

THE IMPLEMENTATION AND MAINTENANCE OF GOOD STORAGE PRACTICE (GSP) PRINCIPLES: A SURVEY OF THE HOSPITALS IN HO CHI MINH CITY, VIETNAM

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ABSTRACT

Objective: Good Storage Practice (GSP) is one of five measures to provide qualified medicines for patients. Currently, the hospitals in Ho Chi Minh City (HCMC), Vietnam, strive to apply the GSP model to improve the preservation of drugs. This study was established to survey drug storage facts according to GSP requirements at the HCMC University of Medicine and Pharmacy Hospital, the HCMC Orthopedic Trauma Hospital, and Children's Hospital 1, all in HCMC, Vietnam.

Methods: The study employed retrospective research methodology and was a cross-sectional study based on GSP requirements.

Results: Three hospitals in Ho Chi Minh City, Vietnam, have made progress and satisfied some of the GSP requirements. To satisfy all the requirements of GSP, all three hospitals in HCMC must solve the remaining problems.

Conclusion: This is a model for other hospitals to apply GSP standards for storing drugs in hospital conditions.

Key words: Good Storage Practices, drug warehouse, hospital, Ho Chi Minh City, Vietnam.

INTRODUCTION

Good Storage Practices (GSP) are a set of principles that provide specialised measures for the treatment of raw materials and products for use in medications at all stages of production, preservation, storage, transportation, and distribution to ensure the quality of the finished products when they reach consumers [1-3]. These principles outline the general guidelines for good drug storage practices; however, these guidelines may be adjusted to separately meet specific requirements while still ensuring the end drug products have defined quality [4-6]. Circular No.22/2011/TT-BYT of the Ministry of Health of Vietnam, which regulates the

organisation and operation of the Hospital Pharmacy Department, was issued by the Ministry of Health on 10 June 2011 to replace the existing 'Regulations on Pharmacy,' 'Pharmacist in Charge of Warehouse and Distribution,' 'Pharmacist Who Prepared Drugs,' and 'Head of Pharmacy' guidelines that were issued in 1997. Accordingly, one of the Hospital Pharmacy Department's function is managing and advising the hospital pharmaceutical directors to ensure adequate and timely supply of quality drugs, as well as safe and rational use of drugs [7]. In order to meet the increasing requirements of medical examination and treatment, it is imperative that hospitals in Ho Chi Minh City (HCMC) complete medical examination and treatment. In particular, ensuring the quality of drugs for patients requires strict control. Therefore, this study was undertaken as an essential means to help hospitals improve drug quality assurance to better serve patients. The study investigates the status of drug stores according to GSP standards in the HCMC University of Medicine and Pharmacy Hospital, the HCMC Orthopedic Trauma Hospital, and Children's Hospital 1 and provides appropriate solutions to build warehouses according to GSP standards.

MATERIALS AND METHODS

Study design

The research method was data retrospective, cross-sectional, and used a survey composed according to GSP standards. This study was based on the data collected from HCMC University of Medicine and Pharmacy Hospital (HCMCMP), HCMC Orthopedic Trauma Hospital (HCMCOT), and Children's Hospital 1 (C1). The number and types of drugs, the number of hospital staff, the number of patients examined by the end of 2016, and the drug stores were assessed according to GSP standards.

Study site

This research was conducted in HCMC (10°46'N, 106°42'E), the Vietnamese capital and the largest city in the southeastern region of Vietnam [8]. About 1,760 kilometers south of Hanoi, the total area of HCMC is 2,097 square kilometers, and the population was over 14 million inhabitants in 2016 [9]. This city is the economic center of Vietnam and accounted for 21.3% of the gross domestic product and 29.4% of the total national budget in 2012 [10]. The healthcare system is comparatively well developed, with a chain of about one hundred government owned hospitals or healthcare centers and dozens of privately-owned hospital and clinics.

Study subjects

A cluster sampling method was applied to select the hospitals for inclusion in the study [11]. A list of 20 public hospitals in HCMC was adapted from the authority office, which were numbered from 01 to 50. One company was randomly chosen, then with a step of six, another hospital was chosen. The selection continued until the first hospital was returned. As consequence, three hospitals were selected for the next stage of the study.

Study instrument

A checklist was designed after a discussion between a council of experts in different fields, including physicians, a pharmacist, a lawyer, and a governmental manager. The checklist was based on the latest government document on GSP. Three volunteers were trained over the course of a day to manage the checklist prior to visiting the hospitals. These volunteers were the staff of the authority office, whose expertise is in inspection.

Data analysis

Based on the collected results, the study synthesised, compared, and assessed the current situations of the drug stores in the three hospitals so the study could make general comments on the current status of drug preservation in the Faculty of Pharmacy institute. Data collected was entered into and managed using Microsoft Excel 2010 for Windows®. Descriptive statistics were used to assess the results according to frequency and percentage. There was no further statistical analysis due to time limitation.

RESULTS

In recent years, pharmaceutical human resources in hospitals have become less authoritative. Pharmacists often choose to work at pharmaceutical companies with attractive salaries rather than at hospitals, which suggests that the wages for hospital pharmacists should be reconsidered. The situations at the three hospitals, HCMCMP, HCMCOT, and C1 (coded), were assessed, and the survey results are detailed below. **Table 1** shows

the number of hospital pharmacy staff. **Figure 1** reveals the percentage of pharmacy staff in the hospitals. **Figure 2** indicates the proportion of staff levels at the hospital pharmacies.

Table 1: Number of hospital pharmacy staff

Characteristics	C1 Hospital	HCMCOT Hospital	HCMCMP Hospital
Pharmacy department staff	40	25	78
Hospital staff	1400	700	1433
Ratio of pharmacy staff/hospital staff	2.8%	3.5%	5.4%
Bachelor pharmacist	5	5	12
Intermediate pharmacist	33	7	54
Pre-intermediate pharmacist	2	7	6
Other	-	6	6
Ratio bachelor pharmacist/intermediate pharmacist	5/33	5/7	12/54
Standard of ratio bachelor pharmacist/intermediate pharmacist		1/2-1/2.5	

Percentage of pharmacy department staff in hospital (%)

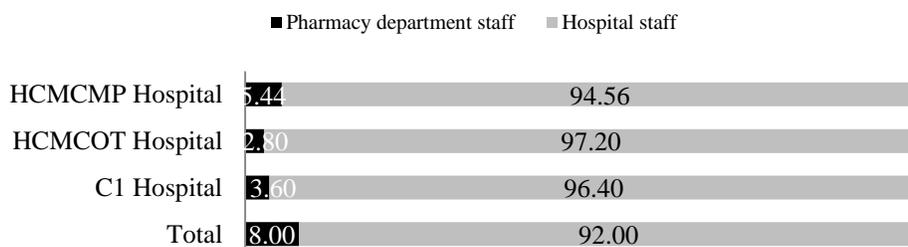


Fig 1: Chart of the ratio of number of pharmacy staff in hospitals

Percentage pharmacy department staff qualifications (%)

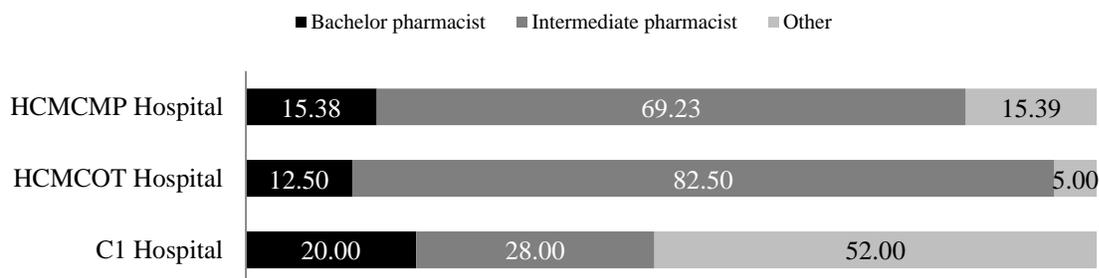


Fig 2: Chart of staff qualification scale of pharmacy departments in hospitals

Table 2: illustrates whether GSP training was organised in the hospitals

Table 2: Organisation of GSP training at hospitals

	C1 Hospital	HCMCOT Hospital	HCMCMP Hospital
GSP training	-	+	+
Annual training	-	±	+
Note: +: Yes ±: Annual training in the form of reminders -: No			

Table 3 shows whether the hospitals had a warehouse organisation diagram and a job description sheet. Storage conditions at HCMCMP are shown in **Table 4**. **Table 5** shows a summary of the status of drug stores in the hospitals. **Table 6** shows division areas in stock. **Table 7** reveals the equipment in the hospital drug stores. **Figure 3**. shows the diagram of the steps to prepare and apply SOP.

Table 3: Warehouse organisation diagram and job description sheet at hospitals

	C1 Hospital	HCMCOT Hospital	HCMCMP Hospital	Percentage (%)
Organisation chart of medicine arrangement	-	-	-	-
Job description sheet	+	+	+	100.0
Assign tasks through words	+	-	-	33.3
Note: + : Yes - : No				

Table 4: Storage conditions in storage at HCMCMP Hospital

	Main warehouse	Retailing warehouse	GSP requirements
Common storage conditions			
Temperature	Maintain 25°C (in each period up to 30 °C)	Maintain 25°C (in each period up to 30°C)	Temperature 15–25°C (in each period up to 30°C)
Humidity	Maintain < 70 %	Maintain < 70%	< 70%
Cold storage conditions			
Temperature	Maintain 2–8°C	Maintain 2–8°C	2–8°C
Special storage requirements			
ND, PD and PUD	There are separate cabinets, lockers, and bachelor pharmacists manage them	There are separate cabinets, lockers, and bachelor pharmacists manage them	There are separate cabinets, lockers, and bachelor pharmacists manage them

Note: ND: narcotic drugs, PD: psychotropic drugs, PUD: precursors used as drugs.

Table 5: Summary of status of drug stores in hospitals

	Number of types of medicines in drug store	Warehouse area	Hospital area	Hospital classification
C1 Hospital	300–350	184 m ²	About 21,000 m ²	Specialty class 1
HCMCOT Hospital	150–200	110 m ²	About 5,000 m ²	Specialty class 1
HCMCMP Hospital	300–500	71 m ²	About 3,200 m ²	Head to 1 st class general hospital

Table 6: Division area in stock

Characteristics	C1 Hospital	HCMCOT Hospital	HCMCMP Hospital
Reception area	+	+	±
Drug delivery area	±	±	±
Drug storage area is not up to standard for treatment	±	±	±
Storage areas require special storage	+	+	+
Out-of-place areas, labelled	-	-	-
Note: + : There is a clear distinction ±: The distinction is not clear - : No distinction			

Table 7: Equipment in hospital drug stores

Characteristics	C1 Hospital	HCMCOT Hospital	HCMCMP Hospital
Air conditioner	+	+	+
Ventilators	+	+	+
Trolley	+	+	+
Thermal hygrometer	+	+	+
Retail medicine tool	+	+	-
Note: +: Yes -: No			

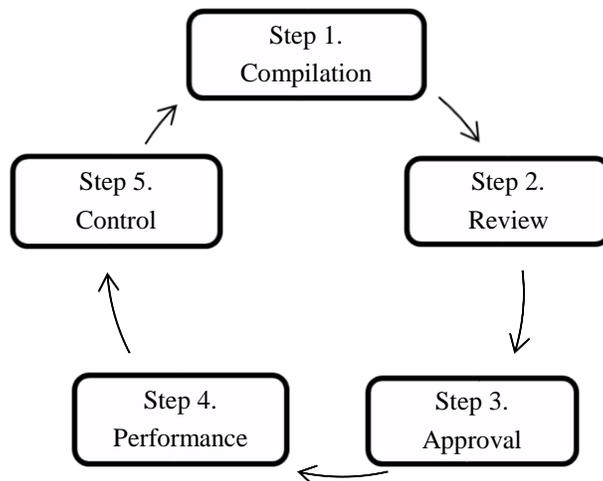


Fig 3: Diagram of steps to prepare and apply SOP

DISCUSSION

Through this study, we conducted a survey of the status of the contents of the drug stores of the HCMCMP Hospital, HCMCOT Hospital, and C1 Hospital, for a total of three drug stores, according to the requirements of GSP. The general situation of each drug store revealed that the pharmaceutical human resources were seriously lacking. The proportion of pharmacy staff compared to total hospital staff of the three surveyed hospitals was lower than 8%. C1 was 2.8%, HCMCOT was 3.5%, and HCMCMP was 5.44% (Figure 1). All three hospitals surveyed had a staff shortage compared to what was needed to properly implement GSP. According to Joint Circular No. 08/2007/TTLT-BNV-BYT of Ministry of Health of Vietnam, the proportion of professional/graduate students in hospitals should be 1/2 to 1/2.5 (7). C1 Hospital's rate was 1/6, HCMCMP Hospital's was 1/4, and HCMCOT Hospital's was 5/7 (Figure 2). At this rate, two-thirds of the surveyed hospitals had inadequate pharmaceutical human resources, including a lack of intermediate pharmacists.

At present, 2/3 of surveyed hospitals have organised GSP training for drug store staff. Regarding the annual update and re-training, the HCMCMP Hospital strictly follows the GSP standards. At the HCMCMP Hospital, GSP training is organised once a year, re-training all drug store employees. Although there were difficulties in human resources and organisation, the storage conditions of the medicines in the warehouses were ensured to the best possible extent (Table 2). The drug stores of the surveyed hospitals did not have medicine arrangement diagrams in the warehouses (Table 3). The numbers of employees were not sufficient, so many employees concurrently held more than one job, overloading them with work. Furthermore, the numbers and types of drugs in the warehouses were not fixed, changing according to the year, so the layout of drugs in the warehouses was not consistent. Through the direct survey, it was seen that the drug store of the HCMCMP Hospital was solidly built, clean, tidy, and had good storage conditions (Table 4). The equipment in the warehouse was relatively complete and in good condition. The main warehouse was only 26 meters squared, a modest area for the HCMCMP Hospital, the leading general hospital in HCMC. With the requirements of GSP, the problem of storage area was the most difficult obstacle, especially for the hospital in the city 'crowded land crowded.' The statuses of C1 Hospital and HCMCOT Hospital were comparable. Another key factor that in the storage of drugs is the layout of the warehouse; the arrangements of the warehouses in the study are shown in Table 6. Given that the areas of the warehouses were not enough to meet GSP standards, employees must use the existing storage area to maximum reasonable capacity; thus, dividing the areas in the warehouses to ensure GSP standards would be extremely difficult. Regarding equipment in stock, all three hospitals were fully equipped, including air conditioners, ventilation fans, trolleys, and hygrometers. In particular, temperature and humidity measuring devices were calibrated annually (Table 7).

The issuance of SOPs in drug preservation in hospital medicine warehouses was also surveyed. All three hospitals were developing SOPs according to GSP requirements but had not issued any SOPs. At HCMCMP Hospital, an SOP on allocation had been issued, and other SOPs were in the development phase. HCMCMP Hospital planned to continue to issue all basic SOPs based on GSP, ensuring standardised drug storage,

contributing to ensuring the supply of quality medicines for patients. Currently, 3/3 hospitals are developing SOPs, but in order to issue them, there are numerous steps that must be taken, as shown in Figure 3. After being developed and edited, SOPs are approved and issued. The original SOP is stored in the quality system, and the copy is then distributed to the executing object. Given the shortage of labour and work overload, issued SOPs are difficult to draft, review, and approve in a timely manner.

CONCLUSIONS

Through and exploration of the statuses of the three drug stores of the HCMCMP Hospital, HCMCOT Hospital, and C1 Hospital, it was found to be necessary to supplement pharmaceutical human resources, expand storage areas, and better equip the infrastructure of the Pharmacy Department.

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CONFLICTS OF INTERESTS

The authors have no conflicts of interests to declare.

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