

# Use of Non-Formulary Medicines at a Kenyan Private Hospital

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## Abstract

**Background:** Hospital formularies are used to encourage the use of safe, effective and most affordable medications. Institutions need to make provisions for non-formulary medicines (NFM) due to the dynamic nature of diseases and their management. The aim of this study was to describe the patterns of non-formulary medicine prescriptions at the Nairobi Hospital, the reasons for their purchase as well as the duration taken to avail them. **Methods:** A descriptive review of all the non-formulary medicine prescriptions from January 2021 to June 2022. The medicines were listed and categorized according to the WHO Anatomical Therapeutic Chemical (ATC) classification system. Correspondence between pharmacy and procurement was reviewed to understand the reason for the requests and the duration it took to avail the medicines. **Results:** A total of 183 NFM were purchased, with a general increase in the number from January 2021 to June 2022. Vitamins, Mineral supplements and General nutrients accounted for 41 (22.4%) of the NFM. Dermatologicals 27 (14.6%), Genito-urinary system drugs and sex hormones 20 (10.9%), Ophthalmologicals 14 (7.6%) and Antineoplastic and Immunomodulating agents 12 (6.6%) were also frequently purchased out of formulary. The main reasons for NFM purchases were: having no therapeutic equivalents in the hospital formulary 72 (39.3%) and prescriber or patient preference 69 (37.7%). It took a median (IQR) of 4 (2 - 7) days for the pharmacy to avail these drugs; with 18.6% being availed in 1 day and 55.2% taking more than 3 days. For the NFM where no alternative was available in the hospital formulary, sales amounted to USD 63,362 which was 79.1% of the value of all the NFM sales. **Conclusion:** There's a need to regularly update the hospital formulary and to emphasize to the prescribers the importance of adhering to it, as much as possible.

## Keywords

Drug Formulary, Non-Formulary Medicine, Therapeutic Equivalent

## 1. Introduction

A hospital formulary lists medicines, devices and related products, used to diagnose and treat diseases and supported by evidence based information, judgement of physicians and pharmacists and other experts [1]. It enables the healthcare team to effectively use the available resources to promote clinically sound, cost-effective medication therapy to achieve positive therapeutic outcomes. Usually, a Pharmacy (or Medicines) and Therapeutics committee is responsible for regularly updating the formulary based on emerging clinical information on management of diseases, new molecules and formulations, and economics data such as healthcare costs [1] [2]. Faced with the multiplicity of medications in the market, a well-coordinated formulary system allows healthcare institutions to objectively discriminate superior and marginal medications thus providing patients with access to the most efficacious, safe, and cost effective agents for routine use [2].

It may not be feasible to have an exhaustive formulary at any one point due to the dynamic nature of diseases and their management. New drug molecules are continuously discovered and approved for use, while others are discontinued in some markets or generally become unavailable for various reasons. It is therefore important for institutions that use formularies to have policies in place to provide physicians and patients access to non-formulary drugs where medically necessary. Considering that these drugs are not routinely stocked in the hospital pharmacies, sourcing for them may take slightly longer and has the potential to delay commencement or continuation of treatment and compromise the quality of care [3].

It has been observed that the frequent and inappropriate use of non-formulary medicines has the potential to cause medication errors due to unfamiliarity with the drugs, increase healthcare costs, and impact the quality of care [3] [4] [5]. Further, more medicines in a formulary lead to a larger inventory which is expensive to manage. Not much information exists in the literature on this subject especially in Africa. A few studies in America and Europe indicate that NFM orders are mainly for the patient's own medication and newly marketed drugs [3] [5]. In one study, close to 90% of all the NFM had suitable alternatives in the formulary and a third of the recommendations to substitute the drugs were accepted [6].

The aim of this study therefore was to describe the non-formulary medicine prescriptions at the Nairobi Hospital in order to understand the patterns, the reasons for their purchase as well as the duration taken to avail them.

## 2. Methods

### 2.1. Study Design

This was a descriptive review of all the non-formulary medicine prescriptions at the Nairobi Hospital from January 2021 to June 2022.

## 2.2. Study Area and the Medicine Procurement Process

The Nairobi Hospital is a 350-bed not-for-profit hospital in Nairobi City, the capital of Kenya. It has 3 pharmacies dedicated to admitted patients and 12 out-patient pharmacy outlets. Medicines are procured centrally and stored by the pharmacy stores before distribution to the different pharmacy units and thereafter, dispensed to patients. The hospital has an in-house medicines formulary which is currently in its 3<sup>rd</sup> edition. This formulary lists all the possible proprietary and non-proprietary medicines that have been approved to be stocked in the hospital pharmacies. The medicines are approved by the hospital's medicines and therapeutics committee (MTC). Companies and suppliers who wish to have their products included in the formulary apply to the MTC, which reviews the applications and regularly updates the formulary. Criteria for acceptance includes: therapeutic need, clear advantages over existing brands, quality and comparative costs of the products, among other requirements.

In every procurement cycle, the senior pharmacist-in-charge of the pharmacy stores lists and quantifies the drugs to be restocked based on consumption and morbidity patterns. This purchasing order undergoes several approvals internally and is then sent to the respective suppliers. Different suppliers take different durations before supplying the medicines to the hospital. Some medicines that are not locally available have to be imported and take a longer time to be delivered to the hospital.

The pharmacy department has a "100% prescription fill" policy. Ideally, the procurement department should only purchase medicine brands listed in the formulary. However, there are many occasions when the pharmacies receive prescriptions for medicines that are not listed in the formulary. These medicines are referred to as NFM, defined as medications that are not a part of the drug formulary [1]. If such a prescribed drug has an alternative already in the formulary, the prescriber and patient are informed and the drug is substituted with the brand or drug in the formulary. If no suitable alternative exists in the formulary, then the Chief pharmacist (on behalf of the MTC) grants the procurement department permission to purchase the drug for that particular patient. If more of such prescriptions are encountered subsequently, then that's an indicator of the therapeutic need for that drug and it's eventually vetted by the MTC to allow inclusion into the hospital formulary.

On receipt of a prescription of a non-formulary medicine, a pharmacy staff writes an email to the pharmacy administration and procurement department requesting for the drug to be sourced. Requests for quotations are then sent to potential suppliers and once found, the medicine is procured, and the patient is informed to come and collect it.

## 2.3. Sample Size, Inclusion and Exclusion Criteria

All medicines that were not in the hospital formulary, but were procured and dispensed during the study period were included. Those that were not ultimately

bought by the hospital because no supplier had them or those that were declined by the clients were excluded.

## 2.4. Data Collection

All emails sent to the senior pharmacist in procurement and pharmacy administration requesting for any non-formulary medicine to be purchased during the study period were retrieved. The correspondence was analyzed to determine the reason for the request and the duration it took to avail the drug. The pharmacy staff that made the inquiry was contacted if any clarification was needed.

## 2.5. Variables

Product class, time period, availability of alternative, reason for request, duration to avail product, cost of the NFM.

## 2.6. Data Analysis

The medicines were listed and categorized according to the WHO Anatomical Therapeutic Chemical (ATC) classification system [7]. The data was transcribed into SPSS statistics version 26 for analysis. Continuous variables were summarized as the sum, median and interquartile range, where applicable and then transformed into categories. Categorical variables were summarized as frequencies and proportions.

## 2.7. Ethical Considerations

The study received ethical approval from The Nairobi Hospital Ethics and Research Committee (TNH-ERC/DMSR/RP/042/22). It was purely descriptive and no intervention was made.

## 3. Results

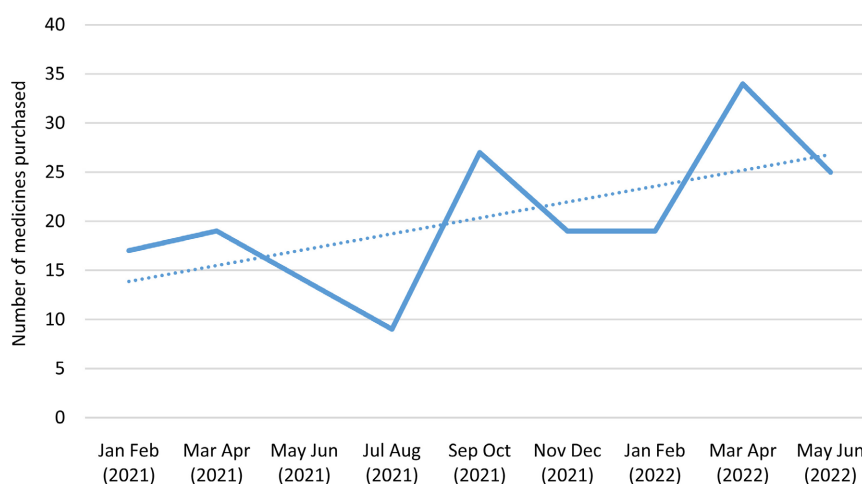
During the period under review, 286 inquiries for NFM were made. Out of these, 183 products were purchased.

### 3.1. Trend of Non-Formulary Medicine Use

There was a general increase in the number of non-formulary drug purchases from January 2021 to June 2022. There were declines from May to August 2021 as well as the end of 2021 and beginning of 2022. The most requests were made in March and April 2022 (**Figure 1**).

### 3.2. Categories of the Non-Formulary Medicines

Generally, dietary supplements and products that are really not disease specific formed the bulk of the NFM sales. Vitamins (A11), Mineral supplements (A12) and General nutrients (V06) accounted for 41 (22.4%) of all the non-formulary drugs sold during the review period. Dermatologicals 27 (14.6%), Genito-urinary system drugs and sex hormones 20 (10.9%), Ophthalmologicals 14 (7.6%) and



**Figure 1.** Trend of non-formulary drug purchases.

Antineoplastic and Immuno-modulating agents 12 (6.6%) were also frequently purchased out of formulary. Rarely were there non-formulary requests for Anti-infectives and Systemic hormonal preparations (**Table 1**).

### 3.3. Reasons for Requests for the Non-Formulary Medicines

In general, the main reasons for NFM purchases were: having no therapeutic equivalents in the hospital formulary 72 (39.3%) and prescriber or patient preference 69 (37.7%). Non-formulary requests for Antineoplastic and Immuno-modulating agents (75%) and Cardiovascular system drugs (61.5%) were due to the lack of therapeutic equivalents in the formulary. Half of the requests for Sex hormones and modulators of the genital system as well as Psycholeptics were because their formulary equivalents were out of stock. Prescriber or patient preference accounted for 65.9% of Nutritional supplements and 83.3% of Drugs for Acid related disorders (**Table 2**).

### 3.4. Characteristics of the Non-Formulary Medicine Requisitions and Sales

It took a median of 4 days for the pharmacy to avail these drugs; with 18.6% being availed in 1 day and 55.2% taking more than 3 days. There were no repeat sales for 45.4% of the products, while 35.5% were prescribed and sold up to 5 additional times. The first sales of the 183 items generated USD 36,527. Total revenue from the initial and subsequent sales of these non-formulary products was USD 80,129. For the NFM where no alternative was available in the hospital formulary, sales amounted to USD 63,362 which was about 79.1% of the value of all the NFM sales (**Table 3**).

## 4. Discussion

It is important for a hospital's Medicines and Therapeutics Committee (MTC) to continually assess NFM use as part of the medication management process [8].

**Table 1.** Categories of the non-formulary medicines.

ATC CLASSIFICATION: 1 <sup>st</sup> and 2 <sup>nd</sup> level	Number
<b>Alimentary tract and Metabolism</b>	<b>36</b>
Vitamins (A11)	12
Mineral supplements (A12)	9
Drugs for Acid related disorders (A02)	6
Drugs for functional Gastrointestinal disorders (A03)	3
Drugs used in Diabetes (A10)	2
Other Alimentary tract and Metabolism products (A16)	2
Antidiarrheals, Intestinal anti-inflammatory/anti-infective agents (A07)	1
Bile and Liver therapy (A05)	1
<b>Various</b>	<b>23</b>
General nutrients (V06)	20
All other therapeutic products (V03)	2
All other non-therapeutic products (V07)	1
<b>Dermatologicals</b>	<b>27</b>
Emollients and Protectives (D02)	12
Other Dermatological preparations (D11)	5
Antifungals for Dermatological use (D01)	3
Anti-acne preparations (D10)	2
Corticosteroids, Dermatological preparations (D07)	2
Preparations for treatment of wounds and ulcers (D03)	2
Antipruritics, incl. Antihistamines, Anesthetics, etc. (D04)	1
<b>Genito-urinary system and sex hormones</b>	<b>20</b>
Sex hormones and modulators of the genital system (G03)	8
Urologicals (G04)	8
Gynecological Anti-infectives and Antiseptics (G01)	4
<b>Sensory organs</b>	<b>14</b>
Ophthalmologicals (S01)	14
<b>Cardiovascular system</b>	<b>13</b>
Agents acting on the renin-angiotensin system (C09)	5
Diuretics (C03)	3
Antihypertensives (C02)	2

**Continued**

Calcium channel blockers (C08)	1
Cardiac therapy (C01)	1
Vasoprotectives (C05)	1
<b>Nervous system</b>	<b>12</b>
Psycholeptics (N05)	6
Analgesics (N02)	2
Antiepileptics (N03)	2
Other nervous system drugs (N07)	2
<b>Antineoplastic and Immuno-modulating agents</b>	<b>12</b>
Antineoplastic agents (L01)	7
Immunosuppressants (L04)	5
<b>Respiratory system</b>	<b>6</b>
Drugs for Obstructive Airway diseases (R03)	2
Nasal preparations (R01)	2
Antihistamines for systemic use (R06)	1
Cough and Cold preparations (R05)	1
<b>Musculo-skeletal system</b>	<b>8</b>
Anti-inflammatory and Anti-rheumatic products (M01)	3
Drugs for treatment of bone diseases (M05)	2
Topical products for Joint and Muscular pain (M02)	3
<b>Blood and Blood forming organs</b>	<b>4</b>
Blood substitutes and perfusion solutions (B05)	2
Antianemic preparations (B03)	1
Antithrombotic agents (B01)	1
<b>Anti-infectives for systemic use</b>	<b>4</b>
Antibacterials for Systemic use (J01)	2
Antimycotics for Systemic use (J02)	1
Antivirals for Systemic use (J05)	1
<b>Anti-parasitic products</b>	<b>2</b>
Antiprotozoals (P01)	2
<b>Systemic hormonal preparations</b>	<b>2</b>
Thyroid therapy (H03)	2

\*ATC: Anatomical Therapeutic Chemical.

**Table 2.** Reasons for requests of the non-formulary medicines.

Medicine category	Different formulation or presentation n (%)	Formulary drug out of stock n (%)	No therapeutic equivalent n (%)	Prescriber or patient preference n (%)	Total
General nutrients (V06), Vitamins (A11), Mineral supplements (A12)	3 (7.3)	1 (2.4)	10 (24.4)	27 (65.9)	41
Ophthalmologicals (S01)	2 (14.3)	6 (42.9)	6 (42.9)	0 (0.0)	14
Cardiovascular system (C)	1 (7.7)	4 (30.8)	8 (61.5)	0 (0.0)	13
Antineoplastic and Immuno-modulating agents (L)	0 (0.0)	2 (16.7)	9 (75.0)	1 (8.3)	12
Emollients and Protectives (D02)	0 (0.0)	0 (0.0)	6 (50.0)	6 (50.0)	12
Sex hormones and modulators of the genital system (G03)	2 (25.0)	4 (50.0)	0 (0.0)	2 (25.0)	8
Urologicals (G04)	0 (0.0)	3 (37.5)	2 (25.0)	3 (37.5)	8
Drugs for Acid related disorders (A02)	0 (0.0)	0 (0.0)	1 (16.7)	5 (83.3)	6
Psycholeptics (N05)	1 (16.7)	3 (50.0)	2 (33.3)	0 (0.0)	6
Others	2 (3.2)	8 (12.7)	28 (44.4)	25 (39.7)	63
<b>Total</b>	<b>11 (6.0)</b>	<b>31 (16.9)</b>	<b>72 (39.3)</b>	<b>69 (37.7)</b>	<b>183</b>

**Table 3.** Characteristics of the non-formulary medicine requisitions and sales.

CHARACTERISTIC	N (%) or value
<b>Duration to avail the drugs</b>	
Median (IQR) days	4 (2 - 7)
Up to 1 day	34 (18.6)
2 to 3 days	48 (26.2)
4 to 5 days	32 (17.5)
6 days or more	69 (37.7)
<b>Number of subsequent NFM sales</b>	
Median (IQR)	1 (0 - 4)
No subsequent sale	83 (45.4)
Sold up to 5 other times	65 (35.5)
More than 5 repeat sales	35 (19.1)
<b>Value of first NFM sale (USD)</b>	
Sum (range)	36527.3 (2.05 - 7267.8)
≤20	81 (44.3)
>20 - 40	41 (22.4)
>40	61 (33.3)
<b>Value of subsequent NFM sales (USD)</b>	
Sum (range)	43602.6 (0 - 14171.3)
Total value of NFM sales where no therapeutic equivalent was available in the hospital formulary (USD)	63362.8

\*IQR: Inter-Quartile Range.



The committee needs to look at the types of NFM requests and their formulary alternatives, number of times used in the previous 6 - 12 months, safety issues and cost impact. This will inform on the need for formulary addition, or development of guidelines for use of a drug within a therapeutic class or disease state [1].

We analyzed 183 NFM and found a continued increase in the number of these drugs along the study period. There were reductions in these numbers in July/August 2021 and December 2021. These coincided with the periods immediately after formulary reviews whereby the MTC, after thorough vetting, added some of the drugs that were previously regarded as non-formulary. About 100 products were added to the formulary in July and 60 products in December. This underscores the importance of regular review of the drugs formulary.

In our study, most NFM were in the Vitamins, Mineral supplements, General nutrients, Dermatologicals, Ophthalmologicals, Genito-urinary system drugs and hormones, Immuno-modulators, Cardiovascular system and Nervous system categories. In a case-control study in the Netherlands, the odds of NFM purchases were high for the Cardiovascular/hematological, Genito-urinary and Immuno-oncological categories [9]. In a prospective observational study at a University hospital in Pennsylvania, Immuno-oncological, neuropsychiatric and pulmonary and cardiovascular drugs comprised most of the NFM [3]. From a retrospective review conducted in Spain, the most commonly involved ATC groups were Urological preparations, agents acting in the cardiovascular and respiratory systems and Ophthalmologicals [6]. All these indicate the uniqueness of the needs for each institution or region.

Nutritional supplements account for majority of our NFM because they are quite many in the market with varying compositions. It is therefore not easy to allocate therapeutic equivalence. By definition, therapeutically equivalent products have different chemical structures but are of the same therapeutic class and are thus expected to produce similar effects [10]. In a situation where the pharmacist is unable to convince the prescriber or patient that the suggested formulary drug will provide the same effects, the hospital is forced to procure the NFM. This creates an unnecessarily wide range of products in this category, increases workload and contributes to inefficiency [5].

The main reasons for NFM use in our hospital were unavailability of therapeutic alternatives and prescribers' or patients' preferences. About 6% were due to being of a different formulation or presentation from that of the one in the formulary. A similar observation was made by Rodriguez-Carrero *et al.* [8]. In their study, majority of the NFM had no alternatives in the formulary or were medicines that patients had already been stabilized on before admission. They also report that different strengths or dosage forms of formulary drugs accounted for 11.4% of the NFM. On the contrary, over 80% of NFM had substitutes in the formulary in two reviews [3] [6]. In some settings, acceptance to switch to the formulary medicine was high [6] [11] but in others, it was low [8]. Our formulary is not restrictive, thus several molecules from the same pharma-

cologic class or even brands of the same molecule are listed in the formulary. That would translate to having very few NFM requests. We found that 16.9% of the NFM were of drugs in the formulary but out of stock. Drug shortages are a challenge in our set up and stem from issues to do with drug manufacture and distribution.

Cardiovascular NFM were due to the fact that numerous combinations of different molecules keep being formulated in order to reduce the patient's bill burden. Ophthalmologicals are a special category because of the sensitiveness of the eye. The prescribers are therefore usually quite specific. Dermatologicals, have a cosmetic element and that could explain why the reason for their requests were predominantly patient preference. There's a need to strongly enforce formulary restrictions for Drugs for Acid related disorders (A02), General nutrients (V06), Vitamins (A11), and Mineral supplements (A12). Most NFM in these categories were due to prescriber or patient preference yet the formulary has lots therapeutic equivalents. Formulary compliance was enforced through 'hard stop therapeutic interchanges' for select product categories that contributed the most to the NFM requests [12] [13]. These resulted in substantial decreases in formulary non-adherence. Such interventions might be difficult to put in place considering that majority of our prescriptions are manual. For starters, however, prescribers need to be educated and encouraged to become familiar with the hospital formulary [3]. They need to understand that formularies lead to increased efficiency and improved medication safety and that they play a key role in actualizing this [5].

Most of the requested NFM were availed within 4 days with less than a fifth being delivered in 1 day. There's paucity of information regarding this in literature. Seventy-seven percent of NFM were delivered within 5 hours and 96% within 72 hours in one study [3]. The study indicates that majority of the NFM were already in the pharmacy which definitely explains the promptness. Question is: why were they being regarded as NFM yet they were already in stock? In our set up, these NFDs are totally new drugs which have never been stocked before. The procurement process actually starts by trying to locate a potential supplier by sending out requests for quotations. Feedback regarding the cost and availability is then communicated to the client and a decision is made to buy the drug. This stage alone, can take a duration ranging from a few hours to a week, depending on the day of the week, and responses from the suppliers and clients. The duration taken thereafter is relatively shorter and involves approvals by the relevant procurement and finance staff of the hospital. Suppliers also differ on how quickly they deliver an item on receipt of a purchasing order. Drugs are not locally available and have to be imported, take close to 2 weeks to be availed.

The Joint Commission International Accreditation Standards for Hospitals states that there should be a well-defined procurement process for medicines, which should be communicated to medical staff such that expectations are managed [14]. Such a process should ideally not exceed 24 hours [1]. Formulary medicines are usually procured in a cyclic manner based on consumption. There

are a few unpredictable instances which may necessitate restocking a formulary drug such as an unusually large sale. Having many NFM reduces the time that would otherwise have been spent doing proper forecasting and quantification of the formulary medicines.

The cost avoidance resulting from converting a NFM to one in the formulary increased 5-fold in one study. This cost outweighed the cost of the pharmacist's time required to make the intervention [15]. Similarly, the mean drug acquisition costs per order when a NFM was dispensed were higher than the cost of converting a NFM to a formulary alternative [11]. We did not evaluate these aspects in our study, but the value of NFM sales where no therapeutic equivalent was available in the hospital formulary accounted for the bulk of the value of all the NFM sales. NFM where indicated are a genuine source of revenue for an institution.

#### **Limitations**

To our knowledge, this is the first analysis of the use of NFM in the region. We did not analyze the costs involved in the entire process of procuring NFM to see the value especially for those that had no therapeutic equivalent. We did not analyze the cost savings made in switching from NFM to alternative ones.

## **5. Conclusion**

A lack of therapeutic equivalents in the formulary as well as prescriber preferences were the major reasons for the non-formulary medicine prescriptions. Requests for these medicines should therefore be evaluated on a case to case basis to justify their purchase. Prescribers should be engaged to prevent unnecessary purchase of drugs for which suitable alternatives exist in the formulary.

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## **Conflicts of Interest**

The authors declare no conflicts of interest regarding the publication of this paper.

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