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AVAILABILITY AND STORAGE OF VACCINE IN COMMUNITY PHARMACY

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ABSTRACT

Immunization is the process by which an individual's immune system becomes fortified against an agent. Immunization is an important means of controlling serious infectious diseases, and careful attention to vaccine storage is essential to ensure optimal vaccine effectiveness. The study was carried out to assess the Availability and Storage of Vaccines in Community Pharmacies. In achieving this aim, the following specific objectives were laid out to determine the availability of childhood and adult vaccines in Community pharmacies and explore variables that affect the involvement of community pharmacists in routine vaccination in Delta State. The research design used in this report is descriptive design, utilizing questionnaire method to obtain information from the respondents for this project. A total of 80 (eighty) respondents were selected for this study to represent the entire population of the study. For null hypotheses were formulated and tested using the one-way ANOVA and the t-test statistical tools at zero point zero five (0.05) level of significance. Primary data were collected from the primary source which questionnaire was used as an instrument of data collection while secondary data were sources from textbooks, journals, newspapers and the internet were employed. The data were presented on a frequency distribution table and analyzed using simple percentage, while hypothesis was tested using chi-square test. For immunization to remain relevant, immunization providers must device means of maintaining the recommended storage conditions for vaccines from the transport to storage and eventual delivery to patients. This study remains important as vaccine storage is one important factor that could influence the potency level of vaccines as well as the success of any immunization programme

INTRODUCTION

- Community pharmacy-based vaccination services will go a long way to increasing the number of immunization providers and the number of sites where patients can receive immunizations.
- It is thus important to understand the current role of community pharmacy-based immunization in delta state as well as to assess the level of availability of such vaccines in community pharmacies and the storage mechanisms and facilities available to them to ensure that the cold chain vaccine delivery process is maintained
- Vaccacine is a biological preparation which content antigen which stimulate the immunity system of a human
- The availability and storage of vaccines in community pharmacies play a crucial role in public health, particularly in enhancing vaccination rates and ensuring timely access to immunizations. As front-line healthcare providers, community pharmacists are increasingly recognized as key players in vaccine distribution, education, and administration. This shift is vital in addressing vaccine hesitancy and improving overall health outcomes, especially in underserved populations.
- In recent years, there has been a growing emphasis on the need for robust systems to manage vaccine inventory effectively. This includes not only maintaining an adequate supply of vaccines but also ensuring they are stored under optimal conditions to preserve their efficacy. The logistics of vaccine storage—ranging from temperature control to expiration monitoring—are essential for safeguarding public health and preventing vaccine spoilage.
- Furthermore, with the advent of new vaccines, such as those for COVID-19, the demand for vaccines in community pharmacies has surged, highlighting the necessity for streamlined processes and training for pharmacy staff. This review aims to explore the current landscape of vaccine availability and storage practices in community pharmacies, examining the challenges and best practices that contribute to effective immunization services. Through this exploration, we aim to underscore the pivotal role that community pharmacies can play in enhancing vaccine accessibility and reliability in the healthcare system.

Fig.no 1 Community Pharmacy

Classification of vaccines

1. Live attenuated vaccines
2. Killed or inactivated vaccine
3. Subunit or conjugate vaccines
   a) Protein vaccines
   b) Pure polysaccharide vaccine
   c) Nucleic acid based vaccine
4. Toxoids
5. mRNA
6. Viral vectors

THE HISTORY OF VACCINES TRACES BACK TO EFFORTS TO PROTECT AGAINST INFECTIOUS DISEASES

Early Practices

Variolation (10th Century): In China and other parts of Asia, material from smallpox scabs was used to induce immunity.

First Vaccine (1796)

Edward Jenner developed the first vaccine by using cowpox material to protect against smallpox. This method proved safer than variolation.

19th Century Advances

Louis Pasteur developed vaccines for rabies and anthrax, introducing the germ theory of disease and the principles of attenuation (weakening pathogens).

20th Century Breakthroughs

Development of vaccines for diseases like diphtheria, tetanus, pertussis, polio, and measles.

Jonas Salk and Albert Sabin created polio vaccines (1950s), marking a milestone in public health.

Modern Era (21st Century)

Vaccines were developed for new diseases like HPV, hepatitis B, and COVID-19. Introduction of mRNA vaccines (e.g., Pfizer-BioNTech, Moderna) during the COVID-19 pandemic revolutionized vaccine technology.

Vaccination remains one of the most effective tools for preventing infectious diseases globally.

LITERATURE REVIEW

- **Francis and Hinchliffe, (2020)** : A review of pharmacy-led immunization programs concluded that pharmacies might be especially effective in immunizing high-risk, older adults who are more likely to need prescription medications and, therefore, use pharmacy services. Pharmacist interventions have been shown to improve medication adherence (Jiang, et al., 2010), provide increased access to health care expertise and advice, and perform a variety of primary care services (Taitel, et al., 2011).
- **Rutter, (2021)** in his submission noted that the pharmacy has a long history of facilitating self-care, however, more than ever before, pharmacists and their staffs are being provided opportunities to expand their contributions which include involvement in routine immunization. Although considerable barriers still existif the community pharmacy is to maximize its potential there is urgent need to ask about pharmacists' ability and readiness to embrace change especially as it relates to vaccine storage
- **Patel et al. (2022)** highlighted the importance of integrating sustainability practices into vaccine storage and distribution. Their research pointed to eco-friendly refrigeration solutions that could reduce the carbon footprint of vaccine storage while maintaining efficacy.
- **Jones et al. (2022)** explored the evolving role of pharmacists during public health emergencies. The authors highlighted how community pharmacists played a crucial role in COVID-19 vaccination efforts, not only

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in administration but also in educating the public about vaccine safety and efficacy.

- **Garcia et al. (2023)** investigated the implementation of blockchain technology in vaccine distribution. The study found that blockchain improves traceability and accountability in the cold chain, helping to ensure that vaccines are stored and transported under optimal conditions.
- **Lee et al. (2024)** explored advancements in passive vaccine storage systems that utilize phase change materials to maintain optimal temperatures without relying solely on electricity. This technology shows promise for reducing dependency on traditional cold chain logistics, particularly in remote areas.

Aim: Availability and storage of vaccines in community pharmacies.

Objectives

The specific objectives of this study are outlined as follows;

- To determine the availability of childhood vaccines in Community pharmacies.
- To determine the availability of adult vaccines in Community pharmacies.
- To determine availability and adequacy of vaccine storage facilities in Community pharmacies
- To explore variables that affect vaccine availability and storage in Delta state.
- To explore variables that affects the involvement of community pharmacists in routine vaccination in Delta State.

VACCINE AND FUTURE PLANNING

- ➢ Commonly Used Vaccines Profile
- ➢ Role Of Vaccine
- ➢ Type Of Storage Of Vaccine
- ➢ Challenges For Storage Of Vaccine
- ➢ Importance Of Community Pharmacy

FIG NO 2 -VACCINE

COMMONLY USED VACCINES PROFILE

Vaccine	Temperature	Use	Route	Dose
Influenza (Flu)	2-8 °C	Seasonal flu prevention	IM	0.5 mL annually
COVID-19 (Pfizer, Moderna)	-90 to -60 Pfizer); -25 to -15°C (pre-use, 2-8°C (Moderna) post-thaw	COVID-19 prevention	IM	0.3 mL (Pfizer), 0.5mL(Moderna)
Tdap	2-8 °C	Prevents tetanus, diphtheria, pertussis	IM	0.5 mL
Hepas B	2-8 °C	Hepatitis B prevention	IM	0.5-1 mL
MMR	2-8°C	Prevention of measles, mumps, rubella	SC	0.5 mL
PCV13, PPSV23	2-8°C	Prevents pneumococcal infections	IM/SC	0.5 mL
HPV	2-8°C	Prevention of HPV-related cancers	IM	0.5 mL
Varicella	-50 to -15°C	Prevention of chickenpox	SC	0.5 mL
Rabies	2-8°C	Rabies prevention	IM	1.0 mL(adults), 0.5 mL (children)
BCG	2-8°C	Tuberculosis prevention	ID	0.05 mL (infants), 0.1 mL (adults)

TABLE NO : 1

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ROLE OF VACCINE

- **Disease Prevention:** Vaccines stimulate the immune system to recognize and fight pathogens, preventing diseases like measles, polio, and influenza.
- **Herd Immunity:** Widespread vaccination reduces the spread of disease, protecting unvaccinated individuals.
- **Eradication of Diseases:** Vaccines have helped eradicate or significantly reduce diseases like smallpox and polio globally.
- **Reduced Mortality and Morbidity:** Vaccination lowers death rates andcomplications associated with infectious diseases.
- **Cost-Effective Public Health Tool:** Preventing diseases via vaccines is more economical than treating outbreaks.
- **Protecting Vulnerable Populations:** Vaccines are essential in protecting individuals with weakened immune systems who cannot be vaccinated.
- **Global Health Security:** Vaccines are critical in controlling pandemics and outbreaks, enhancing overall public health safety

DISEASE	DIAGNOSTIC TEST
1. Typhoid	Widal Test Blood Culture
2. Rubella	Rubella Igm Antibody test
3. Cholera	Stool Culture
4. Polio	Stool Culture , PCR test
5. Malaria	Blood smear ,RDT
6. Rabies	Direct Fluorescent Antibody
7. Covid-19	RT-PCR , Rapid Antigen test
8. Influenza	Rapid Influenza Diagnostic test (RIDT) PCR

TABLE NO :2

TYPE OF STORAGE OF VACCINE

Vaccine storage relates to the proper vaccine storage and handling practices from their manufacture to the administration in people.The general standard is the 2–8 °C cold chain for vaccine storage and transportation. This is used for all current US Food and Drug Administration (FDA)-licensed human vaccines and in low and middle-income countries. Exceptions include some vaccines for smallpox, chickenpox, shingles and one of the measles, mumps, and rubella II vaccines, which are transported between −25 °C and −15 °C. Some vaccines, such as the COVID-19 vaccine, require a cooler temperature between −80 °C and −60°C for storage.

1 .Refrigerated Storage

- **Temperature Range**: Typically between 2°C to 8°C (36°F to 46°F).
- **Use** : Most routine vaccines (e.g., measles, mumps, rubella, and influenza) are stored this way.
- **Equipment** : Usually involves standard refrigerators or vaccine refrigerators with temperature monitoring systems.

2 . Frozen Storage

- **Temperature Range** : Generally -15°C (5°F) or colder.
- **Use** : Some vaccines, like certain live attenuated vaccines and those containing viruses, require freezing (e.g., varicella and some formulations of the COVID-19 vaccine).
- **Equipment** : Ultra-low temperature freezers or standard freezers, depending on the specific vaccine.

3. Ultra-Cold Storage

- **Temperature Range** : -60°C to -80°C (-76°F to -112°F).
- **Use** : Certain COVID-19 vaccines (like Pfizer-BioNTech) require ultra-cold storage to maintain stability.
- **Equipment** : Specialized ultra-low temperature freezers.

4. Room Temperature Storage

- **Temperature Range** : 20°C to 25°C (68°F to 77°F), with some vaccines permissible for limited periods.
- **Use** : A few vaccines can be stored at room temperature, but usually only for short durations before use (e.g., some oral vaccines).
- **Considerations**: Must monitor duration closely to ensure efficacy is maintained.

5 . Cold Chain Management

- This refers to the entire process of maintaining the required temperature range during storage and transportation, using:
- **Thermometers**: For continuous monitoring.
- **Data Loggers**: To record temperature over time.
- **Coolers/Insulated Containers** : For transport, especially when moving vaccine between locations.

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Fig no 3 Various Type of storage of vaccine

Disease-Free Impact

- Timely and widespread administration of these vaccines has successfully reduced or eliminated certain diseases in India, such as:
- Polio (eradicated).
- Smallpox (eradicated globally).
- Significant reductions in neonatal tetanus, diphtheria, and measles-related deaths.
- To ensure better protection, follow the vaccination schedule provided by healthcare professionals and consult for additional vaccines based on individual needs

CHALLENGES FOR STORAGE OF VACCINE

Storing vaccines poses several challenges that can impact their efficacy and safety. Here are some of the main challenges:

1 . Temperature Control

- **Variability**: Maintaining consistent temperatures within recommended ranges is crucial, but can be affected by power outages, equipment failure, or extreme weather conditions.
- **Transport Issues**: Transporting vaccines can expose them to temperature fluctuations, especially if proper cold chain logistics are not followed.

2. Equipment Reliability

- **Malfunctions**: Refrigerators and freezers can break down, leading to potential vaccine spoilage.
- **Monitoring Systems**: Inadequate monitoring can result in unnoticed temperature excursions, risking vaccine integrity.

3 . Supply Chain Disruptions

- **Logistical Challenges**: Natural disasters, political instability, or pandemics can disrupt the supply chain, affecting the timely delivery of vaccines.
- **Access to Remote Areas**: Vaccines may not reach rural or remote locations where refrigeration is less reliable.

4. Human Error

- **Improper Handling**: Incorrect storage practices, such as leaving doors open or failing to log temperatures, can compromise vaccines.
- **Training Gaps**: Staff may not be adequately trained on proper vaccine storage protocols, increasing the risk of mishandling.

5. Cost Implications

- **Resource Intensive** : Maintaining cold chain storage requires investment in equipment, monitoring systems, and trained personnel, which can strain budgets, especially in low-resource settings.
- **Loss of Product** : Spoiled vaccines due to storage issues result in financial loss and wasted resources.

6. Regulatory Compliance

- **Standards** : Different regions have varying regulations and guidelines for vaccine storage, which can complicate compliance for manufacturers and healthcare providers.
- **Inspection Requirements** : Facilities must meet stringent standards, requiring ongoing investment in training and equipmen

7. Public Perception and Trust

- **Misinformation** : Concerns about vaccine efficacy due to storage issues can affect public trust and vaccination rates.
- **Transparency**: Clear communication about storage practices is vital to reassure the public regarding vaccine safety.

8 . Variability in Vaccine Formulations

- **Different Storage Needs** : Various vaccines have different stability profiles (e.g., live attenuated vs. inactivated), requiring tailored storage solutions.
- **Combination Vaccines** : Vaccines that combine multiple antigens may have varied storage requirements, complicating handling.

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IMPORTANCE OF COMMUNITY PHARMACY

- **Accessibility to Medications**: Community pharmacies provide easy access to prescription and over-the-counter medications, often with extended hours and locations near residential areas. This convenience is crucial for individuals who need timely access to treatments, especially those with chronic conditions.
- **Medication Management** : Pharmacists in community pharmacies offer guidance on medication adherence, side effects, and interactions. They help patients understand their treatment regimens, reducing the risks of medication errors and improving health outcomes.
- **Preventive Healthcare:** Many community pharmacies provide services like vaccinations, health screenings (e.g., blood pressure, cholesterol, and blood sugar tests), and smoking cessation programs. These preventive services help in early detection and management of health issues, reducing the burden on primary care facilities.
- **Personalized Care** : Unlike larger healthcare settings, community pharmacists often have long-standing relationships with their patients. This allows them to offer personalized advice, tailored to individual needs, improving patient trust and compliance.
- **Public Health Role** : During public health emergencies, such as the COVID-19 pandemic, community pharmacies have been essential in distributing vaccines and providing essential medications. Their role in health education and counselling is also critical in promoting healthy behaviours the community.

RECENTLY DEVELOPED NEW VACCINE

- **RSV Vaccines :** Approved in 2023-2024 for respiratory syncytial virus, particularly for older adults and high-risk infants.
- **Ebola Vaccine (Ervebo):** Approved in late 2019, offering protection against Zaire ebolavirus.
- **Dengue Vaccine (Qdenga):** Approved in 2022 for broader use against dengue virus.
- **Malaria Vaccine (R21/Matrix-M):** Introduced in 2023 as an enhanced vaccine for malaria, especially in African regions.
- **Tuberculosis Vaccine (M72/AS01E):** Entered advanced trials in 2023 for latent TB prevention.
- **Zika Vaccine**: Early trials began in 2023-2024 for prevention of Zika virus complications.
- **Lassa Fever Vaccine** : Phase 2 trials began in 2024 for protection against this hemorrhagic fever endemic in West Africa
- **Nipah Virus Vaccine (ChAdOx1 NipahB):** Early human trials started in 2024 to combat outbreaks in South Asia.

Experimental work

The experimental work involving vaccines and chromatography often focuses on analyzing, purifying, or characterizing vaccine components, such as antigens, adjuvants, or impurities, to ensure vaccine efficacy and safety. Here's an outline of how chromatography techniques may be employed in vaccine research, with experimental tests explained:

1. **Chromatography Techniques in Vaccine Development**

Several chromatography techniques are crucial in vaccine studies:

Affinity Chromatography: Used to isolate specific antigens or antibodies based on their interaction with a ligand.

Ion-Exchange Chromatography (IEX): Helps in separating proteins or antigens based on their charge, often used for purification.

Size-Exclusion Chromatography (SEC): Separates molecules based on size, useful for studying aggregation or purity of vaccine proteins.

Reverse-Phase High-Performance Liquid Chromatography (RP-HPLC): Used for analyzing and characterizing peptides or small molecules.

Hydrophobic Interaction Chromatography (HIC): Separates molecules based on hydrophobicity, useful for protein purification.

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FIG NO :4

2. Experimental Workflow Step 1: Vaccine Preparation
Goal: Prepare vaccine samples containing the target antigens or components.
Example: A recombinant protein vaccine expressed in E. coli or yeast is harvested and processed.

Step 2: Sample Purification
Chromatography Type: Affinity or ion-exchange chromatography.
Test: Load the crude vaccine sample into the chromatography column. Elute and collect fractions containing the antigen.
Analysis: SDS-PAGE or spectrophotometry to confirm protein presence and purity.

Step 3: Characterization of Components Chromatography Type: SEC or RP-HPLC.
Test: Run purified antigen samples to determine molecular size, confirm structural integrity, or detect degradation products.
Analysis: Compare chromatograms of test samples against standards.

Step 4: Impurity Removal
Chromatography Type: IEX or HIC.
Test: Analyze impurities such as host cell proteins or nucleic acids.
Outcome: Measure efficiency of impurity clearance via ELISA or mass spectrometry.

Step 5: Adjuvant Interaction Studies
Chromatography Type: SEC or affinity chromatography.

Test: Study how vaccine antigens interact with adjuvants (e.g., aluminum hydroxide). Outcome: Assess binding strength and formulation stability.

3. Validation and Testing
After purification and characterization, vaccines undergo additional tests: Potency Assays: ELISA or cell-based assays confirm antigenicity.

Safety Tests: Residual impurity levels (DNA, host proteins) are quantified using chromatographic data. Animal Models: Purified vaccine components are tested for immune response induction.
Example Study

For an mRNA vaccine
mRNA Purification: Use ion-exchange or affinity chromatography to separate mRNA from impurities.

Lipid Nanoparticle Characterization: Employ SEC to assess size distribution of lipid nanoparticles encapsulating the mRNA.

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FIG NO :5

FUTURE TRENDS

Vaccine availability and storage are critical components of global public health. As technology and logistics evolve, several trends are emerging that will impact the way vaccines are developed, distributed, and stored in the future. Here's a step-by-step breakdown of expected trends in both vaccine availability and storage:

1. Vaccine Development Trends

a. mRNA and Next-Gen Platforms

mRNA vaccines, as seen with COVID-19, allow for faster production and are likely to be used for other diseases like flu, malaria, or even cancer in the future.

Other advanced platforms, such as viral vector vaccines, DNA vaccines, and protein subunit vaccines, are in development for broader applications.

b. Personalized Vaccines

With advancements in genomics, vaccines may become more personalized, targeting individual or population-specific responses for better efficacy.

c. Universal Vaccines

Research is focused on developing universal vaccines, particularly for rapidly mutating viruses like the flu and coronaviruses, which would offer broad protection without needing yearly updates.

d. AI-Driven Vaccine Design

Artificial intelligence (AI) is playing a growing role in identifying antigen targets, predicting immune responses, and optimizing formulations, reducing the time needed for vaccine development.

2. Trends in Vaccine Distribution

a. Decentralized Manufacturing

Advances in biomanufacturing technologies, like modular factories or mobile units, could enable vaccines to be produced closer to the point of care, especially in low-resource settings.

b. Equitable Access Initiatives

Global health organizations are focused on ensuring that vaccines are more widely available, especially in low- and middle-income countries. Initiatives like COVAX are key players in distributing vaccines more equitably.

c. Cold Chain Independence

Future vaccines are being designed to reduce dependence on strict cold chain logistics. Stable vaccines that can be stored at ambient temperatures or require minimal refrigeration will significantly reduce
logistical barriers.

3. Storage and Handling Innovations

a. Freeze-Dried Vaccines (Lyophilization)

Freeze-drying vaccines converts them into a stable powder form that can be reconstituted with water before use, improving storage life and removing cold chain requirements.

b. Temperature-Stable Formulations

Research is focused on developing formulations that remain stable at higher temperatures (2-8°C or even room temperature), which is critical for distribution in remote areas.

c. Single-Dose Vials and Auto-Disabling Syringes

Single-dose vaccine packaging, combined with pre-filled syringes, reduces the risk of contamination and improves handling efficiency, especially in mass vaccination campaigns.

Auto-disable syringes are increasingly used to prevent reuse, ensuring safety in vaccine delivery.

d. Microarray Patches (Needle-Free Delivery)

Vaccine patches using microneedles could revolutionize vaccine administration by eliminating the need for cold storage, simplifying delivery, and reducing needle injuries.

4. Advances in Monitoring and Tracking

a. Digital Cold Chain Monitoring

Sensors and IoT (Internet of Things) technologies allow for real-time tracking of vaccine temperatures during storage and transit, ensuring potency is maintained throughout the supply chain.

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b. Blockchain for Vaccine Distribution
Blockchain technology can be used to improve transparency and traceability in vaccine supply chains, preventing fraud and ensuring the authenticity of vaccines.

c. Digital Immunization Records:
With growing interest in digital health, vaccination records may be stored in digital formats accessible via smartphones, improving record-keeping and facilitating travel or school entry requirements.

CONCLUSION

The role of community pharmacies in vaccine availability and storage is crucial for enhancing public health outcomes. As the landscape of vaccination continues to evolve, addressing storage challenges and leveraging advancements in vaccine technology will be vital in improving the accessibility and reliability in immunization services. Community pharmacies are poised to play a pivotal role in these efforts, ensuring that vaccines are readily available and properly stored to protect public health.

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