PHARMACOVIGILANCE
NEWSLETTER

VOL. 17 No.3 2024

Perils in preservation: exploring how inadequate storage conditions transform pharmaceuticals into menaces

Content

Health professionals and patients are encouraged to **report adverse events** or **quality problems** experienced with the use of **vaccines and medicines** to the nearest NAFDAC office or via pharmacovigilance@nafdac.gov.ng or via eReporting platform available on the NAFDAC website www.nafdac.gov.ng or via Med Safety Application available for download on Android and IOS stores.

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EDITOR'S NOTE...

We wish to thank our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC is committed to sending out the quarterly newsletter to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on medicine safety issues, to promote rational use of drugs and to promote reporting of Adverse Drugs Reactions (ADRs) and AEFIs. This edition of the newsletter focuses on: **Perils in preservation: exploring how inadequate storage conditions transform pharmaceuticals into menaces**

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions and AEFIs. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

Thank you for your relentless efforts in strengthening Pharmacovigilance System in Nigeria.

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Introduction

NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products 2023 defines Storage as the storing of pharmaceutical products up to the point of use. Preservation is the act of keeping something the same or of preventing it from being damaged. Home storage of medications is common around the world and it involves both prescription medicines and over-the-counter (OTC) medications indicated for acute and chronic conditions. Recent years have shown changes in medicine consumption patterns resulting in larger purchasing volumes and, consequently, excessive amounts stored at home (Martins et al., 2017).

The accumulation of medications in homes may be associated with harm to the patients, to their family, and even to the environment. An association between the accumulation of medications and multiple storage locations at home, and unfavorable clinical outcomes or decreased adherence to treatment has been described. This negative association is more likely to be harmful to older adults, who frequently have multiple diseases and a greater number of medications at home, leading to a higher frequency of administration errors, medication interactions, and adverse reactions. Having a large quantity of medicines in the household has also been implicated in an increased risk of inappropriate self-medication, especially through the administrations of leftover medicines. Improper disposal of antimicrobials has the risk of the risk of the development of multidrug-resistant organisms, a potential public health problem. Undoubtedly, the widespread use of the domestic waste and the public sewage system for disposal of medicines in many countries leads to extensive environmental contamination (Martins et al., 2017).

Pharmaceutical compounds are sometimes released into the environment as a result of use and improper disposal and this has negative effects. Having appropriate systems in place for the collection of unused or expired pharmaceuticals is not sufficient because there is also a need to educate society on how to dispose unwanted medications properly (Rogowska, J. and Zimmermann, A., 2022).

The World Health Organization has formulated international regulatory standards, which include stability, packaging, storage, and bioequivalence. Care must be taken to ensure that active pharmaceutical compounds remain stable and unaffected by packaging materials or storage conditions. Further, the establishment of bioequivalence standards between originator and generic medicines is of great importance given WHO's support of generic products and their potential to increase access to essential medicines.

The NAFDAC Good Distribution Practices (GDP) Guidelines for Pharmaceutical Products (2023) provide adequate advice on the various components of GDP. Good Distribution Practice is that part of quality assurance that ensures that the quality of a pharmaceutical product is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure

the distribution system from unapproved, illegally imported, stolen, counterfeit, substandard, adulterated, and/or misbranded pharmaceutical products. The distribution of pharmaceutical products is an important activity in the supply chain and involves several players. It consists of procuring, holding, supplying, importing and exporting of pharmaceutical products. Distribution activities are carried out by manufacturers, importers, wholesalers/distributors, retailers and other persons authorized to supply pharmaceutical products in the public and private sectors. The Good Distribution Practice (GDP) guidelines are intended to help players in the supply chain of pharmaceutical products comply with NAFDAC Good Distribution Practice Regulations; it provides appropriate tools to assist all categories of distributors in conducting their activities in order to maintain the quality of pharmaceutical Products and prevent counterfeits from entering the legal supply chain. The guidelines are intended to help in minimizing the inherent risks in distribution such as mix-ups, adulteration, contamination, cross contamination and diversions. Some injections like Oxytocin and Tetanus toxoid must be stored in a dedicated refrigerator for drugs to prevent losses in potency and denaturation respectively.

General Principles of GDP

The principles of good distribution practice (GDP) entail that all parties involved in the distribution of pharmaceutical products have a responsibility to ensure that the quality of pharmaceutical products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient. These principles of are applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing the product to the end user; and to products which are moving backwards in the chain such as it obtains in return and recall.

The principles of GDP are also applicable to donated pharmaceutical products. All distributors should apply due diligence with adherence to the principles of GDP, for example, in procedures relating to traceability and in recognition of security risks. All distributors should comply with the extant national legislations on pharmaceutical products. Distributors should be appropriately authorized and can be held accountable for all the activities that relate to the storage and distribution of pharmaceutical products.

Components of GDP

Some relevant components of GDP as elaborated in NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products are as follows:

Premises, warehousing and storage facilities- Distributors must have suitable and adequate premises to ensure proper storage, distribution of pharmaceutical products and adequate space in warehouses for movement of personnel & efficient cleaning. In particular, the premises should be clean, dry and maintained within acceptable temperature limits

Vehicles and equipment- It is the responsibility of the distributor of pharmaceutical products to ensure that Components of GDP vehicles and equipment used to distribute, store or handle pharmaceutical products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and integrity

Operations management- All actions taken by distributors should ensure that the identity of the pharmaceutical product is not lost, and that the distribution of pharmaceutical products is performed according to the information on the outer packaging.

Self-inspection- Self-inspections should be conducted in order to monitor implementation and compliance with GDP principles and to propose necessary corrective measures.

Training- Training of personnel is key to entrenching Good storage and Distribution practices in facilities. It is noteworthy that records of temperature monitoring data should be available for review in the premises. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year. Temperature mapping should show uniformity of the temperature across the storage facility and at different seasons (dry and rainy). It is recommended that temperature monitors be in areas that are most likely to show fluctuations. Equipment used for monitoring of storage conditions should also be calibrated at defined intervals. The storage conditions for products should follow the required storage specification of the product (this is a very important labelling requirement by NAFDAC). Where the temperature is not stated (in terms of range) on the label of the products, the following definitions should be used as seen below:

Freezer	The temperature is thermostatically controlled between –25oC and –10oC
Refrigerator	The temperature is thermostatically controlled between 2oC and 8 oC

Cold place	the temperature does not exceed 8 oC
Room temperature	The temperature is between 22OC and 25oC
Ambient temperature	The required storage temperature of non refrigerated pharmaceutical product; usually stated on the product label as 'store below 25 °C' or 'store below 30 °C'.
Warm	The temperature is between 30oC and 40oC
Excessive heat	The temperature is above 40oC
Do not store over 30oc	The temperature is between 2oC and 30Oc
Do not store over 25oc	The temperature is between 2oC and 25oC
Do not store over 8oc	The temperature is between 2oC and 8 oC
Do not store below 8oc	The temperature is between 2oC and 8 oC
Protect from moisture	The temperature is between 8oC and 25oC. Not more than 60% relative humidity in normal Storage conditions to be provided to a patient in a Moisture resistant container
Protect from light	To be provided to the user in a light resistant container

Prevalence and risk factors of inadequate medicine home storage: a community-based study by Martins et al, 2017

A cross-sectional, observational survey was conducted in Cuité, a community of about 20,000 inhabitants located in the State of Paraíba, in Northeastern Brazil in 2014. It was carried out with the aim to assess the extent of inadequate home storage of medicines and identify important risk factors.

The survey was based on a probability sample in the community, conducted in 267 households. Logistic regression was used to study the risk factors. The prevalence of households with inadequate storage was 76.0%. Problems with storage include direct exposure to sunlight in 10.9% of households, the presence of dust in 23.6%, and storage within reach of children in 76.0%. The study revealed that unused medications are usually disposed of into the environment in 92.1% of households. It concluded that Physicians and pharmacists should advise patients on how to adequately store medicines at home,

especially when the person in charge of medications is a male or an older adult.

Most medications did not have secondary packaging (66.8%) and 38.4% had not been used in the previous seven days. There were few medicines past their expiration date (19, 2.4%). The prevalence of households with inadequate storage was 76.0% (95%CI 70.5–81.0). Direct exposure to sunlight was observed in 29 households (10.9%, 95%CI 7.4–15.2) and the presence of pollutants in 63 (23.6%, 95%CI 18.6–29.1). It was common to find medications were stored within the reach of children, as was observed in 76.0% (95%CI 70.5–81.0) of households. The average temperature and relative humidity in the storage location were 86.7°F (SD = 36.1; equivalent to 30.4°C [SD = 2.3]) and 50.4% (SD = 7.3), respectively. The area of the house most often used for storage of medicines was the kitchen (52.9%, 95%CI 49.5–56.5), followed by the bedroom (33.2%; 95%CI 30.0–36.7). The most common method of medicine disposal was into the environment, either through the household waste or into the public sewerage system (92.1%, 95%CI 88.2–95.1).

Conclusion

Indeed, inadequate storage conditions transform pharmaceuticals into menaces. Appropriate temperature storage and environmental monitoring will definitely prevent alterations in drug potency,

denaturation of vaccines, insulin and other causes of therapeutic failure.

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