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FEATURE ARTICLE:

Bridging the gap in attainment of Universal Healthcare Coverage: the role of Pharmacists

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CONTENTS

The Pharmaceutical Society of Kenya (PSK) is a representative organization that was formed enabling Pharmacists' to employ their professional expertise in the care of patients.

Established in 1964, PSK has its roots in the Pharmaceutical Society of East Africa, which was registered in 1950. Since its formation, PSK continues to promote a common standard for professional conduct and code of ethics for its members, as well as advocate for the welfare of Pharmacists.

EDITORIAL

NEW MODELS IN PHARMACEUTICAL CARE SERVICES

Prof. Apollo O. Maima, PhD, MPSK
Editor-in-Chief and Chair of the Editorial Board, Pharmaceutical Journal of Kenya

Pharmaceutical care is transforming into a technology-driven, patient-centered model. Pharmacists use electronic health records and robotic dispensing to enhance patient access and outcomes. Innovations such as virtual pharmacy services and artificial intelligence (AI) in drug discovery highlight the importance of community collaboration. Both AI and Data Analytics predict adverse reactions and tailor therapies. Emerging Models of Pharmaceutical Care includes Virtual Clinical Pharmacy Services (VCPS); Cloud Pharmacy Care that leverages social media for managing chronic diseases during quarantines; Specialty Pharmacy Models; Integrated HIV Care; E-Pharmacy and Telepharmacy that provide online consultations and remote lab services. These models are facilitated by ***Technological Integration, 8-Star Pharmacist Framework, Collaborative Care in inter-professional teams;*** and ***Sustainability and Access***.

Similarly ***game-changing Innovations and Models include:*** Integrated Pharmacist Model (promoting better stewardship and outcomes); Automation and Robotics (increasing efficiency, allowing more patient interaction); Pharmacogenomics and Precision Medicine (customizing therapies based on genetics); Digital Patient Engagement through apps improving adherence tracking; while Smart Supply Chain (IoT) optimizes inventory monitoring. These innovations seek to improve patient outcomes and operational efficacy within healthcare systems.

Pharmaceutical care incorporates medication therapy management (MTM), which tailors services to accommodate the diverse needs of patients, thus fostering a holistic approach that prioritizes communication over a mere disease-focused perspective. Despite the objective of MTM to enhance health outcomes, access to retail services remains restricted; therefore, licensed pharmacists are collaborating with prescribers in clinical settings to augment service delivery. The USA's Affordable Care Act has triggered initiatives such as "Team-Based Medication Therapy Management," aimed at enhancing access for Medicare beneficiaries by synchronizing care protocols.

The ***integration of digital health necessitates value networks that leverage technology***, although existing disparities among healthcare systems frequently impede collaboration. In Brazil, social determinants significantly impact medication access, and limited resources further compromise the delivery of pharmaceutical care. Effective management of chronic illnesses is critical for improving health outcomes, yet many providers neglect the associated essential services.

Telepharmacy has proven beneficial in extending access to care in rural communities through digital consultations. Innovative strategies such as home delivery of medications by pharmacies can substantially benefit patients in these areas. The World Health Organization has identified social determinants that influence health, underscoring the pivotal role of pharmacists in enhancing medication accessibility. Current trends highlight a shift towards value-based pharmacy initiatives aimed at bettering patient outcomes. Policymakers are advocating for the documentation of the impacts of pharmacy services, yet numerous financial models remain inadequately supported by robust evidence. Community pharmacies play a vital role within value-based care frameworks, incentivizing the delivery of high-quality, cost-effective services.

It is ***imperative that pharmacists engage in direct patient care*** to maintain their professional relevance within the evolving healthcare landscape. Non-dispensing services necessitate the establishment of sustainable payment models, as performance-based systems may yield unintended consequences. The advent of pharmacy-based point-of-care testing has improved health accessibility and safety; however, it also presents challenges, particularly pertaining to managing complex medication regimens. Medication reconciliation is fundamental in preventing adverse events and enhancing adherence among at-risk populations.

New competency frameworks are guiding pharmacist education, with an emphasis on collaboration in inter-professional environments to elevate the quality of care. The influence of digital health on pharmacy practice presents opportunities for innovative interventions and enriches the understanding of health-seeking behaviors. While AI holds the potential to optimize medication management, it mandates thorough investigation beyond initial drug modeling. The ***generation of real-world evidence*** encounters obstacles, whereas block-chain technologies promise advancements in supply chain integrity; nonetheless, logistical challenges impede effective data sharing for regulatory compliance. Collectively, the ongoing advancement of pharmaceutical care underscores the necessity for effective practices, innovative solutions, and educational reforms to address prevailing healthcare challenges, thereby establishing a robust framework for pharmacist-led initiatives..

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Meningitis in Children: A Retrospective Analysis of Types, Management and Predictors of Clinical Outcomes in a Kenyan Tertiary Referral Hospital

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Abstract

Background: Meningitis is a global health challenge associated with considerable morbidity, mortality, and long-term neurological sequelae despite available treatment. In Kenya, limited local evidence exists on the types of paediatric meningitis, treatment practices, and factors influencing clinical outcomes.

Objective: This study assessed the types of paediatric meningitis, management patterns, and independent predictors of clinical outcomes among children treated at Kenyatta National Hospital

Methods: This retrospective cross-sectional study reviewed 132 medical files of children treated for meningitis at Kenyatta National Hospital. Participants were selected through systematic random sampling, and data collected included sociodemographic characteristics, meningitis type, management patterns, and clinical outcomes. Statistical analysis was performed using STATA Version 28, with bivariate tests examining associations between age and length of hospital stay, and between drug therapy and clinical outcomes. Statistical significance was set at $p \leq 0.05$.

Results: Participants were predominantly male (55.3%) with a mean age of 3.5 ± 4.4 years, and infants aged 1–11 months formed the largest age group (35.6%). Bacterial meningitis accounted for 90.2% of cases, followed by viral (4.5%), tuberculous (3.0%), and fungal (1.5%) forms. Ceftriaxone was prescribed in 84.1% of cases, and meropenem in 23.5%. Supportive care frequently included hydration (79.5%) and nutritional supplementation (60.6%). Patients' age showed a significant association with hospital stay: infants stayed beyond 15 days (p=0.037), while children aged 7–12 years stayed under 15 days (p=0.009). Mortality reached 18.9%, and 16.7% developed neurological complications, chiefly seizures (7.6%).

Conclusion: Bacterial meningitis was the leading type among hospitalized children, underscoring the need for empirical therapy, stronger antimicrobial stewardship, and improved childhood vaccination. Future studies should examine long-term neurological outcomes and the effectiveness of various treatments.

Key Words: *Paediatric meningitis, Clinical outcomes, Management patterns, Antimicrobial therapy, Neurological complications*

Introduction

Meningitis is an inflammation of the meninges caused by infection of the membranes surrounding the brain and spinal cord by bacteria, viruses, fungi, protozoa, or helminths [1, 2]. It remains a major cause of morbidity and mortality in children due to immature immune systems and delayed symptom recognition [3]. In 2019, over one million meningitis cases and more than 100,000 deaths were reported among children under five years [4]. The disease continues to pose a significant global health burden, especially in low- and middle-income countries (LMICs) where diagnostic and treatment capacities are sparse [2].

Bacterial meningitis is the most severe and fatal form, with a high prevalence along the African meningitis belt [3]. Fungal meningitis often occurs in advanced stages of acquired immune deficiency syndrome (AIDS) associated with human immunodeficiency virus (HIV), while viral meningitis mainly affects young children, commonly caused by enteroviruses, herpes simplex virus, and mumps virus [5]. The protozoan *Naegleria fowleri* causes primary amoebic meningoencephalitis [6], whereas eosinophilic meningitis arises from helminth infestations, predominantly *Angiostrongylus cantonensis, Gnathostoma spinigerum,* and *Baylisascaris procyonis* [7]. Limited data exists on meningitis types in low-resource settings, and evaluating these patterns may provide valuable insights to enhance clinical practice.

Globally, the management of childhood meningitis centres on prompt empiric antibiotic therapy with third-generation cephalosporins such as ceftriaxone or cefotaxime, alongside dexamethasone to minimize neurological complications [8]. Supportive care, including seizure control, fever management, and reduction of raised intracranial pressure, is equally vital. Although the treatment protocols for meningitis in Africa generally aligns with the recommendations provided by the World Health Organization (WHO), optimal management is often hindered by resource constraints and diagnostic delays. In Kenya, empiric ceftriaxone remains the

primary treatment, though adherence to corticosteroid use is inconsistent [9]. The Ministry of Health's *Basic Paediatric Protocols* advise immediate intravenous ceftriaxone and dexamethasone for suspected cases [10], yet local data on actual management practices are scarce, underscoring the need for this study.

Treatment outcomes for childhood meningitis differ globally due to variations in healthcare capacity and diagnostic access [11]. While high-income countries benefit from rapid diagnostics and neurocritical care, low-resource settings face delayed presentation and limited laboratory support, resulting in poorer outcomes [12]. Factors such as age, nutritional status, causative organism, and comorbidities, including HIV infection, affect prognosis, with *Streptococcus pneumoniae* infections linked to worse neurological sequelae [8, 13]. Evaluating these outcome predictors in Kenya's largest referral hospital is essential to inform practice and align with the WHO's Defeat Meningitis by 2030 strategy [14]. This study aimed to retrospectively analyze the types, management approaches, and predictors of clinical outcomes among children diagnosed with meningitis in a Kenyan tertiary referral hospital.

Methodology

Study design

This was a retrospective cross-sectional study covering the period January 2020 – May 2024 among 132 children aged 0-17 years diagnosed with meningitis and treated at the Kenyatta National Hospital (KNH), the largest teaching and referral hospital in East and Central Africa.

Inclusion and exclusion criteria

Only complete medical files of children aged between one day and 17 years, diagnosed and treated for meningitis at the KNH in the period between 1st January 2020 and 31st May 2024, were included in the study. Conversely, the study excluded medical records of patients above 17 years old, children who received treatment outside the Jan 2020-May 2024 timeframe, and those with incomplete data.

Sampling and data collection technique

The sample size of 132 patients' files was calculated using the Cochran formula for descriptive studies with categorical variables [15]. Hospital records that met the inclusion criteria were recruited in the study by systematic random sampling. The study population was compiled into a list and arranged at random. The total population size was divided by the intended sample size to find the sampling interval, k. A random starting point was chosen between 1 and k. From the starting point, every k^{th} element was selected until the required sample size was obtained. Patients' data were collected using a data abstraction form. The information collected included the patient's age, gender, type of meningitis, treatment approaches, drug dosages, route of administration, duration of treatment, supportive therapy, and outcomes of treatment such as length of stay in hospital, complications associated with the disease, and mortality.

Study variables

The main outcome variables of interest were the length of hospital stay, neurological complications, and mortality. Independent variables included pharmacotherapy and supportive care. Drug therapy consisted of type of drugs, dosages, and duration of drug therapy, while supportive therapy consisted of management of symptoms, hydration, nutritional support, and long-term care. The possible confounders identified in this study included access to a quality healthcare facility, availability of clinical guidelines and host genetic makeup. These variables were controlled by getting the participants from the same pool in the KNH records department and conducting multivariable analysis of the collected data.

Data processing and analysis

The raw data was entered into Microsoft Excel® 2024 to create a database, which was exported to STATA® Version 28.0 software for analysis. Summary statistics were generated for sociodemographic and clinical characteristics, treatment approaches, and clinical outcomes. The Pearson's Chi-square and Fischer's Exact tests were used to determine associations between the dependent and independent variables such as association of medication used for the management of meningitis and development of complications, type of meningitis and duration of drug therapy, and age of patient and duration of hospital stay. Statistical significance was set at $p \leq 0.05$.

Ethical considerations

Approval to carry out this study was granted by the Kenyatta National Hospital/University of Nairobi-Ethics and Research Committee (Reference number UP665/08/2024). The patients' data were kept confidential and concealed by use of serialized unique alphanumeric identifiers.

Results

Sociodemographic characteristics of the study patients

The mean age of the participants was 3.5 ± 4.4 years with slightly over a third (35.6%) being infants (1-11 months old). Over half of the participants were male (55.3%), Christians (96.2%), had no education (67.4%), and resided in urban areas (69.7%). As regards the participants' parents, 70% were married, less than half (49.2%) were formally employed, and 40.9% were self-employed (Table 1).

Table 1. Sociodemographic characteristics of the study patients (N=132)

Characteristic	Category	Frequency, n	Percentage (%)
Age	<1 month (Newborn) 1-11 months (Infant) 1-3 years (Toddler) 4-6 years (Preschool) 7-12 years (School age) 13-17 years (Adolescent)	8 47 34 15 19 9	6.1 35.6 25.8 11.4 14.4 6.8
Gender	Female Male	59 73	44.7 55.3
Area of residence	Rural Urban	40 92	30.3 69.7

Level of education	Informal Primary school Secondary school	89 35 8	67.4 26.5 6.1
Religion	Christian Muslim	127 5	96.2 3.7
Marital status of the parents	Married Single Separated Divorced Widowed	91 25 10 4 2	68.9 18.9 7.6 3.0 1.5
Employment status of the parents	Formally employed Self-employed Unemployed	65 54 13	49.2 40.9 9.8

Types of meningitis among the study population

Five types of paediatric meningitis were encountered, namely bacterial (90.2%), viral (4.5%), tubercular (3.0%), fungal (1.5%), and post-traumatic meningitis (0.8%), as shown in Figure 1.

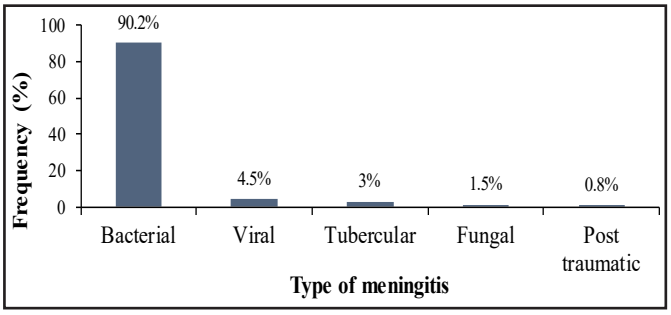

Figure 1. Types of meningitis among the study population.

Management of paediatric meningitis

Antibacterial agents (99.2%) were the most common type of drug therapy, followed by antiviral agents (21.2%), and corticosteroids (13.4%). Antifungal (4.5%) and antitubercular (3.0%) medications registered the least utility as shown in Figure 2. Ceftriaxone (84.1%) was the most utilized antibacterial, while amoxiclav and cefotaxime were the least prescribed as shown in Table 2. Six study participants were on antifungal agents, with five (3.8%) on fluconazole and only one used flucytosine. The duration of antifungal therapy varied widely, with fluconazole lasting a minimum of two days and a maximum of 21 days, while flucytosine was prescribed for 21 days.

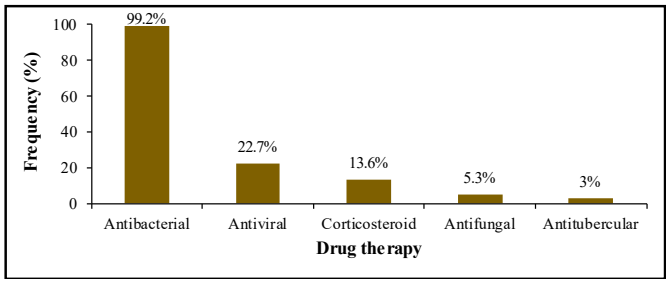

Figure 2. Drug therapy among study subjects.

Conversely, acyclovir (20.4%) was the most prescribed antiviral agent, with the duration of therapy ranging from a minimum of one day to a maximum of 27 days and a median of 10 days, while ganciclovir was administered for 21 days. Corticosteroids were used in 19 (14.4%) participants, with dexamethasone being the most common corticosteroid. Four (3.03%) participants received oral antitubercular therapy consisting of rifampicin, isoniazid, pyrazinamide and ethambutol. The duration of antitubercular medication was two months for three patients, while one patient received it for 28 days. For non-pharmacological management, hydration, consisting of normal saline and Ringer's lactate, was the most prevalent, used among 105 (79.5%) participants, followed by nutritional support (60.6%), oxygen supplement (46.2%), occupational therapy (12.1%), and physiotherapy (3.8%).

Table 2. Specific medications prescribed for meningitis in children (N=132)

Drug **Antibacterials**	Frequency (%)	Drug **Antifungals**	Frequency (%)
Ceftriaxone	111 (84.1%)	Fluconazole	5 (3.8%)
Meropenem	31 (23.5%)	Flucytosine	1 (0.8%)
Amikacin	23 (17.4%)		
Ceftazidime	12 (9.1%)	**Antivirals**	
Vancomycin	10 (7.6%)	Acyclovir	27 (20.4%)
Benzyl penicillin	3 (2.3%)	Ganciclovir	1 (0.8%)
Gentamicin	2 (1.5%)		
Metronidazole	2 (1.5%)	**Corticosteroids**	
Piperacillin/tazobactam	2 (1.5%)	Dexamethasone	12 (9.1%)
Cefotaxime	1 (0.8%)	Prednisolone	6 (4.5%)
Amoxiclav	1 (0.8%)	Methylprednisolone	1 (0.8%)

Clinical outcome of management of meningitis

Length of hospital stay

Slightly more than half (58.3%) of the patients were hospitalized for 15 days or less, with a quarter (25%) of study participants being hospitalized for 11–15 days. A proportion (22.7%) were hospitalized for more than 20 days (Figure 3).

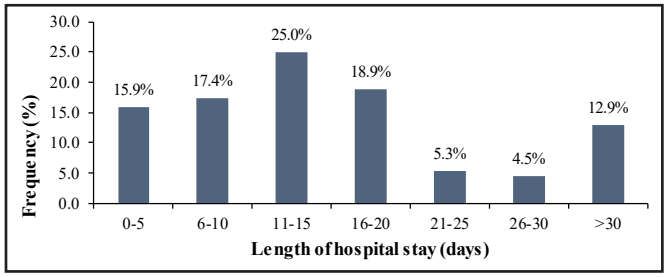

Figure 3. Length of hospital stay among study participants.

Assuming 15 days as the median length of hospital stay, statistical analysis explored associations between sociodemographic variables and length of hospital stay for ≤15 days and >15 days. A statistically significant association was found between patient's age and length of hospital stay, with those aged 1-11 months (p=0.037) having been hospitalized for >15 days while those aged 7-12 years (p=0.009) stayed in the hospital for ≤15 days (Table 3).

Table 3. Association between participants' age and length of hospital stay

Patients age	≤15 days, n (%)	>15 days, n (%)	p-value
<1 month (newborn) Other age groups	6 (75.0) 55 (44.4)	2 (25.0)* 69 (55.6)	0.143
1-11 months (infant) Other age groups	16 (34.0) 61 (46.2)	31 (66.0) 40 (47.1)	0.037

1-3 years (toddler) Other age groups	14 (41.2) 47 (48.0)	20 (58.8) 51 (52.0)	0.494
4-6 years (preschooler) Other age groups	7 (46.7) 54 (46.2)	8 (53.3) 63 (53.8)	0.970
7-12 years (school age) Other age groups	14 (73.7) 47 (41.6)	5 (26.3)* 66 (58.4)	0.009
13-17 years (adolescent) Other age groups	4 (44.4) 57(46.3)	5 (55.6) * 66(53.7)	1.000

*Exact test. The rest were Chi square test.

On the other hand, the Chi-square test revealed that patients who used meropenem (p=0.028) and vancomycin (p=0.002) significantly stayed in the hospital for >15 days as shown in Table 4.

Table 4. Association between medication therapy and length of hospital stay

Drug therapy	Drug	Length of hospital stay		p-value
		<15 days	≥15 days	
Antibacterial	Ceftriaxone Meropenem Piperacillin/Tazobactam Vancomycin Ceftazidime Cefotaxime Benzyl penicillin Amikacin Gentamicin Metronidazole Amoxiclav	53 (47.7%) 9 (29.0%) 2 (100.0%) 0 (0.0%) 6 (50.0%) 0 (0.0%) 2 (66.7%) 10 (43.5%) 2 (100.0%) 1 (50.0%) 0 (0.0%)	.58 (52.3%) 22 (71.0%) 0 (0.0%) 10 (100.0%) 6 (50.0%) 1 (100.0%) 1 (33.3%) 13 (56.5%) 0 (0.0%) 1 (50.0%) 1 (100.0%)	0.416 0.028 0.124 0.002 0.783 0.352 0.472 0.772 0.124 0.914 0.352
Antiviral	Acyclovir Ganciclovir	9 (33.3%) 0 (0.0%)	18 (66.7%) 1 (100.0%)	0.196
Antifungal	Flucytosine Fluconazole	0 (0.0%) 1 (20%)	1 (100%) 4 (80%)	0.62
Corticosteroids	Dexamethasone Methylprednisolone Prednisolone	1 (8.3%) 0 (0.0%) 3 (50.0%)	11 (91.7) 1 (100.0%) 3 (50.0%)	0.626

Neurological complications

Among the study population, twenty-two (16.7%) study participants developed neurological complications, the most prevalent being seizures that affected 10 (7.6%) participants followed by visual disorders, 6 (4.5%). Others included motor deficit, hydrocephalus, cerebral atrophy, encephalitis, cognitive impairment, and cerebral palsy (Figure 4). On bivariate analysis, only amoxiclav had statistically significant association with neurological complications (p=0.025).

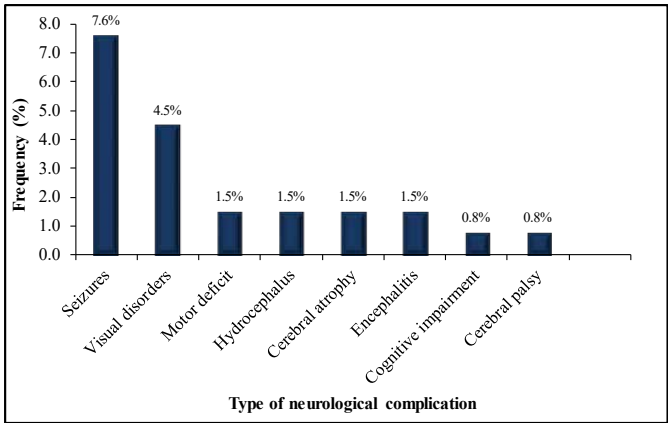

Figure 4. Neurological complications among the study participants.

Mortality

Among the 132 study participants, 107 (81.1%) survived while 25 (18.9%) died. Nevertheless, the age and type of drug therapy did not have statistically significant association with mortality (p>0.05).

Discussion

The present study characterized the aetiology, management and predictors of clinical outcomes of paediatric meningitis in a leading public referral hospital in East and Central Africa. The most common cause of paediatric meningitis was bacteria. Though the management varied across the aetiologies, most participants had prolonged hospitalization and developed neurological sequelae. In addition, most of the children afflicted by meningitis were aged less than one year.

The current study revealed high prevalence of bacterial and viral meningitis. The finding contradicts studies and literature review which assert that viral meningitis is the most common in children [16]. The variance could be explained by the observation that viral meningitis is often self-limiting and may not always require hospitalization, potentially leading to underrepresentation in hospital-based studies. Additionally, KNH being a tertiary referral hospital receives severe cases, with bacterial meningitis accounting for most cases requiring hospitalization as compared to viral meningitis. The low prevalence of fungal meningitis observed in our study is consistent with findings from other research, which indicate that fungal meningitis is uncommon in children, particularly those who are not immunocompromised [17]. Moreover, the absence of parasitic meningitis cases in the current study is consistent with a study carried out in Thailand [18] which indicated that there is limited reporting of parasitic meningitis in children.

Expectedly, antibacterials were the most common type of drug therapy used. The trend paralleled the high prevalence of bacterial meningitis among the study population. Ceftriaxone was the most frequently prescribed antibacterial, consistent with a similar finding in an Ethiopian study [19]. An interesting finding in the present study is the observed high utility of the second-line reserved antibacterial meropenem suggesting that a significant proportion of patients may have had severe infections or suspected drug-resistant pathogens [20].

The results of this study show that antiviral agents were the second most frequently used drug therapy, with acyclovir being the most utilized drug. This observation is comparable to a Jordanian study where acyclovir was the drug of choice for empiric antiviral therapy in suspected cases of viral meningitis [21]. Less than 10% of patients received antifungal therapy, with fluconazole being the most administered drug. This finding was however contrary to a related study done in China which reported that amphotericin B combined with 5-flucytosine was more effective than monotherapy in managing cryptococcal meningitis in children [22]. Perhaps, this difference in treatment approaches is primarily

attributed to the high cost of amphotericin B locally and that the Chinese study focused on cryptococcal meningitis.

Slightly over 10% of patients received corticosteroids, majorly dexamethasone. The findings in this investigation were lower than that of a study done in Ethiopia [19]. This difference can be explained in part by variations in treatment protocols as well as the differing characteristics of the study population. Furthermore, a study carried out in Japan revealed that early corticosteroid use in children with meningitis did not reduce mortality or neurological complications [23]. Nevertheless, the use of corticosteroids in meningitis has been shown to be beneficial depending on the bacterial species [24]. Hydration was the most prevalent non-pharmacological management, followed by nutritional support, oxygen supplementation, occupational therapy, and physiotherapy. These findings aligned with results of a study conducted in Ethiopia, which highlighted the significance of supportive measures like hydration and oxygen therapy in improving clinical outcomes [25].

There was a significant association between age and length of hospital stay, with infants aged 1-11 months (p=0.037) more likely to have longer hospital stays. This finding is consistent with the increased vulnerability of young infants to severe infections and complications, as noted in other studies [26]. On the other hand, neurological complications were observed in about a fifth of patients with seizures being the most common. This rate of complications is lower than reported in the literature [27]. The lower rate in the study could be due to effective management strategies and differences in pathogen virulence.

Mortality was high at 18.9% in the current study consistent with similar findings in the LMICs [28]. Nevertheless, there was no demonstratable statistically significant association between patients' age and mortality as well as drug therapy and mortality, suggesting that other factors, such as time to treatment initiation, or underlying health conditions, may be more influential in determining clinical outcomes of meningitis among children admitted at the KNH.

Limitations

The study was conducted with a relatively small sample size of 132 patients, which may limit generalizability of the study findings. This was mitigated by use of systemic random sampling to improve the representativeness of the sample while minimizing selection bias. Additionally, the study was a retrospective in nature hence it relied on existing medical records, which may have had incomplete or inaccurate information. This was mitigated by ensuring only files with complete and well-documented clinical information were selected. Furthermore, the study may not have captured long-term neurological sequelae that could have developed after patient discharge.

Conclusion

Bacterial meningitis was the most common type among children admitted at KNH, with frequent use of ceftriaxone and notable use of meropenem, suggesting possible guidelines non-adherence or emerging resistance. Strengthening childhood vaccination programs is crucial to reduce the disease burden. Infants aged 1–11 months had longer hospital stays, highlighting the need for structured follow-up care, including neurological and rehabilitative support. Future studies should assess long-term cognitive and developmental outcomes and treatment effectiveness among survivors.

Consent for publication

This is not applicable.

Disclosure of interest

The authors declare no conflict of interest.

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Authors Contributions

LMN conceptualized the idea and conducted the actual study and the statistical analysis. DGN was involved in developing the idea, designing the study, data analysis, and interpretation as well as revision of the manuscript. PMN drafted the manuscript. All authors approved the final manuscript for publication.

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Pharmacy-Based Delivery of Long-Acting Injectable Human Immunodeficiency Virus Pre-Exposure Prophylaxis in Sub-Saharan Africa: A Review of Opportunities, Barriers, and the Path Forward

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Abstract

Introduction

With over 20 million people living with HIV in Sub-Saharan Africa, long-acting injectable Pre-Exposure Prophylaxis (LAI-PrEP) offers a promising prevention strategy that could improve adherence, reduce stigma and the daily burden of taking pills. Community pharmacies are widely accessible and hold potential for expanding Human Immunodeficiency Virus (HIV) prevention services. However, the feasibility and readiness for pharmacy-based delivery of LAI-PrEP in this region remain uncertain.

Objectives

This narrative review examined existing evidence on the opportunities and barriers to implementing LAI-PrEP through community pharmacies in Sub-Saharan Africa.

Methodology

A narrative review was conducted using peer-reviewed and grey literature published between 2018 and 2025. With inclusion criteria of Sub-Saharan countries represented by 3 African regions and an exclusion of countries not in the Sub-Saharan region. Searches were performed in PubMed, Google Scholar, and the WHO Global Health Library, using terms related to "pharmacy-based delivery," "PrEP," "long-acting injectables," "Sub-Saharan Africa," and key country names (e.g., Kenya, Nigeria, South Africa). Out of 50 identified literatures, 25 met the inclusion criteria, focusing on literature addressing oral or injectable PrEP offered through community pharmacies.

Results

Key barriers included limited cold-chain capacity for injectable storage, regulatory restrictions on pharmacists administering injections, and gaps in training for pharmacy personnel. Despite these challenges, both clients and providers expressed high interest and willingness to deliver or receive LAI-PrEP through pharmacies.

Conclusions

Expanding HIV prevention through community pharmacies can significantly improve access to LAI-PrEP in Sub-Saharan Africa. However, identified barriers to implementation of pharmacy-based delivery of LAI-PrEP include cold-chain infrastructure, regulatory frameworks, and targeted training for pharmacy staff. Addressing these barriers would be an essential step toward achieving the UNAIDS 95-95-95 targets and ending AIDS by 2030.

Key Words: *Long-Acting Injectable Pre-Exposure Prophylaxis (PrEP), Community Pharmacies, HIV Prevention, Sub-Saharan Africa, Pharmacy-Based Delivery.*

Introduction

Though progress has been made in the prevention, diagnosis, and treatment of HIV/AIDS globally, the Sub-Saharan Africa region continues to bear a heavy burden of HIV infections. With an estimated 25 million persons living with HIV in Sub-Saharan Africa, the region accounts for approximately two-thirds of the global HIV burden [1]. The region bore a burden of over 700,000 of the 1.5 million infections in 2021, and almost 300,000 of the 650,000 AIDS related deaths [1]. Daily oral pre-exposure prophylaxis (PrEP) is highly effective in preventing HIV among at-risk populations [2]. However, several barriers, such as poor adherence, stigma, and logistical constraints in the use of daily pills, have hindered the effectiveness of daily oral PrEP in most settings, with consequent high level of PrEP cessation [2,3].

Administered once every two months, long-acting cabotegravir (CAB-LA) offers what some may describe as a "game-changing" option for HIV prevention. Still, this optimism is based on controlled trials and essentially ideal scenarios. Phase III studies (such as HPTN 083 and 084) have shown the effectiveness of CAB-LA in reducing HIV incidence [3]. Different studies have also revealed that preferences for long-acting injectables PrEP over Oral PrEP have been documented among at-risk HIV populations in various settings in Sub-Saharan Africa [4]. However, there might still be a notable gap between their efficacy under controlled settings and their practical feasibility. Particularly, questions about their implementation in overstretched health systems, such as in most Sub-Saharan African countries, are yet to be fully answered.

Under current models, long-acting injectable PrEP (LAI-PrEP) is expected to be delivered through clinics [3]. This expectation, however, may overlook the operational realities of many health systems in Sub-Saharan Africa, where facility-based care is often under-resourced and geographically limited [5]. In contrast, community pharmacies are increasingly recognised as accessible and trusted points of patient care [6]. They are more evenly distributed across rural and urban areas, and in many cases, serve as the first point of contact for individuals seeking health advice or medication [6]. A pilot study in Kenya revealed a notable demand for PrEP services when they are offered at pharmacies [7]. The study further revealed that pharmacies are better able to serve the underrepresented populations at clinics who are at high risk of HIV and need PrEP services without compromising the continuation of PrEP services [7].

A number of factors, regulatory, infrastructural, and educational, however, are essential to consider as regards integrating LAI-PrEP into pharmacy practice [8]. For example, in Kenya, pharmacy providers are prohibited from prescribing PrEP or performing the blood-based HIV testing that WHO recommends for PrEP initiation and monitoring [9]. More broadly across the region, pharmacy providers are not legally authorised to prescribe antiretrovirals or administer HIV testing unless through special pilot project approval or certification provisions [8,9]. Even where legal frameworks allow for expanded services, pharmacy staff may lack sufficient training in PrEP counselling, HIV risk assessment, and pharmacovigilance [9,10,11]. While research on these issues may be increasing, it still provides only partial insights and lacks the depth needed to guide effective policies or programs.

This review seeks to examine the current landscape of pharmacy-based LAI-PrEP delivery in Sub-Saharan Africa. The review considers both the promise and the limitations of this delivery model, outlining its potential to advance HIV prevention in the region or to fall short of its goals by critically examining the factors that may influence the success of pharmacy-based LAI-PrEP.

Methodology

This narrative review used a purposive approach to gather and analyse studies on the delivery of long-acting injectable PrEP through pharmacies in Sub-Saharan Africa. The search strategy included both peer-reviewed and grey literature published between 2018 and 2025. The review sought to examine early trials, pilot initiatives, shifts in national policies, and developments in implementation research. Electronic databases including PubMed, Scopus, and Web of Science were searched using Boolean logic and Medical Subject Headings (MeSH) terms such as: "long-acting PrEP," "CAB-LA," "HIV prevention," "pharmacy," "community pharmacy,""injection,""Sub-Saharan Africa,""implementation," "acceptability," and "task shifting." Grey literature from the World Health Organisation (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS), AIDS Vaccine Advocacy Coalition (AVAC), the Clinton Health Access Initiative (CHAI), as well as national ministries of health, and pharmacy associations across the region were also included in the review.

To ensure relevance, inclusion criteria were deliberately broad. Studies, reports, or commentaries were considered eligible if they focused on (a) LAI-PrEP, (b) HIV prevention delivery models, (c) pharmacy-based interventions, or (d) health systems in Sub-Saharan Africa. Given the qualitative, quantitative, and mixed-method nature of the topic, no exclusions were made based on study design. However, documents unrelated to HIV prevention or outside the regional context were excluded, unless they offered transferable lessons or frameworks.

To identify recurring themes, tensions, and innovations relevant to the implementation of pharmacy-based LAI-PrEP, the review process prioritised thematic saturation over exhaustive retrieval, an approach frequently employed in scoping and realist-informed reviews. Screening was conducted by four reviewers, with the first conducting initial database searching and title/abstract screening, the second provided oversight on inclusion/exclusion criteria and methodological rigour, the third contributed expertise on feasibility and practical considerations for pharmacy-based PrEP delivery, and the fourth validated and refined coding categories iteratively. The selected literature was reviewed in full and analysed using inductive thematic analysis after initial screening. Coding categories were developed iteratively, with attention to feasibility, acceptability, barriers, enablers, ethical considerations, and policy implications.

Recognising that global health literature often privileges northern voices and technocratic framings, the review also sought to centre African-led evidence and community-informed perspectives. In doing so, attention was paid to whose voices were present and whose were absent and not only to what the literature claimed. This helped identify gaps in research equity, policy responsiveness, and end-user inclusion, particularly as they relate to pharmacy integration. Though narrative reviews carry an inherent risk of selection bias, transparency in

search strategy and thematic framing was prioritised throughout. The review does not aim to provide a definitive judgment, but rather to open critical questions and pathways for future inquiry and implementation design.

Ethical approval of this study was not applicable. This is due to the use of secondary data contained in the reviewed literature.

Results

Twenty-five (25) sources met the inclusion criteria. These included studies, grey literature, policy briefs, implementation reports, and commentaries spanning several Sub-Saharan African countries, including Nigeria, South Africa, Kenya, Uganda, and Zimbabwe (Table 1). The table outlines the Country-Level Implementation Landscape for Pharmacy-Based LAI-PrEP in Sub-Saharan Africa.

Table 1. Country-Level Implementation Landscape for Pharmacy-Based LAI-PrEP in Sub-Saharan Africa

Country (Region Represented)	Status of Pharmacy-Based PrEP	Legal Authority for Pharmacists to Inject	Cold-chain Availability	Pilot Studies/ Programs
Kenya (East Africa)	Active pilots	Limited, special waivers	In select locations	Yes (e.g., Jilinde, Stand-alone model)
Nigeria (West Africa)	Planning stage	Not yet permitted	Rare in community setups	Ongoing consultations, Integrate project
South Africa (Southern Africa)	Advanced planning (PIMART)	Permitted under PIMART (pending final approval)	Moderate in urban areas	Yes (e.g., PIMART pilots)
Uganda (East Africa)	Early exploration	Restricted; exception under pilot programs	Limited to major pharmacies	Some pilot efforts are ongoing
Zimbabwe (Southern Africa)	Informal models emerging	Not formalized	Generally limited	Exploratory research only

Key

PIMART: Pharmacist-initiated Management of Antiretroviral Therapy

The reviewed literature collectively offered insights into both systemic and localised experiences surrounding PrEP delivery in pharmacies, as well as emerging considerations for the rollout of long-acting injectable PrEP (LAI-PrEP). Findings are presented thematically under four main domains: regulatory and policy context, logistics and infrastructure, health workforce capacity, and community acceptability.

1. Regulatory and Policy Landscape

Currently, most pharmacy providers in Sub-Saharan Africa, including pharmaceutical technologists and pharmacists, are not legally permitted to prescribe antiretrovirals or administer HIV testing without special approvals or certification provisions [8]. However, this regulatory landscape is changing rapidly as countries recognise the potential of pharmacies to expand HIV service access.

Kenya has taken a progressive approach by granting pharmacy providers in selected research studies special permission from the Ministry of Health to prescribe PrEP using a structured checklist system with remote clinician oversight [12]. South Africa similarly developed a more comprehensive certification framework called "pharmacist-initiated management of antiretroviral therapy" (PIMART), which was approved by the South African Pharmacy Council in June 2020 [8,13]. This program allows appropriately trained pharmacists and pharmacy-based nurses to prescribe antiretrovirals for pre-exposure prophylaxis, post-exposure prophylaxis, and treatment according to adapted Department of Health guidelines [13]. However, trained providers are still awaiting final approval of Section 22A (15) permits from the Director General of Health to begin implementation [13]. In 2017, the Kenyan Ministry identified pharmacy-based delivery of PrEP as one of its research priorities [12]. That same year, it released a 5-year plan to scale access to PrEP [9,14]. This scale-up plan included provisions for the delivery of PrEP services at retail pharmacies [9,14]. However, a 2020 study pointed out barriers in policy, such as the lack of guidelines on how or if pharmacists can test for HIV, as well as the price and procurement of PrEP [12]. Another study also revealed that informal pharmacy-based delivery of PrEP might be taking place in Kenya, similar to how it occurred with early adoption of HIV self-testing kits and injectable contraceptives [9,15]. Meanwhile, in Nigeria, a stakeholder consultation study revealed that expansion of PrEP access for vulnerable populations is a top priority for Nigeria's Ministry of Health, and the country is seeking to incorporate pharmacy-based PrEP services into the National Health Promotion Policy (NHPP) as part of broader integration into the national health promotion framework [10].

2. Logistics and Cold Chain Infrastructure

The issue of cold chain management is also a significant concern in nearly all reviewed documents. Unlike oral PrEP, which can be stored at room temperature, LAI-PrEP (e.g., long-acting cabotegravir) requires refrigeration and stringent temperature controls throughout storage and transport [5]. This has profound implications for pharmacies, particularly in rural and peri-urban areas in Sub-Saharan Africa, where cold chain capabilities can be limited and require substantial investment in expanding infrastructure [16].

Experience from vaccine implementation programs across Sub-Saharan Africa could also provide insights into cold chain challenges. Studies of Human papilloma virus (HPV) and malaria vaccine rollouts in six countries documented significant logistical barriers, including cold chain infrastructure gaps and facility-level storage shortfalls in urban South African and Kenyan settings [17]. Although some stakeholders propose partnerships with cold chain logistics companies or government health facilities, few concrete strategies have been trialled [8,9,10]. A study in Kenya piloted the use of mobile cold boxes for short-term PrEP delivery in outreach settings, but scalability and sustainability were not assessed [18]. Interestingly, only one of the reviewed documents explored solar-powered

refrigeration units [5]. Thus, while the physical act of storing and administering LAI-PrEP in pharmacies is not impossible, it currently hinges on infrastructural investments that many pharmacy owners may be unwilling or unable to make without financial or policy incentives.

3. Pharmacist Training and Health Workforce Readiness

Another recurring theme was the knowledge and skills gap among community pharmacy staff concerning HIV prevention, PrEP counselling, and injectable administration. Many studies raised questions about whether pharmacists are adequately trained to counsel clients on LAI-PrEP's unique adherence requirements, potential side effects, and implications for drug resistance.

PrEP delivery involves relatively straightforward components, including HIV testing, counselling on adherence and risk reduction, prescribing with assessment of acute HIV infection and side effects, and drug dispensing - all of which can be performed by pharmacists or pharmaceutical technologists in low-resource settings, particularly with remote clinician oversight [19]. This model leverages existing pharmacy infrastructure, as many private pharmacies already provide counselling on medication adherence for chronic conditions like hypertension and diabetes, as well as guidance on condom use for pregnancy and sexually transmitted infection prevention [19].

Training models for pharmacy-delivered PrEP in Sub-Saharan Africa are currently in early development stages, with most programs adapting existing clinical materials rather than using pharmacy-specific curricula. In Kenya, stakeholders have recommended using the National AIDS and STI Control Programme (NASCOP) PrEP materials and guidelines to train pharmacy providers, while suggesting that future scale-up efforts should establish formal training requirements designed explicitly for retail pharmacy settings [19]. Pilot implementations have utilised 2-day virtual training programs that cover core components, including HIV risk counselling, PrEP safety, provider-assisted HIV self-testing, drug dispensing, and record keeping [14,20]. These training programs are typically supplemented with ongoing technical assistance, which is gradually phased out as providers gain experience [14]. Evidence suggests that with proper training and oversight, pharmacy providers can safely initiate and manage PrEP clients, though standardised training programs remain limited. South Africa has developed a promising model called pharmacist-initiated management of ART (PIMART), which provides specialised training for pharmacists to prescribe and manage clients on PrEP, PEP, and first-line ART [9]. However, across much of Sub-Saharan Africa, government and regulatory bodies have not established harmonised guidelines or standard training requirements for sexual and reproductive health services in community pharmacy settings, which affects both in-service training quality and service standardisation [21]. This contrasts with developed countries, where community pharmacists pursue additional training through continuous professional development programs to provide expanded services [21].

4. Community Acceptability and Client Perspectives

On the client side, the acceptability of LAI-PrEP through pharmacies appears promising. Most participants across multiple studies expressed strong support for expanding PrEP to retail pharmacies, though they conditioned their acceptance on assurances that care would be private, respectful, safe, and affordable [9]. Kenyan stakeholders found the concept of pharmacy PrEP delivery to be acceptable under these same conditions, with most participants considering retail pharmacies an ideal venue for reaching individuals at HIV risk who are unable or unwilling to obtain PrEP at public clinics [9].

Several anticipated benefits drive the high acceptability. Participants, especially PrEP providers and clients, expected that pharmacy PrEP would circumvent the stigma that clients often face when accessing PrEP in HIV clinics [9]. The convenience factor is particularly compelling, as clients anticipated that pharmacy PrEP would save them travel time and fare since most lived within walking distance of their preferred retail pharmacy, with shorter wait times compared to clinics [9]. Many participants stated that pharmacy-based PrEP delivery would be more convenient than clinic-based delivery because retail pharmacies have longer opening-hours [9].

Adolescent Girls and Young Women (AGYW) in Kenya preferred pharmacies for accessing PrEP and were willing to pay for services even if available for free at clinics, citing accessibility, lack of queues and medication stockouts, privacy, anonymity, autonomy, and high-quality counselling as primary reasons [22,23].

This pattern of acceptance has been documented across the region. In formative research, Kenyan pharmacy providers and clients anticipated pharmacy-delivered PrEP services would be feasible and acceptable as long as services were private, respectful, safe and affordable, with PrEP clinicians and pharmacy providers expressing willingness to collaborate [8]. Other studies found that pharmacy-delivered PrEP was of interest to community members in Kenya, preferable to clinic-based delivery among young people in South Africa, and of interest to AGYW in Tanzania [8, 23]. A study from Nigeria shows similar enthusiasm, with stakeholders expressing support for pharmacy-based PrEP delivery while acknowledging challenges associated with clinic-based services, such as stigma, limited hours, and long wait times [10]. Research in Kenya found that participants expressed satisfaction with the safety, privacy, and respect they received during the process, along with the affordability of services at the community pharmacy [21].

However, acceptance comes with essential conditions. Both clients and providers stated that they would only find pharmacy PrEP agreeable if they felt confident that pharmacy PrEP providers were not "quacks" but possessed adequate PrEP knowledge and skills [9]. Clients also explained that their acceptance would depend on pharmacy providers' ability to maintain client confidentiality, treat clients with respect, and prioritise clients' well-being over profit-making [9]. The main concerns included potential

missed opportunities for counselling and clinical assessments among clients, with changes in client flow perceived to result in fewer opportunities for counselling, particularly among clients in HIV serodiscordant relationships who may need regular counselling [18]. Notably, one study in South Africa found that young women anticipated they would prefer clinics to pharmacies for accessing long-acting PrEP once it becomes available [8].

Discussion

Most studies are focused on pharmacy-based delivery of Oral PrEP, with only a few exploring long-acting injectable PrEP [12]. Moving away from relying solely on hospitals and clinics, introducing LAI-PrEP through pharmacies in Sub-Saharan Africa could change how HIV prevention services are delivered. Globally, studies have proven pharmacy-based delivery of PrEP as one of the successful models of PrEP delivery [24,25]. Community pharmacies can improve access, particularly for underserved populations. However, it also brings challenges, such as the need for proper regulation, pharmacist training, reliable supply systems, and long-term planning. Although the literature shows strong interest from stakeholders, including pharmacists and end-users, putting this model into practice remains complex.

First, the feasibility of pharmacy-based LAI-PrEP is largely contingent upon structural and regulatory readiness, which remains uneven across the region. Many countries have yet to formalise the legal scope under which pharmacists can administer injectables. The slow pace of regulatory change may also suggest that policymakers are uncertain about the changing role of pharmacists in public health. For many institutions, pharmacists are still primarily viewed as medicine dispensers, rather than frontline healthcare providers. This long-standing perception may be a key reason for the resistance to expanding their responsibilities.

While pilot projects often serve as proof of concept, there is a risk that their success may be mistakenly taken as evidence of systemic readiness. For instance, demonstration studies in Kenya and South Africa have shown high user satisfaction and feasibility of pharmacy-based oral PrEP delivery; however, the sustainability of this approach remains unclear once external funding ceases. The challenge, then, lies in distinguishing between what is temporarily achievable under optimised conditions and what is structurally replicable at scale.

Maintaining the cold chain, a necessary condition for LAI-PrEP, was repeatedly identified as a significant obstacle. Although this issue can be addressed technically, it raises serious concerns about cost, energy reliability, and whether such systems can be prioritised in settings with limited resources. Even in urban pharmacies with better infrastructure, inconsistencies in cold storage maintenance are not uncommon.

Furthermore, the training gaps among pharmacy personnel regarding PrEP counselling and injectable administration suggest a broader issue: the health workforce strategy in the region may not yet recognise pharmacists as preventive care providers.

Although willingness to receive LAI-PrEP in pharmacies was reportedly high [9], probably such acceptability reflects an aspirational preference, an expression of what respondents hope the system might become, rather than a full endorsement of its current state. The preference for clinic-based delivery of injectable PrEP among South African young women suggests that the benefits of pharmacy delivery may not translate directly from oral to injectable formulations, possibly due to the clinical nature of injection administration, need for medical supervision, or other factors specific to long-acting injectable products.

The limited research on this specific topic also represents a significant knowledge gap, particularly given the potential advantages that pharmacy-based delivery has demonstrated for oral PrEP access. To guide context-sensitive planning and help align implementation strategies across health systems, a logic model has been developed and included in Appendix 1. It synthesizes the necessary inputs, key activities, and intended outcomes for effective pharmacy-based LAI-PrEP delivery and is intended as a conceptual framework to support adaptation, evaluation, and policy engagement. This model aligns with Differentiated Service Delivery (DSD) frameworks for HIV care, in that, it is a people living with HIV (PLHIV)-centered approach, which will simplify provision of services to meet the diverse needs of PLHIV. This model can reduce the burden of PLHIV stigmatization, with consequent improvement on HIV care accessibility and efficiency.

Conclusion

The opportunities for pharmacy-based delivery of LAI-PrEP in Sub-Saharan Africa include that community pharmacies are highly accessible, affordable, and trusted, making them well-positioned to expand access. Significant barriers remain, including unclear policies on task-shifting, weak regulatory frameworks, limited pharmacist training, and cold-chain infrastructure. Improved access to LAI-PrEP and retention of the impact are crucial to the realization of the UNAIDS 95-95-95 targets and termination of AIDS by 2030.

Recommendations

Effective implementation will require regulatory reform, investment in workforce capacity, and robust monitoring to avoid deepening health inequities. In addition, interdisciplinary and context-specific implementation studies to generate further local data are critical to determine how pharmacy models can be scaled sustainably and equitably.

Conflict of Interest

The authors declare no conflict of interest.

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Authors' Contributions

FE and OE conceptualised the study. Literature retrieval was carried out by FE, OE, RB, MD, IN, LO, CO, and DU. Analysis was conducted by FE, OE, CO, RB and MD. The initial draft was prepared by FE, OE, RB, IN and MD. Proofreading was carried out by FE, OE, RB, MD, IN, LO, CO, and DU. The final approval of the manuscript was done by FE, OE, RB, MD, IN, LO, CO, and DU.

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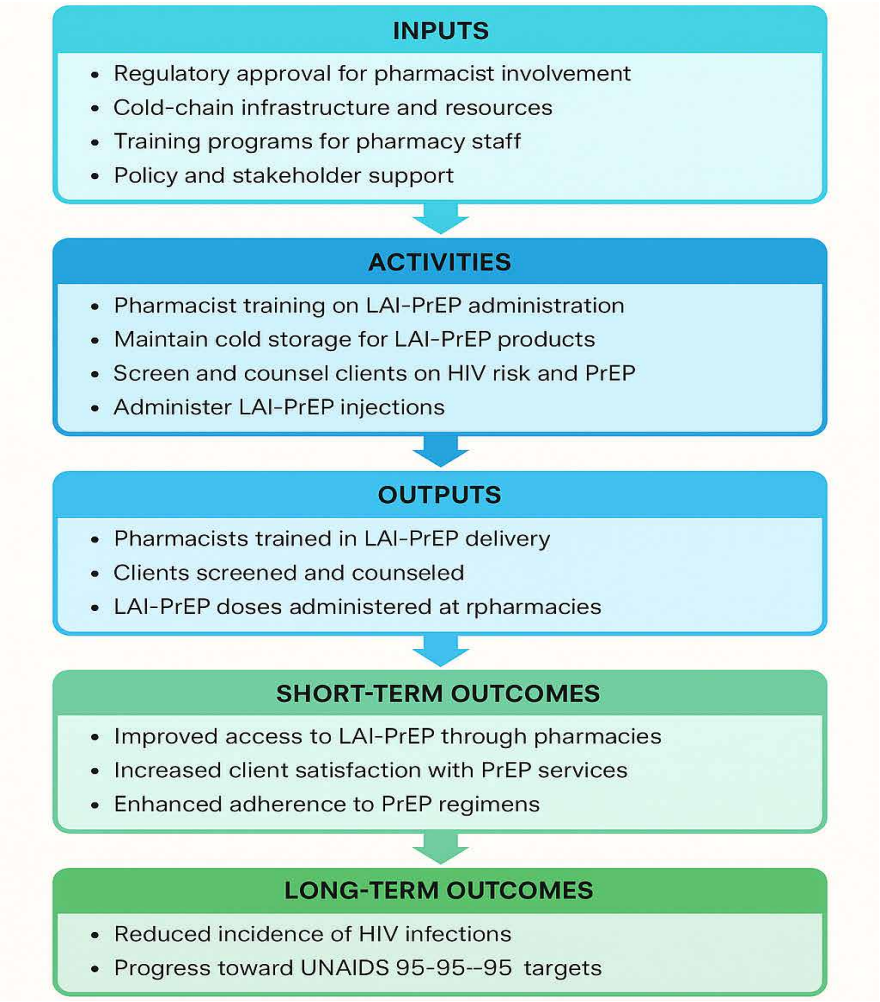
Appendix 1

Logic Model for Pharmacy-Based Delivery of Long-Acting Injectable HIV Pre-Exposure Prophylaxis



Bridging the gap in attainment of Universal Healthcare Coverage: the role of Pharmacists

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Abstract

Despite global commitments to Universal Health Coverage (UHC), nearly half the world's population lacks access to essential health services, often resulting in financial hardship. In Kenya, UHC is a national priority, yet systemic gaps persist, particularly in the integration of pharmacists into the healthcare framework. This paper explores the evolving role of pharmacists in Kenya's health system and their potential to bridge the UHC gap. Using a qualitative literature review of policy documents, health system reports, and peer-reviewed publications, the study identifies barriers to pharmacist inclusion, highlights their infrastructure and capabilities, and outlines the broader impact of their integration beyond cost savings. Findings suggest that pharmacists are well-positioned to improve access, enhance preventive care, and strengthen health system efficiency. Policy reforms and expanded scope of practice are recommended to fully leverage their potential.

Keywords: *Universal Health Coverage, Pharmacists, Kenya, Health Systems, Healthcare Access*

Introduction

Universal Health Coverage (UHC) is a cornerstone of the Sustainable Development Goals (SDGs), aiming to ensure that all individuals receive quality health services without financial hardship. According to the World Bank and WHO nearly 50% of the global population lacks full coverage, with out-of-pocket payments pushing millions into poverty (1). In Kenya, UHC is one of the "Big Four" development priorities, aligning with the UN's Sustainable Development Goals (SDGs). Currently, Healthcare is one of the five core pillars of the Bottom-Up Economic Transformation Agenda (BETA) under the Fourth Medium-Term Plan (MTP IV, 2023–2027) (2). Achieving UHC requires a multidisciplinary approach, and pharmacists are critical yet underutilized contributors. Kenya's UHC Policy 2020–2030 outlines objectives to strengthen access, improve service quality, and protect citizens from health-related financial risks (3). However, the policy does not fully integrate pharmacists into its strategic framework, limiting their potential contributions.

Pharmacists have transitioned from traditional roles of dispensing medication to more dynamic functions in public health, patient education, and chronic disease management. Pharmacists' contributions to rational drug use and health promotion are well documented (4). In Low and Middle-Income Countries (LMICs), pharmacists often serve as the most accessible healthcare providers (5), especially in rural areas where physician density is low.

Despite global commitments to UHC, nearly half the world's population continues to lack access to essential health services, often resulting in financial hardship (6). In Kenya, systemic gaps persist, particularly in the integration of pharmacists into the broader healthcare framework. Pharmacists are often viewed narrowly as dispensers of medication, rather than as frontline healthcare providers capable of delivering preventive care, chronic disease management, and health education. This limited perception, reinforced by fragmented policy frameworks and minimal interdisciplinary collaboration, has excluded them from many UHC initiatives despite their accessibility and expertise (3).

Nevertheless, pharmacists are uniquely positioned to support UHC due to their infrastructure, widespread presence in both urban and rural settings, and expertise in medication therapy management, public health services, and patient-centered care (7). Kenya has a robust pharmacy infrastructure that includes thousands of registered pharmacies, a growing cadre of trained professionals with expertise in pharmacovigilance, immunization, and patient counseling, and digitized pharmaceutical systems that support inventory tracking, medication safety, and supply chain monitoring (8). These assets make pharmacists a critical yet overlooked resource in achieving equitable and efficient healthcare delivery, especially in underserved regions.

While pharmacists can help reduce healthcare costs through rational drug use and improved adherence, integrating them into UHC could yield transformative breakthroughs. Their inclusion can improve health outcomes through early detection of disease and medication optimization; reduce hospital burden by managing chronic conditions and minimizing avoidable admissions; enhance patient empowerment by bridging the gap between complex medical information and community understanding (4); and expand access to preventive services such as immunizations and screenings (5). Moreover, pharmacists can serve as vital connectors between communities and formal health systems, particularly in underserved areas.

This paper explores the evolving role of pharmacists in Kenya's healthcare system and their potential to bridge the UHC gap; it offers a scalable model for other LMICs facing similar challenges (9).

Methodology

This study employed a qualitative literature review to examine the role of pharmacists in advancing Universal Health Coverage (UHC) in Kenya, with broader implications for low- and middle-income countries (LMICs). The review focused on publicly available sources, including peer-reviewed journal articles, WHO publications, Kenya's national health strategies, and health system reports.

Databases searched included PubMed, Google Scholar, and the WHO Global Health Observatory. Keywords used in the search strategy included "pharmacists," "Universal Health Coverage," "Kenya," and "LMICs." Relevant documents were screened for thematic relevance and methodological rigor. Extracted data were coded into thematic categories such as: Medication management, Public health services, Policy integration, Infrastructure readiness

Insights from Kenya were compared with case studies from other LMICs to identify scalable practices and contextual differences. The study relied exclusively on publicly accessible documents, which may exclude unpublished or region-specific practices. In cases where source material lacked granular detail on pharmacists' roles, interpretive synthesis was applied to derive contextual meaning.

Findings and Discussions

Pharmacists as Frontline Providers

Pharmacists in Kenya frequently serve as the initial point of contact for health-related advice, particularly in underserved regions where access to physicians is limited. Their widespread presence and established trust within communities position them as key facilitators of promotive and preventive healthcare services. Traditionally, pharmacists have operated within retail and hospital settings, primarily focusing on medication dispensing and patient counseling. However, their roles are evolving to include immunization delivery, chronic disease screening, and health education initiatives (7). This transition, highlights pharmacists' expanding contributions to primary healthcare teams (7).

Despite their growing relevance, pharmacists face systemic barriers that hinder their full integration into Kenya's Universal Health Coverage (UHC) framework. One major challenge is policy fragmentation; national health strategies often fail to recognize pharmacists as core healthcare providers. For instance, the Kenya UHC Policy 2020–2030 outlines broad objectives for improving access and service quality but does not explicitly incorporate pharmacists into its strategic implementation plans (3). Furthermore, restrictive legal and institutional frameworks—such as those outlined in the Health Act of 2017—limit pharmacists' scope of practice, preventing them from offering preventive and diagnostic services (10). Workforce distribution also presents a significant challenge. While urban centers benefit from a relatively high concentration of qualified pharmacists, rural and remote areas continue to experience critical shortages (6). This disparity undermines equitable access to pharmaceutical care and weakens the potential of pharmacists to contribute meaningfully to UHC goals. Additionally, limited interprofessional collaboration further constrains pharmacists' ability to engage in multidisciplinary care teams, reducing opportunities for integrated service delivery.

Pharmacists function within patient-centered primary care teams, serving as a bridge between multidisciplinary health professionals and UHC goals (4). They contribute directly to key UHC goals such as improved access to essential medicines, better health outcomes, and financial risk protection, as illustrated in Figure 1a. In addition, pharmacist's involvement across five key domains of UHC: promotive, preventive, curative, rehabilitative, and palliative care is illustrated in Figures 1b. This integrated role highlights their potential to strengthen health systems and improve access to quality care.

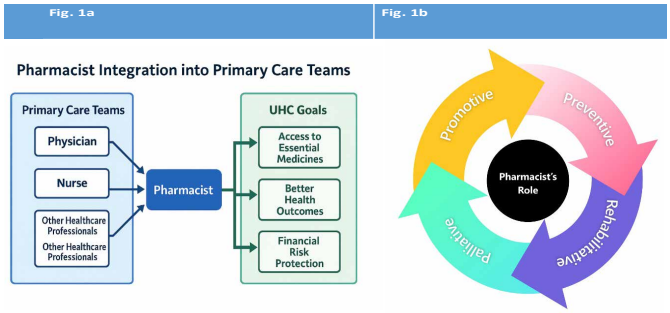

Figure 1. Pharmacist's Role across the Universal Health Coverage (UHC) Continuum

Medication Management and Rational Use

Effective medication management is a cornerstone of quality healthcare delivery. Pharmacists play a pivotal role in ensuring the rational use of medicines, monitoring drug interactions, and managing pharmaceutical inventory to prevent stock-outs. Their expertise in pharmacovigilance enhances patient safety and contributes to cost-effective care (11). Integrating pharmacists into Kenya's Universal Health Coverage (UHC) framework can significantly improve medication safety. Nationally, over 60% of adverse drug reactions (ADRs) go unreported; however, counties with active pharmacist-led pharmacovigilance programs demonstrate up to fivefold higher reporting rates, underscoring the impact of pharmacist involvement (12).

Beyond cost containment, broader integration of pharmacists into UHC yields transformative health system benefits. These include improved medication adherence and safety through patient counseling and therapeutic monitoring (13), expanded preventive care services such as immunizations, screenings, and health promotion (14), reduced hospital burden through chronic disease management and triage of minor ailments (3), and enhanced

equity as community pharmacies increasingly serve marginalized populations (7).

Drug Interaction Monitoring and Stewardship

Pharmacists are central to pharmacovigilance and drug interaction monitoring. Adverse Drug Reaction (ADR) underreporting remains a major concern in Kenya. A study conducted in Kirinyaga County revealed that only 5% of ADRs were reported to the Pharmacy and Poisons Board (PPB), despite the county ranking fifth nationally (12). The Pharmacy and Poisons (Pharmacovigilance and Post Market Surveillance) Rules, 2022 mandate pharmacists to monitor, document, and report drug interactions and adverse effects, reinforcing their role in medication safety (15).

Best practice discourages dispensing medications without diagnostic confirmation. Kenya's National Pharmaceutical Policy advocates for evidence-based prescribing and dispensing, emphasizing the need for laboratory support (12). Pharmacists can verify lab results through integrated digital platforms and point-of-care testing (POCT), ensuring stewardship and reducing empirical treatment (12). To embed stewardship within Universal Health Coverage (UHC), pharmacists will verify lab results before dispensing through integrated digital platforms and lab portals; monitor drug interactions using national pharmacovigilance tools and reporting systems mandated by PPB; educate patients on the importance of diagnostics and risks of self-medication; and collaborate with clinicians to ensure prescriptions align with diagnostic findings.

Kenya's pharmacy sector is well-positioned to support UHC: Digital platforms such as e-prescription systems and inventory tracking tools enhance medication safety and access (12); Training institutions produce a growing number of pharmacists with clinical and public health competencies (16, 17); Community pharmacies offer walk-in access, reducing barriers to care for underserved populations (15).

Training in pharmacovigilance and diagnostics is now embedded in Continuing Professional Development (CPD) programs and postgraduate modules. Policy support from the Ministry of Health includes the Quality Healthcare and Patient Safety Bill, alongside reforms at Kenya Medical Supplies Authority (KEMSA) and the Kenya Health Products & Technologies Regulatory Authority (KHPTRA) aimed at standardizing safe dispensing practices (18).

Modern pharmacists engage in immunization programs, health screenings, and chronic disease management. They also contribute to policy development, supply chain optimization, and health education campaigns. These expanded roles align with the World Health Organization's vision for integrated, people-centered health services (19). Countries such as Rwanda and Ghana have successfully integrated pharmacists into public health initiatives. Ghana's pharmacist-led UHC model improved medication access and reduced preventable hospitalizations, offering a scalable blueprint for Kenya (13).

Challenges and Opportunities

Despite their potential, pharmacists face regulatory, infrastructural, and recognition barriers. Limited integration into national health strategies and lack of standardized training hinder their full contribution (19). However, initiatives like Kenya's NHIF reforms and task-shifting policies offer opportunities for greater pharmacist involvement (20).

Key milestones and actions needed to fully integrate pharmacists into Kenya's UHC framework are outlined in Fig. 2, emphasizing foundational steps such as monitoring and evaluation, and culminating in formal high-level policy recognition. Each layer builds upon the previous, emphasizing a strategic and sustainable integration of pharmacists into the national health system.

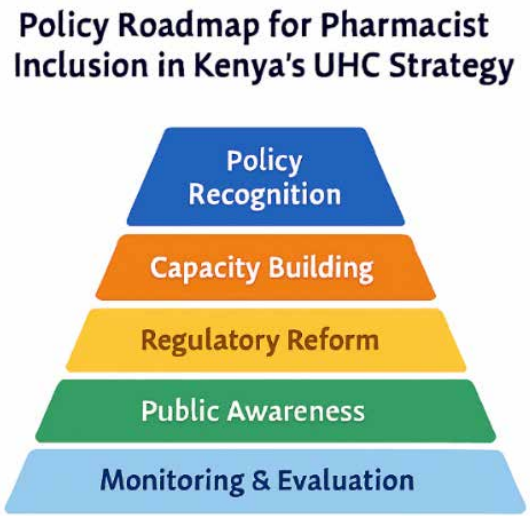

Figure 2. Policy Roadmap for Pharmacist Inclusion in Kenya's UHC Strategy.

A conceptual diagram illustrating the pharmacist's role across the UHC spectrum: promotive, preventive, curative, rehabilitative, and palliative care is shown in Table 1.

Table 1: Expanded Roles of Pharmacists in UHC

Traditional Role	Expanded Role in UHC	Impact on Health System
Dispensing medications	Medication therapy management	Improved adherence and reduced complications
Inventory management	Supply chain optimization	Reduced stock-outs and waste
Patient counseling	Chronic disease monitoring and education	Better disease control and prevention
Product distribution	Immunization and screening services	Increased coverage and early detection

Conclusion and Recommendations

Conclusion

Kenya's UHC efforts face persistent gaps in access and service delivery. Pharmacists, though underutilized, have the infrastructure and expertise to bridge these gaps. Their inclusion can improve outcomes, reduce costs, and promote

equity. Recognizing pharmacists as essential UHC providers is both a strategic and necessary step.

Recommendations

To fully leverage pharmacists in achieving UHC, the following actions are recommended:

1. **Policy Reform:** Revise national health strategies to formally recognize pharmacists as core UHC providers. Kenya UHC Policy 2020–2030 is the cornerstone document guiding UHC implementation. It must explicitly recognize pharmacists as frontline providers in primary care, preventive services, and chronic disease management (3). Sessional Paper No. 2 of 2017 (21) can be leveraged to advocate for pharmacist inclusion in UHC workforce planning
2. **Scope Expansion:** Broaden pharmacists' legal scope of practice to include preventive services, chronic disease management, and immunization. Health Act 2017 is the legislation that governs health service delivery and professional roles. Amendments could expand pharmacists' scope to include immunization, screening, and health education (10).
3. **Interprofessional Collaboration:** Foster stronger partnerships between pharmacists, physicians, nurses, and community health workers.
4. **Infrastructure Support:** Strengthen digital health tools and supply chain systems to enhance pharmaceutical service delivery.
5. **Community Engagement:** Promote awareness of pharmacists' expanded roles to build public trust and utilization. Kenya Health Policy 2014–2030, the broader health sector strategy should be revised to include pharmacists in community health and public health delivery models. Countries like Rwanda and Ghana have successfully integrated pharmacists into public health initiatives. Ghana's pharmacist-led UHC model improved medication access and reduced preventable hospitalizations (13), offering a scalable blueprint for Kenya.
6. **Capacity Building:** Invest in training programs that equip pharmacists with public health and clinical competencies. These skills are increasingly offered through specialized courses like the ***Public Health Pharmacy and Vaccination Programs Training Course*** in Kenya, which blends theory with practical case studies (17). Key training areas include ***Public Health Principles***: Epidemiology, health promotion, and disease prevention; ***Immunization Practices***: Safe vaccine administration and cold chain management; ***Pharmacovigilance***: Monitoring and reporting adverse drug reactions; ***Health Communication***: Patient counseling and community engagement; ***Supply Chain Management***: Ensuring availability and safety of essential medicines; and ***Pandemic Preparedness***: Responding to outbreaks and supporting emergency health services (17).

These trainings can be acquired at various levels; i) **Undergraduate Level**: Public health modules should be embedded in Bachelor of Pharmacy curricula to build foundational competencies, ii) I**nternship and Licensing Phase**: Practical exposure during internships can reinforce public health roles, iii) **Postgraduate and CPD**: Continuous Professional Development (CPD) programs should offer targeted training in emerging areas like digital health, immunization, and chronic care, iv), **Policy-Driven Upskilling**: The Ministry of Health is working with education regulators to align training institutions with UHC goals, ensuring pharmacists are prepared for expanded roles (21).

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Practice Review: Best Practices in Investigational Product Handling for Oncology Clinical Trials

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Abstract

The handling of investigational products (IP) in oncology clinical trials presents complex challenges due to the hazardous nature of many agents, narrow therapeutic indices, and the personalized dosing regimens often required. Ensuring the safety of patients and the integrity of trial data depends heavily on how the IP is stored, accounted for, and handled by qualified personnel. These elements form the backbone of operational compliance must be implemented with rigor at every clinical trial site. This article explores these three pillars (storage, accountability, and personnel qualifications), highlighting the best practices and common pitfalls in oncology IP handling. A lapse in adhering to set standards during clinical trials leads to financial losses, missed deadlines, dissatisfied stakeholders, and missed opportunities to make promising therapies available to patients in need of these drugs. Ultimately, consistent implementation of these best practices strengthens trial quality, safeguards patient safety, and supports the successful development of effective oncology therapies.

Key Words: *Oncology, clinical trials, investigational products*.

Introduction

Cancer remains one of the most formidable global health challenges, exerting a profound impact on individuals, families, and healthcare systems. In 2020 alone, cancer accounted for nearly 10 million deaths worldwide [1]. This burden continues to grow, with projections indicating a steady rise in both new cases and cancer-related mortality in the coming decades.

In response to this escalating crisis, clinical trials serve as a cornerstone in the development of effective cancer therapies. These trials not only generate evidence-based answers to pressing clinical questions but also help translate biological insights into targeted treatment options. By systematically evaluating new drugs, combinations, and therapeutic strategies, clinical trials provide the scientific pathway through which potential cancer treatments are identified, refined, and ultimately approved for patient use. They bridge the gap between laboratory discoveries and real-world clinical practice, ensuring that promising innovations can be safely and effectively brought to the patients who need them most [2]. The oncology research landscape has evolved significantly in recent years, emphasizing personalized medicine, biomarker-driven strategies, and novel therapeutic combinations.

Within this complex environment, the handling of IP in oncology clinical trials presents unique operational and regulatory challenges. Unlike other therapeutic areas, oncology trials often involve:

Multi-agent regimens - Oncology trials often use multiple drugs together, making IP handling more complex. Pharmacists must handle, store, label, and track several agents at the same time, while managing potential drug-drug interactions. Dispensing is tightly controlled by treatment cycles and protocols, increasing the risk of dosing or timing errors. Each drug requires separate accountability records, which adds workload and increases audit risk.

Narrow therapeutic indices - Oncology investigational products often have a narrow therapeutic index, meaning small dosing errors can quickly lead to serious toxicity or treatment failure. This requires highly precise, individualized dosing based on patient-specific factors, frequent dose adjustments guided by laboratory and clinical findings, rigorous double-check procedures, and controlled preparation in specialized safety environments.

Heightened safety concerns - Oncology IPs carry heightened safety risks and require strict handling procedures to protect staff and the environment. This includes mandatory use of personal protective equipment (PPE), secure hazardous drug storage, use of closed transfer systems to prevent spills and exposure, ready access to spill response tools, and proper disposal of waste as cytotoxic or biohazardous materials under strict regulations.

These factors demand a meticulous approach to IP handling to ensure patient safety, maintain product integrity, and uphold data and regulatory compliance.

The success of an oncology clinical trial depends not only on the scientific innovation behind the investigational molecule but also on the precision with which it is handled at the clinical site. Every step from storage and preparation to administration and documentation must be carefully controlled. Even minor deviations can compromise the intended therapeutic effect or the validity of trial data. Therefore, robust IP management systems are essential to support the safe and effective conduct of oncology trials.

Effective IP handling is not the responsibility of a single individual; it is a team effort. Investigators, pharmacists, CRCs (Clinical Research coordinators), sponsors, and monitors must work together closely to ensure protocol adherence, proper documentation, and timely communication. This multidisciplinary coordination is essential to minimize errors, uphold regulatory standards, and support high-quality oncology research [3].

Objective

To outline the best practices and operational strategies for IP handling in oncology trials, focusing specifically on storage, accountability, and personnel qualification at clinical trial sites.

Significance

Many oncology IPs are biologically sensitive, with short shelf lives or narrow temperature ranges that demand strict storage and handling protocols. Even minor deviations can compromise patient safety and trial integrity [4]. Any deviation in temperature or expiration tracking could render the product ineffective or unsafe. This makes real-time monitoring and staff training non-negotiable elements of IP handling.

The success rate of new anticancer agents that enter clinical testing and achieve regulatory approval is low, only 3.4% [5]. How these IPs are handled could partly contribute to this failure rate. This highlights how critical every aspect of the clinical trial process is. Given the substantial investment and high risk, proper IP handling ensures that investigational agents are administered correctly, maintaining the scientific validity of the trial.

Scope and Methodology

This practice review synthesizes best practices for oncology IP handling through a comprehensive literature review of international regulatory guidance, institutional policies, and expert consultations with clinical trial pharmacists and oncology investigators. The article aims to provide actionable operational guidance on storage, accountability, and personnel qualifications for clinical trial sites engaged in oncology research.

Key Aspects of IP Handling

This will focus on three key aspects of IP handling: storage, which include proper temperature control, security measures, segregation, and continuous monitoring; Accountability procedures, covering comprehensive documentation, tracking, reconciliation, and reporting throughout the product's lifecycle; and personnel qualifications, emphasizing the necessary training, competencies, and appropriate delegation of responsibilities for all staff involved in handling the investigational product.

Storage

Storage of Oncology IPs and Clinical Trial Pharmacy Requirements

Research site pharmacies must remain out of bounds for blinded study staff and blinded clinical research associates (CRAs), unless access is required for a protocol-mandated procedure. In such cases, a formal documented request should be submitted through the Principal Investigator (PI) and Study Pharmacist. Unblinded research personnel and unblinded CRAs should obtain pharmacy access by completing an access log capturing their identity, role, time of entry, and reason for visiting the pharmacy. These controls are essential to ensure IP security, protect blinding, and maintain compliance with accountability and good clinical practice (GCP) requirements and align with ICH GCP E6(R2), Section 5.13.5, and FDA Guidance on Blinding in Clinical Trials (2018), which require maintaining blinding integrity and restricting IP access to authorized personnel only.

Proper storage of IPs is a cornerstone of oncology clinical trial conduct. Challenges include maintaining appropriate packaging and labeling to avoid degradation or contamination, sustaining correct environmental conditions, preventing blinding breaches, and meeting regulatory and GCP-compliant documentation standards. Improper storage can cause IP degradation, contamination, or loss of stability, ultimately compromising participant safety or invalidating study results.

Many IPs that require cold storage including biologics and cell and gene therapies require ultra-low temperature storage during shipping. However, factors like customs delays, temperature fluctuations during transit, and dry ice sublimation pose risks to product integrity. This puts drug efficacy and safety at risk, which can invalidate entire batches and cause significant trial setbacks [7]. Optimized cold chain logistics processes such as pre-approved customs clearance, stability-tested packaging, and real-time temperature monitoring should be put in place to safeguard products during transit [8].

Oncology IPs often require stringent storage conditions due to chemical instability and toxicity. Products such as monoclonal antibodies, cellular therapies, and cytotoxics may require refrigeration (2–8°C), freezing (–20°C), or cryogenic storage (below –150°C), all with tight temperature tolerances [9]. Clinical trial sites must implement validated temperature monitoring systems with alarm functionality and well-documented excursion protocols [10].

Environmental risk factors also disrupt proper storage such as light exposure for photosensitive agents, humidity variations that damage biologics and oral solids, or power outages that compromise refrigeration. There should be a dedicated, segregated space for investigational drugs; overcrowding increases the risk of selecting look-alike products, missing expiry dates, or compromising blinding. Expired or damaged products, contamination, and cross-contamination are more likely when storage areas are poorly

designed or inadequately segregated. The IP lifecycle is summarized in figure 1.

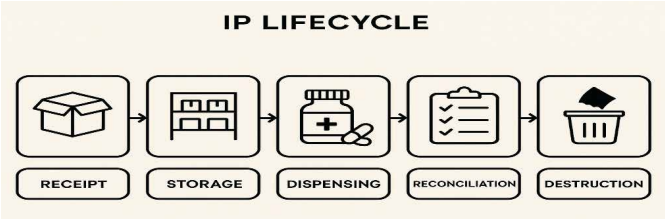

Figure 1 shows the IP lifecycle

Core Storage Requirements of a Clinical Trial Pharmacy

1. Secure, Access-Controlled Storage

The pharmacy must restrict entry to authorized personnel only, using locked doors, keys, coded access, or key-card systems. Logs documenting entry and purpose of visit ensure chain of custody and support audit-readiness. These measures prevent diversion, maintain blinding, and meet GCP traceability standards.

2. Temperature-Controlled Storage

Pharmacies require calibrated refrigerators and freezers capable of maintaining defined ranges (ambient, 2–8°C, –20°C, –80°C, or cryogenic) essential for product stability. Temperature deviations may cause loss of potency, participant harm, or invalidation of results.

3. Continuous Temperature Monitoring

Continuous monitoring systems and digital data loggers with 24-hour recording, SMS/email alarms, and automated backup storage enable immediate response to excursions and provide defensible documentation for audits and inspections.

4. Humidity Control

Moisture-sensitive IPs such as biologics and certain oral solids require controlled humidity environments. Use of desiccant cabinets or humidity-controlled rooms prevents clumping, microbial growth, and degradation.

5. Segregation of Study Products

Segregation of IPs by study, blinded vs. unblinded stock, active vs. expired/quarantined products, prevents dispensing errors, maintains blinding integrity, and ensures proper chain-of-custody documentation.

6. Adequate Shelving and Organization

Shelving must allow clear labeling, visibility of expiry dates, and prevent crowding. IPs should never be stored on the floor or near potential contaminants.

7. Clean, Pest-Free, Controlled Environment

A well-maintained environment with a regular cleaning schedule, pest control, and proper ventilation minimizes contamination and supports GMP/GCP compliance.

8. Backup Power Supply

Uninterrupted power supply (UPS), generators, or solar backup systems are essential to protect temperature-sensitive IPs during outages especially critical for biologics and vaccines and in low-resource settings with unstable power supply.

9. Validated and Calibrated Storage Equipment

Storage equipment must undergo installation, operational, and performance qualification (IQ/OQ/PQ). Temperature devices require scheduled calibration, and sites must maintain evidence of equipment performance for regulatory scrutiny.

10. Quarantine and Disposal Areas

Designated segregated areas for expired, damaged, or returned IP ensure that non-compliant stock cannot be inadvertently dispensed. Disposal should follow sponsor and national regulatory SOPs.

11. Proper Documentation and Record Storage

Accountability logs, temperature records, dispensing logs, training records, and chain-of-custody documents (paper or electronic) must be maintained to support GCP compliance and enable smooth audits/inspections.

Procedures for Documenting and Reporting Temperature Excursions

Any instance in which an IP is exposed to temperatures outside the manufacturer-specified range must be thoroughly documented and escalated without delay to protect product integrity and participant safety. When an excursion is identified, affected IP should be immediately quarantined, clearly labelled as "Quarantine Temperature Excursion Pending Assessment," and removed from clinical use. Staff should stabilise the storage conditions by restoring the equipment to the correct temperature range and confirming that it is functioning properly. Initial details including the date, time, temperature reading, and method of detection, such as an alarm, data logger alert, or visual inspection must be captured promptly to support accurate reporting.

All temperature excursions must be documented in real time using site-specific or sponsor-provided tools. The primary record is the Temperature Excursion or Deviation Log, which should detail the start and end times of the excursion, recorded temperature values, duration, affected IP information (such as batch or lot numbers and quantities), initial actions taken by staff, and a preliminary assessment of impact. The name and signature of the reporting staff member must also be included. When an excursion is linked to equipment or facility issues, an Equipment/Facility Deviation Record should be completed to capture the nature of the malfunction, any corrective and preventive actions (CAPA), and details of maintenance or repairs conducted. In all cases, data logger printouts or digital temperature records must be attached to provide a timestamped excursion profile for sponsor and quality assurance review.

To ensure timely decision-making regarding IP disposition, escalation must follow strict timelines. Within the first 0–30 minutes, the designated IP pharmacist or study coordinator should be notified, and the deviation or temperature excursion form should be initiated (Table 1). Within 1–2 hours, the sponsor or medical monitor must be informed through the communication pathway outlined in the pharmacy manual or study-specific instructions, and all available documentations, such as excursion details, data logger outputs, and quarantine status should be provided. A formal deviation report must be submitted within 24 hours via the sponsor's electronic system (e.g., eTMF or CTMS), along with documentation of any interim CAPA. Between 48 and 72 hours, the site should receive the sponsor's or manufacturer's disposition decision (such as "use as is," continued quarantine, or destruction) and must document final CAPA before closing the deviation according to site SOPs.

The sponsor or manufacturer assesses each excursion based on stability data, duration and severity of exposure, cumulative temperature burden, and the sensitivity of the IP formulation and packaging. Their disposition decision must be documented in writing and appended to the excursion log. After the deviation is closed, the site must evaluate the root cause—whether human error, equipment malfunction, or power fluctuation and implement appropriate CAPA, which may include staff retraining, equipment servicing, increased monitoring frequency, or installation of automated alarm systems. All CAPA activities and follow-up timelines must be documented to ensure sustained compliance.

Finally, all records related to temperature excursions must be archived in accordance with Good Clinical Practice (GCP) and local regulatory requirements, typically for at least two years after study completion or longer if required by the sponsor (Table 1). Archived documents should include completed excursion or deviation forms, data logger reports, disposition letters from the sponsor, and all CAPA documentation, ensuring a complete and traceable record of the event.

Table 1. Summary of Temperature Excursion Documentation and Reporting.

Step	Actions Required	Documentation	Escalation Timeline
1. Detect Excursion	- Identify temperature out of range - Quarantine affected IP - Stabilize storage conditions	- Initial log entry (time, temperature, device)	0–30 minutes Notify IP pharmacist/study coordinator
2. Record Details	- Capture duration and temperature profile - Verify equipment function	- Temperature Excursion/ Deviation Log - Data logger printout/download	Within 1–2 hours Notify sponsor/ medical monitor with available documentation
3. Submit Formal Report	- Complete formal deviation form - Upload documents to CTMS/eTMF	- Site deviation record - Equipment/ facility deviation form (if applicable)	Within 24 hours
4. Sponsor Assessment	- Sponsor/ manufacturer reviews stability data - Determines IP disposition	- Sponsor disposition email/ letter	Within 48–72 hours Implement final decision
5. Implement CAPA	- Identify root cause - Conduct staff retraining/ maintenance - Update procedures if required	- CAPA plan - Follow-up verification notes	After disposition issued
6. Archive Records	- Store all logs, disposition letters, CAPA - Retain per GCP & sponsor policy	- Complete documentation package	End of trial + required retention period

Hazardous Drug Storage (USP <800>)

Hazardous drugs must be stored in compliance with USP <800> guidelines, which mandate negative pressure rooms, externally vented containment storage, and secure containment systems to protect personnel and the environment (USP <800>). Proper segregation from routine pharmacy stock prevents mix-ups, protects against exposure, and ensures product integrity. Availability of full USP <800> infrastructure varies widely: high-resource centers may meet the standard, while many low- and middle-income countries, including Kenya, face limitations due to cost, space, and engineering requirements.

Where full USP <800> facilities are unavailable, risk-based mitigation strategies include:

- Segregated, clearly labeled hazardous drug areas
- Storage in sealed secondary containers
- Mandatory PPE (chemotherapy gloves, gowns, masks)
- Use of spill kits and emergency response procedures
- Restricting access to trained personnel
- Routine environmental cleaning with validated agents
- Documenting a Hazardous Drug Risk Assessment (HDRA)

Sponsors may permit handling under enhanced PPE if IP risk is low; however, highly cytotoxic IPs may require storage or preparation at referral pharmacies compliant with USP <800> standards.

Challenges in Low-Income Settings and Mitigation Strategies

Challenges	Challenge description	Mitigation
1. Power Instability	-Frequent outages threaten temperature-sensitive IPs.	- solar-powered WHO-PQ refrigerators, UPS systems, generators, and hybrid backup systems.
2. Limited Access to Specialized Equipment	- Ultra-low freezers and automated temperature systems may be unaffordable.	- sponsor-provided equipment, shared infrastructure (e.g., AMPATH network).
3. Supply Chain and Maintenance Gaps	- Repairs, calibration, and spare parts may be difficult to obtain	- local calibration providers, preventive maintenance contracts
4. Space Limitations	- Older or repurposed facilities may have inadequate storage rooms.	- modular container-based pharmacies, reorganized shelving, SOP-guided workflows.

5. Limited Trained Pharmacy Personne	- Few staff have prior experience with IP handling.	- sponsor-funded GCP/IP training, on-site mentorship (e.g., at MP Shah, Aga Khan University, KEMRI).
6. Harsh Environmental Conditions	-High temperatures and humidity compromise IP integrity.	- air conditioning, dehumidifiers, insulated passive transport containers.

IP Accountability

IP accountability refers to the systematic process of documenting, tracking, and verifying the movement and use of study medications throughout their entire lifecycle from release by the sponsor, shipment to site, receipt, storage, dispensing to participants, returns, reconciliation, and final destruction. In essence, accountability ensures full traceability of every unit of IP, confirming that it is used only as intended, by the correct participant, at the correct time, and under approved conditions.

Importance of IP Accountability in Clinical Trials

Proper accountability is essential for ensuring participant safety, data integrity, and regulatory compliance. Inadequate accountability can introduce major risks mislabeling, dispensing errors, stock discrepancies, or undocumented temperature excursions which may compromise product integrity and ultimately threaten trial validity. Regulators expect sites to demonstrate complete traceability; failure to do so may result in findings during inspections, protocol deviations, or rejection of trial data.

If accountability is compromised, it can lead to inconsistencies in safety and efficacy assessments, undermining confidence in trial outcomes and compromising scientific integrity. Ultimately, strong accountability protects participants, preserves blinding, and supports compliance with GCP and sponsor requirements.

How IP Accountability Is Conducted

Accountability should be demonstrated by maintaining complete traceability of the IP from initial release, ordering, allocation, and dispensing, through return-to-site, reconciliation, and eventual destruction. If adequate accountability in these areas cannot be demonstrated, trial results are at risk.

Although IP accountability compliance is essential, there are no clearly defined regulatory paths for how sites must perform accountability, as regulations do not specify exact tools or systems for use [11]. Consequently, sites may adopt paper-based logs, electronic tools, or hybrid systems.

Key site-level activities include:

1. ***Receipt and Verification of Shipments:*** Upon receipt of oncology IPs, pharmacists verify shipment contents, cross-check documentation, confirm temperature control, and review any temperature excursion reports to ensure drug integrity [13].
2. ***Inventory Management and Tracking***: Continuous tracking via manual logs or sponsor-provided systems - such as Interactive Response Technology (IRT) must accurately reflect stock levels, dispensing events, expiry dates, and returns.
3. ***Dispensing and Documentation:*** Given the frequent dose adjustments, interruptions, and cycle-specific dosing common in oncology trials, meticulous documentation is required. Each dispensed dose must be traceable to the subject, visit, date, dose, and prescriber.
4. ***Returns, Reconciliation, and Destruction:*** Returned and unused IP must be reconciled against dispensing logs. Destruction should follow documented sponsor-approved procedures. Discrepancies or miscalculations must be addressed via deviation reports, including root cause analysis and corrective and preventive actions (CAPA) [14].
5. ***Chain of Custody Controls:*** A Chain of Custody SOP ensures IP integrity and secure handling, guaranteeing that only authorized, trained staff access and manage IP.

Electronic vs. Paper Accountability Systems

Use of multiple systems, paper-based logs, or inadequate tools can create challenges in reconciling data. Electronic applications offer considerable benefits over paper records by:

- Enhancing visibility across the IP chain of custody
- Centralizing accountability data in a single system
- Improving data quality and reporting
- Reducing transcription errors

However, these systems require reliable infrastructure and trained staff.

Common IP accountability challenges

Common challenges, especially in resource-limited settings include:

1. ***Reliance on Paper-Based Systems:*** Increases the risk of transcription errors, misplaced logs, and delays in reconciliation.
2. ***Multiple or Fragmented Systems:*** Using different systems for ordering, inventory, and dispensing makes it difficult to maintain a single source of truth.
3. ***High Staff Turnover or Limited Training:*** Leads to inconsistent practice and errors in documentation.
4. ***Frequent Dose Modifications in Oncology Studies:*** Creates higher workload and increases the risk of miscalculations or incomplete records.
5. ***Infrastructure Limitations:*** Unreliable internet, lack of validated software, or limited physical storage can hinder electronic tracking and secure storage.
6. ***Temperature Excursions:*** Poor monitoring systems may lead to undocumented excursions that affect IP viability.

Accountability Mitigation Measures

To strengthen IP accountability, sites and sponsors can implement:

1. ***Standardized SOPs:*** Clear workflows for receipt, storage, dispensing, reconciliation, and destruction.
2. ***Training and Competency Assessments:*** Routine refresher training, competency checks, and documentation practice drills.
3. ***Use of Electronic Systems Where Possible:*** Adoption of IRT, electronic accountability logs, and integrated pharmacy management platforms.
4. ***Strong Chain of Custody Procedures:*** Restricted access, use of keycard or biometric access, and documented handovers.
5. ***Regular Inventory Audits:*** Scheduled and unscheduled checks to identify discrepancies early.
6. ***Proper Infrastructure Investment:*** Functional refrigerators/freezers, calibrated temperature monitors, backup power supply, and validated equipment.
7. ***Sponsor Support for Low-Resource Settings:*** Provision of temperature monitoring equipment, validated systems, and training tailored to site needs.

Personnel

Training, Experience, and Qualifications

Trained and experienced pharmacy staff play a critical role in protecting patient safety and ensuring the integrity of clinical trials. IPs are often highly potent, hazardous, and require complex handling procedures. Without proper training in preparation techniques, aseptic compounding, and administration protocols, the risk of contamination, incorrect dosing, or inappropriate delivery increases significantly. It has been demonstrated that pharmacist interventions reduce prescribing errors in oncology trials, underscoring the link between trained staff and reduced patient risk. [15]

Experience refers to practical, hands-on exposure to clinical trial processes, IP handling, and oncology-specific procedures. It goes beyond theoretical knowledge and includes:

- Direct involvement in dispensing, preparing, and documenting IP under supervision
- Repeated execution of protocol-specific procedures, such as dose calculations, kit allocation, and temperature log reviews
- Exposure to multiple trial phases or varied therapeutic areas, which builds familiarity with different protocol structures

Gaining this experience typically occurs through:

- Working under a trained clinical trial pharmacist
- Participating in structured competency programs
- Completing in-service training, simulations, and mentorship cycles

Conditions that constitute "experience" usually include a minimum duration, often 6–12 months of consistent clinical trial pharmacy work, completion of protocol-specific competency checklists, and supervisory sign-off confirming readiness for independent practice.

Minimum Qualifications and Required Training

Personnel responsible for handling oncology IPs must have the professional background and training required to execute specialized tasks safely. At minimum:

- Pharmacists: Bachelor of Pharmacy, licensed by the national regulatory authority (Pharmacy and Poisons Board - PPB).
- Pharmacy Technologists: Diploma in pharmaceutical technology directly supervised by trial pharmacists.
- Nurses and Clinical Research Coordinators - CRCs involved in drug administration: Nursing diploma or degree and clinical trial training.

Additional training required includes:

- Good Clinical Practice (GCP)
- Protocol-specific training
- Hazardous drug handling training (e.g., USP <800> principles)
- Aseptic technique
- IP accountability procedures
- Use of electronic systems (IVRS/IWRS, eTMF, temperature monitoring systems)

This combination ensures staff can maintain compliance, manage risk, and understand the nuances of oncology investigational drug handling.

Competency Framework (aligned to GCP/SoCRA/PPB)

Competency Area	Assessment Criteria	Documents
GCP Knowledge	Certification exams, quizzes	Training certificates, CV
IP Handling Skills	Observed practice, competency checklists	Delegation logs, training records
Documentation Accuracy	Observed practice, competency checklists	Quality reports

Staff Documentation

Training and refresher sessions are documented via delegation logs, updated CVs, and signed certificates, with refresher intervals annually or per SOP updates.

Role of competent staff in achieving Clinical Trial purpose

Clinical trials exist to generate reliable evidence on the safety, efficacy, and optimal use of investigational therapies. Competent staff ensure:

- Accurate dosing and administration
- Correct application of eligibility, timing, and protocol procedures
- High-quality, complete, and error-free data

Inadequate staff competency directly threatens trial validity, patient safety, and regulatory acceptability—therefore trained personnel remain central to achieving the purpose of clinical trials.

Protocol Interpretation and Adherence

Clinical trial protocols contain complex and detailed instructions regarding drug dosing schedules, eligibility criteria, and administration procedures. Experienced personnel are more adept at interpreting and consistently applying these instructions, thereby reducing the likelihood of deviations. Improper investigational drug handling, often linked to inadequate training, has been identified as a frequent cause of protocol violations during audits in China. [16]

Staff Competency and Error Prevention

Trained staff significantly reduce medication errors and are essential in preventing incidents such as incorrect dose calculations, dispensing the wrong kit, or labeling mistakes. These errors have serious consequences for patient safety and trial integrity. A study by the Institute for Safe Medication Practices (ISMP) emphasizes that medication safety in trials depends heavily on staff competence and systematic double-checks. [17]

Accountability roles of personnel

Accountability is a core component of staff competency. Proper IP traceability from receipt to destruction is a staff-driven function. Competent personnel understand how to:

- Maintain precise inventory logs
- Conduct temperature monitoring
- Document chain-of-custody events
- Manage batch and expiry verification

FDA warning letters have cited poor record-keeping and inadequate staff training as major compliance issues, demonstrating that accountability failures often arise from insufficient staff competency and training. [18]

Regulatory Compliance and Professional Standards

Clinical research requires strict adherence to Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Distribution Practice (GDP), and applicable regulatory frameworks (e.g., PPB, FDA, EMA). Inadequate training or assignment of unqualified personnel significantly increases the risk of protocol deviations, documentation errors, and regulatory findings. Many investigational drug services have been found to lack consistent safety and verification practices such as independent double-checking, often linked to training deficiencies. Robust, role-specific training, complete documentation practices, and continuous inspection readiness are therefore essential to maintain regulatory compliance and ensure patient safety [19]

Efficiency, Timelines, and Rapid Adaptation to Amendments

Efficient and experienced staff streamline trial operations by reducing delays during trial initiation and execution. From preparing pharmacy SOPs to adapting to protocol amendments, knowledgeable personnel minimize operational challenges that can delay dosing, enrollment, or documentation. Clinical sites with more experienced staff demonstrate fewer delays and better audit outcomes, improving trial efficiency and timelines [16]

Clinical trials frequently undergo amendments requiring rapid updates to handling or administration procedures. Trained staff can implement these changes immediately without compromising protocol adherence or patient safety. This agility is especially crucial in adaptive or complex oncology trials.

Staff Competency and Data Quality

The accuracy and completeness of clinical trial data—particularly relating to drug administration, accountability, and adverse events—depend heavily on the competency of pharmacy and clinical staff. Errors or omissions compromise study results and regulatory submissions. Pharmacist involvement has been shown to significantly improve documentation quality in clinical trial settings [15]

Need for Professionally Trained, Oncology-Ready Personnel

The specialized nature of oncology IP handling necessitates a workforce with formal qualifications, demonstrated competency, and clinical trial specific training. Site pharmacists, nurses, and clinical research coordinators must receive protocol-specific instruction, as well as general training in aseptic technique, hazardous drug handling, and IP accountability procedures [20]

Cases of personnel related operational errors and Competency deficiencies

Dispensing Error Leading to Patient Death – R v Lee Case (UK, 2007)

In this case, pharmacist Elizabeth Lee mistakenly dispensed propranolol instead of the prescribed prednisolone to a 72-year-old patient. The patient consumed the incorrect medication and died three days later. Although the coroner concluded that the dispensing error was not the direct cause of death, Lee was convicted under the Medicines Act for supplying a medicinal product not of the nature or quality demanded (Table 2). She received a suspended prison sentence, highlighting the severe legal repercussions of dispensing errors due to inadequate checks and training [21].

FDA Warning Letters to Compounding Pharmacies (USA, 2017–2022)

The FDA issued multiple warning letters to compounding pharmacies for violations such as missing batch records,

inadequate review of documents, and insanitary conditions. For instance, one pharmacy failed to prepare complete batch production and control records, violating 21 CFR 211.188. These deficiencies often stem from insufficient staff training and oversight, posing risks to patient safety and trial integrity [22].

Audit Findings on Investigational Medicinal Product (IMP) Handling Errors

A 2025 study analyzing audit experiences in clinical trials found frequent errors in IMP handling, including missing shipment documents and incorrect labeling. These errors were significantly associated with staff's age, work experience, and prior audit exposure, underscoring the impact of personnel training and experience on trial conduct [23].

Pharmacist Interventions Reducing Prescribing Errors in Oncology Trials

A study assessing pharmacist interventions in oncology clinical trials revealed that active pharmacist involvement reduced prescribing errors from 6.1% to 4.7%. Errors included incorrect dosing and wrong kit numbers, often due to unfamiliarity with protocol-defined calculations. This emphasizes the importance of specialized training for pharmacy staff in complex clinical trials. [24].

Safety Risks in Investigational Drug Services (IDS) within Veterans Affairs Health System

A survey of IDS pharmacists in the Veterans Affairs health system identified concerns about medication safety practices, particularly the lack of independent double checks during dispensing. Only 35% of sites routinely performed this error prevention strategy, indicating a need for standardized training and protocols to mitigate risks associated with investigational drug dispensing. [25].

Experience in prior oncology trials is often expected, especially when managing blinded studies or investigational therapies such as CAR-T cells or radiolabeled antibodies. Delegation of responsibilities must be clear, and documentation such as delegation logs and CVs should be readily available for monitoring visits. Competency assessments and refresher courses are recommended, particularly in the context of protocol amendments or new staff onboarding.

Table 2. Summary of cases of personnel related operational errors and Competency deficiencies.

Case	Error	Consequence	Lesson
R v Lee	Dispensing wrong medication	Patient death, legal conviction	Strict dispensing checks and training
FDA Letters	Missing batch records, insanitary conditions	Warning letters, corrective actions	Staff training and oversight critical
IMP Audit Errors (2025)	Missing shipment docs, mislabeling	Trial delays and findings	Experience and audit preparedness vital
Pharmacist Interventions	Incorrect dosing/kits reduced with training	Reduced prescribing errors	Specialized pharmacy training important
Veterans Affairs IDS	Lack of double checks	Medication safety concerns	Standardized protocols and training needed

Integration of Systems and Team Coordination

Effective IP handling requires close coordination among pharmacy, clinical, and administrative teams. Site pharmacists must liaise with investigators and coordinators to adjust dosing schedules based on clinical assessments, adverse events, or lab results. Synchronization with IRT systems, electronic medical records (EMRs), and scheduling platforms will streamline workflows and reduce dispensing errors.

Routine interdepartmental meetings or "huddles" are a best practice in high-enrollment oncology trials. These meetings ensure alignment on visit schedules, drug preparation times, and any anticipated protocol deviations [3]. Sponsor monitors and study auditors reinforce these processes, ensuring that site operations remain compliant and adaptive throughout the trial lifecycle.

Conclusion

In the high-stakes environment of oncology clinical trials, the integrity of IP handling cannot be overstated. From maintaining cold chain integrity to ensuring proper documentation and deploying trained personnel, every aspect of IP handling must be executed with precision. Sites that prioritize rigorous storage conditions, transparent and traceable accountability systems, and robust staff training protocols not only reduce regulatory risk but also contribute meaningfully to patient safety and data validity. As oncology trials evolve in complexity, adherence to these operational fundamentals remains essential for trial success and should strictly be followed and adopted to all clinical trial sites where interventional studies are carried out.

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Enhancing Kenya's Pharmaceutical Technical Capacity Through Integrated Theory and Practice

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Abstract

Introduction: Kenya remains dependent on imported pharmaceutical products to meet domestic healthcare needs. A major constraint on local production is insufficient technical capacity within the sector. This limitation is partly attributable to the insufficient practical industrial skills of newly qualified graduates, thereby posing risks to manufacturing operations. This skills gap restricts employability and the sector's capacity to meet obligations.

Objective: This concept paper proposes an 'integrated theory and practice teaching model' which advocates for inclusion of manufacturing simulations into the curriculum to provide hands-on-training for pharmacy students. Pharmacy schools will be encouraged to set up formulation and mini-industry units on campus. This competency-based teaching model is expected to strengthen the pharmaceutical workforce, increase graduate employability, and foster innovation and development of pharmaceutical products.

Keywords: *Kenya, Pharmaceutical Industry, Practice, Teaching Model, Technical Capacity..*

Background

The pharmaceutical industry contributes immensely to the health obligations of nations through innovative technologies for drug development. Target 3.8 of the post-2015 Sustainable Development Goals aims to achieve universal health coverage including access to quality and affordable medicines by 2030 [1]. Consequently, Kenya has established the Kenya National Pharmaceutical Policy that endeavours to promote self-sufficiency in essential medicines through expansion of local production [2]. Despite efforts to strengthen local manufacturing, Kenya continues to rely significantly on imports to meet its Health Products and Technologies (HPTs) needs [3-5]. According to Vugigi et al. (2017), about 67.5% of pharmaceutical brands in Kenya are imported, while only 38% of the products on the Kenya Medical Essential List (KEML) could be produced locally. Local manufacturers operate at an average of just 27.4% of their production capacity, highlighting underutilization and a heavy reliance on imports [5]. A 2024 report by the Ministry of Health, Kenya, on local medicine manufacturing capacity, based on data from 28 manufacturing sites and key stakeholders revealed that only 20% of KEML formulations are produced locally [6].

The Government of Kenya has expressed its commitment to revitalising the manufacturing sector through Vision 2030, the country's long-term development blueprint [7]. The intention is to increase the proportion of national pharmaceutical demand met by locally manufactured products to approximately 65% [8]. In 2023, Kenya's President pronounced that at least 50% of KEML formulations should be produced locally by 2026 [9]. However, the local industry faces numerous challenges that hinder the realization of this goal, which require to be addressed through a comprehensive and coordinated intervention.

Factors contributing to the dominance of foreign products include limited innovation capacity, production of similar products by the industry, and inadequate personnel with specialized skills essential in the manufacturing industry [10-13]. Further, research and development of new products is nascent in this industry. This is attributed to insufficient funding, risks associated with research, inadequate research skills, insufficient collaboration with local universities and research institutions and non - utilization of technology transfer opportunities [14]. Moreover, the sector faces a critical shortage of technical personnel, as most manufacturing facilities employ, on average, only two pharmacists [5]. This absorption capacity is insufficient relative to the number of pharmacy graduates produced annually by the nine pharmacy schools in the Republic [15]. According to the Kenya Pharmaceutical Industry Diagnostic Report (2020), there exists a substantial gap in the preparedness of newly graduated pharmacists [8]. This is largely attributed to inadequate practical skills, which are essential for effective pharmacy practice and a prerequisite by drug regulatory standards. The pharmaceutical manufacturing sector continues to experience a shortage of suitably skilled local professionals to fill critical roles in production, quality assurance, and formulation development. Currently, many companies in this sector rely on expatriates, primarily from India, to provide the technical expertise and specialized human resources required for manufacturing operations [16-17].

The rigorous requirements for practicing as a pharmacist in the manufacturing sector are driven by the responsibilities and risks inherent in the role which impact patient safety. This necessitates a solid grounding in both theoretical knowledge and hands-on experience. The current training model which includes a four - week industrial attachment

during the fourth year of study and a two - month internship after graduation does not provide sufficient experiential learning to prepare graduates for the complex demands of the profession. Further, during their attachments and internships, pharmacy students are often not allowed to perform key pharmaceutical operations, as Good Manufacturing Practice (GMP) guidelines require that such activities be carried out by qualified and trained personnel. This limits their exposure to essential industry practices. Furthermore, the limited number of licensed pharmaceutical manufacturers in Kenya, approximately 30 [15], is insufficient to provide adequate internship opportunities for the growing number of pharmaceutical science students across diploma, bachelor's, and master's programs. As a result, many pharmacy graduates are underprepared, and not fit for the available positions in the manufacturing sector. Additionally, a significant disconnect exists between the curriculum offered in pharmacy schools and the practical demands of roles within the pharmaceutical manufacturing sector. This disparity contributes to low confidence among graduates and reduces their motivation to seek employment in the industry. For example, the role of a pharmacist in quality assurance includes GMP administration, handling of deviations, complaints, and out of specification results. The role extends beyond the foundational theoretical knowledge provided in academic curricula. It requires advanced competency in the application of pharmaceutical sciences, proficiency in GMPs, and the ability to make sound, risk-based decisions aligned with regulatory compliance standards. Table 1 presents some of the common skill - gaps experienced by fresh graduates in the pharmaceutical manufacturing industry.

Table 1. Competency and Common Skill – Gaps in Pharma Industry

Competency	Skill- Gaps
Risk management	Application of risk-based approach in decision making. To identify, assess, categorize, mitigate, monitor risks to ensure quality and continuous improvement.
Document and process management	Ability to prepare, implement, maintain, and revise SOPs to ensure compliance, consistency and efficiency.
Material Control	Tracking, handling, storage, and movement of materials throughout the manufacturing process.
Mix-Up Prevention and Control	Systems that ensure avoidance of mix ups and errors including accurate labelling, material segregation, line clearance execution, compliance with SOPs, verification and double-checking, accurate documentation, root cause analysis, staff training, and use of tracking technology.
Potent Drug Handling	Practical handling of hazardous drugs, Use of Personal Protective Equipment, controlled environment operation, strict material handling, and thorough documentation to ensure regulatory compliance.
Cross-Contamination Control	Practical segregation, cleaning, and containment strategies.
Validations	Execution of validation and qualification, preparation of protocols, equipment operation, critical process parameters, sampling, data collection and analysis, and deviation handling.
Environmental Controls	Selection and use of airflow systems, isolators and related guidelines, where to use air locks and types of air locks.

Source: Author generated (2025)

Bridging the gap between classroom learning and industry practice is essential for workforce readiness. This paper proposes a teaching model, termed the 'Integrated Theory and Practice (ITP) Model' which intentionally amalgamates practical experience within the theoretical curriculum.

The Approach

The proposed teaching model aims to enhance human capacity by equipping students with job-ready skills through manufacturing simulations, industry partnerships, and structured practical modules. The concept proposes a multifaceted approach comprising an on-campus product formulation component, the development of a mini-pharma manufacturing unit, and the fostering of robust academia–industry partnerships. Academia will contribute expertise in research and trainings and pharmaceutical industry attachments, technology transfer and commercialization pathways. Beyond theoretical instruction, the model will provide hands-on training for undergraduate pharmacy students, equipping them with practical skills in pharmaceutical manufacturing and compliance with GMP. In addition, short-term professional development programs for practicing pharmacists and regulatory professionals will be provided.

The formulation unit will focus on the design and development of various dosage forms, including tablets, capsules, suspensions, semi-solids, and novel delivery systems. It will support both academic research and the early-stage development of pharmaceutical products. The unit will also serve as a practical learning environment for students to apply theoretical knowledge in drug formulation and pre-formulation studies. This will drive innovation, product licensing, and academia–industry collaboration.

The Mini-Industry is GMP-aligned, small-scale manufacturing facility that simulates an industrial environment, enabling students and trainees to gain hands-on experience in pharmaceutical production. It will support scale-up studies, batch production for research or educational use, and provide a platform for technology transfer. The mini-industry unit will bridge the gap between lab-scale development and real-world manufacturing processes. The mini- industry will encompass an equipped quality control laboratory, adequate to enable comprehensive physicochemical and quality analysis of pharmaceutical products. Activities will include method development, stability testing, and regulatory documentation. This unit will serve both teaching and research purposes and support the quality assurance of formulations developed within the department.

A dedicated Training and Professional Development Unit will coordinate structured, practice-based short courses for practicing pharmacists and other industry personnel. The training courses will cover a range of practice-based topics such as GMP, quality assurance, regulatory compliance, industrial pharmacy, and pharmaceutical technology, design of extemporaneous preparations rooms for high risk products in hospitals, the HVAC and containment strategies and emerging pharmaceutical technologies, thereby

strengthening the link between academia and industry. The unit will also support continuing professional development and foster academia–pharma sector collaboration.

Implementation framework and expected outcomes

Technical capacity in the pharma sector can be enhanced as detailed in the framework presented in Table 2. The independent variables, shaped by the contributing factors will be implemented, leading to the realization of dependent variables-the enhanced technical capacity [18]. Achieving the desired outcomes outlined in Table 2 will require the identification of key success factors, detailed in Table 3, their translation into strategic objectives, alignment with defined timelines, and disciplined execution. Continuous evaluation and monitoring are essential to track progress, ensure alignment with goals, and enable timely adjustments. Table 4 presents examples of institutions that have successfully established mini-industries on their campuses.

Table 2. Conceptual Frame Work

Independent variables	Contributing Factors	Activities & Outputs	Dependent variables
Establishment of Formulation & Mini - industry	Institutional support • Funding • Equipment availability	**Activities:** Set up mini-manufacturing industry **Outputs:** Functional training unit operations Outcomes: Increased practical exposure	Enhanced technical capacity
Industry collaborations (internships, co-projects, teaching)	• Industry willingness • Regulatory support • Curriculum alignment	**Activities:** Collaborate with industries **Outputs:** MoUs signed, student attachments **Outcomes:** Better alignment with market	
Delivery of professional training (certifications, workshops)	• Skilled trainers • Motivated participants • Financial support	**Activities:** Conduct training programs **Outputs:** Number of trainings completed **Outcomes:** Enhanced knowledge and skills	
	• Evaluation systems	Evaluation reports, improved programs	

Source: Author generated (2025)

Table 3. Concept Success Factors for Enhancing Technical Capacity

Success Factor	Description
Institutional duty	Leadership and administrative commitment to implement and sustain programs.
Funding resources	Adequate financial and material resources for setup and operations.
Effective partnerships	Collaboration with the pharma industry for attachments and job opportunities.
Qualified trainers and staff	Skilled personnel both from academia and the industry to deliver practical and up-to-date training and mentorship.
University curriculum	The content to be aligned with industry workforce needs.
Student interest	Learners' willingness to actively engage and apply skills.
Government support	Government or institutional policies that promote technical skill development.
Sustainability	Systems to track performance, measure outcomes, and inform improvements.

Source: Author generated (2025)

Table 4. Pharmacy Schools with Established Pilot Pharmaceutical Facilities.

Institution & Location	Pilot Plant Description
Mahidol University, Thailand	On-campus GMP-certified plant for pharmaceutical manufacturing education and research.
University of Nigeria, Nsukka	Pilot Production Unit for hands-on training in small-scale pharmaceutical manufacturing.
University of Navarra, Spain	Pilot plant for industrial pharmacy and formulation training.
NMIMS School of Pharmacy, India	Industrial pharmacy lab with pilot-scale equipment for batch production and training.

Source: Author generated (2025)

Despite its potential benefits, the ITP teaching model faces several feasibility constraints. These include limited resources for laboratory upgrades, inadequate instructor capacity, and insufficient industry engagement. Policy direction from the Ministry of Education is required to guide and incentivize academia in transitioning from the current curriculum to the integrated hybrid teaching model. Ensuring long-term sustainability will necessitate substantive funding for equipment procurement and maintenance, as well as continuous alignment of course content with evolving industry standards. Ultimately, the curriculum must remain globally relevant and aligned with international best practices to secure its long-term impact and competitiveness.

Conclusion

The Integrated Theory and Practice teaching model proposes intentionally amalgamating practical aspects into the theoretical curriculum. This competency-based teaching model is expected to strengthen the pharmaceutical workforce, increase graduate employability, foster innovation, and enhance the quality and competitiveness of locally developed pharmaceutical products. It is essential that the Ministry of Education provide a policy direction and support for skill-based training and the establishment of mini-industries, as well as develop systems to enhance collaborations that enhance technical capacity in the pharmaceutical manufacturing sector.

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