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# Drug Diversion Prevention
## The Mayo Clinic Experience

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***"In order to be trusted….we must be safe."***

***John H. Noseworthy, M.D., President & CEO, Mayo Clinic***

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## Conflict of Interest Declaration

No conflicts to disclose

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# Learning Objectives

**Learning Objectives**

1. Describe the key components of the Mayo Clinic Drug Diversion & Prevention Program.
2. Describe the Mayo Clinic "Elements of Best Practice: Drug Diversion Prevention and Detection"
3. Describe the role of law enforcement in healthcare drug diversion.
4. Understand the affordability of a Drug Diversion Prevention and Detection Program.



# The Mayo Clinic Journey….

- High profile fentanyl tampering (2008) – Catalyst for Change
- Drug Diversion & Prevention Task Force
  - *Charge:* Comprehensively review the existing controlled substance system to identify opportunities for improvement
  - *Scope*: Hospital Inpatient, Hospital-based OP, Clinic OP
  - Multidisciplinary
- Approach to Work:

→ **Failure Mode Effects Analysis**

→ **Surveillance Program**

→ **Investigation & Response**

## Failure Mode Effects Analysis

- Multidisciplinary Workgroup
- Mapped current CS medication use processes (prescribing, procurement, storage, preparing & dispensing, administration, monitoring)
- Identified diversion risk points and potential causes
- Identified process changes that will minimize risk points



## Risk Point Categories

1. Unobserved Single Individual Access to Controlled Substances
   - Potential for diversion when same person performs the task; minimal or busy staffing in the area; and minimal double checks in place
   - Current standard of practice in most areas

     Examples:
     - Nurse / Anesthesiologist / Other Practitioner retrieves CS from Pyxis machine and administers to patient
     - Pharmacy Technician delivers CS from Pharmacy to patient care area

2. Unattended Product During Medication Use Processes
   - Potential for diversion when the chain of custody is broken

     Examples:
     - CS located unattended waiting RPh verification
     - CS located in a procedural room waiting administration
     - CS located on a Pharmacy delivery cart
     - Technician returning CS from floors to CII Safe
     - Medications left in procedural drawers

## Risk Point Categories

3. Deviation from Policy / Procedures
   - Potential for diversion when process steps are skipped or minimized due to reasons of efficiency / convenience / necessity
   - Employee performance

     Examples:
     - "Unwitnessed witnessing" of CS waste
     - Sharing of Pyxis system passwords

4. Lack of Audit Process / Known Deterrent
   - Any time there is a known lack of an audit process or deterrent there is potential for deviant behavior

     Examples:
     - Lack of integration between CS retrieval and administration documentation
     - Presence / absence of camera
     - Timeliness of surveillance audits and feedback

5. Other Process Assessments
   - Patients Own Meds processes

**123 potential process improvement changes identified**



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Current Program

## 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

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Current Program

## Reporting Process

- Established “Hot Line” – 24x7 pager
  - Widely publicized
  - Originally signage on Pyxis machines - removed
- Institutional compliance line
- Anonymous reporting if desired



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Current Program

## Surveillance Program

- Report generation & data analytics
  - ADM and medical record data utilized
  - 26 + reports (daily, weekly, monthly) - FMEA risk points
  - Analytics tool (vendor, in-house)
  - Moving towards centralization
- 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)
- OP prescription monitoring

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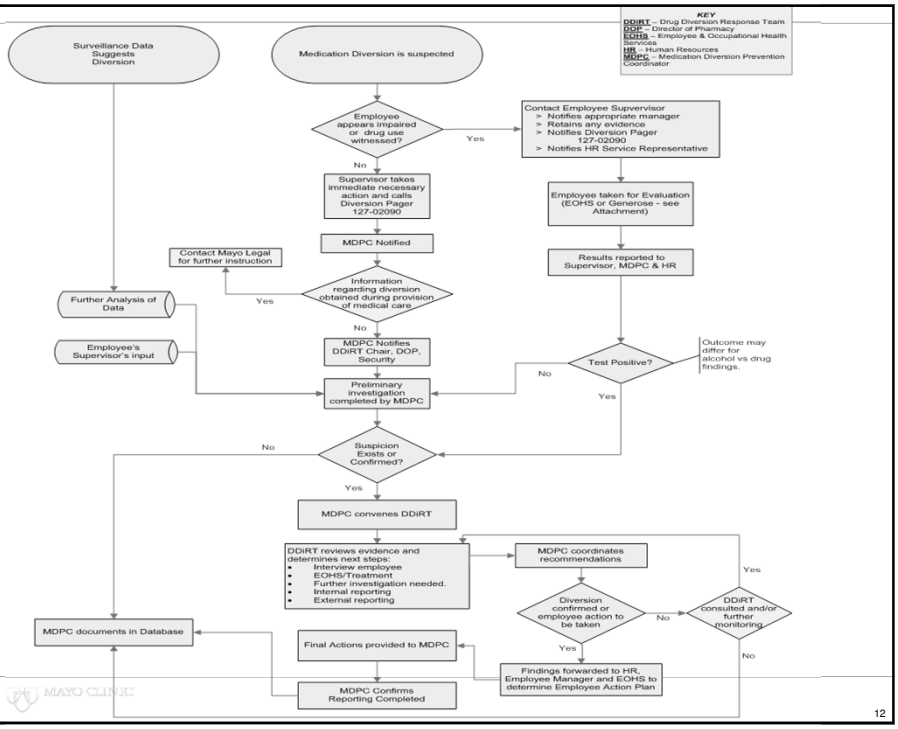
Current Program

## 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





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Current Program

## 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



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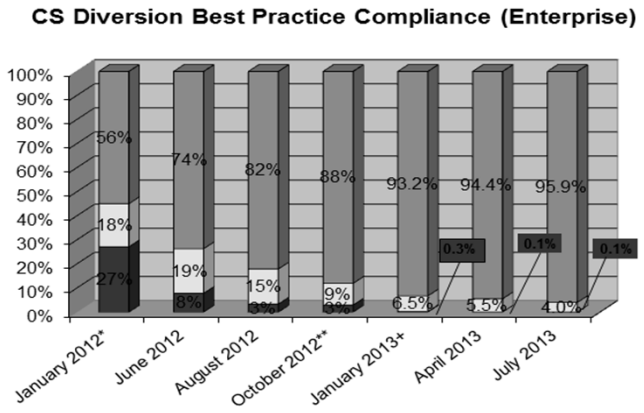
Current Program

## Elements of Best Practice (Late 2010)

- 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
- Expectation is ALL sites implement
- NEW! Elements of Best Practice – Outpatient Pharmacy!

## Elements of Best Practice Compliance






## When / How to Involve Law Enforcement

- Often times confusing and even contentious issue
- Establish contact with local law enforcement before the need arises
- Be familiar with reporting requirements (local, state, federal)
  - "Significant Loss" and any theft must be reported to DEA within one business day
  - Boards of Nursing, Pharmacy, Medicine, etc…
- Considerations:
  - Law Enforcement brings different skills and "tool kit"
  - Facilitates criminal prosecution case
  - Loss of "control"

## How can we afford it?

- Schaefer, Perz Mayo Clinic Proceedings article (see resources)
  - Provides a unique & frightening look at the harm a drug-diverting healthcare worker can inflict
  - Identified 6 US Outbreaks of drug diversion-related bloodstream infections from 2003-2013
    - 2 outbreaks: gram neg bacteremia
      - 34 patients
    - 4 outbreaks: hepatitis C transmission
      - 84 patients
  - Collateral Damage
    - 4 Hep C outbreaks = potential exposure of 30,000 patients
      - Patient notifications, testing, anxiety
      - Lawsuits!
        - Impacted patients
        - Reverse lawsuits
  - Question becomes not "How can we afford a program to prevent and detect drug diversion by HCW's?" but instead "How can we afford to <u>not</u> have such a program?"



## Summary / Lessons Learned

- Theft of controlled substances is common in the healthcare workplace.
- This is a journey….not a destination. Learn from each episode.
- Have a drug diversion detection and prevention program in place.
- Addiction & Diversion is a multi-victim crime.
- 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).

## Summary / Lessons Learned

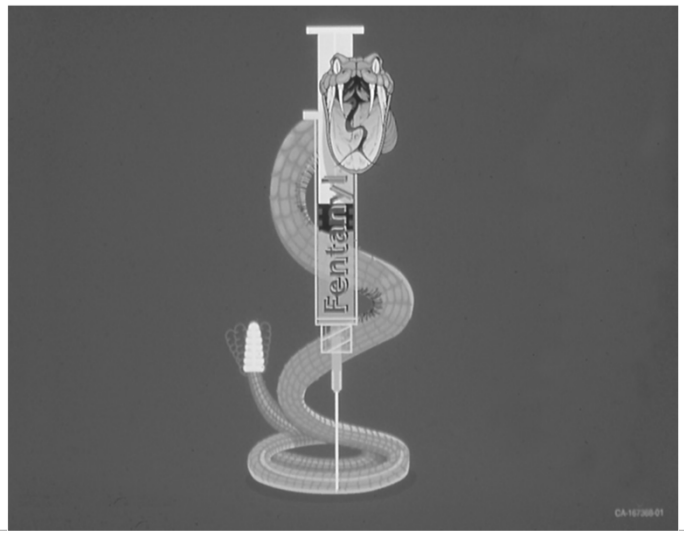
- Robust surveillance is critical. If you look…you will find it. If you don't find it…you're probably not looking hard enough.
- All employees divert, even employees with "no access to drugs"
- Waste stream is under constant attack
- Educate and be transparent…solicit the help of the 99.9%
- Requires strong, active multidisciplinary leadership
- Optimize technology
- Requires resources
- Don't recreate the wheel



## Resources

- Minnesota Controlled Substance Diversion Prevention Coalition
  - Coordinated by the Minnesota Department of Health and the Minnesota Hospital Association
  - http://www.health.state.mn.us/patientsafety/drugdiversion/index.html
- Diversion of Drugs Within Health Care Facilities, a Multi-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection and Prevention. KH Berge, KR Dillon, et al. Mayo Clinic Proceedings. July 2012; 87(7): 674-682.
- Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel. MK Schaefer, JF Perz. Mayo Clinic Proceedings. July 2014; 89(7):878-887.
- Bloodstream Infection Outbreaks Related to Opioid-Diverting Health Care Workers: A Cost-Benefit Analysis of Prevention and Detection Programs – Editorial. KH Berge, WL Lanier. Mayo Clinic Proceedings. July 2014; 89(7):866-868.

# Thank You!

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