

**STUDY ON MAINTAINING OF GOOD PHARMACY PRACTICE
IN BEN TRE PROVINCE IN 2020**

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ABSTRACT

Background: Good pharmacy practice is the quality standards and guidelines for practicing in a pharmacy and small drugstore (this word means the establishment that sale the medicines but with the smaller and simpler requirement than a pharmacy) in order to distribute medicine directly to people who take the medicines, and to encourage the effective and safe in using a drug. **Objectives:** Determine the percentage of pharmacies and small drugstores that maintained GPP standards in Ben Tre province in 2020. **Materials and methods:** A cross-sectional descriptive study was carried out on 250 pharmacies and small drugstores in Ben Tre province that met the standards of Good Pharmacy Practice by using the questionnaires, the data were analyzed by SPSS software. **Results:** The percentages of pharmacies and small drugstores that have kept the GPP standards of human resource, facilities and professional activities were in the order 89.40%, 69.33% and 76.31%. **Conclusions:** The rate of maintaining good pharmacy practice in Ben Tre province was low.

Keywords: Good Pharmacy Practice (GPP), Ben Tre province.

I. INTRODUCTION

Medicines have become the indispensable need in human life. Health care requires the participation of several factors, in which drug is one of the most important factors that plays basic role in achieving the goal of the health to protect and improve the health of citizen [2]. On January 22, 2018, the Ministry of Health issued Circular No. 02/2018/TT-BYT about GPP and following it, the set of standards about good pharmacy practices, the activity ranges of the pharmacies, the conditional storages of medicines, the consultancy about safe using of medicines for patients is also issued. However, the medicinal distributive system has many limitations in the implementation of the current regulations on pharmaceuticals, for example, pharmacists were absent during work hours of the drugstores, the establishments didn't list the price of drugs. Moreover, lots of pharmacies haven't used the internet and IT into their activities in order to control the origin and price of medicines. So as to evaluate the operation of drugstores and the difficulty in the execution GPP standards in Ben Tre province, we studied *the maintaining of good pharmacy practice standards in Ben Tre province in 2020* with the aim of determining the rate of pharmacies and small drugstores maintaining criteria in accordance with standards of the Circular No.02/2018/TT-BYT in Ben Tre province in 2020 [4], [6], [7].

II. MATERIALS AND METHODS

2.1. Materials

Pharmacies and small drugstores that had achieved the good pharmacy practice in Ben Tre province in 2020.

We included the operating establishments had a certificate of eligibility for drug trading and had achieved GPP's certificate; the staff of the establishments have professional qualifications in pharmacy operating.

We excluded the pharmacies that were closed during the study period and people who are practicing at the pharmacies but are not on the list of workers.

2.2. Methods

Research design: A cross-sectional descriptive study [8].

Sample size:

$$n = \frac{Z_{(1-\alpha/2)}^2 \cdot p(1-P)}{d^2}$$

We selected $p = 0.8$ (p was the percentage of drug retailers maintaining GPP standards according to research by Dang Thi Thu Hong (2016) in Chau Thanh district, Tay Ninh city, Tay Ninh province) in the formula and the sample size was 245. With an expected error of 5%, we got $n = 250$ drug retailers [3].

Sampling method: Using random lot sampling method for a total of 250 samples of pharmacies and small drugstores in Ben Tre province (8 districts and 01 city). We selected 01 establishment in communes and wards when there were less than 10 establishments, 02 establishments in communes and wards if they had from 10 to 20 pharmacies, 03 establishments in communes and wards if they had from 20 to 30 pharmacies, 04 establishments in communes and wards with more than 30 pharmacies or small drugstores. In total, $n = 250$ establishments were selected.

Methods of data collection: Observation and directly interview with available questionnaire.

Data processing methods: Analysis and processing data by excel software.

III. RESULTS

3.1 Personnel criteria

Table 1. Personnel criteria

Criteria	Number of regulatory compliance establishments				Number of regulatory non-compliance establishments				Total (n = 250)			
	Pharmacies (n=25)		Drugstores (n=225)		Pharmacies (n=25)		Drugstores (n=225)		Number of regulatory compliance establishments		Number of regulatory non-compliance establishments	
	n	%	n	%	n	%	n	%	n	%	n	%
Establishments with practice certificates	25	100.00	225	100.00	-	-	-	-	250	100.00	-	-
Establishments with pharmacist who meet the prescribed conditions	18	72.00	179	79.56	7	28.00	46	20.44	197	78.80	53	21.20
									224	89.40	27	10.60

69.33% of retail establishments met the personnel criteria according to good practice of drug retailers and 30.67% of establishments did not meet the personnel criteria.

3.2 Material and technical facilities criteria

Table 2. Technical facilities criteria

Criteria	Number of regulatory compliance establishments				Number of regulatory non-compliance establishments				Total (n=250)			
	Pharmacies (n=25)		Drugstores (n=225)		Pharmacies (n=25)		Drugstores (n=225)		Number of regulatory compliance establishments		Number of regulatory non-compliance establishments	
	N	%	n	%	n	%	N	%	n	%	N	%
The rate of pharmacies had the separate area for dietary supplements and medical materials	20	80.00	166	73.78	5	20.00	59	26.22	186	74.40	64	25.60
The rate of pharmacies maintained temperature, humidity, time recording of temperature and humidity	21	84.00	150	66.67	4	16.00	75	33.33	171	68.40	79	31.60
Rate of pharmacies gave the unpack medicines obeying the regulations	19	76.00	157	69.78	6	24.00	68	30.22	176	70.40	74	29.60

Criteria	Number of regulatory compliance establishments				Number of regulatory non-compliance establishments				Total (n=250)			
	Pharmacies (n=25)		Drugstores (n=225)		Pharmacies (n=25)		Drugstores (n=225)		Number of regulatory compliance establishments		Number of regulatory non-compliance establishments	
	N	%	n	%	n	%	N	%	n	%	N	%
The rate of pharmacies checked drugs before delivering to customers	21	84.00	191	84.89	4	16.00	34	15.11	212	84.80	38	15.20
The rate of pharmacies saved the information of drugs into the software	19	76.00	150	66.67	6	24.00	75	33.33	169	67.60	81	32.40
The rate of establishments had account to connect to the National Database System	25	100.00	101	44.89	-	-	124	55.11	126	50.40	124	49.60
									173	69.33	77	30.67

69.33% of retail establishments met the technical facilities criteria according to good pharmacy practice and 30.67% did not meet the technical facilities criteria.

3.3 Professional performance criteria

Table 3. Professional performance criteria

Criteria	Number of regulatory compliance establishments				Number of regulatory non-compliance establishments				Total (n=250)			
	Pharmacies (n=25)		Drugstores (n=225)		Pharmacies (n=25)		Drugstores (n=225)		Number of regulatory compliance establishments		Number of regulatory non-compliance establishments	
	n	%	n	%	N	%	n	%	n	%	n	%
The rate of medicines owned registration number permitted for circulation	25	100.00	225	100.00	-	-	-	-	250	100.00	-	-
The rates of establishments had the drugs list with the retail prices	21	84.00	182	80.89	4	16.00	43	19.11	203	81.20	47	18.80
The rate of pharmacies sole prescribed drugs only if the prescriptions were valid	23	92.00	183	81.33	2	8.00	42	18.67	206	82.40	44	17.60
The rate of pharmacist was present when the pharmacies opened.	19	76.00	205	91.11	6	24.00	20	8.89	224	89.60	26	10.40

Criteria	Number of regulatory compliance establishments				Number of regulatory non-compliance establishments				Total (n=250)			
	Pharmacies (n=25)		Drugstores (n=225)		Pharmacies (n=25)		Drugstores (n=225)		Number of regulatory compliance establishments		Number of regulatory non-compliance establishments	
	n	%	n	%	N	%	n	%	n	%	n	%
The rate of staffs wore blouse and name tag	15	60.00	117	52.00	10	40.00	108	48.00	132	52.80	118	47.20
The rate of pharmacies maintained the drug retail area	21	84.00	155	68.89	4	16.00	70	31.11	176	70.40	74	29.60
The rate of pharmacies maintained a consultation area or private consultation desk	20	80.00	150	66.67	5	20.00	75	33.33	170	68.00	80	32.00
The rate of pharmacies maintained to consult of medical using	19	76.00	162	72.00	6	24.00	63	28.00	181	72.40	69	27.60
The rate of employees had been trained	18	72.00	157	69.78	7	28.00	68	30.22	175	70.00	75	30.00
									191	76.31	59	23.69

76.31% of retail establishments met the professional performance criteria according to good practices of pharmacies and small drugstores and 23.69% of establishments did not meet the criteria for professional performance.

IV. DISCUSSION

4.1 Personnel criteria

Personnel criteria was one of three main criteria on business conditions of a pharmacy, directly related to the establishment's owner and the pharmacist assistants. Under the provisions of the Circular No.02/2018/TT-BYT, the establishment's owner must have qualifications suitable to the requirements of each form of drug trading such as the pharmacy's owner must be a university pharmacist, the small drugstore's owner must have qualifications of intermediate pharmacist or higher [6]. According to the study, 100% owners of the pharmacies and small drugstores had suitable qualifications and pharmacy practice certificate form the Provincial Department of Health.

Under the provisions of the Circular No.02, pharmacist assistants must have qualifications suitable to each type of business, be healthy, and not be disciplined in the field of pharmacy. However, there were only 78,8% of pharmacies or small drugstores fixed with the requirement, and until 21.20% of pharmacies or small drugstores had unsuitable pharmacist assistants - they had not owned the health certificates. This result was higher than the result of Truong Van Hoa in 2010 in Ba Tri district and Ben Tre city, Ben Tre province which reached 62% [10]. In fact, that the medical examination for people who worked at the pharmacies and small drugstores only needed when the establishments registered the practice record at the Department of Health for the first time and then

the inspection only done when requested by state management agencies.

4.2 Material and technical facilities criteria

Material and technical facility was the second of the three main criteria on business conditions of a pharmacy/small drugstore. These criteria reflected medicine storage conditions of establishments and related directly to medicine's quality. At the same time, it involved many mandatory criteria such as facility area, construction design, drug storage equipment, accounting books and professional documents. Almost of the establishments stayed at the secure, airy, and clean places; all of them were not less than 10m², had the dustless ceiling and could protect the medicine from the sunlight. There were many different areas for the drugs storage, supplements and cosmetics storage, the consultants, drugs' dividing, etc. However, there were up to 30.67% of establishments didn't meet the standards of technical facilities such as the information of drugs weren't saved into the software (32.40%), or the pharmacies couldn't show the account connecting to the National Database System (49.60%). With the permission of the People's Committee of Ben Tre province in Official Dispatch 3676/UBND-KGVX dated on August 9, 2018 on agreeing the policy of deploying information technology application to connect drugs providers in Ben Tre province. The Department of Health and Vietnam Posts and Telecommunications Group (VNPT) organized the training courses on VNPT- Pharmacy information connection software for pharmacy business establishments in the province. The connection and provision of accounts of pharmacies to the website of the Ministry of Health was conducted in 2019 and in 2020, this was completed small drugstores. Every year, Ben Tre Department of Health had documents urging and guiding the implementation and strengthening the connection with drug providers such as Official Dispatch 1411/SYT-NVD dated May 14, 2020 on strengthening management and connection with drug providers, but the results were not high (49.6%), because the punishment were not strict enough [1], [5].

4.3 Professional performance criteria

In general, in terms of professional performance criteria, we recorded 76.31% of establishments meeting good pharmacy practice standards of retailers. In contrast, up to 23.69% of establishments did not achieve the criteria specified in the Circular No.02. The main reasons were not the compliance with prescribing regulations, the absence of pharmacist at the operating facility, the maintaining of the consultation area or private consultation desk, which was also common situation around the country. the provisions of Circular 02 / TT-BYT also required the staff of pharmacies or small drugstores must wear the blouse and name tag at the work but many pharmacist assistants didn't obey, the rate was about 47.2%; it was lower than the research of Dang Thi Thuy Hong in 2016 in Tay Ninh province (87.2%) and higher than the study of Truong Quoc Duy in 2018 in Hau Giang province (42.1%) [6].

Out of 224 (89.6%) pharmacists were present when the establishments operate (including someone who had the authority); there were 19 pharmacies (76%) and 205 drugstores (91.19%). This result was higher than the research result in 2018 at pharmacies and small drugstores in Hau Giang province by Truong Quoc Duy (82.7%) as well as higher than 62% in the study of Truong Van Hoa in Ba Tri district and Ben Tre city, Ben Tre province and 79.66% in the research by Dang Thi Thuy Hong in Tay Ninh province in 2016, the reason may be the regular inspection of the government [3], [9], [10].

V. CONCLUSIONS

The study showed that the rate of pharmacies and small drugstores met the personnel criteria, material and technological facilities criteria and professional performance criteria in GPP standards was ordered 89.40%, 69.33% and 76.31% respectively. Although establishments were knowledgeable about the regulations on good pharmacy practice, compliance with the regulations was very low due to many factors influencing the implementation of the regulations.

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