



## Regular inspection and committing major malpractices: Case of Pakdasht pharmacies

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### ABSTRACT

**Background:** It is necessary to regulate the pharmacies' services to maintain their qualities for providing services to patients. One side that should be considered is to prevent pharmacy malpractices. Depending on the types and recurrences of illegal acts, regulatory affairs and enforcements could reduce malpractices in health care providers. The aim of this study was to evaluate the efficacy of pharmacy inspection.

**Method:** In this study, we evaluated the efficacy of pharmacy inspection on preventing probable malpractices. Data were collected from inspection forms provided by Vice-Chancellor's Office in Food and Drug Supervision in Shahid Beheshti University of Medical Sciences and were filled by inspectors between January 2013 and April 2014. Seven major illegal acts are considered in this study including pharmacist absences during the pharmacy opening hours, delivery of Non Prescription Drugs (NPDs) without pharmacist supervision, existence of expired drugs in pharmacy, existence of counterfeit drugs or cosmetics in pharmacy, existence of any illegal narcotic or amphetamine drugs without Drug-Sale-License, inappropriate drug storage condition, and insufficient consideration in Galenic formulation. The inspections were assessed in all 26 private pharmacies in Pakdasht, Tehran, Iran.

**Results:** The results showed that the scores of second inspection in quantitative assessment became better than the first one. The average score of existence of illegal drugs in the second inspection was soared to 89.92 from 58.11 in the first inspection. According to the qualitative assessment, the number of malpractices, except delivery of prescription drugs and inappropriate storage condition had decreased entirely from the first to the last inspection. Existence of illegal narcotics and amphetamines in pharmacy reduced from 13% to zero.

**Conclusion:** Pharmacy inspection could reduce malpractices if it is performed routinely and the penalties are strict and suitable.

**Keywords:** Malpractice; Regularity affair; Inspection; Pharmacy

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### 1. Introduction

In treatment of a disease, pharmacies usually are the last place that patients receive the healthcare services [1]. Thus, it is important to control and supervise the pharmaceutical services provided in pharmacies to maintain the standard level of services in pharmacies. In all over the world, it is necessary to control the quality of healthcare services in private sectors [2-7].

The terms and condition of pharmacies in Iran (Iran pharmacy bylaw) originated from a legislation which came to effect in 1955 and following an amendment in 1988. In clause 2 of Iran pharmacy bylaw, pharmacy introduced as a medical institution having authorization from ministry of health and medical education and a responsible pharmacist controls pharmaceutical affairs to deliver medicines and drugs, infant formula, medical equipment and cosmetics [8].

Some of the responsible pharmacist duties, as clause 25 of Iran pharmacy bylaw states, include; 1. Attending and working actively in pharmacy according to the definite time period, 2. Checking the prescriptions and delivering medicines to patients, 3. Delivering non-prescription drugs (NPDs) according to the legal drug list, 4. Giving consultation about medicines, 5. Providing the storage conditions such as appropriate temperature and humidity, 6. Checking the expiry dates, 7. Formulating Galenic medicine from authorized ingredients, 7. Preventing the involvement of non-pharmacist staffs in technical pharmaceutical affairs [8]. According to provision of clause 27 and 28 of Iran pharmacy bylaw, if a pharmacy commits any malpractice which may cause endangering public health and medicine consumers; the local medical university committee, as a legal representative of ministry of health and medical education, could decide to penalize the pharmacy [8].

There are two different sectors of pharmacies in Iran; governmental and private pharmacies. All the pharmacies are controlled under

supervision of provincial medical universities linked with the Ministry of Health and Medical Education. Based on the current rules, pharmacist should manage pharmacies. Pharmacists not only have responsibility to provide medicines and pharmaceutical affairs for patients, but also have a role as a manager. It is illegal to manage a pharmacy by non-pharmacists.

Due to the governmental rules in the Ministry of Health, malpractices could lead to record and fine the committed pharmacies. In the literature, there are many reports of malpractices occurred in pharmacies, especially in developing countries. Butt et al. study in Rawalpindi (Pakistan) revealed that only 4.8% pharmacies had air conditioner to maintain medicines in proper temperature, and 10.3% had thermometer to control the temperature of storing conditions [9]. Most pharmacies in developing countries have unprofessional personnel for delivering medicines. Therefore, drugs are sold frequently without considering if the customer had a physician prescription or not [6, 9-13]. Moreover, Dadfar et al. revealed that community pharmacies in Tehran are confronting serious troubles in service quality [1].

Another malpractice that patients may face is delivering counterfeit drugs. Public awareness about counterfeit drugs in developing and low-income countries where drug supervision are feeble [14-23] has increased during the decades [15, 24-26]. Moreover, there are some dispensing medicine errors, such as delivery of expired drugs, which might cope with some serious problems [27, 28].

The most retail pharmacies in low-income countries belongs to the private sector and they are considering their incomes by selling medicines and outlets [6, 29-31]. It is necessary to perform Good Pharmacy Practice (GPP) in pharmacies. The Ministry of Health and Medical Education in Iran spends a lot of money and human sources for

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inspection. Consequently, it is important to evaluate its efficacy if it can improve the services in health care centers.

On the basis of article 30 in Iran Pharmacy Bylaw, regulatory actions and enforcement against malpractices in pharmacies contains several degrees depending on the types and recurrences of illegal acts. As a first degree, the pharmacy is warned and receives oral notice by recording in the inspection form. Second degree contains written notice while recording under the frame-sheet of the pharmacy in the university. After third time or more, the pharmacy is introduced to the competent authorities for temporary or permanent suspension [32].

In this study, we focused on private pharmacies in Pakdasht-Tehran and regulated their services by inspecting them in routine periods between January 2013 and April 2014. We studied whether the regular inspections have any effects on the quality of the services in pharmacies.

### 3. Results

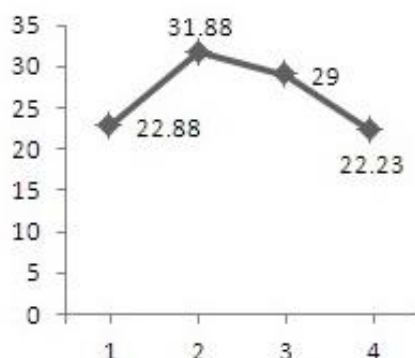
#### 1) Absence of pharmacist in the pharmacy

The percentage of pharmacies without pharmacist, who must be present actively in the pharmacy, declined from 34.6% in the first inspection to 30% in the fourth. However, the percentage of this malpractice was less than 30% in the second and the third inspections (20% and 23%, respectively).

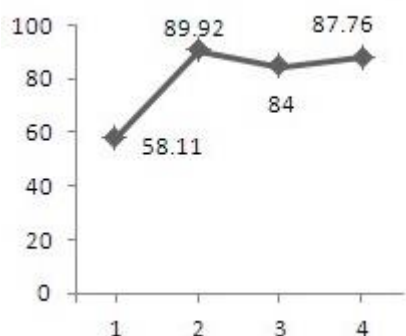
#### 2) Delivery of prescription drugs without physician prescription

There was a reduction in the percentage of pharmacies delivered prescription drugs without any physician prescription from 84% in the first inspection to 65% in the third one, while it increased in the last inspection up to 96%.

In Figure 1, the average score for prescription drugs delivery in four



**Figure 3.** Quantitative evaluation in OTC drugs delivery. The horizontal and vertical axis show the order of inspection and the score points, respectively. The maximum point is 40.



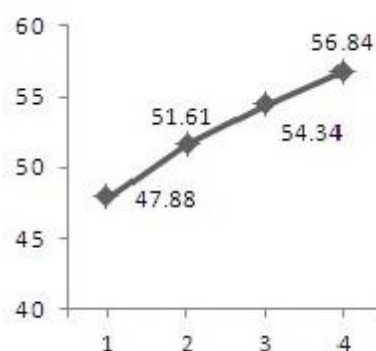
**Figure 4.** Quantitative evaluation in correct performance against illegal, counterfeit, narcotics and amphetamines drugs which maximum point is 100. The horizontal and vertical axis show the order of inspection and the score points, respectively.

inspections has been shown. The average score increased in the second inspection (31.88%) in comparison to the first one (22.88%). The score decreased in the follow-up inspections and finally in the last inspection, it was approximately similar to the beginning of the study.

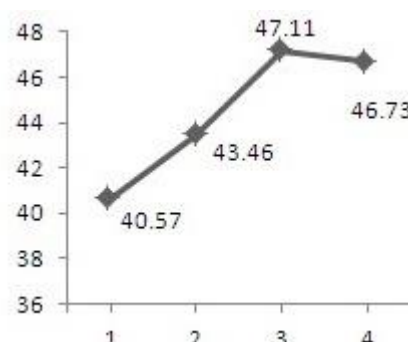
#### 3) Existence of illegal or counterfeit drugs, narcotics and amphetamines in pharmacy

The average score in the second inspection was soared to 89.92 from 58.11 in the first inspection (Figure 2). The score has remained upper than 80 in the follow-up inspections.

Moreover, the existence of illegal narcotics and amphetamines in pharmacy reduced from 13% to zero. It is claimed that in the last inspection no illegal narcotics and amphetamines were found in pharmacies.



**Figure 1.** Quantitative evaluation the drugs storing condition which maximum point is 75. The horizontal and vertical axis show the order of inspection and the score points, respectively.



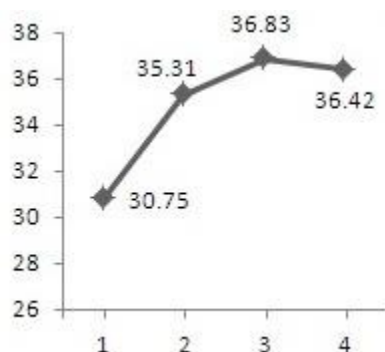
**Figure 2.** Quantitative evaluation in correct acts against expired date drugs which maximum point is 50. The horizontal and vertical axis show the order of inspection and the score points, respectively.

#### 4) Storage condition

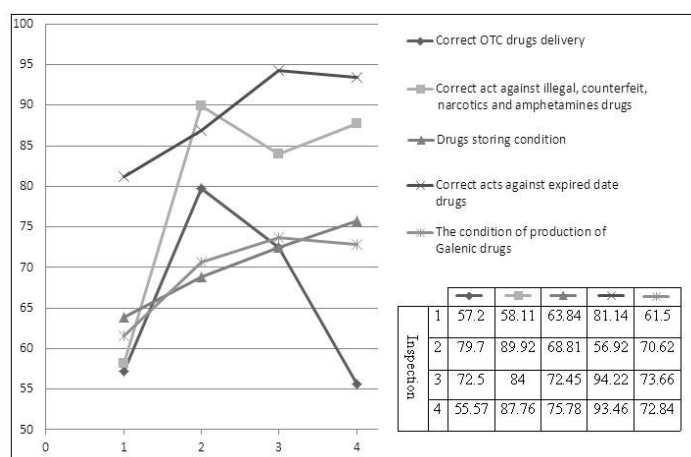
The percentage of pharmacies disregarding the drugs storage condition reduced slightly in second inspection (from 15% to 11.5%) then turned back to the prior position in the follow-up inspection. However, according to Figure 3, the average score of storage condition, in the quantitative study, elevated in each inspection in comparison to the previous one.

#### 5) Existence of expired drugs

The percentage of pharmacies storing or selling expired drugs rose from 30% to 42% in the second inspection, and then decreased into 7% in the fourth inspection. According to the figure 4 the average score in this field increased from 40 to almost 50.



**Figure 5.** Quantitative evaluation in respecting the condition of production of Galenic drugs which maximum point is 50. The horizontal and vertical axis show the order of inspection and the score points, respectively.



**Figure 6.** The average scores in quantitative factors which transformed to 100. The numbers in table show the average score in each factor. The horizontal axis and vertical axis in the curve show the time of inspection and the score points, respectively.

### 6) Galenic drugs production and its condition

The percentage of pharmacies using inappropriate ingredients for Galenic drugs decreased in comparison to their previous inspection (from the first to fourth inspection, there are 75%, 70%, 20%, 15%, respectively). In addition, according to the Figure 5, the average score of proper producing of Galenic drugs increased in the third and the fourth inspection; however, the differences between the first and the second inspection was negligible.

### Comparing different effects of inspection on each malpractice

Figure 6 shows that the average score in all factors in quantitative study transform to 100 as the highest score in each factor; therefore, it is possible to assess the entire factors together equivalently. In each case, the highest score, based on the standard inspection form, are equalized to 100 and the achieved scores are calculated from 100. The highest score belongs to absence of expired drugs in pharmacy. In the second inspection, all the scores became better than the first one in comparison with other consecutive inspections; moreover, the most considerable changing in score to a better one belonged to absence of illegal or counterfeit drugs in pharmacy. To be focused on “NPD delivery” score, the score increases in the second inspection, while it decreases in the follow-up inspection, even less than the score achieved in the first inspection. The changing scores of “storage condition” and “Galenic drugs producing condition” is approximately similar with parallel rate.

## 2. Methods

In this study, seven major illegal acts based on the rules of Vice-Chancellor’s Office in Food and Drug Supervision at Shahid Beheshti University of Medical Sciences were inspected in all 25 private daily pharmacies (open 9 A.M to 9 P.M) and 1 private 24-hours pharmacy in Pakdasht. The illegal acts include: 1. Pharmacist absence during the pharmacy’s opening hours, 2. Delivery of Non-Prescription Drugs (NPDs) without pharmacist’s supervision, 3. Existence of expired drugs in pharmacy, 4. Existence of counterfeit drugs or cosmetics in pharmacy, 5. Existence of any illegal narcotic or amphetamine drugs without Drug-Sale-License, 6. Inappropriate drug storage condition and 7. Insufficient consideration in Galenic formulation.

Pharmacies were inspected regularly every 3-4 months with two inspectors who were pharmacist and worked in supervision sector of pharmaceutical affair in Pakdasht health network. The inspectors were almost newly graduated pharmacy students who did their compulsory employment after their graduation, based on the rules of the Ministry of Health in Iran. Vice Chancellor’s Office in Food and Drug Supervision at Shahid Beheshti University of Medical Sciences trained the inspectors before the study started. There were two inspectional assessments; one of them was qualitative assessment with yes-no questions (Table-1 in the appendix) and the other one was quantitative assessment. Both forms were provided by Vice-Chancellor’s Office of Food and Drug Supervision at Shahid Beheshti University of Medical Sciences. The quantitative form has many factors, which can be assessed; however only factors categorized as major crimes were involved in this investigation (Table-2 in appendix). In the quantitative study, the higher score means that the pharmacy commits fewer malpractices. Both forms were used in inspection processes for all the pharmacies under supervision of the Vice Chancellor’s Office in Food and Drug Supervision in Shahid Beheshti University of Medical Sciences.

In qualitative study, the factors were checked and the data reported as the percentage of pharmacies committed malpractices in each inspection. One of the inspectors checked the quantitative form and gave a point. Finally, the data reported as the average of pharmacies’ scores in each inspection. Noticeably, to lessen the differences between individuals, each form checked twice by both inspectors. The data were analyzed by Microsoft Office Excel 2010.

## 4. Discussion

Prior to discuss about the results, it is necessary to mention as a fact that the patient expectations from services can be different considering aspects such as social relationships, previous experience, and physical and psychological essentials of the patients. Additionally, services can have many insubstantial sides, which are principally qualitative and make challenge in assessment of service quality [1]. In this study, we focused on the factors mentioned in the inspection form provided by the Vice Chancellor’s Office in Food and Drug Supervision. Since there are concerns about quality and safety of medicines, GPP should be considered. Wijesinghe et al. showed that there is poor compliance to GPP in private sectors in Sri Lanka [33]. There is moreover another study in Iran, which shows pharmacists’ knowledge about GPP is not sufficient, therefore it is needed to organize an educational program to introduce GPP and equip community pharmacists to do their responsibilities properly [34].

To study the inspection effect on the quality of pharmacy, Pakdasht pharmacies could be one of the best choices, because many of pharmacies there, was not inspected for a long time, so that it could be easily to compare the effects between the first and the follow-up inspections. To distinguish more about differences in quality, some criteria were scored and evaluated by only one of the inspectors

according to quantitative form and were checked by the other inspector to minimize the individual biases.

Based on the law in Iran, at least one pharmacist should be present in a pharmacy to distribute and deliver medicines to patients. In this investigation, it is shown that general trend of absence of pharmacist decreased, especially in the second inspection that is concluded the inspection leads to induce pharmacists to attend more actively in pharmacy. This criterion was only assessed quantitatively.

Prescription drugs delivery without physician prescription was studied quantitatively and qualitatively. The maximum score for this criterion is 40. This malpractice had no significant changes between the first and last inspection whereas it decreased sequentially until the third inspection. Although there are penalties for malpractices, most of these penalties are not so serious to prevent pharmacies from committing the crime again. Drug sellers would like to sell most of drugs without any consideration to physician allowance. Moreover, the drugs' interest margin is usually low and insurance companies pay back the money with a long delay. Moreover, insurer do not cover some of the fees, such as the fee of pharmaceutical technical services [35]. These reasons make drug sellers concerned about their incomes. In the third inspection, there was a paradox between quantitative and qualitative investigation. In qualitative study if only one blister of prescription drugs was delivered without any physician prescription and without any pharmacist consultation, the pharmacy would miss the point and categorize as a pharmacy that did not dispense non-OTC drugs correctly, however in quantitative study this factor divided into four 10-marked sub-factors.

"Existence and selling the illegal or counterfeit drugs" as a malpractice, has extreme punishment at least impounding all the illegal or counterfeit drugs with a considerable financial loss for a culprit. Additionally, the pharmacy might be referred to the Tazirat Office (it is an organization that evaluate the illegal acts, judge and give a sentence while necessary) [36]. Due to these punishments, it is obvious that the general trend of doing this malpractice decreases after inspection. There was a sharp decrease of this malpractice in the second inspection while the intense of decreases in the follow-up inspections was lower. Due to the intensive punishments, drug sellers would not have tendency to dispense these kinds of drugs. This trend was predictable for narcotics and amphetamines substances, too. Existence and selling illegal narcotics and amphetamines would impound. Moreover, the pharmacy might be closed temporarily as a punishment, as a result, the frequency of this malpractice reached to zero point in the last inspection in this investigation. Furthermore, it is considered for better public health that education programs for both patients and pharmacists at various levels could help to decrease the counterfeit medicines demands and requests [37].

In this study, the storage condition was assessed. In qualitative assessment, if inappropriate condition caused changing the quality of drugs for instance changing in color, odors or any issues known in the medicine references, the drugs would be disposed and the pharmacy would be introduced as a pharmacy with inappropriate storage condition.

In qualitative assessment, focusing on expired drugs issue, if there was only one blister of expired drugs in drug shelves, it was marked as a pharmacy that has stored and dispensed expired drugs. The rate of existing expired drugs in the second inspection increased and then decreased in the follow-up inspection. Considering the achievement scores, the availability and dispensing of expired drugs reduced due to the inspection. The score increased from 40 in the first inspection to about 47 in the last inspection. The cause of different results superficially in quantitative and qualitative study, especially in second inspection was that there were so many factors in quantitative assessment which a pharmacy could achieve the points although it had

only one blister of expired drug and missed the point in qualitative assessment.

Both of the scores in quantitative assessment and frequencies in appropriate Galenic drugs increased in the consecutive inspections.

To be able to compare all malpractices studied quantitatively in this investigation, all the scores were converted to 100-point scale. The most considerable change in malpractice committing was dispensing the illegal and counterfeit drugs. It is concluded that if appropriate penalties accomplished, the prevention effect in committing malpractices would be observed. These penalties are included impounding the illegal drugs and reporting the cases to Tazirat office. As there were no regulation pharmacy inspections before this study in Pakdasht, most pharmacies had bad situation in the first inspection. For overall issues, there was an increase in scores of pharmacies in quantitative assessment and decrease in frequencies of malpractice in pharmacies from first to second inspections. It is affirming that inspecting can prevent to commit malpractices; however by continuing this trend, the penalties should be fitting enough. For instance, there was no serious punishment about dispensing non-OTC drugs. Therefore, in the follow-up inspections after the prior prevention effect, this trend was not observed. Through the expired drugs existence, higher score was perceived compared with previous inspection depicting this malpractice was a mistake.

The inspection procedure is effective when it is permanent and have regular schedule, and it has suitable executive power to fine delinquents.

The restriction of this study was small number of the involved pharmacies. A similar study in a larger community is recommended. It is also necessary to study the effects of acclamation (financial or non-financial) on pharmacist promotion to act and do services in the best manner.

## 5. Conclusion

It is concluded that inspection could decline malpractices if it is performed routinely; and also need proper penalties which are compatible with the extent of malpractices. If there are no serious executive penalties for a malpractice the score will not increase as good standing declaration after intervention.

## 6. Acknowledgement

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## Appendixes

### Appendix 1. Pharmacy inspection qualitative form

	Yes	No
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### Appendix 2. Assessment form for quantitative study

<b>Assessment for OTC drugs</b>			
No.	Service items	Maximum score	Acquired score
1	Not selling prescribing drugs without valid prescription	10	
2	Correct practice on OTC drugs	10	
3	Not involving non-pharmacist in dispensing prescriptions	10	
4	Not dispensing prescription when pharmacist is absent	10	
	Total	40	
<b>Assessment for expired drugs</b>			
No.	Service items	Maximum score	Acquired score
1	Not keeping expired drugs and not selling them	50	
	Total	50	
<b>Assessment for counterfeit drugs</b>			
No.	Service items	Maximum score	Acquired score
1	Not existing counterfeit drugs	50	
2	Not selling counterfeit drugs	10	
3	Not buying drugs from illegal distributor centers	10	
4	Not existing other counterfeit goods (cosmetics)	30	
	Total	100	
<b>Assessment for drugs storage condition</b>			
No.	Service items	Maximum score	Acquired score
1	Accurate thermometer installed in pharmacy	15	
2	Considering appropriate temperature for medicine in pharmacy	20	
3	Light condition and protecting drugs from direct sources of light	10	
4	Storing drugs in appropriate refrigerator which are sensitized to room temperature	10	
5	Accurate thermometer installed in pharmacy depot	5	
6	Considering appropriate temperature for medicine in depot	15	
	Total	75	
<b>Assessment for making Galenic medicines</b>			
No.	Service items	Maximum score	Acquired score
1	Making the combined drugs and supervising by pharmacist	15	

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2	Proper time for making combined drugs	5
3	Proper instrument and clean place for making combined drugs	10
4	Good quality of ingredients	10
5	Good labeling	5
6	Consideration temperature condition to maintenance products	5
	Total	50