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Voice in Healthcare

# Drug Diversion: Infection Prevention & Control



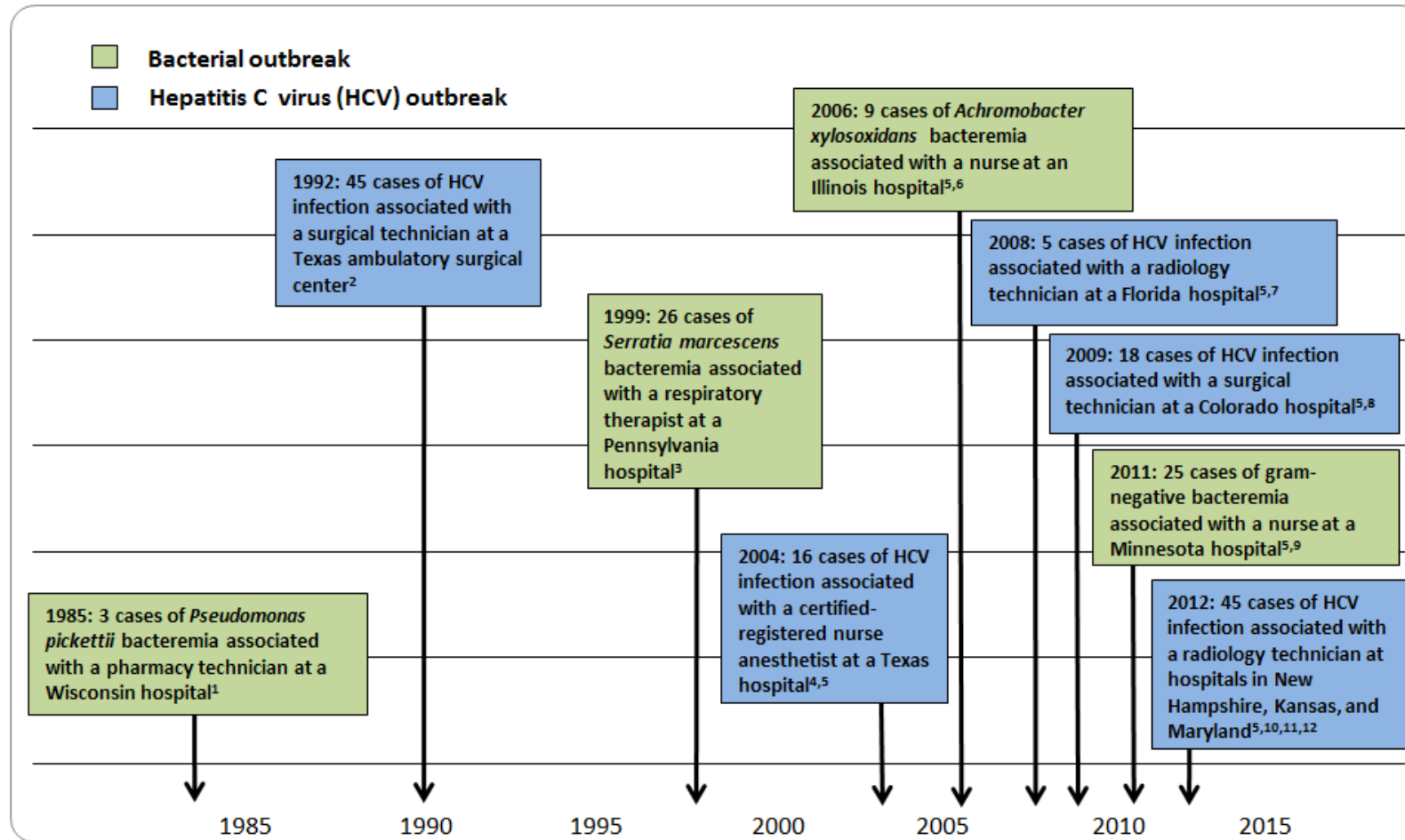
James Davis, MSN, RN, CCRN-K, HEM, CIC, FAPIC  
Manager Infection Prevention and Control Services

# Objectives

1. Describe the connection between drug diversion and the spread of infection.
2. Discuss common methods of drug diversion.
3. Define the role of the Infection Preventionist in monitoring for drug diversion.



# Drug Diversion Outbreaks Acute Care



<https://www.cdc.gov/injectionsafety/drugdiversion/drug-diversion-2013.html>

# Drug Diversion Outbreaks Acute Care

Year	Cases	Outbreak
2018	12	HCV infections associated with an emergency department nurse at a hospital in Washington [ <a href="#">Footnote 1</a> ]
2018	6	<i>Sphingomonas paucimobilis</i> bacteremia associated with a nurse at a cancer center in New York [ <a href="#">Footnote 2</a> ]
2015	7	HCV infections associated with a nurse at a Utah hospital [ <a href="#">Footnote 3</a> ]
2014	5	<i>Serratia marcescens</i> bacteremia associated with a nurse in a post-anesthesia care unit at a hospital in Wisconsin [ <a href="#">Footnote 4</a> ]

<https://www.cdc.gov/injectionsafety/drugdiversion/index.html>

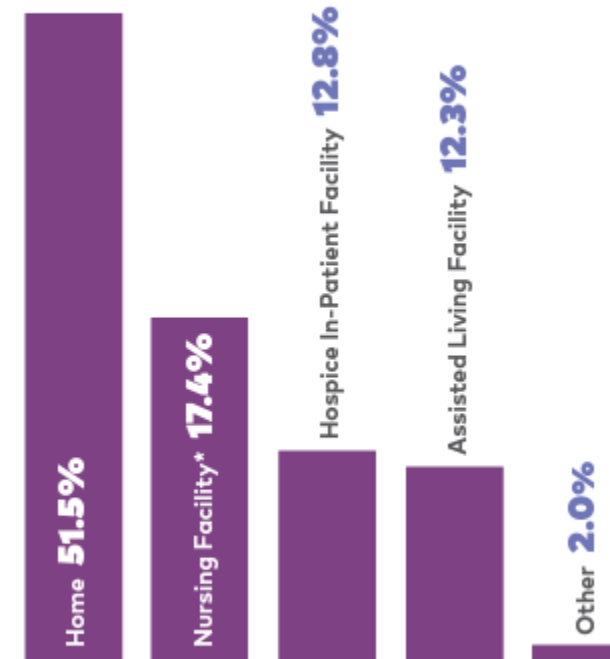
# Home Care & Hospice

**Table 1: Average Lifetime Length of Stay**

Year	Patients	Total Days	Avg. Days of Care
2014	1.32M	91.9M	88.2
2015	1.38M	95.9M	86.7
2016	1.43M	101.2M	87.0
2017	1.49M	106.3M	88.1
2018	1.55M	113.5M	89.6

Source: MedPAC March Report to Congress, Various years

**Figure 16: Decedent % by Location of Death**



\* Includes skilled nursing facilities, nursing facilities, and long-term care facilities. Source: CMS Data sourced by HCCI for NHPCO

“Nearly a third of hospices experience at least one case of confirmed medication diversion per quarter” [out of 112 surveyed]

Orrin D. Ware, John G. Cagle, Mary Lynn McPherson, Paul Sacco, Jodi Frey, Jack Guralnik, Confirmed Medication Diversion in Hospice Care: Qualitative Findings From a National Sample of Agencies, Journal of Pain and Symptom Management, Volume 61, Issue 4, 2021, Pages 789-796, ISSN 0885-3924, <https://doi.org/10.1016/j.jpainsymman.2020.09.013>.

# Diversion From Family or Friends

- According to the 2018 National Survey on Drug Use and Health, nearly 10 million people either diverted or misused opioids within a 12-month period.
  - Of these individuals, more than nine million misused prescription pain relievers with approximately 51.3% of people reporting that the most recently used pain reliever was obtained from a family member or a friend.

<https://www.samhsa.gov/data/release/2018-national-survey-drug-use-and-health-nsduh-releases>



**Today, we try to prevent falls and pressure ulcers in the hospital. Tomorrow, we will try to prevent falls and pressure ulcers at the patient's home.**

Eyal Zimlichman, MD, MSc, Wendy Nicklin, BN, MSc(A), ICDD, Rajesh Aggarwal, MD, PhD, FRCS, FACS, and David W. Bates, MD, MSc Health Care 2030: The Coming Transformation. NEJM Catalyst. March 3, 2021 <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0569>





# David Kwiatkowski – Healthcare Worker Diversion

1. Syringe stolen from operating room (preloaded and unattended)
2. Healthcare worker went to bathroom stall to inject
3. Mislabeled syringe (succinylcholine labeled as fentanyl)
4. Injected half the dose before paralysis set in – stopped injecting as he felt the effects
5. Removed syringe and threw into toilet – then collapsed out of the stall
6. Another worker witnessed the syringe in the toilet - fentanyl label still attached
7. Someone called the police, the hospital refused to cooperate
  - There had been an audit two months earlier that revealed a nurse had been diverting
  - The situation had not been addressed or remedied

# The Aftermath

- Kwiatkowski returned to his *hotel*
  - An agency had a listing for a job in Philadelphia
    - He filled out the online application and hit the sack
    - He received a call the next day and accepted the job
- This was in fact his MO, lose a job related to addiction and diversion, leave and show up at another hospital.
  - Being a traveler enabled his lifestyle
  - Liability concerns from facilities kept him from being caught or turned into a licensure issue

# The Patient Safety Impact

- Kwiatkowski had been positive for the hepatitis C virus for quite some time
- By traveling state to state he potentially exposed thousands to his blood, as some of the syringes and vials he diverted were used on patients
- The CDC recommended at least 12,000 people be tested due to possible exposure related to Kwiatkowski's diversions
  - It is known that at least 45 people contracted hepatitis C
  - 1 patient died
- Kwiatkowski is currently serving out year 8 of his maximum 39-year sentence

<https://www.newsweek.com/2015/06/26/traveler-one-junkies-harrowing-journey-across-america-344125.html>



PRESS RELEASE

# Texas Anesthesiologist Arrested on Criminal Charges Related to Alleged Tampering with IV Bags Implicated in Death, Surgical Emergencies

Thursday, September 15, 2022

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**For Immediate Release**

U.S. Attorney's Office, Northern District of Texas

A Dallas anesthesiologist who allegedly injected nerve blocking agents and other drugs into patient IV bags at a local surgery center –resulting in at least one death and multiple cardiac emergencies –was arrested Wednesday on federal criminal charges, Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division, and U.S. Attorney for the Northern District of Texas Chad E. Meacham announced today.

# Examples of Diversion Techniques

- Tampering
  - Drips
  - Prefilled syringes - waste
  - Vials
  - Refilling and restocking
  - Standing anesthesia order sets
    - 4 PRNs for Hydromorphone (Dilaudid) 0.5mg Q5min X4
  - Wasting

# Tampering/Defeating of Intravenous Lock Boxes



# Lock Boxes & Bad Actors – Keyed Locks



<https://youtube.com/shorts/HJmsQy7zM5c?si=79OB1DwwUQkmr8Mf>

[Clinical Evidence Assessment - General Topics - Guidance](#)

# Strategies for Preventing Unauthorized Access to Patient-Controlled Analgesia Pump Lockbox

Published 9/7/2023

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## EXECUTIVE SUMMARY

### Curated Literature Search

**Description:** Lockboxes on analgesia pumps are intended to prevent unauthorized access to controlled substances (i.e., theft, misuse) and tampering with pump controls. Healthcare facilities have reported infusion pump lockboxes being opened by patients or visitors or by hospital employees assessing device security using common objects that can be found in or easily brought into care settings to manipulate the latch or lock. Tamper-resistant features available in some intravenous (IV) lockboxes include keyless digital or combination locks and pole clamps located within the lockbox.



**Table 1. Clinical Literature**

Author/Year	Case Descriptions	Conclusions Presented by Authors
<b>Case Study</b>		
<p>Block et al. Case studies and considerations for combating the diversion of infusion drugs. <i>Journal of Clinical Engineering</i>. 2018;43(1):18-21.</p> <p><u>Abstract</u></p>	<p>Case 1: Nurses found a punctured and drained opioid bag within an infusion lockbox. The box appeared to be locked, but employees later determined it could be opened with a paperclip.</p> <p>Case 2: Employees found that infusion lockboxes could be opened with a finger or small object. No patients were affected.</p>	<p>“From this report review and the case studies described, safety mechanisms in certain infusion and PCA [patient-controlled analgesia] pumps may have the potential to be defeated in certain instances. Inspection of drug locking mechanisms and verification of their security are recommended to prevent potential theft or tampering after the infusion has been started because not all infusion pump enclosures provide the level of security assumed. User facilities that are purchasing equipment to provide security for opioid medication delivery to patients such as IV pump and syringe pump lock boxes, security cases, etc, should consider what kinds of alarm notifications and mechanical safeguards the device provides when tampering is attempted.</p> <p>The FDA should be informed of any damage to the equipment through the MedSun or MedWatch reporting avenues. A thorough investigation of the drug-related incident should be performed to determine where the break-down occurred which allowed the drug to be diverted.”</p>

**Table 2. Selected Web Resources**

Source/Year	Title/Link	Key Statements
Axiom Medical Supplies  Accessed August 2023	<a href="#">MarketLab IV Lock Boxes With Keyless Entry Digital Lock</a>	<p>"Made of impact resistant acrylic that is 65x stronger than standard acrylic to prevent damage</p> <p>Ideal for use with an infusion of controlled substances li &gt;</p> <p>Available keylock, combo cam-lock, or digital keyless locking ability to store up to 1000 ml IV bags"</p>
Health Care Logistics, Inc.  Accessed August 2023	<a href="#">Lock-To-Pole IV Lock Box with Key Lock</a>	<p>"Dual clamps secure the box to the pole and the door shuts over the pole to lock the box to the pole."</p> <p>"Models with key locks are keyed alike. Contact our Resource Group (ext: 1252) for other keying and locking options.</p> <p>Choose from four styles:</p> <p>Clear Standard Key Lock (featured here)</p> <p>Clear Keyless Entry Digital Lock (#17958)</p> <p>Amber Standard Key Lock (#19169)</p> <p>Amber Keyless Entry Digital Lock (#19170)"</p>
ICU Medical  Accessed August 2023	<a href="#">CADD-Solis Infusion System</a>	<p>"CADD medication cassette reservoirs</p> <ul style="list-style-type: none"> <li>• Durable, self-contained reservoirs lock directly onto the pumps, which helps to provide medication security</li> <li>• The pump and reservoir maintain a small footprint</li> <li>• Multiple sizes and color choices for therapy flexibility and visual identification</li> <li>• Flow stop feature helps prevent medication free-flow</li> <li>• Available with NRFit connectors to help reduce the risk of misconnections"</li> </ul>
Smiths Medical International Ltd.  Accessed August 2023	<a href="#">CADD-Solis Operator's Manual</a>	<p>"Cassette/Keypad Lock</p> <p>This allows you to secure the cassette to the pump using the pump key provided. The cassette latch must be latched before it can be locked. The Cassette/keypad can be configured to unlock only the cassette latch or to unlock the cassette latch as well as the keypad. This is configured by your CADD-Solis system administrator. (See <i>Security Settings</i> on page 21.)"</p>

**Table 3. Guidelines, Position and Consensus Statements**

Organization/Year	Key Recommendations or Statements
<b>Clinical Guidelines</b>	
<p>American Society of Health-System Pharmacists (ASHP). <u><i>ASHP Guidelines on Preventing Diversion of Controlled Substances</i></u>.</p> <p>2022</p>	<p>p.2289: “Where keys are used (eg, lockboxes, refrigerated storage boxes, and infusion pumps), they are unique to the device, when possible, and there is a procedure to track keys and their chain of custody, secure keys after hours, replace lost keys, and change locks if keys are lost. ...Patient-specific CS [controlled substance] infusions are contained in secure lockbox utilizing no-port tubing unless under constant surveillance. Keys and access to these controls are limited and tracked as with any keys and lockboxes.”</p> <p>p.2302: “Patient-specific CS infusions are contained in a secured, locked box utilizing no-port tubing unless under constant surveillance. Keys and access to these controls are limited and tracked.”</p>

Accession Number: H0393

ECRI Priority: High

Published: 08/15/2017

Channel: Devices

FDA: Not Specified

Last Updated: 08/17/2017

Smiths—CADD-Solis Infusion Pumps: Lockbox Can Be Defeated, Providing Medication Access to Unauthorized Persons [ECRI Exclusive Hazard Report]

**Product Identifier:** +

**Manufacturer(s):**

Smiths Medical , 6000 Nathan Ln N, Minneapolis, MN 55442, United States

**Problem:**

1. The lockbox of the CADD-Solis pump may be defeated using items that are available in a care unit.
2. A patient or other unauthorized persons (e.g., family members) may tamper with the lockbox without breaking it and gain access to medication.
  - a. The ability to gain access to the medication presents a risk that unauthorized persons will tamper with and/or steal the medication.
3. Interruption and/or delay in pain therapy may result.
4. The pump does not recognize or alarm if the lockbox is tampered with, even if an infusion is ongoing.

**ECRI Recommendations:**

1. Notify clinician staff about the possibility for unauthorized persons to gain access to medication when a Smiths lockbox is used.
2. Clinicians should conduct a physical and visual check that lockbox is appropriately secured at a specific interval (e.g., every shift change).
3. Consider the use of proprietary Smiths CADD cassettes instead of the lockbox to better secure the medication.
  - The use of CADD cassettes is an alternative to the use of the CADD pump with a lockbox.
4. If unauthorized access to medication is suspected, report the incident per your facility policy.

**Manufacturer's Comments:**

Smiths Medical states that the lockbox is not tamper-proof, but it is tamper-resistant as specified in the user instructions.

**Background:**

- ECRI Institute has received reports from a member facility about the potential for unauthorized access to Smiths lockboxes.
  - In our laboratory testing, ECRI Institute has been able to verify the potential to gain access to the Smiths lockbox without a key.
- Proprietary Smiths CADD cassettes provide an alternative to the lockbox.
  - Cassettes, which we believe better secure the medication, are available in 50 mL to 250 mL sizes.
- In the past, ECRI Institute has received reports and investigated incidents mainly in regard to medication diversion by hospital staff. Recent reports of patients gaining access to their medications suggest a growing trend. Considering the ongoing opioid epidemic in the U.S., we want to ensure that facilities are aware of these shortcomings and provide them with recommendations to respond accordingly.

Defeated in our lab by squeezing the case – Smiths has since fixed the issue by adding another bar behind the lock.

**Channel:** Devices

**FDA:** Not Specified

**Last Updated:** 08/15/2017

**ICU Medical/Q Core Medical—Sapphire Lockboxes: Can Be Defeated, Providing Medication Access to Unauthorized Persons [ECRI Exclusive Hazard Report]**

**Product Identifier:** +

**Manufacturer(s):**

Q Core Medical Ltd, 29 Yad Haruzim Street, Netanya IL-42505, Israel

**Distributor(s):**

ICU Medical Inc, 951 Calle Amanecer, San Clemente, CA 92673, United States

**Problem:**

1. ICU Medical/Q Core Medical Sapphire lockboxes may be defeated with items available in a care unit.
2. Patients or other unauthorized persons (e.g., family members) may tamper with the lockbox without breaking it and gain access to medication.
  - The ability to gain access to the medication presents a risk of unauthorized persons tampering with and/or stealing the medication.
3. Interruption and/or delay in pain therapy may occur as a result of this problem.
4. The pump does not recognize or alarm if the lockbox is tampered with, even if an infusion is ongoing.

**ECRI Recommendations:**

1. Notify clinician staff about the potential for unauthorized persons to gain access to medication when an ICU Medical/Q Core Medical lockbox is used.
2. Clinicians should conduct a physical and visual check at a specific interval (e.g., every shift change) to ensure that the lockbox is appropriately secured.
3. If unauthorized access to medication is suspected, report the incident per your facility's policy.

**Manufacturer's Perspectives or Comments:**

1. The ICU Medical/Q Core Medical operational manual states:
  - "PCA Lockboxes are designed to secure the IV bag, primarily for treatments involving narcotics or opioids, without interrupting the treatment workflow."
2. There are no known cases of medication diversion when locked in the Sapphire lockbox.

**Background:**

- ECRI Institute has received reports from member facilities about patients gaining access to patient-controlled analgesia (PCA) pump lockboxes.
  - Reports pertain to a different manufacturer's PCA pump lockbox than what is discussed in this report.
- ECRI Institute identified the ability to gain access to the ICU Medical/Q Core Medical lockbox without a key in our laboratory testing.
- ECRI Institute is currently not aware of any alternative methods to secure the medication, beyond the lockbox, with this particular pump model.
- In the past, ECRI Institute has mainly received reports and investigated incidents regarding medication diversion by hospital staff. Recent reports of patients gaining access to their medications suggest a growing trend. Considering the ongoing opioid epidemic in the U.S., we want to ensure that facilities are aware of these shortcomings and provide them with recommendations to act accordingly.

Accession Number: H0396

ECRI Priority: High

Published: 08/15/2017

Channel: Devices

FDA: Not Specified

Last Updated: 08/25/2017

BD—Alaris PCA Modules: Lockbox and Keypad Lock Can Be Defeated, Providing Medication and Programming Access for Unauthorized Persons [ECRI Exclusive Hazard Report]

Product Identifier: +

**Manufacturer(s):**

CareFusion Alaris A BD Co, 3750 Torrey View Ct, San Diego, CA 92130-2622, United States

**Summary:**

On August 18, 2017, ECRI Institute updated the Product Identifier field to reflect the specific affected model.

On August 25, 2017, ECRI Institute modified Recommendation 4 below and added a second perspective/comment from the manufacturer.

**Problem:**

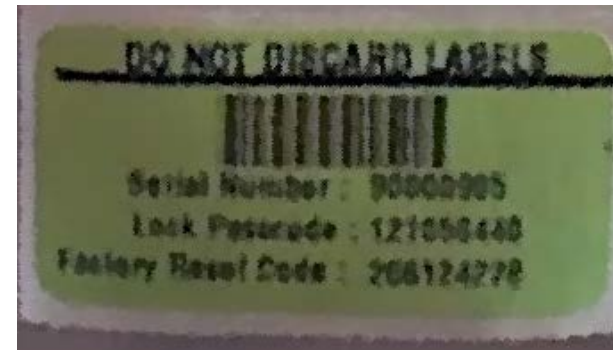
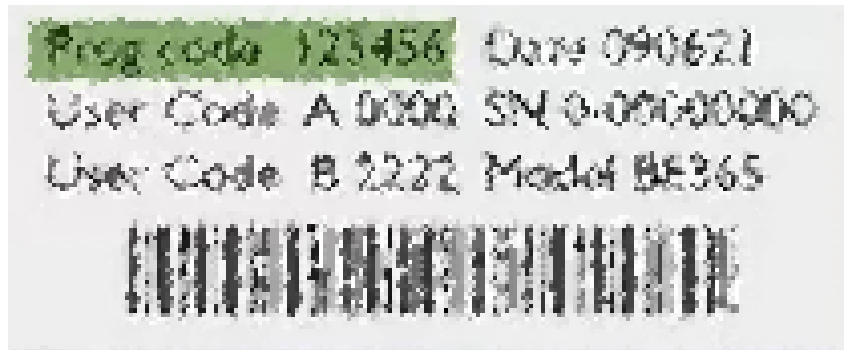
1. The lockbox and keypad/programming lock on the above modules may be defeated with items available in a care unit.
2. The patient or other unauthorized persons (e.g., family members) may tamper with the lockbox/keypad lock without breaking it, gain access to the medication container, and gain access to modifying the pump programming.
  - The ability to gain access to the medication presents a risk of unauthorized persons tampering with and/or stealing the medication.
  - The ability to gain access to the pump programming presents a risk of unauthorized persons tampering with infusion parameters.
3. Modification, interruption, and/or delay in pain therapy may result.

**ECRI Recommendations:**

1. Notify clinician staff about the potential for unauthorized personnel to gain access to medication and pump programming with affected modules.
2. Clinicians should conduct a physical and visual check that the lockbox is appropriately secured and that programming corresponds to the order at a specific interval (e.g., every shift change).
3. If unauthorized access to medication or tampering with the infusion parameters is suspected, report the incident according to your facility policy.
4. Consider the use of Auto ID module, if available. This may aid in preventing unauthorized programming on the device without an appropriate clinician ID. However, this does not eliminate the problem identified in this Alert but rather reduces the risk of unauthorized programming. Auto ID is an accessory available for the BD Alaris infusion platform.

Defeated in our lab with a pair of scissors. The reporting facility opened it with a barrel cabinet key

# Lock Boxes & Bad Actors – Electronic Locks



Electronic locks with auditing capability and tracking – may have limitations as well...

# Accessing Tubing & Bags





# Tubing and Bags

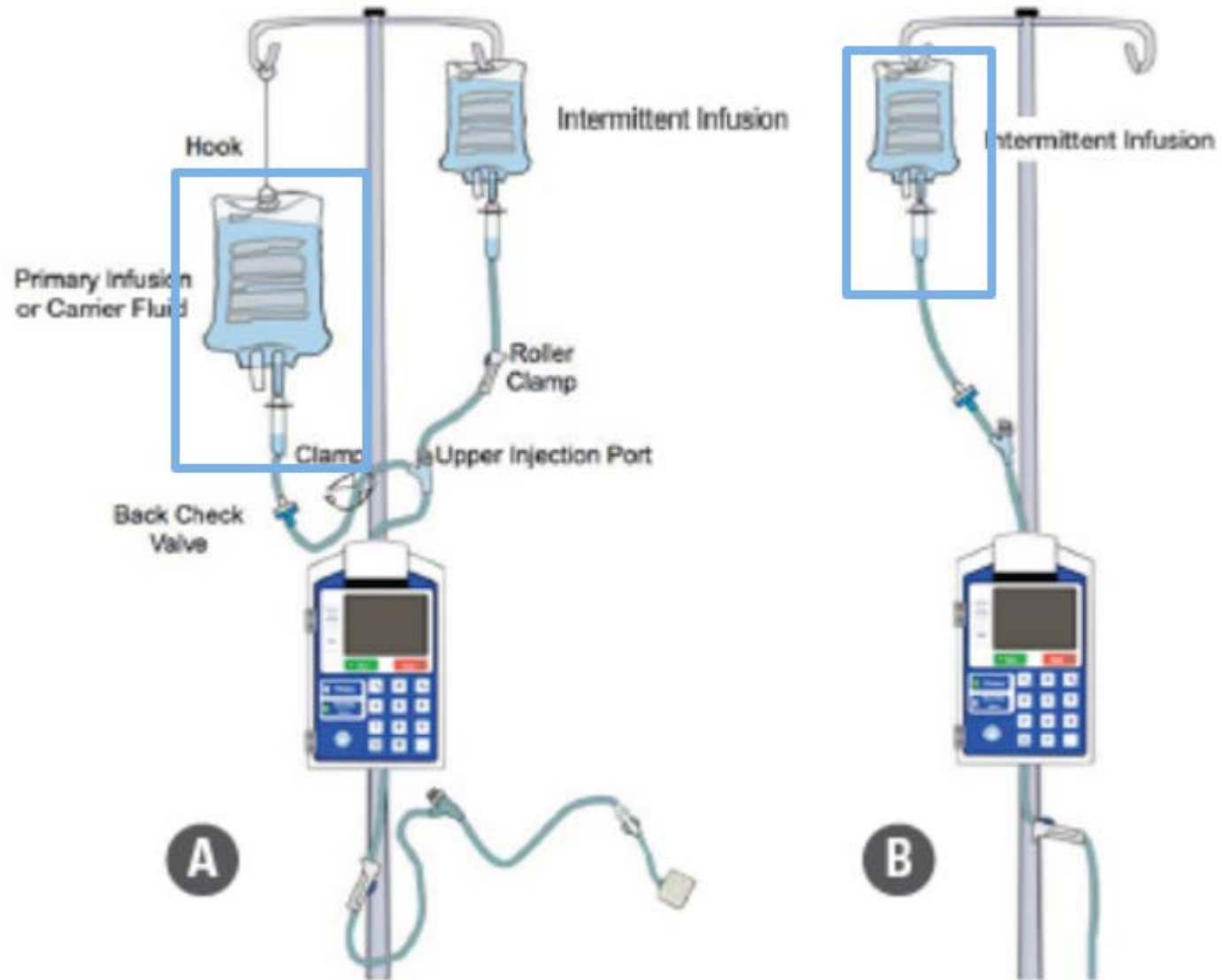


Illustration courtesy of ISMP



Photo: Davis/ECRI

# Automated Dispensing



# Automated Dispensing Cabinets



Above photos: Shutterstock



Above photo: courtesy ISMP

# Vials and Pre-filled Syringes



# Vials and Pre-filled Syringes

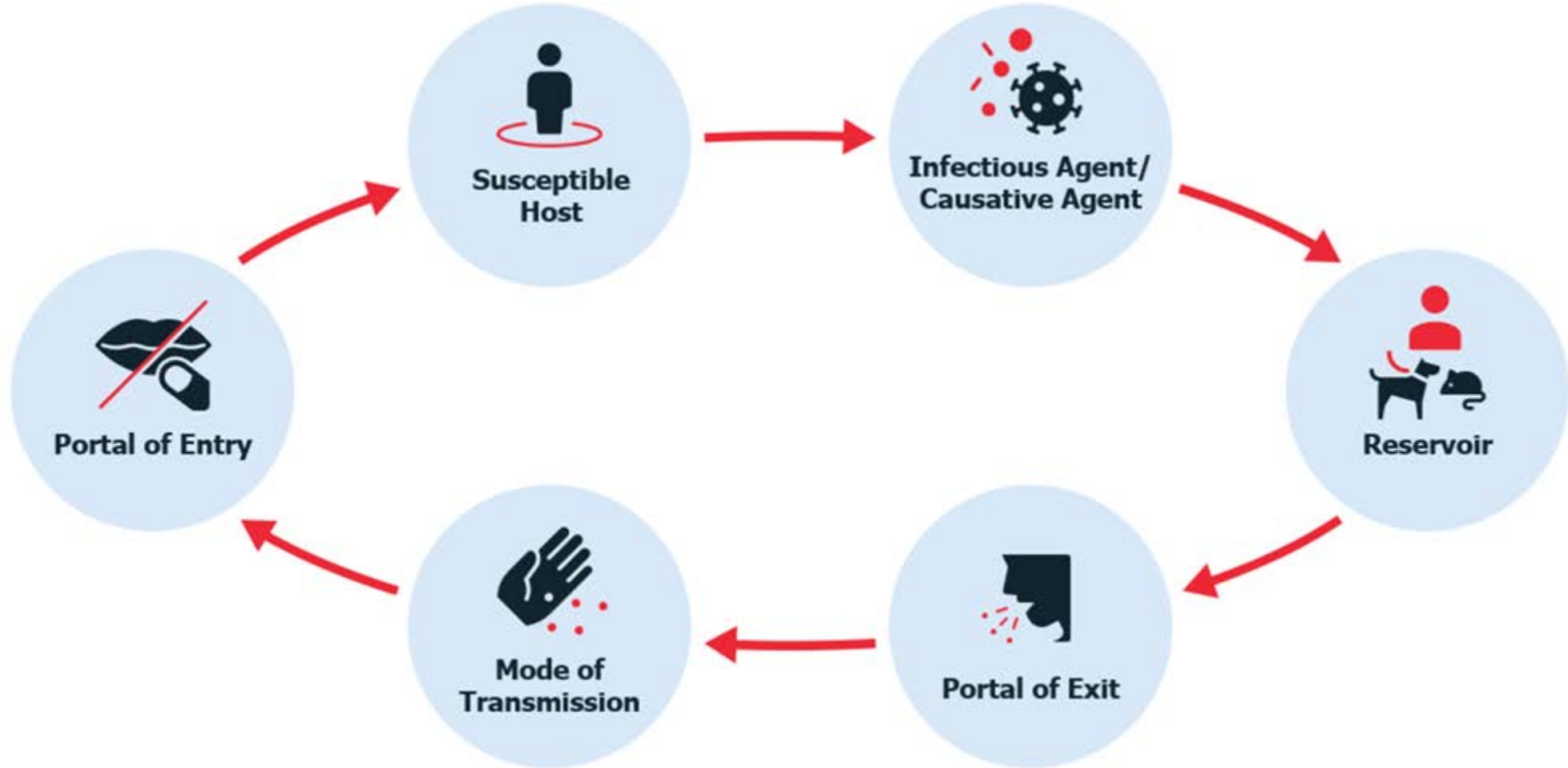


<https://youtu.be/yFAAYNUcmuY?si=tDxv4I8MwAGsdhan>



Images and photos courtesy ISMP

# The Chain of Infection



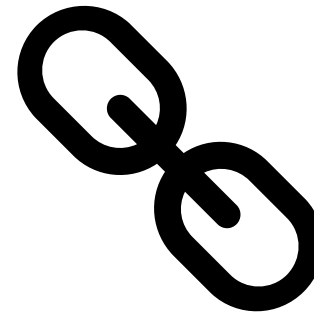
# Breaking the Chain, Detection, & the Future

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# Break The Chain – Surveillance and the Infection Preventionist

## — Assess for facility/organization awareness

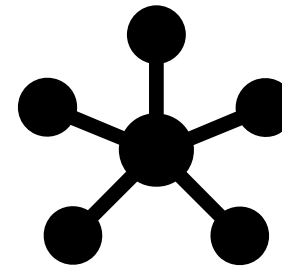
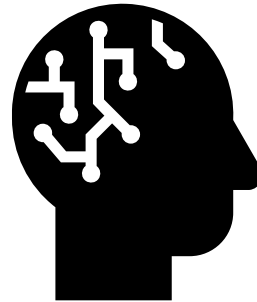
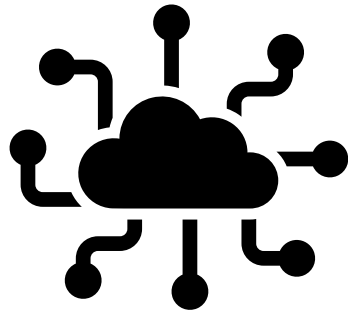
- Surveillance
  - Pharmacy data
  - Human Resources
  - Quality audits
  - Other staff
  - Clinical data/oddities





# Future Detection of Surrogate Clinical Indicators of IV Drug Diversion

- Using a surveillance system to identify and treat newly acquired healthcare hepatitis C infection (and other infections)
- Connecting the dots...



# Start a Formal Program Targeting Prevention: ASHP Guidelines 2022

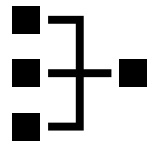
## — Core elements

- Legal & regulatory
- Organization oversight & accountability



## — System-level controls

- Human Resources/employee health
- Automation & technology
- Monitoring & surveillance
- Investigation & reporting



## — Individual level controls

- Chain of custody
- Storage & security
- Internal pharmacy controls
- Prescribing & administration
- Returns, wastes, & Disposal



<https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx>

<https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/controlled-substances/diversion-prevention-whats-a-pharmacy-to-do.pdf>

