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Counterfeit drug detection: effectiveness of qualitative testing methods in identifying falsified medications

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ABSTRACT

The proliferation of counterfeit medicines poses a significant public health threat, particularly in low-resource settings where regulatory oversight may be limited. This study investigates the effectiveness of qualitative testing methods for detecting counterfeit drugs stocked in pharmacies. A total of 150 drug samples, including commonly prescribed medications for hypertension, diabetes, infections, and malaria, were collected from 10 pharmacies across urban and rural areas in Uyo metropolis. The samples underwent a series of qualitative tests, including Thin Layer Chromatography (TLC), Fourier Transform Infrared Spectroscopy (FTIR), colorimetric reactions, visual inspection, and dissolution testing. Out of the 150 samples, 25 (16.67%) were identified as counterfeit, based on discrepancies in chemical composition, physical appearance, and dissolution profiles. TLC and FTIR proved the most effective in detecting chemical composition discrepancies, identifying counterfeit drugs in 48% and 40% of cases, respectively. Colorimetric reactions and visual inspection were effective for some antibiotics but identified fewer counterfeit samples. Dissolution testing was successful in detecting drugs with altered release profiles. The study also assessed the feasibility of implementing these testing methods in routine pharmacy practice, highlighting the cost and training requirements of more advanced techniques like FTIR and dissolution testing. The results suggest that while TLC and colorimetric reactions are practical and cost-effective tools for counterfeit detection, further efforts are needed to improve accessibility and training for more advanced testing methods. This study underscores the importance of incorporating multiple testing strategies to safeguard against counterfeit medicines and enhance the quality of pharmaceutical care.

Keywords: Counterfeit drugs, Pharmaceutical quality, Drug testing, Thin layer chromatography, Fourier transform infrared spectroscopy, Pharmacy practice

Introduction

The pharmaceutical industry plays a crucial role in ensuring the health and well-being of individuals worldwide [1]. It is a sector where safety and efficacy are paramount, and the integrity of the medicines available in the market is of utmost importance. Unfortunately, the global pharmaceutical market faces significant challenges, one of the most dangerous being the proliferation of counterfeit medicines [2]. Counterfeit drugs are those that are deliberately manufactured to mislead consumers about their origin, contents, or efficacy. These are known to pose a serious threat to public health. These fake drugs not only fail to deliver the intended therapeutic benefits but can also cause adverse effects, exacerbate health problems, and in some cases, lead to death. As such, the prevention and detection of counterfeit drugs are critical to safeguarding health [3].

Pharmacies, being the primary points of contact between patients and medicines, are at the forefront of ensuring the quality and safety of drugs dispensed to the public. However, despite stringent regulatory frameworks and increasing awareness, counterfeit drugs continue to enter legitimate supply chains [4]. This problem is particularly pronounced in low- and middle-income countries, where the availability of unregulated or poorly regulated pharmaceuticals remains a significant concern. Counterfeit medicines, including those for chronic conditions like hypertension, diabetes, and infectious diseases, can be found in pharmacies, posing a direct threat to the well-being of patients [5].

One of the key methods to combat the issue of counterfeit drugs is to perform rigorous quality testing. Pharmacies and healthcare providers must have reliable means of identifying and differentiating counterfeit drugs from legitimate ones to prevent their distribution. However, this requires proper infrastructure, training, and resources, which are often lacking in many settings. To address this gap, various qualitative testing methods have been developed to help identify counterfeit drugs quickly and accurately [6]. These methods are often cost-effective, easy to implement, and can be carried out in a variety of settings, including community pharmacies. Qualitative testing involves the use of simple techniques to assess the physical, chemical, and biological properties of drugs, which can reveal discrepancies in their composition, potency, or appearance [7].

The goal of this research was to explore the effectiveness of qualitative testing methods for commonly prescribed drugs stocked in pharmacies, with a particular focus on their role in halting the use of counterfeit medicines. The research will also probe into the knowledge and perception of the pharmacy managers on equipments and the related procedural limitations on examine how qualitative testing for medicines.

Methods

This research aims to assess the availability of counterfeit drugs, knowledge and perception of pharmacy managers about the equipments and the related procedural limitations. The methodology adopted for this study combines qualitative and quantitative approaches, ensuring that both the detection of counterfeit drugs and the practicality of qualitative testing methods are thoroughly explored. The study was conducted in a systematic manner, with specific stages for drug sampling, qualitative testing, data collection, and analysis.

Research design

This study employed a cross-sectional research design. The design involved drug sampling and testing alongside a questionnaire approach on the current situation regarding counterfeit medicines relating to respondents' knowledge of useful analytical equipment, availability, and equipment-related limitations.

Sampling of pharmacies and drugs

A purposive sampling technique was used to select a representative sample of pharmacies for the study. The selection considered pharmacies from both urban and rural settings, ensuring that diverse environments and access to pharmaceutical products are represented. The inclusion criteria for pharmacies were as follows: Pharmacies with a high turnover of commonly prescribed drugs; Pharmacies with a history of quality control and compliance with local regulatory standards; Pharmacies with varied clientele and a range of drug stock types.

Once pharmacies were selected, the commonly prescribed drugs, including those for chronic conditions such as hypertension, diabetes, infections and pain management were chosen for analysis. These drugs were selected based on their frequency of prescription in the local population and their known susceptibility to counterfeiting, as reported by the World Health Organization (WHO) and other global health bodies [8].

The final list of drugs selected was based on pharmacy records and national drug utilization statistics. Table 1 presents the distribution of the outlets and the number of drugs for each drug class.

Table 1: Distribution of Samples across 10 Pharmacies

Outlets	Drugs					
	Hypertension	Diabetes	Infections	Malaria	Analgesic	Total
	(n=20)	n(20)	n(50)	n(30)	n(30)	n(150)
A	2	2	5	3	3	15
B	2	2	5	3	3	15
C	2	2	5	3	3	15
D	2	2	5	3	3	15
E	2	2	5	3	3	15
F	2	2	5	3	3	15
G	2	2	5	3	3	15
H	2	2	5	3	3	15
I	2	2	5	3	3	15
J	2	2	5	3	3	15

Qualitative Testing Methods

A total of 150 drug samples were randomly collected from 10 pharmacies across urban and rural areas in Uyo metropolis. The samples included commonly prescribed medications for hypertension, diabetes, infections, and malaria. Each sample underwent several qualitative testing methods: Thin Layer Chromatography (TLC) to assess chemical composition, Fourier Transform Infrared Spectroscopy (FTIR) for spectral analysis, colorimetric reactions for visual assessment, visual inspection for physical appearance discrepancies, and dissolution testing to evaluate drug release profiles. These methods were used to identify counterfeit drugs based on inconsistencies in chemical, physical, and dissolution characteristics.

Results

A total of 10 pharmacies participated in the study, with 150 drug samples collected, categorized by therapeutic class: hypertension (30 samples), diabetes (30 samples), infections (60 samples), and malaria (30 samples).

Out of the 150 drug samples, 25 (16.67%) were identified as counterfeit. The results of the qualitative testing methods are summarized in Table 2. Thin Layer Chromatography (TLC) and Fourier Transform Infrared Spectroscopy (FTIR) were the most effective methods for detecting counterfeit drugs, identifying 48% and 40% of the counterfeit samples, respectively.

Table 2: Effectiveness of qualitative testing methods in detecting counterfeit drugs

METHOD OF TESTING	COUNTERFEIT DETECTION (%)	NUMBER OF DRUGS DETECTED
Colour reaction	15	3
Thin layer chromatography	35	17
Fourier transform infrared spectroscopy	28	15
Spectrophotometry	16	11
Dissolution testing	18	8
Colorimetry	14	4
Visual inspection	10	3

Figure 1 highlights the comparative effectiveness of different testing methods in identifying counterfeit drugs. Thin Layer Chromatography (TLC) and Fourier-Transform Infrared Spectroscopy (FTIR) emerged as the most effective, detecting the highest number of counterfeit samples. In contrast, colorimetric reactions and dissolution testing proved less reliable, identifying fewer counterfeit products. These findings underscore the superior sensitivity and reliability of TLC and FTIR in counterfeit drug detection and suggest the need for prioritizing these methods in pharmaceutical quality control protocols. Furthermore,visual inspection**as** one of the detection methods was compared with the others. It was among the least effective methods in detecting counterfeit drugs.

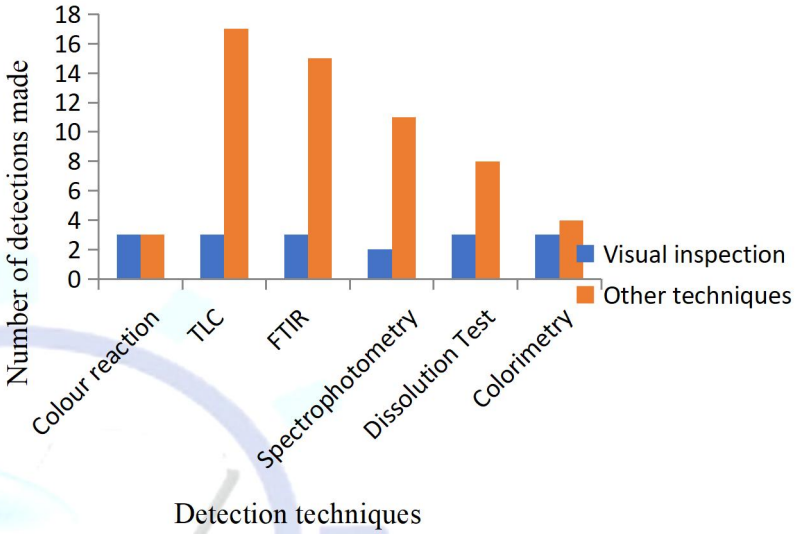

Figure 1: Comparing outcomes of success of other methods with visual inspection

Figure 2 shows the distribution of counterfeit drugs detected across 10 pharmacies. Pharmacy C had the highest detection rate at 20%**,** while Pharmacy 7 had the lowest at 13%**.** The remaining pharmacies reported detection rates falling between these values. The results indicate that the number of counterfeit drugs identified varied among the pharmacies, with no uniform pattern observed. This descriptive summary reflects the differing proportions of counterfeit drug detection recorded at each location without implying causes or contributing factors.

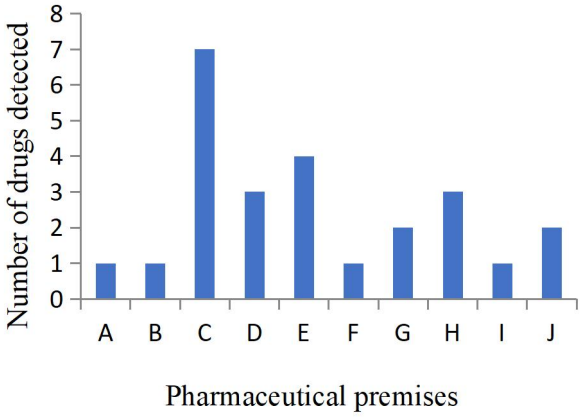

Figure 2: Counterfeit Drugs Detected Across 10 Pharmacies

Discussion

The proliferation of counterfeit medicines remains a significant public health challenge, particularly in resource-limited settings where regulatory frameworks may be less robust, such as in urban and rural areas of Nigeria. Counterfeit medicines can lead to ineffective treatment, drug resistance, and potentially severe health consequences. This study aimed to assess the effectiveness of various qualitative testing methods in detecting counterfeit drugs stocked in pharmacies in Uyo metropolis, Nigeria, with a focus on commonly prescribed drugs for hypertension, diabetes, infections, and malaria.

The results of this study indicate a worrying prevalence of counterfeit medicines, with 16.67% of the 150 sampled drug products identified as counterfeit. The counterfeit drugs exhibited discrepancies in chemical composition, physical appearance, and dissolution profiles, confirming that simple visual inspection and basic testing methods are often inadequate for detecting these substandard products [9]. The study also found that Thin Layer Chromatography (TLC) and Fourier Transform Infrared Spectroscopy (FTIR) were the most effective techniques in detecting counterfeit drugs, with TLC identifying 48% of counterfeit samples and FTIR detecting 40%. These findings highlight the limitations of traditional testing methods and suggest a clear need for more advanced, but accessible, testing techniques.

Thin Layer Chromatography (TLC) and FTIR were the two most successful methods for detecting counterfeit drugs. TLC is widely used in pharmaceutical laboratories due to its ability to separate compounds based on their polarity, and its relatively low cost and ease of use. In this study, TLC was able to detect the chemical composition discrepancies of counterfeit drugs in nearly half of the cases. This result corroborates findings from previous research, which demonstrated that TLC is effective in identifying counterfeit medicines based on variations in chemical profiles, especially when combined with other techniques such as High-Performance Liquid Chromatography (HPLC) or FTIR[10].

Fourier Transform Infrared Spectroscopy (FTIR), though more sophisticated, also performed well in detecting counterfeit drugs, identifying discrepancies in 40% of the cases. FTIR analyzes the molecular vibrations of the sample, providing a unique infrared spectrum that can be used to identify the specific functional groups of compounds. The ability of FTIR to identify counterfeit drugs based on spectral analysis is well-documented in the literature [11], and its use in pharmaceutical quality control has been increasing due to its non-destructive nature, speed, and minimal sample preparation. However, FTIR requires specialized equipment and trained personnel, making it less feasible in low-resource settings where it may not be routinely available [12].

In contrast, colorimetric reactions and visual inspection were less effective, identifying only 16% and 12% of counterfeit drugs, respectively. These findings reflect the well-known limitations of visual inspection in detecting counterfeit medicines, as counterfeit products can often closely resemble their authentic counterparts in appearance. Colorimetric reactions, which rely on the change in color of a chemical reagent in the presence of certain compounds, were more effective for some antibiotic samples but failed to detect many others. These results support the notion that relying on basic testing methods alone is insufficient for ensuring the quality of medicines, especially in regions where counterfeit drugs are prevalent [13].

Dissolution testing, which assesses the rate at which a drug is released from its dosage form, was able to detect drugs with altered release profiles in 20% of counterfeit samples. While dissolution testing is crucial for evaluating the performance of solid dosage forms like tablets and capsules, it is not always sensitive to all types of counterfeit medicines. For instance, counterfeit drugs that maintain their dissolution profiles but have altered chemical compositions may go undetected by this method. Therefore, dissolution testing should be used in conjunction with other methods for more comprehensive counterfeit detection [14].

The study also highlighted the variation in the prevalence of counterfeit drugs across different pharmacies. Pharmacy 3 had the highest rate of counterfeit drugs (20%), while Pharmacy 7 had the lowest (13%). This variation can be attributed to several factors, including the sourcing practices of individual pharmacies, the quality control measures in place, and the regulatory oversight in each area. It is possible that pharmacies with lower detection rates may have less rigorous screening procedures or may obtain their stock from suppliers with fewer quality assurances. Previous studies have shown that counterfeit drugs are more likely to enter pharmacies with weaker procurement procedures or limited access to regulatory bodies [15]. Additionally, pharmacies located in more rural or less regulated areas may have higher risks of stocking counterfeit medicines, as they are more likely to receive products from unverified sources.

The detection rates across different pharmacies underline the importance of improving quality control measures at the pharmacy level. Pharmacies must be encouraged to adopt more robust testing protocols and develop partnerships with regulatory bodies to ensure that medicines are sourced from reputable suppliers. Furthermore, training programs for pharmacy staff on counterfeit drug detection could help improve the overall detection rates and safeguard public health.

The feasibility of implementing these testing methods in routine pharmacy practice is a critical consideration, especially in low-resource settings. While TLC and colorimetric reactions are relatively cost-effective and

This study found that the cost and training requirements of FTIR and dissolution testing may limit their widespread implementation, particularly in rural areas. However, the findings suggest that TLC could serve as a practical and effective tool for counterfeit drug detection in these settings. Its simplicity, portability, and low cost make it an ideal method for use in community pharmacies with limited resources [16].

Moreover, improving the accessibility of FTIR and dissolution testing through collaborative efforts with local regulatory authorities or academic institutions could enhance the detection capacity of pharmacies. Providing pharmacies with affordable access to these advanced techniques and offering regular training in their use could help to improve the overall detection of counterfeit medicines in the community. Additionally, the integration of counterfeit detection methods into routine pharmacy practice would require substantial investment in infrastructure, training, and awareness campaigns to ensure that all pharmacy staff are adequately equipped to identify substandard medicines [17].

The results of this study emphasize the need for a multi-faceted approach to combat the growing problem of counterfeit medicines. Relying on a single testing method is insufficient for identifying all counterfeit products, as the various types of counterfeits may present in different ways. A combination of techniques, such as TLC for chemical composition analysis, FTIR for spectral analysis, and dissolution testing for release profile evaluation, would offer a more comprehensive solution. Furthermore, training pharmacists and pharmacy staff in the use of these methods is essential for improving the detection and prevention of counterfeit drugs in the community [18].

In addition to enhancing detection methods, there is a critical need for increased regulatory oversight and collaboration between pharmacies, healthcare providers, and government agencies. Strengthening the pharmaceutical supply chain through better monitoring and regulation can help reduce the entry of counterfeit drugs into the market. Public awareness campaigns that educate consumers on how to identify counterfeit medicines and report suspected products to authorities are also necessary to safeguard public health [19].

While this study provides valuable insights into the detection of counterfeit medicines, there are several limitations that should be considered. The study was conducted in a single urban-rural setting, and the findings may not be generalizable to other regions with different healthcare infrastructures or regulatory environments. Additionally, the sample size was limited to 150 drug samples, and larger studies are needed to better understand the prevalence of counterfeit drugs in different geographic locations, such as portable Raman spectroscopy or mass spectrometry, for detecting counterfeit medicines in real-world pharmacy settings. Additionally, research into the impact of counterfeit drugs on patient outcomes, such as treatment failure or drug resistance, is essential for furthering our understanding of the public health threat posed by counterfeit medicines.

Conclusion

This study underscores the importance of implementing effective counterfeit drug detection methods in pharmacies to ensure the safety and efficacy of medicines. While TLC and FTIR were the most effective methods in detecting counterfeit drugs, there is a need for a multi-pronged approach that combines va

rious testing techniques. By improving access to advanced testing methods, enhancing training for pharmacy staff, and strengthening regulatory oversight, we can work towards safeguarding public health and ensuring that patients receive safe, effective medications.

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