Reducing Adverse Drug Events: Strategies to Accelerate Improvement Webinar - Opioid Safety

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Objectives

- Describe the elements of a safe system
- List three interventions to improve opioid safety
- Describe two measures to determine if your efforts to improve opioid safety have succeeded
- List the benefits to patients
Starting Your Journey to Improved Opioid Safety

- Understand the principles of a safe system
- Prevent errors and harm
- Identify errors and harm before each progresses to more serious event
- Mitigate intervene to minimize the impact of the error or harm
Differentiate between Harm and Errors

First Target

Errors

Harm (ADE)

PADE

ADE: Adverse Drug Events
PADE: Potential Adverse Drug Event

Adapted from Bates
## New Harm vs. Old Errors

<table>
<thead>
<tr>
<th>New</th>
<th>Old</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentrates less on people, more on systems</td>
<td>Errors are the focus of discussion and solutions</td>
</tr>
<tr>
<td>Looks at all unintended results</td>
<td>Tends to focus only on those results felt to be related to error; ignores other events</td>
</tr>
<tr>
<td>Makes measurement easier</td>
<td>Requires judgment</td>
</tr>
<tr>
<td>Concentrates on harm and those errors that cause harm</td>
<td>Humans found responsible for most of the errors</td>
</tr>
</tbody>
</table>
Errors that Contribute to Harm

- Mix-ups between morphine and HYDROMorphone outnumbered all other medication-pair errors
- Dosing error
- Pump errors
- Administration errors
- Prescribing errors
- Confusion between immediate- and sustained-release formulations.

Of the 41,727 events involving opioids, 11.9% (n = 4,958) were reported as wrong-drug events.

Common Risks

- Look-alike drug names and packages
- Concentration errors
- Use of dangerous abbreviations
- Dosing errors
- Line confusion
- Adverse drug reactions
- Mislabeled syringes
- Patient monitoring problems
- Unintended use
Definition of Harm

In the IHI Global Trigger Tool, the definition used for harm is as follows:

*Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death.*
Accepting the Harm Burden

Concept of moving from a focus on error and the preventable to the measurement of global institutional harm, whether preventable or not
Common Opioid-related Harm

- Death Due To Opioids
  - Intentional and Unintentional
- Unintentional Opioid Poisoning
- Opioid Induced Respiratory Depression (OIRD)
- Falls
- Fractures
- Oversedation
Opioids in The Hospital Setting: Increased Risk of Cardio-Pulmonary Arrest
Opioids Induced Constipation
Opioids and Fracture Risk in the Elderly
Opioids and Fall Risks in Younger Persons
Second Victim Phenomena

- **Newborns**
  - Neonatal Abstinence Syndrome
  - Possible impact on future addiction and health\(^1\)

- **Children**
  - Risk for harm and abuse
  - May lead to inadvertent substance use/abuse and poisoning.

- **Families**
  - Increased risk of family stress and possibly suicide

- **Society**
  - Increased demands on law enforcement and criminal justice system.
  - Increased costs for insurance and risk management resources.
  - Increased costs for treatment of addiction and substance use disorders as well as healthcare resource utilization and healthcare worker burnout.
  - Increased risks and costs to workplaces and workers
  - Increased risks and costs to rest of society in form of diverted resources and reduction in taxpayer base.

Opioid Knowledge Self-Assessment

Healthcare facilities can use this assessment for practitioners who prescribe, dispense, and/or administer opioid products (e.g., fentanyl, HYDROMorphone, morphine, oxyCODONE). The assessment addresses selection, dosing, and patient monitoring when using opioid products, and it was developed by the Pennsylvania Patient Safety Authority in collaboration with the Pennsylvania Medical Society. Aggregating and analyzing the results of practitioner assessments can help healthcare facilities identify opportunities for improvement and aid in the development of targeted, high-leverage strategies to improve the safe use of opioids. The target answers are included in this copy of the assessment.

Demographics

1. Select the one answer that best describes your staff position in your facility:
   - a. Attending or staff physician
   - b. Resident physician or physician in training
   - c. Physician assistant or nurse practitioner
   - d. Registered nurse
   - e. Pharmacist
   - f. Other, please specify: ________________________________

2. How long have you worked in this hospital?
   - a. Fewer than 5 years
   - b. 5 to 9 years
   - c. 10 to 14 years
   - d. 15 to 19 years
   - e. 20 or more years

Opioid Knowledge Assessment

1. Patients who are considered opioid-tolerant are those who have been:
   - a. Taking acetaminophen 300 mg with codeine 30 mg, up to 5 doses a week.
   - b. Taking oxyCODONE 10 mg with acetaminophen 325 mg 4 times daily for 5 days.
   - c. Taking oxyCODONE 10 mg with acetaminophen 325 mg 4 times daily for 14 days.

Finding Harms in Your Health System

- The IHI Global Trigger Tool
- Adverse Event Trigger Tool Data Analysis
- Organizational Assessment of Safe Opioid Practices
- Go and See
- Data Analytics
- Patient Identified Harms
- Standardized Mortality Rate (SMR)
- Population Health Statistics (Community Level)
- PCA Safety Checklist
Error and Harm Reduction Overview: Hierarchy of Controls

Standardization & Simplification

Mitigate

Policies, Training, Inspection

Minimize consequences of errors

Make errors visible

Facilitate

Make it easy to do the right thing

Eliminate the opportunity for error

Human Factors

Eliminate

Make it hard to do the wrong thing

Adapted by D. Bonacum KP
## The Three Faces of Performance Measurement

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Improvement</th>
<th>Accountability</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Aim</strong></td>
<td>Improvement of care</td>
<td>Comparison, choice, reassurance, spur for change</td>
<td>New knowledge</td>
</tr>
<tr>
<td><strong>Methods:</strong></td>
<td>Test observable</td>
<td>No test, evaluate current performance</td>
<td>Test blinded or controlled</td>
</tr>
<tr>
<td>• Test Observability</td>
<td>Accept consistent bias</td>
<td>Measure and adjust to reduce bias</td>
<td>Design to eliminate bias</td>
</tr>
<tr>
<td>• Bias</td>
<td>“Just enough” data, small sequential samples</td>
<td>Obtain 100% of available, relevant data</td>
<td>“Just in case” data</td>
</tr>
<tr>
<td>• Sample Size</td>
<td>Hypothesis flexible, changes as learning takes place</td>
<td>No hypothesis</td>
<td>Fixed hypothesis</td>
</tr>
<tr>
<td>• Flexibility of Hypothesis</td>
<td>Sequential tests</td>
<td>No tests</td>
<td>One large test</td>
</tr>
<tr>
<td>• Testing Strategy</td>
<td>Run charts or Shewhart control charts</td>
<td>No change focus</td>
<td>Hypothesis, statistical tests (t-test, F-test, chi square), p-values</td>
</tr>
<tr>
<td>• Determining if a change is an improvement</td>
<td>Data used only by those involved with improvement</td>
<td>Data available for public consumption and review</td>
<td>Research subjects’ identities protected</td>
</tr>
<tr>
<td>• Confidentiality of the data</td>
<td></td>
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Use Multiple Measures

- **Outcome Measures** (voice of the customer or patient): How is the system performing? What is the result?
  - Adverse Drug Events related to opioids per 100 Patients with an opioid administered

- **Process Measures** (voice of the workings of the system): Are the parts/steps in the system performing as planned?
  - Percent of Narcotic Administrations Appropriately Managed According to Protocol
  - Percent of Patients Receiving an Opioid Who Receive Subsequent Treatment with Naloxone

- **Balancing Measures** (looking at a system from different directions/dimensions): Are changes designed to improve one part of the system causing new problems in other parts of the system?
  - Are patients underdosed?
  - Are there delays in treatment?
Examples of Measures

- Have you developed a protocol or order set for all appropriate medications?
  - Is the protocol or order set being used?

- Have you developed dose-conversion charts to minimize errors when changing from one medication to another? For pain medications?
  - If you have developed dose conversion charts, are they being used?

- Are patients monitored using established protocols?
## Measures

<table>
<thead>
<tr>
<th>Name of Measure</th>
<th>Is this an Outcome, Process or Balancing Measure?</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Patient Harm from constipation</td>
<td>Outcome</td>
</tr>
<tr>
<td>% Laxatives Charted concurrently with opioids</td>
<td>Process</td>
</tr>
<tr>
<td>% Laxatives Administered on time</td>
<td>Process</td>
</tr>
<tr>
<td>% Bowels Monitored Regularly</td>
<td>Process</td>
</tr>
<tr>
<td>% Patients who developed diarrhoea</td>
<td>Balancing</td>
</tr>
<tr>
<td>% Patients who refused</td>
<td>Balancing</td>
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</table>
Tips for Effective Measures

- Use a sample of, at most, ten patient charts per week on the unit where you are testing the new process
- Plot data over time
- Seek usefulness, not perfection
- Use sampling
- Integrate measurement into the daily routine
- Use qualitative and quantitative data
RUN CHART

Adverse Events per 1000 Days

AEs per 1000 Days


Sample Size
20 Records per Month
How long do we measure?

Outcomes: ALWAYS

Processes

- Daily until stable
- Weekly x 6; if stable then:
- Biweekly x 4; if stable then:
- Monthly x 4; if stable then:
- Quarterly, no less.

Variation within the clinical area? Manage in the area.
Variation across clinical areas? Leadership investigates and manages.
Primary Outcome

Opioid Safety

Need goal

Primary Drivers

1. __Assessment___
2. __

2. ___Opioid Management___

3. _Non-RX alternatives____

4. Patient and family engagement

Secondary Drivers

1. _____
2. _____
3. ______

1. _____
2. _____
3. ______

1. _____
2. _____
3. ______

1. _____
2. _____
3. ______
Driver for Safe, Effective Pain Management

Effective, safe management of pain

Reduction in harms from treatment
- Medicines
  - Opioids
  - NSAIDS
  - Other
  - Placebo
  - Correct Diagnosis
- Diagnostics
  - Safe Tests
  - Medications
- Treatments
  - Other Modalities
  - Individual Coping
  - Societal Expectations
- Resiliency
  - Community Involvement & Support Systems

Improvement in pain
- Physical
  - Physical Conditioning
  - Secondary Health Factor Improvement
- Mental
  - Medical Therapy
  - Counseling

Improvement in Function
- Patients
  - Treatment Availability
  - Treatment Effectiveness
- Public
  - Policy
  - Standardized Approach
- Individuals
  - Medicine
  - Non-Medical Options

Improvement in perceived experience of care
Opioid Induced Constipation Driver Diagram

Reduce Prevalence and Incidence of Opioid Induced Constipation

Prevention
- Prophylactic Medication Regimen(s)
- Preventative Measures, Other
- Patient, Family and Provider Education
- Identification of Secondary Causes

Treatment
- Medications
- Therapeutic Activities
- Patient, Family Provider Education

Patient, Family and Provider Education
To reduce Opioid related constipation from 30% to 15% on Ward 10 by 1 July 2013

**Prevention**
Laxatives given regularly with opioids

**Daily Monitoring**
Bowel Charts

**Patient Education**
Leaflets

**Opioid Prescribing**
Is it necessary?

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**Prescribing**
Laxatives charted in conjunction with opioids

**Administration**
Laxatives given with opioids

**Nursing**
Using Bowel Charts on a daily basis

**Patient**
Inform staff if BNO as per usual

**Pain Team**
Review necessity
### Emerging composite care bundle element

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<tr>
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<th><strong>Patient/whānau information</strong></th>
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<tbody>
<tr>
<td>1</td>
<td>Provide patients/consumers and family/whānau with information about opioid use for pain management and associated risk of harms that includes, at a minimum, opioid-induced constipation (OIC), opioid-induced ventilatory impairment (OIVI) and opioid-induced nausea and vomiting (OINV), in formats appropriate to their needs.</td>
</tr>
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<tr>
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<th><strong>Identify patients at increased risk</strong></th>
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<td>2</td>
<td>Identify patients with an increased risk of opioid-related harm using standardised risk assessment tools and methods.</td>
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<th><strong>Utilise pharmacological and non-pharmacological approaches</strong></th>
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<td>3</td>
<td>When prescribing and administering opioids, anticipate, prevent and manage harm using pharmacological and non-pharmacological approaches that should include: opioid-sparing analgesics and techniques; dietary measures, fluid and co-prescribed laxatives for OIC; rational use of naloxone for OIVI; and anti-emetics for OINV.</td>
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<th><strong>Monitor and document to identify harm and the effectiveness of any related interventions</strong></th>
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<tr>
<td>4</td>
<td>Monitor and document to identify harm (sedation level and respiratory rate, bowel movements, nausea and vomiting, pain behaviours/indicators) and effectiveness of any related interventions, using evidence-based guidelines and methods.</td>
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<tr>
<td>5</td>
<td>Regularly educate staff about pain management and opioid use, opioid-related harms and risk reduction strategies. Education includes assessment of knowledge and skills, educational intervention(s) and reassessment.</td>
</tr>
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</table>

This composite bundle reflects the key interventions that were tested in the sector to support a reduction in opioid-related harms in hospitals. The data that informed this bundle is explored in detail in the following section.
Improving Opioid Safety

- Segment the population. Begin by working with patients whose treatment is initiated in-house. This does not imply that all patients should not receive the same care. Once your team has implemented improvements with this group, spread the improvements to other groups.
- Start by designing for a homogeneous population and control as many variables as possible to test the design.
- Use small tests of change to test the design. (See the Model for Improvement.
- Measure the process; if the science is right, the outcomes will follow.
- Use standard approaches such as order sets, but remember that these alone will not accomplish the goal.
- Develop the order sets using evidence-based medicine and society guidelines.
Postoperative Induced Respiratory Depression (POIRD)

- 48 million inpatient procedures performed annually in the U.S.
- Undetected critical POIRD results in respiratory failure and cardiac arrest.
  - Hypoxic injury or death in 80% of cases.
- As many as 113 events per 1000 patients.
  - By strict OIRD diagnostic criteria, incidence may be as high as 41%!
- Opioid induced respiratory depression can occur any time a patient has an opioid agent in their system.
  - Effects occur minutes to days after opioid initiation.

John Kruger Source
Who is At Risk for Opioid Adverse Drug Events: The Joint Commission Data

High Risk Patient Characteristics for Adverse Drug Event’s With Opioids in Hospital Setting

- Sleep apnea or sleep disorder diagnosis
- Morbid obesity with high risk of sleep apnea
- Persons who snore
- Persons of advanced age:
  - Age 61-70: 2.8 x higher risk for complication
  - Age 71-80: 5.4 x higher risk for complication
  - > Age 80: 8.7 x higher risk for complication
- Opioid use naïve patients
- Post-surgical patients, particularly if upper abdominal or thoracic surgery
- Thoracic or other surgical incisions that may impair breathing
- Preexisting pulmonary or cardiac disease or dysfunction or major organ failure
- Persons with increased opioid dose requirement or those with opioid habituation
- Patients who underwent longer length of time receiving general anesthesia during surgery
- Persons co-prescribed other sedating drugs to include:
  - Benzodiazepines
  - Antihistamine such as diphenhydramine
  - Sedatives and sedative hypnotic agents,
- Smokers
- Increased ICP patients and those with Arnold Chiari Type I malformation.


Multiple Contributing Sources Referenced and Found at:
http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf

John Kruger
Questions
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