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Patient Harm with Opioids: Can We Truly Reduce the Risk?

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Disclosure

Ali-Reza Shah-Mohammadi has no actual or potential conflict of interest in relation to this program or presentation.

Why Opioids?



U.S. Food and Drug Administration
Protecting and Promoting Your Health

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Drugs

Home > Drugs > Drug Safety and Availability

Drug Safety and Availability

- Drug Alerts and Safety Information
- Medication Guides
- Drug Safety Communications
- Drug Shortages
- Postmarket Drug Surveillance Information for Providers
- Information for Patients
- Medication Errors
- Drug Safety Alerts
- Safe Use Initiatives
- Drug Recalls
- Drug Supply

TJC Defends Its Pain Management Standards

The organization notes that op released requirements for treat

Published: April 20, 2016
Category: Outpatient Surgery > Pain

FDA Panel: Physician Opioid Training Should Be Mandatory

Pauline Anderson



Opioid history: From 'wonder drug' to abuse epidemic

17:31 PM, May 12, 2016

The abuse of opioids, including prescription painkillers and drugs like heroin, is something the U.S. has struggled with for decades.



Congressman: Opioid addiction requires action, not silver bullet

23:58 PM, May 11, 2016

There are no easy answers to the opioid addiction crisis, says Rep. Hal Rogers, but scaling local approaches and passing new laws offer tools for action.

treatments and including misu

opioid use disorders, and reduce the su

in the environment of today's prescri says David Baker, MD, MPH, FACP statement. "Often, The Joint Commis critics to look at our exact standards, what our accredited organizations an

Opioid Abuse

Opioid Toxicity

Opioid Equivalents and Conversions

be tied to the recently released Centers for Disease Control and Prevention (CDC) guidelines, and involve mental health and suicide screening.

At the meeting, the joint committee discussed results of assessments of ER/LA REMS. The FDA had received four assessments of the ER/LA opioid REMS from the "applicant holders" (manufacturers of opioid products).

Objectives

- Describe common preventable adverse events and their causes with opioid therapy
- Identify effective strategies to improve the safety of prescribing, dispensing, and administering opioids
- Select the use of appropriate drug-specific metrics for opioids at your institution

Definitions

- **Medication error** – is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer
- **Adverse drug reaction (ADR)** – a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function
- **Adverse drug event (ADE)** – any injury resulting from medical intervention related to a drug
- **Adverse event (AE)** – any undesirable experience associated with the use of a medicinal product in a patient

1. National Coordinating Council for Medication Error Reporting and Prevention. Available at: www.nccmerp.org. Accessed 05/16/16.
2. Cohen MR. Medication Errors. 2nd ed. Washington, DC: American Pharmacists Association;2007:235-274, 513-550.
3. U.S. Food and Drug Administration. What is a Serious Adverse Event? Available at: <http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>. Accessed 05/16/16.

Adverse Events Continue to Happen

- Patient underwent surgical repair of a heel injury and within 15 minutes of arrival in the PACU, he received doses of:
 - meperidine 75 mg
 - morphine 4 mg
 - fentaNYL 25 mcg
- Also has a PCA order for morphine 1 mg/mL
 - 3 mg per demand dose
 - lockout of 10 minutes
 - basal rate of 1 mg/hour
- Patient gave himself 3 doses in 30 minutes and over the next 5 hours, gave himself 17 more doses. Was found in respiratory arrest and resuscitation efforts were unsuccessful

Adverse Events Continue to Happen...again

- Post-operative patient with a morphine infusion running immediately after surgery
- Prior to discharge the next day, a nurse applied a prescribed fenta**NYL** patch (75 mcg/hour) to the patient
- Patient was given 3 patches to take home and a prescription for oxy**CODONE** PRN every 4-6 hours
- The patient died within 12 hours of discharge

Adverse Events Continue to Happen...and again

- A 17-year-old was having a tonsillectomy performed in an outpatient ambulatory surgery center
- Following surgery, the nurse anesthetist administered a dose of fentaNYL by slow IV push to help manage pain
- The teen was not observed or assessed for some time and 25 minutes later, the patient was found pulseless and breathless and resuscitation efforts were initiated
- Due to oxygen deprivation, the patient suffered profound, irreversible brain injury and died

Harmful Medication Errors

Generic Name	n	%
Insulin ^a	428	16.2
Morphine ^a	123	4.6
Heparin ^a	83	3.1
Hydromorphone ^a	71	2.7
Warfarin ^a	61	2.3
Fentanyl ^a	59	2.2
Potassium Chloride ^a	53	2.0
Vancomycin	45	1.7
Enoxaparin ^a	44	1.7
Diltiazem	37	1.4
Furosemide	31	1.2
Total Parenteral Nutrition	28	1.1
Promethazine	25	0.9
Levofloxacin	23	0.9
Oxycodone	22	0.8
Ceftriaxone	21	0.8
Midazolam	21	0.8
Phenytoin	21	0.8
Clonidine	20	0.8
Hydrocodone and Acetaminophen	20	0.8
Sodium Chloride	20	0.8
Lorazepam	19	0.7
Meperidine	19	0.7
Metoprolol Tartrate	19	0.7
Cefazolin	18	0.7

Note: Data based on 2,209 records associated with 2,650 selections and 435 unique products

a A high-alert medication

1. MEDMARX® Data Report. A Report on the Relationship of Drug Names and Medication Errors in Response to the Institute of Medicine's Call for Action. Accessed 05/16/16.

The Joint Commission Sentinel Event Database

- Opioid-related ADEs that were reported to The Joint Commission's Sentinel Event database from 2004-2011 showed:
 - 47% were wrong dose medication errors
 - 29% were related to improper monitoring of the patient
 - 11% were related to other factors
 - excessive dosing
 - medication interactions
 - ADRs

Causes for Adverse Events with Opioid Use

- Lack of knowledge about potency differences among opioids
- Improper prescribing and administration of multiple opioids and modalities of opioid administration
- Inadequate monitoring of patients on opioids

1. The Joint Commission. Sentinel Event Alert. Available at: https://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf. Accessed 05/16/16.

Other Potential Causes

- Growing concerns regarding under treatment of pain in the U.S.
 - Pain assessment and treatment standards established in 2001
- HCAHPS and Press Ganey scores
 - HCAHPS questions ask about pain control
- Practitioner telling the patient that “you will be pain free”

1. The Joint Commission. Joint Commission Statement on Pain Management. Available at: https://www.jointcommission.org/topics/pain_management.aspx. Accessed 05/16/16.
2. MedPageToday. Opioid Crisis: Scrap Pain as 5th Vital Sign? Available at: <http://www.medpagetoday.com/publichealthpolicy/publichealth/57336>. Accessed 05/16/16.

Polling Question

*How does the potency of IV **HYDRO**morphine compare to IV morphine:*

- A. **HYDRO**morphine 1 mg $\approx$ morphine 1 mg
- B. **HYDRO**morphine 1 mg $\approx$ morphine 4 mg
- C. **HYDRO**morphine 1 mg $\approx$ morphine 7 mg
- D. Not certain

Helping You Remember

HYDROmorphone
HELPING YOU REMEMBER

Home Run



HYDROmorphone
1 mg

$\approx$

Touchdown



Morphine
7 mg

Listed in the Top 10 Drugs Causing Patient Harm in

- Health and Human Services – Office of the Inspector General Report – “Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries”
- MEDMARX database
- Pennsylvania’s Patient Safety Authority database

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

1. Institute for Safe Medication Practices. HYDROmorphone – Helping You Remember. Available at: <https://www.ismp.org/tools/Hydromorphone.pdf>. Accessed 05/16/16.

Polling Question

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 oxy**CODONE** 10 mg with acetaminophen 325 mg 4 times daily for 5 days
- C. Taking oxy**CODONE** 10 mg with acetaminophen 325 mg 4 times daily for 14 days
- D. Taking extended-release morphine 15 mg twice daily for 1 week
- E. All the above

Opioid Tolerant Patient

- Patients who are opioid tolerant are those receiving, for one week or longer, at least:
 - 60 mg oral morphine per day,
 - 25 mcg transdermal fenta**NYL** per hour,
 - 30 mg oral oxy**CODONE** per day,
 - 8 mg oral **HYDRO**morphine per day,
 - 25 mg oral oxymorphone per day,
 - or an equianalgesic dose of another opioid.
- An opioid naïve patient would be one that does not meet the definition of opioid tolerant

1. U.S. Food and Drug Administration. Extended-Release (ER) and Long-Acting (LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS) Available at: <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM311290.pdf>. Accessed 05/16/16.

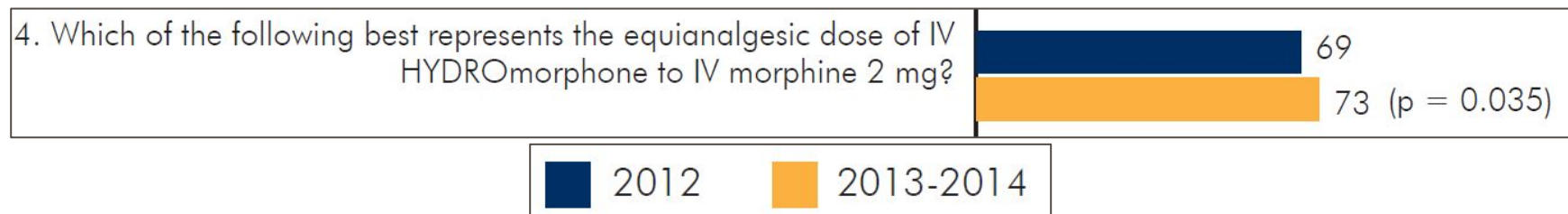
Opioid Knowledge Assessment (2012)

- Overall percentage of correctly answering equianalgesic dose of IV **HYDRO**morphine to IV morphine was 67.2%

Practitioner Type (n = 1,898)	Percentage of correctly answered
Attending/Staff Physician	70.1
Resident Physician/Physician in Training	80.6
Physician Assistant/Nurse Practitioner	73.2
Registered Nurse	55.8
Pharmacist	92.6
Other	66.7

Opioid Knowledge Assessment (2013-2014)

- Same question asked in the 2013-2014 assessment
- Hospitals participating in opioid knowledge assessment:
 - 2012 – 29 hospitals participating in the PA-HEN ADE collaboration
 - 24 hospitals participated in knowledge assessment
 - 2013 to 2014 – 22 hospitals participating in the PA-HEN ADE collaboration
 - 12 of these were invited to participate as they participated in 2012
 - 10 hospitals participated



Opioid Knowledge Assessment (2012)

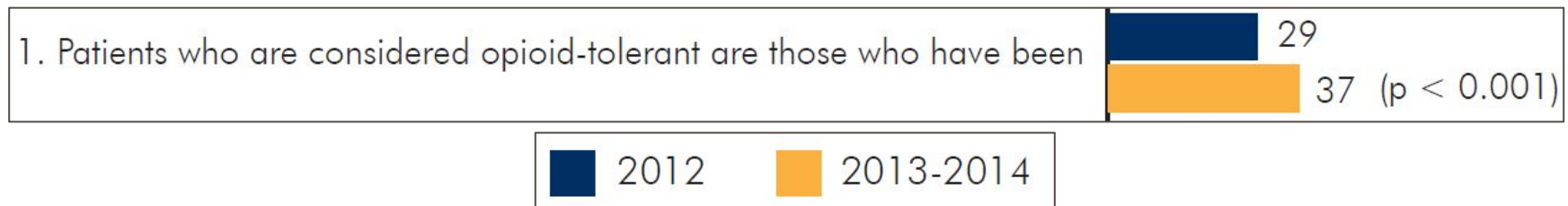
- Overall percentage of correctly answering question about opioid tolerance was 29.1%

Practitioner Type (n = 2,024)	Percentage of correctly answered
Attending/Staff Physician	34.2
Resident Physician/Physician in Training	24
Physician Assistant/Nurse Practitioner	32.5
Registered Nurse	25.5
Pharmacist	40.5
Other	20.7

- Almost 53% of all respondents answered “all of the above”
 - 49.3% of physicians
 - 57.4% of nurses
 - 37.8% of pharmacists

Opioid Knowledge Assessment (2013-2014)

- Same question asked in the 2013-2014 assessment



Polling Question

Which of the following statements about long-acting opioids is true?

- A. They are intended for use for pain on an as-needed basis
- B. They are indicated for pain in the immediate postoperative period (12 to 24 hours following surgery)
- C. They are indicated for pain during the postoperative period, if the pain is not expected to persist for an extended period of time
- D. They are only indicated if the patient is opioid tolerant and has already been receiving the drug prior to surgery
- E. All of the above

Opioid Knowledge Assessment (2012)

- Overall percentage of correctly answering question about long-acting opioids was 56.5%

Practitioner Type (n = 2,024)	Percentage of correctly answered
Attending/Staff Physician	71.6
Resident Physician/Physician in Training	58.3
Physician Assistant/Nurse Practitioner	71.4
Registered Nurse	46.4
Pharmacist	78.6
Other	31.1

Opioid Knowledge Assessment (2013-2014)

- Same question asked in the 2013-2014 assessment



Polling Question

*Which of the following patient-specific parameters is/are the most important to monitor in patients receiving IV **HYDRO**morphone?*

- A. Patient-reported pain intensity
- B. Level of sedation
- C. Adequacy of ventilation
- D. Respiratory rate
- E. A and D
- F. A, B, and C

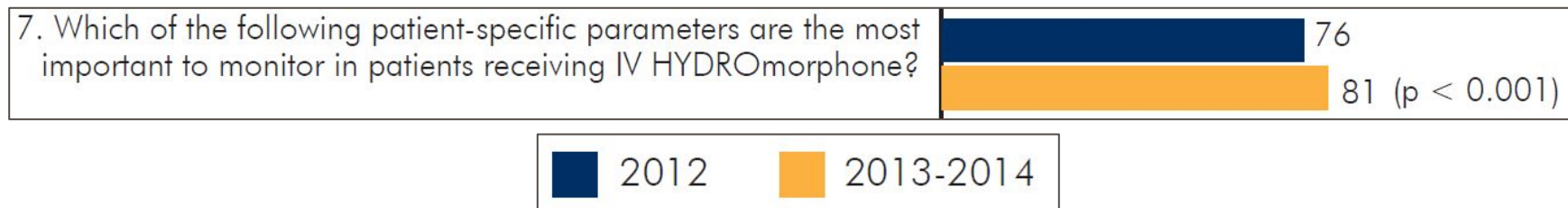
Opioid Knowledge Assessment (2012)

- Overall percentage of correctly identifying patient-specific parameters most important to monitor was 76.2%

Practitioner Type (n = 1,831)	Percentage of correctly answered
Attending/Staff Physician	77.3
Resident Physician/Physician in Training	75
Physician Assistant/Nurse Practitioner	89.9
Registered Nurse	76.3
Pharmacist	74.9
Other	69.1

Opioid Knowledge Assessment (2013-2014)

- Same question asked in the 2013-2014 assessment



Strategies to improve the safety of opioids

Rank Order of Error Reduction Strategies

Error-Reduction Strategy	Power (leverage)
Fail-safes and constraints	 High Low
Forcing functions	
Automation and computerization	
Standardization	
Redundancies	
Reminders and checklists	
Rules and policies	
Education and information	
Suggestions to be more careful or vigilant	

1. ISMP Medication Safety Alert! Community/Ambulatory Care Edition. February 2006;5(2):2.

Fail-Safes and Forcing Functions

- Use smart infusion pumps (i.e., infusion pumps with dose error reduction software) with soft and hard stops enabled to alert the user to unsafe doses for continuous opioid infusions and patient-controlled analgesia (PCA) therapy
- Use oral syringes for administration of oral liquid products. To further reduce the risk of unintended administration of oral medications via the IV route, have pharmacy dispense all oral liquids that are not commercially available as unit dose product in an oral syringe
- Leverage technology to ensure medication reconciliation is conducted and an assessment of opioid status is determined. Determine who should make the assessment and inform pharmacy

1. Gaunt MJ, Alghamdi D, and Grissinger MC. *Pa Patient Saf Advis*. 2014 Sep;11(3):124-30.
2. Shah-Mohammadi A and Gaunt MJ. *Pa Patient Saf Advis*. 2013 Sep;10(3):85-91.

Constraints

- Limit the variety of opioids, concentrations of each opioid, and formulations of each opioid included on the hospital formulary
- Consider requiring practitioners to undergo a privileging process to verify proficiency with PCA pain management
- Consider restricting fentanyl PCA use to anesthesia or pain management team members only
- Implement standard order sets for PCA therapy, with all sections completed, and limit verbal orders to dose changes
- Take into consideration important information about the patient that could affect the prescribing of opioids (e.g., patient's current medication profile for drugs with additive central nervous system or respiratory depressant side effects, age, renal function, total current opioid therapy)

Constraints (continued)

- Avoid storing concentrated oral forms of opioids in floor stock and automated dispensing cabinets (ADCs). Dispense only when ordered for a specific patient
- Store only the smallest-size package, concentration, and dose of opioids in floor stock and ADCs
- Store each medication in a separate, lock-lidded bin or drawer in the ADC to help prevent drug-selection errors. In the pharmacy, segregate prefilled syringes and vials of these drugs, especially if they contain the same concentration
- Separate morphine and **HYDRO**morphine in drug storage areas

1. Gaunt MJ, Alghamdi D, and Grissinger MC. *Pa Patient Saf Advis*. 2014 Sep;11(3):124-30.
2. *ISMP Medication Safety Alert!* July 24, 2003;8(15):2.

Standardization

- Ensure current pain management protocols and guidelines for opioid use are available to guide prescribers, pharmacists, and nurses when opioids are prescribed, dispensed, administered, or monitored
- Implement a standardized pain scale(s) appropriate to the patient population to assess a patient's level of comfort/pain
- Use standardized preprinted order forms and computerized prescriber order entry (CPOE) order sets to prescribe oral and parenteral opioids. Design patient monitoring requirements and include these interventions in order sets
- Ensure patients with continuous opioid infusions and PCAs have continuous monitoring of respiratory status using capnography or pulse oximetry

1. Gaunt MJ, Alghamdi D, and Grissinger MC. *Pa Patient Saf Advis*. 2014 Sep;11(3):124-30.
2. *ISMP Medication Safety Alert!* May 30, 2013;18(11):1-3.

Standardization (continued)

- Standardize concentrations of parenteral opioid infusions for adult patients to a single concentration per drug, and use these in at least 90% of the cases
- Standardize concentrations of parenteral opioid infusions for pediatric patients (including neonates) to a single concentration per drug, and use these in at least 90% of the cases
- Standardize preprinted order forms and CPOE order sets used for PCAs
- Establish protocols for reversal agents that can be administered without additional physician orders when warranted

Redundancies

- Implement an independent double check for all parenteral opioids that are compounded in the pharmacy
- At the point of administration, implement an independent double check with each new infusion bag, bottle, or syringe, as well as with changes in the rate of infusion of parenteral opioids
- At the point of administration, implement an independent double check with each new PCA infusion bag, bottle, or syringe, as well as with changes in the rate of PCA administration of parenteral opioids

Education

- Provide practitioners involved in medication use with ongoing education about medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused
- Consider providing staff with ongoing education about medication errors that have occurred within the organization and in other organizations, as well as strategies to prevent these errors
- Expand on extensive pain management education and training in medical, nursing, and pharmacy education programs and new-practitioner training
- Encourage internal and external (FDA and ISMP) reporting of errors

Education (continued)

- Improve access to information regarding:
 - Signs and symptoms of opioid toxicity, withdrawal, and allergic reactions
 - Dosing of opioids, particularly in opioid naïve patients
 - Equianalgesia conversions from opioid-to-opioid
 - Proper use of PCAs before initiation, including establishing patient selection criteria
 - Warning family members about the danger of PCA by proxy

Appropriate drug-specific metrics for opioids

Common Question Received by ISMP

What denominator should I use to calculate my organization's medication error rate?

- A. Patient Days?
- B. Doses Dispensed?
- C. Other?

Answer to ISMP's most FAQ

NONE!!!

- Numerator = number of error reports received, but...
- No such reliable measure exists
- Therefore, organizations are unable to “benchmark” to any certainty a reliable “error rate” against anyone else
- Can calculate an error reporting rate

Answer to ISMP's most FAQ

**Medication
Errors**



**Errors
Reported**

?

Error Rate $\neq$ Reporting Rate

Benchmarking

- A myth that one can gauge quality and safety by simply comparing error rates
- Differences in:
 - Culture
 - Definition of error (harm, close calls)
 - Patient populations (tertiary vs. rehabilitation)
 - Types of reporting (passive vs. active)
- False sense of security

NCC MERP

- There is no acceptable incidence rate for medication errors
- Use of medication error rates to compare health care organizations is of no value
- The sheer number of error reports is less important than:
 - the quality of the information collected in the reports,
 - the health care organization's analysis of the information, and
 - its actions to improve the system to prevent harm to patients

Event Detection Methods

- Voluntary event reporting
- Chart review
- Direct observation
- Trigger tools

Outcome Measures

- Purpose of error reporting is to find out more information about where breakdowns occur
- Medication error reports cannot provide reliable quantitative data
- Assess outcome measures to determine if your efforts to improve medication safety have been successful

Metrics for Consideration

- Instances of naloxone use
 - Instead of focusing on the “number” of episodes of naloxone use, how about:

Number of episodes a reversal agent (naloxone) is administered to an inpatient prescribed opioids
Number of inpatients prescribed opioids

- Pharmacist interventions
 - Instead of focusing on the “number” of interventions, how about:

Number of pharmacist interventions placed regarding opioids
Total number of pharmacist interventions

Metrics for Consideration

- Review of opioid status in PACU
 - Instead of focusing on the “number” of opioid events, how about:

$$\frac{\text{Number of patients with a documented opioid status assessment (naïve vs. tolerant) in PACU}}{\text{Number of patients prescribed opioids in PACU}}$$

- Review of opioid status in PACU
 - Instead of focusing on the “number” of opioid events, how about:

$$\frac{\text{Number of patients with documentation of a pre-operative opioid status assessment}}{\text{Number of patients prescribed opioids post-operatively in the PACU}}$$

Metrics for Consideration

- Review of opioid status with long-acting opioids
 - Instead of focusing on the “number” of opioid events, how about:

$$\frac{\text{Number of patients with a documented opioid status assessment (naïve vs. tolerant)}}{\text{Number of patients prescribed long-acting opioids}}$$

- Activation of a rapid response team (RRT)
 - Instead of focusing on the “number” of RRT activations, how about:

$$\frac{\text{RRT activations related to opioids}}{\text{Total number of RRT activations}}$$

Metrics for Consideration

- Documentation of reassessments
 - Instead of focusing on the “number” of opioid events, how about:

Number of documented reassessments of RR, quality of respirations, level of sedation, and BP
Total number of patients on unit with PRN orders for and administered IM or IV opioids

- Prescribing practices
 - Instead of focusing on the “number” of opioid events, how about:

Number of opioid orders not using a standard protocol or preprinted order form
Total number of new orders for opioids

Measurement Pearls

- Important to collect the same data over time to show improvement
- Once measurement consistency is reached, decide to do “spot check” and instead measure something else
- Share the data and lessons learned but avoid focusing solely on the numbers

Questions

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