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Controlled Substances Diversion: Is Your ASC at Risk?

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Learning Objectives

- Discuss rates of abuse in healthcare professionals and list examples of the most commonly diverted controlled substances. Recognize opportunities to divert in the ambulatory surgery setting and how diversion occurs
- Explain financial implications related to diversions and recent settlements
- Propose strategies for diversion prevention in your surgery setting
- Apply real diversion cases to help prevent or recognize diversion in your surgery center

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Disclosures

Disclosure statement: the following individual has the following to disclose concerning possible financial or personal relationships with commercial entities (or their competitors) that may be referenced in this presentation.

- I have nothing to disclose

–Lea Schilit, PharmD, MS, CPh, RD, LD/N has nothing to disclose

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Where are We At? What are the Current Statistics?

- ~841,000 people have died since 1999 from drug overdoses
- 100,306 overdose deaths from May 2020 to April 2021
  - 275 per day or 11 per hour
  - 28.5% increase since 2019 (78,056)

CDC Understanding the Epidemic
CDC Drug Overdose Deaths

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COVID-19 and Overdose Deaths

- Synthetic opioids (fentanyl and primarily illicitly manufactured fentanyl), and methamphetamines primary driver of the increases in overdose deaths
- 78,056 overdose deaths in the U.S. from May 2020 to April 2021 due to opioids
  - Accounted for 75% of the total overdose deaths
- Most recorded overdose deaths in one year ever
  - 3x that of traffic accidents deaths and 2x that of gun deaths in same time period

CDC Overdose Deaths Accelerating During COVID-19
CDC Save Lives Now. Overdose Deaths have increased during COVID-19
Harvard School of Public Health. Drug Overdose Deaths hit record high.

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Substance Abuse by Healthcare Professionals

- It is estimated that 10-15% of healthcare professionals will misuse drugs at some point in their career
- Higher rates of prescription drug use than the general public
  - Greater access to controlled substances
  - Tend to use drugs readily available in practice setting

Cohn MR, et al. *Hosp Pharm.* 2016.
Baldisseri MR. *Crit Care Med.* 2007.

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Anesthesiologist Statistics

- Rate of substance abuse disorder for physicians ~10-14%
- Rate is 2.7 times greater for anesthesiologists than any other physician specialty
- 62% of anesthesia residency program directors report at least 1 resident with a substance abuse problem

Minn Med. 2010 Feb; 93(2): 46-9.
BJA Education. 2016 July; 16(7): 236-41.
Cohen MR, et al. *Hosp Pharm.* 2016.
Baldisseri MR. *Crit Care Med.* 2007.

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Anesthesiologist Statistics

- Recovery rate: 74-90%; most return to practice (many in another specialty)
- It is estimated that "more than 400 drug-addicted anesthesiologists and residents may be working in operating rooms at this moment"

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Certified Registered Nurse Anesthetist (CRNA) Statistics

- 1 of 10 practicing CRNAs are likely to misuse controlled drugs
  - Similar to rate of general public
- ~64% report poly-drug abuse

AANA Journal. 1999 April; 67(2): 133-40.
Substance Use Disorder in Nursing. NCSBN. 2011.

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HOW EASY ARE WE MAKING IT?

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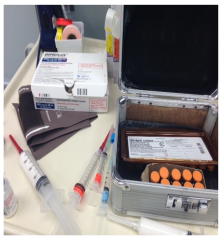

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What is Wrong Here?

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Drugs of Choice

- December 2018, CDC reported that fentanyl had surpassed heroin as the drug most frequently associated with overdose deaths in the United States
  - 2011: Oxycodone
  - 2012-2015: Heroin
- Rate of drug overdose deaths related to fentanyl doubled each year from 2011-2016

Warnsley, L. NPR. Dec. 2018.

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Drugs of Choice: 2020 Diversion Data

- 82% of diversion events included one type of opioid
- Most common diverted controlled substances:
  - Oxycodone
  - Fentanyl
  - Hydrocodone

Drug Diversion Digest 2021

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Gaps in the Surgical Process

- Limited technology/automation
  - Electronic health records
  - Automated dispensing machines
  - Barcode medication administration
- Predominately paper charting
- Manual auditing
- Quick turn-over, fast-paced environment
- Controlled substances immediately available
- ↑↑↑ Narcotic waste and reconciliation process
- Contracted and, often, inconsistent staff

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Common Methods of Diversion

- Diverting pharmaceutical waste
- Inconspicuously switching out syringes or filling vials with saline or another substance
- Diluting medications
- Diversion from patients
- Blatant theft
- Falsification of documentation for medication administration

American Association of Nurse Anesthetists. Addressing Substance Use Disorder for Anesthesia Processionals. 2016.

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UTSW DEA Settlement

- On Dec. 15, 2016, a UTSW nurse overdosed on fentanyl diverted from UTSW's Clements University Hospital and was found deceased in a hospital bathroom
- 16 months later, on April 16, 2018, another nurse overdosed on diverted opioids, including fentanyl, and was found deceased in a different Clements Hospital bathroom
- Prompted a 3 year DEA and U.S. Attorney's Office investigation of UTSW's handling of controlled substances

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UTSW DEA Settlement

- Violated Controlled Substance Act (CSA) over a five-year period
- Failure to maintain effective controls to consistently detect and monitor suspected diversion
- UTSW did report certain instances of theft and loss to the DEA, it did not do so in a timely manner

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UTSW Diversion Settlement

- Did not properly document the dispensing and "wasting" of controlled substances
- Made errors in forms documenting the ordering, receipt, and distribution of controlled substances
- Violated certain recordkeeping and reporting obligations which included monitoring all controlled substance activity within its facilities
- UT Southwestern to Pay $4.5 Million
  - University of Michigan case was $4.3 million
  - Effingham Health System was $4.1 million

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UTSW DEA Settlement

- 3 year agreement between the DEA and UTSW
  - External auditor to conduct unannounced audits
  - Training program designed to help employees identify symptoms of addiction and signs of diversion
  - Employee compliance hotline that permits anonymous reporting of suspected drug diversion or drug impairment

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UTSW DEA Settlement

- Security cameras installation
- Database of employees who have been discharged or resigned because of drug diversion, and disclosing relevant information to requesting health facilities conducting pre-employment inquiries
- Permit DEA personnel to enter UTSW facilities at any time, without prior notice and without a warrant, to verify compliance

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How Do We Protect our Patients and Staff from Diversion?

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Strategies for Diversion Prevention

- Multi-disciplinary, medication diversion team
- Technology and automation
- Investigating variations in practices
- Diversion risk rounds
- Monitoring for program compliance
- Reconciliation processes for returned/wasted medications
- Accountability, Duty to report

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Strategies for Diversion Prevention

- Conducting Root Cause Analyses
- Identify and close gaps
- Coaching and corrective action
- Segregation of duties
- Ensure appropriate chain of custody
- Preparing for next diversion
- Anesthesia staff education
- Annual diversion education and open communication

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This is Reality

Recent Diversion Cases

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Is that a Syringe in Your Pocket?

- Suspicious behavior reported
  - RN would always volunteer to stay late hours and for closing shifts
  - Only wanted to work in recovery
  - Lunch breaks out of the building and often came back late
- One shift arrived very early and within 15 minutes of shift starting, seen walking into the locker room with a syringe of hydromorphone

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Is that a Syringe in Your Pocket?

- RN said went to locker room to get a pen→ forgot syringe was in pocket
  - "I'm a little concerned that this is going to go against me, especially since I had issues at my old employment over a similar event"
- Syringe sent for analysis and RN sent to drug screen
- RN asked if any medications may show on screen- stated takes Norco and Tramadol for back pain
  - States taken for ten years, thinks told manager

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Is that a Syringe in Your Pocket?

- RN locker searched:
  - 2 (10 mL) syringes labeled Normal Saline (one was still in wrapper one was not)— these were sent for analysis
  - 4 (3 mL) empty syringes
  - 30 and 25 gauge needles

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Is that a Syringe in Your Pocket?

- RN searched and on them :
  - 3 (3 mL) empty syringes
  - 2 (10 mL) syringes (one was still in wrapper)
  - 2 (22 gauge) needles
  - 2 filter needles
  - 1 vial of 100mcg/ml fentanyl (empty)
  - 1 vial of 2mg/mL Dilaudid (empty)

Remember this RN had only started their shift 15 minutes prior

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Is that a Syringe in Your Pocket?

- Syringe containing hydromorphone concentration came back at 0.35 mg/mL
- RN was taken for drug testing→ those results were never posted or received
- RN was ultimately terminated from employment for breach of policy. She was also reported to the Board of Nursing and an initial notification to the DEA was also sent

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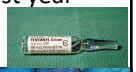
Water or Fentanyl?

- Endo center- medication sample sent for routine testing- administrator who had access → maternity leave
- Months later pharmacist obtains results= fentanyl 1mcg/mL
- CRNA denied diversion, Medical Director sure the CRNA isn't diverting
- CRNA taken to testing center for drug screen and during ride admits diverting for past year



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Water or Fentanyl?

- CRNA would go into room before everyone, draw up 1mL and put in empty water bottle in the room
- Then from vial would pull 2nd mL to give to the patient, then pull back on line 1 mL to show as waste
- Per CRNA started to divert because nurses never watched when wasting being done

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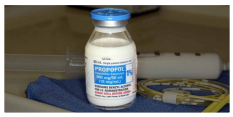
Do You Count Your Propofol?

- Freestanding endoscopy center , ~2,000 cases/month
- CRNA 2 was taking over cases and propofol vials from CRNA 1, Propofol chain of custody count performed
  - Expected 20 vials but counted 21 vials



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Do You Count Your Propofol?

- CRNA 1 put "extra" propofol vial in his pocket
- Both CRNA 1 & CRNA 2 signed the kit record attesting that 20 vials of propofol were present
- Anesthesia leadership approached CRNA 1 while they were taking a break in their car

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Do You Count Your Propofol?

- Asked where missing propofol vial was located
  - CRNA stated that when the propofol count exceeds what is expected, CRNA keeps the extra vial in their bag in the car so that could use it if the was ever "under"
  - CRNA then produced 2 propofol vials
- Ad Hoc MDT Held, CRNA 1 was terminated and CRNA 2 had disciplinary action, Both propofol vials sent off for analysis and identification

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A Change in Practice

- Endoscopy center
- CRNA with recent abdominal surgery
- Procedure nurses report to manager
  - Question if patients receiving medication
  - Noticed CRNA started using fentanyl and propofol
- Recovery nurses- patients coming into recovery wide awake despite receiving above medications
- Report to Pharmacist → Head Anesthesiologist → Drug Screen

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Questions to Ask

- How are our centers at risk for an events like these?
- Do we have issues with waste witness/documentation issues? How can we improve on that?
- Are there ways someone could easily divert at our centers?

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Questions to Ask

- Are there vulnerable areas (narcotic boxes/carts/cabinet locks) that need to be replaced?
- Do we openly discuss risk for diversion at our center?
- Do we provide annual diversion education?
- Diversion Drills?

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Questions?

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