Student's Journal of Health Research Africa
Vol. 4 No. 9 (2023): September 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i9.531
Original article

FACTORS AFFECTING COLD CHAIN MANAGEMENT PRACTICES OF PHARMACEUTICAL PRODUCTS AMONG HEALTH WORKERS IN VIRIKA HOSPITAL, KABAROLE DISTRICT. A CROSS–SECTIONAL OBSERVATION STUDY.

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Abstract

Background

The cold chain is a supply of temperature-sensitive products that include vaccines, insulin, chemotherapy drugs, and other treatments such as Oxytocin, therefore, millions of these products are produced, transported, stored, and distributed worldwide yet the cost of these products and control of temperature is essential in the healthcare industry. The research will help health workers to improve the storage practices of cold-chain pharmaceutical products. The general objective was to assess the cold chain storage practices of pharmaceutical products in Virika Hospital Kabarole district.

Methodology:

The study design employed was cross-sectional with a study sample of 36 respondents using structured and semi-structured questionnaires as a data collection tool, finally the data was analyzed using Microsoft Excel.

Results

From the study findings, most respondents were nurses (77.7%), followed by clinicians (11.1%) and pharmacy technicians and pharmacists (5.6%).within the hospital there was an automated generator, and most of the respondents(94.4%) had connections to the automated generator and a few (5.6%) had no connections yet and the following factors were found out to be affecting cold chain medicines; unstable power supply to the hospital, time for the refrigerators being operative is limited and insufficient knowledge of some health workers (8.3%), about the accurate temperature under which the cold chain can be maintained.

Conclusion

In conclusion, the overall factors that affect cold chain medicines were not such pleasing though the health workers' knowledge about cold chain practices was not alerting.

Recommendation

The hospital administration in touch with the Ministry of Health should conduct training in hospitals and health facilities that store or issue cold chain medicines to empower health workers with knowledge for the storage of cold chain medicines.

Keywords: Cold chain, cold storage, inventory, stock out, stock control, room temperatures,
Submitted: 2023-07-01 Accepted: 2023-07-20

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1. Background

The cold chain is a supply of temperature-sensitive products that include vaccines, insulin, chemotherapy drugs, and other treatments such as Oxytocin which is used to induce uterine contraction during labor in health facilities (Hatchett, 2017)

The personnel who handle pharmaceutical products must have high levels of expertise so they can take action to ensure that the temperatures are not negatively affected by sub-standard practices. But temperature monitoring systems including temperature sensors should be available to monitor the storage of these cold chain pharmaceutical products (Chen. et.al., 2011).

Temperature control is a key point in cold chain operations and the most important factor when prolonging the practical shelf life of pharmaceutical products (Ruiz. et.al. 2012). The major- ity of cold-chain pharmaceutical drugs are stable enough to be preserved in cold chambers at 40C before their use (Andrieu. et al., 2014). One of the challenges encountered is the accidental freezing of vaccines which is a growing threat and a real risk for national immunization programs when the potency of many vaccines can be compromised if they are exposed to sub-zero temperatures in the cold (Lloyd, 2015).

However, some of the challenges encountered can be addressed with the training of health workers, minor design modifications, and parent and community education (Guillermet *et al*., 2015). Accidental freezing can be avoided with the use of sub-standard domestic cold chain equipment instead of equipping the program with medical refrigerators designed specifically for storing vaccines and temperature-sensitive pharmaceuticals (Lloyd. *et al*., 2015).

1.1. General objective

To assess the cold chain storage practices of pharmaceutical products in Virika Hospital Kabarole district.

1.1.1. Specific objectives

- To determine the availability of functioning storage equipment for cold-chain pharmaceutical products.
- To find out the storage conditions of cold chain pharmaceutical products.
- To determine the availability of power backup services for cold chain pharmaceutical products.

2. METHODOLOGY

2.1. Study design

The research design refers to the overall strategy utilized to carry out research that defines a succinct plan to tackle established research questions through the collection, interpretation, analysis, and discussion of data (Claybaught. et. al. 2020).

Incorporation of the design of the research study will depend on the standpoint of the researcher over their beliefs like the knowledge and then reality often shaped by the disciplinary areas, the researcher belongs to (Wright et.al. 2016).

The study design is a cross–sectional observation study of the suitability of storage practices of cold chain pharmaceutical products in Virika Hospital Kabarole district. This type of study will enable me to collect the data efficiently.

2.2. Area of Study

The study is focused on the cold chain storage of drugs in Virika Hospital located in a district away from fort portal Kasese road. The geographical coordinates are 0038'16.0"N, 30016'06.0E. (Latitude 0.637767, longitude 30.268329). This research will be carried out for one month and much emphasis will be put on equipment used for cold storage, monitoring the temperatures of pharmaceutical products, the presence of power backup supply, and the pharmaceutical products stored in the cold chain.

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2.3. Study population

According to the hospital statistics, the estimated health workers population is 40 workers. This is the liable number of health work- ers who work in cold chain systems like laboratories, stores, pharmacies, and in immunization programs.

2.4. Materials for the study

- Questionnaires
- Interviews
- Checklists

2.5. Sampling technique

Data collection was based on a purposive technique where only individuals who participate in medicine storage, ordering, quantification, and procurement were interviewed. This helped me to get the right information about the cold chain practices because these people had much more content about the cold chain system.

2.6. Sampling procedure

I approached health workers in virika hospital who participate in medicine storage and consent forms were issued to them whereby those who consented with me, were to be given questionnaires.

2.7. Sample size determination

The sample size used was estimated according to the formula of sloveren's

where

n=sample size required,

N=total population estimated, e=margin of error.

Considering a study population of 40 people

n=36

40=1 +40(0.05)

2.8. Data collection

The different methods that were used to collect data included a survey, on-site observations of processes, examination of records, and interaction with respondents. The main primary data gathering instruments for the survey were structured questionnaires as data collection tools.

2.9. Inclusion and exclusion criteria

2.9.1. Inclusion criteria.

All health workers that work in pharmacies, laboratories, stores, theatre maternity wards pediatric wards, and those involved in immunization programs are all included.

2.9.2. Exclusion criteria.

All non-health workers in Virika Hospital like administrators and security guards are excluded.

2.10. Ethical considerations

This research requires mandatory ethical clearance from my institution Kampala School of health sciences and my supervisor before I could use or visit the hospital facility for the research. The ethics of the research requires that the participants be given a written consent form that every respondent will read and sign and finally, participants given assurance through debriefing information that all information shared will be used purely for research purposes, they will be kept confidential and the participants' anonymity will be maintained as only pseudonyms will be used and participant's names withheld. In all, each of the questionnaires administered will contain an informed consent sheet for each of the respondents in line with ethical requirements.

2.11. Data collection tools

2.11.1. Questionnaires

A pre-tested, semi-structured questionnaire with both open and closed questions written in the English language was used to collect data. Here large amounts of information were collected from health workers within a short period and at a relatively low cost.

3. STUDY FINDINGS:

3.1. To determine the availability of functioning storage equipment's for cold chain pharmaceutical products.

From table 1, most of the respondents were nurses (77.7%) followed by clinicians (11.1%) and the least (5.6%) were pharmacists and pharmacy technicians.

Table 1: Shows the distribution of respondents according to their occupation (N=36)

Respondents	frequency	Percentage (%)
Nurse	28	77.7
Pharmacy technician	2	5.6
Pharmacist	2	5.6
Clinician	4	11.1
Total	36	100

Basing on the study findings relating to occupation, majority were nurses (77.7%) and the least were (5.6%) pharmacists and pharmacy technicians.

From table 2, most (83.3%) the respondents, have ever attended training about the storage distribution and handling of cold chain medicines as compared to the list number (16.7%) of the respondents who had never attended.

From table 3, all the respondents (100%) are aware of the presence of the well- functioning storage equipment's in the hospital.

From table 4, all the respondents (100%) reported that there are thermometers in the refrigerators for temperature monitoring in their different departments for the storage of the cold chain pharmaceutical products.

From table 5, all (100%) of the respondents have the high and low temperature alarms in the refrigerators in their respective departments.

3.2. To find out the conditions for the storage of pharmaceutical products.

From table 6, most of the respondents (91.7%) knew the temperature range for the storage of the cold chain drugs whereas the least of the respondents (8.3%) did not know the exact temperature range.

From table 7, most (86.1%) of the respondents had the instructions (sops) describing storage procedures, material handling and documentation and a few (13.9%) respondents did not have.

From table 8, most (55.5%) of the respondents thought that fault in the storage conditions can be as a result of the unreliable power supply to the facility, followed by 22.2% of the respondents who also thought of the low level of knowledge of the health care takers about the storage of the cold chain medicines, 8.3% of the respondents thought of the lack of gas and 5.6%of the respondents thought of the delayed replacement of the malfunctioning fridge.

From table 9, all (100%) respondents clearly said that there is always daily temperature monitoring to ensure efficacy of the cold chain drugs.1, majority of the respondents (94.4%) said they have connections to the automated generator in their departments in case of any power shortage while the least (5.6%)said they are not to the automated generator.

3.3. To determine the availability of power back up services for the cold chain pharmaceutical products.

From figure 1, majority of the respondents (94.4%) said they have connections to the automated generator in their departments in case of any power shortage while the least (5.6%) said they are not yet connected to the automated generator.

4. Discussion.

4.1. To determine the availability of functioning storage equipment for cold-chain pharmaceutical products.

From the study findings, it revealed that all the respondents (100%) had functioning storage equipment within their respective departments. This implies that the cold chain medical products are being maintained up to the time of issuing and the study results were in line with the study that was conducted by the Republic of Lebanon public ministry of Health, 2017. Where they recommended that the storage facility should provide

Table 2: shows the distribution of the respondents if they have ever attended the training on the storage, distribution and handling procedures of cold chain medicines. **N=36**

Response	Frequency (f)	Percentage (%)
Yes	30	83.3
No	6	16.7
Total	**36**	**100**

Table 3: Shows the percentage of the functioning storage equipments in the hospital **N=36**

Response	Frequency(f)	Percentage (%)
Yes	36	100
No	-	-
Total	**36**	**100**

Table 4: Shows the percentage of refrigerators with thermometer. **N=36**

Response	Frequency (f)	Percentage (%)
Yes	36	100
No	-	-
Total	**36**	**36**

Table 5: Shows percentage of the storage devices with temperature alarms. **N=36**

Responses	Frequency (f)	Percentages (%)
Yes	36	100
No	-	-
Total	**36**	**100**

Table 6: **Shows percentage of the appropriate temperatures for the storage of cold chain medicines.**

Responses	Frequency (f)	Percentage (%)
-5^{o}c to +1^{o}c	-	-
+2^{o}c to +8^{o}c	33	91.7
+9^{o}c to +15^{o}c	-	-
+4^{o}c to+8^{o}c	-	-
Don't know	3	8.3
Total	**36**	**100**

Table 7: Shows the percentages of the respondents if there are written instructions (sops) describing storage procedures, materials handling and documentation. **N=36**

Responses	Frequency (f)	Percentages (%)
Yes	31	86.1
No	5	13.9
Total	**36**	**100**

Table 8: Shows percentage respondent's knowledge about what they think can lead to fault in the storage conditions at the facility. **N=36**

Responses	**Frequency (f)**	**Percentages (%)**
Unreliable power supply	20	55.6
Lack of gas	3	8.3
Low level of knowledge of the health care takers	8	22.2
Relayed replacement of the malfunctioning fridge	2	5.6
All of the above	3	8.3
Total	**36**	**100**

Table 9: Shows percentage the respondents about if temperature monitoring is done regularly. **N=36**

Responses	**Frequency (f)**	**Percentages (%)**
Yes	36	100
No	-	-
Total	**36**	**100**

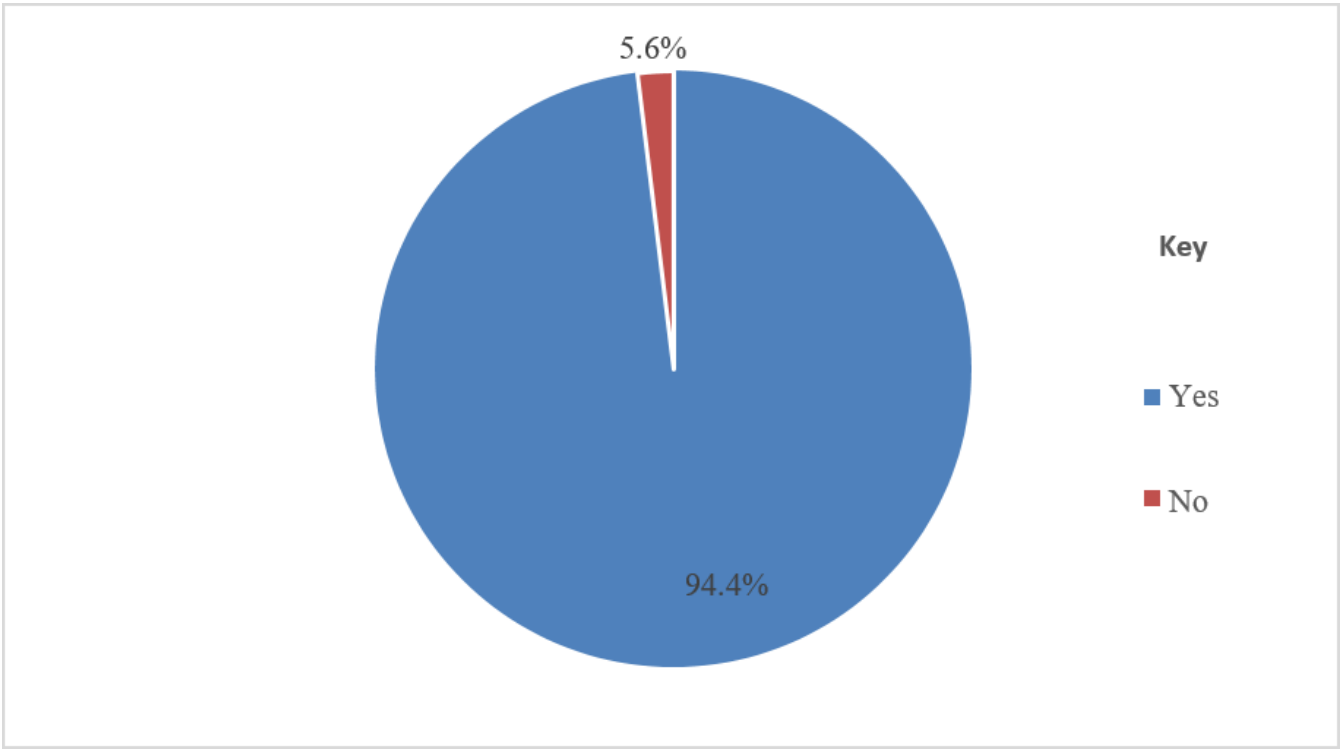

Figure 1: Shows the distribution of respondsif they have an automated generator to caterfor the power shortage in the hospital.

thermostatic temperature control systems for all temperature-sensitive pharmaceutical products.

From the study findings, it indicated that all the respondents had temperature monitoring equipment like thermometers within their cold chain storage equipment to guide them in any alteration in the temperatures. This was in line with the study that was conducted by the Republic of Lebanon's public ministry of Health.

4.2. To find out the storage conditions for the storage of the pharmaceutical prod- ucts.

From the study findings, they revealed that most (91.7%) of the respondents knew the temperature ranges or conditions under which cold chain medicines should be kept. This is compared to the least number (8.3%) of medical workers who were not sure of the exact temperature ranges the cold chain drugs are to be stored. This implies that the rate at which cold-chain pharmaceutical products deteriorate in potency is minimal. This was in line with the study that was conducted by Adamako,2012 where he said that temperatures outside those (+20c to +80c) ranges may reduce the potency of the cold chain medicine leading to a lack of desired response of the drug.

From the study findings, most of the respondents (55.6%), said that fault in the storage conditions can be a result of the unreliable power supply to the facility, followed by 22.2% of the respondents who also thought of the low level of the health caretakers about the storage of the cold chain medicines, 8.3% of the respondents said the lack of gas and 5.6%of the respondents said delayed replacement of the malfunctioning fridge. This was in line with the survey that was conducted on the facilities that issue the cold chain drugs (Provision & Survey, 2015) and this showed that unreliable power supply is a factor that leads to faults in the storage conditions of the pharmaceutical products.

4.3. To determine the availability of power backup services for the cold-chain pharmaceutical products.

From the study, the majority of the respondents (94.4%) said they have connections to the automated generator in case of any power shortage while the least (5.6%) said they are not yet connected to the automated generator. However, this implied that cold chain medicines are being taken under consideration irrespective of the few. This was in line with the study conducted by (Options, Rural, & Centers, 2017) that an unreliable energy source adds to the challenges of cold chain drug deterioration in potency.

The study conducted showed that the hospital has an automated generator to facilitate the power shortage. This was confirmed by the response of the respondents within the hospital whereby all of them (100%) confirmed with it.

5. Conclusion.

Based on the general results of the study the researcher concluded;

The overall results on the factors affecting cold chain management practices of pharmaceutical products, most of them were internal factors and a few were external.

From the study findings, it was found that many factors affect cold chain medicines. However, at Virika Hospital I found out that, the refrigerators are always switched off during night hours as reported by some of the health workers.

Additionally, the unstable power supply to the hospital contributed much to affecting the cold chain medicines. This was evidenced by the health departments that had not yet been connected to the automated generator. They told the researcher that sometimes the power goes off for almost half a day and their stock goes bad in terms of maintaining them without power.

The researcher also found out that some health workers (8.3%) do not know the right temperature range in which cold chain drugs are supposed to be maintained. This is because a few of the health workers (16.3%) rarely attend training about the

storage, distribution, and handling of cold chain medicines.

6. Study limitations.

Some respondents had not much idea about the relative range of temperatures in which the cold chain pharmaceutical products are supposed to be stored.

Some respondents refused to disclose the information needed from them.

7. Recommendations.

The administration of Virika Hospital should be in touch with the Ministry of Health to educate all health workers about the storage, transportation, and distribution of cold-chain pharmaceutical medicines. This can be effective by introducing this education training system in all health facilities and hospitals because the missing storage and poor transportation of these medicines highly affect their potency and therefore putting people's lives at high risk of getting other different infections as a result of immunizing them with an appropriate drug stored under poor conditions.

Secondly, more research should be done on cold chain medicines to find out other relevant factors that could cause alterations in cold chain medicines.

8. Acknowledgment.

With much gratitude, i thank the almighty God for his wonderful peace, knowledge, protection, wisdom, and understanding. It wasn't easy for me during this activity.

Special thanks go to my family especially my daddy Bwambale William and mummy, Muhindo Ellen for their tireless efforts financially and mentorship during hard times while conducting this research report.

Further, thanks go to my supervisor Dr. Niwagiira Mulodokayi for the technical support he offered to me to develop this research report.

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10. Publisher details:

Vol. 4 No. 9 (2023): September 2023 Issue
https://doi.org/10.51168/sjhrafrica.v4i9.531
Original article

Publisher: Student's Journal of Health Research (SJHR)
(ISSN 2709-9997) Online
Category: Non-Governmental & Non-profit Organization
Email: studentsjournal2020@gmail.com
WhatsApp: +256775434261
Location: Wisdom Centre, P.O.BOX. 148, Uganda, East Africa.