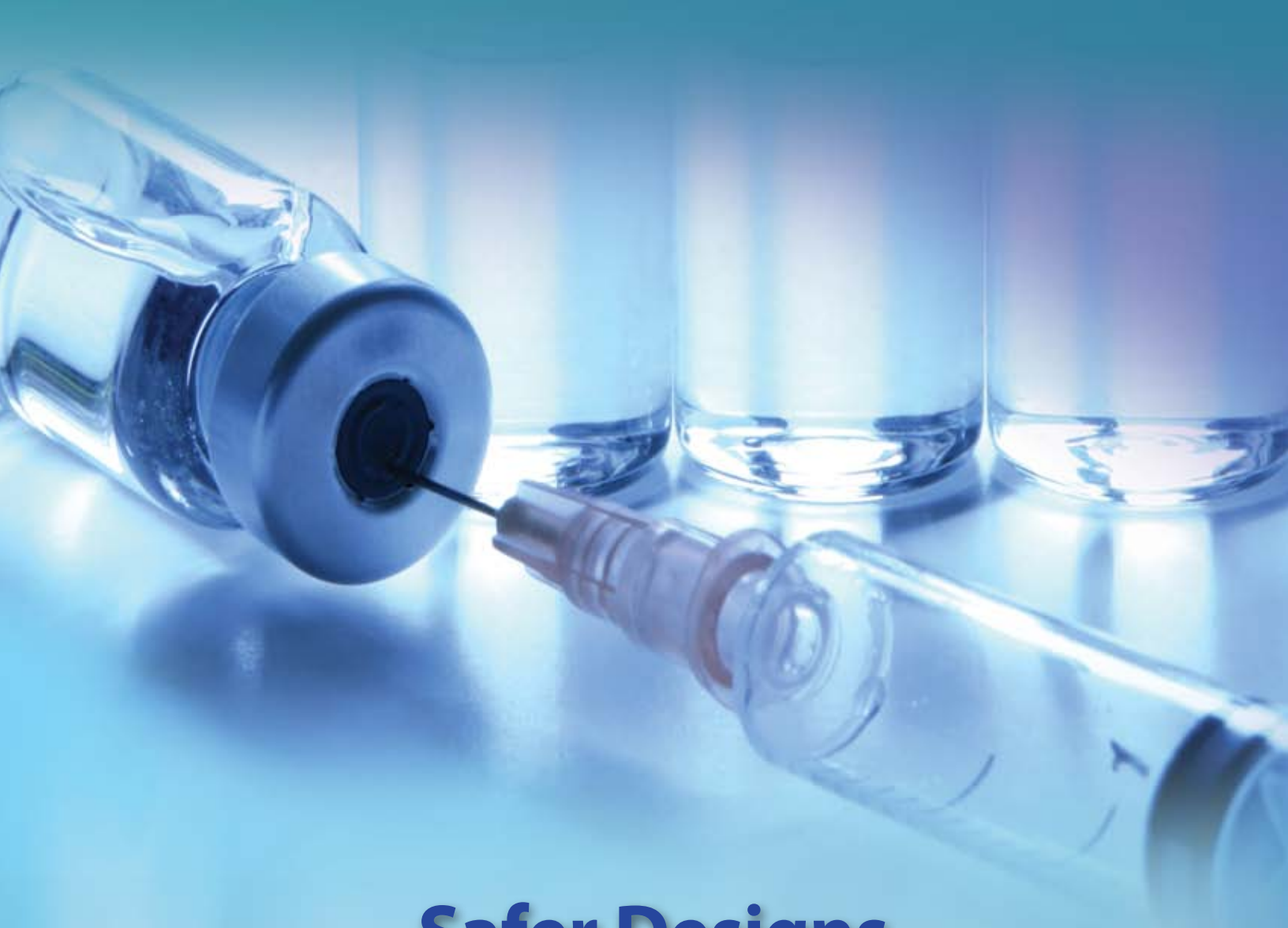

Safer Designs for Safer Injections:

Innovations in Process, Products and Practices

April 26, 2011 • Washington, DC Summary Proceedings

PREMIER

ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.
Safe Injection Practices Coalition

TABLE OF CONTENTS

Please visit:
www.premierinc.com/saferinjectionsmeeting
for these additional downloadable resources:

- Participants list
- Slides from presentations
- University of Michigan Hospitals and Health Center – Resources

EXECUTIVE SUMMARY

In late April 2011, the Premier healthcare alliance in collaboration with the Safe Injection Practices Coalition convened a meeting in Washington, DC to raise awareness and continue the national dialogue on expanding safer and innovative approaches and product designs to protect patients and prevent infections related to unsafe injection practices. The meeting, ***Safer Designs For Safer Injections: Innovations In Process, Products And Practices***, brought together nearly 200 stakeholders representing government, public health, clinicians, patients, product manufacturers and suppliers, and professional, accreditation, and other health-care related organizations.

Meeting participants identified vital needs, including increased use of existing innovations, additional product innovations, improvements in related regulatory standards, and increased education and empowerment of both patients and clinicians about safe practices. There was agreement that injection safety is a basic expectation in all healthcare settings, as well as a serious and on-going challenge. There have been significant strides to develop outreach and educational tools and increase awareness of this issue among the healthcare community and regulatory agencies. However, much work is still needed to eliminate unsafe injection practices. Addressing healthcare cost pressures will continue to be a challenge. This will require greater clinician involvement in purchasing decisions in all care delivery settings. Ultimately, safe injection practices are the responsibility of every healthcare provider and institution.

Proceedings dedicated to the memory of

Judene M. Bartley

1938-2011

A pioneer in infection prevention and patient safety

Safer Designs for Safer Injections:

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INTRODUCTION

In the past decade, failures to follow safe injection practices (e.g., misuse of syringes, needles and vials) have resulted in dozens of outbreaks across a wide variety of U.S. healthcare settings. Moreover, as a result of unsafe injection practices, greater than 125,000 patients have required notification advising them to seek testing for bloodborne pathogens such as hepatitis B, hepatitis C and HIV. The Premier healthcare alliance and the Safe Injection Practices Coalition collaborated to host an open meeting, ***Safer Designs for Safer Injections: Innovations in Process, Products and Practices*** on Tuesday, April 26, 2011, in Washington, DC. The goal was to bring stakeholders together to advance injection safety by raising awareness and continuing the national dialogue on expanding safer, innovative approaches and product designs to protect patients and prevent infections (Meeting agenda: Page 16).

More than 200 participants attended the conference, including clinicians; researchers; healthcare worker and patient safety experts; representatives of professional organizations; healthcare associations and governmental agencies; and suppliers/manufacturers of medical devices, products, and pharmaceuticals. A list of meeting participants and a compendium of resources they provided is included in the background materials available at www.premierinc.com/saferinjectionsmeeting.

Following a series of presentations providing background and updates on the issues from organizations and federal agencies, the attendees participated in breakout sessions to discuss potential solutions for safer injections related to ***processes, products and practices*** and to identify how to move forward and increase the momentum to address this critical issue.

Welcome and Opening Presentation

Co-sponsors, the Premier healthcare alliance and the Safe Injection Practices Coalition welcomed attendees and provided background for the current conference.

David Edwards
Vice President, Premier healthcare alliance

Lisa Thiemann
Safe Injection Practices Coalition

Gina Pugliese
Vice President, Premier Safety Institute®

David Edwards
Vice President, Premier healthcare alliance

On behalf of the Premier healthcare alliance, we are privileged to co-host today's meeting in collaboration with the Safe Injection Practices Coalition. We are extremely pleased to see the tremendous interest today in this important issue of eliminating patient harm from unsafe injection practices. We are also excited to assemble so many stakeholders to collaborate and expand on the discussions and accomplishments we have already seen.

Ensuring safe injection practices is an important component of the Premier healthcare alliance's core purpose, to improve the health of communities. As a performance improvement alliance of more than 2,500 hospitals and over 73,000 other healthcare sites in the U.S., we are working together to improve the quality, safety and affordability of healthcare. Premier also maintains the nation's most comprehensive data repository of clinical, financial and outcomes information and knowledge sharing network for improving patient outcomes while safely reducing the cost of care. Premier in partnership with CMS led a six-year pay-for-performance demonstration project, the Hospital Quality Incentive Demonstration™ that resulted in more than $787 million in validated savings to participating hospitals in 2008 alone. Premier is currently involved in QUEST®, a multiyear collaborative of more than 200 hospitals whose charter hospitals have improved quality of care, reduced harm, and saved more than 25,000 lives and an estimated $4.4 billion in costs.

Premier also operates a leading healthcare purchasing network to provide members with options for high quality, safe and cost-effective products, equipment, pharmaceuticals, services and tools to improve supply chain efficiency. Finally, through our Safety Institute and its publicly accessible website, we provide education, tools, and resources on important patient and healthcare worker safety topics, such as safe injection practices and sharps injury prevention. Thank you for joining us today.

Lisa Thiemann, CRNA, MNA
Senior Director, Professional Practice Division
American Association of Nurse Anesthetists
Representing the Safe Injection Practices Coalition

The Safe Injection Practices Coalition is honored to co-host today's meeting in collaboration with the Premier healthcare alliance. Since 1999, more than 125,000 patients in the United States have been notified of potential exposure to hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV due to lapses in basic infection control practices associated with injections. Driven by collective concerns regarding the growing number of healthcare-related bloodborne pathogen transmissions due to syringe reuse and medication mishandling, the Safe Injection Practices Coalition, or SIPC was established in 2008. The SIPC is a partnership of healthcare-related organizations that came together to promote safe injection practices across all U.S. healthcare settings. The SIPC, working in conjunction with and led by the Centers for Disease Control and Prevention (CDC) has developed the One & Only Campaign. This public health campaign aims to eradicate outbreaks resulting from unsafe injection practices.

Through public and healthcare provider education activities, the One & Only Campaign seeks to increase awareness about safe injection practices, to increase patient engagement and empowerment as a strategy to promote healthcare provider adherence to safe injection practices, and looks to increase the understanding and implementation of safe injection practices by healthcare providers. Patients and providers must insist on one needle, one syringe, and only one time for each and every injection to minimize the risk of infection. You will hear more about the One & Only Campaign activities later on today from Sara Weir. The SIPC, through active participation in collaborations that seek to promote safe injection practices, is pleased to co-host today's meeting. We feel strongly that through public-private partnerships we can improve care delivery to patients across this country. The SIPC members look forward to several productive and thought-provoking discussions here today. Thank you.

Gina Pugliese, RN, MS
Vice President, Premier Safety Institute

The Premier Safety Institute is pleased to be able to work closely with the Safe Injection Practices Coalition to host this meeting and assemble so many interested public and private stakeholders, along with healthcare providers, to develop solutions for this important safety challenge. A special thank you goes to the Program Committee and the Supplier Advisory Committee for their assistance in planning this meeting (Committee membership: Page 17).

The Safety Institute provides tools, resources, news and education on patient, worker and environmental safety on its publicly accessible website. The Safety Institute supports national efforts to improve patient and healthcare worker safety related to injections, in collaboration with members and public and private stakeholders, including participation in the Safe Injection Practices Coalition. Premier will continue to publicly promote safe injection practices through our Safety Institute website, educational programs, newsletters and other forums.

Summary of Presentations

The conference began with presentations by selected stakeholders and federal agencies that have worked on the issue of safe injection practices (Speaker biographies: Page 18 and Slides: www.premierinc.com/saferinjectionsmeeting). The presentations provided data, perspectives, reviews of device and medication regulations and clinical observations that contributed to the dialogue throughout the day. Below is a summary of these opening presentations.

Review of Outbreaks: Incidents, Lessons Learned and Implications for Injections without Infections

Joseph Perz, DrPH, MA
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

The Department of Health and Human Services recently launched its "Partnership for Patients" initiative which builds upon the Institute of Medicine' landmark 1999 report, "To Err is Human: Building a Safer Health System." Efforts to build safer systems of care have resulted in growing emphasis on the prevention of healthcare-associated infections (HAIs). As we will discuss today, across the healthcare spectrum, there remains a need for basic patient protections from infections following medical errors involving syringe reuse and other unsafe injection practices.

Transmission of bloodborne viruses or other life-threatening bacterial infections from contaminated injections are examples of unacceptable or "never/ seriously reportable" events in healthcare delivery.

Safe injection practices are measures taken to perform injections in a safe manner for patients and providers. Transmission of bloodborne viruses or other life-threatening bacterial infections from contaminated injections are examples of unacceptable or "never/ seriously reportable" events in healthcare delivery . The basic principles of practice, as outlined by CDC under Standard Precautions, include the following:

- Never administer medications from the same syringe to more than one patient.
- Do not enter a vial with a used syringe or needle.
- Minimize the use of shared medications.
- Do not administer medications from single-dose vials to multiple patients.
- Maintain aseptic technique at all times during the preparation and administration of injected medications.

Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. Improper use of syringes, needles, and medication vials has resulted in:

- Outbreaks of hepatitis C virus (HCV), hepatitis B virus (HBV), and bacterial infections;
- Notification of thousands of patients of possible exposure to bloodborne pathogens and recommendation that they be tested for HCV, HBV and HIV;
- Referral of providers to licensing boards for disciplinary action; and
- Legal actions such as malpractice suits filed by patients.

Awareness, understanding and implementation of safe injection practices all remain suboptimal. Efforts toward enforcement of basic standards of infection control are being pursued at both the state and federal levels. However, in addition to enforcement strategies, there are still many opportunities and needs for targeted educational initiatives to help overcome the numerous "myths and misperceptions" and assumptions (a.k.a. "the Big Ifs") that continue to undermine patient safety. These are summarized, along with U.S. outbreak experience and CDC guidelines and initiatives, in a key 2010 publication that is freely available at: http://download.journals.elsevierhealth.com/pdfs/journals/1089-3261/PIIS1089326109000853.pdf

CDC leads the Safe Injection Practices Coalition, a broad-based group of national healthcare leaders, established in 2008. This coalition is working to raise awareness and knowledge of safe injection practices among the public and healthcare providers through the One & Only Campaign.

In addition to promoting safe injection and infection control practices among healthcare personnel through education and improved oversight, innovations in medical products and equipment have tremendous potential. Efforts to engineer safety into devices and medication packaging are needed, along with enhanced marketing and promotion strategies. Better integration of injection preparation and delivery with pharmacy practices also holds great promise. Ultimately, we must strive to build safer systems and promote innovations in process, products and practices across the full spectrum of healthcare, to make every injection a safe one.

Additional information on CDC's injection safety activities is available at: www.cdc.gov/injectionsafety/ and www.OneAndOnlyCampaign.org

For information on outbreaks and patient notifications stemming from unsafe injection practices, see: http://www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

http://download.journals.elsevierhealth.com/pdfs/journals/1089-3261/PIIS1089326109000853.pdf

http://www.annals.org/content/150/1/33.full.pdf+html

A Patient's Story

Evelyn McKnight, AuD
President, HONOReform
Hepatitis Outbreaks National Organization for Reform

The HONOReform Foundation, led by Evelyn McKnight is one of SIPC's founding organizations. Evelyn's personal experience motivated her to bring attention to, and advocate on behalf of, safe injection practices. Evelyn was infected with hepatitis C virus (HCV) while battling breast cancer in 2000. In total, 99 patients at the oncology clinic where she was being treated became infected with HCV when their provider failed to follow safe injection practices. This was one of the largest known healthcare-associated outbreak of HCV in the U.S. HONOReform Foundation, founded in 2006, works from the grassroots level to the legislative level to encourage safety by design, incentive and education.

Evelyn and 98 other cancer patients had been infected with HCV that was transmitted by reused, contaminated syringes during chemotherapy treatments.

Evelyn shared her personal story that began in the small farming community of Fremont, NE, when she sadly learned that she had breast cancer. In 2000, she turned to Dr. Tahir Javed, an oncologist at the new, local cancer treatment center. Dr. McKnight received chemotherapy for six months with great hope of recovery. Unfortunately, the cancer recurred and she sought care at the University of Nebraska Medical Center (UNMC).

During the workup for an aggressive treatment procedure at the UNMC, she learned that she had hepatitis C. This shocking news ultimately led to an investigation of her oncologist by public health authorities. An extensive outbreak investigation determined that she, along with 98 other cancer patients, had been infected with HCV that was transmitted by reused, contaminated syringes during chemotherapy treatments. Nurses, working under the direction of her oncologist, used unsafe practices and had reused syringes to access containers of saline used as part of her treatment regimen.

More than 600 patients were notified of their potential exposure, 450 patients were tested, 99 patients with HCV were identified and six deaths among these cancer patients were attributed to HCV (not their cancer). Evelyn remains committed to eliminating unsafe injection practices.

Evelyn founded the HONOReform Foundation that focuses on a three-pronged approach to promoting and advocating for injection safety, through culture change and empowerment, safety by design, and safety by incentive. More information about the HONOReform Foundation is available at www.honoreform.org.

FDA's Approach to Optimize Safe Injection Practices

Karen Weiss, MD, MPH
Center for Drug Evaluation and Research
Food and Drug Administration

Reducing unsafe injection practices requires both regulatory and non-regulatory strategies. An example of a non-regulatory strategy and key collaborative effort is FDA's Safe Use Initiative, launched in November 2009. The mission of the Safe Use Initiative is to create and facilitate public and private collaboration within the healthcare community. Its goal is to reduce preventable harm by identifying specific, preventable medication risks and developing, implementing and evaluating cross-sector interventions with partners who are committed to safe medication use. Potential partners include other federal agencies, healthcare professionals and professional societies, pharmacies, hospitals and other healthcare delivery entities, patients, caregivers and consumers.

Injection safety is one of the Safe Use Initiative's projects, as listed on the Safe Use Opportunities website. The project began with discussions between the FDA and CDC regarding patient infections from misuse and mishandling of FDA-regulated medications. Of the approximately 12 drugs CDC identified as associated with patient infections, propofol was at the top of the list. In July 2009, the FDA convened a meeting of stakeholders to address challenges and barriers related to safe use of propofol. Stakeholders reaffirmed that propofol was just one of the drugs associated with unsafe injection practices that contributed to patient infections and outbreaks. Stakeholder groups identified confusion about terminology as one of the

challenges with propofol use. Although propofol is labeled for "single patient use," the amount in the larger size vials implies there can be more than one dose. As an outgrowth of the stakeholder meeting, the FDA is now engaged in an effort with the U.S. Pharmacopeia to assess healthcare provider understanding of terms such as single dose, single use, multi-dose and multi-use, and to seek ways to improve consistency in labeling.

The Safe Use Initiative program held a public meeting in November 2010 to highlight its ongoing safe use activities and identify potential new projects. Injection safety was one of the specific preventable medication-related risks addressed at the public meeting. The injection safety session was a forum to highlight the Safe Injection Practices Coalition, a broad-based coalition consisting of government agencies, state health departments, industry, professional organizations and many others dedicated to education about safe injection practices. Two individuals spoke during the open public hearing portion of the meeting to reinforce the need to promote injection safety and to applaud the FDA's Safe Use Initiative for taking on this issue. The FDA joined the Safe injection Practices Coalition in an advisory capacity to further facilitate the public and private collaborations needed to eliminate unsafe injections.

The FDA joined the Safe injection Practices Coalition in an advisory capacity to further facilitate the collaborations needed to eliminate unsafe injections.

Regulatory Approaches to Optimize Safe Injection Practices

Laurie Muldowney, MD
Medical Officer, Center for Drug Evaluation and Research
Food and Drug Administration

The FDA is collaborating with the U.S. Pharmacopeia (USP) in addressing issues related to reducing unsafe injection practices. The USP is a non-governmental organization that is the official public standards-setting authority for prescription and over-the-counter drugs in the United States, including standards for labeling, packaging and nomenclature. Because the FDA is responsible for enforcement of standards which are set by the USP, it is important that the FDA and USP work closely together in the development of standards to ensure agreement and consistency.

It is recognized by both the FDA and USP that unsafe practices occur that have been associated with single-dose vials through their use for more than one patient; multiple entries/withdrawals for a single patient with same syringe, thereby contaminating the vial; and failure to discard vials immediately after use.

The FDA and USP are collaborating to identify the factors

FDA and USP are collaborating to identify the factors that may contribute to unsafe injection practices

that may contribute to unsafe injection practices, such as inconsistent, confusing or unclear container labeling, vial fill issues, and instructions for discarding medications. One example of confusion in vial labeling that may contribute to misuse and unsafe practices is the misinterpretation of terms such as, "single dose" and "single use," which are both used on vials intended to be used only one time by a single patient. It was also pointed out that the reuse of single-dose/single-use vials may be related to vial size and perceived cost savings by users if medication is left over in a single-dose vial.

The FDA conducted a small informal survey of government healthcare professionals to gather input on terminology in current use and to identify what terms would most clearly indicate that a vial should be used only once and then discarded. The majority indicated that "single-use" was a clearer term, and that the term should be accompanied by specific discard instructions, but did not have any clear preference on wording. Cost of drugs and hospital culture were identified as factors contributing to unsafe injection practices.

The USP and FDA are collaborating on a larger computer-based survey of healthcare providers focusing on practices at the point of care, including single dose/single use terminology as well as discard instructions in Q2-Q3 2011.

Regulatory approaches that are being pursued by the FDA include those related to appropriate vial fill sizes for single-dose vials. Each container of injectable products are filled with a volume in slight excess of the labeled "size," this is sometimes referred to as overfill. This excess volume is intended to be sufficient to permit withdrawal and administration of the labeled volumes. It was noted, however, that when this excess volume is too large or too small, medication errors or misuse may occur. The agency is also considering appropriately labeled vial fill sizes for single-dose containers. Single-dose vials containing far greater than a single dose of a drug product may contribute to inappropriate use of the single-dose vial, (e.g. multiple vial entries) as a cost saving measure and also because of the mistaken belief that larger volume in vials makes it suitable for multiple patients. The FDA is developing internal procedures for product quality review and documentation related to vial fill of injectable drug product applications.

The USP is reviewing and updating the terminology and definitions in its Chapter 7 on "Labeling." The USP and FDA will be collaborating with CDC and other organizations and expert advisors. The FDA and USP are also collaborating to create educational messages for end-users focusing on clear/consistent labels. No single solution will prevent unsafe injection practices, but rather the issue will require a multi-faceted approach, including education, regulation, enforcement, collaboration and innovation.

Centers for Medicare & Medicaid Services: Viewpoint

Daniel Schwartz, MD, MBA
Chief Medical Officer, Survey and Certification Group
Centers for Medicare & Medicaid Services

Among the responsibilities of the Centers for Medicare & Medicaid (CMS) is to promote the timely delivery of cost-effective, high-quality and safe healthcare services to beneficiaries of Medicare and Medicaid. One element of the program is inspection of healthcare facilities, including ambulatory surgical centers (ASCs). The recent outbreaks related to unsafe injection practices prompted CMS in collaboration with the CDC to develop an infection control audit tool that incorporated elements from CDC/HICPAC guidelines, emphasizing injection safety and medication handling, as well as hand hygiene, glove use, instrument reprocessing, environmental cleaning, and handling of point-of-care equipment, such as blood glucose monitoring devices. The new audit tool was pilot tested by CMS in a sample of 68 ASCs in Maryland, North Carolina and Oklahoma. Overall, 68 percent (46 out of 68) of the ASCs had at least one lapse in infection control;17 percent (12 of 68) had lapses identified in three or more of the five infection control categories; and 28 percent (19 of 67) had lapses in injection safety and medication handling. The results of this survey were published in Schaefer et al. JAMA 2010;303:2273-2279. Article available for download at www.cdc.gov/injectionsafety under "recent publications." This infection control worksheet outlines what surveyors are likely to look for during surveys for compliance with Medicare Conditions of Participation or Coverage, and facilities are encouraged to use it to conduct regular self-audits of practices.

CMS is developing worksheets for healthcare settings and plans to assess injection safety anywhere patients are receiving injections.

As of October 2009, the infection control worksheet has been incorporated into all ASC inspections and more than 1,500 ASCs have been now been surveyed. CMS is developing similar worksheets for other healthcare settings, including hospitals, and plans to assess injection safety anywhere patients are receiving injections. The message for infection prevention and control needs to be targeted to all healthcare professionals, starting in their professional training. The governing bodies and leadership of all healthcare facilities should take responsibility for ensuring the care of patients is of high quality and safe.

The Joint Commission Status on CDC Safe Injection Practices Guidelines

Crystal A. Riley, PharmD, R.Ph.
Associate Director, Federal Relations
The Joint Commission

The Joint Commission's position on safe injection practices is summarized in the October 2010 issue of Joint Commission Perspectives. It specifies that all Joint Commission accredited facilities, including ambulatory care, behavioral healthcare, critical access hospitals, home care, hospitals, laboratories, long-term care, and office-based surgery organizations are required to follow relevant scientific guidelines for infection prevention per Infection Control (IC) Standard (IC.01.05.01, EP 1), including the CDC 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Safe injection practices are also a key component of standard precautions required under IC.02.01.01, EP 2. Standard Precautions are infection prevention and control measures to protect against exposure to infectious agents and are applicable to all patients.

All Joint Commission accredited facilities are required to follow relevant scientific guidelines for infection prevention including safe injection practices.

Two specific elements of performance (EP) in the Infection Control Standard IC.01.05.01 that address safe injection practices are: EP 1, "must incorporate CDC Safe Injection Guidelines into IC policies and procedures;" and EP 2, "must follow CDC Safe Injection Guidelines in practice."

The Joint Commission surveyor focus will include review of the use of proper aseptic technique, and protective equipment (gloves, masks as indicated, etc.) when injecting medications, and practices that address "no use of a needle, syringe, or administration set in more than one patient, with specific emphasis on radiology and procedural areas, and including devices such as insulin pens. Other areas of focus will be review of policies and practices to ensure there is no administration of medications from single-dose vials to multiple patients, no use of bags or bottles of IV solutions as a common source for multiple patients, and no storing of multi-dose vials in immediate patient treatment area (including OR suite, patient room, patient bay or procedure room).

Aseptic technique when preparing and administering injectable medications is applicable to all healthcare settings, including pharmacy. However, the CDC has clarified that there are specific standards and recommended practices (e.g., USP 797) that are applicable to handling medication vials and related products in pharmacy and during pharmacy compounding, e.g., under a laminar flow hood.

The Safe Injection Practices Coalition (SIPC)

Sara Weir, MS
Vice President , B&D Consulting, Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations that was formed to promote safe injection practices in all U.S. healthcare settings.

The Safe Injection Practices Coalition (SIPC) is a partnership that was formed to promote safe injection practices.

The SIPC has developed the One & Only Campaign, a public health education and awareness campaign aimed at both healthcare providers and patients to advance and promote safe injection practices.

The three specific aims of the One & Only Campaign include:

- Increased awareness among the general public and healthcare providers about safe injection practices;
- Increased patient involvement/empowerment as a strategy to promote healthcare provider adherence to safe injection practices; and
- Increased understanding and implementation of safe injection practices among healthcare providers.

Recent SIPC efforts to advance and promote safe injection practices:

- Disseminating campaign resources (i.e., videos, brochures and posters) aimed at providers and consumers;
- Launching a safe injection practices training video;
- Promoting public service announcements (PSAs) to educate providers on safe injection practices; and
- Launching a CME tool on safe injection practices.

The SIPC currently has three state partners – Nevada, New Jersey and New York. The SIPC state partners help disseminate the messages and materials of the One & Only Campaign. State partners conduct educational outreach, create state-based activities, and further promote the campaign's goal to raise awareness among patients and healthcare providers about safe injection practices.

Coalition partners include the following organizations: Accreditation Association for Ambulatory Health Care, Ambulatory Surgery Foundation, American Association of Nurse Anesthetists, Association for Professionals in Infection Control and Epidemiology Inc., BD (Becton, Dickinson and Company), Centers for Disease Control and Prevention, CDC Foundation, Covidien, Hospira, HONOReform Foundation, MEDRAD, National Association of County & City Health Officials, Nebraska Medical Association, Nevada State Medical Association and the Premier healthcare alliance.

For more information, please visit:
www.OneAndOnlyCampaign.org

Injection Practices of Clinicians in U.S. Healthcare Settings

Gina Pugliese, RN, MS
Vice President, Premier Safety Institute
Premier healthcare alliance

Since 1999, the Premier Safety Institute has been committed to promoting safer healthcare for patients, workers, the environment and communities.

A dangerous minority of clinicians are engaged in unsafe injection practices – practices linked to outbreaks and patient notifications across the U.S.

As part of its commitment, Premier conducted a survey of clinicians to identify trends in injection practices in U.S. healthcare settings. The findings indicated that the majority of the 5,446 responding clinicians reported practices that were consistent with current recommendations. However, a dangerous minority engaged in unsafe practices – practices linked to outbreaks and patient notifications across the U .S. Specifically,

- 318 (6 percent), reported they "sometimes or always" use single-dose/single-use vials for more than one patient.
- 45 (1 percent) reported "sometimes or always" reusing a syringe but changing the needle for use on a second patient.
- 797 (15 percent) reported reuse of a syringe to enter a multi dose vial, and then
  - » 51 (1 percent overall) of these healthcare professionals reported saving that vial for use on another patient.
  - » Half of these 51 reported working in hospital settings and the other half in non-hospital settings.

When multiplied across the many thousands of injections that are administered each day, these rates of substandard injection practices can translate into substantial impacts and harms. These findings confirm that ensuring safe injection practices in all healthcare settings will require collaboration among all stakeholders and a multifaceted approach that includes monitoring, oversight, enforcement, education and improvements in clinical practices and product design. This research was published in the December 2010 issue of the American Journal of Infection Control and is available at www.ajicjournal.org (Pugliese G, Gosnell C, Bartley J, Robinson S, Am J Infect Control 2010;38:789-98).

The Premier Safety Institute maintains an extensive website with more than 45,000 pages of information, news, resources and tools on patient, worker and environmental safety with a special Web section devoted to safe injection practices at www.premierinc.com/injectionpractices.

Injection Practices from the Front Line

Lisa Sturm, MPH, CIC
Supervisor, Infection Control and Epidemiology
University of Michigan Hospitals & Health Center (UMHS)

As an infection preventionist at UMHS, we employ organization-wide efforts to evaluate and ensure the use of safe injection practices among clinicians across a variety of departments/units. An assessment tool called SPIRIT (Safe Practices Injection Review It Tool), was derived from CDC guidelines and the APIC position paper on safe injection practices (available at www.apic.org) and is used to evaluate practice on each individual unit. The tool assesses the spectrum of risks that could contribute to the transmission of a bloodborne pathogen (BBP) and identifies situations where inappropriate practices might be occurring. For example, the tool assesses practices related to aseptic technique (hand hygiene, storage of supplies); IV solutions (aseptic access, flushing procedures, discard protocols); vial and syringe access (single needle/syringe for entry and single patient); glucose monitoring (cleaning protocols and single patient use lancet) and frequency of staff training on safe injection practices. The tool also assesses issues related to injection safety to prevent healthcare worker injuries from needlesticks, including knowledge of methods to report exposures, compliance with use of safety devices, and activation prior to disposal. (SPIRIT tool: www.premierinc.com/saferinjectionsmeeting).

One example of ongoing monitoring practices is routine audits of anesthesia carts after procedures to evaluate for unsecured narcotics, improperly labeled syringes, and used single dose vial (SDV) medications.

One example of ongoing monitoring practices is the Anesthesiology Quality Assurance Department routine audits of anesthesia carts after procedures to evaluate for unsecured narcotics, improperly labeled syringes, and used single dose vial (SDV) medications left behind. The anesthesia provider is left with a small "scorecard" for their immediate feedback when they return to the room for the next case. These audits are conducted at all sites where anesthesia is administered, including the surgical suites, C-section procedure rooms, cardiac catheterization labs, and interventional radiology.

UMHS also has a consistent protocol to respond to patients potentially exposed to a BBP (sometimes called a reverse exposure), including their risk assessment, disclosure, and evaluation for follow-up and testing of patient(s) and employee (if involved). Additional details on their protocol are available in the UMHS Anesthesiology newsletter. (QA Focus on Syringe Reuse: www.premierinc.com/saferinjectionsmeeting).

Another challenge for infection preventionists that is often underappreciated in many healthcare organizations is awareness and management of employee IV drug diverters. Numerous reports of healthcare-associated HCV infection have been attributed to drug diversion by a HCV-infected worker. A standardized approach is needed in each organization to manage employees with drug addictions, as well as follow-up protocols, to include employee testing when surveillance and investigation of healthcare-associated HCV infection indicates potential drug diversion or drug tampering. In addition, there is a need for specific measures to reduce risk from drug tampering through strict narcotic security.

CONCURRENT BREAKOUT SESSIONS

During the afternoon, participants were able to select one of three topics to pursue for discussion in smaller groups. The goal was to use these sessions to address barriers and challenges to safer injections, identify current and future innovations, as well as designs and solutions for parenteral/IV injections. The three topic sections were grouped as process, product and practice.

Process innovations

This group focused on purchasing, distribution, cost, reimbursement and impact of clinical processes/procedures for handling, preparation and administration.

Existing innovations

There is value in looking at successful models for process change. For example, a successful model for process change is the industry movement from the use of glass capillary tubes to non-glass capillary tubes. Broken glass capillary tubes filled with blood posed a significant occupational risk of injury and infection with bloodborne pathogens, including HIV, HCV and HBV. The transition was successful because the non-glass capillary tubes resulted in the same clinical outcome, required no change in practice, and the cost was similar.

Barriers

Several barriers that were mentioned by this breakout group were echoed by other groups in their reports and are discussed in detail here, then mentioned only briefly in the remaining summaries.

Cost was the first barrier identified by participants. Many professionals need help assessing the full cost of newer devices and performing cost comparisons to understand that in many instances, techniques believed to be cost saving are not really savings at all. First, the cost comparison for developing a new product must consider all steps from the point of manufacture to the point of use. Then there is always the risk in developing a new device that no one or few will buy. There are also issues with incomplete analyses in some purchasing decisions. For example, a full understanding is needed of the cost comparison and associated risk of batch preparation of flush syringes from a common bag of IV solution (which is not supported by current guidelines and regulations), compared to the purchase and use of prefilled syringes. Another example is that the cost to assemble all the components for an injection from a multi-dose vial may outweigh the cost of single-dose packaging or assembly in the pharmacy.

For example, financial incentives could be enhanced by rewarding purchasers for safety – that is, for selecting the newer, safer injection devices when negotiating group purchasing contracts. Further, negotiations with third party insurance providers can also set expectations for safety. For example, insurance companies can reward safety practices and procedures or increase pressure on physician offices and facilities' to use safer injection devices. A desired outcome could include discounted premiums for providing evidence such as use of safer devices, leading to a safer patient environment.

Cost ownership is also an issue. Many clinicians believe it is their duty to save the organization money and that it will avoid other cost cutting measures. For example, unaware of the risks, many clinicians use a common IV bag for filling "prefilled" syringes and perceive this unacceptable practice as reducing cost and helping save their organization money.

Communication challenges include the gap in communication between upper level managers who may make purchasing decisions based on the lowest cost of large volumes of equipment including safety devices affecting patients, without input from clinicians using the devices. Injection safety may not be on the radar of these purchasing decision makers. Making an effective business case for change requires a recognized link between cost and reduction of risk. Purchasing managers need to be informed by the users about the true costs of decisions that may be not only less safe, but more expensive due to injury, unsafe infection practices, and other unintended consequences.

Purchasing – Another barrier is the shift in the *purchasing chain of command*. An apparent shift back to making *purchasing decisions* at one level of the organization without sufficient input from clinical users of safer devices requires an effort to realign and coordinate decision-making processes by including front-line clinicians in that process. On the other hand, practice standards in individual facilities may drive purchasing decisions but may not be acceptable, by not including current safety criteria. Accountability requires safe injection practice standards to be informed, current and based on recognized guidelines, such as the CDC recommendations. If practices are not current, newly hired staff that used "best practice" elsewhere may not maintain their knowledge of safe practices and proper use of safer devices.

Redesign of products continues to offer challenges for communication. For example, some phlebotomy devices incorporate an auditory or visual indicator when safety devices have been successfully activated. Staff must also educate patients about the intent of such indicators to ensure they know the meaning of such "clicks" or color changes, and that they exist for their own safety.

Customization – The need for a range of different doses of a specific medication is another barrier to broader uptake of single-dose medications. Some procedures, e.g., in radiology and anesthesia, or practice areas such as pediatrics, require customization of medication doses. If single-dose vials or pre-filled syringes are only available in certain sizes, customization is difficult. One suggested solution would be to have a limited range of preset sizes and dosages.

Process solutions

- Expand the activities of CMS related to improved standards and enforcement for safer injection practices to all care settings. Reimbursement and fear of lawsuits or bad publicity affects executive level decisions about product selection processes. Explore potential for insurance discounts for improving injection safety devices affecting patients. (See Cost section above.)
- Move as much preparation as possible back to the pharmacy to reduce errors at the point of delivery. This may be more safe and cost-effective.
- Support SIPC and federal partners to fund research and leverage partnerships with pharmacy professionals and human factors engineers .
- Investigate using cost calculators for decision making and to dispel myths. For example, pre-filled single-dose syringes may be less expensive than use of multi-dose vials if the full cost of preparing single-dose syringes on-site from multi dose vials is calculated, especially if associated infection risks are taken into account.
- Plan new employee orientation, annual updates, and cross-training of care-givers on practice standards to include safer injection processes and proper use of devices to set the acceptable standard for injection safety in a facility.
- Make new devices accessible and explore systems that can minimize the risk that staff will bring their own devices.

Product innovations

The Product Innovations groups discussed current and future designs, engineering controls, packaging, and labeling of products for safer injections (e.g., containers, vials, ampoules, injection devices, delivery systems).

Alternative delivery systems (no needles) and devices with obvious tamper indicators should be further explored. Other innovations to consider are mechanical, self-destructing vials; automated dispensing systems; electro-mechanical injection devices that use a pre-filled cartridge; other types of prefilled equipment; using bar codes for delivery; and products that reduce reliability on labels for safe use. Some innovative technology is already in use and should be evaluated for expansion in additional settings, such as auto-disabling syringes used commonly in the developing world.

Future designs, solutions, interventions

Change management is always a consideration when implementing and using any new products. The goal should be to provide safer delivery and to identify problems in the transfer/replacement process. A root cause analysis may help identify the basic cause(s) and lead to possible solutions

The connection between safer devices that improve worker and patient injection safety by both eliminating needlestick injuries, as well as bloodborne pathogen transmission, is a "win-win" and needs additional research and attention.

Passive devices are rare; that is, safety devices that do not rely on users' judgment or action to engage or activate a safety

feature. Suggestions for design changes included exploring increased application of non-needle delivery systems; for example, dermal, sublingual or nasal delivery. Other ideas included controls on the vial, such as a vial that seals once it has been used; enlarged labels on vials to highlight important information; color indicators when the vial has been accessed; and changes to stoppers to prevent reentry. Suggestions were made to expand the designs that would prevent syringe reuse including auto-disabled syringes, syringes that change shape after use, color indicators to prevent unintentional reuse, and implementation of single-use bar codes.

Barriers

Cost of purchasing new technology is often a barrier. Developing newer devices from point of manufacture to the bedside, including distributing the new devices and risking whether they are even purchased, adds to their expense. Facilities need to consider the total cost of the less safe alternatives and infection risks when comparing current devices, rather than just the apparent costs.

Limited demand for new technology can be a barrier to new product development. A large financial investment is required by manufacturers to bring a new product to market. If demand for the new product is low, product cost is likely to be high until demand can be created. To create significant demand for a new product, efficacy studies are often required.

Regulatory approval for new products can be a barrier to new product development and innovative technology and propagate misunderstanding and confusion from an infection control perspective. The FDA needs to streamline and improve their approval process.

Product solutions

- Study lessons learned in other products successes/failures (e.g., safety devices intended to reduce sharps injuries or anesthesia medication errors).
- Examine whether multi-dose vials are really needed in clinical settings. Should they be limited to pharmacy settings? How can overall vial use, including both multi-dose and single dose containers, be minimized in the clinical environment?
- Offer clinicians/end users more input directly into purchasing decisions. Use focus groups of practitioners and clinicians to identify needs. Review new products with clinicians as purchasing decisions are made and give their opinions greater weight.
- Create financial incentives; hospitals may be motivated to purchase new products if for example they prevent loss of CMS reimbursement for "Never Events."
- Advocate for changes to the FDA approval process to allow a more streamlined and consistent evaluation of new products and technologies.
- Connect injection safety for patients, needlestick injury prevention for healthcare workers, and reduction of medication errors into product selection, including the cost equation and impact analyses.

Practice innovations

The Practice Innovations groups discussed the role of guidelines, standards, education, oversight, outreach, and enforcement related to safe injection practices.

Existing practices

Guidelines – Existing evidence-based or mandatory guidelines to consider as resources for developing safe injection best practices are beginning to be identified. Getting injection safety guidelines to clinicians will require a continued effort. There are some useful tools and selected sections of the following guidelines available to guide practice. For example, the CDC Injection Safety website (http://www.cdc.gov/injectionsafety/) and the Safe Injection Practices Coalition website (http://www.OneAndOnlyCampaign.org/) provide useful educational tools and are easily accessible. The U.S. Pharmacopoeia Standard USP-797 website (http://usp797.org) is also quite relevant, but is more technical and not as easy for the general public to navigate. This site describes the regulations focused on pharmacy practices and procedures (but also extending to clinical practices) that are designed to reduce patient infections from pharmaceutical products and to better protect staff working in pharmacies.

Professional organizations – Premier's recent survey identified the professional organizations as the most common source of information about injection safety. Efforts should be made to contact additional professional organizations that are not currently involved in injection safety education and encourage them to provide resources on injection safety for their members. This could include recommendations to share existing guidelines from the CDC or to streamline and customize the guidelines for their members' specific applications.

Workarounds – Many healthcare providers do not always adhere to best practices and may create workarounds that are not consistent with CDC guidelines and related standards. Such workarounds are often developed to save time and/or money, but have unintended consequences and actually result in unsafe injection practices.

Future designs, solutions, interventions

The information about safe injection practice needs to be consolidated and simplified to improve and ensure clearer communication. Training of care providers could be brought closer to their patient care unit, by providing presentations using handheld devices for some workers and paper handouts for other workers, along with other innovations.

There are multiple players involved in resolving practice issues, including caregivers, industry representatives, professional organizations, regulators and suppliers. Each of these has a role in implementing safe injection practices. If change is to occur, high-level efforts to engage each group, such as today's workshop, must continue.

Barriers

Finding training time among other clinician demands is a barrier when new products/processes are introduced. Behavioral change is always challenging. The perceived level of risk varies across different healthcare settings. It's necessary to create a universal concept about risk and infection prevention standards, much the way universal precautions are now perceived.

Practice solutions

- Include safe injection practices in insurers' infection control audits and educational outreach, particularly in outpatient and private practitioners' offices where oversight by regulators may be minimal or even non-existent.
- Develop a standardized educational model for clinicians that emphasizes safe injection practices and other aspects of Standard Precautions. This could also be required for re credentialing of physicians and nurses, such as currently done for CPR.
- Incorporate safe injection practices into worker safety initiatives that are currently required under the OSHA Bloodborne Pathogen Standard and Needlestick Safety Act.
- Investigate the issue of workarounds and address these practices through educational programs.
- Expand the *"One and Only Campaign"* using social media tools. For example, increase use of smart phone applications for transmitting information to clinicians.
- Explore adding a celebrity face to the issue to enhance public awareness.
- Develop educational materials that recognize the setting specific characteristics which influence provider adherence.
- Consider writing articles and performing outreach aimed at specific populations and provider groups (e.g., cardiologists or other specialty practice clinicians).

There must be collaboration among all stakeholders with a strong commitment and significant investment of resources to build on existing efforts.

Recommendations – next steps

The conference closed with a final general session that included reports from the breakout groups and discussion of recommendations and next steps. Overall recommendations from the meeting are categorized and summarized as follows.

Education

- Expand the One and Only Campaign.
- Educate patients to explain safe injections and how to ensure they are receiving safe care.
- Educate clinicians and broadly disseminate best practice guidelines based on evidence-based safe practices for infection prevention and control.
- Identify resources to increase awareness of guidelines and related requirements, implement and measure adherence to basic safe practices, and promote best practices and safer systems.
- Correct or refute mistaken information on safe injection practices.
- Assess the obstacles to using current safety technologies and educate clinicians on appropriate use.
- Dispel myths and misperceptions about what is safe practice and discourage inappropriate reuse in the interest of conserving costs.

Clinical best practices

- Set clear expectation for safe injection practices and basic infection prevention and control across all care settings.
- Carefully and regularly review infection prevention and control protocols.
- Ensure safe practices are understood and followed by all clinical staff.
- Create a safety culture whereby every provider is empowered to stop any colleague from engaging in unsafe injection practices.
- Collaborate with pharmacy partners, human factors experts, and others so that medications are supplied in a form that is ready to deliver, minimizing the need for manipulation and opportunities for contamination and disease transmission.
- Work to develop curricula in nursing, medical, and other healthcare professional training and vocational programs on safe injection practices.
- Request safe design information from manufacturers as part of the clinical evaluation and purchasing process.

Research and surveillance

- Conduct epidemiologic and human factors studies to evaluate safer practices and identify/respond to safety signals.
- Continue to research clinical practice to ensure continuous progress is being made.
- Improve surveillance of healthcare-associated infections (HAI) at the state as well as the national and institutional levels so the impact of HAI prevention can be documented and shared.
- Develop calculators and value analysis methodologies that assess the total cost of products, balanced with quality and outcomes implications.

Product design

- Redesign injection devices to make compliance with safety best practices easy and error-proof.
- Develop consistent and clear labeling of injection-related products, including medication vials, containers and devices to encourage intended usage.
- Consider options for packaging, such as right-sized syringes or vials for specific clinical application.
- Create clear, consistent and understandable labeling requirements.

Collaboration

- Support collaboration between providers and manufacturers to design products that support easy compliance with safe injection practices.
- Collaborate across governmental agencies and among stakeholders to promote solutions and identify resources and policy levers to protect patients and workers from the risks of unsafe injection practices.

CONCLUSION

There was general consensus among the participants that injection safety represents a basic expectation in all healthcare settings as well as a serious and on-going challenge. Although there have been significant strides made to increase awareness of this issue, develop outreach and educational tools, and bring the issue to the attention of regulatory agencies, there is still much work ahead to eliminate unsafe injection practices. This Safer Designs for Safer Injections meeting identified vital needs, including increased use of existing innovations and additional product innovation, improvements in related regulatory standards, and increased education and empowerment of patients and clinicians about safe practices. Addressing healthcare cost pressures will continue to be a challenge. This will require greater involvement from clinicians in purchasing decisions in all care delivery settings. Ultimately, safe injection practices are the responsibility of every healthcare provider and institution.

As Dr. Joseph Perz summed up well, the strategies for enhancing safe injection practices focus on the "four E's": engineering, economics, education and enforcement.

Continued collaboration among all stakeholders was a recurring theme throughout the meeting. This collaboration requires a strong commitment and investment of resources to build on existing efforts.

This meeting is just one example of collaboration that continues through the efforts of the Safe Injection Practices Coalition, Premier Safety Institute, and other government and non-government organizations.. Together, we can work to ensure that process, product, and practice innovations move us steadily forward to our goal of safe injections for all .

Together, we can work to ensure that process, product, and practice innovations move us steadily forward to our goal of safe injections for all.

APPENDICES

Safer Designs for Safer Injections: Innovations in Process, Products, and Practices

Open meeting sponsored by the Premier healthcare alliance incollaboration with the Safe Injection Practices Coalition.
April 26, 2011, Omni Shoreham Hotel, Washington, DC

AGENDA

8:30–8:40 a.m. — **General Session/Welcome**
Premier healthcare alliance, David Edwards, Vice President
Safe Injection Practices Coalition, Lisa J. Thiemann, CRNA, MNA
Premier Safety Institute®, Gina Pugliese, RN, MS, Vice President

8:40–9:20 a.m. — **Review of Outbreaks: Incidents, lessons learned and implications for injections without infections**
Joseph Perz, DrPH, MA; CDC

9:20–9:35 a.m. — **A patient's story –** Evelyn McKnight, AuD

9:35–11:15 a.m. — **Panel: Updates on National-Federal Activities**

- Food and Drug Administration (FDA) Safe Use Initiative – Karen Weiss, MD, MPH
- FDA and collaboration with United States Pharmacopeia – Laurie Muldowney, MD
- Centers for Medicare & Medicaid Services – Daniel Schwartz, MD, MBA
- The Joint Commission – Crystal Riley, Pharm D, RPh
- Safe Injection Practices Coalition – Sara Weir, MS, and Erin Justen, MPH
- Current status of injection practices in U.S. healthcare settings – Gina Pugliese, RN, MS, and Lisa Sturm, MPH, CIC

11:15–Noon. — **Moderated question and answer session with discussion**

Noon–1:00 p.m. — **Lunch**

1:00–2:30 p.m. — **Concurrent Breakout Sessions**
Discussions address barriers and challenges to safer injections, current and future innovations, and designs and solutions for parenteral/IV injections without patient infections.

Topic 1) Process innovations: Purchasing, distribution, cost, reimbursement, and impact of clinical processes/procedures for handling, preparation and administration.

Topic 2) Product innovations: Current and future designs, engineering controls, packaging, and labeling of products for safer injections (e.g., containers, vials, ampoules, injection devices, delivery systems).

Topic 3) Practice innovations: Role of guidelines, standards, education, oversight, outreach, and enforcement related to safe practices.

2:30–4:15 p.m. — **General Session – Empire Ballroom**

2:45–4:15 p.m. — **Reports from breakout sessions in full group moderated discussion**

4:15–4:30 p.m. — **Concluding remarks**

4:30 p.m. — **Adjourn**

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Speaker biographies

Dave Edwards
Vice President, Supplier Relations and Business Development
Premier healthcare alliance

As vice president of Supplier Relations and Business Development, Dave Edwards has been an enthusiastic champion of creating win/win scenarios through collaboration between healthcare providers and suppliers to achieve high quality, cost-effective care at Premier, a performance improvement alliance of more than 2,500 U.S. hospitals and 73,000-plus other healthcare sites. For the past 10 years he has been a key executive leader in developing comprehensive supply chain services for the Premier healthcare alliance and helping members deliver measurable improvements in care supported by the nation's most comprehensive repository of clinical, financial, operational and outcomes information. Dave is an energetic leader with a proven record of success as part of a Fortune 500 company, a start-up-device company, as a partner of a small medical manufacturer, and for the past 10 years, as an executive with Premier.

Dr. Evelyn McKnight, AuD
President HONOReform; HONOReform Foundation
Fremont, Nebraska

Dr. Evelyn McKnight is a practicing audiologist in Fremont, Nebraska. Evelyn is one of ninety-nine cancer survivors who contracted hepatitis C through substandard medical care at the Fremont Cancer Center in 2000-2001. She is one of the founders of HONOReform and the HONOReform Foundation (www.HONOReform.org). She was instrumental in the development and securing of funds for the One and Only Campaign, which HONOReform co-convened with the CDC Foundation. Evelyn has been featured on a number of national news outlets including CBS News, CNN, USA Today, and Newsday. Evelyn is also a co-author of "A Never Event: Exposing the Largest Outbreak of Hepatitis C in American Healthcare History," which chronicles the story of the Nebraska hepatitis C outbreak.

Laurie Muldowney, MD
FDA - Medical Officer
Center for Drug Evaluation & Research, Office of Pharmaceutical Science

Dr Laurie Muldowney is a medical officer in the Office of Pharmaceutical Science at FDA's Center for Drug Evaluation and Research. In this role, Dr Muldowney focuses on issues related to the intersection of drug quality and safety. She received a bachelor of science degree in chemistry from the College of William and Mary and earned her medical doctorate from Jefferson Medical College in Philadelphia, PA, where she graduated cum laude and was elected to Alpha Omega Alpha Honor Medical Society. Following additional postgraduate training, Dr Muldowney served as a primary care physician with the United States Navy. Prior to joining the FDA, Dr. Muldowney worked as a medical science liaison and medical writer for a medical communications company, where she was responsible for creating educational programming aimed at practicing physicians, pharmacists, and other healthcare professionals.

Joseph Perz, DrPH, MA
Team Leader, ambulatory and long term care
Centers for Disease Control and Prevention/DHQP

Dr. Joseph Perz is with the CDC's Division of Healthcare Quality Promotion, based in Atlanta, Georgia. He serves as the team leader for Ambulatory and Long Term Care in the Prevention and Response Branch. Dr. Perz entered the field of public health after training as an engineer and environmental scientist. After receiving a Doctorate in Public Health from Columbia University, he served as an Epidemic Intelligence Service Officer with the Tennessee Department of Health. During his 12 years with the Centers for Disease Control and Prevention, Dr. Perz has guided dozens of outbreak investigations and special studies, drawing attention to the needs for injection safety and other basic infection control. He has authored or co-authored over 50 peer-reviewed journal articles, MMWR articles and book chapters. His team's activities are currently focused on interagency collaboration, support to health departments, and partnership efforts to expand prevention activities to ambulatory and long-term care settings.

Gina Pugliese, RN, MS
Vice President, Premier Safety Institute
Premier healthcare alliance

Gina Pugliese is the vice president of the Safety Institute, Premier healthcare alliance and associate faculty, University of Illinois School of Public Health and Rush University College of Nursing. Pugliese is senior associate editor of *Infection Control and Hospital Epidemiology,* on the faculty of the international Healthcare Epidemiology Training Program, co-sponsored by the Society for Healthcare Epidemiology of America (SHEA) and the Centers for Disease Control and Prevention (CDC). She is the author of more than 140 publications and frequent lecturer on patient, worker and environmental safety and infection prevention. She has received numerous awards and recognitions, including the establishment of SHEA's Gina Pugliese Scholarship in recognition of her contributions to the field of healthcare epidemiology.

Crystal A. Riley, PharmD, RPh
Associate Director for Federal Relations
The Joint Commission

Crystal A. Riley, PharmD, RPh, is an associate director for federal relations for The Joint Commission. She is active in a number of Joint Commission activities, but her main purview involves drug information, quality measures, and hospital issues. Before joining The Joint Commission, Dr. Riley worked as a clinical pharmacist in large community hospitals, focusing on quality research, drug information, and training staff on various quality initiatives and clinical protocols. Dr. Riley also worked for a large third party payor, where she provided drug information services and clinical review for state-sponsored public assistance pharmacy claims. She was also on staff at a national pharmacist organization, where she acted as a policy and practice liaison to outside organizations and federal agencies in her role as Director of Professional Affairs. Dr. Riley earned her doctorate of pharmacy from Howard University in Washington, DC, and is currently completing a dual masters' degree in Healthcare Administration and Business at the University of Maryland.

Daniel Schwartz, MD, MBA
Chief Medical Officer – Survey and Certification Group
Centers for Medicare & Medicaid Services

After graduating from George Washington University School of Medicine and completing his Urology Residency at University of Maryland, Dr. Daniel Schwartz has held a variety of positions. In addition to more than 20 years of clinical practice in military medicine, private practice and with Kaiser Permanente, he has management and leadership experience including oversight of an ambulatory surgical center. After earning a MBA and becoming passionate about healthcare policy and quality improvement, in May 2010, Dr. Schwartz joined the Survey and Certification Group at CMS as chief medical officer. One of his areas of focus is clarifying the best infection control practices that will decrease healthcare-associated infections across facilities.

Lisa Sturm, MPH, CIC
Supervisor, Infection Control & Epidemiology
University of Michigan Hospitals & Health Center

Lisa Sturm is a supervisor in Infection Control & Epidemiology at the University of Michigan Health System. She has a master's in Public Health in Hospital and Molecular Epidemiology, with a specialty is surgical site infection prevention and infection prevention in the perioperative setting. She is Certified in Infection Control and has been active in infection prevention for 18 years. Prior to her current career in infection prevention, she was a employed in industry as a nuclear medicine technologist and biotechnologist. She is a guest lecturer at the University of Michigan School of Public Health and an active member in the Association for Professionals in Infection Control, Greater Detroit Chapter (APIC-GD), including past-president and program chair.

Sara Hart Weir, MS
Vice President
B&D Consulting

Sara Weir is a vice president at B&D Consulting. At B&D Consulting, Sara consults on innovative public-private partnerships and other alliances to drive translation research and public health promotion and prevention. Sara helps patient advocacy organizations, pharmaceutical and medical device manufacturers, health care providers, and academic institutions effectively advocate before Congress and a wide variety of federal departments and agencies. Sara applies her background in public policy to design and execute comprehensive and creative government relations strategies to advance the interests of clients in the health and life sciences sector. Most recently, Sara has been working to support a national public health education and awareness campaign, the One & Only Campaign, focused on safe injection practices.

Karen Weiss, MD, MPH
FDA - Associate Director for Medical Affairs & Safe Use program
Center for Drug Evaluation and Research

Dr. Karen Weiss is the lead for the Safe Use Initiative in the FDA's Center for Drug Evaluation and Research. Under this initiative, FDA creates partnerships with the healthcare community to improve the safe use of marketed prescription and non-prescription medicines. In her 20 years at FDA, Dr Weiss was involved in variety of activities, including regulation of therapeutic biologicals, pediatric drug development, oncology drug development, and now, drug safety. She received her undergraduate and medical degrees at The Ohio State University, completed a pediatric residency in Grand Rapids, Michigan, a Pediatric Hematology-Oncology fellowship at St Jude Children's Research Hospital, and earned her masters of public health from Johns Hopkins University. She was an assistant professor at Georgetown University before she joined FDA.

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