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Increasing Medication Access by Promoting Appropriate Use of Multi-dose Vials

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Medication shortage is a problem that affects patients, providers, and institutions of all sizes and scope across the United States. The objective of this quality improvement project was to promote the appropriate use of multi-dose vials (MDVs) by anesthesia providers at an independent plastic surgery office. Multi-dose vials can be used to decrease waste and potentially cost, thus increasing access to necessary medications for the patients at this practice. A focus group was used to obtain an understanding of barriers to the use of MDVs at this practice. A focused E-learning module on safe use based on established guidelines was then created, and a simplified flow sheet was implemented and placed in medication preparation areas as a cognitive aid. The education and flow sheet focused on identification and preparation of the medication area, proper identification of MDVs versus single-use vials, hand hygiene, proper beyond-use labeling, septum cleaning, use of a new sterile syringe and needle, and administration time frames. Provider feedback included high levels of satisfaction with the E-learning module. Our comparison of the use of ketamine from MDVs during the pre- and postimplementation phases showed a 14% increase in the number of doses used per vial. This finding suggests that were similar practices implemented at a larger site with MDVs of medications other than ketamine, resources could be impacted to manage shortages and increase access to medications.

Medication shortages are detrimental to providers, institutions, and patients. In 2012, shortages gained national attention and have remained an ongoing concern; landmark surveys have shown their impact in the United States. A survey of pharmacy directors by McLaughlin et al. (2013) found medication shortages impacting institutions ranging from large inpatient hospitals to ambulatory care and surgical centers. Of the respondents, 59% reported medication shortage as the likely cause of adverse events including death, disabling events, medication errors, and delayed or cancelled care (McLaughlin et al., 2013).

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Current medication shortages can be found on the U.S. Food and Drug Administration (FDA) Drug Shortages Database (U.S. FDA, 2020a) and on the American Society of Health-System Pharmacists (ASHP) drug shortage list (ASHP, 2020). The ASHP notes that shortages remain an issue despite the passage of legislation in 2012 requiring the FDA to be notified of medication production changes (ASHP, 2018). Events such as Hurricane Maria's 2017 devastation of Puerto Rico, the location of a large manufacturer of saline bags, affect shortages and cannot be controlled.

Although manufacturers' advanced warning to the FDA of reduction in medication supplies has been useful, shortages occur if other companies cannot compensate for announced reductions and absorb the burden (ASHP, 2018). Common drugs used by anesthesia providers that have previously been on shortage include, but are not limited to, ketamine, labetalol, fentanyl, vecuronium, rocuronium, lidocaine, and etomidate (ASHP, 2020). When shortages occur, providers look for alternative medications; however, similar therapeutic agents may also be on shortage (Gulbis, Ruiz, & Denktas, 2013). Dependence on unfamiliar alternative medications increases provider stress, tension between disciplines, and helplessness in staff members (Gulbis et al., 2013).

The World Health Organization (2014) states that MDVs reduce medication wastage and cost and can be effective during times of medication shortage; yet, MDVs are not recommended by the Centers for Disease Control and

Prevention (CDC) for routine use. The CDC (2019) defines an MDV as a vial used for parenteral medication that contains multiple doses of medication in addition to an antimicrobial preservative. Multi-dose vials allow a specific patient dose to be drawn up while leaving the remaining medication for other patients; however, the CDC has attributed a number of outbreaks such as methicillin-resistant *Staphylococcus aureus* infection, hepatitis B (HBV), and hepatitis C (HCV) in the United States to improper use of MDVs (CDC, 2012). The organization states, "The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices" (CDC, 2012). In 2013, a pulmonary teaching hospital in Iran showed a higher microbial contamination rate in MDVs (7.5%) than in single-use vials (4.85%) (Baniasadi, Dorudinia, Mobarhan, Karimi Gamishan, & Fahimi, 2013). The authors stated that nonbacterial or fungal contaminations are not fully prevented by preservatives found in MDVs (Baniasadi et al., 2013). Dr. Melissa Schaefer, a medical officer from the CDC's Division of Healthcare Quality Promotion, noted that two thirds of the 70 ambulatory surgical centers across three states had lapses in infection control policies, including environmental cleaning, medication handling, injection safety, hand hygiene, equipment sterilization/disinfection, and proper use of personal protective equipment (Schaefer et al., 2010).

The United States Pharmacopeia 797 (USP) guidelines direct that sterile drug products be prepared using primary engineering controls, which are unavailable in many outpatient ambulatory care areas. The USP 797 is a standard enforceable by State Boards of Pharmacy and the FDA, and any manipulation of sterile products falls under the current recommendations. Because of room air quality, medications drawn up in ambulatory care areas should be administered within 1 hr (immediate-use category) to avoid risk of contamination (USP, 2008).

The CDC 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings state, "In all cases, transmission has been attributed to failure to adhere to fundamental infection control principles, including safe injection practices and aseptic technique" (Siegel, Rhinehart, Jackson, Chiarello, Healthcare Infection Control Practices Advisory Committee, 2019, p. 37). The 2007 CDC guidelines state that the most fundamental practice for reducing transmission of infectious agents is hand hygiene, noting that an approved alcohol-based hand sanitizer is preferred for disinfection when hands are not soiled. Likewise, the guidelines prohibit artificial nails, which can harbor bacteria. Guidelines also call for the use of a "sterile, single-use, disposable needle and syringe for each injection" in response to four large HBV and HCV outbreaks in ambulatory care facilities (Siegel et al. 2019, p. 70). When an MDV is opened, the USP 797 guidelines require strict labeling of the medication vial with a beyond-use date (BUD) of no more than 28 days unless the manufacturer specifies otherwise. The 2007 CDC guidelines state that MDVs should not be kept in the patient treatment area and should be stored per the recommendation of the manufacturer (Siegel et al., 2019). These techniques can be performed by all providers without expensive equipment or a clean room and can facilitate simple medication preparation in the outpatient surgery setting.

The authors of the 2007 CDC guidelines noted that guideline adherence rates generally decrease for nurses and physicians as years of practice increase (Siegel et al., 2019); however, evidence has shown that the use of a checklist increases adherence to existing guidelines and protocols in a wide variety of fields (Marx Delaney et al., 2017; Pugel, Simianu, Flum, & Patchen Dellinger, 2015).

The objective of this quality improvement (QI) project was to assist certified registered nurse anesthetists (CRNAs) at an office-based plastic surgery facility to use MDVs knowledgeably, comfortably, and safely by providing formalized and focused education along with a visual flow sheet on the proper manipulation of an MDV. Teaching CRNAs to manipulate sterile products properly allows providers to increase access to a limited supply of medication and to decrease medication waste and associated cost. By providing continued access to medications on shortage, providers can optimize medication use for patient care.

METHODS

Prior to implementation, this project was formally evaluated and determined to meet the institutional definition for a QI project; therefore, it was exempt from institutional review board oversight.

Organizational Setting

This project was implemented at an ambulatory outpatient plastic and cosmetic surgery office operated and owned by a board-certified plastic surgeon in a metropolitan region of central North Carolina. Anesthesia services for the clinic are provided by six independently practcing CRNAs. Approximately 200 surgical procedures per year are performed at the facility. The practice performs a wide variety of elective procedures; however, the three most common procedures requiring anesthetic care are breast augmentation, face lifts, and liposuction.

The participants in this QI project included all six of the CRNAs who worked independently at the practice. All were experienced providers with approximately 7+ years of experience who had worked in a multitude of settings, but specialized in outpatient procedures. All the providers were expected to participate in the focus group and surveys and to adhere to the flow sheet if exclusions were not applicable. The primary causes of exclusion from use

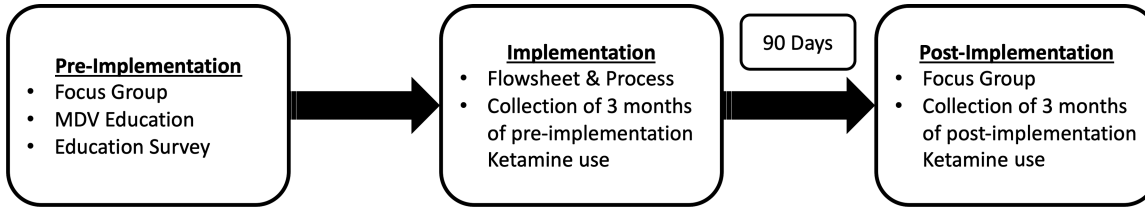

FIGURE 1. Quality improvement project progression. MDV = multi-dose vial.

of MDVs included situations in which (a) the medication needed to be drawn up in the immediate patient care area or (b) the vial may have been compromised.

This QI project used a pre/posttest design outlined in Figure 1. Ketamine is commonly used as an anesthetic in this organization, and it has the advantages of a detailed dose administration log and inventory records due to its classification as a U.S. Drug Enforcement Administration Schedule III controlled substance. In addition, the practice uses a single concentration and vial size of ketamine. Ketamine was selected as an ideal drug for collection of MDV usage data pre- and postimplementation.

Initially, a focus group of the CRNA practitioners was held to assess the current use of MDVs in the practice and to identify barriers to their use. Following this, education based on CDC and USP 797 guidelines about proper MDV use was provided via an E-learning module. Feedback from the learners about the E-learning module was assessed via a survey. A flow sheet outlining the procedure for handling MDVs was developed and placed in areas of medication preparation and storage in the practice. The number of ketamine vials and doses used per vial in the 90 days preceding implementation was recorded. After 90 days, postimplementation data were collected and a final focus group was held to garner feedback about effectiveness of the QI project. Following implementation of the flow sheet, inventories of the number of vials and doses per vial used before and during the 90 days of implementation were compared.

Implementation

This project, which focused on immediate-use medications, emphasized adhering to proper techniques recommended by the CDC and referenced by the USP for manipulating sterile intravenous medications in order to minimize risk of contamination (Siegel et al., 2019; USP, 2008).

Preimplementation Focus Group

The initial stage required obtaining feedback from CRNA providers, which was accomplished through a videoconference call. This format allowed all practitioners to be in attendance, although they worked at a variety of outpatient sites. The focus group was performed to discover barriers to the use of MDVs at the practice and to assess participants' current comfort and knowledge surrounding MDV use. The responses of the providers to multiple open-ended questions were transcribed and evaluated for common elements and themes.

MDV Education

An E-learning module, which summarized the appropriate use of MDVs based on the CDC and USP 797 guidelines was designed and developed with the assistance of a pharmacist (Siegel et al., 2019; USP, 2008).

The E-learning module was sent out to the CRNAs via personal e-mail along with a link to a post-education survey, which they were encouraged to take. Once completed, the respondents, including the director of the anesthesia practice, were presented with a $10 gift card.

The survey was modified from the National League of Nursing (2003) Student Satisfaction and Self-Confidence in Learning questionnaire, which is a 13-item instrument. This tool uses a 5-point Likert scale and asks respondents to rate their attitudes to statements made regarding the education session.

Flow Sheet Development and Implementation

In order to help ensure safe use of the MDVs, a procedural flow sheet was created to serve as a visual checklist. The flow sheet focused on important steps that could be overlooked. The flow sheet included key components related to appropriate use of MDVs. It was created with attention to recommendations from the CDC and USP 797 guidance documents (Siegel et al., 2019; USP, 2008) regarding (a) ensuring identification and proper preparation of an appropriate medication preparation area, (b) hand hygiene, (c) labeling of MDVs, (d) septum cleaning, (e) use of new sterile syringes and needles, and (f) administration time frames.

The flow sheet was placed in critical areas of medication preparation and storage after the E-Learning module was completed, marking the beginning of a 3-month implementation period for the new process.

Ketamine MDV Usage

Ketamine MDV usage data were collected for the previous 90 days from the daily inventory logs including the number of doses and vials used. Similar information was

TABLE 1 Primary Themes From the Pre-Implementation Focus Group
• Concerns about reliability of estimates for remaining medication in vials for controlled substance logs
• Lack of provider confidence about proper handling of MDVs due to lack of formalized process for multiple providers accessing vials
• Avoiding inappropriate MDV use (e.g., accessing in patient care area)
Note. MDV = multi-dose vial.

collected for a 90-day postimplementation period, beginning 3 months after the new process was implemented.

Postimplementation Focus Group

A follow-up focus group was held using videoconference 1 month after the end of the postimplementation data collection phase. The purpose of the focus group was to gather feedback about the process and the providers' current attitudes. This focus group addressed the (a) usefulness of the educational module and flow sheet, (b) identification of current issues with MDV use, and (c) recap of the QI project.

Data Management

Data collected were stored in a password-protected folder. This information was only accessible to the project lead, the statistician, and other approved project participants. This QI project did not require any collection of or access to protected health information. The CRNA practitioners and patients were kept anonymous.

RESULTS

Preimplementation Focus Group

Feedback from the focus group was reviewed and summarized as three main themes listed in Table 1. The barriers identified were related to lack of provider confidence about appropriate handling of MDVs; they were addressed during the development of the E-learning module and flow sheet.

MDV Guideline Education and Posteducation Survey

All the CRNA providers reported a high level of satisfaction with the E-learning module due to its concise focus on material pertinent to practice. For example, the providers indicated that the methods used were helpful and effective and that they were confident that they were mastering the material in the educational module.

Ketamine MDV Usage

Ketamine MDV concentration and vial size (50 mg/ml, 10 ml per vial) remained consistent throughout the pre- and postimplementation data collection periods. Ketamine MDV usage data are presented in Table 2.

These results demonstrate a modest increase in the mean and median doses per vial, representing a 14% increase in the mean number of doses per vial in the postimplementation phase compared with preimplementation. There were three similar incidences of wasted medication occurring in both the pre- and postimplementation phases.

Postimplementation Focus Group

Four of the six providers were in attendance for the postimplementation focus group. A review and analysis of themes was performed with common elements identified in Table 3.

None of the providers expressed concerns about MDV use at this time, and they all reported satisfaction with having a formalized practice in place. They reported having greater confidence in appropriate use of MDVs. The providers reported high satisfaction with the E-learning module consistent with the results of the posteducation survey administered. Respondents noted that it was useful to stay up to date in their practice and helpful to have a refresher on this topic and that the module based on evidence-based CDC and USP guidelines was useful for ensuring patient safety.

TABLE 2 Pre- and Postimplementation Data		
	Preimplementation (90 days)	Postimplementation (90 days)
Number of doses	37	30
Number of vials used	9	6
Mean ± *SD* doses per vial	4.2 ± 1.0	4.8 ± 1.1
Median doses per vial	4	5
Dose range	50–250 mg	50–200 mg

TABLE 3 Primary Themes Emerging From the Postimplementation Focus Group
• No concerns about MDV use
• Benefit of flow sheet to providers was secondary to the E-learning educational module provided
• E-learning module was easy to access and a good refresher on best practices to ensure patient safety
Note. MDV = multi-dose vial.

DISCUSSION

This QI project focused on (a) discovering barriers to proper use of MDVs at a small office-based plastic surgery practice and (b) providing focused education and cognitive aids on the proper use of MDVs in compliance with professional guidance documents in order to improve provider access to medications in short supply. This project suggests that implementation of education and a standardized process consistent with best practices in a small outpatient practice can result in more effective use of MDVs. Likewise, the results of the provider survey and the postimplementation focus group suggest increased confidence in the use of MDVs by the CRNA providers. These findings address two of the three primary barriers identified by the preimplementation provider focus group; however, some provider concerns about MDV use were difficult or impractical to address (e.g., increasing reliability of estimates for remaining medication in MDVs).

Based on the focus group responses, although there was disinterest from the providers in using the flow sheet to its full effect, the training and education component was quite favorably received and reinforced provider confidence in handling MDVs properly and in promoting their appropriate use. Although the 14% increase in doses per vial was not statistically significant and financial impact was not evaluated by our project, similar increased appropriate use of all MDVs could potentially result in cost savings.

This QI project was based on a small sample of providers and cases performed at an outpatient plastic surgical office. A larger sample size would provide better feedback about (a) the value of implementing an educational module and process flow sheet, and (b) participants' knowledge and attitudes toward MDVs. This feedback could facilitate improved implementation of the process at other sites.

Further work needs to be performed to assess and improve practitioners' understanding of medication shortages and increase their ability to successfully respond to shortages.

1. Because many sterile injectables may be manufactured by a single company, the FDA may find it difficult to identify suitable alternative manufacturing options as needed (ASHP, 2018).
2. Improved accurate reporting by manufacturers could allow the FDA to review and expedite the potential for various companies to manufacture the needed medication.
3. Changes to systems need to occur on a large governmental scale; for example, the Federal Trade Commission (2019) could evaluate the impact of pharmaceutical mergers on medication shortages.
4. A current tool that has been recently provided by the FDA is the Extended Use Dates database, developed in conjunction with manufacturers to provide extended expiration dates, when possible, of certain lot numbers of medication that are currently on the shortage list (U.S. FDA, 2020b).

Some of the factors that impact drug shortages are outside the scope and control of providers in the immediate patient care area; however, providers in all institutions can be taught to use MDVs properly. This QI project shows that focused education and simple tools can help practitioners address the issue by providing confidence in their ability to use MDVs appropriately.

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