

Inspection Practices for Regulating Prescription Handling and Antibiotics Control in Ilala Community Pharmacies of Dar es Salaam, Tanzania: Qualitative Assessment

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Abstract

Aim: The study aimed to explore inspection practices of prescription handling and antibiotics control in the context of Tanzania's community pharmacies.

Design: Qualitative exploratory study.

Methods: This qualitative study held 14 in-depth interviews with pharmacists (three), pharmaceutical technicians (seven), and pharmacy council representatives (four) to collect data on the inspection processes for regulating prescription handling and antibiotic control in community-based pharmacies. The data was then subjected to content analysis with the help of NVivo12.

Results: The study found that even though routine inspections were conducted to regulate prescription handling and antibiotic control in community pharmacies, there were inconsistencies in prescription retention, inadequate documentation in the inventory system, and improper antibiotic storage, with less attention paid to inspecting antibiotic sales practices. Implicitly, the efficiency and effectiveness of such inspections were open to question. Moreover, many clients frequented these visits to community pharmacies without prescriptions, yet they were dispensed with non-over-the-counter antibiotics. Furthermore, there were generally disparities between regulatory expectations and practical implementation in community pharmacies.

Conclusion: More emphasis is necessary on antibiotic prescriptions and retention in community pharmacies coupled with standardized inspection protocol to help enhance inspection regulation activities and promote better dispensing practices for prolonged medicine life, improved efficacy, and health outcomes.

Keywords: Inspection practices, prescription handling, antibiotics control, community pharmacies

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Introduction

Antibiotics, since their discovery in 1928, have helped to reduce global mortality rates caused by bacterial infections (da Cunha et al., 2019). Although classified as prescription-only medication, antibiotics are frequently accessible without prescriptions in community pharmacies (Auta et al., 2019). This loophole significantly challenges regulating their rational use, contributing to the alarming rise in Antimicrobial Resistance (AMR), recurrent infections, increased treatment costs, and poor health outcomes (Aljeldah, 2022; Morrison & Zembower, 2020). AMR is a critical global public health threat, accounting for about 700,000 annual deaths due to drug-resistant infections. The over-the-counter (OTC) sale of antibiotics is a grave global public health concern, particularly in low- and middle-income countries (LMICs), where such practices persist despite having regulations in place (Vazquez-Lago et al., 2017a). According to the World Health Organisation (WHO), the inappropriate use of antibiotics largely stems from suboptimal pharmacy practices (Miller & Goodman, 2016).

In Africa, where healthcare infrastructure is often inadequate, community pharmacies are the primary point of contact for healthcare services (Ayukekbong et al., 2017). Thus, these regions need robust inspection practices to regulate prescriptions and the sale of antibiotics. Even though regulatory bodies in many of these countries have appointed inspectors to oversee and check for compliance with the antibiotics-selling regulations (Porter et al., 2021), how they operate and their experience enforcing antibiotic-selling regulations are not well-documented. Inspection of community pharmacies in LMICs has proven to be daunting due to resource constraints in these countries. Specifically, a critical shortage of well-trained human resources for conducting inspections has been compounded by poor financial support to execute inspection activities (Ayukekbong et al., 2017). When such inspections occur, they are often sporadic and deviate from the recommended frequency as outlined in the guidelines (Oseni, 2021).

Studies conducted in African countries show that most community pharmacies sell and dispense medications without regulatory authorities' permit and use unauthorized—sometimes even unqualified—personnel or authorized personnel who lack a clear understanding of prescription medication regulations against AMR (Wafula et al., 2014). In Tanzania, antibiotics are prescription-only medications, with their sale in both part I and part II pharmacies requiring a valid prescription. Antibiotic prescription regulations fall under the Ministry of Health (MoH), and the Pharmacy Council. The authorities are mandated to safeguard the public by ensuring acceptable standards of pharmacy practice through regular inspections and enforcement of prescription handling guidelines.

In April 2020, the Tanzania MoH introduced the prescription handling and control regulations (Crabbe, 2021) to enforce the sale of prescription-only medications, including antibiotics. These regulations require that patients present a valid medical prescription before medication can be dispensed. Moreover, the dispensers must check the validity of those prescriptions, retain the original handwritten prescription and give the patient a copy.

Despite the availability and clarity of the regulations on antibiotic dispensing, studies in Tanzania show that a high proportion of pharmacies dispense antibiotics without prescription (Nkinda et al., 2022), with figures reaching a staggering 88.2% [95%CI 86.3–89.9%] (Ndaki et al., 2021). In practice, people can access a variety of medicines, including antibiotics, from community pharmacies without any valid prescriptions (Nkinda et al., 2022). In other words, the prescription-only medication classification and dispensing guidelines are largely ineffectual. Consequently, the

rate of national consumption of antibiotics in the private sector, including community pharmacies in the country, remains high, with 80.8 ± 39.35 defined daily doses (DDDs) per 1,000 inhabitants each day, with amoxicillin and doxycycline being the most widely dispensed antibiotics (Mbwasi et al., 2020). As a result, the consumption rate far outstrips that of high-income countries (Mbwasi et al., 2020; Westbrook & Kirk, 2007). This alarmingly high consumption of these prescription-only drugs will continue to contribute to the emergence and spread of AMR (Poyongo & Sangeda, 2020), particularly in the absence of effective curbs, and negatively impact people's health and well-being as well as public health generally.

The external and internal factors have accounted for dispensing antibiotics without prescriptions. The factors external to the pharmacist include the client's inability to obtain prescription (Bianco et al., 2021), self-prescription and medication practices (Nepal & Bhatta, 2018) and inadequate regulatory inspections and enforcement as well as the absence of accountability mechanisms (Torres et al., 2020). On the other hand, internal factors include capitalizing on the available openings to maximize sales and gain supper profits (Poyongo & Sangeda, 2020), and negative attitudes, insufficient knowledge, and fear of disappointing clients (Vazquez-Lago et al., 2017b). Other internal factors include irrational dispensing and misuse of antibiotics aggravated by the community pharmacists' poor knowledge, attitude, and practices related to antibiotics (Nkinda et al., 2022).

As such, a better understanding of the modus operandi of the community pharmacies in handling prescriptions in the face of existing control mechanisms could yield useful insights into informed approaches to dealing effectively with irrational dispensing of antibiotics. After all, regulatory infringement on antibiotic dispensing without prescription is common in Tanzania (Horumpende et al., 2018; Mboya et al., 2018; Myemba et al., 2022) with several dispensers perceiving the regulatory authorities as lenient, hence leading to intentional unauthorised dispensing of prescription-only medications to augment their sales and income (Poyongo & Sangeda, 2020). As a rule, and in theory, antibiotics prescriptions should be retained at the pharmacies upon dispensing, and the patient should only get a copy of that prescription.

Antibiotics prescription retention is a critical aspect of regulatory adherence that needs monitoring during inspections; however, information on how prescription handling and regulations are implemented, particularly in the community pharmacies, remains scarce in the context of Tanzania. This study aimed to bridge this knowledge gap through a detailed understanding of how the inspection practices designed to regulate prescription handling and antibiotics control are enforced in community-based pharmacies. Understanding these practices could inform targeted interventions aimed to enhance enforcement of prescription handling and antibiotics control regulations for improved dispensing practices, people's health and well-being generally.

Significantly, this study was carried out to identify loopholes within the regulatory framework of Tanzania and how to plug them. An efficiency and effective antibiotic regulatory framework are key for improving rational antibiotics prescription and use as well as improved patient's health outcomes.

Materials and Methods

Study design and settings

The study employed qualitative research design and in-depth interviews to collect data. This qualitative research suited the study due to its exploratory nature intended to elicit participants

experiences and views (Mack et al., 2005) on the inspection practices for regulating prescription handling and controlling of dispensing antibiotics in community pharmacies. The use of in-depth interviews elicited detailed understanding of the phenomena in question (Rutledge & Hogg, 2020) and enabled the study to gain a comprehensive grasping of the participants' views and experiences essential in addressing the research objective.

The study was conducted in Ilala district of Dar es Salaam city, a densely populated area with about 1,649,912 residents as of the 2022 census (NBS, 2022). Ilala district had the highest number of registered pharmacies, about 311 establishments, when compared to the remaining four administrative councils in Dar es Salaam region of Kinondoni, Kigamboni, Temeke, and Ubungo. Such a high concentration of registered pharmacies made Ilala a unique context to explore the inspection practices in place for regulating prescription handling and antibiotics control in community pharmacies.

We conducted in-depth interviews with the regulators in charge of inspecting the community pharmacies to understand how they enforced the inspection regulations on prescription handling and control in community pharmacies. In addition, we engaged with dispensers working in community pharmacies, who included pharmacists and pharmaceutical technicians, to share their experiences of being inspected on antibiotics prescription handling and control by the regulatory authorities.

Recruitment of participants

The study participants were purposively recruited based on their position and experiences with prescription handling and control in community pharmacies. The research team in consultation with the Pharmacy Council, a regulator which works to ensure adherence to the standards of pharmacy practice in public interest, identified individuals who were directly involved in the regulation of community pharmacies.

These individuals were also involved in community pharmacy inspections and regulating antibiotics prescription handling and control. In addition, we purposively recruited dispensers who comprised the pharmacists and pharmaceutical technicians to gain insights into their experiences with regulating prescription handling and control practices. All these participants were informed in detail about the nature of the study and its objectives before they could provide their informed consent.

During such briefings, they had ample opportunities to ask questions or seek clarification from the research team before affirming their willingness to participate in the study. The recruitment process ended after reaching a data saturation with only those who provided consent participating in the study.

Data collection and analysis

Researcher (LC) supported by a research assistant collected the data. Both have a pharmacist background and broad-based experience in qualitative data collection in various health-related fields in urban and rural settings of Tanzania. Before data collection, the research assistant was informed about the study objectives and trained on data collection guides, data handling, data storage, and ethical considerations during data collection activities. An interview guide, refined after a pilot study, facilitated the interviews.

The guide covered several themes aimed to explore how the inspection of community pharmacies was done, who did the inspection, challenges experienced during the inspection, and

suggestions for improving these inspections. In all, 14 interviews (four with interviewees from the pharmacy council, three pharmacists, and seven pharmacy technicians) were conducted in Kiswahili, a language spoken by all the study participants. During interviews, probing questions helped to understand the participants' opinions and experiences better.

The researcher conducted all the interviews while the research assistant took field notes in addition to helping to identify any data inconsistency during the data collection process. The interviews were audio-recorded with the participant's permission and lasted 25 to 55 minutes. The interviews were conducted until the data saturation point was reached when no new information could further be generated (Mwita, 2022). Even though the data saturation point was reached at the 12 interviews, we added two more interviews to confirm such saturation.

The audio-recorded files were transcribed verbatim within 48 hours of being generated and saved into Swahili Word files. The Swahili word files were then translated into English language and both the transcriptions and translations were crosschecked by the principal researcher (LC) for quality and clarity before importation into NVivo 12 software for further management and analysis. We adopted and applied Graneheim and Lundman's approach to qualitative content analysis (Graneheim & Lundman, 2004).

Content analysis enabled the inductive generation of the codes and categories essential in capturing the participants' unique experiences (Bengtsson, 2016). After selectively dividing the text into meaning units, data was condensed, abstracted, and labelled with codes. Codes were compared for similarities and differences based on the discussions and agreement among all authors before applying them to the remaining transcripts. The resulting codes were further compared, merged to form sub-categories, and eventually consolidated into categories through collaborative agreement with all the authors (Stahl & King, 2020)

Ethical clearance

The study received ethical clearance from the Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Review Board (DA/282/298/01.c/1633). Permission to conduct the study in the community pharmacies was obtained from the Tanzania Pharmacy Council and the managers of the privately-owned community pharmacies in Ilala district council. All the methods in the study were performed following the relevant guidelines and regulations (Declaration of Helsinki). Before their involvement in the study, we explained the research objectives and procedures to the participants before obtaining their written informed consent.

Results

The study results describe the main categories that emerged from the data: inspection of antibiotics prescription retention, inspection of inventory management, inspection of proper storage of antibiotics; and challenges to inspection for regulating prescription handling.

Inspection of antibiotics prescription retention

The interviews with the regulators at the Pharmacy Council revealed that they usually conducted routine inspections to check whether the pharmacies received, retained, and stored prescriptions after dispensing the prescription-only antibiotics. In most cases, they said, only a few pharmacies received and retained such prescriptions for antibiotics.

The regulators reported that the main reasons for the pharmacies not keeping the records included government restrictions imposed on getting prescriptions outside the health facilities.

The government promotion policy “get everything in the hospital” discourages the provision of prescriptions to patients to obtain medicines outside the health facilities. In consequence, most of the customers visiting pharmacies to buy antibiotics lack such prescriptions, and the pharmacists dispense the medicines accordingly:

“The government, on the other hand, says that prescriptions should not leave the facility. So, you find someone sitting in a pharmacy with investments, but no prescriptions are forthcoming. What do you expect will happen? Someone will demand medication, and without a prescription, they will be listened to. The medicines dispensed to them because the government doesn’t allow prescriptions to get out of the [health] facilities” (R04, Regulator Pharmacy Council).

Interviews with community pharmacies affirmed that most of the clients they attended to did not have a prescription but were knowledgeable about the type of antibiotics they needed. Moreover, they reported being inspected routinely on prescription retention but also noted that the regulators emphasized inspecting the pharmacy premises, the permit, and the surrounding environment in addition to ascertaining the qualifications of pharmaceutical technicians and pharmacists:

“For the case of the Pharmacy Council, they routinely visit us for inspecting the prescription retentions but they mostly check for registration of personnel and whether or not they have paid for their licences, the validity of premises registrations. They rarely check general practice when it comes to antibiotics. They mainly inspect controlled drugs” (R07 Pharmaceutical technician).

Inspection of Inventory Management

Regulators reported that during inspections, they usually checked the medicine registry and the inventory systems. In so doing, they reported experiencing challenges because some pharmacies neither kept dispensing register nor did they have a computer record system. They further pointed out that the absence of a dispensing register was a punishable offense, yet enforcement was largely lacking:

“During routine inspections, we check for medication registers and inventory systems. Some pharmacies do not have any form of inventory management, meaning dispensing registers and computer systems. Although this is a punishable offense in pharmacy practice, this enforcement is not stringent because we usually see the medication register. Still, it contains incomplete information” (R03, Regulator Pharmacy Council).

During interviews with community pharmacies, most pharmacists and pharmaceutical technicians instead expressed concern about the relative lack of emphasis on the documentation of antibiotics in the inventory system. The pharmacists cautioned that inspectors needed to be careful when reviewing the pharmacy records to ensure the numbers for what had been ordered tallied with what appeared in records as sold or in stock. They insisted that doing so could help to ensure that there were no antibiotics that could be dispensed without prescriptions:

“Regulators should carefully review the pharmacy records during inspections. If, let’s say, a certain pharmacy has bought a given number of antibiotics orders, upon selling, the number of prescriptions should match the amount sold or present in stock, just like medications such as diazepam; they can’t be dispensed without prescriptions...” (R02, Pharmacist).

Inspection of Proper Storage of Antibiotics

Inspection of proper storage of antibiotics is one of the critical areas that receive special attention during these inspections. Regulators reported that they pay more attention in inspecting proper storage conditions of the antibiotics to maintain their quality and efficacy. They ensure these antibiotics are not displayed in the public area (over the counter). Instead, they emphasize designating secure storage space for these antibiotics away from public view:

“We have been inquiring about where prescriptions are stored, and medications dispensed based on prescriptions should be stored in the designated store space, not displayed on the counter. When these medications are dispensed, it must be done according to the established procedures, which require a valid prescription” (R02, Regulator, Pharmacy Council).

The dispensers at community pharmacies also reported similar ideas that the regulators are diligent in verifying whether pharmacies have established adequate measures to secure antibiotics in designated storage areas:

“Regulators are keen on checking for antibiotic storage. They do not want us to display antibiotics out in the open together with other over-the-counter medications. This is the first thing they ascertain after ensuring that we have the necessary certification for conducting business and premise permits” (R04, Pharmaceutical Technician).

Inspection Challenges to Regulating Prescription Handling

Pharmacists and technicians faced challenges in adhering to regulations mandating the retention of antibiotic prescriptions. They reported often receiving incomplete prescriptions with insufficient information that the prescription handling and control regulations required them to retain:

“I have seen several prescriptions with antibiotics; they are incompatible and are not well written, and this is why we do not keep the prescriptions. Because most of them are incomplete, they do not give you a clue” (R04, Pharmaceutical Technician).

In addition, those near hospital settings received just a single copy from patients, contrary to guidelines specifying the availing of two copies:

“We do receive a few prescriptions from patients coming from the hospital, usually when medications are out of stock in these hospitals. We dispense these medications according to the prescription requirements, and we cannot retain this prescription as regulations demand because patients have to return them to their respective wards” (R05, Pharmacist).

Regulators also reported the challenges emerging from the comprehensive nature of prescription regulations, which involve all areas of health service provision, including hospitals. They noted

that, currently, no inspections were conducted in hospital settings, hence limiting the distribution of vital guidelines, including issuance of prescriptions to patients. As a result, they implored the Pharmacy Council inspectors to assess hospital pharmacies to enforce compliance with regulations and facilitate the effective dissemination of essential guidelines:

“The regulation for prescription handling and control cuts across all areas of health service provision, so, most of these hospitals and health centres are unaware of this regulation. There is a need for effective communication between these institutions and the Council” (Ro2, Regulator, pharmacy Council).

Discussion

This study explored the inspection practices in regulating prescription handling and antibiotics control in community pharmacies in the context of Tanzania. Using in-depth interviews, the study generated comprehensive information on the participants' insights into their experiences with pharmacy inspections and regulation of antibiotics. This study comes in handy because qualitative studies assessing the inspection regulations and antibiotic control in the community pharmacies in Tanzania are largely limited. Such study results are critical in informing targeted interventions for strengthening pharmacy inspection practices, regulations, and antibiotic control measures to promote the rational use of medicines for better health outcomes, prolonged medicine life, and improved efficacy.

The study found that, even though routine inspection ensures community pharmacies comply with the national regulations and guidelines on prescription and antibiotic control, such oversight was primarily limited, undermining its effectiveness. On the one hand, the participants reported that during the inspection process, inspectors focused not only on prescription and antibiotic dispensing but also on various aspects such as personnel qualifications, registration permits, and antibiotic storage conditions to ensure medication safety in the pharmacies.

Similar observations were also reported in Lebanon (Badro et al., 2020) and Uganda (Trap et al., 2016), where regular inspections of community pharmacies were conducted to ensure adherence to good pharmacy practices, including prescription handling and antibiotic control. This similarity underlies the multifaceted nature of these routine inspections covering diverse pharmacy operations dimensions. When conducted properly, these inspections can serve as an effective regulatory practice to control irrational medicine use, reduce preventable deaths and improve the quality of health services and people's quality of life (Alhusein & Watson, 2019). Efforts to strengthen inspection practices in community pharmacies are necessary to ensure public access safe and effective medications.

On the other hand, the participants reported disparities in inspection practices related to the dispensing and using of antibiotics regardless of the routine inspections conducted. The routine inspections covered qualifications and medication quality but without necessarily paying specific attention to antibiotic handling and control. This finding is consistent with a study that reported inspections often prioritizing general compliance with registration regulations at the expense of antibiotic-specific practices in community pharmacies (Jacobs et al., 2019a). Yet enhancing inspection practices related to antibiotic use is a common theme across multiple studies, which signals the need to address this gap in regulatory oversight functions. Such efforts could be strengthened by the engagement of all stakeholders as antimicrobial stewardship to monitor, influence, guide, and encourage responsive antibiotic use.

The challenges related to inspecting prescription retention in community pharmacies emanated from failure to receive and document prescriptions, particularly after antibiotics issuance by established procedures and regulatory requirements. This shortcoming is evident in prior research (Torres et al., 2020), where incomplete or missing prescription details hindered the community pharmacies' adherence to prescription retention ability. Based on the testimonies from the participants, this anomaly arose because of various factors, including patients receiving only a single copy of the prescription from healthcare facilities. This practice contravenes the regulatory mandate for pharmacies to maintain a copy for documentation and accountability purposes. (Servia-Dopazo & Figueiras, 2018) reported similar documentation struggles in community pharmacies owing to hospitals emphasizing on electronic systems and streamlining the prescription process within the health facilities.

As a result, community pharmacies struggled to receive and ensure proper documentation. Notably, the regulatory body in our study acknowledged this discrepancy, emphasizing the imperative for collaboration between private sectors (community pharmacies) and healthcare institutions to address this issue effectively (Servia-Dopazo & Figueiras, 2018). This observation aligns with previous research underscoring the significance of enhancing cooperation between stakeholders in the healthcare system to bridge the gap between regulatory requirements and practical implementation (Monnier et al., 2019).

The study results further suggest that inspecting inventory management constitutes an essential area during routine inspections. However, inspecting inventory management continued to present a challenge as some pharmacies had no dispensing register or computer system, resulting in incomplete inventory information documentation. In this regard, our study found that inspectors lacked focus in inventory management due to inherent challenges, contrary to a study that established documentation and inventory management practices as critical focus areas during routine inspections (Shrestha & Ghale, 2018). Usually, and as standard practice, inspectors pay close attention to the accuracy and completeness of recorded information to ensure proper record-keeping and inventory management (Jacobs et al., 2019b). In this study, drug dispensers similarly called on pharmacy inspectors to scrutinize medicine registers or inventory systems to verify the proper recording of antibiotics and stock levels. Documentation and inventory management should be a universal concern in regulatory inspections.

Furthermore, the study found that inspectors prioritized checking antibiotic storage conditions to ensure that they were not displayed in the over-the-counter area and away from public access. These results coincide with a study conducted in Boston (Ching et al., 2023) that highlighted the significance of designated storage areas for antibiotics, away from direct sunlight and public access, to prevent misuse or unauthorized handling (Badro et al., 2020). This correlation indicates a consensus among studies regarding the importance of proper antibiotic storage practices. One might argue the conclusions from this study reflect what could be happening in many parts of the country. However, the study results may have limited application to other parts of the nation, considering that the study was conducted in a predominantly urban area (Ilala) of Tanzania's business hub, Dar es Salaam. The less stringent enforcement of the inspections to regulate prescription handling and antibiotics control in community pharmacies of a readily accessible metropolitan area suggests that the situation in the distant hard-to-reach areas might be much worse. A more comprehensive study covering both urban and rural settings could, therefore, further broaden our understanding of the regulation practices for antibiotics prescription and control for even more informed strategies for improving the practices.

Conclusion

This study unveiled challenges to effectively regulating antibiotic prescriptions, notably in prescription retention, inventory management, and oversight of antibiotic sales. These challenges suggest a need for the Pharmacy Council to develop standardized inspection protocols accentuating the critical aspects of prescription handling, including proper storage, prescription retention, and meticulous documentation of antibiotic transactions. This measure could encourage best practices in community pharmacies and enhance compliance with prescription handling regulations. Furthermore, fostering effective communication between hospital settings and community pharmacies is crucial in aligning practices with prescription handling regulations. Such communication should also facilitate the sharing of guidelines, including prescription issuance, and ensure consistent adherence to regulatory standards. Implementing these actions can substantially reduce over-the-counter antibiotic sales and dispensing, safeguard public health, and support global efforts to combat antimicrobial resistance.

Data availability

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request

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Conflict of interest

The authors have no conflict of interest relevant to this article.

Authors contribution

LC: Conceptualisation of the study, data acquisition, and manuscript drafting. EM and GF: Conceptualised the study, coordinated and supervised data acquisition, and drafted the manuscript. All authors read and approved the final manuscript

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