

Diversion is a Threat to Patient Safety: Adopting Best Practices for Safe Management of Controlled Substances



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Learning Objectives

Following the completion of this activity, participants will be able to:

1. Recognize the impact of diversion in the healthcare system and the safety of medication use.
2. Identify nursing practices that support medication safety and eliminate risk for drug diversion.



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Adopting Best Practices for Safe Management of Controlled Substances

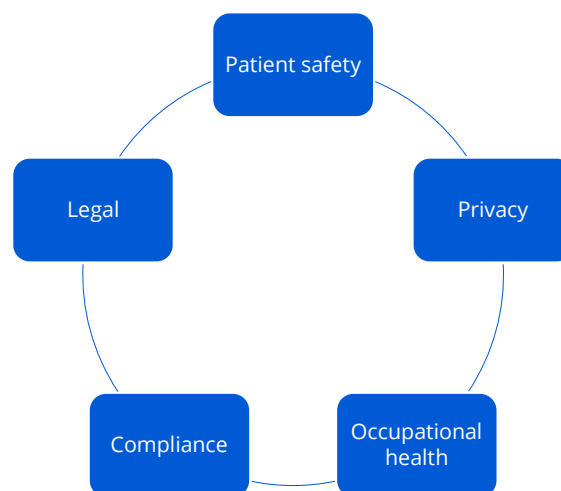
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Diversion: A threat to patient safety

Drug diversion:
prescription
drugs obtained
or used illegally

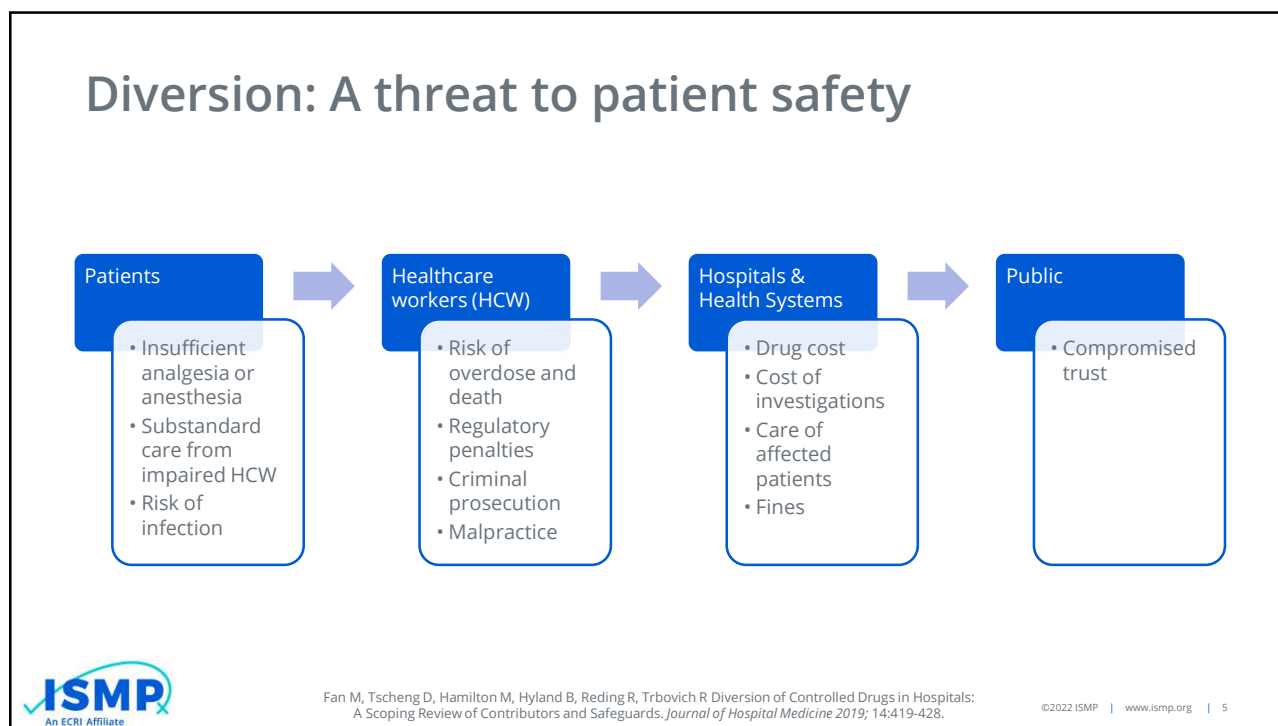


<https://www.cdc.gov/injectionsafety/drugdiversion/index.html?msclkid=dc3ef86ba62c11ecb37ca867fb86b704>

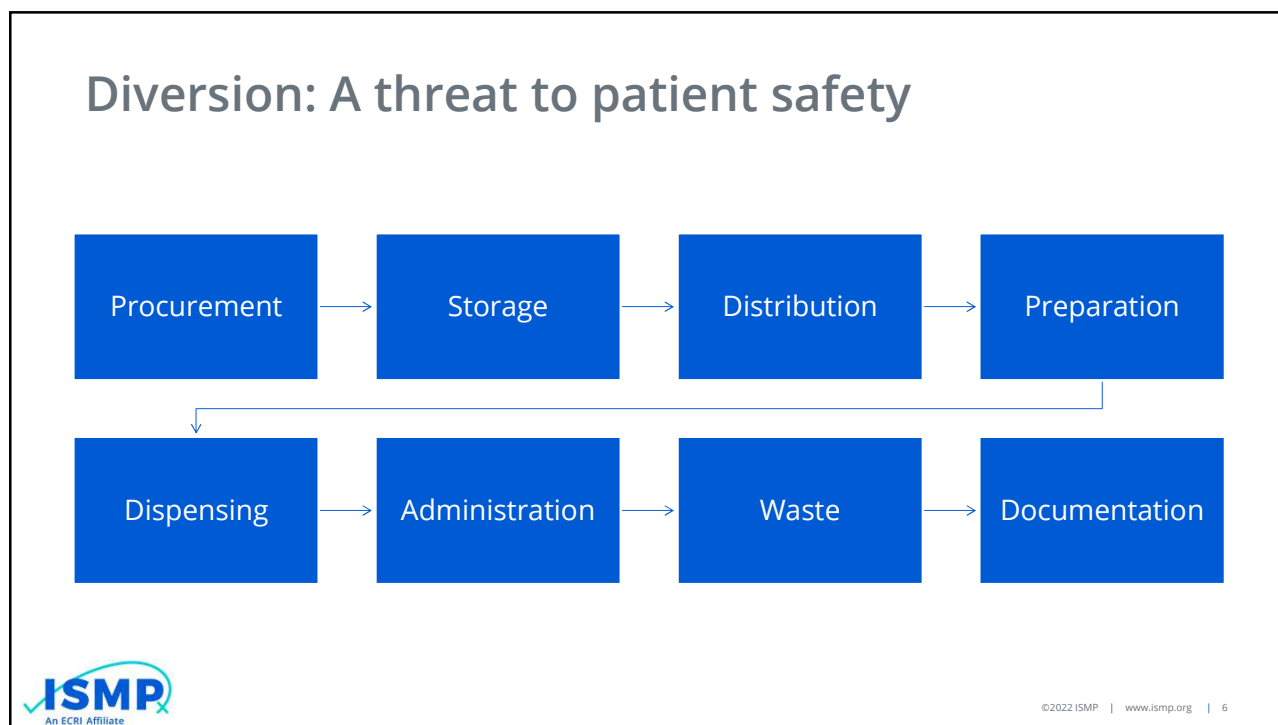
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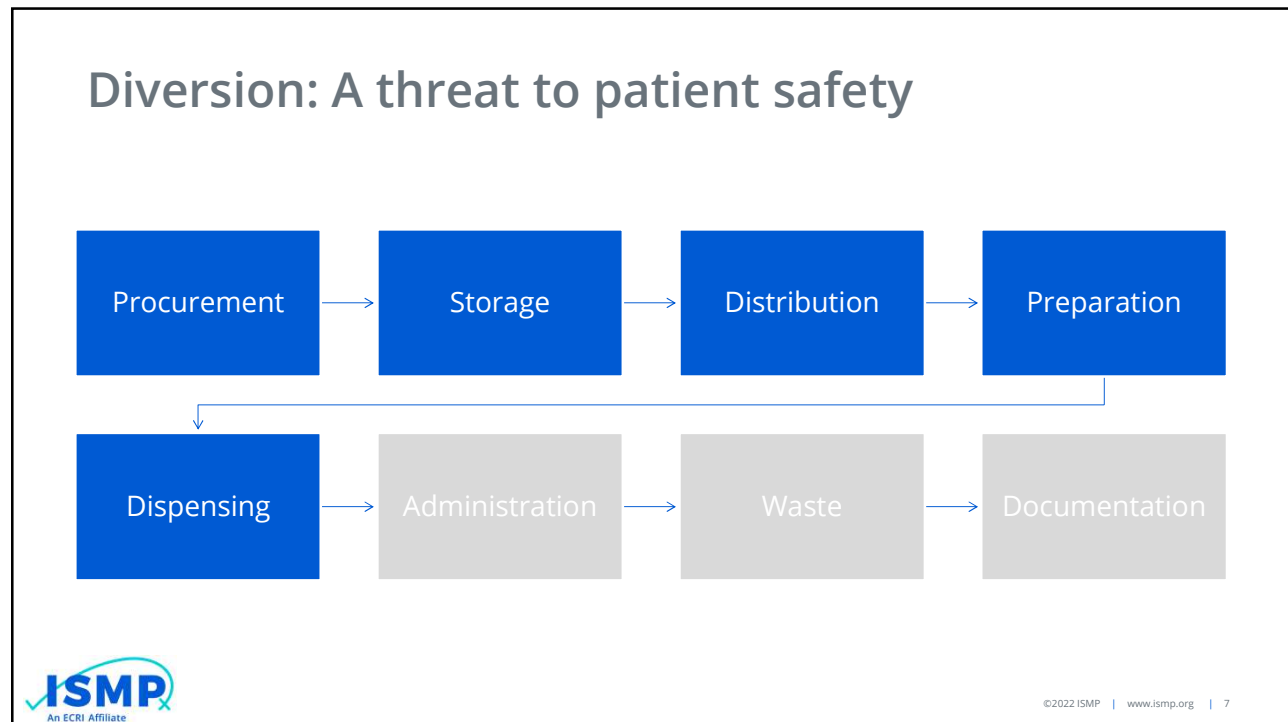


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Procurement

Practices that support medication safety and eliminate risk for drug diversion

- Authorized purchasers
- Receipt process
- Product selection
- Limit the number of individuals with authorization to purchase
- Different individual receives and verifies delivery
- Ready-to-use
- Variety of doses available to avoid waste
- Tamper evident packaging

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Storage

Practices that support medication safety and eliminate risk for drug diversion

- Location
- Inventory verification
- Separation of products
- Secured storage; monitored; access limited
- Removal and routine inventory count verification; blinded count where possible
- Integrity of packaging
- Discrepancy investigation
- Strategies to separate products in storage locations



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Distribution

Practices that support medication safety and eliminate risk for drug diversion

- Par levels
- Replenishment process
- Verification
- Return to stock
- Define and monitor compliance with par levels
- Removal, delivery, receipt is double checked and audited
- Barcode verification where possible
- Manual calculations audited
- Integrity of packaging



<https://www.ismp.org/resources/guidelines-safe-use-automated-dispensing-cabinets>

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Preparation

Practices that support medication safety and eliminate risk for drug diversion

- Repackaging
- Compounding
- Avoid storing partial packages
- Utilize tamper evident packaging
- Avoid waste; expect overfill
- Measurement verification



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Dispensing Prescriptions

Practices that support medication safety and eliminate risk for drug diversion

- Prescription verification
- *I had run out of my ADHD medication before the month of January was over. I thought it was odd.... I counted it 3 to 4 times I only had 50 and the quantity on the bottle reads 60*
- *Pharmacy dispensed incorrect quantity of a controlled substance. They were supposed to fill a 90-day supply; they charged for 90, but only dispensed 30*
- *My prescription for Buprenorphine/Nalox 8MG/2MG SL TAB was ready for pick up; the prescription was for 28 & I only received 23! I read an article in the local newspaper about a sting operation where an employee was caught on camera stealing medications when filling prescriptions*



<https://consumermedsafety.org/>

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Other safety risks

Practices that support medication safety and eliminate risk for drug diversion

- Waste procedures
- Patient lists
- Infusions
- Unit closures
- Hard/software downtime
- Staff turnover



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Other safety risks

Practices that support medication safety and eliminate risk for drug diversion

- Patient's own supply
- Chain of custody
- Handoffs between practitioners
- Reconciliation with medical record
- Safe prescribing
- Staff education and resources



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- Division of Public Health Services (DPHS) was notified of 4 newly diagnosed hepatitis C virus (HCV) infections in this area
- Initial investigation noted a possible link to the hospital cardiac catheterization laboratory (CCL)
 - Infected persons: 3 CCL patients and a CCL technician
 - HCV testing identified an additional 32 of 1,074 CCL patients infected with same strain
- The investigation revealed:
 - evidence of drug diversion by the HCV-positive CCL tech
 - gaps in controlled medication control (drawn syringes left unattended)
 - higher fentanyl use in procedures where there were confirmed cases
 - card key access records and patterns indicating that the technician was present during days when transmission occurred
 - erratic behavior of this unlicensed tech noted by staff, but unreported^{1,23}

Case Study: Outbreak of Hepatitis C

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HCV infections compared to procedure dates

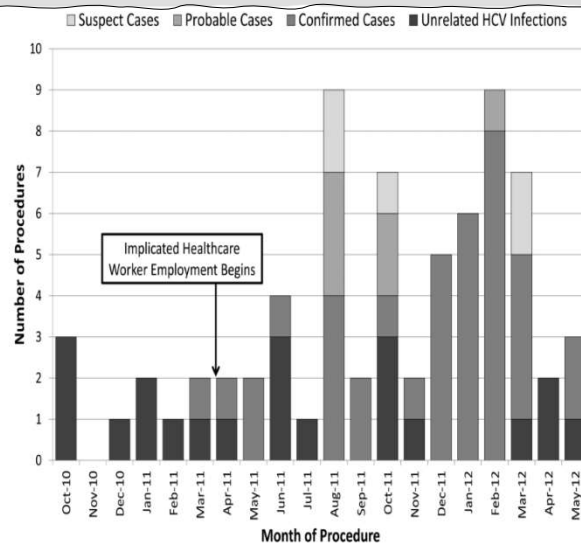


Figure 3. Procedure dates by month for outbreak- and non-outbreak-related hepatitis C virus (HCV)-positive patients; drug diversion-associated HCV outbreak, New Hampshire.

Alroy-Preis S, Daly ER, Adamski C, Dionne-Odom J, Talbot EA, Gao F, Cavallo SJ, Hansen K, Mahoney JC, Metcalf E, Loring C, Bean C, Drobeniuc J, Xia GL, Kamili S, Montero JT; New Hampshire and Centers for Disease Control and Prevention Investigation Teams. Large Outbreak of Hepatitis C Virus Associated With Drug Diversion by a Healthcare Technician. Clin Infect Dis. 2018 Aug 31;67(6):845-853. doi: 10.1093/cid/ciy193. PMID: 29767683. This article is work of the United States government. Such works are public domain.

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What is Drug Diversion?

- Lack of a widely accepted best practice or guidelines in literature to improve diversion detection; lack of evidence-based educational approach to prevent and detect^{10,30,32,39}
 - **Drug Addiction:** a chronic disorder characterized by compulsive drug seeking and use despite adverse consequences²⁶
 - **Drug Diversion:** “removal of Drug-Enforcement Admin (DEA)-scheduled medication from and within the lawful process of a hospital or healthcare system to an unlawful channel of distribution or use”³⁰ (p. 1158)
 - Addiction is the number one reason for diversion^{21,32,39}
 - **Impaired practice:** “functioning poorly or with diminished competence, as evident in changes in work habits, job performance, appearance or other behaviors...in any setting”² (p. 59)
 - **Substance Use Disorder (SUD):** can be diagnosed by criteria that specify a pattern of pathological behavior on a continuum: impaired control, social impairment, risky use, and pharmacological criteria¹¹
 - **Medications most often diverted:** opioids most frequent (Fentanyl), anabolic steroids, depressants, hallucinogens, stimulants^{3,11,21,40}





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Cost of Drug Diversion

- **Patients:** are at risk for ineffective treatment (e.g. inadequate analgesia), substandard care from impaired clinicians, infections from contaminated medication delivery, and from adverse reaction to incorrect medication administration^{3,10,26,29,33,40,41,43}
- **Healthcare (HC) worker who diverts:** impact on personal health; impaired performance; loss of license, loss of trust from family, patients, co-workers; criminal record; malpractice actions²⁶
- **Co-workers:** may contribute to diversion with/without their knowledge, sense of betrayal, negative consequences for failure to report, stress of added workload^{3,14,31,41}
- **Facility:** poor work quality (absenteeism, turnover, reduced productivity), civil and criminal penalties, financial loss, erosion of public trust^{18,26,28}
- **Healthcare:** annual drug diversion cost in US estimated at \$25 billion, reduced workforce³²
- **Professional image of nursing:** loss of public trust^{19,22}

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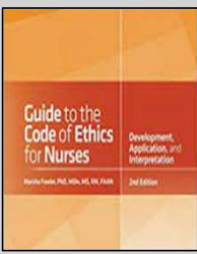






Governance and Guidance



National Council of State Boards of Nursing | NCSBN

- **Governmental Oversight**
 - Controlled Substances Act 1970, DEA (Drug Enforcement Agency), The Joint Commission, Centers for Disease Control and Prevention (CDC), Americans with Disabilities Act^{19,21,28,41}
 - **Medicare Conditions of Participation:** Hospitals must provide a safe care environment for patients, with prevention of tampering and substitution and must have ongoing surveillance to identify infectious risks, communicable disease concerns²⁸
- **Nursing Profession**
 - **Nurse Practice Act (NPA):** outlines scope of practice, protects health, safety and well being of state's residents^{11,13,22,35}
 - **State Boards of Nursing:** provide regulatory oversight of the NPA to ensure public safety; authorized to discipline for violations of NPA^{11,13,22}
 - **American Nurses Association (ANA) Code of Ethics:** "nurses must protect the patient, the public, and the profession from potential harm when practice is impaired"² (p. 9)
 - **Infusion Nurses Society (INS):** Standard 1.5: "Ethical principles are used as a foundation for decision-making. The clinician acts as a patient advocate; maintains patient confidentiality, safety, and security; and respects, promotes, and preserves human autonomy, dignity, rights and diversity."¹⁵ (S13)

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Prevalence in Nursing

*... "91.5% of the nurses with substance dependence in this study were currently working in nursing positions and not known by either their employer (97.5%) or regulator (98%)."*²² (p. 67)

- Nationwide prevalence of substance abuse is increasing¹¹
- Opioids felt to be highest abused medication in US and Canada, despite acknowledgement of universally inadequate pain control
 - Urgent need to effectively prevent/reduce misuse of drugs while still providing access to adequate pain management⁴²
- Estimated that 15% of HC professionals are impaired or in recovery from alcohol and/or drug use⁴¹
- Substance misuse, abuse, addiction may be as high as 20% in nursing¹⁶
 - Involves high percentage of those prior to entry into nursing profession^{13,20,26,37}
 - Anonymous survey of nurses currently/recently in a peer health assistance (PHA) program:
 - 48% reported drug or alcohol use at work
 - 40% felt competency level was affected by their use while on duty
 - Over 2/3 felt the problem could have been recognized sooner⁶
- Study of prevalence of SUD in nursing:
 - 23.2% felt they needed help but had not asked for assistance²²

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Impact of COVID-19

- Less research conducted due to competing priorities
- Constantly changing workflows as pandemic evolved with little to no time to monitor compliance
- Drug shortages, varieties of packaging/dosing making tracking more difficult
- Relaxed restrictions on prescriptions of some medications
- Weakened support systems for highly stress staff
- Perception among nurses that their quality of care declined
- Increased maladaptive coping process: psychological trauma, burnout
- Increased travel nursing, reduced surveillance and ability to track and investigate across state lines^{8,12,14,24,25,36}

FOREVER CHANGED

Fear of infecting own family

Mental Health Crisis NOW!!

PTSD Anxiety Depression

Amplified Vulnerabilities

Tsunami of DEATH

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Substance Abuse as Chronic Illness

- **INS Standard 11: Adverse and Serious Adverse Events** “Improve safety within an organization through prevention focused approach through: culture of safety, process improvement rather than blaming the clinician; coaching safe behavioral choices.”¹⁵ (S43)
- **Nursing as a trusted profession:** stigma of getting caught and viewed negatively by colleagues and public; fear of exposing a colleague allows diversion to continue²⁶
 - When viewed negatively, supports maladaptive behaviors, not recovery²⁷
 - The general outlook on patients who abuse drugs impacts how the professional who diverts feel that they will be treated by others in their profession³⁴
- **Need to find balance between:**
 - Public protection and the safety and compassion for an individual with chronic disease^{11,16,26,39}
 - Confidentiality for the individual and the need to reverse the “culture of silence”^{19,34}
- **Need to view as chronic disease** with remission and relapses, that can be treated with sufficient support^{11,27,37,38}
 - Will explore using the lens of primary, secondary, tertiary prevention^{14,27,37,41}

“The nursing profession promotes a nonpunitive environment that encourages rehabilitation and recovery for impaired nurses”³¹ (p. 12)

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Primary Prevention

- **Primary prevention:** aims to prevent disease or injury before it ever occurs¹⁸
- **INS Perspective:**
 - “Standard 5.1: To provide for patient safety and public protection, clinicians meet licensing requirements and core competencies according to their specific profession.
 - 5.2 Due to the invasive, high-risk nature, the clinician with responsibility for the safe delivery of infusion therapy...demonstrates competency.”¹⁵ (S26)
- **Failure Modes Effects Analysis (FMEA):**
 - Diversion is very difficult to detect and investigate when suspected
 - Systematic approach should be utilized to identify vulnerabilities for diversion in multiple processes and workflows^{11,16,26,39}
- **Risk analysis:**
 - Access: considered a chief causative factor, but may not be the root cause
 - Stress: traumatic work environment, stigma of inability to cope
 - Attitudes: justification of abuse, “pharmacological overconfidence”
 - Education: vast learning needs in recognition of risk factors and behaviors in students and licensed nurses^{13,34}

“I was using so I could do my job, not just for the sake of using.”²⁶ (p.564)

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Primary Prevention	
ACCESS: <ul style="list-style-type: none"> • Automated dispensing cabinets to control access Updating staff access after leaving a unit Satellite pharmacy in areas that require rapid access to medications (O.R.) Limitations on override list Prompt removal of patients from system on discharge or transfer Limit temporary patient access • Removal and Administration processes Badge access, biometrics, prompt sign out Avoiding “just-in-case” removals Limiting amount that can be removed, no range orders Avoid saving of partial doses for later use Tamper-evident packaging, locked infusion pumps Waste at time of removal; do not allow “zero” waste • Monitoring, Post administration processes Camera surveillance, security patrols Consistent witness process Controlled substance inventories, discrepancies resolved Chain of custody for prepared/unused, wasted, and expired medications Tamper proof waste receptacles • Restrictions on access to prescription pads 	STRESS: <ul style="list-style-type: none"> Pre-employment screening Safe work environment Staffing ratios Reduction of work-related injuries Leadership and peer support Programs to reduce work-place violence
	ATTITUDE/EDUCATION: <ul style="list-style-type: none"> Culture of safety, personal accountability Just culture to address errors, performance Confidentiality Close monitoring of work-flows to assure compliance Staff education and competency development on risk factors and reporting structures Clear expectations for professional behavior <p>3,4,6,9-11,13,16,19-21,27,28,34,37,39-42</p>
	High Risk Areas: ICU, Emergency room, Surgery, long term care, oncology, psychiatry ^{4,14,19}

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CDC “One and Only Campaign”

- “Unsafe injection practices put patients and healthcare personnel at risk of disease transmission, including bacterial infections like MRSA or bloodborne pathogens like hepatitis C virus.”⁷
 - <https://www.cdc.gov/injectionsafety/one-and-only.html>
- **INS Standard 20:** Compounding/preparation of parenteral solutions & medications:
 - “Adhere to safe injection practices when preparing parenteral medications and solutions outside of the pharmacy environment
 - Use medications packaged as single dose or single use for only 1 patient.
 - Discard a single dose vial after a single entry
 - Use a new needle and syringe for every injection
 - Never use the same syringe to administer medication to more than one patient
 - Prepare medications immediately prior to administration
 - Do not withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration”¹⁵ (S59-60)

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Secondary Prevention

See Something,
Say Something

- **Secondary prevention:** aims to reduce the impact of a disease or injury that has already occurred¹⁸
 - A just culture facilitates early detection^{22,40}
 - Rapid removal from practice protects patients and facilitates rapid entry to treatment^{4,27}
 - Even if investigation does not detect diversion, it may uncover addiction and facilitate treatment³⁹
- **Barriers:** fear and embarrassment at exposure, concern for losing license (income/insurance), not aware of available resources, fear of criminal record, underestimation of the impact of their substance abuse^{6,22,26,34,38}
 - The person that diverts medications will not be likely to act until the problem has reached a critical level (e.g. causes patient harm)⁴¹
- Survey of nurses in or recently in peer health assistance (PHA) program:
 - 25% reported obtaining drugs in workplace
 - 12% ordered medications for their own use
 - 9% obtained medications from waste in the sharps container
 - 8% replaced drugs taken for themselves with other drugs
 - 27% acknowledged putting patients at risk with their behaviors⁶
- **Vastly under-reported:**
 - SUD in nursing is often unidentified, unreported, with nurses continuing to practice without benefit of recovery^{3,27,41}
 - Awareness: diversion can happen in variety of settings, including homecare, hospice^{5,14}
 - Termination by a facility, without reporting, passively expands diversion and increases risk to patients^{11,13,23}

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Secondary Prevention

"Nurses must protect the patient, the public, and the profession from potential harm when practice appears to be impaired."² (p. 12)

- **INS Safe Medication Administration:**
 - Standard 10 Documentation: accurate, complete, and objective; reflects continuity, quality and safety of care for all patient interactions (S40)
 - Standard 59: Infusion Medication and solution administration: "Administer solutions and medications prepared and dispensed by the pharmacy or as commercially prepared solutions and medications whenever possible."¹⁵ (S180)
- **Approach should be multi-faceted:**
 - Review all diversion cases thoroughly to continue to improve processes; careful to maintain confidentiality^{10,14,16,28}
 - Randomized drug testing, but will not detect someone diverting for someone else¹⁹
 - Drug diversion officer role³⁹
 - Facilities are to report theft or loss of controlled substances to the DEA^{4,19}
 - Testing may be done to detect saline replacement^{10,39}
- **ADC Report Examples:** usage per clinician, pain rating patterns, temporary patients, cancelled medication removal, full dose wasting, zero waste documentation, unverified orders, overrides
 - Need to investigate suspicious trends, validate data promptly^{4,16,30,39}
 - High traffic areas for surveillance: medication room, staff restroom, storage areas, soiled utility³⁹

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Early Recognition	
Risk Factors	Behaviors
<p>Work-related:</p> <ul style="list-style-type: none"> • Inconsistent work schedule • Role strain, high expectations at work • Exposure to trauma at work • Work-related injuries • Inadequate preventative measures in the work environment to limit access • Workplace violence, secondary trauma • Lower surveillance settings (home, hospice) <p>Personal:</p> <ul style="list-style-type: none"> • Depression, anxiety, chronic pain • History of sexual abuse • Family history of depression, alcohol, drug abuse • History of adverse childhood experiences (ACE) • High risk behaviors: previous abuse, socializing with others who abuse substances 	<ul style="list-style-type: none"> • Often very bright, inventive in concealing abuse • Changes in physical and/or emotional condition <ul style="list-style-type: none"> • Behaviors likely to depend on the substance being diverted/used • Unusual patterns of pain medication removal • Repeated absenteeism, tardiness, unreliability • Unusual patterns of medication waste • Unexplained disappearances during shift • Working extra shifts • Present in a unit when not scheduled • Denial, feel competent to self-medicate (often for chronic pain) • Lapses in clinical judgement often a late sign <p>1,5,6,11,14,19,20,26,34,38,39,41</p>

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Tertiary Prevention
<ul style="list-style-type: none"> • Tertiary prevention: aims to reduce the impact of an ongoing illness or injury that has long lasting effects¹⁸ • INS Perspective: Standard 6-Quality Improvement; Practice Recommendation: <ul style="list-style-type: none"> • “Foster a just culture and individual accountability through a focus on improving systems and processes by clinicians and leaders.”¹⁵ (s31) • Voluntary reporting: While most will deny when first confronted, may avoid disciplinary action if self-report and pursue rehabilitation^{11,39,41} • ATD (Alternative to Discipline) programs: <ul style="list-style-type: none"> • “generally administered by third party through contractual agreements with a state board of nursing—the nurse refrains from practice for a designated time while undergoing treatment, establishing sobriety and a program of recovery”³⁸ (p. 105) • Focus: short/long term needs, Individualization of plan, confidentiality^{19,22,39,42} • Needs to be individualized, allow feedback....if unquestioned compliance is mandated, it may cause resistance^{11,35} • Significant challenges during recovery period: licensure restrictions, insurance coverage, re-employment, shame/guilt, drain on colleagues²⁶ • What promotes success: <ul style="list-style-type: none"> • non-punitive atmosphere, knowledge that they may be able to maintain license, support of leaders/peer/friends, alleviating fear of punishment, assist in regaining employment^{6,22,26,27,34,35}

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Summary and Questions

- "Drug diversion is a patient safety issue, a patient privacy issue (e.g., patient records are inappropriately accessed to identify opportunities for diversion), an occupational health issue given the higher risk of opioid-related SUD faced by HCWs, a regulatory compliance issue and a legal issue."¹⁰ (p. 424)
- Educational imperative for HC students and staff on risk factors, behaviors to foster recognition
- Prevention measures include improving the workplace environment, assuring adherence to preventative workflows/processes
- Staff must understand their responsibility and the methods to report, while maintaining confidentiality
- **Recovery is achievable and sustainable:**
 - Early detection is critical followed by evidence-based treatment through a long-term monitoring program and drug testing; strives to retain nurses (students and licensed staff) and decreases risk to patients^{20,22,27}
 - ATD programs associated with increased success in recovery and return to practice^{30,38}

?

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