

Engaging the OR and Procedural Areas to Mitigate Risks with Controlled Substance Medications



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Learning Objectives

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

1. Cite the scope and impact of diversion issues within OR and procedural areas.
2. Apply two interventions to minimize diversion of controlled substances in the OR and procedural areas.
3. Engage key stakeholders in waste reduction through the implementations of a diversion management plan.



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Engaging the OR in Medication Security

Ed Pollak MD, FASA, CPPS
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Henry Ford Medical Group

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MICHIGAN

UM pays \$4.3M to settle federal charges for stolen drugs, but criminal charges possible



Karen Bouffard
The Detroit News

Published 3:48 p.m. ET Aug. 30, 2018 | Updated 11:17 p.m. ET Aug. 30, 2018

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CRIME

Mount Carmel pharmacist on Husel's painkiller orders: "I had concerns about the doses"

 **Holly Zachariah**
The Columbus Dispatch

Published 3:40 p.m. ET Feb. 24, 2022 | Updated 6:46 p.m. ET Feb. 24, 2022

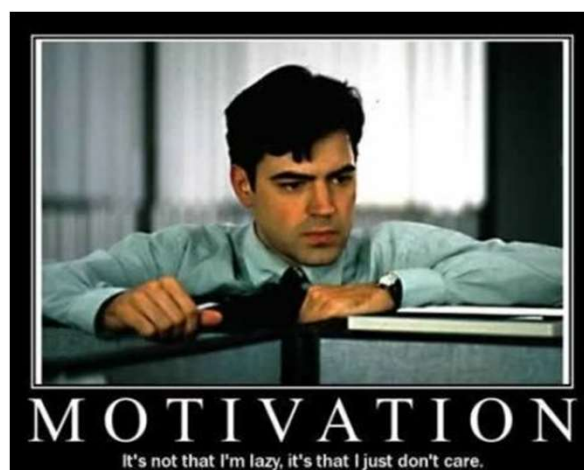
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Compliance vs Engagement



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Covid Precautions

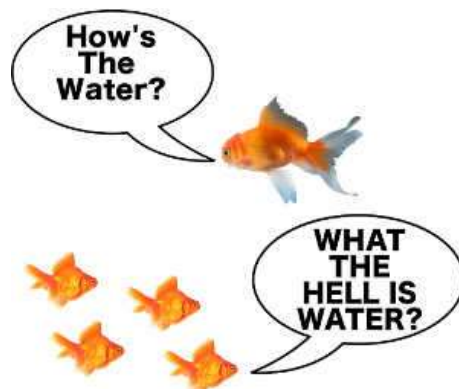


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Culture

- Attitudes, values, beliefs which guide thinking and action



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Culture

- Organizational studies, safety science show variability across units
- Consider Cath lab/OB/ECT/ASCs/Main ORs
- Social Influence: Exam cheating and rule following contagious
- What *really* moved the needle are peer influencers

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There is a right answer



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Detecting Gas Leak



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Perioperative Environment is Error Producing

- Unclear/inconsistent instructions
- Poor design
- Time pressure
- Crowding
- Hot or cold
- Noise
- Fatigue
- Unfamiliar team members

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OR Pharmacy



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Anesthetizing Locations

- Main ORs/ ASCs
- **OB ORs Rooms**
- **ICUs/Emergency Department**
- **Cath/EP Lab/Echocardiography**
- **Endoscopy**
- **Interventional, Ultrasound, CT, MRI, PET, Multimodal CT/MRI/PET, Radiation oncology**
- **ECT**
- **Dental Offices**
- **Lithotripsy**

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MRI



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Safety culture promoted by system design

- Avoid reliance on memory and vigilance
- Standardize common processes & equipment
- Simplify task structure, reduce complexity
- Integrate solutions into existing workflow
- Make the default choice the correct choice

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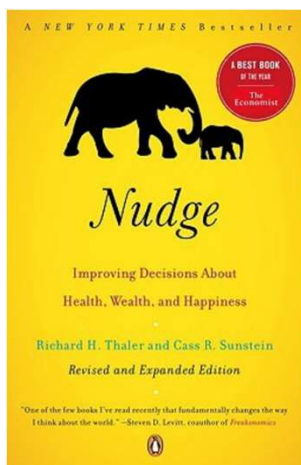
Who do you need to engage

- High risk cases not just in main hospital settings
- Biggest growth of anesthesia NORA and ASCs
- Often left out of health system med security discussion
- **Inventory all anesthetizing locations and be sure they are included**

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How to Drive change



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Safety science: use data to drive performance

- Data are never perfect
- Indicate when a change is an improvement in PDSA cycle
- Engagement vs compliance requires unit specific individual level data

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Normalization of Deviance



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Drift



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Keys to Quality Improvement

- *Leadership is the art of getting someone to do something, because they want to do it*
- Most industries standardize 90% with 10% variation--health care reverses this
- Culture/context influences individual behavior
- Best improvement when physicians own the problem
- **Not a pharmacy problem this key part to perioperative quality and safety**

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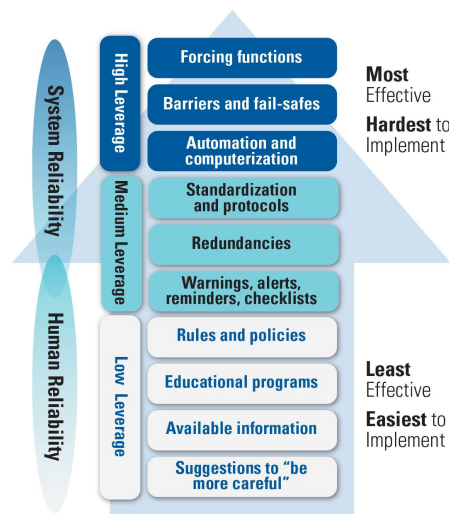
Aligning safe medication practices to workflow

- What if you don't have profiled ADCs and OR pharmacist
- Prefilled syringes eliminate hazards related to aseptic technique
- Don't have to remember to wipe vial and draw smallest dose
- Purchase smallest appropriate dose-- minimizes waste and time reconciling
- Tamper evident packaging

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Rank Order of Error-Reduction Strategies™

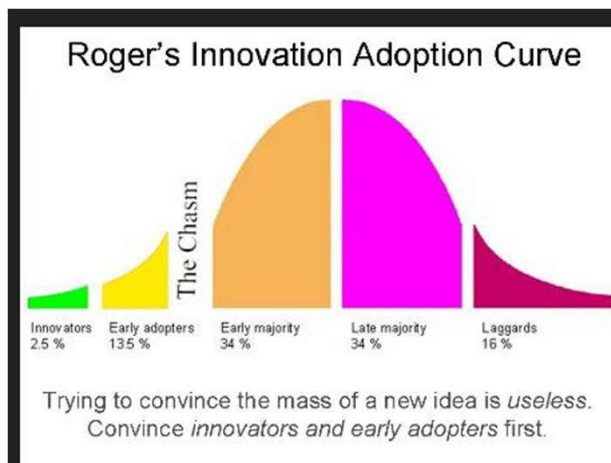


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The Tipping Point

The
TIPPING POINT

*How Little Things Can
Make a Big Difference*

MALCOLM
GLADWELL

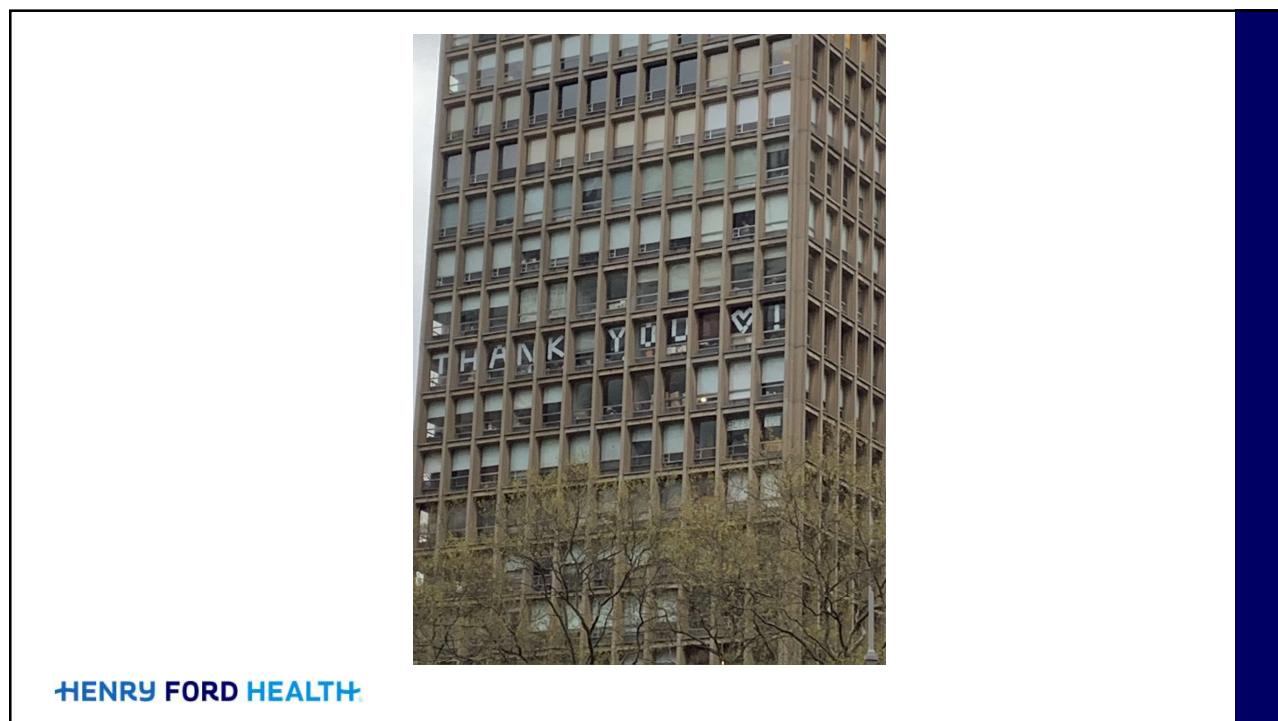
*"The name given to that one
dramatic moment in an
epidemic when everything
can change all at once."*

-- M. Gladwell, *The Tipping Point* (2000)

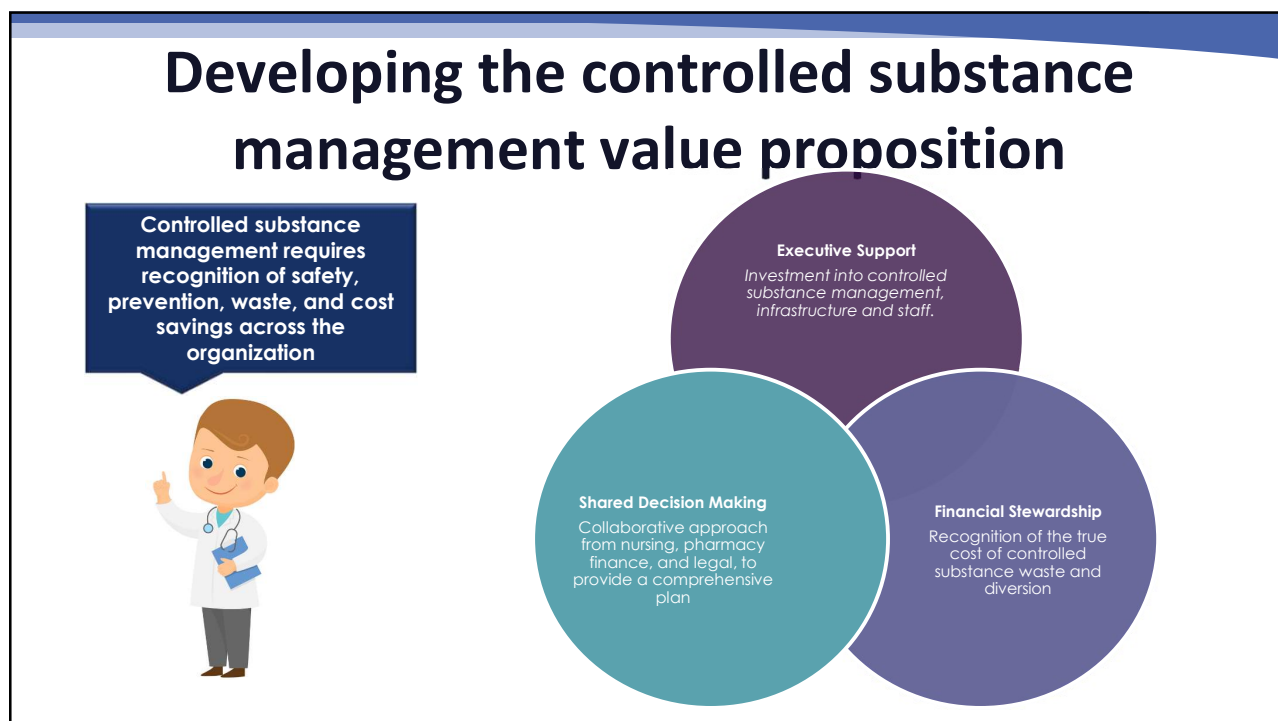
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Diversion is costly to organizations

University of Michigan Health System to pay record drug diversion settlement

Updated: Jan. 30, 2019, 1:10 a.m. | Published: Aug. 30, 2018, 5:28 p.m.



University Hospital, part of the University of Michigan Health System. Katie McLean | The Ann Arbor News Katie McLean | MLive.com (Submitted photo)

Establishing a comprehensive diversion program requires investment in:

- Automation
- Artificial Intelligence
- Audit team
- Waste mitigation
- Changing practices

Michigan 2021. [online] Available at: <https://www.mlive.com/news/ann-arbor/2018/08/university_of_michigan_health_33.html> [Accessed 3 November 2021].

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Quantifying Controlled Substance Related Expenses

Leveraging published literature is important to identify all direct and indirect costs of managing controlled substance waste and adopting a validated approach



Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T, A continuous Observation Workflow Time Study to Assess Intravenous Push Waste. *Hosp Pharm*. Published online ahead of print. 2020 May

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The goals of cost-effective controlled substance management

- Acquisition cost is important but **total cost of care** is more indicative of expenses
- Understand how appropriate management of waste, medication safety, disposal, and labor can decrease organizational liability and spend

Decrease overall expenses

i.e. total cost of care

- Medication related events
- Drug waste
- Labor worked hours
- Excess monitoring

Improved Stewardship

i.e. Reduction in excess spend

- Improved safety
- Better utilization of staff
- Most appropriate dosage form

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T, A continuous Observation Workflow Time Study to Assess Intravenous Push Waste. *Hosp Pharm*. Published online ahead of print. 2020 May

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Direct Costs related to Controlled Substance Waste

- Each waste activity requires the labor of a nurse or healthcare provider
- If dosage forms are not optimized each unit of waste leads to additional expense



stockphoto.com. 2021. Two Nurses Stock Photos, Pictures & Royalty-Free Images - iStock. [online] Available at: <<https://www.istockphoto.com/search/2/image?phrase=two+nurses>> [Accessed 3 November 2021].

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Indirect Impacts of Medication Waste

- Increased documentation and witnessing of controlled substance waste
- Required pharmacy follow up on unreconciled administrations
- Lack of aseptic technique utilized at the bedside with immediate administration
- Risk of healthcare provider diversion and DEA fines

Joint Commission on Accreditation of Healthcare Organizations (2019). *Medication Management Standard MM.08.01.01*. Oakbrook Terrace, IL: Joint Commission Resources

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Pharmaceutical Waste Management

- As of August 21, 2020, the EPA has banned sewerage of controlled substance medications under the federal Resource Conservation and Recovery Act (RCRA)
- The DEA additionally requires controlled substances to be “rendered irretrievable” if any waste exists after administration
- The antiquated method of “free” sewerage of controlled substance waste down a sink is no longer acceptable
- Rx waste disposal systems add recurrent costs to a health care facility’s budget that many forget to factor in the cost of drug waste

Erich Brechtelsbauer, PharmD, MS, BCPS, Shailly Shah, PharmD, MS, BCPS, Update on pharmaceutical waste disposal regulations: Strategies for success, *American Journal of Health-System Pharmacy*, Volume 77, Issue 7, 1 April 2020, Pages 574–582, <https://doi.org/10.1093/ajhp/zxz360>

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Emerging treatment locations

- Ambulatory procedural locations
- Typically fast paced environment within the healthcare environment
- Typically less automation and controlled substance oversight
- Medication use documented within the EMR or Paper Charts
- Reconciliation can be difficult without appropriate wasting techniques or resources
- Controlled substance storage varies based on size and space needs



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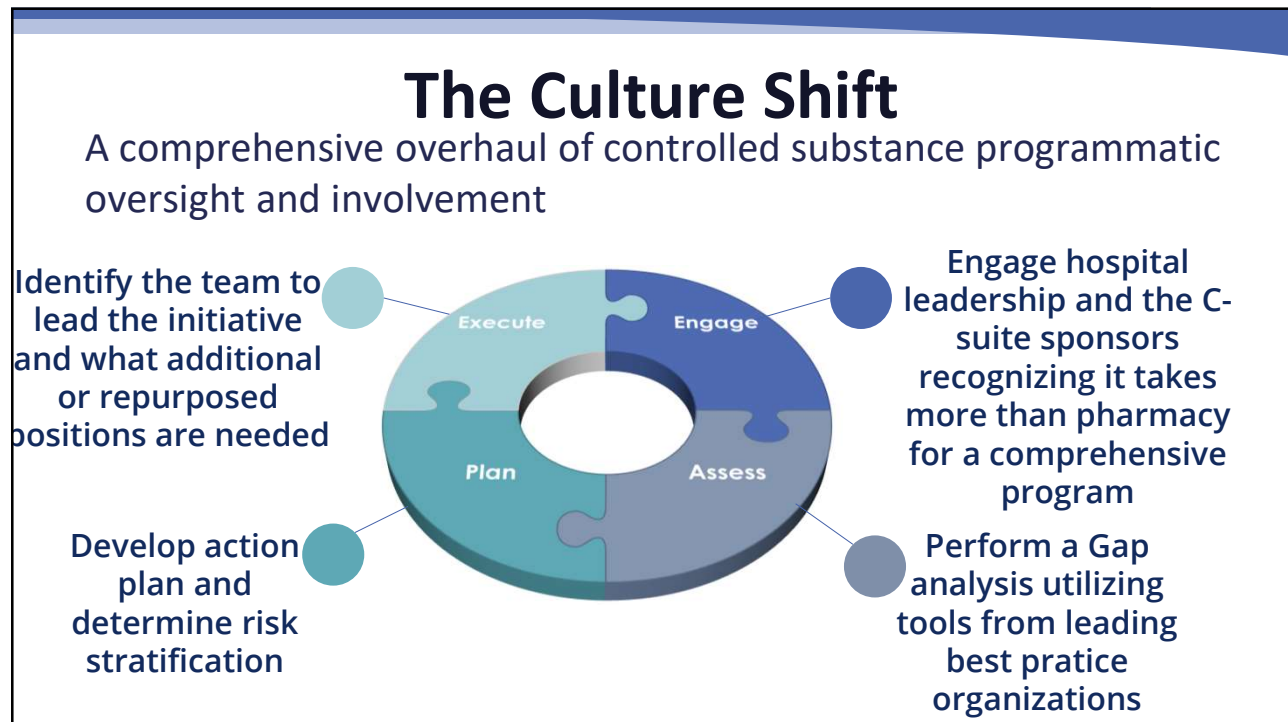
Trust, but Verify

“Doverey, No Proverey” – President Ronald Regan

- Patient care was often cited as one of the reasons why workaround needed to be utilized
- There were less restrictions on buyer access in case they needed to above and beyond and help with receiving too
- Procedural areas historically lacked automation and “just in time” processes were seen as more provider friendly
- Checks and balances existed but meaningful accountability did not always back them up
- No diversion problems detected could mean a bigger problem is brewing

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Engagement of Health System Leadership

- Ensure a culture of continuous compliance is embraced
 - Not satisfied with steady state
- Investment into several detection strategies across roles
- Accountability for drug diversion extends past pharmacy
 - SMART goals identified and to be reviewed at procedure leadership meetings
 - Consistent executive summaries available each month for hospital leadership
- Include supply chain and finance on the controlled substance committee

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Prevention through Education

Creating educational opportunities across job roles

- Required annual competency around controlled substance diversion
- Controlled substance education incorporated into patient services orientation
 - Nursing, etc
- System learning from individual medication related events
- Incorporation of medication safety risks pertaining to controlled substance use and abuse

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The Art of Perpetual Inventory

Lifecycle of controlled substances

- Account for every dosage form from order generation to administration
 - Utilization of controlled substance management system within an integrated platform
 - Controlled substance order generation based on specific perioperative utilization or established par levels
 - All par level adjustments can be tracked and documented



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Traceability of Controlled Substances

Controlled Substance Movement

- Have transactions occur through automated dispensing cabinets (ADC) when feasible
- Direct hand to hand delivery of non-automated dispensing cabinet stock with signature confirmation
- All issues should be documented

Controlled Substance Reconciliation

- Documentation of waste within an electronic or manual system
 - Witness should be required for signoff
- Controlled Substance Administration Record to patient medical record
- Returns can also be linked to healthcare employee and patient

AAHA Guide to Safeguarding Controlled Substances. 2020

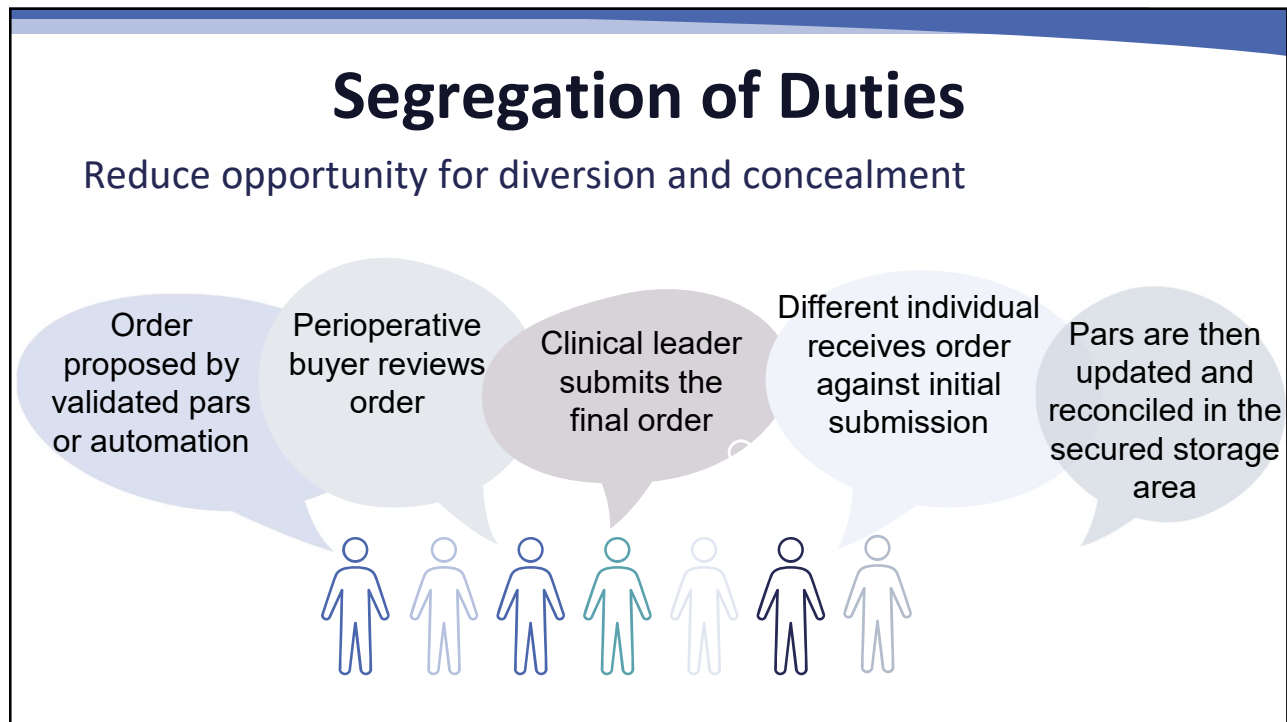
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Segregation of Duties

- One of the most important strategies utilized for internal control
- Duties are considered incompatible if someone can carry out and conceal an activity based on their daily responsibilities
- Limiting access to the Controlled Substance Ordering System
- No one is immune from oversight and separation
- Periodic reviews of responsibility are important and warranted
- Regardless of size this is an important principle to implement

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Oversight within the perioperative setting

- Create receiving practices that do not involve receiving dock
- De-identify controlled substance shipments but have them delivered directly to pharmacy
- Limit individuals that can receive controlled substances
- Establish robust camera surveillance with multiple angles covered

Brummond PW, et al. Am J Health Syst Pharm. 2017;74(5):325-348

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Oversight within the facility

- Create an electronic or physical matching system
 - Order generation should match order submission with exception well documented, packing slip should match invoice, and invoice should be reconciled directly into automation
- Limit access to controlled substance vault



Brummond PW, et al. Am J Health Syst Pharm. 2017;74(5):325-348

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Safe Handling of Controlled Substances

Best practices for administration of medications

- Utilizing the smallest dosage form possible to reduce waste or medication error
- Using pre-filled ready to administer syringes to reduce compounding and product manipulation after dispense
- Consistently utilize same NDC and dosage form to create consistent practice across the hospital areas
- Avoiding bulk dosage forms but sending up all doses in patient specific forms



AAHA Guide to Safeguarding Controlled Substances. 2020

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Proactive Process Review and Monitoring

Becoming more proactive rather than reactive

- Selecting a third party software to establish an ongoing review of automated dispensing cabinet data
 - Selection has migrated from third party auditing software to now artificial intelligence that has learning capabilities
- Running reports with relevant frequency and create robust follow up
 - Being intentional with the data and requiring real time review and feedback
- Establishing benchmarks for all areas of the hospital

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Gap Analysis Focus Areas

Procurement

- Delivery of medications to the pharmacy
- Reconciliation of purchases or order generation

Dispensing

- Multi-dose vial overfill
- Prepared syringe contents diluted or replaced with water

Prescribing

- Prescription pads are diverted or used inappropriately
- Verbal orders for controlled substances created but not verified

Administration

- Controlled substances pulled on discharged patient
- Medication documented as given, but not administered

Waste

- Waste is not adequately witnessed by observation
- Expired controlled substance taken from holding area

Brummond PW, et al. Am J Health Syst Pharm. 2017;74(5):325-348


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Controlled substance gap analysis tool				
SECTION	ITEM	Priority	COMMENT	TIMELINE
	Ambulatory perioperative settings are authorized to procure CS, there are checks and balances established to ensure the same policies and procedures are consistently followed throughout the organization.			Complete
1.1	Separation of duties exists between the ordering and receipt of CS:			Complete
1.11	Two authorized individuals count and sign (two signatures) for CS upon receipt (packing slip), and confirm that what is received matches what was ordered and invoiced (purchase order and invoice).			< 1 year
1.13	Automated technology or secured vault is utilized in as the main storage location.			3+ years


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Evaluate the Gap - Procurement

 Order methodology

 Ordering CS rights and privileges

 Location of order received

 Receiving the order

 Order content verification

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Quantify facility specific financial impact of waste



Leverage reports from automated dispensing cabinets or electronic medical record to identify medications with highest waste



Identify waste events to quantify labor expense associated with each occurrence



Quantify total drug waste by drug in ml



Extrapolate cost per ml of drug wasted to total waste and quantify total worked hours associated with waste events

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Quantifying impact

Medication	Medication expense (AWP) per mL	Average mL wasted per dose	Total mL wasted annualized	Medication waste expense annualized	Workforce expense per waste	Total doses wasted	Workforce waste expense annualized	Disposal bin expense	Disposal bin capacity in mL	Disposal bin expense annualized	Total Annual Expense (USD)	Total waste expense per dose (USD)
Fentanyl (50µg/mL)	\$0.78	1	3,444	\$2,686	\$0.73	3,444	\$2,514	\$68	3785	\$68	\$2,969.57	\$5,268

Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T, A continuous Observation Workflow Time Study to Assess Intravenous Push Waste. *Hosp Pharm*. Published online ahead of print. 2020 May

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Consider the Total Cost of Care

- Consider acquisition cost, but more importantly the total waste that could be generated from a specific medication
- Aim to decrease waste events to better manage labor worked hours within nursing and pharmacy
- Evaluate the costs of diversion when reviewing medication use or adopting new practices

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Key Takeaways to Optimize Controlled Substance Practices

- Create medication order sets where dose ordered matches medication product
 - This is especially important in procedural areas where controlled substance waste is generated in high volumes
- Consider purchasing ready to use dosage forms that reduce any manipulation at the bedside
- Utilize one NDC if possible to consolidate product use and familiarity

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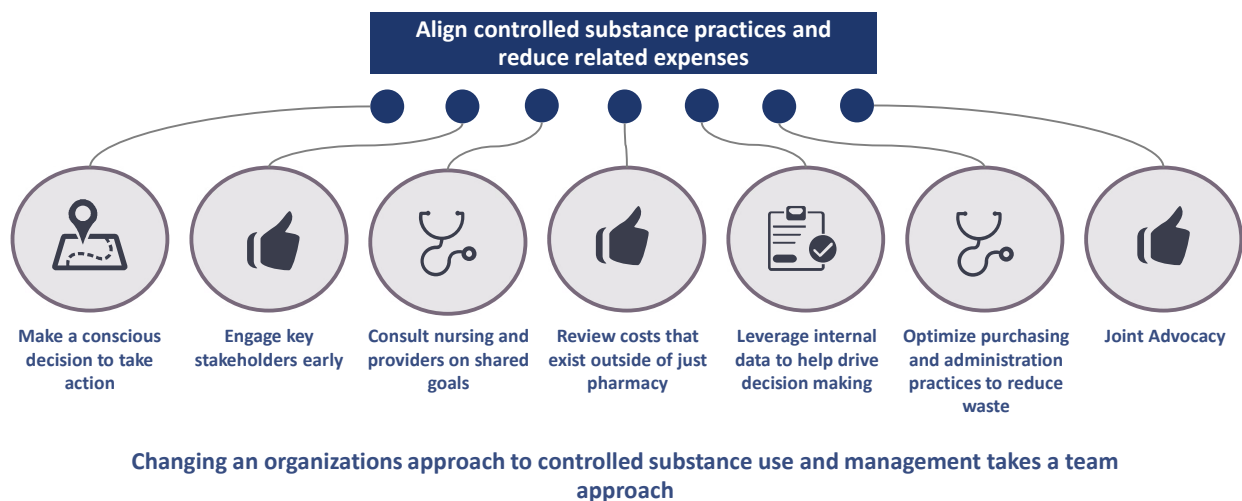
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Creating a Cross Discipline Value Proposition

- Recognize that change must be initiated across disciplines for lasting impact
- Gaining provider and nursing buy in is key
 - Quantify cost saving opportunities both inside and outside of the pharmacy department
 - Emphasize labor and financial stewardship opportunities that can be achieved within a controlled substance management program
- Organizations more than ever before are looking for initiatives that can improve standard work and lean principles

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Putting it all together



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Selected Resources

- Hertig JB, Jarrell K, Arora P, Nwabueze J, Moureaud C, Degnan D, Trujillo T, A continuous Observation Workflow Time Study to Assess Intravenous Push Waste. *Hosp Pharm*. Published online ahead of print. 2020 May
- Joint Commission on Accreditation of Healthcare Organizations (2019). *Medication Management Standard MM.08.01.01*. Oakbrook Terrace, IL: Joint Commission Resources
- Erich Brechtelsbauer, PharmD, MS, BCPS, Shailly Shah, PharmD, MS, BCPS, Update on pharmaceutical waste disposal regulations: Strategies for success, *American Journal of Health-System Pharmacy*, Volume 77, Issue 7, 1 April 2020, Pages 574–582, <https://doi.org/10.1093/ajhp/zxz360>

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Questions?

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