



## Tufts Medical Center – A Case Study

Leveraging the Grifols PharmacyKeeper Verification IV  
Workflow Management System to Meet Current and  
Future Pharmacy Service Challenges

**GRIFOLS**

## Introduction

Recognized nationally for its innovation and research, Tufts Medical Center is a 415-bed academic medical center serving the Boston, Massachusetts and greater area. Its pharmacy provides acute care and outpatient services for adult and pediatric patients with support from 170 full-time equivalent staff operating in an integrated pharmacy practice setting, using a hybrid distribution model comprised of 70% decentralized and 30% centralized distribution. With a volume of 155,000 sterile products compounded annually and about 400–450 sterile products compounded daily, the pharmacy's sterile compounding responsibilities are extensive.

## Background and Challenge

Medication compounding errors have been reported frequently across the country and are of grave concern, as they can occur with devastating consequences.<sup>1</sup>

The topic came to the forefront publicly in 2012 when contaminated steroid injections processed by the New England Compounding Center caused a multi-state fungal meningitis outbreak, infecting 800 people and resulting in several deaths. This led to passage of the Drug Quality and Security Act in 2013 to increase regulatory control, including for patient-specific medication compounding.<sup>2</sup>

Regulatory oversight continued to expand with the release of several US Food and Drug Administration draft guidance documents applicable to clinical compounding, as well as the publication of US Pharmacopeia (USP) General Chapter <800> for safe handling of hazardous drugs and revision of USP <797> for compounding of sterile preparations.<sup>3,4</sup> These, along with other state and federal policies, contribute to a current landscape shaped by tragic compounding errors, expanding regulatory requirements, and increasing complexity for pharmacists and institutions.<sup>2</sup>

Against this backdrop, Tufts committed as a leader in the medical community to identify a new pharmacy workflow solution to better ensure the safety and quality of their sterile compounding processes. This commitment was underscored by the Tufts overarching focus on patient safety and a commitment to fully address state regulatory requirements.

## Strategy for Change

Based on a needs assessment, Tufts wanted the new solution to deliver improvement in three key process areas: **Patient Safety, Metrics/Benchmarking, and Efficiency/Throughput.** The solution also had to fit well within their existing pharmacy environment, include mandatory barcode scanning throughout the entire process, and exhibit flexibility to accommodate future opportunities or changes in regulatory requirements. Finally, the system had to be a one-system approach to manage all workflow facets—while being scalable, intuitive, customizable, highly feasible, and able to produce measurable outcomes.

## Selection of PharmacyKeeper as the Preferred Solution

Of the options evaluated, Tufts found the Grifols PharmacyKeeper workflow solution to best fit their needs and requirements. They appreciated the PharmacyKeeper design philosophy of integrating non-proprietary, commercially available hardware—mobile devices, touchscreens, cameras, barcode readers, and foot pedals—with the proprietary PharmacyKeeper software. Among its many features, the software ensured monitoring and documentation of all steps in the Tufts IV preparation process, enabled remote review and approval by pharmacy staff, and enhanced overall safety and efficiency.

## ERROR RATES

### Hospital medication compounding errors

**9%:** Mean error rate reported in a 5-hospital study assessing accuracy of injectables, chemotherapy, and parenteral nutrition. Higher error rates were found in specific areas<sup>1,5</sup>:

- **37%:** Error rate for manual preparation of complex solutions such as parenteral nutrition<sup>1,5</sup>
- **22%:** Error rate for partly automated preparation of parenteral nutrition<sup>1,5</sup>

**30%:** Percent of hospitals reporting occurrence of a patient event involving a compounding error in the past 5 years, in a 2009 survey<sup>6</sup>

## Roll-out of PharmacyKeeper Modules

The Tufts pharmacy team defined three phases for rollout of multiple PharmacyKeeper modules:

### Phase 1

During the first phase, Tufts decided to roll out the Verification, Training, and Carts modules:

- **Verification** module – To ensure accurate information and volumetric workflow capture during the compounding process.
- **Training** module – To ensure staff are adequately prepared to use and understand the new system, including competency completion and documentation.
- **Carts** module – To apply standard mapping, barcode scanning, and tracking components to the pharmacy's kits and cart trays that were in use throughout the institution.

### Phase 2

Tufts deployed the **Activities** module during the second phase to document required and/or standard work and assess alignment with standard operating procedures, internal and external regulations, and other applicable requirements.

### Phase 3

In this last phase, Tufts released the **Tracking** module to ensure transparency in medication distribution, using continuously updated location and time parameters for compounded medications.

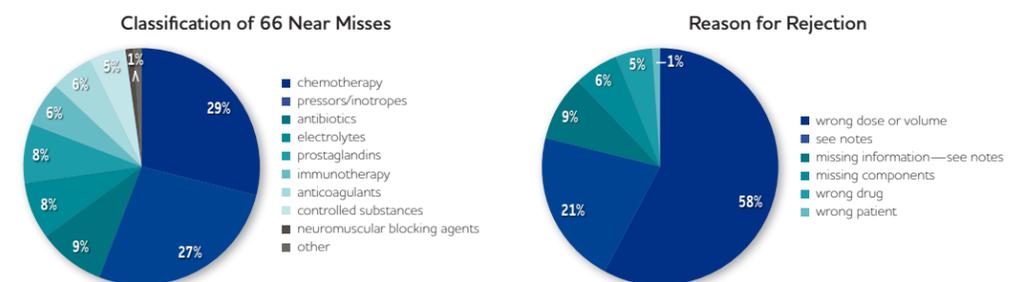
In addition, the **Inspections** module was deployed to enable protocol adherence for auditability purposes.

## Outcomes

Overall, Tufts found PharmacyKeeper's ongoing verification and operations support invaluable in improving the safety and efficiency by identifying compounding issues prior to use and maximizing pharmacy operational efficiencies.

## Patient Safety

**Near-miss data.** PharmacyKeeper prevented 66 errors over 5 months, with all errors considered undetectable without PharmacyKeeper's **Verification** and **Tracking** modules. Most error types were for chemotherapy agents (29%) or pressors/inotropes (27%), with the most common reason identified being wrong dose or volume (58%).



As a result of the near-miss findings, Tufts instituted specific corrective actions to ensure high-alert medications received an extra level of scrutiny, and developed targeted training aimed at known user errors.

Near-miss data were collected over a 5-month time period in 2019, with "near-miss" defined as a system-triggered, pharmacist-generated rejection based on inconsistent information during verification, e.g., recognition of a wrong dose or wrong volume. Any inconsistency generated a notice requiring pharmacist review and determination of further action, labeled as "incomplete", "reject", or "approve".

## Metrics/Benchmarking

**Tracking.** Tufts used PharmacyKeeper's **Tracking** module dose location transparency to influence and reinforce multiple nursing administration practices, such as locating medications or managing sequenced regimens for chemotherapy.

*As a key benefit, Tufts found that PharmacyKeeper greatly improved management of the process for medications leaving the pharmacy and arriving at the correct destination. PharmacyKeeper medication tracking proved especially useful during a major renovation of the Tufts infusion center.*

**Code Blue trays.** Tufts staff successfully completed 758 Code Blue verifications over 6 months without any significant workload spikes. In addition to improving workload management, they were more easily able to monitor tray expirations by using expiration date analysis provided by the PharmacyKeeper **Carts** module.

## Efficiency/Throughput

**Inspections.** With its readily accessible inpatient medication room inspection form, PharmacyKeeper helped Tufts set a new standard for inspections and compliance.

*Inspection improvements included standard medication room layouts to improve efficiency and reduce errors, best practice development based on inspection results, communication of inspection results to nursing leadership, and a higher level of regulatory readiness.*

**Quality and Compliance.** Tufts found PharmacyKeeper **Activities** and **Training** modules brought order and efficiency to the myriad cleaning tasks required for meeting compliance and regulatory standards. Staff training was improved by enabling staff competencies to be easily housed, assigned, and tracked.

**Disposal/Waste.** New practices incorporating electronic tracking via PharmacyKeeper's **Tracking** module ensured waste and disposal were accurately monitored to comply with safety and regulatory compliance, with thorough documentation providing further assurance.

## Summary

**Tufts was enthusiastic about the safety and quality benefits achieved with the implementation of PharmacyKeeper. As part of their continuing improvement process, they evaluated key learnings and, given the measure of success, chose to identify future expansion areas for continued use of PharmacyKeeper within their institution.**

### Key learnings:

- Priority setting and vision development are critical in identifying the best product.
- Robust planning contributes to a smooth implementation.
- Time studies and expectation setting are essential for staff buy-in.
- Workflow adaptation and supplementation helps ensure the technology solution grows with pharmacy services.

### Future directions for expanded implementation of PharmacyKeeper:

- Benchmark employee productivity
- Incorporate staff competencies beyond the central pharmacy
- Implement USP <800> practices
- Expand tracking capabilities to the ambulatory pharmacy
- Utilize tracking during operational changes
- Extend inspections to additional areas

**References:** **1.** Institute for Safe Medication Practices. ISMP guidelines for safe preparation of compounded sterile preparations. <https://www.ismp.org/guidelines/sterile-compounding>. Revised 2016. Accessed April 10, 2020. **2.** Quertermous J, et al. The practice of compounding, associated compounding regulations, and the impact on dermatologists. *J Drugs Dermatol*. 2018;17(7)Suppl:17-22. **3.** United States Pharmacopeia. USP general chapter <800> Hazardous drugs – Handling in healthcare settings. <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>. Published February 1, 2016. Official: December 1, 2019. Accessed April 10, 2020. **4.** United States Pharmacopeia. General chapter <797> Pharmaceutical compounding – Sterile preparations. <https://www.usp.org/compounding/general-chapter-797>. Revised June 1, 2019. Official: 2008 revision. Accessed April 10, 2020. **5.** Flynn EA, et al. Observational study of accuracy in compounding i.v. admixtures at five hospitals. *Am J Health Syst Pharm*. 1997;54(8):904-912. **6.** Halvorsen D. The 2009 state of pharmacy compounding. Survey results. *Pharm Purchasing Products*. 2009;6(4):2–20. <https://www.pppmag.com/digitalmag/Main.php?MagNo=43&PageNo=1#page/1>. Accessed April 10, 2020.

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The logo for Inclusiv compounding portfolio features a teal arch above the word "inclusiv" in a bold, lowercase, sans-serif font. Below "inclusiv" is the phrase "compounding portfolio" in a smaller, lowercase, sans-serif font.