The Roadmap to Success:

Adverse Drug Event (ADE)—Opioids

HSAG HQIC

Preparing for Your Journey

Any successful journey begins with planning and preparation. Three key areas should be addressed before beginning any quality improvement or patient safety initiative.

Leadership Commitment

The success of a project can be determined by the level of commitment and support from leadership. It is important for hospital leaders to communicate a consistent, frequent message in support of the project. The executive project champion can establish accountability, dedicate resources, and break through barriers.

Project Champion

It is important to have a person(s) who is a significant influence with frontline staff, physicians, and other key personnel. Frequently, we think of a physician as a champion as they are instrumental in garnering provider buy-in and practice change. However, depending on the project, it can be any key personnel with the authority and skills to influence change, lead by example, and assist in essential messaging of the goals and vision for a project.

Multidisciplinary Project Team

The project team should consist of representatives from key areas throughout your facility with the skills, knowledge, and experience in their fields of expertise. A team member should possess strong communication skills, have a collaborative mindset, and show a commitment to change. It is vital to **have representation from frontline staff who will be impacted most by the change**. It is also important to keep the size of your team manageable. Remember, a team can have ad hoc members whose role is to provide expertise in a specific area for a short period of time.

For more information on team forming, access the following resource at www.hsag.com/hqic-quality-series:
- Quality and Safety Series Video on Team Forming
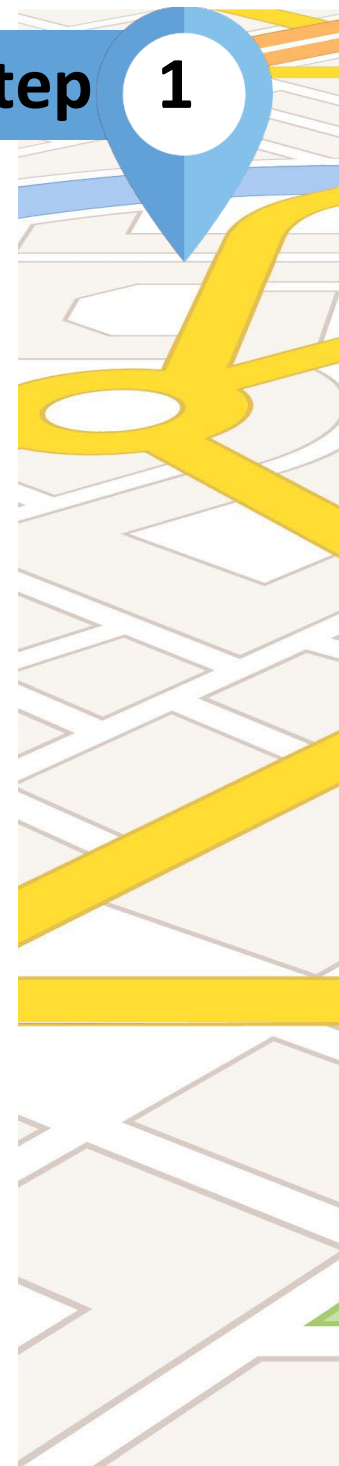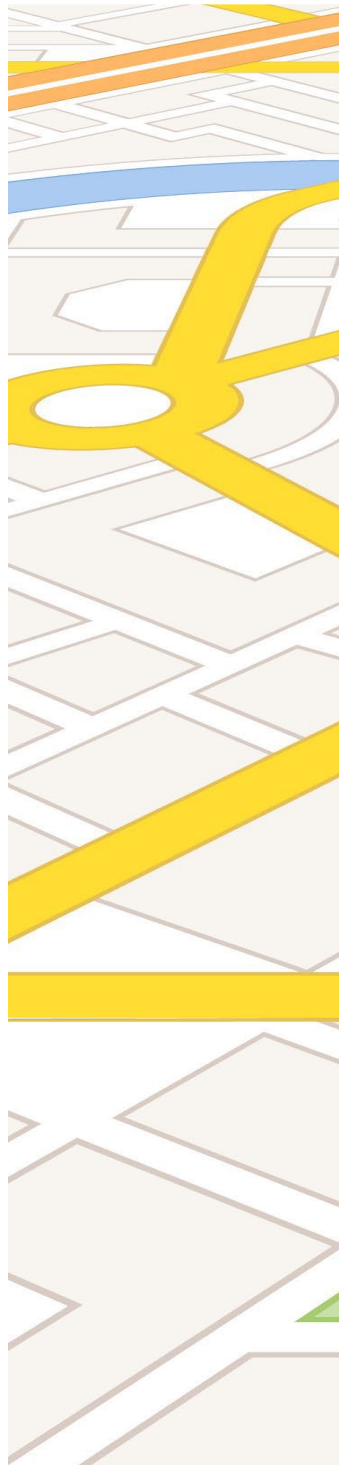
Science-Driven Prevention and Treatment—Step 1

Rationale:

Opioids are high-risk medications due to complex dosing, insufficient monitoring, and inconsistent patient compliance. Use of science-based prevention and treatment strategies ensure that the appropriate medication for the indication is selected, as well as the appropriate dose and frequency of the medication.

Implementing evidence-based guidelines and protocols is an integral part of opioid management to minimize the risk of adverse drug events (ADEs).

Strategies to Implement	Tools and Resources
☐ Integrate appropriate national guidelines into organizational policies and workflows. Standardize policies and order sets based on procedural area and specialty that emphasizes the importance of appropriate prescribing and pain management options for different types of pain, including: • Acute/postoperative pain. • Chronic pain with acute needs. • Serious illness, cancer, palliative, and end-of-life. • History of or active opioid use disorder (OUD) or substance use disorder.	• Centers for Disease Control and Prevention (CDC) Prescribing Guideline Resources: https://www.cdc.gov/opioids/providers/prescribing/index.html
☐ Use a standardized pain assessment tool and ensure nursing applies it consistently (e.g., pain scales or assessment of function). • Use activity and function-based pain scales instead of 0–10 pain intensity sales. • Develop patient-specific pain treatment plans based on evidence-based practices and the patient's clinical condition, past medical history, and pain management goals.	• Institute for Clinical Systems Improvement (ICSI) Guidelines—Pain Assessment: Non-opioid Treatment Approaches, and Opioid Management: https://www.icsi.org/guideline/pain/ • Society of Hospital Medicine (SHM) Reducing Adverse Drug Events related to Opioids (RADEO) Guide: https://www.hospitalmedicine.org/clinical-topics/opioid-safety/ • The Joint Commission (TJC) Pain Management Standards for Accredited Organizations: https://www.jointcommission.org/resources/patient-safety-topics/pain-management-standards-for-accredited-organizations/
☐ Ensure that preoperative and preadmission guidelines instruct patients to bring their continuous positive airway pressure (CPAP) machine with them if they are expected to be on an opioid therapy.	• University of Florida Health Pain Assessment and Management Initiative (PAMI)—Pain Assessment Tools and Pain Management Scales: https://pami.emergency.med.jax.ufl.edu/resources/provider-resources/pain-assessment-scales/
☐ Provide education to ensure all prescribers understand "multimodal analgesia"—the combination of pain management techniques that act by different mechanisms. Develop clear patient education policies, which enable clinicians to provide effective and consistent education on risks and benefits of appropriate pain management options.	• SHM Multimodal Pain Management Strategies Guide for Postoperative Pain Management: https://www.hospitalmedicine.org/globalassets/clinical-topics/clinical-pdf/ctr-17-0004-multi-

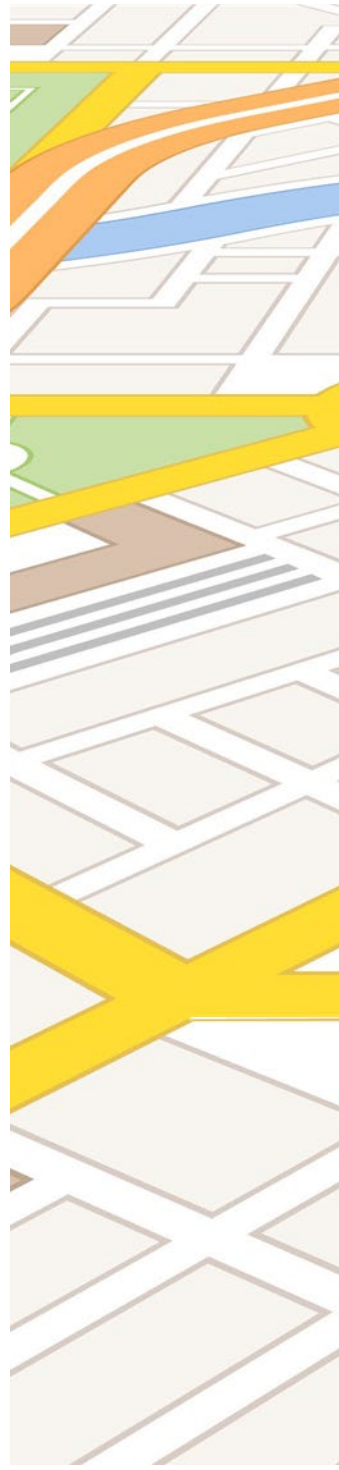| Strategies to Implement	Tools and Resources
☐ Provide staff with the latest evidence-based information to guide their pain management practice. Interdisciplinary education on opioid therapy includes: • Initial training for new hires and existing staff, including protocols and guidelines. • Post-test to demonstrate proficiency. • Topics such as dose stacking, dose equivalency, interpretation of vital signs, and monitoring equipment.	model-pain-project-pdf-version-m1.pdf • U.S. Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations (May 2019): https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
☐ Leverage electronic health record (EHR) capabilities that support opioid management by: • Embedding Prescription Drug Monitoring Program (PDMP) access and pain management protocols and policies into the clinician workflow. • Reviewing the default number of opioid doses into the EHR and consider reducing it if the default exceeds clinical guidelines. • Creating an alert to notify practitioners when a dose adjustment is required due to age, renal or liver impairment, or when patients are prescribed other sedating medications.	• HHS, Guideline for Prescribing Opioids: Online Training: https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf • Centers of Excellence in Pain Education (CoEPEs) Interactive Modules: https://coepes.nih.gov/ • Health Information Technology (IT) Playbook, Section 4: Opioid Epidemic and Health IT: https://www.healthit.gov/playbook/opioid-epidemic-and-health-it/
☐ Set clear goals for appropriate opioid prescribing and utilization. • Use agreed-upon benchmarks to identify outliers in opioid prescribing by service line, and include local and national benchmarks in feedback reports, when available. • Develop processes to address clinicians whose prescribing practices are outliers amongst their peers.	• Healthcare IT News: An in-depth look at how one health system customized its Epic EHR to fight the opioid crisis: https://www.healthcareitnews.com/news/depth-look-how-one-health-system-customized-its-epic-ehr-fight-opioid-crisis

Promote Safer Care—Step 2

Rationale:

Healthcare providers have a basic responsibility to protect patients from accidental harm. Identifying common, preventable, and measurable healthcare-associated opioid ADEs is a key component of quality improvement efforts to drive prevention, benchmark progress, and promote a culture of opioid safety.

Strategies to Implement	Tools and Resources
☐ Develop a standardized risk assessment process and/or screening procedure to identify patients with complex pain management needs and those at risk of opioid-related adverse events and/or OUD, and ensure organizational policies detail their use. Ensure standardization of risk stratification policies and practices. Key elements include: • Defining and identifying if a patient is opioid naïve or tolerant. • Assessing and documenting risk factors for respiratory depression. • Using a validated, standardized sedation scale to guide the assessment and early detection of unintended advancing sedation during opioid therapy. • Reviewing concomitant non-opioid medications that increase risk of additive sedation when administered with opioids (e.g., benzodiazepines and sedative hypnotics).	• Institute for Safe Medication Practices (ISMP), Medication Safety Assessment® for High-Alert Medications: https://www.ismp.org/sites/default/files/attachments/2018-01/EntireAssessmentWorkbook.pdf • SHM Reducing ADEs RADEO Guide: https://www.hospitalmedicine.org/clinical-topics/opioid-safety/ • Pasero Opioid-induced Sedation Scale (POSS) with Interventions: https://www.qualityhealthnd.org/wp-content/uploads/Pasero-Opioid-induced-Sedation-Scale.pdf • Berlin Questionnaire (for sleep apnea): http://cpap.1800cpap.com/tests/BerlinQuestionnaire.pdf
☐ Improve pharmacy practices by: • Limiting the override list at an automated dispensing cabinet. • Using barcode scan verification of product ingredients. • Drawing up patient-specific doses in the pharmacy. • Restricting concentrated product stock to the pharmacy. • Focusing prevention efforts on pumps, tubing, and standard labeling. • Having a process in place to differentiate look-alike, sound-alike medications. • Using smart infusion pumps with drug libraries for the IV administration of all opioids with functionality employed to intercept and prevent wrong dose and wrong infusion rate errors, when available.	• American Society of Health-System Pharmacists (ASHP) Guidelines on Preventing Medication Errors in Hospitals: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-hospitals.ashx • Minnesota Department of Health, Opioid Prescribing Guidelines: https://mn.gov/dhs/assets/mn-opioid-prescribing-guidelines_tcm1053-337012.pdf

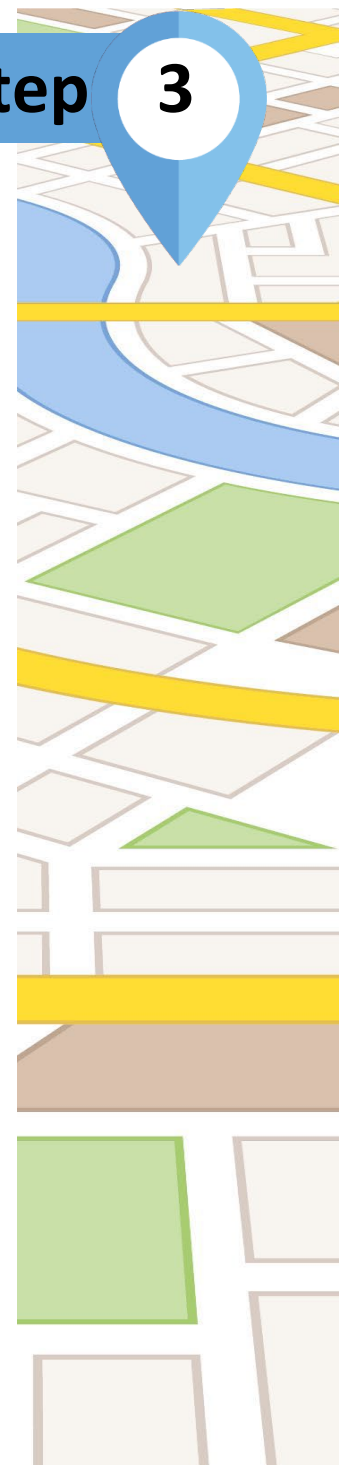| Strategies to Implement	Tools and Resources

☐ Ensure prescribing and administering guidelines address the following components:
• A standard conversion tool that is used when changing the opioid medication or route of administration.
• Defining best practice for PRN (as needed) analgesic prescribing while limiting range orders, therapeutic duplication, and guarding against dose stacking.
• A process for an independent double-check of smart pump programming with:
  – New opioid infusion, IV, neuraxial, and patient-controlled analgesia (PCA) starts.
  – Every new bag or setting change thereafter, when available.
• Opioid therapy titration for appropriate and safe clinical response.
• Defining resources and processes for managing pain in patients receiving medication assisted therapy (MAT) for OUDs.
• Defining when PDMP is reviewed (e.g., prior to prescribing opioids for acute pain) to understand the patient's opioid use history.
• An opioid protocol or standing order set for nursing/clinical staff if there is an active order for an opioid (e.g., resuscitation equipment, supplemental oxygen, naloxone).
	• ISMP, Targeted Medication Best Safety Practices for Hospitals (2020-2021): https://www.ismp.org/sites/default/files/attachments/2020-02/2020-2021%20TMSBP-%20FINAL_1.pdf
	
	• U.S. Department of Veterans Affairs, Acute Pain Management Provider Guide: Meeting the Challenges: https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/Pain_Provider_AcutePainProviderEducationalGuide_IB10998.pdf
	
	• Safer and More Appropriate Opioid Prescribing: A Large Health Healthcare System's Comprehensive Approach: https://onlinelibrary.wiley.com/doi/full/10.1111/jep.12756
	
	• Colorado Hospital Association, 2019 Hospital Overdose Education and Naloxone Distribution Guidelines: Strategies for Hospitals and Hospital-Based Clinicians to Decrease Rates of Opioid Overdose Death: https://cha.com/wp-content/uploads/2019/10/CHA.179-Naloxone-Guidelines_final.pdf

☐ Establish a standardized naloxone program to ensure patients at increased risk of opioid overdose are co-prescribed naloxone (e.g., those with a history of overdose or history of substance use disorder).	

Effective Communication and Care Coordination—Step 3

Rationale:
Effective team collaboration and care coordination are essential. When the care team is not communicating effectively, patient safety is at risk for several reasons, including lack of critical information, misinterpretation of information, unclear orders, and overlooked changes in status. Lack of communication creates situations in which ADEs can occur. These ADEs have the potential to cause severe injury or unexpected patient death.

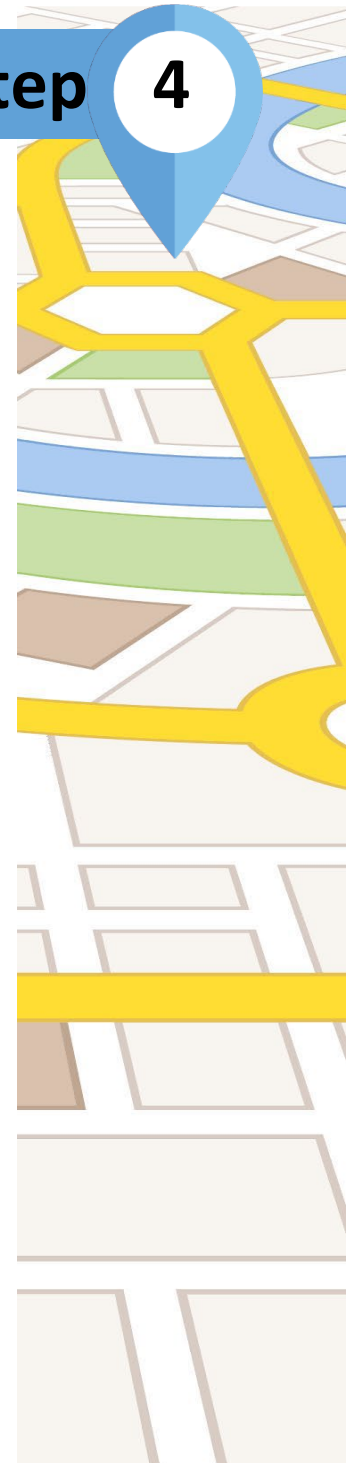| Strategies to Implement	Tools and Resources
☐ Support the development of—or access to—an integrated, interdisciplinary care team, including rehabilitation, social work, and behavioral health specialists.	• Patient Safety Movement Foundation, Hand-Off Communications: https://patientsafetymovement.org/wp-content/uploads/2016/02/HOC.pdf
☐ Have a standard hand-off/transition communication process in place for all patients receiving opioids, which includes: • Patient's opioid status (naïve or tolerant). • Recent pain assessment. • Sedation scores. • Mediations administered. • Drug and dose history from the previous shift. • History of snoring, obesity, and sleep apnea.	• Improving Pain Management for Hospitalized Medical Patients: A Society of Hospital Medicine Implementation Guide: https://www.hospitalmedicine.org/globalassets/clinical-topics/clinical-pdf/shm_painmanagement_guide.pdf • Substance Abuse and Mental Health Services Administration (SAMHSA), Use of Medication-Assisted Treatment in EDs: https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/pep21-pl-guide-5.pdf
☐ Leverage the EHR use to improve provider communication and care coordination.	
☐ Promote a sound understanding of referral networks for addiction services to facilitate formal addiction treatment plans, information about MAT, and warm hand-off referrals to treatment prior to hospital discharge. • Initiate MAT in the emergency department (ED), if possible.	• Pennsylvania Department of Drug and Alcohol Program, ED Warm Handoff Protocol: Opioid Use Disorder: https://warmhandoff.org/pennsylvania/

Patient and Family Engagement—Step 4

Rationale:

Patients and families are valuable partners to prevent opioid ADEs, such as respiratory depression and oversedation. Nonadherence to opioid therapy places patients at risk for accidental overdose that can lead to severe ADEs or unexpected patient death.

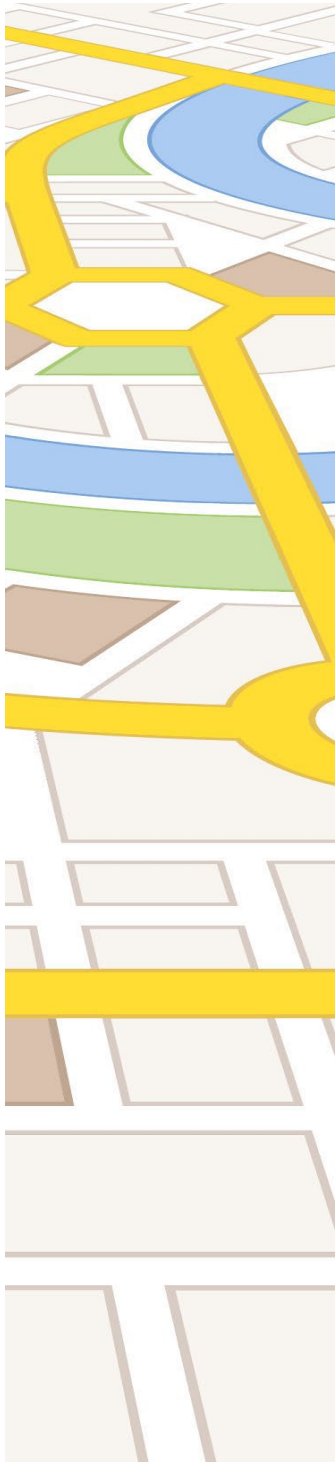| Strategies to Implement	Tools and Resources
☐ Educate patients and family caregivers on pain management options, reiterating that nonpharmacologic and low-risk pharmacologic pain management techniques are the preferred first line of treatment. Engage patients and family caregivers as partners in setting pain management goals based on realistic expectations for safe and effective pain relief and functional outcomes.	• HSAG HQIC Managing Your Pain in the Hospital: https://www.hsag.com/globalassets/hqic/hqic_painmgtflyer.pdf • HSAG HQIC Managing Your Pain in the Hospital—Spanish: https://www.hsag.com/globalassets/hqic/hqic_painmgtflyer_sp.pdf • HSAG HQIC What to Ask Your Doctor Before Taking Opioids: A Checklist: https://www.hsag.com/globalassets/hqic/hqic_whattoaskopioidchecklist.pdf • CDC Helpful Materials for Patients: https://www.cdc.gov/opioids/patients/materials.html • The American Academy of Pain Medicine, Patient Education and Resources: https://painmed.org/patient-education-resources/ • U.S. Department of Justice, Controlled Substance Public Disposal Locations: https://apps2.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1 • SAMHSA Opioid Overdose Prevention Toolkit: Safety Advise for Patients and Family Members: https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf • Minnesota Department of Health Services, Start the Conversation About Tapering: https://edocs.dhs.state.mn.us/lfserver/Public/DHS-7757C-ENG • U.S. Food and Drug Administration (FDA), Opioid Patient Prescriber Agreement: https://www.fda.gov/media/114694/download
☐ When prescribing opioids, promote patient and family caregiver education and awareness of: • The impact of opioid therapy on psychomotor and cognitive function. • Potential serious interactions with alcohol, central nervous system depressants, and other opioids. • Recognizing early signs of dependence. • Potential risks of tolerance, addiction, physical dependency, and withdrawal symptoms associated with opioid therapy. • Principal risks and side effects of opioids (e.g., constipation, risk of falls, nausea, and vomiting). • Safe and secure storage and disposal of opioid analgesics in the home. • Naloxone availability, indications, and use.	
☐ Set expectation and discuss indications for drug tapering at the time of initial opioid prescription.	
☐ Use informed consent and/or opioid use agreements when prescribing opioids.	

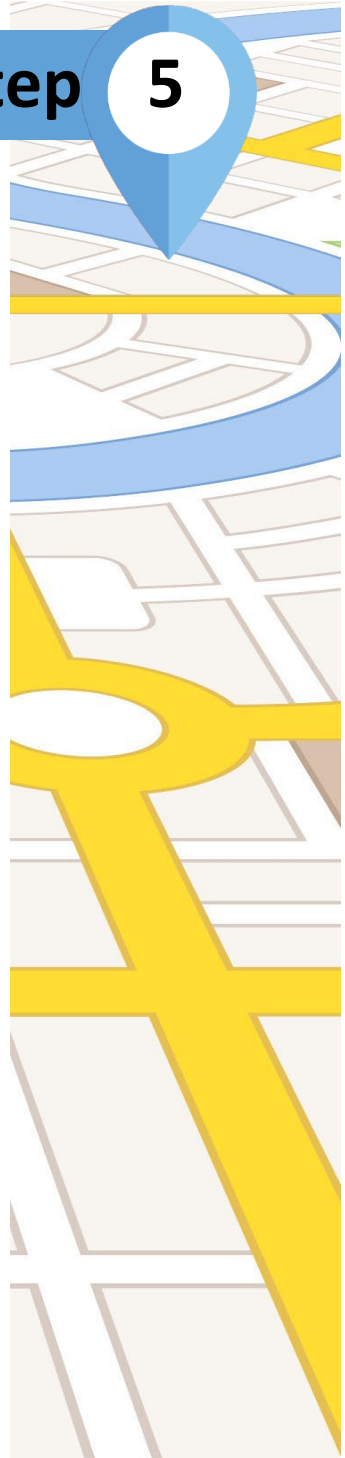| Strategies to Implement	Tools and Resources
☐ Teach patients and families how to activate the rapid response team. Refer patients and family caregivers to support groups and behavioral health treatments when concerns are identified.	• HSAG Opioid Taper Agreement: https://www.hsag.com/contentassets/5fa24d1d8814438ca082c08e010315c0/opioidsiptaperagreementfnl508.pdf • American Society of Addiction Medicine, Opioid Addiction Treatment: A Guide for Patients, Families and Friends: http://eguideline.guidelinecentral.com/i/706017-asam-opioid-patient-piece/0?
☐ Engage patient and family advisory councils (PFACs) to drive continuous quality improvement, raise awareness, and serve as a peer recovery coaches to provide support to current patients.	

Promote Best Practices Within the Community—Step 5

Rationale:

Promotion of best practices within the community, including effective hand-off communication, is vital to ensuring the continuity and safety of the patient's care. It is essential to recognize individual support needs when transitioning from the hospital to home. Patients who face social disparities such as poverty, limited literacy, or belonging to a racial or ethnic minority group are particularly at risk for experiencing poor transitions of care.

Strategies to Implement	Tools and Resources
☐ Designate an individual or team responsible for acting as an integrator between the hospital and the community. Collaborate with local community organizations to promote: • Appropriate use, storage, and disposal of opioids. • Opioid harm reduction. • Referrals and treatment for patients experiencing OUD.	• American Hospital Association (AHA), A Playbook for Fostering Hospital-Community Partnerships to Build a Culture of Health: https://www.aha.org/system/files/hpoe/Reports-HPOE/2017/A-playbook-for-fostering-hospitalcommunity-partnerships.pdf
☐ Facilitate education on naloxone use and distribution programs and events.	• Flex Monitoring Team, Addressing Opioid Use in Rural Communities: https://www.flexmonitoring.org/sites/flexmonitoring.umn.edu/files/media/fmt-bp-46-2020.pdf
☐ Educate staff on existing community resources (e.g., information on local addition centers, exercise programs, and community education opportunities).	• AHA, Collaborating with Communities: Resources and Examples to Help Facilitation Community Partnerships and Activities: https://www.aha.org/bibliographylink-page/2018-09-28-collaborating-communities
☐ Establish data-driven goals for community collaboration centered on: • Public education events. • Community pain self-management programs (e.g., increasing the availability of walking groups and exercise classes). • Increasing the availability of drug take-back programs.	• AHA, Stem the Tide: Opioid Stewardship Measurement Implementation Guide: https://www.aha.org/system/files/media/file/2020/07/HIIN-opioid-guide-0520.pdf
☐ Measure the effectiveness of collaborative efforts through data and outcomes (e.g., overdose rates, ED visits for OUD).	

Your Final Destination

Now that you've reached your destination, it is important that your efforts are not futile. One of the most challenging aspects of quality improvement and change is sustaining the gains. These key tactics will help you ensure ongoing success.

Ensuring Your Process Is Stable

Most projects involve monitoring of both process and outcome measures. These data play an important role in identifying when you've achieved change. It is important to review your data to identify and address special cause variation; recognize positive trend changes (six to eight data points at or above goal); and achieve predictable, consistent results. Remember: *"Every system is perfectly designed to get the results it gets."*—W.E. Deming

For more information on data, variation, and change, access the following resource at www.hsag.com/hqic-quality-series:
- Quality and Safety Series Video on Data Plan

Control Plan/Sustainability Plan

A control or sustainability plan is a method for documenting the key elements of quality control that are necessary to assure that process changes and desired outcomes will be maintained. At a minimum, this plan should include ongoing monitoring of process steps that are critical to quality, frequency of monitoring, sampling methodology, and corrective actions if there is noted variation.

For more information on control and sustainability plans, access the following resource at www.hsag.com/hqic-quality-series:
- Quality and Safety Series Video on Sustainability and Control Plan

Project Hand-Off

Depending on the size of your facility and resources that are available, it may be necessary to hand off your project to a "process owner." A process owner is a person or department responsible for monitoring a process and sustaining the changes according to the control or sustainability plan. The person or department should be the entity that will most significantly experience the gains of the improved process or project.

Tools and Resources

- The Joint Commission—National Patient Safety Goals Effective January 2021 for the Hospital Program. Available at: https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2021/npsg_chapter_hap_jan2021.pdf. Accessed on October 20, 2021.

- Minnesota Hospital Association—Opioid Averse Drug Event (ADE) Prevention Roadmap. Available at: https://www.mnhospitals.org/quality-patient-safety/quality-patient-safety-improvement-topics/medication-safety/opioids. Accessed on October 26, 2021.

- National Quality Forum (NQF)—NQF Playbook™: Opioid Stewardship. Available at: https://www.qualityforum.org/National_Quality_Partners_Opioid_Stewardship_Action_Team.aspx. Accessed on October 26, 2021.