

Infection Control Resource

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Prevention Strategies for IC Practitioners and Professional Nurses

In this issue

Transmission of infection via contaminated multi-dose vials (MDVs) has been well documented, increasing the risk of serious facility-wide outbreaks. From 1983 to 2003, there have been reports of nearly 30 outbreaks of infections associated with MDVs. One of the proposed JCAHO National Patient Safety Goals for 2006 is the elimination of multiple-dose medication vials, whenever possible, and by switching to single-use IV flush vials. In her article, Ms. DeBaun describes MDV contamination and subsequent infections including bacterial, viral and yeast and strategies for prevention of MDV-associated infections.

In large studies of hospitalized adults, medication errors are the most frequent cause of injuries from medical care. Roughly 5% of hospitalized adults experience adverse drug events (ADE), and an additional 5% experience a potential ADE. For every 25,000 admissions in the US, it is estimated that \$3.2 million is spent on ADEs. Infection control professionals (ICPs) have skill sets that are uniquely designed for the challenge of addressing patient safety issues. Ms. Barnard demonstrates how ICPs can use their special tools and techniques of surveillance and epidemiology to plan interventions that lead to decreased rates of adverse events.

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Transmission of infection with multi-dose vials

By Barbara DeBaun, RN, MSN, CIC

Multiple-dose vials (MDVs) are widely used in all healthcare settings. By definition, an MDV contains antibacterial preservatives and, according to manufacturer's recommendations, may be used more than once.¹ It is important to recognize that although common preservatives used in MDVs are effective against most bacteria, they are not antiviral agents. In addition, contaminating pathogens are able to survive in MDVs for approximately two hours before the preservative takes full effect. It is possible that endotoxins survive even after the preservative inactivates the organism.² There is significant variation in user techniques associated with MDVs, and faulty aseptic technique is the primary cause of vial contamination—for example, Plott and colleagues demonstrated that 25% of practitioners reentered a vial with a needle that had been introduced into a patient.³

Studies have demonstrated that the bacterial contamination rates of multiple-dose vials vary significantly. Longfield and colleagues reported that the contamination rate in published studies has been as low as 0% and as high as 27%.⁴

In response to a report of two patients who died of meningitis caused by *Pseudomonas aeruginosa* in a German hospital in July 2001, Mattner and Gastmeier conducted a one-day prevalence study to investigate the use and contamination of MDVs.¹ All MDVs used in a tertiary-care hospital that particular day were collected and tested for sterility. The results revealed poor compliance with infection control practices, including labeling of vials and maintenance of proper temperatures for storage. The contamination prevalence rate was determined to be 0.9% (CI95 0.15%-3%).

MDV contamination and subsequent infection

Reports describing nearly 30 outbreaks of illness associated with MDVs occurring between 1983 and 2002 have been published in the scientific literature. Medications included propofol,

saline, epoetin alfa, DTP vaccine, heparin, dextrose, TPN, distilled water, bupivacaine, methylprednisone, and iomeprol. Pathogens responsible for the outbreaks included viruses (HIV, hepatitis B, and C), bacteria (*E. cloacae*, *S. marcescens*, *S. aureus*, *K. pneumoniae*, group A streptococcus, and *P. aeruginosa*), and yeast (*C. albicans*).

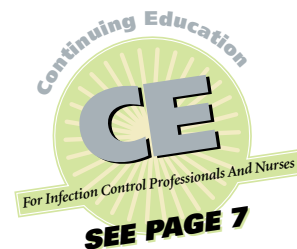
Certain types of medications are more likely to be associated with outbreaks than others. Lipid-containing medications such as propofol are the most commonly reported culprits, followed by preservative-free solutions. It is interesting that the preservatives utilized in vaccine MDVs do not appear to interrupt short-term bacterial contamination;⁵ however, they are quite effective in the preservation of heparin and insulin.⁶

Bacterial infections

In 1996, the Centers for Disease Control and Prevention (CDC) were asked to assist in the investigation of gram-negative bloodstream infections that occurred in neonates in a public hospital in Puerto Rico. These neonates, two of whom expired, were infected with *Enterobacter cloacae* and/or *Pseudomonas aeruginosa* over a period of five days, and a common source was highly suspected.⁷ Although the investigators were unable to confirm vial contamination, as all used vials had since been discarded, their epidemiologic data suggested that a contaminated vial containing dextrose was the most plausible explanation for the outbreak. The CDC's Guideline for Prevention of Intravascular Device-related Infections, published that same year, recommends the use of single-dose vials for parenteral additives or medications whenever possible.⁸ If multi-dose vials are used, the guideline recommends disinfecting the rubber diaphragm with an EPA-approved disinfectant and allowing it to dry prior to insertion of the needle.

Hepatitis B

Hepatitis B virus (HBV) is present in extraordinarily high titers in the blood and certain



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Medication errors and the role of the ICP

by Bonnie Barnard, MPH, CIC

The Institute of Medicine (IOM) Committee on the Quality of Health Care in America was formed in 1998 and tasked with developing a strategy that would result in substantial improvement in the quality of health care over the next ten years. Its first report—*To Err is Human: Building a Safer Health System*—published in 1999, laid out a comprehensive strategy for addressing the problem of errors.¹ The report classified medical errors as shown in Table 1. These errors result in significant adverse events for patients in the healthcare system. Although the title of the report stated that to err is human, endeavors over the last several years have clearly focused on the role of poorly designed and implemented systems of care in the occurrence of errors.

The second IOM report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, was published in 2001.² It may, in the end, have a more sweeping impact on the healthcare system as a whole. It outlines a strategy for providing care that is evidence-based, patient-centered, and systems-oriented:

- care based on continuous healing relationships
- customization based on patient needs and values
- the patient as the source of control
- shared knowledge and the free flow of information
- evidence-based decision-making
- safety as a system property
- the need for transparency
- anticipation of needs
- continuous decrease in waste
- cooperation among clinicians

It is a call for a total shift in the way health care is delivered, in the roles and responsibilities of patients and families, and in the role, self-image, and work of front-line healthcare workers.

The response to the first IOM report has been an overwhelming commitment to create a healthcare environment that is safe. Although the second report in the series received much less fanfare, it is even more sweeping in its recommendations concerning the fundamental structure and function of the healthcare system in the United States. The breadth and depth of support for these initiatives has been strong from government agencies (e.g., Agency for Healthcare Quality and Research), the business community (e.g., National Quality Forum, Leapfrog), healthcare insurers, accreditation agencies (e.g., JCAHO), healthcare providers, and patient advocate groups (e.g., Consumers Union).

The IOM report *Priority Areas for National Action: Transforming Health Care Quality* published in 2003 created selection criteria and a process for identifying areas upon which the healthcare system should focus to improve the quality of care.³ The framework for determining priority areas included:

- living with illness/disability—chronic care;
- getting better—acute care;
- coping with end of life—palliative care;
- staying healthy—preventive care;
- cross-cutting systems—interventions.

Criteria for prioritizing topics included impact, improvability, and inclusiveness. The final set of 20 priority areas included many different topics, including medication management (e.g., preventing medication errors and overuse of antibiotics) and nosocomial infections (e.g., prevention and surveillance).

The aim of the medication management priority area is to provide ongoing surveillance and prevention of adverse drug events (ADEs) and to reduce inappropriate antibiotic use, in particular for acute respiratory infections. The report outlines the impact

of these events, assesses the potential for improvability, and discusses the inclusiveness of the impact of this issue. Clearly, reduction of adverse drug events and, in particular, reduction of inappropriate antibiotic use is on the national agenda for the provision of quality care.

Medication errors: overview

In large studies of hospitalized adults, medication errors are the most frequent cause of injuries from medical care.^{4,5} Roughly 5% of hospitalized adults experience ADEs, and an additional 5% experience a potential ADE (i.e., the error reached the patient, but no harm occurred).⁴

The cost of these errors is astronomical. In one study at Intermountain Health Care in Salt Lake City, Utah, the additional length of stay attributable to an ADE was 1.74 days or \$2013 per admission.⁶ Another study at Brigham and Women's Hospital in Boston, Massachusetts found that an ADE caused 2.2 days of additional stay at a cost of \$2595 per admission.⁷ For every 25,000 admissions in this country, it is estimated that \$3.2 million is spent on ADEs. These estimates do not take into consideration the trauma to the patient or his/her family and the cost in terms of bad publicity for the healthcare facility.

Medication errors: classification

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) system recognizes two classes of mistakes in medication:

- **medication error.** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, or systems (including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use).
- **adverse drug event.** An adverse drug event is any injury resulting from a medical intervention related to a drug. Examples of such injuries include heart rhythm disturbances, diarrhea, fever, nausea and vomiting, renal failure, mental confusion, rash, low blood pressure, and bleeding.

These two types of errors can be further broken down into the categories shown in Table 2. It is important to note that not all medication errors result in harm to the patient. Only categories E through I are considered adverse drug events. However, any medication error could be an indication that there is a system problem that could lead to harm in the future.

Table 1. IMC classification of medical errors

Diagnostic	
• error or delay in diagnosis	
• failure to employ indicated tests	
• use of outmoded tests or therapy	
• failure to act on results of monitoring or testing	
Treatment	
• error in the performance of an operation, procedure, or test	
• error in administering the treatment	
• error in the dose or method of using a drug	
• avoidable delay in treatment or in responding to an abnormal test	
• inappropriate (not indicated) care	
Prevention	
• failure to provide prophylactic treatment	
• inadequate monitoring or follow-up of treatment	
Other	
• failure of communication	
• equipment failure	
• other system failure	

Medication errors: when they occur

Medication errors can occur at any stage of the medication administration process and are related to any number of factors (table 3). In general, the causes of medication error can be classified into one of four categories:

- patient-knowledge deficiency
- medication-knowledge deficiency
- non-adherence to policies and procedures
- miscellaneous

Medication errors: prevention

In addition to involving pharmacists more directly in the ordering process, prevention strategies can include educational interventions directed at physicians and targeting abbreviations, prescribing practices, and even handwriting legibility. However, “hard-wired” solutions such as barcoding of medications, unit dose dispensing, and computerized physician order entry are more desirable than behavioral modification approaches.

Computerized physician order entry (CPOE) is one of the most talked-about interventions to prevent ordering errors. CPOE refers to a software application that allows doctors to electronically enter all orders; it replaces handwritten orders. CPOE occurs at a point in the medical management process where decision is turned into action—the point at which feedback to the prescriber is most useful and the earliest, most efficient point at which to intercept potential mistakes and offer decision support. The volume and complexity of information available for drugs has far surpassed any individual’s capacity to know and account for all variables. Even the most basic CPOE system eliminates issues of illegibility and ensures that orders are complete and in a standard format, thus preventing ambiguous orders. Sophisticated CPOE systems provide additional decision support such as drug-allergy checking, drug-drug interaction checking, etc.

Since most hospitals do not have such sophisticated medication ordering systems, the need remains for nurses and physicians to observe basic patient safety practices related to order writing:

- Always write orders legibly.
- Use abbreviations sparingly. (ISMP has a list of abbreviations to avoid.)
- Design order forms to require specification of dose, route, interval, duration.
- Communicate directly to nurses and pharmacists regarding potentially confusing orders.
- Minimize the use of verbal orders; if they are given, use a read-back process for clarification.

There also exist convenient, commercially available medical devices with simple, but effective technology that can help to minimize medication errors. For example, a pre-fill flushing syringe (MONOJECT PREFILL, Tyco

Table 2. NCCMERP index for categorizing errors & events

Class	Category	Description
Medication errors	A	circumstances or events that have the capacity to cause error
	B	errors that do not reach the patient
	C	errors that reach the patient but do not cause patient harm
	D	errors that reach the patient and require monitoring or intervention to confirm that they result in no harm to the patient
Adverse drug events	E	errors that contribute to or result in temporary harm to the patient and require intervention
	F	errors that contribute to or result in temporary harm to the patient and require initial or prolonged hospitalization
	G	errors that contribute to or result in permanent patient harm
	H	errors that require intervention to sustain the patient’s life
	I	errors that contribute to the patient’s death

Healthcare Kendall) is clearly labeled and color-coded to avoid confusion and errors.

Patient-safety culture and medication errors

Any effort to reduce medication errors must include the building blocks of an institution-wide patient safety program:

- governance and leadership support—part of mission and vision; includes accountability; policies and procedures are implemented consistently
- culture of safety—easy reporting of errors, adverse events, and near-misses in a non-punitive environment
- learning environment—issues, best practices, and lessons learned are shared openly at all levels
- patient safety program objectives—goals/objectives are communicated across the organization, with metrics and targets defined
- safe process design—standardization; access to information
- process implementation—clinical resources and process redesign are considered; effectiveness is monitored
- measuring and monitoring—escalation procedures for safety issues; reporting done on a regular basis

A historical preoccupation with human error and underestimation of the importance of system flaws has resulted in decreased reporting in health care due to fear of reprisal; unfortunately, many opportunities for system improvements have been lost in the past due to this error in focus. However, do not forget

the distinction between system error and misconduct: people may still act recklessly, hide information, or deliver untruthful information, no matter how effective we are at creating streamlined systems.

Flexibility is the key to quick response and intervention before harm occurs. Empowering staff-level participation in problem solving creates a safer environment and a more satisfied workforce.

Antimicrobials and resistance

Between 50-60% of the 2 million nosocomial infections occurring each year in the United States are caused by antibiotic-resistant organisms.⁸ Factors contributing to increasing antibiotic resistance in healthcare facilities include increased severity of illness, more severe immunosuppression, new invasive devices and procedures, increasing levels of antibiotic resistance in the community, sub-optimal use of isolation and barrier precautions, increased prophylactic and empiric use of antibiotics, and higher over-all antibiotic use per area or unit time.⁹ Prolonged exposure to broad-spectrum antibiotics increases the risk of colonization and subsequent infection with resistant organisms. Specific issues exist in relation to infection with *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus*, fungi, and extended-spectrum beta-lactamase-producing *Enterobacteriaceae*.

Recent data show an association between inadequate initial antimicrobial therapy and increased mortality among intensive care unit patients.^{10,11} However, it is important to remember that not all febrile patients require

immediate broad-spectrum antibiotic treatment. When a patient is hemodynamically stable and is not immunosuppressed, and no clear site of infection has been identified, it may be useful to wait for culture results before beginning antibiotic therapy. If empiric antibiotic therapy is started, it is imperative that antibiotics be stopped if no evidence of bacterial infection is found. If there is continued hemodynamic instability, immunosuppression, or high clinical suspicion for bacterial infection (despite negative cultures), it is reasonable to continue a course of 7–10 days of antibiotics. If a bacterial infection is identified, culture and sensitivity data should be used to narrow the scope of antibiotic coverage. The caregiver must evaluate response to treatment and assess the need for continued antibiotics based on this information. There is a fine balance between inadequate and excessive use of antibiotics. Ability to walk this line affects the emergence of antibiotic-resistant strains of bacteria and care-utilization costs.

Two Centers for Medicare and Medicaid Services quality improvement projects—National Pneumonia and National Surgical Infection Prevention—have focused on proper use of antimicrobials. Both projects use evidence-based practices to optimize the use of antimicrobials (for treatment in the pneumonia project and for prophylaxis in the surgical-infection prevention project). The surgical infection project has not only addressed proper selection and timing of treatment; it has also reduced overuse by requiring discontinuance of prophylactic antibiotics within 24 hours of incision.

Safe antimicrobial use combined with infection prevention (e.g., barrier precautions) is key to effective patient-safety initiatives, reducing the impact of antimicrobial-resistant organisms within healthcare facilities; the infection control professional should be sure to follow these measures. Overuse of antibiotics can be prevented through the following approaches:

- educating physicians about appropriate practices—using antibiograms and patient-specific susceptibility data, following guidelines, and consulting infectious-disease specialists;
- switching from broad-spectrum antibiotics to narrow-spectrum agents as soon as susceptibility reports are available;
- using informatics to disseminate guidelines, issue prescribing reminders, enable formulary restrictions, issue automatic stop alerts, and provide decision support for antimicrobial prescribing by linking other clinical information to prescribing.

Selective computer-based ordering systems can use decision modeling to assist physicians in issuing appropriate orders. At the LDS Hospital in Utah, a selective computer-based ordering system for antibiotics for ICU

patients has lessened the number of allergic interactions, wrong doses, and susceptibility mismatches; it has also reduced adverse drug events and lowered antibiotic costs, total hospital cost, and length of stay.¹²

Role of infection control professionals

Infection control professionals and healthcare epidemiologists have skill sets that are uniquely designed for the challenge of addressing patient safety issues. Improving patient safety has always been a driving force for the infection control professional. In the past, infection prevention programs and systems to monitor the incidence of healthcare-associated infections have been responsible for decreasing nosocomial bloodstream infections between 31–44%. These measures have also resulted in significant reductions in other types of nosocomial infection.

The late John Eisenberg, MD, MBA, director of the Association for Healthcare Research and Quality stated that “the system (National Nosocomial Infections Study – NNIS) is a particularly good model for reporting medical errors and other adverse outcomes because it uses evidence-based, clinically sensitive case definitions and a well-trained cadre of ICPs to implement interventions.”¹³ The key to the NNIS system is having ICPs who use monitoring data to implement prevention activities. Any new system for preventing adverse health events will need to develop professionals at the healthcare facility to design and implement appropriate interventions.¹⁴ It is critical that healthcare facilities follow the NNIS example, having a person dedicated to improving the systems and changing practices; this can have a significant effect on decreasing adverse events.

Surveillance is a systematic method for collecting, consolidating, and analyzing data about the distribution and determinants of a given disease or event, and then disseminating that information to agents who can improve outcomes.¹⁵ It is the process by which any adverse event can be assessed and improved. It helps us to understand our own experience in order to make decisions regarding intervention and prevention. Surveillance consists of the following steps:

1. Assess the population.
2. Select the outcome or process to survey.
3. Apply surveillance definitions.
4. Collect surveillance data.
5. Calculate rates and analyze surveillance findings.
6. Apply risk stratification methods.
7. Report and use surveillance information to improve care.

The infection control profession is uniquely positioned to assist in patient safety improvements. ICPs use the tools and techniques of surveillance and epidemiology to plan interventions that lead to decreased rates of ad-

verse events. In addition, research in infection control clearly demonstrates the cost benefit of these programmatic interventions.

The ICP possesses the following skills that are applicable to patient safety intervention efforts:

- expertise in the development and implementation of surveillance systems;
- ability to translate performance data into effective interventions that prevent adverse events;
- ability to use science and/or evidence-based information to assess and evaluate programs/problems and make recommendations for improvement;
- ability to educate at all skill levels in health care, from housekeeping to CEO.

These skills are directly transferable to improvement in other adverse-event arenas, including medication-related adverse events.

In an interview with ICANPrevent in the 1990s, the late John Eisenberg of AHRQ stated: “What’s special about the NNIS program, among other things, is that it has a clear definition of what a case is, it has a feedback system incorporated into it, it has a group of people working on it who are educated and trained experts in the field. . . . We believe that the model can be used by other people to collect information related to other hazards to patient safety—collect it, analyze it, benchmark it, and feed it back.”¹⁶

In the landmark Study on the Efficacy of Nosocomial Infection Control (SENIC), hospitals that had the lowest nosocomial infection rates were those that had *both* strong surveillance *and* prevention and control programs.¹⁷ Specifically, infection control programs that had intensive surveillance and were adequately staffed with an infection control coordinator and a trained infection control physician could show a cost benefit. The lesson here for patient safety is clear: good surveillance and a dedicated team have the potential to make a great impact on patient safety in healthcare facilities.

The ICP brings the epidemiologic mindset, expertise in epidemiologic study design and formal epidemiologic analysis, critical thinking skills, and rigor in analytic methods to the patient-safety table. Combine such skills with those of risk managers and quality specialists—comfort with rapid tests of change, project charter/project management, process analysis strategies (e.g., failure mode and effects analysis [FMEA], root-cause analysis [RCA], and human factors—and there is a recipe for a strong, effective patient-safety team.

Are ICPs up to the task? Yes. Despite ICPs’ concerns regarding impediments to expanding their practice, 69% of respondents to a survey conducted by the Association for Professionals in Infection Control and Epidemiology in 2002 were willing to participate in patient safety initiatives in their facilities.¹⁸ This does not mean that ICPs will abandon

their core competency in the prevention and control of healthcare-associated infections; it means only that we will contribute our talents to making certain that other adverse events are prevented, ensuring a safe environment for patients.

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Transmission of infection with multi-dose vials — Continued

other body fluids of infected people ($\geq 10^9$ virus particles per milliliter).⁹ This virus also is an environmental survivor. It is therefore not surprising that HBV has been blamed for horizontally transmitted infections, especially in clinical areas that serve a great number of HBV-infected patients. The use of hepatitis B vaccine along with other control measures advocated by the CDC have significantly impacted the incidence of HBV infection among persons undergoing chronic hemodialysis.¹⁰ The CDC guidelines emphasized that supplies should not be shared among patients; specifically, they stated that if sharing of MDVs is necessary, medications must be prepared in a clean centralized area separate from areas used for patient care, laboratory work, or refuse disposal.

Despite extremely rigid infection control practices that are designed to minimize the transmission of HBV in these settings, occasional breaches of protocol have been associated with nosocomial spread of this virus.

In the early 1980s, Alter and her colleagues were notified of an outbreak of HBV infections in a hemodialysis center in California. Because all infections appeared to occur within a relatively short period of time, a common-source exposure was suggested. The findings of their case-controlled study demonstrated that all infected patients received drug from an MDV of local anesthetic (bupivacaine) compared to 58% of controls ($p=0.03$).¹¹ The investigators concluded that the infection transmission was the result of common exposure to an MDV that was probably contaminated with blood from a patient who was an HBsAG carrier.

Later that decade, Oren et al. described a common-source outbreak of fulminant hepatitis B in a medical center in Israel.¹² Extensive laboratory and epidemiologic evaluation revealed that the probable common-source vehicle of transmission was an MDV of heparin and normal saline flush solution that may have been inadvertently contaminated by blood of a known HBsAG carrier.

In the mid-Nineties, the CDC reported hepatitis B transmission that occurred among hemodialysis patients in five separate centers in California, Nebraska, and Texas.¹³ In each



Fig.1. MONOJECT PREFILL™ Tyco Healthcare Kendall

Medication errors may occur when drugs are packaged in similar vials or when syringes used to draw medication out of an MDV are not labeled properly.

investigation, transmission of HBV was attributed to the failure of the facilities to adhere to one or more of the recommended infection control practices for preventing the transmission of HBV and other bloodborne pathogens in these settings. In one center, partially used heparin vials were routinely returned to a common medication cart. Contamination of a shared MDV was therefore considered the most likely route of HBV infection in at least one center associated with this outbreak.

That same year, Hutin and colleagues described an outbreak of hepatitis B that occurred in two chronic hemodialysis centers in Pennsylvania.¹⁴ The investigators were unable to identify any single event responsible for the disease transmission; however, they postulated that transmission from the source case-patient to other case-patients probably occurred via contaminated multi-dose medication vials or supplies shared among patients in these centers.

Hepatitis C

Approximately 2.7 million people in the United States are chronically infected with hepatitis C virus (HCV).¹⁵ Primary risk factors include IV drug use and receipt of blood or blood products prior to implementation of donor blood screening. For a considerable number of cases, however, no source of infection has ever been determined. Most of the published investigations have proven or suggested that nosocomial transmission of this virus is most often associated with the use of MDVs.

Widell and colleagues described the epidemiological and molecular investigation of ten cases of nosocomial hepatitis C that occurred in a Swedish pediatric oncology ward between 1990 and 1993.¹⁶ Their investigation identified breaches of infection prevention policies including the presence of partially used vials of saline in the ward medication room. As a result of this outbreak, the authors concluded that restriction of multi-dose vials may be prudent.

Krause and colleagues reported an investigation of a cohort of patients hospitalized

in Florida in 1998.¹⁷ They noted that five patients, one most likely the source, were infected with HCV. The other four patients showed no evidence of prior HCV infection. Upon review, it was determined that 50% of the patients received saline flushes of IV catheters within 2–6 hours after the source patient became infected with HCV. The 12 patients in the control group, who did not receive IV flushes, were not infected. The authors concluded that HCV was most likely transmitted from a person chronically infected with the virus after an MDV was contaminated with that patient's blood. They presumed that the saline solution became contaminated by accidental reinsertion of a contaminated needle or improper decontamination of the rubber membrane of the vial. Subsequent flushes of the same vial could then have resulted in transmission of the virus. This outbreak investigation demonstrated the need to adhere to basic infection control procedures. The particular institution ceased using multi-dose vials in favor of single-use vials as a result of this unfortunate outcome.

Nosocomial transmission of HCV was identified in a Japanese hemodialysis unit in 2000.¹⁸ In the spring of that year, eleven patients presented with symptoms of acute hepatitis. By July, additional infection control precautions—including preparing all medications in the pharmacy—were adopted. All patients were subsequently monitored for the following 18 months. There were no seroconversions and no new nosocomial transmissions of HCV identified. The investigators concluded that the probable risk factor was the sharing of MDVs of heparin and saline, and they therefore recommended that staff prepare all medications in a controlled environment.

Medical errors associated with MDVs

An estimated 44,000–98,000 Americans die in hospitals each year as a result of preventable medical errors.¹⁹ Medication errors are the number-one cause of adverse and preventable patient events leading to more than 7,000 deaths annually.¹⁹ According to a large insurer's study, injuries due to drugs were the most frequent cause of procedure-related malpractice claims.²⁰

Medication errors may occur when drugs are packaged in similar vials or when syringes used to draw medication out of an MDV are not labeled properly. If two drugs are packaged in similar vials, and one is mistaken for the other, a serious error may occur. Any medication drawn into a syringe for later use should be labeled accurately and immediately, ideally with a pre-printed, not hand-written, label. Unlabeled and incorrectly labeled syringes invite errors in drug administration and should be discarded. Commercially available pre-fill syringes (MONOJECT PRE-FILL™, Heparin and Saline, Tyco Healthcare

Pre-filled syringes save nursing time and reduce labor costs by approximately 25%–33%.

Kendall) are clearly labeled and color-coded to avoid confusion. The Monoject PreFill™ labels were specifically created for flushing without the risk of cross-contamination (Figure 1).

An example of a near-fatal accident associated with an MDV was reported by the Institute for Safe Medication Practices in 1999.²¹ A pediatric patient was brought to an emergency department where commercially-prepared pre-filled saline syringes were not available, and staff therefore drew up supplies of saline solution from MDVs and labeled them by hand. An unused syringe of vecuronium, a neuromuscular blocking agent, had been prepared for another patient earlier and was also hand-labeled. Somehow, this syringe got mixed in with the saline syringes and was mistakenly used to flush the child's IV line. The patient subsequently ceased breathing and needed to be intubated and placed on a ventilator. Fortunately, the child recovered, but the outcome could have been devastating. This serves as chilling example in which an error could have prevented by using commercially available pre-filled syringes.

Cost analysis

Infection control practitioners will not soon forget the flu fiasco of 2004, when we heard that one of the two major manufacturers of influenza vaccine for the U.S. market was unable to provide any vaccine due to product contamination in their plant. Suddenly the cost of vaccine became irrelevant, and pharmacy purchasers were faced with the task of obtaining whatever precious vaccine they could get their hands on, despite the cost. This, however, is not a typical scenario, and the bottom line is still revenue-driven.

There are authors who promote the use of MDVs based on their cost-effectiveness. Scheifele and his fellow Canadian colleagues conducted a study to compare pre-filled syringes to MDVs containing influenza vaccine.²² They demonstrated that pre-filled syringes save nursing time and reduce labor costs by approximately 25%–33%. This does not, however, offset the greater cost and storage space requirements of the pre-filled syringes. In order to serve 1,000 clients, they required 27 nurse-hours using syringes and 36 nurse-hours using vials; however the sav-

ings for personnel and supplies by the syringe-using group were exceeded by higher vaccine cost and extra storage costs. The authors determined that, depending upon product and packaging style, programs using vials are cheaper by CA\$709–CA\$926 per 100 doses delivered compared to using pre-filled syringes.

A study conducted by Monti a decade ago suggested a tremendous risk potential from MDVs and concluded that, if one considered the estimated cases of nosocomial sepsis that could be prevented if MDVs were eliminated, the cost-effectiveness would be null and void.²³

Justification for using a product that costs more is always a challenge. Clearly, pre-filled syringes save nursing time; however, materials managers may perceive the reduction of nursing hours as soft dollars. It is therefore imperative to critically describe the risks/benefits as they relate to patient safety in order to be successful convincing those who control the purse strings.

Supportive data from JCAHO

In January 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a Sentinel Event Alert addressing infection control.²⁴ This was prompted by the recognition that only 10 infection-related reports had ever been reviewed under the JCAHO sentinel event policy since it was implemented in 1996. JCAHO officials suspected that this was a gross under-estimation and, as a result, issued a directive that required healthcare providers to treat deaths that occur in patients who have acquired healthcare-associated infections as potential sentinel events. As a result of root-cause analyses that have been conducted in response to this directive, multiple strategies have been suggested; one such strategy is switching to single-use IV flush vials. One of the proposed JCAHO National Patient Safety Goals for 2006 is the elimination of multiple-dose medication vials, whenever possible. The Commission proposes that when MDVs are used, that appropriate steps be taken to minimize the risk of transmission of infection between patients. This proposed goal is based on the recognition that MDVs are more likely to become contaminated with infections such as Hepatitis B and C than single dose vials. In addition, the goal is designed to engineer out the "human factors" such as poor technique commonly associated with MDVs.

Education/in-service

Infection control practitioners understand the importance of never underestimating the value of staff training, especially when a change in practice is implemented.

Most pre-filled syringes are packaged in plastic wrappers; however, one must never assume that the external surface of the syringe is sterile simply because it is wrapped.

This was an important point that we stressed when introducing pre-filled saline and heparin syringes in our facility. Too often, staff incorrectly assumed that the entire syringe was sterile, and therefore believed it was acceptable to drop the syringe onto a sterile field, simply because it was contained in a plastic wrapper. Staff also needed to be instructed to avoid pulling back on the plunger, as this may contaminate the contents of the syringe.

It is critical to emphasize that left-over saline or heparin in a pre-filled syringe is preservative-free; therefore it must never be left at the bedside or returned to the medication cart or room for future use. It must be stressed that wasting a portion of the medication is much more cost effective than instilling a medication that has become contaminated.

Summary

In this era with its tremendous emphasis on cost containment, we must find a balance between cost and patient safety. Clearly there are some clinical settings where the cost benefit of using an MDV outweighs the risk of infection—for example, re-using MDVs for a single patient, such as a vial of insulin for a diabetic patient. Also, there is virtually no risk of contaminating MDVs when they are used for compounding in an aseptic environment such as the pharmacy. Certain extremely expensive drugs may be pre-filled and labeled in the pharmacy and dispensed to the patient-care area ready to use, but the alternative is also true: there are areas where the risk of contaminating MDVs is so high that the cost of commercially prepared pre-filled syringes is justifiable. The preponderance of evidence that contaminated MDVs have contributed significantly to morbidity and mortality must not be ignored.

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Provider approved by the California Board of Registered Nursing. Provider #1447

Upon completion of this program, the participant will be able to:

- Describe national initiatives related to reduction of adverse events in health care, particularly adverse drug events.
- Relate infection control practice to adverse drug event issues.
- List three ways that infection control professionals can be involved in adverse drug event reduction efforts in their organizations.
- Describe the varied pathogens responsible for multi-dose vial associated outbreaks.
- Discuss the risk benefits associated with single-dose medications and the impact they have on the financial bottom line.
- Describe two educational challenges associated with implementation of pre-filled flush syringes.

Instructions

- Read both articles.
 - Complete the post-test. (You may make copies of the answer form.)
 - Complete the participant evaluation.
 - Mail or fax the complete answer and evaluation forms to address on back page. You may also take this test online at www.saxetesting.com
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1. The most common type of adverse event in hospitals is:
 - a. Surgical site infections
 - b. Wrong site surgery
 - c. Medication errors
 - d. Inappropriate patient identification
2. Neglecting to administer the pneumococcal vaccine is an error of:
 - a. Treatment
 - b. Prevention
 - c. Judgment
 - d. Time management
3. Which of the following are categories of medications whose use would be of interest to the infection control professional?
 - a. Antimicrobials
 - b. Beta-blockers
 - c. Warfarin
 - d. Antipsychotics
4. What process can be used to assess and improve any healthcare-associated adverse event?
 - a. Calculating rates
 - b. Organizing a committee
 - c. Surveillance
 - d. Leading a revolution
5. What evidence is there that shows that infection control may be a good model for patient safety programs?
 - a. American College of Cardiology
 - b. National Nosocomial Infections Study
 - c. Quality Improvement Organizations
 - d. National Quality Forum
6. The following are NCCMERP categories for adverse drug events
 - a. A – I
 - b. A – D
 - c. D – E
 - d. E – I
7. An institution-wide patient safety program includes the following:
 - a. Governance and Leadership Support
 - b. Learning Environment
 - c. Measure and Monitor
 - d. All of the above
8. The infection control professional is uniquely positioned to assist with patient safety initiatives because he/she has the following skills:
 - a. Expertise in RCA
 - b. Ability to translate performance data into effective interventions
 - c. Ability administer large projects
 - d. Organizational skills
9. The first report from the Institute of Medicine that was the driving force behind the patient safety movement was:
 - a. Crossing the Quality Chasm
 - b. To Err is Human: Building a Safer Health System
 - c. Doing What Counts for Patient Safety
 - d. None of the above
10. Which of the following pathogens have been responsible for multi-dose vial associated outbreaks?
 - a. Hepatitis B
 - b. Hepatitis C
 - c. Hepatitis A
 - d. A and B
11. Which of the following pathogens has not been responsible for multi-dose vial associated outbreaks?
 - a. *Serratia marcescens*
 - b. *Candida albicans*
 - c. *Staphylococcus aureus*
 - d. *Aspergillus*
12. What is the primary cause of multi-dose vial contamination?
 - a. Expired product
 - b. Intentional product contamination
 - c. Faulty aseptic technique
 - d. B and C
13. In what type of setting have the majority of Hepatitis B outbreaks associated with multi-dose vials occurred?
 - a. Post-acute Services
 - b. Neonatal Intensive Care Units
 - c. Hemodialysis Centers
 - d. Out-patient Clinics
14. What is the key message to emphasize when attempting to cost-justify pre-filled syringes vs. multi-dose vials?
 - a. Saves nursing time
 - b. Saves storage space
 - c. Risk-benefit
 - d. Cost savings
15. What is the JCAHO 2006 proposal regarding multi-dose vials?
 - a. They encourage the use as a cost saving measure
 - b. They are neutral on this issue
 - c. They suggest elimination of MDVs whenever possible
 - d. They prohibit MDVs
16. Preservatives used in multi-dose vials are:
 - a. Effective against most viruses
 - b. Effective against most bacteria
 - c. Capable of supporting the growth of endotoxins
 - d. B and C

Participant's Evaluation

What is the highest degree you have earned (circle one)? 1. Diploma 2. Associate 3. Bachelor's
4. Master's 5. Doctorate

Indicate to what degree you met the objectives for this program: Using 1 = Strongly disagree to 6 = strongly agree rating scale, please circle the number that best reflects the extent of your agreement to each statement.

	Strongly Disagree			Strongly Agree		
	1	2	3	4	5	6
a. Describe national initiatives related to reduction of adverse events in health care, particularly adverse drug events.						
b. Relate infection control practice to adverse drug event issues.						
c. List three ways that infection control professionals can be involved in adverse drug event reduction efforts in their organizations.						
d. Describe the varied pathogens responsible for multi-dose vial associated outbreaks.						
e. Discuss the risk benefits associated with single-dose medications and the impact they have on the financial bottom line.						
f. Describe two educational challenges associated with implementation of pre-filled flush syringes.						

How long did it take you to complete this home-study program? _____

What other areas would you like to cover through home study?

Name & Credentials _____

Position/Title _____

Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

Mark your answers with an X in the box next to the correct answer

1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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