ADVERSE DRUG EVENTS
PART 1: FINDING THE DATA

Steven Tremain, MD
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ADVERSE DRUG EVENTS

• Responsible for 40-50% of harm
• High Alert meds are most serious
  – Anticoagulants (warfarin)
  – Hypoglycemics (insulin)
  – Opioids (all)
ADVERSE DRUG EVENTS

• What exactly are they?

ADVERSE DRUG EVENTS

• An adverse event is any injury involving medication use. (AHRQ)
  – Known side affects are ADEs
    • Respiratory depression from opioids
    • Hypoglycemia from insulin
  • Most are preventable
ADVERSE DRUG REACTION: DEFINITION

ANY unexpected, unintended, undesired, or excessive response to a drug that REQUIRES ANY of the following:
• discontinuing the drug (therapeutic or diagnostic),
• changing the drug therapy,
• modifying the dose (except for minor dosage adjustments),
• admission to a hospital,
• prolonged stay in a health care facility,
• supportive treatment,
• significantly complicates diagnosis,
• negatively affects prognosis, results in temporary or permanent harm, disability, or death.

MEDICATION ERROR

• Any error in the medication use process
• All ADRs are ADEs

• THE HRET-HEN IS FOCUSED ON ADE REPORTING...

So all ADRs and all ADEs should be counted!

REPORTING ZERO???

• Are you Good?
• Are you Lucky?
• Are you not looking?
WHERE DO YOU FIND THEM?

• We have to look

• We have to report

• Someone has to listen

• There can be no fear of reprisal
CULTURE OF SAFETY

A set of beliefs:
• A recognition that professionals will make mistakes
• A recognition that even professionals will develop unhealthy norms
• A fierce intolerance for reckless conduct

Just Culture is not about WHO
Just Culture is about HOW and WHY

SO WHAT’S THE BOTTOM LINE?

If you want to minimize the chances of an error occurring or recurring, you must:
• Know of the near miss or error
• Create an environment where staff is not afraid to make the error known
• Aggregate data to know where the error-prone steps are
• Redesign to “design out error”
WHERE DO YOU FIND THEM?

• The low yield:
  – Root Cause Analyses
  – Non purposeful mining of data from electronic medical records
• The high yield:
  – Voluntary reporting (if safe culture)
  – Triggers
  – Focused data mining

WARFARIN MEASURES – OUTCOME

Numerator: # of inpatients with an INR >5

Denominator: # of inpatients receiving warfarin
OPIOID MEASURES – OUTCOME

Numerator: # of patients who received naloxone
Denominator: # of patients who have received an opioid while in the hospital or ED

- Inclusions:
  - Any patient prescribed an opioid agent in the ED, as an inpatient, or related to a procedure in an outpatient procedural area
  - All ‘planned’ reversals

- Exclusions:
  - Emergency Department use for patients arriving with a possible overdose
  - Use for nausea or pruritus (accepted indications)

HYPOGLYCEMIA MEASURES – OUTCOME

Numerator: # of inpatients with a plasma or POC glucose < 50 mg/dl

Denominator: # of inpatients receiving insulin
A WORD ABOUT MEASUREMENT

François-Marie Arouet (Voltaire)

From La Begueule (1772):
“In his writings, a wise Italian says that the best is the enemy of the good.”

A WORD ABOUT MEASUREMENT

Sir Robert Alexander Watson-Watt
Developer of RADAR (defense of Britain 1940)

"Give them the third best to go on with;
the second best comes too late;
the best never comes."
SO HOW DO WE FIND ADE DATA?

• RULE #1: Keep it simple.

• RULE #2: Go Look for it.

• RULE #3: If it is too hard to find then you are probably working too hard!

SO HOW DO WE FIND ADE DATA?

• Warfarin:
  – How many INRs above 5 do you have that are NOT due to warfarin???
  – Count all patients with high INR (numerator)
    • Assume on warfarin
  – Count all patients with warfarin orders (denominator)
  – BINGO! CLOSE ENOUGH
SO HOW DO WE FIND ADE DATA?

• Opioids:
  – How often do you give naloxone to people NOT on opioids?
  – Count all patients who received naloxone (numerator)
    • Assume on opioids
  – Count all patients with who received opioids (denominator)
  – BINGO! CLOSE ENOUGH

• Insulin:
  – How often do you see a glucose <50 in a patient NOT on insulin?
  – Count all patients who had a glucose <50 (numerator)
    • Assume on insulin
  – Count all patients with who received insulin (denominator)
  – BINGO! CLOSE ENOUGH
ADVERSE DRUG EVENTS
PART 2: GETTING IT DONE
FOCUSING ON WARFARIN, OPIOIDS & HYPOGLYCEMIA

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AND THE #1 CAUSE OF MED ERRORS IS....
AND THE #1 CAUSE OF MED ERRORS IS....

- Distractions and Interruptions
- Why?
A WORD ABOUT MEASURES

- Outcomes measures: what you get
- Process measures: what you do
SIMPLIFIED:
STRUCTURE + PROCESS = OUTCOME

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<thead>
<tr>
<th></th>
<th>Bad Outcome</th>
<th>Good Outcome</th>
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<tbody>
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<td>Expected</td>
<td>Dumb Luck</td>
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<tr>
<td>Good process</td>
<td>Refine Process</td>
<td>Expected</td>
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WARFARIN SAFETY: WHAT WORKS

- Pharmacist driven protocols for warfarin management.
- INRs before first inpatient dose
- Daily INRs
- Trending and intervention before high threshold reached

WARFARIN: POSSIBLE PROCESS MEASURES

- % of patients receiving pharmacist driven protocols for warfarin management.
- % of inpatients receiving an INR before first inpatient dose
- % of inpatients receiving daily INRs
- % of warfarin doses modified as a result of pharmacists’ trending and intervention before high threshold reached
REDUCING WARFARIN HARM: IT’S POSSIBLE

- Elkhart General, IN

INPATIENT OPIOID HARM

- 1 out of every 6 medication errors
- Half of preventable opioid ADEs are due to use of multiple opioids and sedatives
- 0.5% to 1.1% of post-operative patients receiving opioids experience respiratory depression
OPIOID SAFETY: WHAT WORKS

• Track and understand the geography of your naloxone use:
  – Where
  – When
  – Doing what

• Use protocols and tables for equianalgesic transition from one opioid to another
• Use alerts to avoid multiple prescriptions of opioids/sedatives
• Set dosing limits
• Minimize “layering”: set alerts and dosage limits on concurrently prescribed opioid potentiators
  – Sedatives, hypnotics, anxiolytics, phenothiazines
  – BEWARE OF BENZOś
OPIOIDS: POSSIBLE PROCESS MEASURES

• Any on the previous slide turned into a measure

• % of patients who received a standard risk assessment (STOP BANG, POSS, RASS) prior to the first dose of an opioid

• % of patients who received a standard risk assessment (POSS, RASS) 15 minutes after each dose and prior to each subsequent dose of an opioid

OPIOID SAFETY: TOOLS

• Identify patients at risk: STOP BANG
  https://www.sleepassociation.org/sleep-apnea-screening-questionnaire-stop-bang/

• Use effective tools to reduce over-sedation from opioids (e.g. risk assessment tools, sedation assessment tools: POSS, RASS)
  http://www.icudelirium.org/docs/RASS.pdf

• End tidal capnography
**OPIOID SAFETY: WHAT WORKS**

- Standardize processes for opioid naïve patients
- PA PSA Opioid Knowledge Assessment
  
  
  - 11 questions
  - No profession scored better than 40%

**OPIOID KNOWLEDGE GAP ANALYSIS**

- Most overestimate opioid tolerance
- Issues with multiple layers of drugs
- Tunnel vision on pain
OPIOID SAFETY: TOOLS

Minnesota Opioid Assessment

Opioid Adverse Drug Event Prevention Gap Analysis
Component of the Medication Safety Road Map

| Specific Action(s)                                      | Gap Analysis Questions                                                                 | Yes | No
|--------------------------------------------------------|----------------------------------------------------------------------------------------|-----|----
| Prevention & Mitigation Strategies                      | Prevention & Mitigation Strategies                                                     |     |    |
| 1) Systems and processes for opioid monitoring practices| The facility has processes in place to eliminate errors in opioid storage, preparation, and dispensing, which include: 1a) Strategies to prevent errors caused by mixing up concentrated and dilute oral liquid narcotics. 1b) Standardizing the choices of epidural infusions per organization/service line and minimizing the formulary. 1c) Established dose equivalency conversion tools are readily available and utilized. |     |    |

OPIOID SAFETY: THE STARS

- Grant Memorial Hospital, Columbus, OH
  - >10,000 surgeries per year
  - 2 used of naloxone in the last 12 months

- How?
  - Every patient receives timely POSS or RASS
  - Nurses rolled it out and “own” it
INSULIN SAFETY: WHAT WORKS

• Target range 140 -180 !!!
• Standard orders for sudden NPO/loss of line
• Insulin drips for critically ill patients with glucose > 180
• Meal and insulin coordination
• Consideration for changing insulin regimen if glucose <100 mg/dl
• Changing insulin regimen if glucose <70 mg/dl

INSULIN SAFETY: POSSIBLE PROCESS MEASURES

• % of patients who maintain glycemic control between 140 – 180 mg/dl
• % of patients on insulin with loss of line or sudden NPO who receive care per standard orders for unexpected loss of nutrition
• % of critically ill patients with glucose > 180 who receive insulin drips
• % of patients who receive their meal with their insulin (meal and insulin coordination)
• % of patients who have their insulin regimen modified after one event of glucose < 70
INSULIN SAFETY: STAY AWAY FROM THE CLIFF

The ADA:
- White line = 100 mg/dl
- Rumble strip = 70 mg/dl
- Guardrail = 50 mg/dl
- Action at 100 and 70 prevents 50!

INSULIN SAFETY:
- UC San Diego, CA
RESOURCES

- [http://www.hret-hen.org/topics/adverse-drug-event.shtml](http://www.hret-hen.org/topics/adverse-drug-event.shtml)
- Change Package
- Top 10 Checklist
- Tools
- Resources
- Webinars/audio + slides

DISCUSSION....QUESTIONS?

Steve Tremain, MD, FACPE
stremain@cynosurehealth.org