Profiles in CSP Insourcing: Tufts Medical Center

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Hospital Profile

Tufts Medical Center (TMC) is a not-for-profit, 415-bed academic medical center subdivided into a full-service adult hospital and the Floating Hospital for Children. The hospital, located in downtown Boston, is a regional referral center for complex and high-risk care, as well as the principal teaching hospital for Tufts University School of Medicine. TMC also has partnerships with Hallmark Health System and Lowell General Hospital.

The TMC Department of Pharmacy currently services the adult and pediatric hospitals via an integrated pharmacy practice model. TMC contains one intravenous (i.v.) sterile compounding clean room in which the scope of i.v. sterile compounding is limited to low- and medium-risk preparations, and one infusion center in which hazardous medications are compounded. Each year the Department of Pharmacy dispenses 2.3 million doses of medication, including 350,000 compounded sterile preparations (CSPs). Currently, we have approximately 8 full-time equivalent (FTE) certified pharmacy technicians and 6 FTE pharmacists whose time is dedicated to CSP operations.

CSP Timeline

Historically, the TMC Department of Nursing and Anesthesiology prepared thousands of CSPs in the patient care areas. In the early 2000s, the Department of Pharmacy began contracting with outside vendors to prepare CSPs in a manufacturing environment where the preparations are assigned extended beyond-use dates that reduce drug waste. At that time, anesthesia drugs in syringes, parenteral nutrition solutions, and high-risk or complex CSPs were prepared by outside vendors. The Department of Pharmacy was able to continue operations and achieve compliance with U.S. Pharmacopeia (USP) chapter <797> requirements for low-risk compounds with existing FTEs and limited operations during the day.

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In 2012, TMC was highly reliant on outside compounding pharmacies for the production of CSPs (80,000 annually). We outsourced over 45 product lines. After the abrupt closure of these outside vendors, TMC began preparing approximately 200 additional doses of CSPs per day, which represented a 30% increase in workload. CSPs previously outsourced were now prepared for specific patients, or vials were loaded in automated dispensing cabinets (ADCs) for nurses or other healthcare providers to prepare in patient care areas. As we reviewed our options, we took into consideration the sterility and stability testing needed for extending beyond-use dates within i.v. clean room operations and storage at room temperature instead of refrigerated storage, and additional FTEs needed to accommodate the increased workload and expanded hours. Sterility and stability testing for extending beyond-use dates was determined to be cost-prohibitive, and insourcing was found to be feasible only for non-controlled medications. Additional resources (e.g., FTEs) and refrigerated storage were justified to support the insourcing of non-controlled medications (45,000 CSPs annually). We also took the opportunity to work with clinicians who were ordering unique CSPs and ascertained whether these CSPs could be replaced with commercially-available products or the concentrations could be standardized.

By converting to commercially-available products and standardizing concentrations we greatly reduced our liability, improved expiration dating, streamlined the product line, and decreased our cost per dose for many CSPs. These product conversions and the additional FTEs enabled us to almost fully insource production and expand our hours of operations. As a result, TMC no longer outsources the majority of i.v. sterile compounding production. In addition, we were able to significantly reduce our dependence on outsourcing pharmacies to 15 line items and less than 30,000 CSPs annually. All in all, we were able to successfully enhance our sterile compounding services to encompass medium-risk CSPs while decreasing our annual operating expense and reduce the overall risk exposure associated with outsourcing i.v. sterile compounding services.

Product Line Changes

TMC has a limited reliance on outsourcing of compounding services that include high-risk and complex admixtures (e.g., parenteral nutrition solutions, anesthesia syringes, dialysate, and controlled substances). When we evaluated our scope of sterile compounding services, we made a conscious decision to insource preparation of only items categorized as low- or medium-risk. However, we reassess the breadth of our sterile compounding services annually. We review outsourced product lines and new ad-hoc requests via a formal process through our pharmacy and therapeutics (P&T) committee. Part of the formal process for evaluating each request takes into consideration whether a sterile product is commercially available. The requestor (with assistance from members of the Department of Pharmacy) must describe the unique elements required to prepare the sterile compound. If a sterile product that is not commercially available meets the criteria for addition to the formulary, whether the preparation is within our scope of service (low or medium risk), the impact on workload and FTE requirements, and the availability of appropriate infrastructure are evaluated. These factors enter into the decision about whether preparation of the CSP is approved as an extended service provided by our central pharmacy i.v. clean room or the product is obtained from a reputable outsourcing vendor. An annual reassessment of whether to continue outsourcing or insource CSP production is performed through a feasibility and impact analysis driven by three themes: (1) safety, quality, and risk; (2) operational performance; and (3) profitability of the organization. This reassessment takes into consideration the current status of vendor reliance/justification for continued use, new federal regulations, quality elements, vulnerabilities to the organization, inventory management and supplies, additional FTEs needed, facility constraints, personnel training, and technology, such as the use of automated compounding systems. Most importantly, the annual reassessment allows us to reexamine our decisions to outsource certain product lines in light of implementation

of new medication safety technology (e.g., barcode medication preparation technology) in our i.v. clean room operations, renovations to increase our capacity, and availability of additional resources. All of these considerations are essential when weighing the decision to insource versus outsource CSP production. For example, our most recent assessment in evaluating the parenteral nutrition solution product line revealed that we are highly reliant on a vendor. A breakeven return on investment (ROI) after 1 year was determined by comparing the cost of insourcing for the increased workload, labor, inventory, and supplies with the cost of outsourcing. However, we are limited by facility constraints (e.g., the number of and space available for hoods) and variability in the availability of certified pharmacy technicians with training in sterile compounding. Although our reassessment shows that insourcing parenteral nutrition solution compounding would reduce our liability and reliance on outside compounding services and have a positive ROI, we would need a substantial amount of resources and space that currently are not available for insourcing. Therefore, continuing to outsource parenteral nutrition solution compounding is the best approach for us at this time.

Personnel

The strategic planning for CSP-related projects at TMC has been a continuous process with a broad spectrum of expertise engaged throughout the process. TMC strategic planning included various core elements from completing a needs assessment to establishing the scope of services and continuously reviewing our financial performance. The strategic planning involved our pharmacy operations manager, i.v. clean room staff, informatics professionals, pharmacy leaders, members of interprofessional committees, and the senior leadership. Our initial strategic plan involved overcoming the challenges that required us to accommodate an abrupt increase in workload with limited resources in 2012. At the time, we completed an assessment of our infrastructure, operations, quality elements, vendor reliance, and an assessment of vulnerabilities. We leaned heavily on our interprofessional committees, such as infection control, P&T, and Pharmacy Nursing (P&N), as well as our leadership to define and support the scope of pharmacy insourcing services. The committees were empowered to assist in standardizing preparations, identifying alternative products, and utilizing commercially-available products. Consensus was built among these committee members and other stakeholders that an immediate investment in our infrastructure was warranted to avoid a shift to nurses or providers preparing products as immediate-use sterile products in patient care areas. These infrastructure and operational changes were designed to address medication safety gaps identified by the Institute of Medication Safety Practices (ISMP).

The TMC senior leadership requested a detailed cost-benefit analysis that included operational performance considerations and eliminated cost-prohibitive elements, such as extended sterility and stability testing. Part of the cost-benefit analysis involved comparing our costs for insourcing versus outsourcing sterile compounding for a variety of product lines differentiated by either operational considerations or complexity and risk level. This comparison allowed us to predict any changes in our financial performance in fiscal year 2013 (FY13) and beyond. Additional unique points that were emphasized with senior leadership were factors driving the outsourcing vs. insourcing decision, infrastructure needed for insourcing, and a tiered approach for implementation. It was also important to periodically provide updates to senior leadership on changes in regulatory requirements and financial performance with respect to insourcing vs. outsourcing of CSP production. These updates allow us to appropriately manage the expectations of the senior leadership about upcoming initiatives and projects mandated by regulations. The reduced reliance on outside compounding services but increased need for infrastructure and resources, such as additional staff, expansion of hours of service, refrigerated storage, software, and dedicated resources to maintain a quality assurance (QA) program for safety

and regulatory compliance, as well as barcode medication preparation technology were addressed in these updates to the senior leadership. In addition, the price increase of outside compounders between FY13 and fiscal year 2016 offset our increased annual operating expense by $550,000 and helped fund our infrastructure investment.

Currently, we are in the process of formalizing our sterile products oversight committee which will allow us to take an interdisciplinary approach to our risk mitigation procedures and commit to the following proposed charges and champion CSP initiatives. The proposed charges include: (1) evaluating the scope of compounding practices based on infrastructure and facility constraints, (2) overseeing and reviewing QA program results for both insourced and outsourced pharmacy services, (3) developing action plans if necessary to address any variances in practices, (4) approving preventive maintenance and infection prevention control plans for patient care areas and the i.v. clean room, and (5) championing the assessment, facility planning and design, and implementation of practices related to federal regulations and state board of pharmacy requirements. The committee convened to take on these charges will have representation and leadership from various departments, disciplines, and locations, including pharmacy (especially the medication safety officer); infection control; microbiology/clinical laboratory; risk, quality, and environmental safety; facilities; and the operating room and procedural areas.

CSP-related challenges

In our experience, enhancing sterile compounding services to include medium-risk products required a commitment to operational changes, additional labor, and infrastructure investments. This required the Department of Pharmacy to develop a very sound "game plan" to successfully move forward with our proposal to insource the preparation of the majority of CSPs.

Our first challenge was to increase staffing levels when the workload and hours of operations expanded. We then submitted a request for the approval of 1.6 FTE pharmacists and 1.6 FTE certified pharmacy technicians, which represents an annualized salary and benefit expense of approximately $280,000. This expense was offset by the proposed cost savings from discontinuation of outsourcing (i.e., shifting drug expense for outsourcing to labor expense for insourcing). To maximize efficiency and safety and reduce waste, we assessed our staffing needs based on production volume and proposed insourcing workflows. Whether we would prepare batches or patient-specific CSPs was part of the workflow analysis. We took into consideration our historical utilization data as well as differences between the use of manual versus automated batch preparation processes. We found that we were most efficient with the use of a repeater pump once a week for batch sizes greater than 45 that yielded about 20% waste instead of a more frequent manual process that was efficient for batch sizes less than 25 that yielded about 10% waste. These analyses allowed us to maximize the use of our resources.

An additional challenge that we faced was staff development and recruitment. We dedicated resources to maintain highly qualified and dedicated personnel within our i.v. clean room operations. Therefore, supervisory roles for a pharmacist and pharmacy technician were created by reorganizing the team to ensure that roles and responsibilities aligned with tasks. These supervisors were empowered to develop additional competences, provide training, and standardize tools and tasks. Installing software to aid in batch production was among the standardized tools designed to ensure quality. Strong focuses of the daily responsibilities of supervisors include leading QA efforts; promoting product integrity, reliability, accuracy, and compliance with regulations; and reducing medication errors while maintaining operational efficiency. The supervisors are essential in maintaining

QA programs, providing expertise in i.v. medication delivery system use, and most importantly, leading efforts in continuous process improvement to maximize efficiency and safety.

Sterile compounding vendors offer unique benefits that are not easily replicated in our operations, such as extensive sterility and stability testing that allows extended beyond-use dating of CSPs. When we were initially completing our cost analysis that compared costs for following the USP chapter <797> requirements for beyond-use dates with costs for sterility and stability tests needed to extend dates beyond those recommended by USP, we found that the additional sterility and stability testing was cost-prohibitive. To ensure that our insourcing initiative was cost-effective, we moved forward with strictly following the requirements in USP chapter <797> only for the compounding of medium-risk CSPs. This required investing in additional refrigerated storage on the nursing units to support the USP chapter <797> requirement for a 9-day beyond-use date for refrigerated storage instead of 24 hours for storage at room temperature. This change meant that high-risk and sound-alike medications would be stored in one location within the automated dispensing refrigerator. In discussing the change with the P&N committee, we identified an increased vulnerability to medication errors from the storage of these high-risk and sound-alike products, especially during emergent situations in intensive care units (ICUs). The committee addressed the problem by approving implementation of a safety intervention involving scanning of these high-risk and sound-alike items at the time of dispensing. There are consistently incorrect ADC scans recorded per month in the critical care units.

Lastly, it was a challenge to replicate the unique labeling and packaging used by compounding vendors because we were limited to a specific brand of labels and were unable to replicate the color and lettering enhancements. However, we followed ISMP best practices for white labels and black ink, which encourages careful reading of the label, while leveraging barcode technology to provide an additional safety barrier to prevent error in reading labels. We also utilized tall-man lettering and a large font size, which is consistent with ISMP recommendations.

We remained committed throughout the insourcing initiative and identified safety measures to overcome challenges and minimize new vulnerabilities in our i.v. medication delivery system. We addressed medication safety gaps identified by ISMP when implementing these infrastructure and operational changes. It was important for us to communicate and enhance visibility of these improvements to the organization.

Future Projects in CSPs

As an organization with the support of senior leadership and recent increases in regulatory oversight, we have committed to formalizing an interprofessional committee to oversee the safety, quality, and risk of sterile compounding services both within our operations and from outsourced vendors. As the scrutiny and complexity of sterile compounds continue to increase, we have a renewed focus on understanding the implications of the regulatory changes both on the local and national level. These changes include implementation of USP chapter <800> hazardous drug handling in healthcare settings. Currently, the organization has made an investment to engage consultants to evaluate our compliance with USP requirements and pending state regulations. The evaluation will drive recommendations for additional space and facility renovations in our central pharmacy and infusion center i.v. clean room, with cost estimates for various scenarios highlighted. The future needs for sterile compounding services based on patient needs and continuation of our insourcing initiative for parenteral nutrition solutions will be taken into consideration. The implications for our operations of various mandated regulations will be shared with our senior leadership to aid in navigating the budget request process by providing cost estimates for future needs. Furthermore, as we continue to evolve as a health system, providing

sterile compounding services across multiple sites is a consideration. Plans for this expansion could spur further infrastructure investments to enhance our operational performance and profitability and reduce our liability and reliance on outside compounding services while meeting high quality and safety standards.

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