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From Local Quality Improvement to National Drug Recall

Kurt R. Herzer, MSc [Medical Scientist Training Program Fellow],

The Johns Hopkins University School of Medicine and Johns Hopkins Bloomberg School of Public Health, Baltimore, MD 21205. kherzer@jhmi.edu

Christine Lim, BS [Medical Student],

University of Maryland School of Medicine, Baltimore, MD 21201.

Christine.Lim@som.umaryland.edu

Matthew Li, BA [Research Assistant],

Department of Anesthesiology and Critical Care Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD 21287. matthew.li@jhu.edu

YanJun Xie, BA [Medical Student],

The Johns Hopkins University School of Medicine, Baltimore, MD 21205. johnny@jhmi.edu

Peter A. Doyle, PhD [Human Factors Engineer],

Clinical Engineering Services, The Johns Hopkins Hospital, Baltimore, MD 21287.

pdoyle6@jhmi.edu

Renee Cover, RN, BSN [Risk Manager], and

The Johns Hopkins Hospital, Baltimore, MD 21287. rcover1@jhmi.edu

Lynette J. Mark, MD [Associate Professor]

Department of Anesthesiology and Critical Care Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD 21287. lmark@jhmi.edu

Abstract

Medication errors due to look-alike drugs put patients at risk and can be fatal. Neuromuscular blocking agents, such as vecuronium, can cause awake-paralysis in patients if administered as a single agent. Recent literature reported six cases in which vecuronium was inadvertently administered instead of the antibiotic drug cefazolin. This article describes a standardized quality improvement process used at The Johns Hopkins Hospital that was locally implemented following an adverse drug event and culminated in a nationwide FDA-mandated drug recall of vecuronium.

Corresponding Author's contact details: Kurt R. Herzer MSc, The Johns Hopkins University School of Medicine, 1830 E. Monument Street, Suite 2-300, Baltimore, MD 21205, Phone: 410.955.7519 | Fax: 410.955.0994 | kherzer@jhmi.edu.

Conflicts of Interest Notification

Kurt R. Herzer has no conflicts of interest to report.

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Introduction

Medication errors due to look-alike drugs put patients at risk and can be fatal. Similar packaging, coloring of labels, and vial sizes and shapes all contribute to this type of error. Neuromuscular blocking agents (NMBAs), such as vecuronium, present a particular safety issue if administered as a single agent as they can cause an awake-paralyzed state in which patients are conscious but cannot breathe. Nearly a third of NMBA errors are “wrong drug” errors.¹ In 2009 there were six reported cases² in which vecuronium was inadvertently administered instead of the antibiotic drug cefazolin.

The Johns Hopkins Hospital (JHH) uses a standardized, six-step, multidisciplinary process for quality improvement³ to (1) identify a hazard to patient safety, (2) report the hazard in a patient safety reporting system, (3) analyze the report with a multidisciplinary team, (4) mitigate the hazard and educate providers, (5) reward those who reported and helped mitigate the hazard, and (6) follow up to verify sustained quality improvement.

The following case demonstrates the impact of successfully applying this process.

Patient Case and Application of the Quality Improvement Process

A 48-year-old woman underwent a surgical procedure at JHH. Prior to incision, the anesthesiologist administered cefazolin. Shortly thereafter, the patient’s tidal volume decreased with weakened respiratory effort. Assisted ventilation with pressure support was initiated and continued throughout the procedure. At the conclusion, the patient was awakened, but complained of difficulty breathing that continued for 20 minutes.

Steps 1 and 2: Identify and Report a Hazard

The anesthesiologist considered a drug look-alike error with inadvertent administration of vecuronium instead of cefazolin. Compromised muscular control was confirmed and fully reversed. The patient suffered no permanent harm. The event was reported to UHC’s Patient Safety Net (PSN).

Step 3: Analyze the Report

Analysis of the event by a multidisciplinary perioperative quality improvement team of physicians, nurses, risk managers, and human factors engineers⁴ revealed that, one week earlier, a certified registered nurse anesthetist (CRNA) had notified the team that cefazolin and vecuronium vials with a similar appearance were adjacent to one another in the automated medication dispenser. Investigation found that the current supply of vecuronium and cefazolin had look-alike packaging and that the vecuronium labeling was noncompliant with United States Pharmacopeia (USP) standards because “Paralyzing Agent” was not on the cap and the ferrule.⁵

Step 4: Mitigate and Educate

1. **Locally:** The pharmacy revised the storage protocol for NMBAs⁶ and enacted an institution-wide withdrawal of vecuronium from this manufacturer. Anesthesia protocol was altered to keep medication vials until case completion in case of a suspected medication error. The event was presented at Anesthesiology Grand Rounds, and the hospital’s insurance consortium was informed so as to alert other institutions.
2. **Nationally:** JHH requested a Food and Drug Administration (FDA) national recall of vecuronium, which was instituted within two weeks. The manufacturer initiated a voluntary urgent market recall.

Steps 5 and 6: Reward and Follow Up

The CRNA and anesthesiologist were awarded a “Good Catch Award”³ to publicly recognize their role in identifying a hazard. The JHH supply of vecuronium has since been compliant.

Conclusion

This case demonstrates the advantages and effectiveness of a standardized, quality improvement process to rapidly identify and mitigate hazards. A local quality improvement with widespread ramifications then became a national quality improvement.

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