Medication Safety
and
Medication Error Reduction Plan
Program

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Center for Healthcare Quality
Learning Objectives

• Identify the key elements of a CDPH MERP survey
• List the common and significant MERP findings since implementation of the program.
• Identify the strategies implemented to address significant medication safety findings.
• Provide CDPH with recommendations for medication safety focus areas for next triennial survey cycle starting January 2012.
Launching of Patient Safety/MERP

November 1999

TO ERR IS HUMAN
BUILDING A SAFER HEALTH SYSTEM

INSTITUTE OF MEDICINE

44,000-98,000
Senator Speier – SB 1875

Condition of licensure  Hospitals adopt a formal plan to eliminate or substantially reduce medication-related errors
Submit plan to CDPH by January 1, 2002 and implement by 2005
Institute of Medicine Report “Identifying and Preventing Medication Errors” July 2006

Every year, 1.5 million Americans suffer injuries from medication errors.
Institute of Medicine Report

- Skilled Nursing Facilities - 800,000
- Outpatient clinics – 530,000
- Hospitals 400,000
  - ONE medication error/patient/day
  - Treatment of medication related injuries in hospitals 3.5 billion/year
  - One in five patients discharged from the hospital ends up sicker within 30 days, over half of these cases are medication related*

Beginning of a journey

- January 2002 received 900 plans
  - Reviewed and approved
  - Includes surgical clinics
- Plans are to be implemented by 2005
- CDPH required to monitor implementation
  - First attempt Fall 2007
  - 2008: Collaboration
Collaboration

- **Stakeholder input meetings**
  - Six meetings – LA, Orange, Inland Valley, SF Bay Area, Sacramento and San Diego: 72 hospitals

- **Outcomes:**
  - Notification All Facilities Letter (AFL 08-12) – March 2008
  - Simulation surveys: Two with 21 hospitals present: North and South – September 2008
  - Survey Process AFL (08-39) – December 2008
  - Surveys pre-announced – (ended with furloughs: AFL 09-31)
  - Established a dedicated email address for questions/concerns
MERP Program

Launched January 1, 2009
MERP Survey Process

- Surveys are triennial
- Managed by CDPH Pharmaceutical Consultant Unit
- Approximately 32 hospitals/quarter
- Outcome(s):
  - No deficiencies
  - Deficiencies noted under State laws (HSC) and Regulations (Title 22)
  - State Immediate Jeopardy finding with or without a penalty.
  - Federal Complaint Validation survey with federal deficiencies with or without Condition Level deficiencies.
  - Federal Immediate Jeopardy finding
  - Failure to report an Adverse Event
Program Enhancements - 2010

- Survey Evaluation -
  - 37% response – average 4.8

- Survey Process – Document request
  - P&Ps related to med errors, emergency med use, etc.
  - Patients last 3 mos: PCA, Fentanyl, Insulin, reversal agents, etc
  - Current MERP & annual reviews
  - Medication error reports for last 3 yrs & outcome data
  - Committee minutes - oversight of MERP 3 yrs

- Survey Questionnaire
  - Organized as a workbook to facilitate collection of data and information that will be requested during interview process
  - Not mandatory
  - Three questions related to frequently cited law - HSC 1339.63(e)(1)(2)(3)
Medication Error Reduction Plan (MERP) Program

Program’s Mission
The MERP Program endeavors to promote safe and effective medication use in General Acute Care Hospitals (GACH) through reduction of preventable medication-related errors and adverse events.

The program’s objectives will be achieved through:
The Department’s survey activities whereby each hospital’s MERP will be assessed for implementation and compliance in accordance with Health and Safety Code Section 133953, including California Code of Regulations, Title 22; and, ongoing collaborative efforts with stakeholders to advance medication safety strategies statewide to decrease identified system vulnerabilities.

MERP E-mail
In our ongoing efforts to provide transparency and collaboration with providers and the public, CDPH, has email address for individuals to submit MERP related questions or comments. The email address will provide a central point of contact where facilities and other interested parties can send emails in regards to MERP surveys and/or the MERP survey process. The email address is: MERP@cdph.ca.gov. Each email received will be acknowledged and the appropriate response subsequently sent by return email. Email responses from the MERP mailbox will be sent under the name “CDPH & C MERP” unless the incoming email is forwarded for further research and specific individual response.

MERP Survey Documents
- MERP Entrance Conference Documents Request (Attachment A)
- MERP Survey Facility Questionnaire (Attachment B)
- MERP Survey Evaluation Form (Attachment C)

Program Related All Facilities Letters (AFLs)

<table>
<thead>
<tr>
<th>BULLETIN NUMBER</th>
<th>TO:</th>
<th>SUBJECT:</th>
<th>RELEASE DATE:</th>
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<tbody>
<tr>
<td>AFL 09-31</td>
<td>All General Acute Care Hospitals and Special Hospitals</td>
<td>Change in Medication Error Reduction Plan (MERP) Survey Process</td>
<td>August 10, 2009</td>
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<tr>
<td>AFL 09-58</td>
<td>All Facilities</td>
<td>Medication Safety: Storage of Medications Requiring Refrigeration</td>
<td>December 31, 2009</td>
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<tr>
<td>AFL 08-20</td>
<td>All General Acute Care Hospitals and Special Hospitals</td>
<td>Survey Process for Medication Plans (MERP)</td>
<td>December 9, 2008</td>
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<td>AFL 07-33</td>
<td>General Acute Care Hospitals</td>
<td>Medication Safety: Use of Medications “boxed Warnings”</td>
<td>November 05, 2007</td>
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<td>AFL 05-02</td>
<td>General Acute Care Hospitals</td>
<td>Storage and Use of Emergency Medications</td>
<td>February 1, 2005</td>
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</table>

MERP Program Presentations
- CDPH Presentation at CMS Region IX Patient Safety Collaborative September 2011
- CDPH Presentation at CSHP Conference October 2010
Best Practices?

“The department may work with the facility's health care community to present an annual symposium to recognize the best practices for each of the procedures and systems.”

[HSC 1339.63 (g)]
Medication Safety Symposium

- Collaboration: CDPH, CHA and Hospital council
  - Hospital Council of Northern and Central: Mary Lopez, Suzanne Ness & Lynn Ashbeck

- Locations
  - Washington Hospital – 7/2010 - Nasim Karmali
  - Children’s Hospital – 1/2011 - Rich Sakai
  - Contra Costa Regional Medical Center & Washington – 8/2011 – Shideh Ataii & Nasim Karmail
  - Sonoma County Hospitals – November 28, 2011
California Department of Public Health

Medication Error Reduction Plan

“We share with readers our support of a statewide initiative in California (CA) to reduce medication-related errors that can be used as an example for all US hospitals to voluntarily adopt a similar initiative.”
UCSF Leadership Summit - 2010

- **65%**: agreed/strongly agreed that “increased regulatory scrutiny over the last 10 years has led to improved patients outcomes”
- **66%**: agreed/strongly agreed that “increases in patient safety in my organization have come primarily from regulatory mandates (e.g. BoP, CDPH, TJC)
- **71%**: agreed/strongly agreed that “having a MERP increased medication safety in our organization.”
Collaboration: It's working... Are we there yet?
Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

11/2010
How the numbers add up

- 15,000
- 180,000
- 44
- 324
- Number 1 cause of adverse events
  - 50
Administrative Penalties

- 201 issued between January 2007-October 2011
- $7 million assessed
- $4.7 million collected
- 154 (77%) administrative penalties generated from Adverse Events

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication errors/ pharmacy related errors</td>
<td>50</td>
<td>25</td>
</tr>
<tr>
<td>Retention of Foreign object</td>
<td>45</td>
<td>22</td>
</tr>
<tr>
<td>Patient Care Issues</td>
<td>35</td>
<td>17</td>
</tr>
<tr>
<td>Patient safety</td>
<td>35</td>
<td>17</td>
</tr>
<tr>
<td>Surgical error</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Staffing/ Training</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>201</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>
MERP Program Activities
MERP Survey Summary
January 2009 – October 2011

- 374 – Hospitals to be surveyed
- 328 – Completed surveys (89%)
- 305 – Noted deficiencies (93%)
- 23 – In compliance (7%)

Data as of 10/31/2011
Common Deficiencies

• 62% - Develop and implement P&Ps for safe and effective use of medications [CCR 70263(c)(1)]
• 60% - Conduct an annual review to assess effectiveness of the implementation of MERP [HSC 1339.63 (e)(2)]
• 43% - Identify weakness or deficiencies that could contribute to errors [HSC 1339.63 (e)(1)]
• 40% - Include a multidisciplinary process to regularly analyze all errors [HSC 1339.63 (e)(6)]
Common Findings

- Management of High Risk Medications
  - Fentanyl Transdermal Patch

- Safe Storage of Medications
  - Expired, contaminated, unusable
  - ADCs – overrides, oversight
  - Includes all areas listed on CDPH issued license (e.g. outpatient)
Common Findings

- PCAs – safe use, monitoring, P&Ps
- Infusions – P&Ps, overrides of stops, protocols not followed, competency
- Management of emergent clinical conditions
  - Code Blue
  - Malignant Hyperthermia
- Medication error analysis
  - Not inclusive of representatives
  - Small sample
Findings  Guidance
CHA Medication Safety Committee
High Alert Medication Guideline - FentaNYL Transdermal Patch
April 2011

Despite warnings from the FDA, manufacturers, and various patient safety agencies, transdermal fentaNYL patches continue to be prescribed inappropriately to treat patients with acute pain and patients who are not opioid tolerant. ISMP issued a Medication Safety Alert in June 2007, which may be found at http://www.ismp.org/Newsletters/acute-care/articles/20070628.asp.

This guideline document is intended to summarize safe use practices to reduce the preventable harm to patients in the hospital setting.

FentaNYL patches are only for patients who are opioid-tolerant for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time AND cannot be managed by other means. The patches are NOT to be used to treat sudden, occasional or mild pain, or pain after surgery.

Opioid tolerance may be identified in individuals who have been taking opioids for a week or longer. Opioid tolerant is defined as taking oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day.

<table>
<thead>
<tr>
<th>Medication Use Step</th>
<th>Actions to Consider to Increase Medication Safety</th>
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</thead>
<tbody>
<tr>
<td>General</td>
<td>Define and educate staff on opiate tolerance. Opioid tolerance may be identified in individuals who have been taking opioids for a week or longer. Opioid tolerant is defined as taking oral morphine 60 mg/day or oral hydromorphone 8 mg/day or oral oxycodone 30 mg/day.</td>
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</tbody>
</table>
December 10, 2009

TO: All Facilities

SUBJECT: Medication Safety: Storage of Medications Requiring Refrigeration

BACKGROUND: The Department of Public Health’s Center for Health Care Quality Licensing and Certification Program is issuing this letter to address concerns pertaining to the safe use of medications that require refrigeration. The concerns identified have been noted throughout the state and have resulted in both licensing and federal noncompliance determinations, including Immediate Jeopardy declarations.

Failure to store medications at the appropriate temperature, as specified by the manufacturer, can have significant impact on patient care. Numerous medications have minimal tolerances for temperatures outside a relatively narrow range and once the manufacturer’s established limits are breached, the product may be rendered less than optimally effective or ineffective. This is particularly true for the majority of vaccines.
Can Medication Safety System Vulnerabilities be identified proactively and objectively?
Medication Safety Event Tracking (Med SET)

Launched September 2011
Med SET

- Objectives:
  - Collect, quantify, and analyze medication safety data reported from deficiencies written by Pharmaceutical Consultants
  - Categorize types of medication-related events associated with Federal/State deficient practices

- Goals:
  - Identify medication safety system vulnerabilities and their trends
  - Use Med SET data to inform and educate internal and external providers on medication safety issues
Med SET

• Data extracted from Statement of Deficiencies
• All facility types: SNF, GACH, Clinics, ESRD, etc.
• Used MERP defined systems or procedures and expanded
• 12 categories with 85 sub-categories
• Compare different facility types
• Present level of harm
<table>
<thead>
<tr>
<th>MERP</th>
<th>Med SET</th>
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</thead>
<tbody>
<tr>
<td>1. Prescribing</td>
<td>1. Prescribing</td>
</tr>
<tr>
<td>2. Prescription order communication</td>
<td>2. Prescription order communication</td>
</tr>
<tr>
<td>3. Product labeling</td>
<td>3. Product labeling, packaging and nomenclature</td>
</tr>
<tr>
<td>4. Packaging and nomenclature</td>
<td>4. Compounding</td>
</tr>
<tr>
<td>5. Compounding</td>
<td>5. Dispensing</td>
</tr>
<tr>
<td>6. Dispensing</td>
<td>6. Distribution</td>
</tr>
<tr>
<td>7. Distribution</td>
<td>7. Administration</td>
</tr>
<tr>
<td>8. Administration</td>
<td>8. Monitoring</td>
</tr>
<tr>
<td>9. Education</td>
<td>9. Competency</td>
</tr>
<tr>
<td>10. Monitoring</td>
<td>10. Use</td>
</tr>
<tr>
<td>11. Use</td>
<td>11. Technology</td>
</tr>
<tr>
<td></td>
<td>12. Transitions in care</td>
</tr>
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</table>
# Medication System Event Tracker

## Error Categories - 20XX

<table>
<thead>
<tr>
<th>Error Category</th>
<th>Number of AP Occurrences</th>
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<tbody>
<tr>
<td>Prescribing</td>
<td>1</td>
</tr>
<tr>
<td>Rx Order Comm</td>
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<tr>
<td>Product Label, Pack...</td>
<td>1</td>
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<tr>
<td>Compounding</td>
<td>2</td>
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<tr>
<td>Dispensing</td>
<td>3</td>
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<tr>
<td>Distribution</td>
<td>2</td>
</tr>
<tr>
<td>Administration</td>
<td>3</td>
</tr>
<tr>
<td>Monitoring</td>
<td>15</td>
</tr>
<tr>
<td>Competency</td>
<td>1</td>
</tr>
<tr>
<td>Use</td>
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</tr>
<tr>
<td>Technology</td>
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</tr>
</tbody>
</table>

**Error Category**

Calgary Department of Public Health
# Med SET

## Medication System Event Tracker

### Error Subcategories

<table>
<thead>
<tr>
<th>Error Subcategory</th>
<th>No. of Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to Order</td>
<td>1</td>
</tr>
<tr>
<td>Unauthorized Prescr...</td>
<td>2</td>
</tr>
<tr>
<td>Wrong Patient</td>
<td>1</td>
</tr>
<tr>
<td>Contraindicated Med...</td>
<td>3</td>
</tr>
<tr>
<td>Wrong Dosage Form</td>
<td>3</td>
</tr>
<tr>
<td>Wrong Dose</td>
<td>2</td>
</tr>
<tr>
<td>Wrong Frequency</td>
<td>2</td>
</tr>
<tr>
<td>Wrong Route</td>
<td>1</td>
</tr>
<tr>
<td>Wrong Duration</td>
<td>1</td>
</tr>
<tr>
<td>Wrong Rate of Infusion</td>
<td>3</td>
</tr>
<tr>
<td>Wrong Indication</td>
<td>4</td>
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<tr>
<td>Unclear Orders</td>
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<tr>
<td>Informed Consent</td>
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<tr>
<td>Unnecessary Med</td>
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</tr>
<tr>
<td>Order Sets</td>
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</tr>
</tbody>
</table>

### Prescribing

- **Prescribing**
  - Failure to Order: 1
  - Unauthorized Prescr.: 2
  - Wrong Patient: 1
  - Contraindicated Med.: 3
  - Wrong Dosage Form: 3
  - Wrong Dose: 2
  - Wrong Frequency: 2
  - Wrong Route: 1
  - Wrong Duration: 1
  - Wrong Rate of Infusion: 3
  - Wrong Indication: 4
  - Unclear Orders: 4
  - Informed Consent: 6
  - Unnecessary Med: 7
  - Order Sets: 1
2012 – Second MERP cycle

Next Steps?