Preventing theft of drugs and controlled substances – a patient safety imperative

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Minnesota Department of Health campaign to respond to drug diversions
• Roadmap, toolkit, training, sample policies
• Flow chart for reporting suspect drug diversion

Mayo Clinic protocol - 77 best practices
• for storage, security, procurement, ordering, prescribing, preparation, dispensing, administration, inventory, recordkeeping, surveillance, investigation, education, QI

References

Berge KH et.al., Diversion of drugs within healthcare facilities, a multiple-victim crime: Patterns of diversion, scope, consequences, detection, and prevention. Mayo Clin Proc 2012;
Lawsuits Mount in Exeter Hep C Disaster

The FBI is investigating the case.

By Jason Claffey | Email the author | July 6, 2012

Exeter Hospital is now facing more than a dozen lawsuits after a hepatitis C outbreak infected 26 of its patients.

The outbreak was likely caused by a drug-stealing hospital worker who spread the disease through dirty needles, state health officials have said. A hospital worker also contracted hepatitis C, but officials have declined to say if that’s the person they suspect caused the outbreak. A criminal investigation has been launched into the matter.

Nearly 50 patients have joined a class-action lawsuit against the hospital, and about a dozen others have filed individual lawsuits. The litigation is being handled in Rockingham County Superior Court.

Medical Technician Might Have Exposed Hundreds To Hepatitis C

July 31, 2012

After five years of crisscrossing the country as a traveling medical technician, David Kwiatkowski landed at New Hampshire's Exeter Hospital in the spring of 2011. A full-time job in the hospital's cardiac unit soon followed.

It was at Exeter that federal prosecutors say the 33-year-old began to divert syringes of the drug Fentanyl. They say Kwiatkowski, who was arrested July 19, would inject himself with the painkiller, and then refill syringes with a saline solution. He is hepatitis C-positive, meaning those tainted needles might have spread the liver-damaging virus.

www.npr.org/blogs/health/2012/07/31/157618353/
Patients slam hospital, N.H. in hep C cases
Concord Monitor - Sep 21, 2012
The patients allege that they were infected with the virus by David Kwiatkowski, a 33-year-old laboratory technician who was arrested in July at a Massachusetts hospital. Kwiatkowski, who is due in court Oct. 9, is accused of drug diversion - stealing syringes ...

Class-action lawsuit eyed in hepatitis C cases
The Union Leader - Sep 22, 2012
He filed a complaint in Rockingham County Superior Court against the hospital in June and has since added the Nebraska-based Triage Staffing Inc., a health care company that hired and placed David Kwiatkowski at Exeter. “Even if the class-action is not ...

Hepatitis C Class-Action Suit Includes 169
Patch.com - Sep 23, 2012
Prosecutors said the outbreak was caused by hospital worker Dave Kwiatkowski, who allegedly spread his hepatitis C to at least 32 patients by injecting himself with their medication to get high. Kwiatkowski would allegedly inject himself then replace the ...

169 sign on to hepatitis C class action suit
NECN - Sep 22, 2012
Authorites allege David Kwiatkowski injected himself with medication intended for patients and then returned the contaminated needles for use in the hospital. Kwiatkowski worked at Exeter Hospital for 13 months. Three of McGrath’s clients spoke out Friday ...

Woman’s life ‘ruined’ by hepatitis C outbreak in New Hampshire
WCWB Boston - Sep 21, 2012
The cases are linked to lab technician David Kwiatkowski, who is accused of injecting himself with pain killers and then putting the used syringes back into use. "This is scary. It’s affecting everybody," said Betsy Smith, whose 5-year-old daughter has tested ...
Growing Awareness of Patient Safety Threat Associated with Narcotics Diversion

- Potential infection risks include bloodborne pathogens
- Three recent examples of Hepatitis C Virus (HCV) transmission associated with Fentanyl tampering

2004 – TX Hospital – Nurse Anesthetist

≥ 16 surgery patients infected

2009 – CO Hospital – Surgical Technician

≥ 24 surgery patients infected

2010 – FL Hospital – Radiology Technician

≥ 5 clinic patients infected

>13,000 patients notified of potential exposures and advised to seek testing
LIVING IN FEAR
Patients in hepatitis C case brace for fateful results

Hepatitis C Outbreak, Colorado 2009

• Outbreak detected by CO Health Department which had received 2 reports of acute hepatitis C
• HCV-infected surgery technician stole fentanyl syringes that had been predrawn by anesthesia staff and left unattended
• Tech refilled contaminated syringes with saline to swap with unused syringes
• 24 patients infected; nearly 6000 notified
  – Notification extended to ambulatory surgical center that employed the technician after she was fired by the hospital
• Technician sentenced to 30-year prison term

http://www.colorado.gov/cs/Satellite/CDPHE-DCEED/CBON/1251607766246
"How do you go to a hospital and then walk out of the hospital with hepatitis C from a dirty needle?"

http://www.thеспic.com/article/620350
"How do you go to a hospital and then walk out of the hospital with hepatitis C from a dirty needle?"
Outbreak of HCV infections at Florida hospital

- 3 cases of incident asymptomatic HCV infection among patients in transplant program
  - All had prior HCV RNA negative results
- HCV isolates found to be genetically related
- Investigation did not identify opportunities for:
  - Patient-to-patient transmission
  - Transmission through common device/product
  - HCW-to-patient transmission through exposure-prone procedure
- HCV transmission through drug diversion by HCV-infected HCW was considered and investigated

Outbreak of HCV infections at Florida hospital

- All 3 patients received narcotics in interventional radiology (IR) unit of the hospital
- 21 employees assigned to IR were recorded as working when each case received a narcotic
- All 21 employees tested for HCV infection
- Radiology technician found to be HCV-infected with virus that shared genetic fingerprint with the 3 cases
- Radiology tech confessed to narcotics diversion

Outbreak of HCV infections at Florida hospital

- 2 methods of diversion reported by the technician
  - Retrieval of syringes containing residual fentanyl from used sharps containers
  - Self-administration of fentanyl from a syringe that had been filled with fentanyl in preparation for patient care
    - Injected the fentanyl
    - Refilled the syringe with saline
    - Returned the filled syringe to patient care

- Total of 5 cases of HCV infection attributed to diversion by the HCV-infected technician

- Technician sentenced to 30 years in prison

Health Care–Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion

Walter C. Hellinger, MD; Laura P. Bacalis, RN; Robyn S. Kay, MPH; Nicola D. Thompson, PhD, MS; Guo-Liang Xia, MD, MPH; Yulin Lin, MD; Yury E. Khudyakov, PhD; and Joseph F. Perz, DrPH

Background: Three cases of genetically related hepatitis C virus (HCV) infection that were unattributable to infection control breaches were identified at a health care facility.

Objective: To investigate HCV transmission from an HCV-infected health care worker to patients through drug diversion.

Design: Cluster and look-back investigations.

Setting: Acute care hospital and affiliated multispecialty clinic.

Patients: Inpatients and outpatients during the period of HCV transmission.

Measurements: Employee work and narcotic dispensing records, blood testing for HCV antibody and RNA, and sequencing of the NS5B gene and the hypervariable region 1 of the E2 gene.

Results: 21 employees were recorded as being at work or as retrieving a narcotic from an automated dispensing cabinet in an area where a narcotic was administered to each of the 3 case patients; all employees provided blood samples for HCV testing. One employee was infected with HCV that had more than 95% NS5B sequence homology with the HCV strains of the 3 case patients. Quasi-species analysis showed close genetic relatedness with variants from each of the case patients and more than 97.9% nucleotide identity. The employee acknowledged parenteral opiate diversion. An investigation identified 6132 patients at risk for exposure to HCV because of the drug diversion. Of the 3929 living patients, 3444 (87.7%) were screened for infection. Two additional cases of genetically related HCV infection attributable to the employee were identified.

Limitation: Of the living patients at risk for HCV exposure, 12.3% were not tested.

Conclusion: Five cases of HCV infection occurring over 3 to 4 years were attributed to drug diversion by an HCV-infected health care worker. Studies of drug diversion and assessments of strategies to prevent narcotics tampering in all health care settings are needed.

Primary Funding Source: None.
St. Cloud nurse charged with painkiller theft

Article by: PAUL WALSH
Star Tribune
September 6, 2012 - 7:43 AM

A nurse who worked at St. Cloud Hospital for 17 years has been charged with stealing a powerful narcotic from at least 23 patients for his own use and replacing the painkiller with salt water.

Blake D. Zenner, 42, of Kimball, Minn., was charged Tuesday in federal court in Minneapolis with taking hydromorphone hydrochloride, a drug commonly sold as Dilaudid, which is used to relieve moderate to severe pain.

Along with being denied their prescribed painkiller, 23 patients in the same hospital unit developed infections because "there was contamination when the nurse removed the drugs from the IV [intravenous] bag,"
Driver in Gwinnett wrong-way crash jailed

Wednesday, Aug. 29, 2012

By David Ibata
The Atlanta Journal-Constitution

A 37-year-old Dacula woman who allegedly caused a wrong-way crash on Ga. 316 in Gwinnett County has been released from a hospital and was booked into the Gwinnett County Detention Center on Friday, jail records show.

Beverly Lynne Wilkins is suspected of having been under the influence of a powerful sedative she had stolen from Gwinnett Medical Center at the time of the wreck, police said.

Wilkins was jailed shortly after noon, charged with five counts of causing serious injury by vehicle and one count each of driving on the wrong side of the road, reckless driving and improper/erratic lane change, jail records showed. She was being held on bonds totaling $32,400.

Police said that after the Aug. 24 accident, they found an IV bag and a needle in the front seat of Wilkins’ wrecked SUV, and later recovered the drug Propofol from her purse.

Wilkins is believed to have injected herself with two vials of the drug just before the accident about 10:30 p.m. Aug. 24 in the westbound lanes of Ga. 316 at Winder Highway, police said.
Healthcare Narcotics Theft a.k.a. “Diversion”

- Narcotics tampering has emerged as the leading cause of provider-to-patient HCV transmission
  - Other types of infections and patient harms
- Prevention needs extend beyond provider education or traditional “infection control”
  - Limit opportunities for access or deception
  - All healthcare settings where narcotics are utilized
  - Recognition, investigation, and reporting
- Highlights need for safety-engineered solutions and a comprehensive systems approach
“Diversion” means:

- **The transfer of a controlled substance from a lawful to an unlawful channel of distribution or use.** (Uniform Controlled Substances Act (1994))

- **Any criminal act involving a prescription drug.** (National Association of Drug Diversion Investigators)

- **For the purposes of this discussion, we will mainly limit our comments to controlled substances.**
Introduction

• We have an ongoing epidemic of prescription drug diversion and abuse in America

• Some of those becoming addicted work in the healthcare setting

• Some of these addicted healthcare workers divert (steal) drugs from their patients and their employers to support their addiction
While some call addiction a “victimless crime,” supporting that addiction by drug diversion from the health care workplace is a multi-victim crime.

- It puts at risk the patient
- It puts at risk the addicted diverter
- It puts at risk their co-workers
- It puts at risk their employer
- It puts at risk society in general
Why the Epidemic?

- Availability
- Perception of safety in relation to street drugs
- Profit motive
# Availability

Table 1. *Retail sales of opioid medications (grams of medication 1997–2005)*

<table>
<thead>
<tr>
<th></th>
<th>1997</th>
<th>2005</th>
<th>% of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>518,737</td>
<td>5,362,815</td>
<td>933%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>4,449,562</td>
<td>30,628,973</td>
<td>588%</td>
</tr>
<tr>
<td>Fentanyl Base</td>
<td>74,086</td>
<td>387,928</td>
<td>423%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>241,078</td>
<td>781,287</td>
<td>244%</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>8,669,311</td>
<td>25,803,544</td>
<td>198%</td>
</tr>
<tr>
<td>Morphine</td>
<td>5,922,872</td>
<td>15,054,846</td>
<td>154%</td>
</tr>
<tr>
<td>Meperidine</td>
<td>5,765,954</td>
<td>4,272,520</td>
<td>-26%</td>
</tr>
<tr>
<td>Codeine</td>
<td>25,071,410</td>
<td>18,960,038</td>
<td>-24%</td>
</tr>
</tbody>
</table>

Figure 1. Annual Numbers (in Millions) of New Nonmedical Users of Pain Relievers Aged 12 or Older: 1970-2001
Specific Illicit Drug Dependence or Abuse in the Past Year among Persons Aged 12 or Older: 2010

National Survey on Drug Use and Health- 2010
Opioid Pain Relievers

CDC Data
Unintentional Drug Overdose Deaths by Major Type of Drug, United States, 1999-2008

- Opioid Analgesic
- Cocaine
- Heroin

Number of Deaths

Leading cause of accidental death

Figure 1. Motor vehicle traffic, poisoning, and drug poisoning death rates: United States, 1980–2008

NOTE: In 1999, the International Classification of Diseases, Tenth Revision (ICD–10) replaced the previous revision of the ICD (ICD–9). This resulted in approximately 5% fewer deaths being classified as motor-vehicle traffic–related deaths and 2% more deaths being classified as poisoning-related deaths. Therefore, death rates for 1998 and earlier are not directly comparable with those computed after 1998. Access data table for Figure 1 at http://www.cdc.gov/nchs/data/databriefs/081_tables.pdf#1.

# Abused Pharmaceutical Substances

National Association of Drug Diversion Investigators, Inc.
410-321-4600  www.naddi.org

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Brand Name</th>
<th>Dosage</th>
<th>Image</th>
</tr>
</thead>
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<tr>
<td>Alprazolam</td>
<td>Xanax®</td>
<td>0.25 mg, 0.5 mg, 1 mg, 2 mg</td>
<td><img src="image1.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Carisoprodol</td>
<td>Soma®</td>
<td>350 mg</td>
<td><img src="image2.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Klonopin®</td>
<td>0.5 mg, 1 mg, 2 mg</td>
<td><img src="image3.jpg" alt="Image" /></td>
</tr>
<tr>
<td>bands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amphetamine Mixture</td>
<td>Adderall®</td>
<td>5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, 25 mg</td>
<td><img src="image4.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Caffeine/Acetaminophen</td>
<td>Snop®</td>
<td>1 mg</td>
<td><img src="image5.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Tylenol CC/Caffeine®</td>
<td>30 mg/300 mg, 60 mg/200 mg, 10 mg/650 mg</td>
<td><img src="image6.jpg" alt="Image" /></td>
<td></td>
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<tr>
<td>Dextromethorphan</td>
<td>Robitussin®</td>
<td>5 mg/500 mg</td>
<td><img src="image7.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Naproxen®</td>
<td>25 mg/500 mg, 50 mg/500 mg</td>
<td><img src="image8.jpg" alt="Image" /></td>
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<tr>
<td>Butorphanol Tartrate</td>
<td>Stadol NS®</td>
<td>10 mg/ml, 80 mg/ml</td>
<td><img src="image9.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Darifenacin</td>
<td>Intas®</td>
<td>5 mg, 7.5 mg, 10 mg</td>
<td><img src="image10.jpg" alt="Image" /></td>
</tr>
<tr>
<td>Meperidine</td>
<td>Demerol®</td>
<td>0.5 mg, 1 mg, 2 mg, 10 mg, 50 mg</td>
<td><img src="image11.jpg" alt="Image" /></td>
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<tr>
<td>Lorazepam</td>
<td>Ativan®</td>
<td>0.5 mg, 1 mg, 2 mg, 20 mg</td>
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<tr>
<td>Methylphenidate</td>
<td>Ritalin®</td>
<td>5 mg, 10 mg, 20 mg</td>
<td><img src="image13.jpg" alt="Image" /></td>
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<tr>
<td>Trazodone</td>
<td>Desyrel®</td>
<td>50 mg, 100 mg</td>
<td><img src="image14.jpg" alt="Image" /></td>
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<tr>
<td>Oxycodone</td>
<td>OxyContin®</td>
<td>5 mg, 15 mg</td>
<td><img src="image15.jpg" alt="Image" /></td>
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<tr>
<td>Tramadol</td>
<td>Ultram®</td>
<td>50 mg, 100 mg</td>
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<tr>
<td>Valproic Acid</td>
<td>Depakene®</td>
<td>50 mg, 100 mg, 200 mg</td>
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<tr>
<td>Naltrexone</td>
<td>Vivitrol®</td>
<td>50 mg, 100 mg, 200 mg</td>
<td><img src="image18.jpg" alt="Image" /></td>
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</tbody>
</table>

*Images are not to scale and may not accurately represent the actual size of the tablets.*
OVER THE COUNTER

Guaifenesin with dextromethorphan (Robitussin® DM)

(Diminished actual size)

Dimenhydrinate (Dramamine®)

Chlorpheniramine with dextromethorphan (Coricidin® HBP cough cold)

(Not shown actual size)
Past Year Initiates for Specific Illicit Drugs, Ages 12+: 2005

Numbers in Thousands

- Marijuana: 2,193
- Inhalants: 1,286
- Stimulants: 877
- Sedatives: 247
- Pain Relievers: 647
- Cocaine: 872
- Ecstasy: 615
- LSD: 243
- Heroin: 108
- PCP: 77
Source Where Psychotherapeutics Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2005

Percent of Past Year Users

- Pain Relievers
- Tranquilizers
- Methamphetamine
- Stimulants

- Other
- Bought on Internet
- Drug Dealer/ Stranger
- 1 or More Doctors
- Bought/Took from Friend/ Relative
- Free from Friend/Relative

Bar chart showing the percentage of past year users for different types of psychotherapeutics and their sources.
Addiction comes to work

- Any healthcare facility which houses controlled substances is at risk for diversion
- Any employee is capable of diversion
- Vigilance is mandatory
- Diversion often happens by seducing co-workers into policy violations e.g., “virtual witnessing” of waste
- Often these are otherwise stellar employees
Number of Events of Theft or Loss by Drug

- Hydrocodone: 61
- Oxycodone: 58
- Hydromorphone: 47
- Morphine Sulfate: 45
- Fentanyl: 26
- Meperidine: 14
- Zolpidem: 13
- Lorazepam: 10
- Methadone: 8
- Midazolam: 7
- Codeine: 6
- Amphetamine Aspartate: 6
- Methylphenidate: 5
- Sufentanil: 4
- D-Amphetamine: 4
- Alprazolam: 4
- Propoxyphene: 3
- Dextroamphetamine: 3
- Clonazepam: 3
- Zaleplon: 2
- Testosterone: 2
- Diazepam: 2
- Cocaine: 2
- Other: 10
High profile fentanyl tampering – Catalyst for change

Drug Diversion & Prevention Task Force

- Failure Mode Effects Analysis
- Surveillance Program
- Investigation & Response
Medication Diversion Prevention Coordinator

- Initial point of contact for all suspected diversions
- Coordinates the preliminary investigation
- Initiates and coordinates meetings with Drug Diversion Response Team (DDiRT)
- Participates in intervention
- Interfaces with law enforcement when needed
- Oversees diversion surveillance program and team members
- Maintains data base of cases
- Assures proper reporting to authorities before case closed
Reporting Process

- Established “Hot Line” – 24x7 pager
- Institutional compliance line
- Signage posted on Pyxis machines & other locations
- Anonymous reporting if desired
Surveillance Program

- Report generation & data analytics
  - ADM data utilized
  - 26 + reports (daily, weekly, monthly)
  - Analytics tool (vendor, in-house)
- Waste collection & analysis
  - CS waste returned to pharmacy in anesthesia areas, ED, GI Labs (expand to other areas?)
  - Randomly assayed (Quantitative vs. Qualitative)
  - Strict reconciliation of records
- Audits
  - Order vs. removal vs. administration vs. pain scales
  - Manual vs. electronic
- Review of Paper CS Inventory & Disposition records
- Camera Surveillance (High volume areas, “For Cause” surveillance)
Drug Diversion Response Team (DDiRT)

- A multidisciplinary team to provide expert consultation and direction regarding suspected medication diversion cases
- Meets within 24 hours – includes applicable manager, HR partner, etc.
- Reviews and discusses available evidence to determine if potential diversion exists
- Recommends next steps (e.g. further monitoring, immediate intervention, employee interview, etc.)
- Internal / External reporting
- Ensures consistent, standardized approach
Elements of Best Practice

- Developed by Pharmacy with consensus input from others.
- Purpose to establish core structure & processes that would optimize the detection and minimize the occurrence of controlled substance diversion.
- 77 elements. Ongoing review.
- Categorized as Tier 1 / Tier 2.
- Used as foundation for independent assessments across other sites.
- Green-Yellow-Red stop light assessment grid to allow tracking of progress.
Committee / Management Oversight

- Medication Diversion and Prevention Subcommittee x 2
- Local (Rochester)
  - Pharmacy & Therapeutics Committee - Medication Diversion and Prevention Subcommittee
  - Multidisciplinary
- Enterprise
  - Mayo Clinic Clinical Practice Committee - Medication Diversion and Prevention Subcommittee
  - Multidisciplinary; Multiple sites; Enterprise based
Experiences / Lessons Learned

- This is a journey...not a destination
- It’s all about the details
- Focus on high risk areas first (e.g. anesthesia, procedural areas, ED) but don’t forget about the unusual areas (e.g. animal research, clinical laboratory)
- Robust surveillance is critical
- Educate and be transparent...solicit the help of the 99.9%
- Requires strong, active multidisciplinary leadership
- Optimize technology
- Requires resources
MN Coalition to Prevent Drug Diversion

- MN Department of Health
- MN Hospital Association
When/How to involve Law Enforcement?

- MN Coalition identified this as a contentious issue
- Recommended establishing contact with local LE before the need arises
- Real world: We still struggle with this
- “Significant Loss” must be reported to DEA within one business day
- ANY THEFT must be reported to DEA
In Summary

• Theft of controlled substances is common in the health care workplace
• If you look, you will find it
• Many divert, even employees with “no access to drugs”
• Learn from each episode- diverters are often very clever
• Waste stream is under constant attack
In Summary

• “The best interest of the patient is the only interest to be considered”  W.J. Mayo- 1910

Therefore:

• Have a system in place to deal with diversion episodes in an organized and pre-planned manner, as

• Responding to these episodes “on the fly” creates undue risks to all involved
Question and answer
Faculty

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Chair, Medication Diversion Prevention Committee, Mayo Clinic, Rochester

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Director of Pharmacy Services, Mayo Clinic

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

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Vice president, Premier Safety Institute, Premier healthcare alliance