

Screening for Adverse Drug Events (ADEs) Associated with Anticoagulants, Antidiabetics and Opioids

List of Targeted Medications and Potential Data Collection Measures

1. Screen patients for ADEs who are:
 - a. Medicare fee for service beneficiaries AND
 - b. Taking at least three total medications AND
 - c. Taking an anticoagulant, antidiabetic and/or opioid medication (Tables 1, 3 and 5). Providers may choose to focus on a sub-population of patients taking these high-risk medications.
2. “Screening” for ADEs means a patient is evaluated by a pharmacy/pharmacist or other health care provider for adverse outcomes resulting from medication use.
3. Each provider setting decides which measure(s) (Tables 2, 4 and 6) to use when determining if a screened patient has experienced an ADE. Based on practicality of obtaining data, a provider may determine that an individual ADE has occurred by using
 - a. One measure alone OR
Example: Patient taking warfarin has an International Normalized Ratio (INR) > 4.
 - b. Two or more measures together
Example: Patient taking insulin has blood glucose < 70 AND signs/symptoms of hypoglycemia.
4. Providers communicate to atom Alliance which measure(s) they will use and maintain consistency with those measures.
5. Providers will use the data collection tool provided by atom Alliance or another data collection method of the provider’s choosing to collect data on all patients screened, whether ADEs are detected or not.
6. The following calculation will be used to determine the ADE rate in the screened patient population:

$$\% \text{ ADEs in screened beneficiaries} = \frac{\text{Total number of ADEs reported}}{\text{Total number of beneficiaries screened for ADEs}} \times 100$$

Anticoagulants

Table 1: Anticoagulant Medications

Apixaban (Eliquis®)	Argatroban	Dabigatran (Pradaxa®)
Dalteparin (Fragmin®)	Desirudin (Iprivask®)	Edoxaban (Savaysa®)
Enoxaparin (Lovenox®)	Fondaparinux (Arixtra®)	Heparin
Rivaroxaban (Xarelto®)	Warfarin (Coumadin®, Jantoven®)	

Table 2: Potential Data Collection Measures for Anticoagulants

Primary ADE of Concern: Bleeding

Lab Values	Reversal Medications/Treatments	Clinical Scenarios
Measures for any Anticoagulant		
Hematocrit drop of > 3 points	Administration of fresh frozen plasma	Anemia due to blood loss
Guaiac positive stool		Blood transfusion without surgery
		<i>Evidence of bleeding, including</i>
		<i>Epistaxis, Hematoma, Hematuria, Hemoptysis</i>
		<i>Hemorrhage, Spontaneous ecchymoses</i>
		Abrupt cessation/hold of anticoagulant*
		Cardiac arrest*
		Life sustaining measures*
		Death*
Measures Specific to Warfarin		
INR > 4	Administration of Vitamin K	
INR > 5		
INR > 6		
Measures Specific to Unfractionated Heparin		
Partial Thromboplastin Time (PTT) > 100	Administration of Protamine	
Measures Specific to Low Molecular Weight Heparin		
	Administration of Protamine	

* Requires presence of another measure

Antidiabetics

Table 3: Antidiabetic Medications

Acarbose (Percose®)	Albiglutide (Tanzeum®)	Alogliptin (Nesina®)
Canagliflozin (Invokana®)	Chlorpropamide (Diabinese®)	Dapagliflozin (Farxiga®)
Dulaglutide (Trulicity®)	Exenatide (Byetta®, Bydureon®)	Glimepiride (Amaryl®)
Glipizide (Glucotrol®)	Glyburide (Diabeta®, Glynase®, Micronase®)	Insulin aspart (Novolog®)
Insulin detemir (Levemir®)	Insulin glargine (Lantus®)	Insulin glulisine (Apidra®)
Insulin lispro (Humalog®)	Insulin NPH (Humulin N®, Novolin N®)	Insulin premixed (Humulin 50/50®, Humalog 75/25®, Humulin 70/30®, Novolin 70/30®, Novolog 70/30®)
Insulin regular (Humulin R®, Novolin R®)	Linagliptin (Tradjenta®)	Liraglutide (Victoza®)
Miglitol (Glyset®)	Metformin (Fortamet®, Glucophage®, Glumetza®, Riomet®)	Nateglinide (Starlix®)
Pioglitazone (Actos®)	Pramlintide (Symlin®)	Repaglinide (Prandin®)
Rosiglitazone (Avandia®)	Saxagliptin (Onglyza®)	Sitagliptin (Januvia®)
Tolazamide		

Note: Medications listed in bold are most likely to cause hypoglycemia.

Table 4: Potential Data Collection Measures for Antidiabetics

Primary ADE of Concern: Hypoglycemia

Lab Values	Reversal Medications/Treatments	Clinical Scenarios
Blood glucose < 50	Administration of 50% dextrose	Abrupt cessation/hold of antidiabetic*
Blood glucose < 60	Administration of glucagon	Life sustaining measures*
Blood glucose < 70	Administration or oral glucose tabs/gel	Loss of consciousness*
	Administration of juice or other sugary food/ beverage to reverse hypoglycemia	Seizures*
		Death*
		Signs/symptoms of hypoglycemia, including <i>Confusion*, Drowsiness*, Excessive sweating*, Tachycardia*, Trembling* and Weakness*</i>

* Requires presence of another measure

Opioids

Table 5: Opioid Medications

Alfentanil (Alfenta®)	Apomorphine (Apokyn®)	Codeine (Tylenol #3 or #4®)
Dihydrocodeine	Fentanyl (Abstral® Actiq®, Duragesic®, Fentora®, Lazanda®, Subsys®)	Hydrocodone (Hycet®, Hydromet®, Lorcet®, Lortab®, Maxidone®, Norco®, Reprexain®, Vicodin®, Vicoprofen®, Xodol®, Zohydro®)
Hydromorphone (Dilaudid®, Exalgo®)	Meperidine (Demerol®)	Methadone (Dolophine®)
Morphine (Avinza®, Duramorph®, Embeda®, Kadian®, MS Contin®, Opium tincture)	Oxycodone (Endocet®, Endodan®, Magnacet®, Oxecta®, Oxycontin®, Percocet®, Primlev®, Roxicet®, Roxicodone®)	Oxymorphone (Opana®)
Sufentanil		

Table 6: Potential Data Collection Measures for Opioids

Primary ADE of Concern: Accidental Overdose/Oversedation/Respiratory Depression

Lab Values	Reversal Medications/Treatments	Clinical Scenarios
	Administration of naloxone	Abrupt cessation/hold of opioid*
		CNS depression
		Death*
		Decreased oxygen saturation
		ETCO2 alterations
		Fall*
		Life sustaining measures*
		Oversedation
		Respiratory arrest
		Respiratory depression (e.g. < 8 or < 10 breaths/minute)

* Requires presence of another measure

Resources Used to Compile List of Possible Data Collection Measures

- Houglund P, Nebeker J, Pickard S, et al. Using ICD-9-CM Codes in Hospital Claims Data to Detect Adverse Events in Patient Safety Surveillance. In: Henriksen K, Battles JB, Keyes MA, et al., editors. *Advances in Patient Safety: New Directions and Alternative Approaches* (Vol. 1: Assessment). Rockville (MD): Agency for Healthcare Research and Quality; 2008 Aug. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK43647/>. Accessed 6/23/15.
- HRET HEN Encyclopedia of Measures v16 (Full). American Hospital Association Hospital Engagement Network, Health Research and Educational Trust. Chicago, IL. Available at: http://www.hret-hen.org/index.php?option=com_phocadownload&view=category&id=77&Itemid=205. Accessed 6/23/15.
- IHI Trigger Tool for Measuring Adverse Drug Events. Institute for Healthcare Improvement (in partnership with Premier, Inc., San Diego, CA) Cambridge, MA. Available at: <http://www.ihl.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDrugEvents.aspx>. Accessed 6/23/15.
- Jarzyna D, Jungquist CR, Pasero C, et al. American Society for Pain Management Nursing guidelines on monitoring for opioid-induced sedation and respiratory depression. *Pain Manag Nurs*. 2011 Sep;12(3):118-145.
- Medicare Patient Safety Monitoring System (MPSMS) Adverse Drug Event Algorithms. Qualidigm, Wethersfield, CA. Available at: <http://www.qualidigm.org/index.php/current-initiatives/mpsms/>. Accessed 6/23/15.
- Mehran R, Rao SV, Bhatt DL, et al. Standardized bleeding definitions for cardiovascular clinical trials: a consensus report from the Bleeding Academic Research Consortium. *Circulation*. 2011 Jun 14;123(23):2736-47.
- National Action Plan for Adverse Drug Event Prevention. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2014). Washington, DC. Available at: <http://www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf>. Accessed 6/23/15.
- Schulman S, Beyth RJ, Kearon C, Levine MN; American College of Chest Physicians. Hemorrhagic complications of anticoagulant and thrombolytic treatment: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest*. 2008 Jun;133(6 Suppl):257S-298S.
- Seaquist ER, Anderson J, Childs B, et al. Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the Endocrine Society. *Diabetes Care*. 2013 May;36(5):1384-95.
- Sentinel Event Alert: Safe Use of Opioids in Hospitals. The Joint Commission. 2012 Aug 8;49:1-5. Available at: http://www.jointcommission.org/assets/1/18/SEA_49_opioids_8_2_12_final.pdf. Accessed 6/23/15.
- Tennessee Center for Patient Safety/Tennessee Pharmacists Coalition Final ADE Measures. Available at: <http://www.tnpatientsafety.com/SafetyQualityInitiatives/AdverseDrugEventsADE/PharmacyResources/tabid/312/Default.aspx>. Accessed 6/23/15.

www.atomAlliance.org