



Client Risk Solutions | Going Beyond Insurance

**Uncommon Sense:
Unsafe
Injection
Practices
in Medical
Groups**



Part II in a Series

October 2017

Abstract

PURPOSE: The purpose of this analysis is to use medical group assessment data to determine key liability risks that may result in patient harm. This is the **second** resource paper in a multi-part series with review and analysis of the findings. The data covers the period of 2013-2016 using information extracted from an American International Group (AIG) scored assessment tool. Questions were developed based on the potential for system defects. Clients used the results to guide redesign of processes and operations to mitigate risks. Domain scores proved useful in analyzing trends, setting priorities for consultation, and creation of new client resources.

RESULTS: Low scores in the risk domain **Infection Control** domain for **Safe Injection** indicate under-developed processes and operations in the prevention of errors that could lead to patient harm. Data has been used to identify risk management issues, develop new resources and implement meaningful recommendations in addressing risk exposures specific to medical groups.

Please refer to the first paper titled “Medical Group Risk: Decluttering Design with Data” to review methods and results for all risk domains within the medical group assessment tool.

Introduction

Isn't this a hospital issue?

The impact of patient harm due to unsafe injection practices is significant yet the harm is preventable. More than 150,000 patients have been at risk to life threatening infections and bloodborne illnesses due to breaches in proper infection control. The breaches often involve providers reusing needles, syringes or single-dose medication each meant for one patient and one procedure. The outbreaks include patients exposed to bacterial infections, or bloodborne illnesses such as Hepatitis B, Hepatitis C and HIV¹ in outpatient and inpatient settings. In a ten year period from 2001-2011, data specific to physician offices and ambulatory surgical centers indicates 50 outbreaks of viral hepatitis or bacterial infections.²

This is not a new risk topic, so we assumed knowledge base for unsafe injection practices was as familiar to clients as poor hand hygiene practices. We were mistaken and saw numerous consulting opportunities. Clients often asked, "Isn't this a hospital issue?" during onsite discussions. Some applicable information shared with clients included the prevalence of ambulatory settings as noted in Table 1:³ and published breaches, noted in Table 2 below:

Table 1

The infographic is divided into two main sections. The left section, titled "Outbreaks Occur In a Variety of Settings", lists various healthcare environments: Hospitals, Primary care clinics, Pediatric offices, Outpatient surgical centers, Pain clinics, Imaging facilities, Oncology clinics, Dental clinics, and Health fairs. The right section, titled "Steps Every Healthcare Provider Should Take", lists seven key practices: 1. Follow proper infection control practices and maintain aseptic technique during the preparation and administration of injected medications (e.g., perform hand hygiene). 2. Never administer medications from the same syringe to more than one patient, even if the needle is changed. 3. Never enter a vial with a used syringe or needle. 4. Do not use medications packaged as single-dose or single-use for more than one patient. 5. Do not use bags of intravenous solution as a common source of supply for more than one patient. 6. Limit the use of multi-dose vials and dedicate them to a single patient whenever possible. 7. Always use facemasks when injecting material or inserting a catheter into the epidural or subdural space. At the bottom, a warning sign icon is accompanied by the text "Injection Safety is Every Provider's Responsibility".

¹ Centers for Disease Control and Prevention (CDC). The one and only campaign; fast facts: unsafe injection practices. Access <https://www.cdc.gov/injectionsafety/1anonly.html>

² Centers for Disease Control and Prevention (CDC). The one and only campaign. Access <https://www.cdc.gov/injectionsafety/1anonly.html>

³ Center for Disease Control and Prevention; one and only campaign; the impact of unsafe medical injections in the U.S.; infographic 508. Access <https://www.cdc.gov>.

Table 2: CDC Sample Cases of Unsafe Injection Practices⁴

Practice or Clinic Location	Breach	Year
Outpatient pain management clinic, Arizona	Outbreak of methicillin-resistant Staphylococcus (MRSA) due to single use vial used on multiple patients. Three patients were treated for severe infections, requiring hospitalizations ranging from 9-41 days; one patient died.	2012
Orthopedic clinic, Delaware	Seven patients contracted a methicillin-susceptible Staphylococcus aureus. Reuse of single-dose vials on multiple patients. Infected patients required an average hospital stay of 6 days to combat the infection.	2012
Oncology practice, New Jersey	Outbreak of Hepatitis B due to reuse of single dose vials for multiple patients and use of a common source saline bag for multiple patients. 4,600 patients notified and 29 cancer patients were infected with Hepatitis B	2009
Endoscopy clinic, Nevada	Outbreak of hepatitis C due to reuse of syringes on multiple patients. 50,000 patients were notified for testing, the largest of its kind in United States healthcare.	2008

⁴ Center for Disease Control and Prevention. Outbreaks and patient notifications in outpatient settings, selected examples 2010-2014. Access:<https://www.cdc.gov>.

Difficulty in Reporting Outbreaks

Many health care professionals opine that known outbreaks do not represent the full extent of such outbreaks.⁵ There are several reasons for the lack of comprehensive data such as: the stigma linked to the myth that hepatitis is always tied to risk behaviors; inability to trace back to specific healthcare facilities; and difficulty in detection of certain types of infections.⁶ Many people infected with hepatitis B or C are unaware they are infected until they have symptoms of cirrhosis or liver cancer several years later.⁷ When their symptoms do appear it may be impossible to determine the exact incident that caused the infection.

Silent Epidemic and Cross-Agency Efforts

Viral hepatitis is referred to as the “silent epidemic in the United States.” Of note, are the following Health and Human Services estimated statistics on viral hepatitis:⁸

- 3.5-5.3 million Americans living with the disease are not aware they are infected with the virus
- 65-75% of those individuals infected with chronic viral hepatitis B and C do not seek treatment
- The leading **infectious cause** of death, claiming 12,000-18,000 Americans a year
- Most common reason for liver transplantation
- Leading cause of liver cancer
- 2007 reported deaths due to viral hepatitis outpaced deaths due to HIV

Recognizing the significant cause of morbidity and mortality, the U.S. Department of Health and Human Services (HHS) led the development of a cross-agency set of strategic efforts. The 2011 report, *Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, provides a roadmap in improving our national response to prevention and treatment of those infected.⁹ This report followed a 2010 report by the National Academy of Medicine report (formerly IOM), that recommended national action be taken to address this “underappreciated health concern of the nation.”¹⁰

An updated plan followed 3 years later with major expansions to other partners to include: U.S. Department of Housing and Urban Development (HUD), THE U.S. Department of Veteran’s Affairs (VA), the U.S. Department Federal Bureau of Prisons, and numerous state and local health departments, academic settings, and community leaders. Infectious disease specialists and other clinicians assume key roles in collaboration with public and private sectors to address the silent epidemic.

Another updated version was published now titled, *National Viral Hepatitis Action Plan 2017-2020*, *reiterated* that this is a national plan not just a federal plan. Much progress still needs to be made, and

⁵ GAO Report (July 2012). Patient safety: HHS has taken steps to address unsafe injection practices but more action is needed.

⁶ Ibid.

⁷ Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, U.S Department of Health and Human Services. Updated 2014-2016. Action Plan for the prevention, care & treatment of viral hepatitis. Access: <https://www.hhs.gov/sites/default/files/viral-hepatitis-action-plan.pdf>

⁸ Ibid

⁹ Ibid.

¹⁰ Ward, J.et al. Hepatitis C virus prevention, care, and treatment: from policy to practice, Clin Infect Dis 2012; 55 (suppl_1); 558-563. Access: <https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/cis392>

details are beyond the scope of this report. However, here are some highlights of some advances since the original report¹¹:

Screening recommendations: Accurate HBV and HCV screening tests exist and they are covered by most health insurance plans without extra charge to the consumer.

Expanded Access to Health Coverage: The Affordable Care Act (ACA) enabled millions more Americans to obtain affordable, quality health insurance and prohibits denial of health coverage based on pre-existing conditions. Also, there are more opportunities for Americans to receive preventive care without cost sharing; Hepatitis A virus (HAV), HBV vaccination, HBV and HCV screening services are covered preventive services.

Developments in a HCV Cure: The approval of highly effective, all-oral therapies have the potential to cure more than 90% of chronic HCV infections or 3.15 million of the 3.5 million people in the US with chronic infections. However, only 54% of people are aware of their infection and only about 9% of infected people had been treated for HCV.

Developments in Syringe Services Program: A 2015 response to the growing opioid epidemic and related increase in transmission of viral hepatitis and HIV, Congress allocated federal funds to support syringe services under certain conditions. These programs reduced viral hepatitis risk, now considered an effective component of a comprehensive disease prevention strategy.

CDC Efforts and Patient Advocacy

We augmented our client discussions with reference to educational materials and public safety efforts by the CDC's *One and Only Campaign* augmented our client discussions.¹² Assessment visits with our clients often included review of excellent CDC free training materials. Notably, in 2009, the Safe Injection Practices Coalition (SIPC), a CDC-led partnership of healthcare-related organizations, patient advocacy organizations, industry partners, and other public health partners, developed the *One and Only Campaign*. The aim of the *One & Only Campaign* is to make sure that patients are protected every time they receive a medical injection. Targeted education and awareness campaigns focus on influencing the culture of patient safety with promotion of: *One Needle, One Syringe, Only One Time for each and every injection*. Advocates believe these efforts will greatly reduce the risk of contracting hepatitis and other infections.¹³

¹¹ Department of Health and Human Service. (2017). National viral hepatitis Action Plan 2017-2020. Access <https://www.hepatitis.va.gov/pdf/HHS-hep-action-plan-2017-2020.pdf>

¹² Ibid

¹³ Ibid

Assessment Results for the Risk Domain *Safe Injection Practices*

Table 1

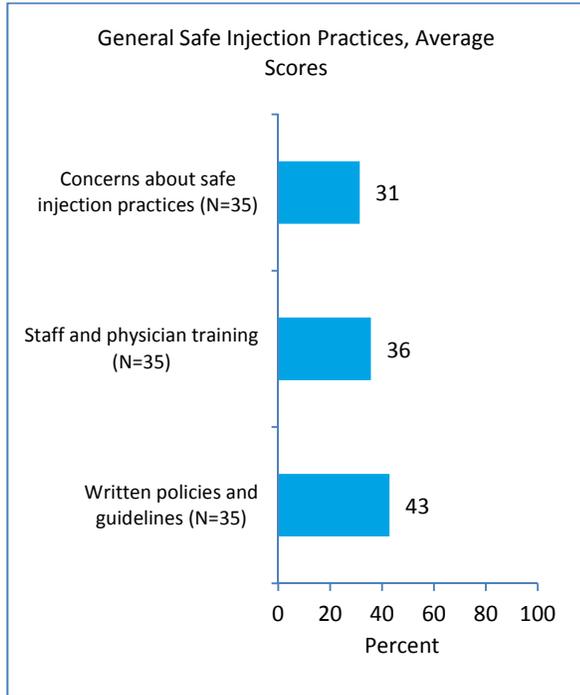


Table 2

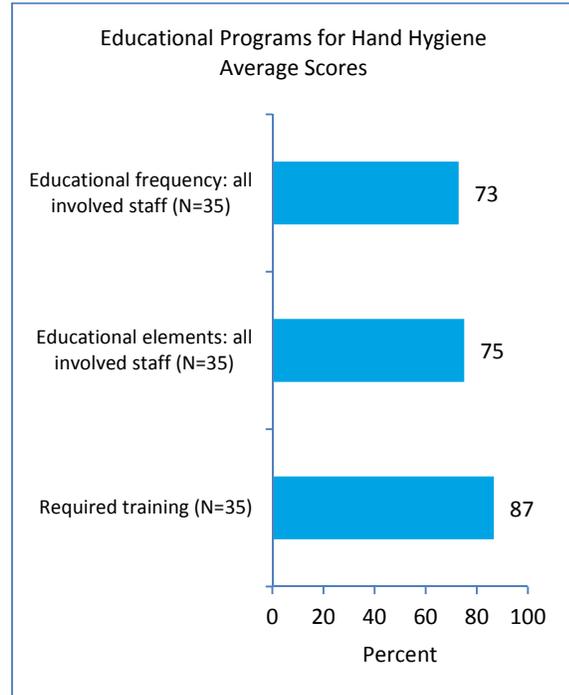


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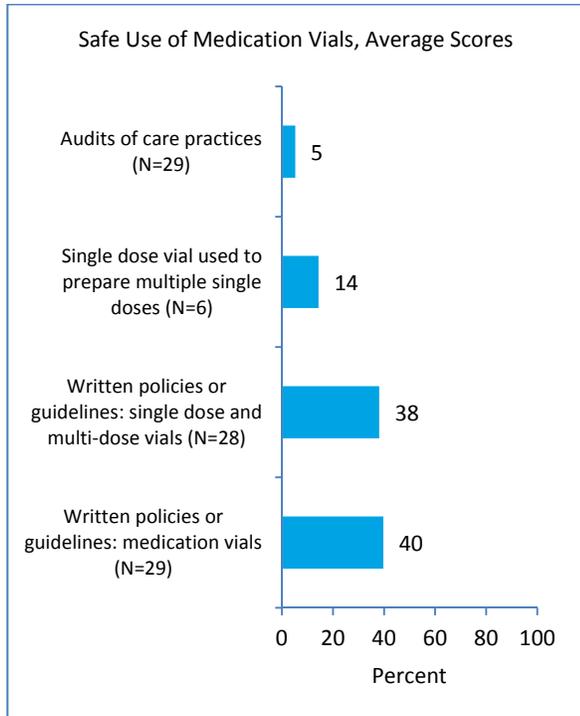
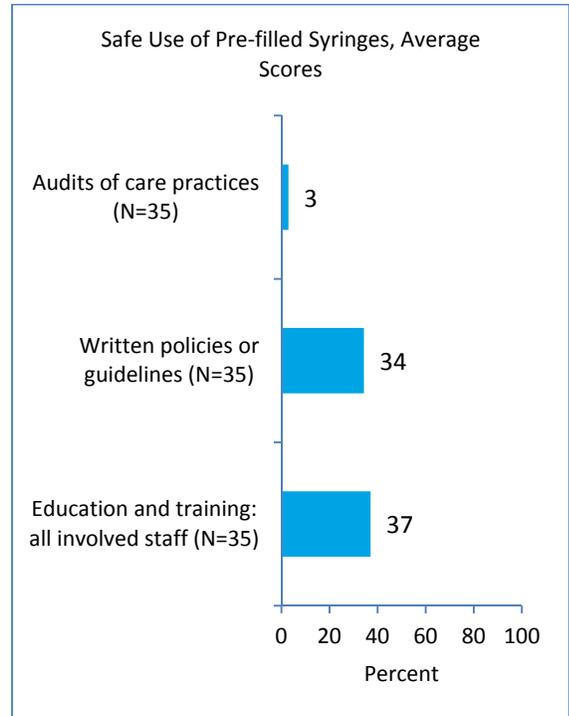
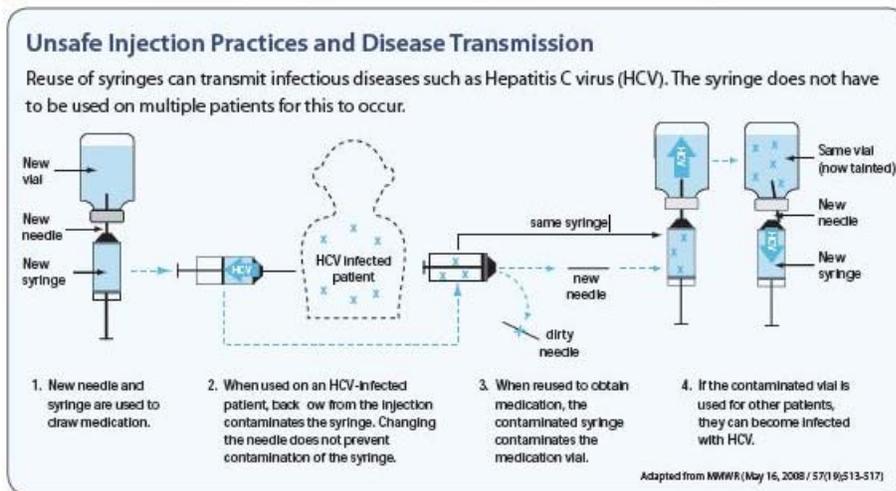


Table 4



The Tables 1, 2, 3, and 4 on Infection Control and Prevention indicates very low scores for all questions relating to safe injection practices. Targeted education, training and audited oversight are important to adequately address this important safety topic.

Outreach from patient advocacy groups in the promotion of safe injection practices play an important role in increasing public and healthcare worker awareness. As an example, Evelyn McKnight, author of “A Never Event” was a victim of unsafe injection practices which lead to her contracting the chronic hepatitis C virus. Also, her terrible experience and battles with the disease motivated her and Travis Bennington to create the patient advocacy organization HONORreform. They are dedicated to protecting patients by safeguarding the medical injection process “from manufacturing to disposal.”¹⁴ Ms. McKnight, an effective presenter and writer, tells her story in her book describing her patient experience back in 2001. Ms. McKnight contracted hepatitis C while being treated for a recurrence of breast cancer at a clinic in Fremont, Nebraska. Under her oncologist’s direction, nurses reused syringes to draw contaminated saline from a vial used for multiple patients, infecting Ms. McKnight and 98 patients with hepatitis C. At the time of the reported breach, it was considered one of the largest health care outbreaks in U.S. history.¹⁵ To illustrate how a breach occurs, the infographic below indicates how reuse of syringes can transmit infectious diseases such as HCV¹⁶:



¹⁴ HONORreform Annual report (2016); access: <http://honoreform.org/tag/international-injection-safety/>

¹⁵ Schroeder, M . Unsafe injections put patients in peril:insist on best practices before you’re stuck.. May 21, 2015. Access <http://health.usnews.com/health-news/patient-advice/articles/2015/05/21/unsafe-injections-put-patients-in-peril>

¹⁶ Centers for Disease Control and Prevention (CDC).The impact of unsafe medical injections in the U.S.Access www.cdc.gov;

Problems Still Persist

Healthcare workers in outpatient settings that do not follow common infection guidelines continue to make headlines, putting patients at risk for infection. In 2014, 1100 patients were recalled for potential exposures to Hepatitis B, Hepatitis C and HIV as a result of reuse of syringes used in a multi-dose vial; needles were changed but syringes were not.¹⁷ The impact of unsafe medical injections is estimated to be in the range of \$16-20 million¹⁸.

As recent as 2015, a nurse administering flu shots to patients, changed the needles for each patient but reused 2 syringes. Sixty-seven patients were contacted to receive recommended testing for potential exposure to hepatitis and HIV.¹⁹

Why is this happening?

Table 5

Myth	Truth
<p>Myth # 1: Changing the needle makes a syringe safe for reuse.</p>	<p>Truth#1: Once they are used, both the needle and syringe are contaminated and must be discarded. A new sterile needle and a new sterile syringe should be used for each injection and each entry into a medication vial.</p>
<p>Myth #2: Syringes and needles can be reused as long as an injection is administered through IV tubing.</p>	<p>Truth #2: Syringes and needles should never be reused. The IV tubing, syringe and other components represent a single interconnected unit. Distance from the patient, gravity or infusion pressure does not ensure that small amounts of blood won't contaminate the syringe once it has been connected to the unit.</p>
<p>Myth #3: If you don't see blood in the IV tubing or syringe, it means that those supplies are safe for reuse.</p>	<p>Truth #3: Germs such as hepatitis C virus and staph or MRSA are invisible to the naked eye, but can easily infect patients even when present in microscopic quantities. Do not reuse syringes needles or IV tubing.</p>

¹⁷ Centers for Disease Control and Prevention (CDC). The impact of unsafe infection practices in the US. Access www.cdc.gov;

¹⁸ Centers for Disease Control and Prevention (CDC).; The impact of unsafe medical injections in the U.S. Access www.cdc.gov

¹⁹ Washington Post, October 7, 2015. Nurse reused syringes during vaccine clinic NJ health authorities say. Access www.washingtonpost.com.

Some clients were puzzled about why this is a patient safety problem since infection guidelines explain contamination consequences linked to reused needles and syringes. Our consultants were often asked by clients: “Don’t you think this is just common sense?”

There are a number of reasons why common sense doesn’t prevail and it is related to various dangerous misperceptions held by healthcare workers:²⁰

What can be done?

Given the prevalence of myths and lack of common sense, what can be done? Hopefully, the excellent public awareness and educational efforts will continue on a number of fronts with organizations such as the CDC, and patient advocacy groups such as HONORreform . In addition, increasing awareness of the ongoing issues need to continue within each practice site. Much can be accomplished by clinicians, staff and patients in medical groups to prevent an exposure to disease as a result of an unsafe injection. The array of solutions is noted below in recommendations, but a couple areas need to be highlighted: audits and a culture of safety. We clarified with our clients that our recommendations for audits included use of a written tool, not just routine observations.²¹ The ability to speak up when someone observes an unsafe practice is also an important component of several organizations in the prevention of tragic cases.²² Certainly a culture of safety requires long term commitment and leadership efforts in office practices as well as healthcare organizations as a whole.

Recommendations

As a result of our assessment findings, here are recommendations that we think are helpful to risk managers, patients, clinicians and all levels of staff in physician offices:

- Implement mandatory education and training of staff to improve understanding of safe injection practices
- Diversify training for staff. Include patient materials from the CDC One and Only Campaign during regular staff meetings; include presentations from Infection Control staff
- Develop and implement policies and procedures to specifically address CDC guidelines to eliminate unsafe medical injections to include the following:²³
 - Needles and syringes are single use devices. They should not be used for more than one patient or reused to draw up additional medication.
 - Do not administer medications from a single-dose vial or IV bag to multiple patients.
 - Limit the use of multiple-dose vials and dedicate them to a single patient whenever possible.

²⁰ Centers for Disease Control and Prevention (CDC). Dangerous misperceptions. Access www.oneandonlycampaign.org

²¹ Centers for Disease Control and Prevention (CDC). Guide to infection prevention for outpatient settings: minimum expectations for safe care. Access www.cdc.gov.
https://www.google.com/search?q=Guide+to+infection+prevention+for+outpatient+settings%3A+minimum+expectations+for+safe+care&sourceid=ie7&rls=com.microsoft:en-US:IE-Address&ie=&oe=&qws_rd=ssl

²² APIC. Infection prevention and you; patients and families. Access: <http://consumers.site.apic.org/infection-prevention-basics/safe-injections-speak-up-and-stay-alert>

²³ Centers for Disease Control and Prevention (CDC).. One and Only Campaign Access.
http://www.oneandonlycampaign.org/safe_injection_practices:

- Periodically *audit* safe infection control practices in physician practices to include direct observation, utilizing a written, standardized tool.²⁴ Similar to efforts that address hand hygiene compliance, regular audits and reported results elevate the importance of safe practices and reinforce policies.
- Consider consultation with an Infection Preventionist to support efforts in physician offices in addressing guidelines to cover principles of safe injections.
- Include procedures needed for pre-filled syringes including expectation of being used in a timely manner according to infection control guidelines²⁵
- Education, training and the organizational culture should support employee's ability to speak up immediately if they see infection guidelines ignored, e.g. reusing a syringe on multiple patients.
- Utilize a culture of safety questionnaire with all physician practices receiving consultation. Staff will be more likely to speak up and prevent an unsafe injection in a culture of safety where they do not fear retributions for reporting an infection control breach.

Reputation Loss

A final note concerns the discussions we had with clients that involved the added stress of “reputation loss” long after an event occurred. A loss of confidence in clinicians and staff can be the consequence of highly publicized breaches for any medical group. Annual compliance courses and one-time orientation review of infection control guidelines are not enough. Priorities for this risk area should be expressed in staff values and ongoing dedicated resources to prevent human error.

²⁴ Centers for Disease Control and Prevention (CDC). Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care. Access www.cdc.gov.

²⁵ United States Pharmacopeia. United States Pharmacopeia. General Chapter 797 Pharmaceutical Compounding—Sterile Preparations. <http://www.usp.org>.

About the Author

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Margaret Ramirez, Director Project Management and Strategic Initiatives, AIG Client Risk Solutions|Healthcare, has developed risk and risk management programs for over 20 years nationwide. Ms. Ramirez is responsible for a number of strategic initiatives and projects for healthcare clients and has particular expertise in the delivery of services to large medical group clients.

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