



## Hospital pharmacy management in a tertiary care charitable hospital: Compliance study with quality standards

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### ABSTRACT

**Objective:** To perform a qualitative and quantitative comparison of the practice and infrastructure with applicable legislations governing hospital pharmacy while the secondary objective was to calculate the average dispensing time of a prescription in the hospital pharmacy.

**Materials and methods:** A prospective observational study was carried out in the hospital pharmacy for one year. A blend of quality control parameters was drafted after referring various guidelines put forward by the statutory bodies. Qualitative data was collected by continuous observation, physical inspection and after a thorough interview of hospital pharmacists. The collected data was summarized and compared with the standards. Quantitative data on the minimum requirement of hospital pharmacy infrastructure and dispensing time was collected by using the designed data collection form and analysis was performed using SPSS (version 20.0).

**Results:** The hospital pharmacy met all the criteria that are necessary to satisfy legal requirements, availability of medicine, medicine and general safety and most of the quality parameters. However, few deviations were observed in the management of the drug store. The shortage in the floor space and waiting area was identified. The average dispensing time without waiting was  $113.93 \pm 28.92$  s and the time spent collectively for dispensing and waiting was measured to be  $533.13 \pm 128.51$  Sec. The average waiting time in the hospital pharmacy was approximately around 419 Sec.

**Conclusion:** Majority of the quality parameters were noted to be compliant with the standards. Few deviations were identified and measures to improve them were suggested.

### 1. Introduction

Hospital pharmacy is an integral department of any hospital that is responsible for the supply and distribution of pharmaceuticals, surgical and medical inventories. Pharmaceuticals are now an inevitable part of health care services.<sup>1,2</sup> There are variations between the proven efficacy of pharmaceuticals and their clinical effectiveness. These variations may be attributed to several factors like the procurement of low-quality pharmaceuticals, substandard formulations, improper storage conditions, patient-related factors, etc. The hospital pharmacy department thus, plays a crucial role in narrowing down the existing gaps.<sup>3,4</sup> Some of the essential roles of hospital pharmacy are deciding the brands, procuring, storage, handling, compounding, and dispensing the drugs.<sup>1,2</sup>

Thus, the hospital pharmacy should fulfill some basic legal requirements and have some required minimum infrastructure in place to ensure the smooth conduct of the aforementioned processes. The quality in pharmacy processes and the organization of hospital pharmacy largely contributes to the quality of healthcare services within the hospital.<sup>5,6</sup>

National Accreditation Board for Hospitals and Healthcare (NABH) is a constituent board of the Quality Council of India that periodically assesses hospitals and medical facilities for the provision of safe and quality health care.<sup>7</sup> Medication order management (MoM) is a crucial chapter of NABH that specifically deals with pharmacy and medication processes in the hospitals.<sup>8</sup> According to NABH, the pharmacy should guide, audit and document these processes. The hospital pharmacy should update the hospital formulary, procurement policy, facility for

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appropriate storage of medicines, patient counseling, adverse drug reactions (ADRs) reporting systems, medication recall mechanism, in addition to a comprehensive and meticulous documentation system.<sup>7,8</sup> India has only 979 NABH accredited hospitals and healthcare setups reflecting the poor-quality management of hospitals and hospital pharmacies across the country.<sup>9</sup> Thus, there is an immediate need to assess the existing practices and improve the qualitative parameters of the hospital pharmacy within the hospital. Due to the justified significance, we aimed to carry out the qualitative and quantitative assessment of hospital pharmacy processes and infrastructures and calculate the average dispensing time of a prescription by the hospital pharmacy.

## 2. Materials and Methods

### 2.1. Ethical approval and permission

This study was approved by the central ethics committee of Nitte (Deemed to be University), (Ref: NU/CEC/2019/0240). All the required permissions to carry out this research in the hospital were obtained from the hospital pharmacy in charge and the medical superintendent of the hospital. The confidentiality of the data was maintained throughout the study and the outcome report was submitted to the hospital management. The study was subsequently registered in the Clinical Trial Registry of India (CTRI Reg. No- CTRI/2019/08/020564).

### 2.2. Design and duration of the study

This was a descriptive observational study conducted over a period of 12 months from January 2020 to December 2020 in the hospital's pharmacy and patient counseling area of a 1000 bed tertiary care hospital in coastal Karnataka, India.

### 2.3. Inclusion and exclusion criteria

The ambulatory patients visiting the pharmacy for receiving the prescribed drugs were randomly selected for calculating the average dispensing time to dispense a prescription. The prescriptions with at least one drug were included whereas, the prescriptions exclusively with the non-pharmacological measures were excluded from the study. The qualitative data regarding the hospital pharmacy infrastructure and its management was collected directly from the hospital's pharmacy.

### 2.4. Design and preparation of data collection tool

We framed our quality assessment guidelines based on a blend of strategies of statutory bodies and quality assurance systems such as NABH,<sup>5,8</sup> schedule N of Drug and Cosmetic Act, 1940 and Rules 1945 (amended August 2013),<sup>7</sup> and drug store management and rational drug use guidelines.<sup>10</sup> The final version of this data collection tool (approved by the research advisory committee after suitable modifications) consisted of:

- Checklist for quality indicators: Include five subsections namely minimum legal requirements, medicine availability, general safety, and quality indicators of the hospital pharmacy
- Organizing drug supplies: Include four subsections such as general organizing measures, the system used for drug arrangement, handling of controlled and hazardous drugs, and the management of expired medicines
- List of minimum equipment for the efficient running of a pharmacy: This section included four subsections namely entrance and premise, furniture and apparatus, general facilities, and area & layout of the hospital pharmacy.

A separate data collection form for collecting prescription dispensing time in the hospital pharmacy included sections to collect date, time of

arrival and departure of patient at the pharmacy/dispensing counter. Waiting time and actual dispensing time were calculated from the above data.

### 2.5. Qualitative data

The entire premise of the pharmacy was observed and physically inspected for collecting relevant information in the data collection tool. Few pharmacy staff including the pharmacy in charge were interviewed to collect the information regarding the handling, control, maintenance, and documentation of controlled, hazardous, high risky and expired medication. The qualitative data on the processes and organization of the hospital pharmacy were collected by regular engagement with the hospital's pharmacy. Observations were made during the regular visits to the pharmacy. The collected data was then cross-checked for possible errors. The final gathered data was analyzed for its compliance with the safety and quality standards framed by the statutory bodies. Non-compliance and deviations during the studies were reported to the hospital authorities with appropriate suggestions. The first wave of coronavirus disease 2019 (COVID-19) pandemic was evidenced during the study period. However, the effect was minimal in the working pattern of hospital pharmacy.

### 2.6. Quantitative data

The total number of hospital pharmacy staff, number of bathrooms, storerooms, dispensing counters and the number of cold storage refrigerators were collected. The temperature of the storage and cold chain area were recorded by using a thermometer. The floor space area of the hospital pharmacy was physically measured by using a measuring tape along with the areas of different sections of the hospital pharmacy. The results were then compared with the minimum requirements of floor space in the hospital and the difference in the required area of hospital pharmacy was calculated.

A total of 300 ambulatory patients visiting the hospital pharmacy were randomly selected in the study. The time elapsed between the person arriving in the pharmacy till s/he reach to the dispensing counter was noted as waiting time. The time between arrival at the dispensing counter till they leave the pharmacy was noted as the actual dispensing time. The sum of waiting and actual dispensing time was calculated as the total dispensing time to dispense a prescription in a hospital pharmacy. The time taken to dispense a prescription was recorded during time points of the day. The time span between 8:00 a.m. to 11:59 p.m. was considered as morning hours, 12:00 p.m. to 14:59 p.m., afternoon hours and 15:00 to 18:00 p.m. was regarded as evening hours. The same stopwatch was used to record the time while calculating the dispensing time.

### 2.7. Data analysis

The qualitative data collected during the study was directly analyzed for compliance with the statutory requirements of NABH (5th edition), Drug store management and rational drug use guidelines and Schedule N of Drug and Cosmetic Acts.<sup>5,7,8,10</sup> The quantitative data collected during the study period were analyzed. The analyzed results were expressed in terms of mean  $\pm$  standard deviation. The comparison of waiting, actual dispensing, and total time between the different sessions of the day were performed by using the descriptive analysis. The results were also compared with the desirable time according to the World Health Organization.

### 3. Results

#### 3.1. Qualitative data collected by observation, physical inspection, and interview of the pharmacists

The qualitative data collected during the study revealed that the persons involved in the dispensing of medicine were registered pharmacists. The hospital pharmacy was meeting all the legal requirements with currently updated documents. There was a separate premise for the pharmacy situated on the ground floor in the middle of the hospital. The pharmacy was following the unit dose drug distribution system. Thus, there was no complete floor stock or combinations of two or more than two drug distribution systems. The floor and premises of the hospital pharmacy were visibly clean and hygienic. The pharmacy used to be cleaned by the housekeeping staff on a daily basis. Initial observation and physical inspection of the pharmacy storage revealed that there was an updated hospital formulary in the pharmacy and all the drugs listed in the hospital formulary were available in the pharmacy at all times.

The pharmacy used the always, better and control (ABC) and vital, essential and desirable (VED) analytic methods for inventory control, maintaining the buffer stock and minimum stock level for the medications. The pharmacists were aware of the “first in first out” and “the first-expiry, first-out policy.” There was a policy for drug acquisition and procurement based on recommendations of a multidisciplinary pharmacy and therapeutic committee. The pharmacy maintained the receipt and documentation system with a physical inventory that is executed every month, safety assessment done every three months, fire drills every six months and an elaborate audit of the complete pharmacy and stock updates yearly. All the medicines of Schedule H and X of Drug and Cosmetic Acts were dispensed only with a valid prescription.

There were proper safety and surveillance measures available in the pharmacy with a sufficient number of CCTVs, fire extinguishers and an emergency evacuation route in the pharmacy. The pharmacy’s detailed physical inspection revealed that the drugs were stored according to the manufacturer’s instructions with controlled the humidity and temperature. The exposure on the drugs to direct sunlight as prevented. Look-alike and sound-alike drugs were stored separately with legit labeling over the rack. The pharmacy had a continuous monitoring system to evaluate the quantity of drug wastage, expiry drugs, out-of-stock drugs, emergency drugs and local purchases.

All the drugs were arranged according to the manufacturer’s instructions. The controlled and narcotic drugs were stored in the steel cupboard with a proper locking facility under the direct control of the pharmacy in charge. There was computer generated and register-based documentation system to record the inflow and outflow of the controlled and narcotic drugs. The waste generated in the pharmacy was segregated at the site of generation and was categorized according to the biomedical handling and management rules. The pharmacy had a clearly written drug wastage plan with adequate and updated training given to the pharmacists. The pharmacist is vaccinated with tetanus toxoid and hepatitis B vaccine at regular intervals. Despite the adequate satisfaction of the hospital’s management and quality parameters, there were few deviations. The hospital pharmacy did not have a standardized system to calculate the dispensing time and the dispensing errors in the hospital pharmacy. Only a few staff were aware of the medication recall process and the saline (large volume parenteral were stored on the floor of the pharmacy.

#### 3.2. Analysis of quantitative data collected by using the data collection tool

The quantitative data collected during the study revealed that there were enough of the refrigerators to store the medicine requiring cold temperature. There were four counters for drug dispensing, one counter for the drug take-back program, one counter for billing and cash purpose. There was one washroom available for the pharmacy in charge and

one for the other staff. The measurement of floor space area found that the working space of the pharmacy was 1790 square feet (2450 square feet total area) in the hospital. This was around 40% of the area required for the efficient functioning of the hospital pharmacy. The complete detail on the floor space area of the hospital pharmacy is depicted in Table 1. There was a water tap with a hand wash basin, but the drinking water point was not available inside the pharmacy (A drinking water dispenser was made available at the waiting area of the pharmacy).

Out of 300 patients, 100 each were enrolled during morning, afternoon and evening sessions. The quantitative data analysis on an average dispensing time to dispense a prescription revealed that the average dispensing time is  $533.13 \pm 128.51$  s. The dispensing time was high during the evening hours ( $606.20 \pm 114.02$  Sec) compared to the afternoon ( $513.30 \pm 114.40$  Sec) and morning session ( $479.9 \pm 124.05$  Sec). This difference was attributed to the high waiting time at the evening hours (493 Sec) compared to afternoon (400 Sec) and morning (365 Sec) hours, whereas the dispensing time was found similar during all sessions of the day. The details on the dispensing time are referenced in Table 2. The minimum time taken to dispense a prescription was 40 s and the maximum time taken was 185 Sec. Similarly, the minimum time taken to dispense a prescription, including waiting time in the pharmacy was 280 Sec, whereas the maximum was 1030 Sec.

### 4. Discussion

A qualitative and quantitative study was conducted to analyze the infrastructure and quality processes in the hospital pharmacy. The study found that the pharmacy was meeting all the legal requirements.<sup>5</sup> Overall, majority of the medication order management procedures were scientific with proper documentations complying with quality parameters.<sup>8</sup> The presence of adequate pharmacy infrastructure is a fundamental need for the efficient functioning of the pharmacy without physical constraints. Availability of these minimum facilities in the pharmacy assures the provision of continuous and adequate services.<sup>11,12</sup> Our study reported the lack of physical infrastructure, especially floor space and the area for drug storage which may in turn lead to the decreased shelf-life of the pharmaceuticals. Thus, we recommended that the pharmacy must implement the floor stock system of drug distribution to occupy the space in several hospital floors effectively. A complete floor stock system also helps in reducing pharmacy-related errors and equally distributes the roles among the pharmacists. In addition, it also utilizes the services of nurses on various floors, ensuring the cross-checking of the medicines and helps minimize medication errors.<sup>13–16</sup> The pharmacy was also recommended to store large volume parenteral, 15–30 cm above the floor.

The hospital pharmacy services are continuous and a dynamic set of processes to provide quality services. The pharmacy needs robust, scientific, reliable and evidence-based procedures in place to deliver quality healthcare with minimal medication-related problems. The

**Table 1**  
Details on the area of hospital pharmacy in 1000 bed hospital.

S.N.	Areas in the hospital pharmacy	The standard requirement of working area (In square feet)	Available working area (In square feet)
1.	Compounding and dispensing area	2210	1027
2.	Storage area	1240	332
3.	Office and circulation/toilets	1140	371 + 60
7.	Total applicable area*	4590	1790

\*Manufacturing and parenteral solution area is not applicable as the manufacturing service was not available in the pharmacy.

(#Note: This was based on various sources of literatures; no legislation is available in India for floor space requirement.).

**Table 2**  
Summary of dispensing time of prescriptions in the hospital pharmacy.

Timings	Average dispensing time (Without waiting time)	Average dispensing time (Including waiting time)	Approximately waiting time in hospital pharmacy
Morning (8:45AM-12:00PM)	115 ± 28.16 Sec	479.9 ± 124.05 Sec	365 Sec
Afternoon (12:01PM-15:00PM)	113.8 ± 30.19 Sec	513.30 ± 114.40 Sec	400 Sec
Evening (15:01PM-18:00PM)	113 ± 28.42 Sec	606.20 ± 114.02 Sec	493 Sec
Average (On a day)	113.93 ± 28.92 Sec	533.13 ± 128.51 Sec	419 Sec

developed procedures for the various services of the pharmacy should comply with the national and global standards. The quality improvement process should be flawless and be updated regularly. In our study, majority of the quality parameters adhered to the standards. However, better services are always desirable. Hence, we would like to put forth some recommendations like the availability of drinking water points inside the pharmacy for the 24-h availability of safe and drinking water.<sup>7,13,14</sup> Another important suggestion was to monitor and document the average dispensing time randomly and dispensing errors occurring in the hospital pharmacy which could continuously minimize the waiting time and incidences of error in the pharmacy. The pharmacists were also recommended to undergo training regarding the medical recall process whenever it might be warranted. Similarly, the services of clinical and research pharmacists in the pharmacy were recommended to document drug-related problems in the pharmacy as well as in the hospital. The services of the former could also be utilized to conduct various prescription pattern and resistance studies and to discuss the findings of the same during the scheduled meeting of hospital formulary (hospital formulary and policy meetings).<sup>8</sup>

The quantitative analysis of an average dispensing time to dispense a prescription revealed a higher time duration compared to the desired as per the World Health Organization and other literature.<sup>17,18</sup> The actual dispensing time (Approx. 114 Sec) of a prescription was well within the desired time (60–180 Sec), but the waiting time of the hospital was more (7 min) than the desired time (desired time is < 3 min). A suitable recommendation like making suitable seating facilities for the patient and/or patient's relatives in the waiting area along with the implementation of the complete floor stock drug distribution in the pharmacy were suggested. Only one hospital was studied, thus these findings are not generalizable to any other pharmacies in the local region, in India or internationally and the inception of first wave of COVID-19 pandemic might have affected the time of dispensing during the study, which might be the limitation of this study.

## 5. Conclusion

The qualitative assessment of hospital pharmacy processes revealed the high compliance rate with the specified standards in the Checklist for quality indicators and organizing drug supplies. Similarly, the quantitative study revealed optimal actual dispensing time but a higher waiting time in the pharmacy. A shortage of floor space was also deciphered during the course of the study. A separate study to analyze the causes for prolonged waiting time was recommended. In addition, the complete floor stock system was suggested to meet the required space area and reducing the waiting time in the pharmacy.

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## Authorship credit

Conceptualization; SC, SKH and CSS, Formal analysis; SC, CSS. Funding acquisition; All the authors (self), Investigation; SC, CSS, SKH, JJJ, Methodology; SC, CSS, SKH, CHK, Project administration; CSS, SKH, Validation; CSS, SKH, CHK, Draft Writing; SC, JJJ Review & editing; CSS, SKH.

## Declaration of competing interest

Authors declare no conflict of interest.

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