Tennessee Pharmacist Coalition on Medication Safety Opioid Adverse Drug Event Gap Analysis

Updated 06/24/2016

Tennessee Pharmacist Coalition
Opioid Adverse Drug Event Gap Analysis

Opioid Management Practices			
Gap Analysis Questions	**Yes**	**No**	**If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.**
1a) The facility has a medication diversion prevention surveillance program including:	☐	☐	
i. An interdisciplinary team, committee, subcommittee or equivalent, as part of the program	☐	☐	
ii. Best practices, core principles or equivalent, concerning physical security of controlled substances, operational policies and procedures to limit diversion, staff education, surveillance and quality improvement (See 77 Best Practices from Mayo Clinic: Berge, 2012, Supplemental Table).	☐	☐	
1b) The facility has assigned responsibility for coordinating opioid monitoring functions.	☐	☐	
1c) The facility has a process in place to ensure fields contained in standard protocols/order sets/flow sheets are consistently populated (manually or automatically) with key information, including at a minimum:			
i. The patient's diagnosis	☐	☐	
ii. Allergies	☐	☐	
iii. Most recent pertinent laboratory results	☐	☐	
1d) The facility has standard policies and practices in place for managing the initiation and maintenance of opioid therapy which include:			
i. The specific medication used (e.g., list specific meds)	☐	☐	
ii. The condition being treated	☐	☐	
iii. The potential for drug interactions	☐	☐	
iv. The potential for patient specific interactions	☐	☐	
v. The facility has a protocol in place to determine the need to reverse supra-therapeutic opioid therapy based on key criteria (e.g., list criteria)	☐	☐	
a. Reversal protocols are active on all patient's MARs if there is an active order for a narcotic	☐	☐	
b. Nurses are allowed to administer, according to protocol, reversal agents without prior physician order	☐	☐	
c. Strategies are in place to guard against dose stacking	☐	☐	
d. Depending on facility size/resources, a rapid response team is utilized to assist with possible narcotic oversedation events	☐	☐	
vi. The facility has a process in place to ensure that opioids are used for the appropriate indication (e.g., list indications)	☐	☐	
vii. Opioid orders include unique prn qualifiers, including pain scales to avoid duplication of therapy.	☐	☐	
1e) The facility's opioid practices to be considered.			
i. Clearly specifies opioids are not used to treat anxiety	☐	☐	
ii. Meperidine use is minimized or eliminated	☐	☐	
iii. Opioid administration is not routinely accompanied by sedatives or anticholinergic drugs such as hydroxyzine	☐	☐	
iv. Opioid dose ranges do not exceed 4x (four times) the original dose (consider limiting to 2x the original dose)	☐	☐	
v. Intramuscular (IM) opioid use is minimized	☐	☐	
vi. Oxygen is used only if therapeutically necessary and only upon physician order	☐	☐	
vii. Opioids should be prescribed upon discharge in a manner to treat the patient, prevent abuse and limit overprescribing of opioids.			
a. The prescribed amount upon discharge should be	☐	☐	

no more than the amount required for treatment until follow-up with their healthcare provider post-discharge. It is recommended that follow-up be provided within 7 days to reassess pain management treatment goals			
b. Assess the risks and benefits of prescribing dosages of ≥50 morphine milligram equivalents (MME)/day and avoid or fully justify dosages of ≥90 MME/day per CDC guidelines (Dowell, 2016)	☐	☐	
viii. Emergency Department providers are following the Tennessee Emergency Department Opioid Prescribing Guidelines	☐	☐	
ix. Primary care clinicians prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care, should follow CDC guidelines (Dowell, 2016) for prescribing opioids for chronic pain http://dx.doi.org/10.15585/mmwr.rr6501e1	☐	☐	

ADE Prevention and Mitigation Practices for Opioids

Gap Analysis Questions	Yes	No	If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
2a) Opioids are included in the organization's defined list of high alert medications.	☐	☐	
2b) A system is in place to alert health care practitioners to significant drug interactions for patients on opioid therapy.	☐	☐	
2c) A system is in place to remind the prescriber to evaluate the need for initiating and reinitiating therapy when opioids are being held.	☐	☐	
2d) The facility separates sound-alike and look-alike opioids and uses TALL man lettering and other techniques to reduce the risk of error.	☐	☐	
2e) The use of a standardized conversion support system for calculating correct doses of opioids to help prevent problems with conversions between opioids and from oral, IV, and transdermal routes of administration.	☐	☐	
2f) Established pediatric dose guidelines are widely available and utilized.	☐	☐	
2g) Pediatric dosage forms are separated from adult dosage forms.	☐	☐	
2h) The facility uses patient-controlled analgesia (PCA) to reduce the risk of oversedation. **i. The facility uses only standardized approved order sets for PCA orders.**	☐	☐	
2i) A pharmacy managed system is in place for opioid drug shortage or supply issues which outlines how standard medication safety processes will be followed.	☐	☐	
2j) The facility has processes in place to eliminate errors in preparation, storage, and dispensing which includes:			
i. Limiting concentrations of opioids stored in automated dispensing machines	☐	☐	
ii. Dispensing commercially prepared, pre-mixed IV solutions of opioids in limited concentrations	☐	☐	
iii. Dispensing commercially prepared, pre-mixed IV solutions of opioids in limited vial sizes	☐	☐	
2k) The facility's nursing practice includes a process to independent double check opioid pump programming.			
i. At the start of the shift	☐	☐	
ii. With new narcotic infusion and PCA starts	☐	☐	
iii. With setting changes or bag changes	☐	☐	

Tennessee Pharmacist Coalition
Opioid Adverse Drug Event Gap Analysis

2l) A standard hand-off/transition communication process is in place for all patients receiving opioids which includes at minimum:			
i. History of snoring, obesity, and sleep apnea	☐	☐	
ii. Opioid administration history for the previous shift	☐	☐	
2m) The facility uses smart infusion pumps for the IV administration of all opioids with functionality employed to:			
i. Intercept and prevent wrong dose errors. a. The facility has a process to evaluate that the ordering parameters and sequence are consistent with the pump. b. The facility has a process to evaluate that the smart pump library and CPOE ordering match in regards to units.	☐	☐	
ii. Intercept and prevent wrong infusion rate errors.	☐	☐	
Gap Analysis Questions	**Yes**	**No**	**If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.**
3a) The facility has a process in place, using a standardized tool, to address and document the following prior to initiating opioid therapy.			
i. Identifies non-opioid and non-pharmacological alternatives	☐	☐	
ii. Opioid naïve or opioid tolerant	☐	☐	
iii. Recent injury, trauma, surgery, etc.	☐	☐	
iv. Chronic pain	☐	☐	
v. Medication allergies	☐	☐	
vi. ADEs experienced while receiving any previous opioid therapy	☐	☐	
vii. Review the Tennessee Controlled Substances Monitoring Database (CSMD) for opioid history and potential for opioid abuse	☐	☐	
viii. Screen for risk factors associated with oversedation and respiratory depression:			
a. History of snoring	☐	☐	
b. Obesity	☐	☐	
c. Sleep apnea	☐	☐	
ix. Drug/drug interactions	☐	☐	
x. Patient specific interactions	☐	☐	
xi. Pharmacists to assist with identification of alternative opioids when contraindications exist	☐	☐	
xii. Monitoring practice guidelines which include:			
a. Vital signs	☐	☐	
b. Continuous pulse oximetry (excluding end of life patients) receiving IV narcotics	☐	☐	
c. Capnography monitors are used when applicable	☐	☐	
d. Monitor alarms can be heard at nursing station for pulse oximetry and capnography and cannot be turned "off"	☐	☐	
xiii. Clinical monitoring plan detailing frequency to conduct assessments	☐	☐	
xiv. The indication and therapeutic goal for opioid therapy is documented in the patient's medical record and communicated to nursing for monitoring and managing patient therapy.	☐	☐	
3b) The facility has processes in place for timely access to routine monitoring results and has defined acceptable lengths of time between scheduled assessments:			
i. Pain assessment	☐	☐	
ii. Sedation assessment	☐	☐	
iii. Respiratory assessment	☐	☐	
iv. For critical rest results reporting, the appropriate healthcare provider is notified and dose changes are considered	☐	☐	

Oral Opioid Management Practices

Gap Analysis Questions	**Yes**	**No**	**If answered "No" – identify the Specific Action plan(s) including persons responsible and**

Tennessee Pharmacist Coalition
Opioid Adverse Drug Event Gap Analysis

			timeline to complete.
4) The facility has standard processes in place for initiation of oral opioid therapy, which include:			
i. Collection of baseline lab values prior to prescribing opioids	☐	☐	
ii. Drug/drug interactions	☐	☐	
iii. History of opioid ADEs	☐	☐	
iv. Recent trauma or surgery	☐	☐	
v. Administering opioid at the same time(s) each day	☐	☐	
vi. Transitioning the patient from one opioid to another	☐	☐	
vii. Renal adjustment policy that is individualized for each agent	☐	☐	
viii. Monitoring and/or discontinuing opioid therapy	☐	☐	
ix. Management of bleeding events	☐	☐	
x. Reversal agents are on formulary with policies for appropriate use	☐	☐	

Parenteral Opioid Management Practices

Gap Analysis Questions	Yes	No	If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
5) The facility has processes in place specific for parenteral opioids.			
i. Safely managing therapy	☐	☐	
ii. Monitoring, discontinuing, and/or reinitiating therapy	☐	☐	
iii. Method to determine therapeutic efficacy.	☐	☐	
iv. Standard guidelines	☐	☐	

Critical Thinking and Knowledge Strategies

Gap Analysis Questions	Yes	No	If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
6) The facility provides interdisciplinary education on opioid therapy, which includes:			
i. Initial training for new hires and existing staff, including protocols and guidelines	☐	☐	
ii. Post-test incorporating a case-study approach to demonstrate proficiency	☐	☐	
iii. Effective technological and clinical monitoring techniques	☐	☐	
iv. Assessing for adverse drug reactions	☐	☐	
v. Recognition of advancing sedation	☐	☐	
vi. Plan for targeting gaps in knowledge	☐	☐	
vii. Ongoing opioid education is provided to direct care staff when new relevant information is available	☐	☐	

Patient Education

Gap Analysis Questions	Yes	No	If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
7a) The facility has a process in place to educate patients and families on opioids, using teach-back method, to ensure safe therapy including:			
i. Indication	☐	☐	
ii. Symptoms for monitoring	☐	☐	
iii. Dietary issues	☐	☐	
iv. Drug interactions	☐	☐	
v. Monitoring requirements	☐	☐	
vi. Duration of therapy	☐	☐	
vii. Potential adverse effects	☐	☐	
viii. Potential serious adverse effects with alcohol and other central nervous systems depressants	☐	☐	
ix. Potential risks of tolerance, addiction, physical dependency, and withdrawal symptoms	☐	☐	
x. Storage	☐	☐	
xi. Provide a phone number and contact person to call with questions after discharge	☐	☐	

7b) Pharmacists are available for consultations to assist with patient education when any health care practitioner identifies a patient who is at risk for non-adherence.	☐	☐	

Evaluation and Assessment Strategies

Gap Analysis Questions	Yes	No	If answered "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete.
8a) Track and analyze opioid-related incidents for quality improvement purposes.	☐	☐	
8b) Assess the need for additional staff or prescriber training and patient education based on the analysis of reported adverse events, near misses, and staff observations.	☐	☐	

Adapted from:

Opioid Adverse Drug Event Prevention Gap Analysis – Component of the Medication Safety Road Map
© 2012 Minnesota Hospital Association

2013 Midyear Clinical Meeting The Joint Commission Update for 2014 – Opioid Safety Gap Analysis
© 2013 American Society of Health-System Pharmacists

CHSP and CalHEN Opioid Adverse Drug Event Prevention Gap Analysis: Survey Findings
© August 14, 2013 California Hospital Engagement Network

Revisions by:

Tennessee Pharmacist Coalition on Medication Safety Best Practices Sub-Workgroup

References:

Berge KH, Dillon KR, Sikkink KM, Taylor TK, Lanier WL. Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention. *Mayo Clinic Proceedings*. 2012;87(7):674-682. DOI:10.1016/j.mayocp.2012.03.013.

Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65:1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e

Tennessee Emergency Department Opioid Prescribing Guidelines. Tennessee College of Emergency Physicians (TCEP). April 28, 2016.

The Joint Commission: Safe use of opioids in hospitals. Sentinel Event Alert #49, August 8, 2012. (Accessed June 1, 2016)