Workforce planning and safe workload in sterile compounding hospital pharmacy services

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Abstract

Purpose. A prospective observational study was conducted to assess sterile compounding time and workforce requirements in a hospital pharmacy, resulting in development of staff benchmarking metrics.

Methods. The study was conducted in the IV room of a quaternary hospital over a total of 7 weeks. Compounding was directly observed and timing data collected for each compounded sterile preparation (CSP). The primary objective was to assess CSP workload, compounding time requirements, and workforce requirements to enable development of a data-driven staffing benchmark.

Results. A total of 320 sterile product preparations were directly observed during the study. Overall, the average time to compound 1 CSP (including small- and large-volume parenteral solutions, chemotherapy CSPs, batched CSPs, and syringes) was 3.25 minutes. Chemotherapy CSPs had the longest average preparation time (17.74 minutes); batched CSPs had the shortest preparation time, at 1.90 minutes per unit. A safe workload analysis indicated that in an 8-hour shift, 1 pharmacy technician can safely prepare 253 batched CSPs; 148 preparations of SVP solutions, LVP solutions, and syringes combined; 31 parenteral nutrition solutions prepared using an automated device; or 29 chemotherapy preparations. Through extrapolation of these results, it was calculated that a hospital with a capacity of 100 beds would require 1.4 pharmacist full-time equivalents (FTEs) and 2.7 technician FTEs to meet its sterile compounding needs, with proportionate increases in those estimates for a 300-bed hospital.

Conclusion. Organizations wishing to use external benchmarking information need to understand data characterization, pharmacy services offered, automation, workflows, and workload before utilizing that information for workforce planning.

Keywords: patient safety, pharmacy, pharmacy technician, staffing, sterile preparation center, workload

Intravenous (IV) sterile preparation is a challenging and vulnerable process that carries a risk of patient harm. A small error in compounding could eventually lead to patient injury or even death. Each year during the period 2009-2011, there were 1.2 million hospitalizations with preventable adverse drug events (ADEs) related to injectable medications in the United States, with an estimated cost between \$2.7 billion and \$5.1 billion annually.¹ Urbine et al² found that automated IV preparations could virtually eliminate compounding errors, yield cost savings, and improve patient safety. This in turn led the Institute for Safe Medication Practices (ISMP) to highlight the importance of workflow standardization adoption and IV automation integration within an enterprise hospital setting to optimize patient safety and prevent harm associated with injectable medication use.³

The Cleveland Clinic Abu Dhabi (CCAD) pharmacy leadership adopted a unique IV sterile preparation workflow in compliance with *United States Pharmacopeia* chapter 797 (USP <797>) and ISMP recommendations to reduce compounding errors and assure patient safety. Multiple studies of IV workflow management system utilization have demonstrated a positive impact on patient safety, costs, and preparation time.⁴⁻⁶ The sterile preparation center (SPC) at CCAD utilizes a standardized operating procedure for IV compounding and employs advanced technology, implemented through the integration of barcode-enabled workflows and an electronic verification system, whereby medication order routing, verification, preparation, checking, dispensing, tracking, and reporting are fully automated. The appendix summarizes the SPC workflow. In addition, a quality compliance checklist was deployed at the go-live of Cleveland Clinic Abu Dhabi in 2015 to identify gaps in the SPC workflow through dashboard interfaces and automatic notifications. Biennial renewal of training competencies was enforced and supported by offering all pharmacy compounding personnel hands-on practice sessions in addition to web-based training. The American Pharmacists Association and ISMP support staffing models that promote the safe provision of patient care services and access to medications.^{7,8} However, evidence of pharmacy workforce planning in the Eastern Mediterranean region to attain these benefits is limited.⁹

The aim of this study was to assess workload in a hospital pharmacy SPC in order to determine workforce requirements by developing a data-driven staffing benchmark that can be used in a similar hospital setup.

Materials and methods

Study design and setting. An observational, prospective, single-center study of sterile preparation workload was conducted in an IV room of a quaternary hospital over 7 weeks (6 weeks in 2020 and 1 week in 2021).

Outcome measures. The primary outcome of this study was to assess the workload in a hospital pharmacy SPC. Secondary outcomes included the determination of workforce requirements and the development of a data-driven staffing benchmark for a similar hospital setup.

Data extraction. Compounding was directly observed and timing data collected for each compounded sterile preparation (CSP) for a total of 7 weeks (June 14-July 26, 2020, and May 27-June 3, 2021). Data collection was performed by a designated group of inpatient pharmacists, pharmacy interns, and the SPC manager. A standard method was followed to minimize variation in data recording and analysis. This was done during various shifts on different weekdays, for an average of 2 hours per day. Compounding timing data for each CSP was then recorded on a spreadsheet (Microsoft Excel 2010; Microsoft Corporation, Redmond, WA), and each CSP was classified as a small-volume parenteral (SVP) solution (volume of <250 mL), large volume parenteral solution (LVP) solution (volume of >250 mL), syringe, batched CSP, chemotherapy CSP, or total parenteral nutrition solution prepared using an automated compounding device. SVP solutions and LVP solutions were further categorized based on microbial contamination risk levels, as defined per USP <797> 2008 standards, as “low-risk level” or “medium-risk level” CSPs. Low-risk level CSPs include those prepared using not more than 3 sterile components and not more than 2 entries into one sterile container, with preparation achieved through simple volume transfer, measuring, and mixing. Medium-risk level CSPs include those prepared using more than 3 sterile components or more than

2 entries into one sterile container and whose preparation involves complex aseptic manipulations other than single-volume transfer.

Compounding timing data were recorded from the moment the pharmacy technician removed the medication label from the printer to the moment at which the medication was placed for double checking by the pharmacist. Batch compounding timing data were recorded from the moment the technician received the medication label signed by the pharmacist to the moment at which the batched CSP was placed for delivery.

Double-check timing data for all CSPs other than batched CSPs were recorded from the moment the pharmacist picked up the medication to be checked until the moment the pharmacist signed the medication label for delivery to the patient's unit. For batched CSPs, double-check timing data included the period during which the pharmacist double checked all the components needed to prepare the batched CSP against the master formulation record until the moment the pharmacist signed the medication label authorizing the technician to start the compounding process.

The number of occupied beds and CSP orders prepared per day from June 14, 2020, through June 14, 2021 were retrieved from CCAD's electronic health record (EHR). Based on the collected data, the number of each CSP that can be prepared safely in an 8-hour shift, as well as the number of labor resources needed per day in the sterile preparation center, were calculated. The required numbers of pharmacy technician and pharmacist full-time equivalents (FTEs) were calculated using staffing data. Through use of all available and collected data, a data-driven model of staffing in an SPC that can be used in a similar hospital setup was developed.

Statistical analysis. Descriptive statistics were used to analyze quantitative variables. Continuous data were summarized as means with standard deviation (SD), while categorical data were summarized as frequencies and percentages. All statistical analyses were performed using Microsoft Excel 2010.

Results

Sterile preparation workload and timing analysis. For the 320 directly observed compounded sterile product preparations, numbers, percentages, and average times for each preparation type are presented in Table 1 and Figure 1.

The overall average time to compound 1 CSP (including SVP solutions, LVP solutions, and syringes) was 3.25 minutes. Chemotherapy CSPs had the longest average preparation time (17.74 minutes), with a large SD value indicating that chemotherapy preparation time depends mainly on the type of medication being prepared. Batched CSPs required the shortest preparation time, with an average value of 1.90 minutes.

An average of 1,003 IV sterile preparations were prepared per day over a 1-year period (June 14, 2020-June 14, 2021), the majority of which consisted of SVP solutions, LVP solutions, and syringes. The average daily patient census was 270 during the same period.

Safe workload. The phrase “safe workload” conveys a concept of safety involving a combination of several aspects of activities in an SPC. It includes but is not limited to the number of hours worked per shift, time off between shifts, rotation of staff, initial and ongoing training of personnel on aseptic technique, proper builds of medication records in a computerized provider order entry (CPOE) system, availability of equipment, proper temperature and ambiance inside the SPC, and, finally, the number of doses prepared in any given shift.

The results of the safe workload estimation analysis indicated that in an 8-hour shift, 1 pharmacy technician can safely prepare 253 batched CSPs; 148 preparations of SVP solutions, LVP solutions, and syringes combined; 31 parenteral nutrition solutions prepared using an automated device; or 29 chemotherapy preparations (Table 2).

Workforce planning. Based on the workload analysis, Table 3 shows the calculated numbers of pharmacy staff FTEs. The number of pharmacy technician FTEs required per year is 2-fold higher than the number of pharmacist FTEs, with values of 10 and 5, respectively, for CCAD. These calculations take into consideration that the required number of worked hours per year for each pharmacy staff member, including time off and annual leave days, is 2,080 hours.

Upon extrapolating the data and estimating labor resources required per hospital capacity of 100 beds or 300 beds (assuming the adoption of the same workflow, automation in IV room, and workload), the findings displayed in Table 3 reveal that the estimated number of pharmacists required per 100 and per 300 beds are 2 and 6, respectively, with an approximately 2-fold increase in the number of technicians vs pharmacists needed, taking into consideration off days and annual leave.

Discussion

This study of SPC staffing in a hospital in the Eastern Mediterranean region aimed at assisting workforce planning. Workforce planning and development are core competencies of pharmacy leaders and impact patient care. In this study, staffing data collected through direct observation were combined to develop a staffing benchmark that can be used by other hospitals with a similar setup.

The results demonstrated that chemotherapy CSP preparation took the most time, followed by automated TPN solution preparation. On the other hand, batched CSP preparation was found to be the least time-consuming process, followed by preparation of SVP solutions (Table 1). This, in turn, explains the reason for higher estimated numbers of batched CSPs, SVP solutions, and syringe preparations in an 8-hour shift. (Table 2).

Based on the hospital EHR data for a 1-year period (June 14, 2020-June 14, 2021), both TPN and chemotherapy CSP accounted for only 4.79% of the total number of CSPs prepared.

Total IV preparation time required per day might differ according to the type of product prepared at any given hospital.

The calculated required total number of pharmacy technician FTEs was almost 2-fold greater than the number of pharmacist FTEs in the estimation models for both 100- and 300-bed hospitals. This finding was consistent with those of a study conducted by Smith et al.¹⁰ It is estimated that 4 pharmacy technician FTEs and 2 pharmacist FTEs are needed in an SPC at a hospital with an average occupancy of 100 beds. These figures increase to around 11 and 6 pharmacy technician and pharmacist FTEs, respectively, for a hospital with an average occupancy of 300 beds (Table 3). The numbers required will be higher once leave and off days are factored into the above calculations. On the contrary, a smaller pharmacy technician:pharmacist FTE ratio of almost 1:1 was found in acute care hospital pharmacies in England, and a higher ratio of 1:1.6 was seen in mental health/social care hospital pharmacies.¹¹ The establishment of a pharmacy staffing plan is highly dependent on the organization's workflow, workload, and the defined roles of pharmacy staff within an IV room. Data gathered in England by Fitzpatrick¹¹ showed wide variations of percentage FTE-pharmacy staff between hospitals within the same region.

Designing an efficient workforce plan plays a major role in reducing medication-related errors. A study conducted in an IV chemotherapy room of a 567-bed tertiary care hospital revealed that the addition of 1 chemotherapy pharmacy technician FTE in efforts to support the increased workload resulted in a decrease in patient safety incidents, medication turnaround time, and the overall turnover rate for pharmacy technicians.¹²

Several limitations of our study should be considered when interpreting the results. First, essential nonproductive work time factors such as hood cleaning and medication restocking were not taken into consideration while calculating pharmacy staff FTE requirements. Second, exact data about IV SVP solutions, LVP solutions, and syringes could not be extracted from the hospital's EHR. Lastly, only a small number of oncology patients are currently seen in the existing setup. Therefore,

these data cannot be generalized to estimate FTE requirements of an SPC in a specialized oncology hospital.

Conclusion

Through this study, sterile compounding workload in a hospital pharmacy sterile preparation center was assessed and a data-driven benchmark developed for use in a similar hospital setup. The data also validated pharmacy staff perceptions about current workload and will help with future workforce planning. Organizations wishing to use external benchmarking information need to understand data characterization, pharmacy services offered, automation, workflows, and workload before utilizing that information for workforce planning.

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Key Points

- Workforce planning and development are core competencies of pharmacy leaders in order to reduce medication-related errors and provide better patient care
- Workforce planning can be achieved by understanding the workload and productivity metrics of one's organization using data-driven staffing-to-demand models.
- There is a need to perform internal benchmarking based on hospital-specific data; organizations wishing to use external benchmarking information need to understand data characterization, pharmacy services offered, automation, workflows, and workload before utilizing such information for workforce planning.

Figure 1. Average preparation times for compounded sterile preparations at Cleveland Clinic Abu Dhabi during 2 observation periods (June 14-July 26, 2020, and May 27-June 3, 2021).

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Appendix—Sterile preparation center (SPC) workflow at Cleveland Clinic Abu Dhabi

Table 1. Total Observations by Type of Compounded Sterile Preparation During 2 Study Periods at Cleveland Clinic Abu Dhabi

CSP Type	Observations, No. (%)	Preparation Time, Mean (SD), min
Low-risk small-volume parenteral (<250 mL)	40 (12.5)	2.85 (0.79)
Low-risk large-volume parenteral (≥250 mL)	40 (12.5)	3.11 (0.94)
Medium-risk small-volume parenteral (<250 mL)	40 (12.5)	3.33 (1.03)
Medium-risk large-volume parenteral (≥250 mL)	40 (12.5)	3.71 (1.18)
Syringes	40 (12.5)	3.23 (0.83)
Batched CSP	40 (12.5)	1.90 (0.83)
Chemotherapy CSP	40 (12.5)	17.74 (7.31)
Total parenteral nutrition (automated compounding device)	40 (12.5)	15.41 (1.87)

Abbreviation: CSP, compounded sterile preparation.

Table 2. Safe CSPs Prepared by Pharmacy Technician in 8-Hour Shift at Cleveland Clinic Abu Dhabi

Preparation Type	Work time/average time per CSP, min
Small-volume parenteral	480/3.25 (<i>n</i> = 148)
Large-volume parenteral	480/3.25 (<i>n</i> = 148)
Syringe	480/3.25 (<i>n</i> = 148)
Batched CSP	480/1.90 (<i>n</i> = 253)
Chemotherapy CSP	480/16.83 (<i>n</i> = 29)
Total parenteral nutrition (prepared using automated compounding device)	480/15.42 (<i>n</i> = 31)

Abbreviation: CSP, compounded sterile preparation.

Table 3. Time and Staff Required for Compounding Sterile Preparations at Cleveland Clinic Abu Dhabi and Estimated FTE Requirements for 100- and 300- Bed Hospitals

Variable	Value
Total work time required per 24 hours for IV preparations, min	58.1
Pharmacy technician FTEs required in 24-hour period	7.2
Pharmacist FTEs required in 24-hour period	4.0
Total work time required per 365 days for IV preparations, min	21,110.67
Pharmacy technician FTEs required per year for SPC at CCAD	10.0
Pharmacist FTEs required per year for SPC at CCAD	5.1
CSPs per bed, mean	3.7
CSPs per 100 beds, mean	371.5
Pharmacy technician FTEs required per 100 beds	2.7
Pharmacist FTEs required per 100 beds	1.4
Pharmacy technician FTEs required per 300 beds	8.1
Pharmacist FTEs required per 300 beds	4.1
Abbreviations: CCAD, Cleveland Clinic Abu Dhabi CSP, compounded sterile preparation; FTE, full-time equivalent; SPC, sterile preparation center.	

Figure 1

Figure 1: Average Preparation Time (minutes) of Compounded Sterile Parenteral Solutions by Type at Cleveland Clinic Abu Dhabi between June 14, 2020 - July 26, 2020, and May 27th, 2021-June 3rd, 2021