the product is not lost and in protecting the patient against using an ineffective pharmaceutical product [24,25].

The majority of facilities classified as having poor cold chain performance show that there are

problems of infrastructure, lack of electricity supply, failure of equipment, and operational procedures. These deficiencies are, however, important for insulin quality and thus may have a negative effect on therapeutic efficacy and may lead to suboptimal glycaemic control in patients. The results also show that systems that monitor do not help unless they can respond to deviations quickly and effectively. Increasing the routine inspection and monitoring of the regulatory agencies to put in place corrective actions would be a good step to take in improving the outcomes of the cold chain in Anambra State.

Limitations of the study

This research was carried out in one State alone. Future research needs to be done on a wider scale with more states and health care units in Nigeria. This would enable wider assessment of the cold chain infrastructure in various zones and give a National overview of the Insulin storage practices. Additionally, the effects of the storage conditions were only evaluated at the facilities. This needs to be followed by further research, which must look at the full insulin distribution chain from manufacturer to importer and then to the transporters. This will assist in the determination of the point(s) in the pharmaceutical supply chain where temperature excursions or handling errors are most likely to occur.

CONCLUSION

The study shows the overall non-observance of optimal cold chain conditions in storing insulin in healthcare facilities in Anambra State. Although there were a few facilities that had good temperature monitoring, most of the facilities did not have good temperature control, as shown by the number of temperature excursions and the length of time they occurred. Based on the study findings, the following recommendations are made: there is an urgent need for regulatory and programmatic intervention to improve cold chain systems in Anambra State and other similar environments. Investment is required in the building of dependable cold chain facilities, which will include the supply of standard medical-grade refrigerators and continuous temperature monitoring devices with alarm systems. In addition, a sustainable cold chain solution can be supported by the government so that there is a continuous power supply that will allow the required temperature control to be easily achieved for the storage of insulin at the Health facilities. This can be done by adopting eco-friendly refrigeration methods such as solar-

powered cold chain storage, Natural refrigerants (The 'Natural five'), which combine ammonia, carbon dioxide, hydrocarbons, water, and air; NH₃/CO₂ Cascade refrigeration systems; evaporative cooling chambers, etc.

DECLARATIONS

Acknowledgement/Funding

We acknowledge the Anambra State Ministry of Health for the approval given to us to carry out this study in the health facilities in the State.

Conflict of Interest

No conflict of interest is associated with this work.

Contribution of Authors

We declare that this work was done by the authors named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. MaryRose Ukamaka Nnamani conceived the study. MaryRose Ukamaka Nnamani, Angus Nnamdi Oli and Charles Okechukwu Esimone designed the study. MaryRose Ukamaka Nnamani collected and analysed the data. All the authors contributed to writing, reading and approving the manuscript for publication.

Ethical Approval

Ethical approval was obtained from the Anambra State Ministry of Health, Approval NO.: MH/COMM/523/V.1/27.

Availability of Data and Materials

Datasets used and/or analyzed during the current study are available from the corresponding author.

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