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Analysis of pharmacy inspection results for retail drugstores in Central region of Vietnam from 2018 to 2022

Phân tích kết quả thanh tra dược đối với cơ sở bán lẻ thuốc khu vực miền Trung Việt Nam giai đoạn 2018 - 2022

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Abstract

Introduction: Ensuring compliance with standards and regulations in the retail pharmaceutical sector is essential for protecting public health through maintaining the quality and safety of medications until their use. This study investigates the publication of inspection results of retail drugstores and the state of regulatory compliance at these facilities in the Central region of Vietnam, focusing on the city of Da Nang and several surrounding provinces. **Methods:** Using a retrospective descriptive method by employing a dual approach of website analysis and keyword searches, the study collected data from official portals and government websites. Selection criteria included reports on pharmaceutical inspection results at pharmacies from 2018 to 2022. Data was gathered and analyzed to assess inspection outcomes, identify common violations, and compare regulatory practices across different jurisdictions. **Results and discussion:** The inspection results analysis of 558 pharmacies revealed 90 violations (16.1%), with main issues including incorrect record-keeping and improper storage processes. Despite a general trend towards transparency and clarity in professional management at retail units, the data indicate that there are still prominent issues that require attention. The findings of this study align with previous global research, indicating common challenges in ensuring regulatory compliance at pharmacies. These findings emphasize the importance and challenges of pharmacies continuing to improve professional quality and compliance, focusing on common violations for prioritization in remediation and prevention.
Conclusion: To enhance the safety and ensure the quality of pharmaceutical products reaching consumers, this study proposes insights and the importance of ongoing monitoring, stricter regulatory enforcement, and innovations in the quality management of pharmacy operations to accommodate evolving trends in the pharmaceutical industry within the context of scientific and technological advancements.

Keywords: Pharmaceutical inspection; regulatory compliance; good pharmacy practice; central region of Vietnam; public health safety.

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Tóm tắt

Giới thiệu: Việc đảm bảo tuân thủ các tiêu chuẩn và quy định trong lĩnh vực bán lẻ dược phẩm là cần thiết để bảo vệ sức khỏe cộng đồng thông qua duy trì chất lượng và tính an toàn của thuốc cho đến khi được sử dụng. Nghiên cứu này khảo sát việc công bố kết quả thanh tra cơ sở bán lẻ thuốc và tình hình tuân thủ quy định chuyên môn tại các cơ sở này ở khu vực miền Trung Việt Nam, tập trung vào thành phố Đà Nẵng và một số tỉnh lân cận.

Phương pháp: Sử dụng phương pháp hồi cứu mô tả, với cách tiếp cận kép gồm phân tích trang web và tìm kiếm theo từ khóa, nghiên cứu thu thập dữ liệu từ các cổng thông tin chính thức và trang web của Chính phủ. Tiêu chí lựa chọn bao gồm các báo cáo kết quả thanh tra dược tại nhà thuốc từ năm 2018 đến 2022. Dữ liệu được thu thập và phân tích các kết quả kiểm tra, xác định các vi phạm phổ biến và so sánh thực tiễn quy định giữa các khu vực pháp lý khác nhau. **Kết quả và thảo luận**: Phân tích kết quả thanh tra trên 558 nhà thuốc cho thấy có 90 nhà thuốc vi phạm (16,1%). Các lỗi vi phạm chủ yếu bao gồm ghi chép số liệu không đúng cách và quy trình lưu trữ không đảm bảo kỹ thuật. Mặc dù có xu hướng chung hướng tới sự minh bạch, rõ ràng trong quản lý chuyên môn tại đơn vị bán lẻ, dữ liệu chỉ ra rằng vẫn còn những vấn đề nổi cộm cần lưu ý. Kết quả của nghiên cứu phù hợp với các nghiên cứu trước đây trên thế giới, cùng chỉ ra các trở ngại phổ biến trong việc đảm bảo tuân thủ quy định tại nhà thuốc. Các phát hiện này nêu ra tầm quan trọng và những thách thức trong việc các nhà thuốc cần tiếp tục nâng cao chất lượng chuyên môn và tuân thủ quy định, chú ý các vi phạm phổ biến để ưu tiên khắc phục và phòng ngừa.

Kết luận: Để nâng cao an toàn và đảm bảo chất lượng sản phẩm thuốc đến tay người dùng, nghiên cứu này đề xuất góc nhìn và tầm quan trọng của việc giám sát liên tục, thực thi quy định nghiêm ngặt hơn nữa, đồng thời cần có những cải tiến trong hệ thống pháp quy nhằm tạo điều kiện thích ứng với các xu hướng ngành dược đang phát triển trong bối cảnh tiến bộ của khoa học công nghệ.

Từ khóa: Thanh tra dược; pháp chế dược; thực hành nhà thuốc tốt; nhà thuốc miền Trung Việt Nam; an toàn sức khỏe cộng đồng.

1. Introduction

The pharmaceutical retail sector plays a critical role in ensuring public access to safe and effective medications, making the lawful operation of drugstores imperative [1]. Oversight of drugstore operations through pharmaceutical inspections, conducted by regulatory authorities, is essential for upholding regulatory compliance and maintaining standards [14,17]. Through periodic inspections and assessments, pharmaceutical inspections ascertain that standards and regulations related to the sale of medicines at drugstores are strictly adhered to, concurrently ensuring the safety and quality of pharmaceutical products accessible to consumers. Developed countries, such as the United States and European Union countries, exhibit stringent compliance to good pharmacy practices (GPP), markedly reducing incidents of expired medication sales and dispensing errors, largely attributed to robust regulatory frameworks and periodic inspections [8]. Conversely, developing regions, including Vietnam, face challenges such as inadequate storage and record-keeping [4,12].

In Vietnam, the management and adherence to regulations regarding the operation of drugstores have received considerable attention and high evaluation from governmental agencies and healthcare organizations. Nevertheless, despite the concentrated efforts from the government and the pharmaceutical sector, challenges persist concerning the enforcement of regulations and standards governing drugstore operations [3].

According to the stipulations of the 2022 Inspection law [18], which replaced the previous 2010 law [17], and the corresponding guiding decrees [14-15], the disclosure of pharmaceutical inspection results on official portals has become mandatory. However, with the new law taking effect from July 2023, specific deadlines for publishing inspection results have been outlined.

This study aims to provide an overview of the current state of affairs regarding the publicization of pharmaceutical inspection results by local government agencies responsible for overseeing retail pharmaceutical

establishments within their jurisdictions. Specifically, the research focuses on examining the practices of Da Nang and several provinces in the Central region. By scrutinizing inspection outcomes and identifying prevalent issues and challenges at the local level, this research seeks to offer insights that can inform concrete solutions to enhance the management effectiveness of good pharmacy practices (GPP) [16]. Ultimately, the goal is to ensure the safety and quality of pharmaceutical products consumed by the public amidst evolving regulatory landscapes and industry trends.

2. Materials and methods

2.1. Sampling method and data collection

Using a retrospective descriptive method by employing a dual approach, this research employs a combination of two methods to gather information on pharmaceutical inspection results. Firstly, the study involves browsing the portal websites of selected provincial health departments to identify relevant sections containing information on pharmaceutical inspection activities and official notifications of inspection results. Secondly, the research utilizes the Google search engine, employing keywords such as "thanh tra" (inspection), "thanh tra dược" (pharmaceutical inspection), "kết quả thanh tra" (inspection results), "nhà thuốc" (pharmacy), "cơ sở bán lẻ" (retail facility), and "hiệu thuốc" (drugstore), along with search limitations using the "site:" operator for domain restriction to government websites (e.g., domain_name.gov.vn).

2.2. Selection criteria

Reports containing inspection-related information are included if they meet specific criteria, including being in common electronic file formats, written using official document formats, and containing digital signatures or clear indications of the signatory's name, date of issuance, and document number. Exclusion criteria encompass webpage articles or other types of content lacking attached files, as well as documents hosted outside the domain of the provincial health department portal.

2.3. Data processing and analysis

Information extracted from the reports meeting the screening criteria includes the date of inspection, the number of drugstores inspected, the number of violations identified, the types of violations, and the actions taken to address violations.

To ensure objectivity and reliability, the research verify data consistency and reliability by cross-checking and comparing data collected from various sources. Key study variables include the number of days from the inspection date to the publication of inspection results (based on the date of issuance), the number of pharmaceutical retail facilities found in violation categorized by the type of violation, and the total number of recorded violations during pharmaceutical inspections at each facility.

Statistical analyses were conducted as follow: ANOVA test was conducted to statistically examine the differences in publishing times among these regions. The differences in the rates of pharmacy violations across various localities were statistically examined using Epi Info 7, conducting Chi-square test with significance set at $p<0.05$. When the expected frequencies in any of the categories were below 5, Fisher-exact test was employed to ensure the validity of the significance testing. Odds Ratios (ORs) quantified the strength of these associations, considered significant if their 95% confidence intervals did not include 1.

Data visualization: Findings were presented through charts and tables, with data visualization conducted using Microsoft Excel.

3. Results

3.1. Overview of pharmaceutical inspection result publication

The examination of pharmaceutical inspection result publication revealed a consistent trend over the years from 2018 to 2022. Figure 1 illustrates the number of reports published each year, indicating fluctuations but an overall stable pattern. The highest number of reports was observed in 2022, with 06 reports published, while the lowest was in 2020, with only 1 report. These figures provide insights into the frequency of publicized inspection outcomes within the selected localities.

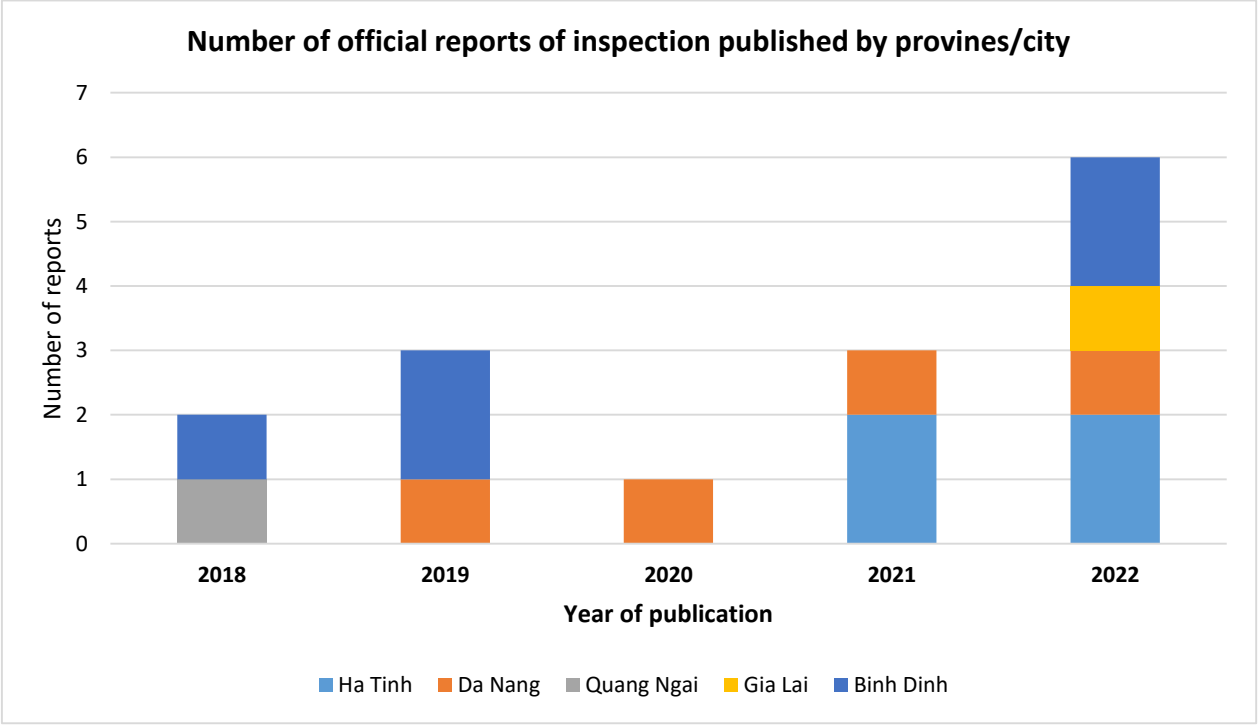

Figure 1. Number of pharmacy inspection reports published each year in surveyed city/provinces

3.2. Inspection results publishing time

Data in Table 1 presents a comparative analysis of the average times required to publish pharmacy inspection results across five distinct provinces/cities. The analysis spans several years, capturing variability in administrative efficiency. Binh Dinh, Da Nang, Gia Lai, Ha Tinh, and Quang Ngai are included, with their respective average publishing times detailed. A noteworthy finding is the range of average times, from as low as 3.0 days in Gia Lai to as high as 18.5 days in Ha Tinh. The overall average across all provinces/cities, calculated at approximately 11.3 days.

Table 1. Average pharmacy inspection result publishing times across localities

Province/City	Average publishing time (days)
Binh Dinh	10.0
Da Nang	5.8
Gia Lai	3.0
Ha Tinh	18.5
Quang Ngai	8.0
Total average	**11.3**

Additionally, an ANOVA test was conducted to statistically examine the differences in publishing times among these regions, yielding an F-statistic of approximately 1.19 and a *p*-value of 0.36 (> 0.05), indicating no statistically significant differences in publishing times among the regions.

3.3. Analysis of pharmaceutical inspection result publication

Out of 558 drugstores inspected within the scope of this study, 90 were found to be in violation of regulations, indicating a substantial compliance gap. Table 2 presents a detailed analysis of the pharmaceutical inspection results, showcasing vital variables and corresponding values. The types of violations varied, with the most common being lack of proper documentation (15.8%), and storage violations (10.6%). On average, each facility recorded approximately 2.9 violations, emphasizing the prevalence of multiple infractions within individual drugstores. The predominant enforcement actions taken included issuing warning notices with suspension of drugstore operations (5.6%) and imposing fines (9%), highlighting the regulatory response to non-compliance by the local authorities. The analysis result suggests the need for stringent enforcement measures to ensure adherence to pharmaceutical regulations and standards.

Table 2. Summary of pharmaceutical inspection result publication

Variable	**Value**
Number of drugstores inspected	558
Number of drugstores found in violation	90
Average number of violations per facility	2.9
Common types of violations	- Lack of proper documentation (15.8%) - Storage violations (10.6%)
Enforcement actions taken	- Warning notices issued, suspension of drugstore operations (5.6%) - Fines imposed (94.4%)

3.4. Comparison of inspection results across localities

Result in Table 3 provides a comparative analysis of inspection results between Da Nang and other provinces in the Central region. In examining inspection results across five localities, significant variability was observed. The $\chi 2$ Test demonstrated that Da Nang, Quang Ngai, and Gia Lai had statistically notable differences in violation frequencies compared to others. The prevalence of pharmacy violations in Da Nang (20.7%) and Gia Lai (32.4%) is respectively 1.75 times (OR=1.75 [1.04-2.93]) and 3.52 times (OR=3.52 [2.03-6.10]) higher compared to other localities in the region. Notably,Quang Ngai has the lowest rate of pharmacy violations (4.3%), which is only 0.24 times (OR=0.24 [0.07-0.63]) that of the other regions. These disparities suggest differential regulatory compliance and enforcement efficacy. Particularly, Gia Lai's markedly higher Odds Ratio warrants further investigation into local practices.

Table 3. Comparison of inspection results across localities

Locality (province/city)	Number of drugstores inspected	Number of violations recorded	Percentage (%)	Comparison to all others provinces/city	
				$\chi 2$ Test *p*-value	Odds Ratio [95%-CI]
Ha Tinh	182	23	12.6	> 0.05	-
Da Nang	116	24	20.7	< **0.05**	1.75 [1.04-2.93]
Quang Ngai	93	4	4.3	< **0.05**	0.24 [0.07-0.63]
Binh Dinh	93	15	16.1	> 0.05	-
Gia Lai	74	24	32.4	< **0.05**	3.52 [2.03-6.10]
Total	**558**	**90**	**16.1**		

3.5. Summary of violations observed during pharmaceutical inspections

The results of the pharmaceutical inspections reveal several noteworthy findings (Table 4). The most common violation observed during these inspections pertains to incomplete recordkeeping of drug purchasing and selling activities, accounting for 15.8% of the total violations identified. Following closely behind is the issue of disorganized storage of drugs, characterized by clutter and dust, which accounted for 10.6% of the violations. Other notable violations include the failure to register accounts connected to the "National Drug Database" system (9.8%), absence of signage indicating "none-drug products" in areas storing cosmetics, dietary supplements, and medical supplies (7.5%), and lack of ledger or computer usage for managing drug inventory (7.2%).

Table 4. Summary of violations observed during pharmaceutical inspections, sorted by frequency

No.	Violation description	Frequency	Percentage
1.	Incomplete recordkeeping of drug purchasing and selling activities	42	15.8
2.	Disorganized storage of drugs, characterized by clutter and dust	28	10.6
3.	Failure to register accounts connected to the "National Drug Database" system	26	9.8
4.	Absence of signage indicating "none-drug products" in areas storing cosmetics, dietary supplements, and medical supplies	20	7.5
5.	Lack of ledger or computer usage for managing drug inventory, including batch numbers, expiration dates, and origins, as per legal requirements	19	7.2
6.	Incomplete or inaccurate price listing	16	6.0
7.	Lack of calibrated temperature and humidity monitoring devices for drug storage	16	6.0
8.	Improper use of retail cabinets for drugs	16	6.0
9.	Absence of self-recording thermometers	15	5.7
10.	Absence of the pharmacist-in-charge during designated times, without proper delegation as per regulations	14	5.3
11.	Pharmacies operating without a valid drug business operation certificate	12	4.5
12.	Inadequate or improper arrangement of controlled drug storage areas	6	2.3
13.	Mixing non-drug products with drugs	6	2.3

No.	Violation description	Frequency	Percentage
14.	Failure to ensure adequate physical and human resources conditions	4	1.5
15.	Placing product crates directly on the floor	4	1.5
16.	Failure to publicly display pharmaceutical professional practice certificates or drug business operation certificates at the establishment	3	1.1
17.	Improper use of waiting or near-expiry drug areas	3	1.1
18.	Selling non-duty-paid imported drugs	3	1.1
19.	Absence of physical barriers for isolation from living areas	2	0.8
20.	Absence of temperature and humidity monitoring logs	2	0.8
21.	Retailing expired drugs	2	0.8
22.	Lack of required professional qualifications for individuals involved in drug retail	1	0.4
23.	Absence of measures to prevent direct sunlight exposure on drugs	1	0.4
24.	Selling controlled drugs without maintaining complete prescription records as required	1	0.4
25.	Pharmacies with a business scope for controlled drugs without supplementing the professional scope in the drug business operation certificate	1	0.4
26.	Pharmacies offering drug business services without a pharmaceutical professional practice certificate	1	0.4
27.	Cosmetics businesses failing to disclose cosmetic product information	1	0.4
	Total:	**265**	**100**

4. Discussion

The findings of this study offer insights into the landscape of pharmaceutical inspection result publication and regulatory compliance in the examined localities. The consistent trend observed in the publication of inspection reports suggests a commendable commitment to transparency and accountability within pharmaceutical oversight mechanisms. However, despite this concerted effort, a notable prevalence of violations during inspections highlights significant areas requiring improvement.

In light of the Inspection laws of 2010 [17], and 2022 [18], our analysis of average pharmacy inspection result publishing times across different localities reveals significant variance (Table 1). This result prompts a crucial examination of regional inspection processes in alignment with the legal mandates for efficiency and transparency. Particularly, the 2022 law, effective from July 1, 2023 [18], suggests the imperative for timely actions and disclosures in inspection activities, advocating for a standardized and efficient approach across all regions. Gia Lai exemplifies the pinnacle of efficiency, setting a benchmark for others. This analysis, devoid of statistically significant disparities, suggests that variations might be rooted in administrative procedures rather than compliance with the legal framework, highlighting an opportunity for optimization based on best practices.

Investigation into drugstore inspection practices and regulatory compliance in the Central region of Vietnam, including Da Nang, reveals pivotal insights into the enforcement of pharmaceutical standards for public health safety. Research by Parinyarux and Yotsombut (2022) indicates the crucial role of customer

satisfaction and compliance with Good Pharmacy Practice (GPP) standards [9], noting that failure to meet these during inspections could jeopardize pharmacy license renewal. This situation calls for rigorous adherence to regulatory norms to maintain service quality and safety. Further analysis by Borges et al. (2017) [5] and Shah et al. (2016) [11] highlights the importance of sanitary surveillance and drug store quality, pointing to the need for strict inspection protocols to address common violations and improve storage practices. Such challenges, including recordkeeping lapses and delays in the publication of inspection results, pose risks to public health and the integrity of pharmaceutical services in Vietnam. The variations of data in Table 3 suggest the necessity for region-specific regulatory strategies to bolster pharmaceutical oversight. The analysis, however, did not consider external factors that may influence these outcomes, such as quality control system or testing capacity [7,11], that indicating a direction for future research.

Additionally, Alsalman and Hasan (2021) discuss the complexities of controlling and inspecting pharmacies [2], suggesting a strong legal and regulatory framework to tackle legal violations in the pharmaceutical sector. Incorporating findings from Trap et al. (2016) regarding good pharmacy practices in Uganda [13], Poudel et al. (2016) on regulatory compliance in Nepal [10], Bagonza et al. (2020) on the inspection of drug shops in Uganda [4], and Kamba et al. (2020) on the compliance of private pharmacies with regulations in Uganda [6], provides a broader perspective on the universal challenges in pharmacy regulation. These studies highlight the necessity of regular inspections, adherence to laws, and the implementation of best practices to elevate pharmacy services and public health safety.

The study notes the widespread issue of incomplete documentation in drug purchase and sales activities as a major violation. The results in Table 4 suggest the importance of robust recordkeeping practices, organized storage systems, and regulatory compliance in ensuring the safety and integrity of pharmaceutical retail establishments. Accurate records are essential for tracking pharmaceutical product flow and ensuring supply chain accountability. The frequent occurrence of such violations indicates a pressing need for better training and supervision to promote recordkeeping among pharmaceutical retailers. Concerns about disorganized drug storage and insufficient documentation reveal gaps in adherence to good storage practices and regulatory standards. Adequate storage is vital for preserving drug efficacy and safety; hence, regulatory bodies should focus on education and enforcement to correct these deficiencies.

To enhance pharmaceutical regulation and safety, it's crucial to prioritize the enforcement of compliance standards, focusing on documentation and storage practices identified as prevalent issues. Implementing streamlined procedures for timely publication of inspection results and leveraging technology can significantly improve transparency. Additionally, providing targeted training for pharmacy staff on good pharmacy practices and establishing continuous monitoring mechanisms will support ongoing improvement. These efforts should collectively aim to elevate the quality and safety of pharmaceutical services, fostering greater public trust in the regulatory framework overseeing the retail pharmacy sector.

5. Conclusion

In conclusion, the outcomes highlight the critical need for ongoing monitoring and

regulatory enforcement to protect public health and ensure pharmaceutical product quality and safety. Identifying common violations and areas for improvement enables regulatory authorities to develop targeted measures to increase compliance and promote a culture of quality and safety in the pharmaceutical retail sector. Continuous efforts to improve transparency and accountability in pharmaceutical oversight are vital for building stakeholder trust and maintaining public confidence in the regulatory system.

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