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

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

Karen Brouillard
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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Compliance vs Engagement
Covid Precautions

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

There is a right answer

Estimating EBL in the OR:

RN  CST  Surgeon  CRNA

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Detecting Gas Leak

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

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
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**

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

Normalization of Deviance

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Drift

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

Rank Order of Error-Reduction Strategies™
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The Tipping Point

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

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Developing the controlled substance management value proposition

Controlled substance management requires recognition of safety, prevention, waste, and cost savings across the organization.

Executive Support
Investment into controlled substance management, infrastructure, and staff.

Financial Stewardship
Recognition of the true cost of controlled substance waste and diversion.

Shared Decision Making
Collaborative approach from nursing, pharmacy, finance, and legal, to provide a comprehensive plan.
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Diversion is costly to organizations

Establishing a comprehensive diversion program requires investment in:
- Automation
- Artificial Intelligence
- Audit team
- Waste mitigation
- Changing practices

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

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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

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

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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

Pharmaceutical Waste Management

- As of August 21, 2020, the EPA has banned sewering 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” sewering 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/zzx360
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

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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The Culture Shift
A comprehensive overhaul of controlled substance programmatic oversight and involvement

- Identify the team to lead the initiative and what additional or repurposed positions are needed
- Develop action plan and determine risk stratification
- Engage hospital leadership and the C-suite sponsors recognizing it takes more than pharmacy for a comprehensive program
- Perform a Gap analysis utilizing tools from leading best practice organizations

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

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

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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Segregation of Duties
Reduce opportunity for diversion and concealment

Order proposed by validated pars or automation
Perioperative buyer reviews order
Clinical leader submits the final order
Different individual receives order against initial submission
Pars are then updated and reconciled in the secured storage area

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

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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


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

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

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 |

Controlled substance gap analysis tool

<table>
<thead>
<tr>
<th>SECTION</th>
<th>ITEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>1.1</td>
<td>Separation of duties exists between the ordering and receipt of CS:</td>
</tr>
<tr>
<td></td>
<td>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).</td>
</tr>
<tr>
<td>1.11</td>
<td>Automated technology or secured vault is utilized in as the main storage location.</td>
</tr>
</tbody>
</table>

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

Quantifying impact

<table>
<thead>
<tr>
<th>Medication</th>
<th>Medication expense (AWP) per mL</th>
<th>Average mL wasted per dose</th>
<th>Total mL wasted annualized</th>
<th>Medication waste expense annualized</th>
<th>Workforce expense per waste</th>
<th>Total doses wasted</th>
<th>Workforce waste expense annualized</th>
<th>Disposal bin expense</th>
<th>Disposal bin capacity in mL</th>
<th>Disposal bin expense annualized</th>
<th>Total Annual Expense (USD)</th>
<th>Total waste expense per dose (USD)</th>
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</thead>
<tbody>
<tr>
<td>Fentanyl (50μg/mL)</td>
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<td>3,444</td>
<td>$2,686</td>
<td>$0.73</td>
<td>3,444</td>
<td>$2,514</td>
<td>$68</td>
<td>3785</td>
<td>$68</td>
<td>$2,969.57</td>
<td>$5,268</td>
</tr>
</tbody>
</table>

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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

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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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 achieved within a controlled substance management program
- Organizations more than every before are looking for initiatives that can improve standard work and lean principles

Putting it all together

Align controlled substance practices and reduce related expenses

- Make a conscious decision to take action
- Engage key stakeholders early
- Consult nursing and providers on shared goals
- Review costs that exist outside of just pharmacy
- Leverage internal data to help drive decision making
- Optimize purchasing and administration practices to reduce waste
- Joint Advocacy

Changing an organizations approach to controlled substance use and management takes a team approach
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Selected Resources


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Questions?