

# Quality Assurance and Performance Improvement

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## Speaker

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## Disclosures

- I have no financial relationships to disclose
- I have no conflicts of interests to disclose
- I will not promote any commercial products or services
- All Planning Committee members, content reviewers, authors, and presenters have been evaluated for conflicts of interest, and there are not any to disclose.

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Objectives

- Participants will be able to identify basic QAPI concepts
  - The participants will review the F-tags pertaining to QAPI
  - The 5-elements of QAPI will be discussed
- Define elements of QAPI
  - Examine the 5-elements and HOW they function in a real-life setting
  - QAPI requires information coming IN and work directed going OUT
  - PIPs and how to make them tangible

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Objectives

- Systematic evaluation
  - Without using benchmarks (external data) and goals (internal data) and evaluation outcome, it is difficult to be successful
  - How to evaluate
  - Why it's best to start "low and slow"

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Tools and Guidance - Free	<ul style="list-style-type: none"><li>• Quality Assurance &amp; Performance Improvement. (2019). <a href="https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html">https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html</a></li><li>• Root Cause Analysis Kit for Long-term Care. (2014). <a href="https://www.stratishealth.org/providers/rca-toolkit/">https://www.stratishealth.org/providers/rca-toolkit/</a></li></ul>
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Basic  
QAPI  
Concepts

- F-tags pertaining to QAPI
- The 5-elements of QAPI

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F 865 -  
Definition

- Must develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on indicators of the outcomes of care and quality of life.
- Maintain documentation and demonstrate evidence of its ongoing QAPI program - systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of **adverse events**; and documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities

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F 865 -  
Definition

- Present its QAPI plan to the State Survey Agency
- Present documentation and evidence of its ongoing QAPI program's implementation and the facility's compliance with requirements to a State Survey Agency, Federal surveyor or CMS upon request – THIS IS HOW YOU ACHIEVE PAST NONCOMPLIANCE

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F 868 QAA

- Committee consisting at a minimum of:
  - The director of nursing services;
  - The Medical Director or his/her designee;
  - At least three other members of the facility's staff, at least one of who must be the administrator, owner, a board member or other individual in a leadership role; and
  - The infection preventionist.

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F 868 QAA Committee

- Reports to the facility's governing body, or designated person(s) functioning as a governing body regarding its activities, including implementation of the QAPI program required under paragraphs (a) through (e) of this section. The committee must:
- Meet at least quarterly and as needed to coordinate and evaluate activities under the QAPI program, such as identifying issues with respect to which quality assessment and assurance activities, including performance improvement projects required under the QAPI program, are necessary.

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QAA Disclosure of Information

(1) May not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

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**QAA  
Disclosure of  
Information**

(2) Demonstration of compliance may require State or Federal surveyor access to:

- (i) Systems and reports demonstrating systematic identification, reporting, investigation, analysis, and prevention of adverse events;
- (ii) Documentation demonstrating the development, implementation, and evaluation of corrective actions or performance improvement activities; And
- (iii) **Other documentation considered necessary by a State or Federal surveyor in assessing compliance.**

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**QAA  
Sanctions**

- Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions

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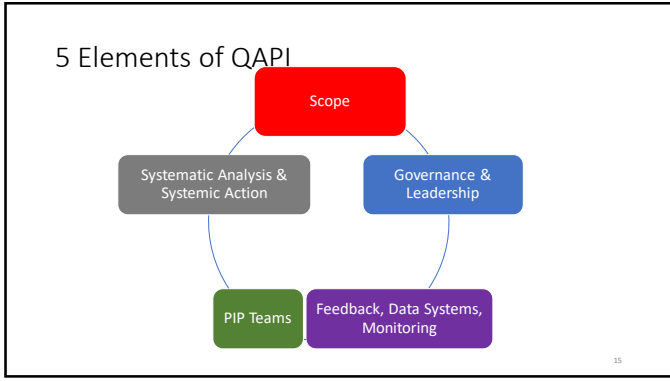
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Examine the 5 Elements

- HOW they function in a real-life setting
- QAPI requires information coming IN and work directed going OUT
- PIPs and how to make them tangible

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QAPI Scope

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F865 – Program Design and Scope

- Address all systems of care and management practices;
- Include clinical care, quality of life, and resident choice;
- Utilize the best available evidence to define and measure indicators of quality and facility goals that reflect processes of care and facility operations that have been shown to be predictive of desired outcomes for residents of a SNF or NF.
- Reflect the complexities, unique care, and services that the facility provides.

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Define the Scope of QAPI

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Connect directly to FACILITY ASSESSMENT

Once identified, determine how each will use QAPI to assess, monitor and improve performance on an ongoing basis.

High risk, high volume	"Sentinel events"	Monitoring: thresholds
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High Risk, High Volume, Problem Prone Adverse Events – separate handouts

- Significant risk to the health or safety of residents, e.g., tracheostomy care; pressure injury prevention; administration of high-risk medications such as warfarin, insulin, and opioids.
- Performed frequently or affecting a large population, thus increasing the scope of the problem, e.g., transcription of orders; medication administration; laboratory testing.
- Historically had repeated problems, e.g., call bell response times; staff turnover; lost laundry
- Adverse event -an untoward, undesirable, and usually unanticipated event that causes death or serious injury, or the risk thereof, which includes **near misses**.

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Governance and Leadership

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**QAPI – Governance and Leadership Responsibilities**

- Addresses identified priorities.
- Sustained during transitions in leadership and staffing;
- Adequately resourced, including ensuring staff time, equipment, and technical training as needed;
- identifies and prioritizes problems and opportunities that reflect organizational process, functions, and services provided to residents based on performance indicator data, and resident and staff input, and other information.
- Corrective actions address gaps in systems, and are evaluated for effectiveness; and
- Clear expectations are set around safety, quality, rights, choice, and respect.

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**QAPI Adequately Resourced**



- Designate one or more persons to be accountable for QAPI leadership and for coordination.
- Indicate the plan for developing leadership and facility-wide training on QAPI.
- Describe the plan to provide caregivers time, equipment, and technical training as needed for QAPI.
- Indicate how you will determine if resources are adequate for QAPI. **FACILITY ASSESSMENT**
- Describe how your caregivers will become and remain proficient with process improvement tools and techniques. How will you assess their level of proficiency?

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**QAPI Leadership (Steering Committee)**

- Small group of individuals who will provide the backbone or structure for QAPI (Mentors & Oversight)
- Describe how this group of people will work together, communicate, and coordinate QAPI activities. This could include but is not limited to:
  - Establishing a format and frequency for meetings
  - Establishing a method for communication between meetings
  - Establishing a designated way to document and track plans and discussions addressing QAPI.
- Describe how the QAPI activities will be reported to the governing body; i.e., Board of Directors, owner.

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**JOB DESCRIPTION AND JOB RESPONSIBILITY**

TABLE OF CONTENTS

- I. Definitions and Objectives
- II. Responsibilities
- III. Content of Job Description
- IV. Job Description, Evaluation and Placement Procedures
- V. Defines an appropriate work assignment for one or more similar...

Performance Objectives for Job Descriptions & Reviews Worksheet

- All job positions in the organization should be oriented to support quality assurance and performance improvement (QAPI) efforts

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Feedback, Data Systems and Monitoring

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Data Management

-  Sources: Connect to Facility Assessment
-  Process
-  Analyze: How findings will be reviewed against benchmarks and/or targets established by the facility

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- Process to communicate the above information. What types of reports will be used, e.g. . dashboard or dashboards for individual performance improvement projects
- Identify who will receive this information (i.e., executive leadership, QAPI leadership, resident/family council, and a center's caregivers), in what format, and how frequently information will be disseminated

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- Meaningful information must come in to get meaningful results
- Data is everywhere. If not using, meaningless. Stop gathering it.
- Taking the time to define the data that you need is key.

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- Areas to consider
  - Clinical care areas
  - Medications,
  - Complaints from residents and families
  - Hospitalizations and other service use
  - Resident satisfaction
  - Caregiver satisfaction

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Develop a Strategy for Collecting and Using Data

- More Areas to consider
  - Resident and caregiver experiences living and working in the setting
  - State survey results and deficiencies
  - Results from MDS resident assessments
  - Business and administrative processes

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Develop a Strategy for Collecting and Using Data

- Systems approach
  - Setting targets for performance in the areas you are monitoring. A target is a goal, usually stated as a percentage
  - Identifying benchmarks

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Develop a Strategy for Collecting and Using Data

- Systems approach
  - Developing a plan for the data you collect.
    - Determine who reviews certain data, and how often. Collecting information is not helpful unless it is actually used.
    - Be purposeful about who should review certain data, and how often—and about the next steps in interpreting the information.

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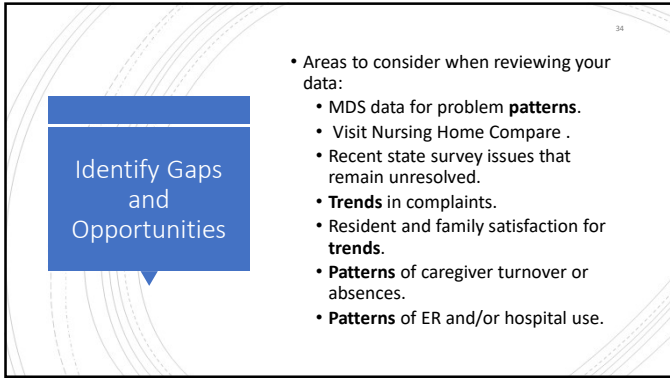
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Identify Gaps and Opportunities

- Areas to consider when reviewing your data:
  - MDS data for problem **patterns**.
  - Visit Nursing Home Compare .
  - Recent state survey issues that remain unresolved.
  - **Trends** in complaints.
  - Resident and family satisfaction for **trends**.
  - **Patterns** of caregiver turnover or absences.
  - **Patterns** of ER and/or hospital use.

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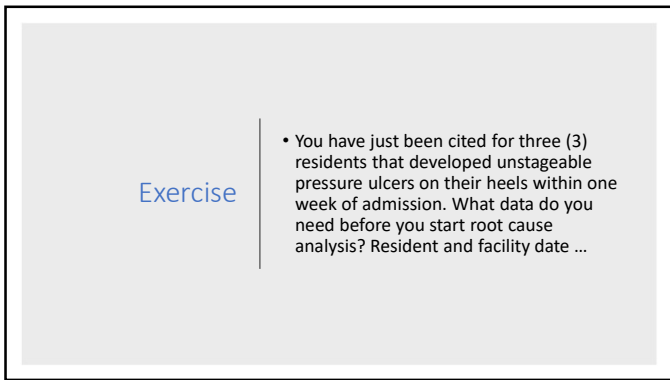
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Exercise

- You have just been cited for three (3) residents that developed unstageable pressure ulcers on their heels within one week of admission. What data do you need before you start root cause analysis? Resident and facility date ...

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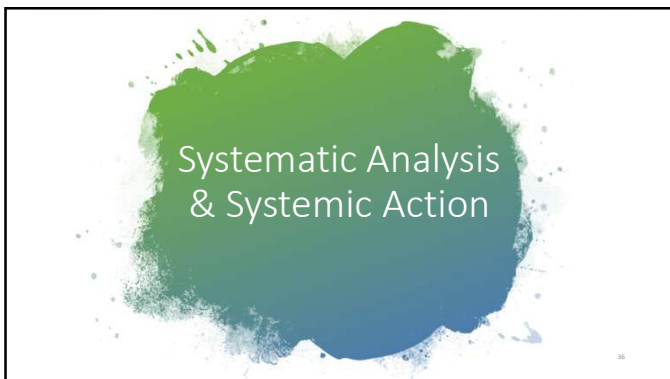
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Systematic Analysis & Systemic Action

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Same scenario  
– Next Step

- You have just been cited for three (3) residents that developed unstageable pressure ulcers on their heels within one week of admission. Work at your table. Develop the PIP.
- Charter the PIT (Performance Improvement Team) – who needed to be on it and why
- Determine what information you need for PIP.
- Determine a timeline and communicate it to the Steering Committee.
- Identify and request any needed supplies or equipment.
- Select or create measurement tools as needed;
- Develop first in series of PDSA Cycles for this PIP

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Root Cause Analysis

- Select a method for RCA: Process you will use to ensure you are getting at the underlying causes of issues, rather than applying quick fixes that address symptoms only.
- Worksheets
  - FMEA
  - RCA
  - Flowcharting
  - Five Why's
  - Fishbone Diagram

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Exercise  
Part 2

- Let's try the Five Why's for These Pressure Injuries based on initial data
- All three residents were on the same hall with new employees who stated they did not know to float the residents' heels. Why?
- Type an answer in the chat box and we will go from there ...

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## **Five Whys Worksheet**

### **Step 4.5 – Identify All Factors**

### **Instructions**

Use this analysis technique and worksheet to help the team identify the root cause of the problem.

### **Introduction**

The Five Whys analysis technique focuses on a problem by asking multiple "Why?" questions or "What caused this problem?" to identify the root cause. When asking the questions, include team members with personal knowledge of the processes and systems involved in the problem being discussed. This technique works well if the problem is simple. If, after asking "Why?" several times, and the answer does not seem correct, further analysis may be needed. The more complex the problem, the more likely it will take further analysis to reach the root cause.

### **How to Use**

1. Develop a clear and specific problem statement.
2. The team facilitator asks why the problem happened and records the team response. Ask the team to consider "If this [the most recent team response] were corrected, is it likely the problem would recur?" If the answer is yes, this is a contributing factor, not a root cause.
3. If the answer provided is a contributing factor to the problem, the team keeps asking "Why?" until there is agreement from the team that the root cause has been identified, and if corrected, the problem would not recur.
4. It often takes three to five times of asking "Why?" But it can take more than five. Keep going until the team agrees the root cause has been identified.

## Five Whys Worksheet

Team members

Date

Problem Statement

Why?

Why?

Why?

Why?

Why?

Root Cause

- 1.
- 2.
- 3.


**To validate root causes, ask the following: “If you removed this root cause, would this event or problem have been prevented?”**

*Adapted with permission from Stratis Health, originally produced 2014 for the Minnesota Department of Health.*

### Systemic Action

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- How you will monitor to ensure that interventions or actions are implemented and effective in making and sustaining improvements?



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### Generate List of Recommended Actions To Correct

1. Clearly link to root causes
2. Addresses all root causes – not just one
3. Reduce likelihood of recurrence
4. Clear and concise
5. Prioritized
6. SMART: Specific, Measurable, Achievable, Realistic, Timed

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### Types of Actions

1. Standardize Equipment
2. Redundancy
3. Force functions
4. Change physical plant
5. Update improving software / systems
6. Use cognitive aids – checklists, labels
7. Simplify
8. Educate
9. Develop policies

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### Impact of Actions

Strong	Intermediate	Weak
<ul style="list-style-type: none"><li>Physical Plant Changes</li><li>System fixes that are facility-wide</li></ul>	<ul style="list-style-type: none"><li>Cognitive aids</li><li>Worksheets</li></ul>	<ul style="list-style-type: none"><li>Relies on Policy and Procedure</li><li>And individual's compliance with the same</li></ul>

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### Take Systemic Action

- Weak: Depend on staff to remember their training or what is written in the policy. (Enhance or enforce existing processes. )
- Examples of weak actions:
  - Double checks
  - Warnings/labels
  - New policies/procedures/memoranda
  - Training/education
  - Additional study

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### Take Systemic Action

- Intermediate: Provide tools to help staff to remember or to promote clear communication. (Modify existing processes.)
- Examples of intermediate actions:
  - Decrease workload
  - Software enhancements/modifications
  - Eliminate/reduce distraction
  - Checklists/cognitive aids/triggers/prompts

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Take Systemic Action

- More examples of intermediate actions:
  - Eliminate look alike and sound alike
  - Read back
  - Enhanced documentation/communication
  - Build in redundancy

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Take Systemic Action

- Strong: Do not depend on staff to remember to do the right thing. Provides strong controls. (Change or re-design the process.)

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Take Systemic Action

- Detect and warn so there is an opportunity to correct before the error reaches the patient.
- Involve hard stops which won't allow the process to continue unless something is corrected or gives the chance to intervene to prevent significant harm.

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Take Systemic Action

- Examples of strong actions:
  - Physical changes: grab bars, non slip strips on tubs/showers.
  - Electronic medical records – cannot continue charting unless all fields filled in.
  - Simplifying: unit dose.
  - Same equipment every neighborhood

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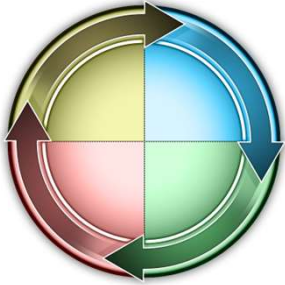
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### Conduct and Document PIPs

- Use a problem-solving model like PDSA (Plan-Do-Study-Act).
- Report results to the Steering Committee.



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### PDSA Cycle



- Change to be made
- Next cycle
- Compare analysis of data
- Compare data to prediction
- Summarize what was learned
- Objective
- Questions / Predictions
- Plan to carry out (who, what, when, where, how)
- Carry out plan
- Document Problems and observations
- Begin analysis

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## Systematic Evaluation

Using benchmarks (external data) and goals (Internal data) and evaluation outcome to be successful  
How to evaluate  
Why it's best to start "low and slow"

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### Process

- QAPI – not individual PIPs. Not single PDSA Cycles. Often POCs are single PDSA cycles
- Purpose of Evaluation: Outline the audiences for QAPI communications and the frequency and format of these communications
- *Hint: QAPI Self-Assessment Tool at least annually*  
DO THIS NOW ... MEASURE CHANGE

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### Benchmarks and Goals

- Every PIP has a goal – internal measurement of success
- Systems have benchmarks – external measurements that you strive to be better than ... e.g. Quality Measures, National Rate of turnover, etc.

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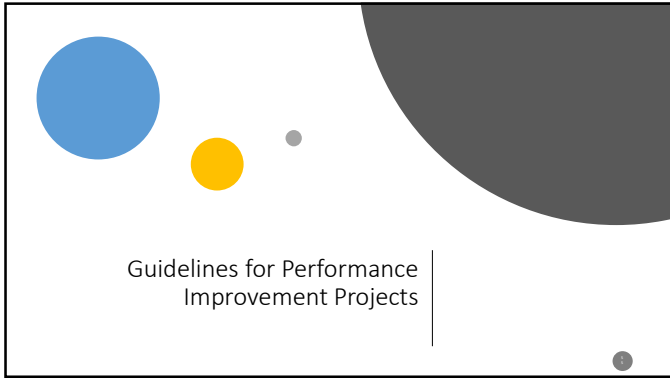
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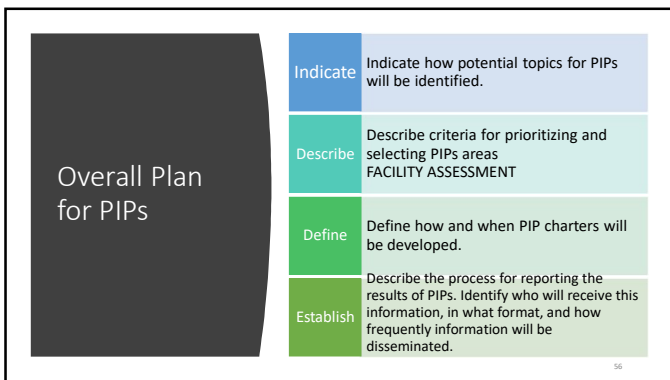
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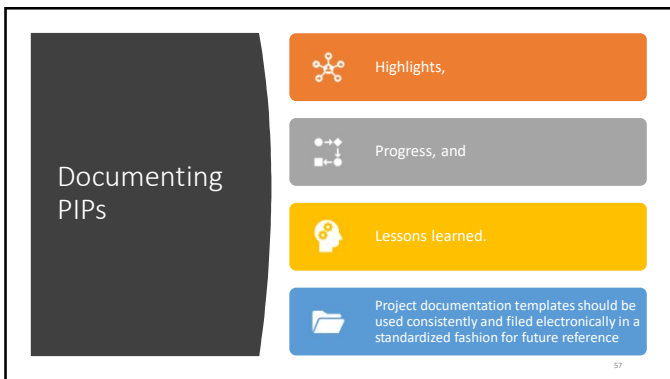
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**Starting Point**

- SLOW DOWN! Systemic change can take 12 – 36 months.
- “Low hanging fruit” – where can you achieve an internal goal most quickly? Let’s go back to the pressure injury issue. You found these root causes:
  1. Braden not being done on admission
  2. CNAs not trained to float heels in last 24 months
  3. Turnover in CNAs is 65%
  4. Orientation does not include pressure relieving methods
  5. The pressure injury prevention program is dated 2002

Which one(s) can you address in 40 days and sustain compliance?

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**And The Onion Peels Back ...**

- Start with the one you chose ... create a PDSA cycle and finish ...
- Use the Fish Bone to dig deeper and identify more root causes.
- Then pick the next priority. Do the root cause analysis of this using the 5 Why’s.
- Create a PDSA cycle or two and address it
- Each PDSA Cycle has an internal goal or checkpoint.
- Continue to monitor these to assure compliance. (QA) Modify if needed.
- Repeat until all issues addressed. It may be a year or two to reach your benchmark (PI)

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Resources

- Quality Assurance & Performance Improvement. (2019). <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html>
- QAPI Tools. <http://www.ihl.org/resources/Pages/Tools/default.aspx>
- QAPI. <https://www.ahcancal.org/Survey-Regulatory-Legal/Pages/QAPI.aspx>
- Root Cause Analysis Kit for Long-term Care. (2014). <https://www.stratishealth.org/providers/rca-toolkit/>

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## Five Whys Worksheet Example

### Step 4.6 – Identify All Factors

This example of the Five Whys demonstrates how a team using this technique can get to the root cause of the problem quickly. Refer to 1.2 Case Study. For instructions on how to use the Five Whys technique, refer to 4.5 Five Whys Worksheet.

<b>Five Whys Worksheet</b>	
<b>Team members</b>	
<b>Date</b>	
<b>Problem Statement</b>	Person missed a physical therapy appointment
<b>Why?</b>	Person was in bed sleeping at the scheduled time for her appointment at 8:30 a.m.
<b>Why was the resident in bed?</b>	Nursing assistant was not aware of the therapy appointment, so did not wake up the person in time to prepare for the therapy session
<b>Why wasn't the nursing assistant aware of the physical therapy appointment?</b>	This information was not shared in morning report and the nursing assistant forgot to check the posted therapy schedule
<b>Why wasn't this information shared in report?</b>	Report was cut short due to another individual being transferred to the hospital during morning report
<b>Why didn't the nursing assistant check the therapy schedule?</b>	Sometimes staff forgets to check the schedule and the schedule is not always correct. It is not consistently updated with changes.
<b>Root Cause</b>	Lack of consistent communication regarding accurate therapy times

*Adapted with permission from Stratis Health, originally produced 2014 for the Minnesota Department of Health.*



# Adverse Drug Event Trigger Tool

## Intended use of this tool:

This tool is intended to assist surveyors to identify:

1. The extent to which facilities have identified resident-specific risk factors for adverse drug events,
2. The extent to which facilities developed and implemented systems and processes to minimize risks associated with medications that are known to be high-risk and problem-prone, and
3. When a preventable adverse event has occurred, and evaluate if the nursing home identified the issue and responded appropriately to mitigate harm to the individual and prevent recurrence.

## Definitions:

- **Adverse Event:** An untoward, undesirable, and usually unanticipated event that causes death, serious injury, harm, or the risk thereof.
- **Adverse Drug Event:** An injury resulting from drug-related medical interventions.
- **Adverse Drug Reaction:** Harm directly caused by a drug at normal doses.
- **Anticholinergic Effects:** Physical symptoms resulting from drugs that counter the action of acetylcholine including increased blood pressure, respiratory distress, clumsiness/unsteadiness, bloating/constipation/ileus, nausea/vomiting, dry mouth, delirium, drowsiness/lethargy/fatigue, urinary retention, hallucinations, memory problems, and blurred vision.
- **Prescribing Cascade:** Adverse reaction to one drug that goes unrecognized or is misinterpreted resulting in the prescriber inappropriately prescribing a subsequent drug to treat the signs/symptoms of the adverse reaction.
- **Polypharmacy:** Multiple definitions exist, but most include reference to drugs without indication and the number of medications used (e.g., more than 10).
- **Risk Factor:** Issue or condition that increases the potential for an adverse event to occur. Risk factors include resident level issues such as medications prescribed, age, and concurrent conditions as well as system level issues such as lack of staff knowledge related to high risk medications and unclear protocols to address lab results.

Disclaimer: Use of this tool is not mandated by the Centers for Medicare & Medicaid Services (CMS) for regulatory compliance nor does its use ensure regulatory compliance.

## Adverse Drug Event Trigger Tool

<b>Adverse Drug Event (ADE)</b>	<b>Risk Factors</b> - These increase the potential for ADEs. Multiple factors increase risk.	<b>Triggers: Signs and Symptoms (S/S)</b> - Any of these may indicate an ADE may have occurred.	<b>Triggers: Clinical Interventions</b> - These actions may indicate an ADE occurred.	<b>Surveyor Probes</b> - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
Change in mental status/delirium related to opioid use	<ul style="list-style-type: none"> <li>• PRN or routine use of opioid medication</li> <li>• Opioid naiveté (someone who has not been taking opioids)</li> <li>• Opioids used in combination with sedatives or other opioids</li> <li>• History of opioid abuse</li> <li>• Opioid tolerance</li> <li>• Severe pain</li> <li>• Low fluid intake/dehydration</li> <li>• Low body weight</li> <li>• History of head injury, traumatic brain injury, or seizures</li> </ul>	<ul style="list-style-type: none"> <li>• Falls</li> <li>• Hallucinations</li> <li>• Delusions</li> <li>• Disorientation or confusion</li> <li>• Light-headedness, dizziness, or vertigo</li> <li>• Lethargy or somnolence</li> <li>• Agitation</li> <li>• Anxiety</li> <li>• Unresponsiveness</li> <li>• Decreased               <ul style="list-style-type: none"> <li>• BP</li> <li>• Pulse</li> <li>• Pulse oximetry</li> <li>• Respirations</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Administration of Narcan</li> <li>• Transfer to hospital</li> <li>• Call to physician regarding new onset of relevant signs or symptoms</li> <li>• Abrupt stop order for medication</li> </ul>	<ul style="list-style-type: none"> <li>• Is there an assessment and determination of pain etiology?</li> <li>• Does the resident's pain management regime address the underlying etiology?</li> <li>• For a change in mental status, is there evidence that the physician conducted an evaluation of the underlying cause, including medications?</li> <li>• Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication (e.g., over-sedation)?</li> <li>• If receiving PRN and routinely, is there consideration for the timing of administration of the PRN?</li> <li>• Can staff describe signs/symptoms of over-sedation?</li> <li>• Is there evidence of a system for ensuring "hand off" communication includes the resident's pain status and time of last dose?</li> <li>• Do the resident, family, and direct caregivers know signs and symptoms of over-sedation and steps to take if noted (e.g., alert the nurse)?</li> <li>• Is there evidence the facility implements non-pharmacological pain management approaches?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Change in mental status/delirium related to	<ul style="list-style-type: none"> <li>• PRN or routine use of psychotropic medication</li> <li>• Use of more than one</li> </ul>	<ul style="list-style-type: none"> <li>• Falls</li> <li>• Confusion</li> <li>• Sedation</li> <li>• Cardiac arrhythmias</li> </ul>	<ul style="list-style-type: none"> <li>• Transfer to hospital</li> <li>• Call to physician regarding new onset of relevant signs or</li> </ul>	<ul style="list-style-type: none"> <li>• Does the medical record include consistent documentation of clinical indication, e.g., do physician notes, care plan, and tracking sheets all address the same indication?</li> </ul>

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psychotropic medication use (including antipsychotics, antidepressants, anxiolytics, and hypnotics)	psychotropic medication including more than one drug from the same class or different classes <ul style="list-style-type: none"> <li>• Advanced age</li> <li>• Polypharmacy</li> </ul>	<ul style="list-style-type: none"> <li>• Orthostatic hypotension</li> <li>• Destabilized blood sugar</li> <li>• Akathisia</li> <li>• Parkinsonism</li> <li>• Anticholinergic effects</li> </ul>	symptoms <ul style="list-style-type: none"> <li>• New order for restraint</li> <li>• Abrupt stop order for medication</li> </ul>	<ul style="list-style-type: none"> <li>• If receiving PRN and routinely, is there consideration for the timing of administration of the PRN?</li> <li>• Is there evidence of a system for ensuring the resident is routinely assessed for effectiveness of the medication and signs/symptoms of adverse drug reactions/events?</li> <li>• Is there a system for monitoring for involuntary movements?</li> <li>• Is there evidence that the facility has attempted gradual dose reduction or rationale documented if not attempted?</li> <li>• Is there evidence the facility implements non-pharmacological approaches and interdisciplinary management of the condition that the medication targets?</li> <li>• Is there evidence in the medical record that the resident or representative were involved in decisions related to medication use?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Hypoglycemia related to use of antidiabetic medication	<ul style="list-style-type: none"> <li>• Insulin use</li> <li>• Sliding scale insulin use</li> <li>• Oral hypoglycemic medication use</li> <li>• Decrease in oral intake while taking antidiabetic medication</li> </ul>	<ul style="list-style-type: none"> <li>• Hypoglycemia (e.g., &lt;50 mg/dl)</li> <li>• Falls</li> <li>• Headache</li> <li>• Shakiness, nervousness, anxiety</li> <li>• Sweating, chills, clamminess</li> <li>• Irritability, impatience</li> <li>• Change in mental</li> </ul>	<ul style="list-style-type: none"> <li>• Stat administration of Glucagon or IV dextrose</li> <li>• Administration of orange juice or other high sugar food or fluids in response to blood sugar reading or symptoms</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Does the care plan reflect interdisciplinary monitoring for:                             <ul style="list-style-type: none"> <li>• Signs/symptoms of hypoglycemic episodes?</li> <li>• Changes in oral intake?</li> </ul> </li> <li>• Is there evidence blood glucose testing and insulin administration are coordinated with meals?</li> <li>• Is there evidence the facility has addressed any pharmacy recommendations?</li> <li>• If sliding scale insulin is used, does the medical</li> </ul>

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		status <ul style="list-style-type: none"> <li>• Emotional changes (including new anger, sadness, stubbornness)</li> <li>• Lightheadedness, dizziness</li> <li>• Hunger</li> <li>• Nausea</li> <li>• Complaints of blurred or impaired vision</li> <li>• Tingling or numbness in lips and/or tongue</li> <li>• Weakness, fatigue, or somnolence</li> <li>• Incoordination</li> <li>• Seizures</li> <li>• Unconsciousness</li> <li>• Rapid heartbeat</li> </ul>		record contain documentation of risk vs. benefits? Clinical rationale? <ul style="list-style-type: none"> <li>• If an EHR is used, are finger stick glucose testing results incorporated into it?</li> <li>• Is there evidence that finger stick glucose results are routinely reviewed for effectiveness as part of the care plan?</li> <li>• Is there evidence that the facility routinely educates caregivers on risk factors and symptoms/signs of hypoglycemia?</li> <li>• Is the resident and family educated regarding the signs and symptoms of hypoglycemia and regarding the resident's diabetes management plan</li> <li>• Does the facility have low blood sugar protocols in place?</li> <li>• Is there a system to ensure lab results, including finger stick blood glucose results, are appropriately communicated to the physician and the dietician including when panic values are obtained?</li> <li>• Is there evidence that glucose monitoring equipment is maintained and that staff technique meets standards of practice.</li> </ul>
Ketoacidosis related to insulin therapy	<ul style="list-style-type: none"> <li>• Diabetic residents with concurrent illnesses</li> <li>• Infection</li> <li>• Diabetic residents with consistently high blood glucose levels</li> <li>• Episodes of high</li> </ul>	Lab results indicating: <ul style="list-style-type: none"> <li>• Profound dehydration</li> <li>• Elevated blood glucose</li> <li>• Ketones in urine</li> <li>• Excessive thirst</li> <li>• Frequent urination</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for lab testing including to evaluate blood sugar and fluid and electrolyte status</li> <li>• Stat order for insulin</li> <li>• New order for and administration of IV</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system for routine monitoring of blood sugar?</li> <li>• If the resident refuses antidiabetic medication or consumes foods not included in usual/planned diet, is there evidence of an interdisciplinary plan to address refusals that includes the prescriber and the family, as appropriate?</li> <li>• For residents with risk factors for ketoacidosis,</li> </ul>

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	<p>physical and/or emotional stress or trauma</p> <ul style="list-style-type: none"> <li>• A diabetic resident that frequently declines antidiabetic medications or consumes foods not included in diet</li> </ul>	<ul style="list-style-type: none"> <li>• Nausea/vomiting</li> <li>• Abdominal pain</li> <li>• Weakness/fatigue</li> <li>• Shortness of breath</li> <li>• Fruity-scented breath</li> <li>• Confusion</li> <li>• Rapid respirations</li> <li>• Elevated temperature</li> </ul>	<p>fluids</p> <ul style="list-style-type: none"> <li>• Transfer to hospital</li> </ul>	<p>does the care plan reflect multi-disciplinary monitoring for signs/symptoms of ketoacidosis?</p> <ul style="list-style-type: none"> <li>• Is there evidence that the facility routinely educates caregivers on risk factors and symptoms/signs of ketoacidosis?</li> <li>• Does the facility have elevated blood sugar protocols in place?</li> <li>• If sliding scale insulin is used, does the medical record contain documentation of risk vs. benefits? Clinical rationale?</li> <li>• Is there a system to ensure lab results, including finger stick results, are appropriately communicated to the physician and the dietician including when panic values are obtained?</li> </ul>
Bleeding related to antithrombotic medication use	<ul style="list-style-type: none"> <li>• Anticoagulant, antiplatelet, or thrombolytic medication use</li> <li>• Concurrent use of more than one antithrombotic medication (e.g., use of aspirin while on anticoagulants)</li> <li>• History of stroke or GI bleed</li> <li>• NSAID medication use while on anticoagulants</li> <li>• Antibiotics use while on anticoagulants</li> <li>• Amiodarone use</li> </ul>	<ul style="list-style-type: none"> <li>• Elevated PT/INR, PTT</li> <li>• Low platelet count</li> <li>• Bruising</li> <li>• Nosebleeds</li> <li>• Bleeding gums</li> <li>• Prolonged bleeding from wound, IV, or surgical sites</li> <li>• Blood in urine, feces, or vomit</li> <li>• Coughing up blood</li> <li>• Abrupt onset hypotension</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for PT/INR, PTT, platelet count, or CBC</li> <li>• Abrupt stop order for medication</li> <li>• Administration of Vitamin K</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Does the medical record include documentation of clinical indication?</li> <li>• Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy?</li> <li>• Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when panic values are obtained?</li> <li>• Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of excessive bleeding due to antithrombotic medications?</li> <li>• Are residents/families educated regarding the risks associated with antithrombotic medication use and the signs and symptoms of excessive bleeding?</li> <li>• Is there evidence of system to alert prescribers</li> </ul>

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	<ul style="list-style-type: none"> <li>• while on anticoagulants</li> <li>• Dietary changes affecting vitamin K intake (e.g., dark leafy greens)</li> </ul>			<ul style="list-style-type: none"> <li>• and nursing staff when anticoagulants are combined with other drugs which increase the risk of bleeding?</li> <li>• Does the resident's dietary plan include recognition of foods that interact with antithrombotic medications (e.g., is there a plan to ensure consistent intake of foods and beverages rich in Vitamin K for residents on warfarin)?</li> </ul>
Thromboembolism related to anticoagulant medication use	<ul style="list-style-type: none"> <li>• Anticoagulant medication used;</li> <li>• Prolonged immobility</li> <li>• Recent major surgery</li> <li>• Prior history of venous thromboembolic events</li> <li>• Consistently sub-therapeutic PT/INR</li> </ul>	<ul style="list-style-type: none"> <li>• Pain or tenderness and swelling of upper or lower extremity</li> <li>• Increased warmth, edema and/or erythema of affected extremity</li> <li>• Unexplained shortness of breath</li> <li>• Chest pain</li> <li>• Coughing</li> <li>• Hemoptysis</li> <li>• Feelings of anxiety or dread</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for PT/INR</li> <li>• Stat chest x-ray,</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence the facility routinely monitors lab results of all residents on anticoagulant/antiplatelet therapy?</li> <li>• Is there a system to ensure lab results, including PT/INRs, are appropriately communicated to the physician including when sub-therapeutic values are obtained?</li> <li>• Is there evidence that the facility educates caregivers on risk factors and symptoms and signs that may be indicative of thromboembolism?</li> </ul>
Prolonged constipation, ileus, or impaction related to opioid medication use	<ul style="list-style-type: none"> <li>• Opioid medication use (routine or PRN)</li> <li>• Uncontrolled pain</li> <li>• Recent abdominal surgery</li> <li>• Advanced age</li> <li>• Diagnosis of dementia,</li> </ul>	<ul style="list-style-type: none"> <li>• Constipation (lack of bowel movement for three or more days or straining to move bowels regardless of frequency)</li> <li>• Bloating or abdominal distension</li> </ul>	<ul style="list-style-type: none"> <li>• New orders for laxative, stool softeners, suppositories and/or enemas</li> <li>• New order for abdominal x-rays</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a bowel regimen in place such as routine orders for stool softener/laxative?</li> <li>• For residents with risk factors for constipation, does the care plan reflect interdisciplinary monitoring for signs/symptoms of constipation and an interdisciplinary plan to prevent it including dietary management?</li> </ul>

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	<p>Parkinson's, multiple sclerosis, or quadriplegia</p> <ul style="list-style-type: none"> <li>• Low fluid intake or dehydration</li> <li>• Decreased mobility</li> </ul>	<ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Headaches associated with symptoms above</li> <li>• Diarrhea or leaking stool</li> <li>• Decreased bowel sounds</li> <li>• Nausea/vomiting</li> <li>• Decreased or absent ability to urinate</li> <li>• Rapid heartbeat</li> <li>• Sweating</li> <li>• Fever</li> <li>• Low or elevated BP</li> </ul>		<ul style="list-style-type: none"> <li>• Is fluid intake monitored?</li> <li>• Are residents/families taught signs/symptoms of constipation and the importance of reporting them?</li> <li>• Are bowel movements (frequency and size) monitored routinely by nursing staff?</li> <li>• Is bowel status routinely addressed by the physician?</li> <li>• Upon the initiation of opioids, did the prescriber acknowledge the increased risk of constipation and adjust the plan of care as indicated?</li> <li>• Is there a protocol in place to address constipation (e.g., a process to provide routine or standing order bowel medications when a resident hasn't had a bowel movement)? If so, is the staff aware of and compliant with the protocol?</li> <li>• Does the clinical record reflect that the dietician was made aware of an opioid being ordered so that nutritional approaches to prevent constipation could be considered?</li> <li>• Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication (e.g., constipation)?</li> <li>• Is there evidence that the facility implements non-pharmacological pain management approaches?</li> </ul>

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Electrolyte imbalance (including dehydration and acute kidney injury) related to diuretic use	<ul style="list-style-type: none"> <li>• Use of diuretics</li> <li>• Advanced age</li> <li>• Dependence in ADLs – especially eating</li> <li>• Diagnosis of dementia</li> <li>• Fluid restrictions</li> <li>• Recent diarrhea or vomiting</li> <li>• Hot weather or other trigger for increased fluid needs</li> <li>• Use of medical devices that increase fluid needs (e.g., air-fluidized mattresses)</li> </ul>	<ul style="list-style-type: none"> <li>• Abnormal electrolytes</li> <li>• Dry skin and mucous membranes including cracked lips</li> <li>• Poor skin turgor</li> <li>• Thirst</li> <li>• Confusion</li> <li>• Concentrated urine and/or decreased output</li> <li>• Lethargy</li> <li>• Elevated temperature</li> <li>• Low BP with increase in pulse</li> <li>• Weight loss</li> </ul>	<ul style="list-style-type: none"> <li>• Abrupt stop order for diuretic medication</li> <li>• New order for labs</li> <li>• New order for and administration of IV fluids</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• For residents with risk factors for dehydration, does the care plan reflect interdisciplinary approaches for prevention including:               <ul style="list-style-type: none"> <li>• Monitoring for signs and symptoms of dehydration, and</li> <li>• Observation/documentation of consumption of liquids?</li> </ul> </li> <li>• Is there evidence of a system for timely identification of residents with risk factors for dehydration?</li> <li>• Does the facility have protocols for:               <ul style="list-style-type: none"> <li>• Hydration?</li> <li>• Monitoring intake and output?</li> <li>• Dehydration risk assessment?</li> <li>• Fluid intake assessment?</li> </ul> </li> <li>• Does every resident have access to fluids?</li> <li>• Are protocols in place to ensure hydration during extreme heat?</li> <li>• Are care plan approaches to ensure adequate hydration resident-specific and known to staff caring for the resident?</li> <li>• Are residents provided with the assistance they need to drink, including between meals?</li> </ul>
Drug toxicity related to acetaminophen	<ul style="list-style-type: none"> <li>• Concurrent routine and PRN orders for acetaminophen and medications containing acetaminophen</li> <li>• Failure to have a maximum daily dose of acetaminophen</li> </ul>	<ul style="list-style-type: none"> <li>• Elevated liver function tests</li> <li>• Fatigue or weakness</li> <li>• Abdominal pain</li> <li>• Loss of appetite</li> <li>• Jaundice, including yellowing of sclera</li> <li>• Itching</li> <li>• Bruising</li> </ul>	<ul style="list-style-type: none"> <li>• Abrupt stop of all acetaminophen products</li> <li>• Transfer to hospital</li> <li>• New order for liver function tests</li> <li>• New order for N-acetylcysteine</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system for ensuring residents with orders for routine or PRN acetaminophen do not receive more than 4 grams in a 24 hour period?</li> <li>• Is there evidence of a system to ensure that medications that contain acetaminophen are flagged to alert medication nurses that the resident has more than one medication containing acetaminophen ordered?</li> </ul>

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	<ul style="list-style-type: none"> <li>order or protocol in place</li> <li>• Maximum daily dose of acetaminophen routinely nears or exceeds 4 gm</li> <li>• Uncontrolled pain</li> <li>• Residents with liver damage</li> <li>• Residents that consume three or more alcoholic drinks per day</li> </ul>	<ul style="list-style-type: none"> <li>• Confusion</li> <li>• Edema/ascites</li> </ul>		<ul style="list-style-type: none"> <li>• Is there evidence of a system to ensure changes in condition are identified, assessed, including an assessment of medications, and communicated to the physician promptly?</li> <li>• Is there evidence that the facility implements non-pharmacological pain management approaches?</li> <li>• Is there evidence of a system for ensuring that residents are routinely assessed for pain, including monitoring for effectiveness of pain relief and side effects of medication?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Drug toxicity related to digoxin	<ul style="list-style-type: none"> <li>• Advanced age</li> <li>• Hypokalemia</li> <li>• Hypomagnesaemia</li> <li>• Hypothyroidism</li> <li>• Decreased renal function</li> <li>• Drugs that impair renal function</li> <li>• Drugs that cause hypokalemia</li> </ul>	<ul style="list-style-type: none"> <li>• Elevated digoxin level</li> <li>• Abnormal electrolytes</li> <li>• Lethargy, drowsiness, fatigue</li> <li>• Neuralgia</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Confusion</li> <li>• Hallucinations</li> <li>• Seizures</li> <li>• Visual disturbances (e.g., yellow-green distortion, snowy vision, photophobia)</li> <li>• Anorexia, weight loss</li> <li>• Nausea/vomiting</li> <li>• Abdominal pain</li> <li>• Diarrhea</li> </ul>	<ul style="list-style-type: none"> <li>• New order for and administration of IV fluids</li> <li>• Transfer to hospital</li> <li>• New order for and administration of activated charcoal</li> <li>• New order for and administration of digoxin-specific antibody (e.g., Digibind)</li> <li>• Abrupt stop order for medication</li> </ul>	<ul style="list-style-type: none"> <li>• Does the care plan reflect interdisciplinary monitoring for signs/symptoms of digoxin toxicity?</li> <li>• Is apical pulse prior to administration of digoxin with the drug held when pulse rate &lt;60 bpm (unless other parameters are set by the physician)?</li> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• Is there evidence of a system for routine monitoring of renal function and serum medication concentration level?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?</li> </ul>

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		<ul style="list-style-type: none"> <li>• Palpitations</li> <li>• Shortness of breath</li> <li>• Syncope</li> <li>• Lower extremity edema</li> <li>• Irregular or slow heart rate</li> <li>• Irregular respirations</li> </ul>		
Drug toxicity related to levothyroxine	<ul style="list-style-type: none"> <li>• History of thyrotoxicosis</li> <li>• Advanced age</li> <li>• Cardiac arrhythmias</li> </ul>	<ul style="list-style-type: none"> <li>• Abnormal thyroid studies, including TSH</li> <li>• Headache</li> <li>• Leg cramps</li> <li>• Tremors</li> <li>• Heat intolerance</li> <li>• Increased sweating</li> <li>• Diarrhea</li> <li>• Nervousness or irritability</li> <li>• Chest pain</li> <li>• Shortness of breath</li> <li>• Rapid or pounding heartbeat</li> <li>• Insomnia</li> </ul>	<ul style="list-style-type: none"> <li>• Abrupt stop order for medication</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• Is there evidence of a system for ensuring lab tests to monitor thyroid functions are ordered and drawn?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?</li> <li>• For residents with risk factors for drug toxicity related to levothyroxine use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to levothyroxine?</li> </ul>
Drug toxicity related to angiotensin-converting enzyme (ACE) inhibitors	<ul style="list-style-type: none"> <li>• Renal artery stenosis</li> <li>• Impaired renal function</li> <li>• Aortic valve stenosis/cardiac outflow obstruction</li> <li>• Congestive Heart Failure</li> </ul>	<p><b>Hyperkalemia S/S</b></p> <ul style="list-style-type: none"> <li>• Elevated potassium levels</li> <li>• Fatigue</li> <li>• Weakness</li> <li>• Dizziness, syncope</li> <li>• Headaches</li> <li>• Slow, weak, or</li> </ul>	<ul style="list-style-type: none"> <li>• Transfer to hospital</li> <li>• Stat order for lab work</li> <li>• Abrupt stop order for medication</li> </ul> <p>For hyperkalemia may also see:</p> <ul style="list-style-type: none"> <li>• Stat order for IV calcium</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• Is there evidence of a system for ensuring serum potassium, BUN, and creatinine levels are drawn routinely?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician</li> </ul>

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## Adverse Drug Event Trigger Tool

<b>Adverse Drug Event (ADE)</b>	<b>Risk Factors</b> - These increase the potential for ADEs. Multiple factors increase risk.	<b>Triggers: Signs and Symptoms (S/S)</b> - Any of these may indicate an ADE may have occurred.	<b>Triggers: Clinical Interventions</b> - These actions may indicate an ADE occurred.	<b>Surveyor Probes</b> - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
	<ul style="list-style-type: none"> <li>• Dehydration</li> <li>• History of hypersensitivity to ACE inhibitors</li> <li>• Concurrent use with:               <ul style="list-style-type: none"> <li>• Diuretics</li> <li>• NSAIDs</li> <li>• Anticoagulants</li> <li>• Cyclosporine</li> <li>• Potassium supplements</li> </ul> </li> </ul>	<p style="margin-left: 20px;">irregular pulse</p> <ul style="list-style-type: none"> <li>• Nausea</li> <li>• Abnormal heart rhythm/ECG abnormalities</li> </ul> <p><b>Angioedema S/S</b></p> <ul style="list-style-type: none"> <li>• Swelling of soft tissues</li> <li>• Shortness of breath</li> <li>• Wheezing</li> <li>• Persistent non-productive cough</li> </ul> <p><b>Acute Kidney Failure S/S</b></p> <ul style="list-style-type: none"> <li>• Elevated BUN/creatinine</li> <li>• Reduced/absent urine output</li> <li>• Swelling of feet/legs</li> <li>• Nausea/vomiting</li> <li>• Anorexia</li> <li>• Flank pain</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for Kayexalate</li> <li>• New order for diuretics</li> </ul>	<p style="margin-left: 20px;">including when panic values are obtained?</p> <ul style="list-style-type: none"> <li>• For residents with risk factors for drug toxicity related to ACE inhibitor use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to ACE Inhibitors?</li> </ul>
Drug toxicity related to phenytoin	<ul style="list-style-type: none"> <li>• Advanced age</li> <li>• Liver impairment</li> <li>• Kidney impairment</li> </ul>	<ul style="list-style-type: none"> <li>• Severe mental status or mood changes</li> <li>• Changes in gait, balance or coordination</li> <li>• Drowsiness</li> <li>• Loss of consciousness</li> <li>• Uncontrollable eye movements</li> </ul>	<ul style="list-style-type: none"> <li>• Stat drug levels and CBC ordered</li> <li>• Abnormal therapeutic drug levels</li> <li>• Abrupt stop order for medication</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence in the medical record for clinical indication?</li> <li>• Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?</li> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed</li> </ul>

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## Adverse Drug Event Trigger Tool

<b>Adverse Drug Event (ADE)</b>	<b>Risk Factors</b> - These increase the potential for ADEs. Multiple factors increase risk.	<b>Triggers: Signs and Symptoms (S/S)</b> - Any of these may indicate an ADE may have occurred.	<b>Triggers: Clinical Interventions</b> - These actions may indicate an ADE occurred.	<b>Surveyor Probes</b> - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
		<ul style="list-style-type: none"> <li>• Uncontrollable shaking/jerking motions</li> <li>• Slow/slurred speech</li> <li>• Nausea/vomiting;</li> <li>• Decreased respirations</li> </ul>		<p>promptly, including an assessment of medications?</p> <ul style="list-style-type: none"> <li>• For residents with risk factors for drug toxicity related to phenytoin use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to phenytoin?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Drug toxicity related to lithium	<ul style="list-style-type: none"> <li>• Advanced age</li> <li>• History of lithium toxicity</li> <li>• Kidney impairment</li> <li>• Hypothyroidism</li> <li>• Decreased PO intake</li> <li>• Dehydration</li> <li>• Concurrent administration of:               <ul style="list-style-type: none"> <li>• Diuretics</li> <li>• ACE inhibitors</li> <li>• NSAIDS</li> <li>• Neuroleptics</li> <li>• Antiepileptics</li> <li>• Calcium antagonists</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Elevated serum lithium level</li> <li>• Elevated serum sodium level</li> <li>• Diarrhea</li> <li>• Nausea/vomiting</li> <li>• Weakness/dizziness</li> <li>• Stomach pain\</li> <li>• Hand tremors or muscle twitches</li> <li>• Slurred speech</li> <li>• Abnormal ECG</li> <li>• Incoordination</li> <li>• Uncontrollable eye movements</li> <li>• Seizures</li> <li>• Coma</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for ECG</li> <li>• Stat order for drug level</li> <li>• Stat order for IV hydration</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence in the medical record for clinical indication?</li> <li>• Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?</li> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• For residents with risk factors for drug toxicity related to lithium use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to lithium?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Drug toxicity related to valproic acid	<ul style="list-style-type: none"> <li>• Existing liver disease</li> <li>• Impaired renal function</li> <li>• Concurrent</li> </ul>	<ul style="list-style-type: none"> <li>• Loss of appetite,</li> <li>• Nausea/vomiting</li> <li>• Confusion</li> <li>• Dizziness</li> </ul>	<ul style="list-style-type: none"> <li>• Stat order for drug level (VPA)</li> <li>• Order for brain CT (looking for edema)</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system for ensuring therapeutic drug levels are drawn routinely?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician</li> </ul>

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## Adverse Drug Event Trigger Tool

<b>Adverse Drug Event (ADE)</b>	<b>Risk Factors</b> - These increase the potential for ADEs. Multiple factors increase risk.	<b>Triggers: Signs and Symptoms (S/S)</b> - Any of these may indicate an ADE may have occurred.	<b>Triggers: Clinical Interventions</b> - These actions may indicate an ADE occurred.	<b>Surveyor Probes</b> - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
	administration: <ul style="list-style-type: none"> <li>• Antidepressants</li> <li>• Benzodiazepines</li> <li>• Antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>• Lethargy</li> <li>• Numbness, tingling, weakness, or involuntary muscle twitching,</li> <li>• Increased heart rate</li> <li>• Decreased respirations</li> </ul>	<ul style="list-style-type: none"> <li>• Order for ECG</li> <li>• Administration of Narcan, L-carnitine, or activated charcoal</li> </ul>	including when panic values are obtained? <ul style="list-style-type: none"> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• For residents with risk factors for drug toxicity related to valproic acid use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to valproic acid?</li> <li>• Is there a system to ensure extended-release formulations are delivered correctly (e.g., medications not crushed)?</li> </ul>
Drug toxicity related to antibiotics	<ul style="list-style-type: none"> <li>• History of renal disease/insufficiency</li> <li>• Concurrent administration with:                             <ul style="list-style-type: none"> <li>• Medications that raise PT/INR or PTT</li> <li>• Phenytoin</li> <li>• Other antibiotics</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Elevated kidney function tests</li> <li>• Elevated liver function tests</li> <li>• Elevated serum potassium</li> <li>• Decrease in platelets</li> <li>• Nausea/vomiting</li> <li>• Diarrhea</li> <li>• Loss of appetite</li> <li>• Flushing of skin</li> <li>• Lethargy</li> <li>• Dizziness</li> <li>• Hearing loss</li> <li>• Rash</li> <li>• Seizures</li> <li>• Ventricular arrhythmias</li> <li>• Peripheral neuropathy</li> </ul>	<ul style="list-style-type: none"> <li>• Orders for abrupt discontinuation of medication</li> <li>• ECG order</li> <li>• Order for Stat lab work</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence in the medical record for clinical indication?</li> <li>• Is the order time limited?</li> <li>• Does the care plan and/or medication administration record (MAR) reflect special instructions related to antibiotic administration such as taking with food or water, infusing IV antibiotic over certain time period, monitoring of drug levels and other labs (as appropriate)?</li> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• Is there a system to ensure lab results are appropriately communicated to the physician including when panic values are obtained?</li> <li>• For residents with liver or kidney disease, is there evidence of additional monitoring to ensure antibiotics do not adversely affect kidney</li> </ul>

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## Adverse Drug Event Trigger Tool

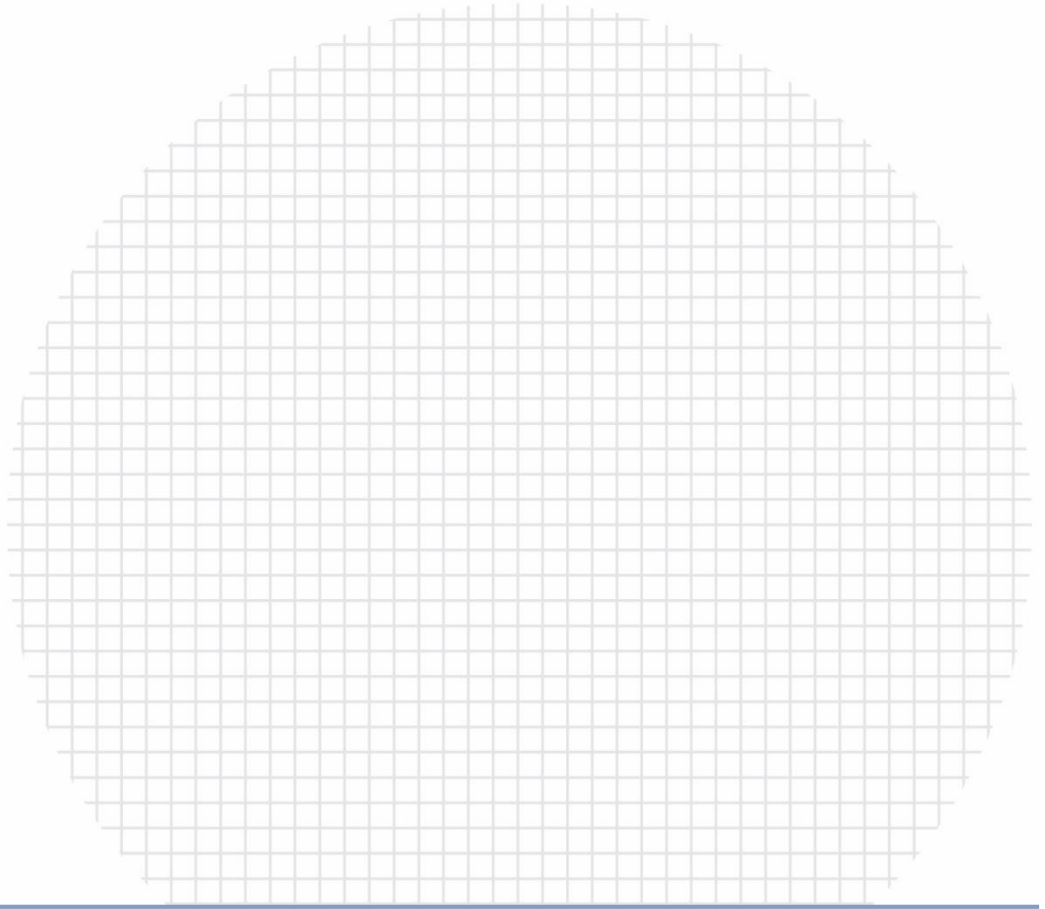
<b>Adverse Drug Event (ADE)</b>	<b>Risk Factors</b> - These increase the potential for ADEs. Multiple factors increase risk.	<b>Triggers: Signs and Symptoms (S/S)</b> - Any of these may indicate an ADE may have occurred.	<b>Triggers: Clinical Interventions</b> - These actions may indicate an ADE occurred.	<b>Surveyor Probes</b> - These questions are designed to assist in the investigation. A negative answer does not necessarily indicate noncompliance.
		<ul style="list-style-type: none"> <li>• Esophagitis</li> <li>• Symptoms of hypoglycemia</li> <li>• Phlebitis</li> </ul>		<p>or liver function, i.e., additional lab work, monitoring intake/output?</p> <ul style="list-style-type: none"> <li>• Is there evidence of a system to evaluate appropriate use of antibiotics, i.e. an antibiotic stewardship program?</li> <li>• For residents with risk factors for drug toxicity related to antibiotic use, does the care plan reflect interdisciplinary monitoring for signs/symptoms of adverse drug reactions to antibiotics?</li> <li>• Is there a system to ensure that dietary adjustments are made if needed when antibiotics are ordered?</li> <li>• Is there a system to ensure antibiotics are not given in conjunction with medications that impact their absorption (e.g., Milk of Magnesia)?</li> </ul>
Altered cardiac output related to cardiac medications (blood pressure medications, beta blockers)	<ul style="list-style-type: none"> <li>• Advanced age</li> <li>• History of heart attack, arrhythmia, cardiomyopathies, or CHF</li> </ul>	<ul style="list-style-type: none"> <li>• Fainting</li> <li>• Falls</li> <li>• Elevation/drop in BP</li> <li>• Bradycardia</li> <li>• Dizziness</li> <li>• Light-headedness</li> <li>• Nausea</li> <li>• Sweating</li> <li>• Weakness/fatigue</li> <li>• Visual disturbances</li> <li>• Clamminess</li> <li>• Loss of consciousness</li> </ul>	<ul style="list-style-type: none"> <li>• Abrupt stop of medication</li> <li>• IV fluids</li> <li>• Transfer to hospital</li> </ul>	<ul style="list-style-type: none"> <li>• Is there evidence of a system to ensure changes in condition are identified and assessed promptly, including an assessment of medications?</li> <li>• For residents with risk factors for altered cardiac input related to cardiac medications, does the care plan reflect interdisciplinary monitoring for signs/symptoms of altered cardiac output?</li> <li>• Is there a system to ensure routine monitoring of cardiac status for residents receiving blood pressure medications (e.g., blood pressure monitoring)?</li> </ul>

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# IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events



AN IHI RESOURCE

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The Institute for Healthcare Improvement (IHI) is a leading innovator in health and health care improvement worldwide. For more than 25 years, we have partnered with visionaries, leaders, and frontline practitioners around the globe to spark bold, inventive ways to improve the health of individuals and populations. Recognized as an innovator, convener, trustworthy partner, and driver of results, IHI is the first place to turn for expertise, help, and encouragement for anyone, anywhere, who wants to change health and health care profoundly for the better. To advance our mission, IHI's work is focused in five key areas: Improvement Capability; Person- and Family-Centered Care; Patient Safety; Quality, Cost, and Value; and Triple Aim for Populations. Learn more at [ihi.org](http://ihi.org).



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## Executive Summary

Traditional efforts to detect adverse events have focused on voluntary reporting and tracking of errors. However, public health researchers have established that only 10 to 20 percent of errors are ever reported and, of those, 90 to 95 percent cause no harm to patients. Health care providers need a more effective way to identify events that cause harm to patients in order to quantify the degree and severity of harm, and to select and test changes to reduce harm.

The Institute for Healthcare Improvement's (IHI) Global Trigger Tool (GTT) methodology is a retrospective review of a random sample of inpatient hospital records using "triggers" (or clues) to identify possible adverse events. The methodology is designed to produce a sampling approach that is sufficient to determine harm rates and observe improvement over time. Many hospitals have used the IHI GTT methodology to identify adverse events, to assess the level of harm from each adverse event, and to determine whether adverse events are reduced over time as a result of improvement efforts.

Based on the GTT methodology, the IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events provides an easy-to-use method for accurately identifying adverse events (harm) and measuring the rate of adverse event incidence over time in skilled nursing facilities (SNFs). Identifying adverse events and the types of harm resulting from such adverse events can lead to opportunities to improve patient and resident safety. Tracking the rate of adverse events over time is a useful way to tell if changes being made are improving the safety of care processes. It is important to note that the IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events is not meant to identify every single adverse event in a patient record.

The IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events provides step-by-step instructions for using this methodology to identify adverse events in SNFs, guidance on designing a Trigger Tool review, detailed descriptions of the Trigger Tool components, and an extensive Frequently Asked Questions section. The guidance presented in this document represents the authors' suggestions for performing a Trigger Tool review within a skilled nursing facility and is based on the IHI GTT methodology.

**Note:** The views expressed in this document represent the authors' views and not necessarily the views or policies of their respective institutions. This document is not intended to be used as guidance to SNFs on how to meet any government requirements in effect or under consideration at the time of its publication.

## Definitions and Key Concepts

**IHI Global Trigger Tool (GTT) methodology:** A retrospective review of a random sample of medical records using “triggers” (or clues) to identify possible adverse events. Reviews are done within a recommend time limit (e.g., 20 minutes). The benefit of IHI GTT methodology is that it is scoped to conserve resources and expedite retrospective reviews of patient records to identify possible adverse events. To accomplish this, trained clinical reviewers review a random sample of patient records to identify possible adverse events and resulting harm. The reviewers assign the harm to a severity category. A physician then independently reviews the results and confirms or revises the determination. The IHI GTT methodology includes only those adverse events related to the active delivery of care (i.e., acts of commission), regardless of whether they are preventable or not preventable, and excludes, as much as possible, issues related to substandard care (i.e., acts of omission).

**Definition of an adverse event:** Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death.

**Definition of all-cause harm:** This term is used to distinguish between efforts focusing on patient harm or injury from any cause (e.g., medication, infection, surgery) and efforts focused on harm from a single source (e.g., medication).

**Distinguishing between medical errors and harm:** The overall goal of improved safety in health care is to reduce patient injury or harm (i.e., adverse events), which requires distinguishing between errors and harm. Medical errors are failures in processes of care and, while they have the potential to be harmful, are not always linked to harm or patient injury. Harm represents actual patient injury with clear clinical outcomes. There is particular value in quantifying adverse events because the clear clinical outcomes are likely to engage both clinicians and administrators in a thorough review of the system factors that led to the adverse event, with a clear focus on improving patient outcomes.

**Definition of skilled nursing facilities (SNFs):** Facilities primarily engaged in providing short-term skilled nursing and rehabilitation services to residents who require such care because of injury, disability, or illness, typically after a stay in an acute care hospital. More than 90 percent of SNFs are dually certified as a SNF and as a nursing home which typically provide less intensive, long-term care services.

**“Patient” versus “resident”:** Although “resident” is the most common term used to describe those receiving treatment in SNFs, the terms “patient” and “resident” are used interchangeably in this document.

**Definition of triggers:** Signs, symptoms, or clinical interventions that could indicate an adverse event may have occurred. Presence of a trigger does not always indicate that the adverse event resulted in patient harm.

# Background

The systematic assessment of adverse event incidence can be challenging for those working to improve the safety of medical care. Adverse events — defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death — are frequent and costly to patients, insurers, and providers. Passive adverse event detection methodologies (e.g., incident reporting systems) have been shown to be unreliable because most harm events are not reported using such methods.<sup>1</sup>

The Institute for Healthcare Improvement (IHI) developed the IHI Global Trigger Tool (IHI GTT) methodology to give hospitals a proactive, cost-efficient way to detect and describe adverse events within a structured review framework.<sup>2</sup> The IHI GTT methodology requires clinical reviewers to review a randomly selected sample of closed patient records for specific “triggers” — or clues — to identify possible adverse events. This document extends the concept of the IHI GTT to the skilled nursing facility (SNF) setting.

## The Value of Systematic Measurement of Harm Using Trigger Tool Reviews

The systematic measurement of adverse events through recurring Trigger Tool reviews can contribute important information for quality and safety improvement efforts within health care facilities or systems. The data generated by a Trigger Tool review can be used in a number of ways, such as calculating a facility-wide incidence rate of harm or identifying the nature of adverse events that routinely occur in a given facility. Quality performance and quality assurance committees may find the information collected from Trigger Tool reviews useful to their efforts to identify and target safety issues and design performance improvement projects within the SNF. The data may also be used to help determine if patient safety improvement efforts are effective in reducing adverse events and harm over time.

## Estimate of Adverse Event Incidence in SNFs

In 2014, the US Department of Health and Human Services’ Office of Inspector General (OIG) reported that an estimated 33 percent of Medicare beneficiaries admitted to SNFs following a hospital stay experienced an adverse event during their SNF stays.<sup>3</sup> Fifty-nine percent of the identified harm events were preventable, largely because of substandard treatment, inadequate resident monitoring, and failure to provide necessary care. The report also found that hospital care resulting from adverse events in SNFs cost Medicare an estimated \$208 million in one month and \$2.8 billion in one year. See Appendix A for a detailed list of the adverse events in SNFs that the OIG identified during this review.

To measure the incidence of adverse events in SNFs, the OIG used a two-stage medical review to identify events experienced by a sample of 653 Medicare beneficiaries discharged from hospitals to SNFs for post-acute care. Sample beneficiaries had SNF stays of 35 days or less. The first stage was a screening process designed to identify sample beneficiaries who may have experienced an adverse event during their stays. A team of screeners (one nurse practitioner and four registered nurses) reviewed the medical records for evidence of harm that occurred during the SNF stays. To facilitate their reviews, the screeners used an early version of what would become the IHI SNF Trigger Tool for Measuring Adverse Events Worksheet (see Appendix C). In the second stage, a team of physicians reviewed the results of the screeners’ reviews, looked for other events experienced by the beneficiaries, and made final determinations on which of the events met the study definition of an adverse event. See Appendix B for a comparison of the objectives and methods used in an IHI GTT review and the OIG’s report on adverse events in SNFs.

Based on the OIG report results and findings, the Centers for Medicare & Medicaid Services (CMS) developed the Adverse Drug Event Trigger Tool and made a draft version available to nursing homes in 2015.<sup>4</sup> CMS defines the tool as a resource document that can help nursing homes evaluate systems of care around high-risk medications. The tool was designed to be a crosswalk that lists common potentially preventable adverse drug events, risk factors related to those events, triggers, and probes to assist surveyors in evaluating systems around high-risk medications.

### **Initial Development and Testing of the IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events**

The IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events is a combination of triggers and guidance adapted with modification from the IHI GTT and new triggers that are specific to the SNF setting. In collaboration with IHI and contracted experts, the OIG developed a list of triggers (operationalized in a worksheet) and guidance to facilitate medical record reviews for their 2014 study of adverse events in SNFs. The development process for the initial version included assessing the triggers in the IHI GTT and the accompanying guidance for applicability to the SNF setting, reviewing literature for other triggers,<sup>5</sup> creating new potential triggers and guidance specific to SNFs, iteratively testing and refining the list of draft triggers through a modified-Delphi decision making process, and finally producing a final list of triggers and guidance. The participants in the Delphi process included IHI GTT experts, geriatricians, a geriatric pharmacist, and nurses employed in SNFs. The authors and contributors to this document further refined the triggers and guidance in the initial version based on lessons learned during the OIG study of adverse events in SNFs, ultimately producing the IHI SNF Trigger Tool for Measuring Adverse Events.

### **Measuring the Severity of Harm**

The National Coordinating Council for Medication Error Reporting and Prevention's (NCC MERP) Medication Error Index (Index) is a frequently used tool to classify harm caused by adverse events.<sup>6</sup> The NCC MERP Index was originally developed to classify medication errors, based on the severity of the outcome, and included nine severity levels. Levels A through D describe near-miss events and Levels E through I describe harm that reached the patient (see Table 1). To make a determination on the level of harm caused by an error, the Index considers factors such as whether the error reached the patient and, if the patient is harmed, to what degree.

**Table 1. The NCC MERP Index for Categorizing Errors**

<b>Near Miss:</b> Harm does not reach patient or resident	A Level	Circumstances or events occurred that had the capacity to cause error.
	B Level	Error occurred but did not reach the patient or resident.
	C Level	Error occurred that reached the patient or resident but did not cause harm.
	D Level	Error occurred that reached the patient or resident and required monitoring to preclude harm or confirm that it caused no harm.
<b>Adverse Event:</b> Harm reaches patient or resident	E Level	Error occurred that may have contributed to or resulted in temporary harm and required intervention.
	F Level	Error occurred that may have contributed to or resulted in harm and required an initial or prolonged facility stay.
	G Level	Error occurred that contributed to or resulted in permanent patient or resident harm.
	H Level	Error occurred that required intervention to sustain the patient's or resident's life.
	I Level	Error occurred that may have contributed to or resulted in patient or resident death.

Source: *NCC MERP Index for Categorizing Medication Errors (February 2001)*

## Step-by-Step Guide and Rules

The IHI SNF Trigger Tool methodology is laid out as a step-by-step process to help SNFs design and implement a Trigger Tool review. We suggest SNFs follow the steps as closely as possible to ensure data collected during reviews are reliable and the process used to generate the data stays consistent over time. SNFs may choose to add elements once they gain experience conducting reviews.

The guidance presented in this document represents the authors' suggestions for performing a Trigger Tool review within a SNF to identify possible adverse events for the purposes of informing patient safety improvement efforts. This document is not intended to be used as guidance to SNFs on how to meet any government requirement in effect or under consideration at the time of its publication.

### Step 1: Defining an Adverse Event

Before beginning a SNF Trigger Tool review, the SNF should define the objectives for their review and how they determine what is (or is not) an adverse event. The following guidelines are included to help facilities define what is considered to be an adverse event so review teams can consistently count such events over time.

- **Include all identified adverse events:** Broadly, adverse events are defined as unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death. Harm is operationalized using a modified version the NCC MERP Index levels of harm (see Table 1 above). Appendix A provides examples of adverse events that can occur in SNFs.
- **Include adverse events regardless of whether the reviewer believes them to be preventable or not preventable:** Some adverse events may have been the result of medical errors, while others may have been seemingly impossible to avoid. Reviewers should capture all adverse events without trying to make a distinction between which adverse events are preventable and which are not preventable.
  - **Include adverse events related to acts of commission:** Reviewers should focus on adverse events related to the active delivery of care (acts of commission) and exclude, as much as possible, events related primarily to the failure to follow evidence-based practices (acts of omission). (See FAQs 2 and 3 below for additional information.) However, as reviewers gain experience, facilities may consider initially including adverse events due to acts of omission in their Trigger Tool reviews (then later exclude these types of events, once reviewers gain experience).
  - Example of harm associated with an act of commission: A patient to whom anticoagulants were administered who subsequently suffered a stroke from an intracerebral bleed.
  - Example of harm associated with an act of omission: A patient not appropriately treated for hypertension who subsequently experienced a stroke.

Although the patient in the second example certainly experienced a medical catastrophe related to poor care, it can be difficult and costly to identify adverse events related to acts of omission using a Trigger Tool-style review (i.e., a review method that emphasizes conservation of resources). These events are likely to be overlooked or missed during Trigger Tool reviews because the evidence of the events is more subtle than evidence of events caused by acts of commission. This subtlety often requires reviewers to judge whether a lack of action resulted in an event, which may be challenging for inexperienced or non-physician reviewers and thereby increase the likelihood that these events will be missed, impacting the data collected during a review. Additionally, describing events related to omission can increase costs because reviewers often need extra time to find evidence of the factors that led to the events, describe the events, perform reviews of the literature on evidence-based factors or standards of care associated with the events, or consult with others (e.g., physicians, specialists).

At a minimum, adverse events related to the omission of care should be referred to quality or risk departments as improvement opportunities when they are identified. These events are common and often serious, so a root cause analysis or other detailed review is likely to generate information that can be used to prevent future occurrences.

Note: This does not mean that the SNF should exclude events that have *an element of omission*, but are *otherwise related to the active delivery of care*, from a Trigger Tool review. For example, include residents who suffer pressure ulcers or falls associated with medication-induced delirium. Although an omission of resident monitoring or care may have been a factor in the pressure ulcer or fall, facilities should count these and other similar events for which a reviewer can reasonably determine that active delivery of care contributed to the event.

- **Exclude near-miss events:** Near-miss events (e.g., wrong medication given but no patient harm resulted, falls without injury) and quality issues (e.g., failing to follow protocols but no

harm resulted) should not be included. When observed, such events or issues can be included in quality improvement efforts.

- **Include adverse events attributable to prior (or *qualifying*) hospital stays or health care providers:** An adverse event that is present on admission (referred to as “POA events”) to the SNF should be included, provided that the event meets the definition of harm related to medical care. All such adverse events are counted because the measure is what the patient experienced, not what happened within the hospital. It is useful to keep track of which events occurred outside the SNF so that this can be noted when reporting data. Such data may indicate an opportunity to collaborate with others outside the SNF —hospitals, office practices, clinics, long-term care facilities — to improve patient and resident safety, even if the adverse events did not result from care provided in the SNF.

Additionally, SNFs are encouraged to read the *IHI Global Trigger Tool for Measuring Adverse Events*<sup>3</sup> before beginning their own record reviews. While the specific directions in the IHI GTT are applicable only to hospital reviewers, much of content in the Background, Tips for Leadership, and Stories from Experienced Organizations sections will benefit SNF reviewers and help them critically examine the guidelines above.

## Step 2: Establishing the Review Team

The review team should consist of three people:

- **Two trained clinicians who serve as the primary record reviewers.** They should have a background in SNF care and knowledge about the contents and layout of the resident record.
  - Note that hospitals that employ the IHI GTT methodology often use Registered Nurses as primary record reviewers. Options for the primary record reviewer in the SNF setting might include the Director of Nursing, Assistant Director of Nursing, unit managers, quality improvement nurse, and supervisors.
- **A physician who does not review the entire resident record, but instead checks and authenticates the adverse events and harm severity category recorded by the primary record reviewers.** The physician reviewer should also be available to answer specific questions the primary reviewers may have during their record reviews. The SNF’s Medical Director may be an ideal physician to perform this review, but facilities may also consider using an external reviewer. To identify an external reviewer, SNFs may consider developing an agreement with a peer facility to exchange reviewers or contract for the services of a patient safety expert.

## Step 3: Defining and Drawing a Sample for Review

Like the IHI GTT, the SNF Trigger Tool is designed to collect meaningful results from reviews of small samples that are collected over many months or years. Data from these small samples may show wide variation from sample to sample. Aggregating results from these samples over time will enable facilities to understand and smooth out these variations and monitor overall trends in harm incidence.

At a minimum, we recommend that facilities select a random sample of 20 resident records every month for review using the Trigger Tool methodology. To ease the burden on reviewers, we



recommend all sampled records be reviewed as close to when they are selected as possible (i.e., within one month) rather than waiting to review several samples at once.

When selecting a sample, facilities conducting SNF Trigger Tool reviews should be sure to clearly define the population (e.g., all SNF residents vs. all SNF residents with urinary catheters) from which they will draw samples. When samples are drawn from the population at random, the results of the reviews should be representative of the trends within the broader population. Samples from a subset of the population will not be representative of the rate of harm. That sample, however, will provide information about the subpopulation that may be useful for specific patient safety efforts.

When drawing a sample, we recommend facilities consider the following:

- **Define the population:** SNFs should carefully define the population (or category of resident) that they want to review. For the purposes of a general review, use a random sample of 20 records drawn from the broader population that consists of all SNF residents. Note: The SNF Trigger Tool was tested on the SNF population (i.e., operationally defined as a length of stay in a SNF of 35 or fewer days) and may not be applicable to the long-term, non-SNF population.
- **Define the observation period for the review:** The observation period is a defined period of time (i.e., one calendar month or two calendar weeks) from which you will draw the sample records for a given review. Findings from the review will be applicable to that observation period only.
  - The observation period for a given review can either be one calendar month or two consecutive weeks. The next review will look at the next calendar month (or two-week window).
  - The observation period will shift forward by the length of the observation period (e.g., one month, two weeks) with each subsequent review.
- **Determine if the review will include only closed resident records, or both open and closed records:** It is preferable to use closed resident records for the review, but selecting a sample from only closed records may exclude residents with long stays and thereby limit the results to a subset of all SNF residents.
  - To ensure that results apply to all types of SNF residents, include open records in the sample if they are selected for review.
  - To reduce the likelihood that an open case is selected, the observation period should be no sooner than four months before the date of the review (e.g., for reviews conducted in May, the observation period would be January of that year). This will increase the likelihood that closed records are selected for the sample.
- **Draw the sample in a consistent, methodologically sound fashion:**
  - **Include only those stays that had an admission date during the observation period:** For example, do not include stays that extended into the observation period but began in the month prior. This will allow you to more easily describe your results as pertaining to stays that began in a particular month.
  - **Use a random sampling technique to draw your sample:** Use a standard random selection method and over-sample by 5 to 10 percent. Oversampling ensures that you're able to select a backup record if a selected record is not available. Because the results of the review rely on the sample being a true random sample, make every effort to collect all sampled records. Continually excluding a certain category of resident because it is

difficult to access records for these residents will bias the sample. See IHI's website for resources on sampling.<sup>7</sup>

- **Draw your sample at consistent intervals:** As noted above, we recommend facilities sample 20 records from the desired one-month observation period. Facilities could also select 10 records every two weeks from a two-week observation period. Either way, each sample should be treated as a single data point (e.g., do not select 20 records for the entire month and divide these 20 records into two 10-record samples).
- **Open records:** If a sampled resident record is open (i.e., the stay is still in progress), include this record in the review.
- **For the selected sample of records, collect complete medical record information:**
  - If possible, collect records for any transfer to a hospital (e.g., emergency department visit, inpatient admissions, observation stay) experienced by a sampled resident that occurred during or within seven days after the sampled SNF stay ended. Include these records in the SNF Trigger Tool review since the information in the records (such as documentation from emergency department visits or discharge summaries from admissions) can be key to an effective review (e.g., determining the extent to which a hospitalized patient was harmed by an adverse event).
  - Before attempting to collect records from another facility, ensure that all HIPAA compliance concerns are accounted for.
  - If it is not possible to access or review records from outside the SNF, reviewers should establish consistent rules for dealing with patients who are transferred to hospitals (e.g., assigning all possible adverse events identified for these residents during the SNF record review an F-level of harm, with the caveat that the true level of harm could not be determined).
  - Review time for non-SNF records should require less than 5 minutes per record. Review these records to determine whether a resident was harmed during their SNF stay, and, if yes, the severity of the harm event that led to an immediate transfer to a hospital. Reviewers should not review the post-SNF hospital records for harm that occurred in the hospital. Because these events did not occur in the SNF, they are not attributable to the SNF and are, therefore, outside the scope of the review. If the complete hospital record is not available, attempt to collect at the very least the discharge summaries, emergency department clinical notes, laboratory tests, and/or medication reconciliation documents.

## Step 4: Structuring the Review Process

The primary reviewer(s) should review each record independently using the SNF Trigger Tool as a guide. Use the review process described below.

- We recommend that reviewers focus on the first 30 days of any sampled SNF stay that is longer than 30 days.<sup>8,9</sup> Reviewing records of resident stays that are longer than 30 days is resource intensive and may require more review time than facilities can afford. If a selected record contains a SNF stay that is longer than 30 days, and the reviewer finishes the review in less than 25 minutes, they should not review any days after day number 30. It may be helpful to mark the end of the 30th day in the record.

- Set a 25-minute limit for review of each resident record once the training period for reviewers has been completed. Not all harms will be identified during the 25-minute review. The intent is to determine a rate of harm. However, based on experience, the majority of events — particularly more severe resident harms — will be identified within the 25-minute review timeframe. Additionally, the 25-minute timeframe will establish consistency in the review process and optimize resources.
- The record should only be reviewed to look for the presence of the triggers and relevant sections of the record associated with those triggers, not to do a comprehensive resident record review.
- Reviewers should familiarize themselves with the SNF Trigger Tool before reviewing the records. Note that, of the three triggers modules, the Patient Care and Medication modules are likely the most frequent triggers within SNFs.
- During the OIG study, experienced reviewers found it helpful to review the records in the following order:

1	Hospital discharge summary	9	Nurse progress notes
2	Diagnoses/operative/coding information from preceding hospitalization	10	Physician progress notes
3	SNF admission diagnoses and intake assessment	11	Minimum Data Set (MDS) Care Area Assessments (CAAs)
4	Skin assessment (to determine new or worsening pressure ulcers)	12	Mental health records, including psychiatry, psychology, psychiatric social worker (particularly when on psychotropic medications)
5	Medication administration record (MAR)	13	Laboratory test results
6	Intake assessment	14	Diabetic treatment/glucose monitoring form
7	Prescriber orders	15	Social service notes (family complaints may be documented here)
8	Pharmacy medication regimen reviews (particularly if acute change in mental status or other possible drug effects)	16	If time permits, other areas of the record, such as physical therapy notes and nutrition notes

## Step 5: Identifying Triggers and Determining Whether an Adverse Event Occurred

Primary record reviewers should examine the resident records for the designated SNF triggers (see the section on Triggers and Definitions). Limit reviews to the first 30 days of the SNF stay or the date of discharge from the SNF (including to a non-SNF, long-term care stay), whichever comes first.

If a trigger is identified in a record, the reviewer should further examine other relevant portions of the record — such as progress notes and orders that were documented in close proximity to the occurrence of the trigger — for evidence that an adverse event occurred. The presence of a trigger does not necessarily mean that there is an adverse event. Documentation that the resident experienced harm from medical care should be present to make the determination that an adverse event has occurred.

For example, an INR level greater than 6 would be a positive trigger. If identified, the reviewer should look for documentation of possible adverse events that can result from over-anticoagulation, such as bleeding or decreased hemoglobin. An abnormally high INR laboratory test in itself is not considered a harm event unless accompanied by bleeding. In another example, a fall identified in the record is a positive trigger. However, the fall is not considered an adverse event unless injury has also occurred.

### Determining Whether an Adverse Event Has Occurred

In determining whether an adverse event has occurred, consider the following four points:

- Does the event meet the definition of harm? If the event was related to medical care and caused harm equivalent to levels E through I on the harm scale, it's likely an adverse event.
- Would you be happy if the event happened to you or your family member? If no, then it's likely that harm occurred.
- Was the event part of the natural progression of the disease process, or a complication of treatment related to the disease process? The harm identified should be the result of some medical intervention. SNF residents may have advanced underlying diseases; advanced cognition disorders with impaired swallowing, immobility, disuse myopathy following hospitalization; vascular diseases; chronic renal impairment; and other conditions that will require reviewer and physician judgment to distinguish an attributable harm from underlying condition of residents.
- A subjective complaint of pain without evidence of harm or injury is not an adverse event. For example, pain while participating in physical therapy does not count as an adverse event. However, pain following a fall may be considered evidence of harm or injury.

### Documenting Review Findings on the SNF Trigger Tool Worksheet

Primary reviewers independently document their initial record review findings using the IHI SNF Trigger Tool Worksheet (see Appendix C), which lists all triggers, categorized into the three modules.

- When a primary reviewer identifies a trigger, the reviewer places a check in the column next to that trigger in the worksheet.

- If the primary reviewer then identifies an adverse event associated with the trigger, the reviewer notes a description and category of harm in the appropriate column.
- The reverse side of the worksheet is blank, and reviewers often use this space to make notes for discussion with other members of the review team or to capture questions that need to be reviewed with the physician.

After independently completing their record reviews on the same sample of records, the two primary reviewers meet to compare findings and come to consensus about the results. The physician reviewer then reviews the consensus findings with the primary reviewers to reach final agreement on the type, number, and severity of harm category for the events. The physician reviewer may refer to the worksheets completed by the two primary reviewers for more information, but does not perform a full review of each sampled resident record. The physician reviewer serves as a final decision maker as to whether or not an event occurred and the associated category of harm.

Other points to remember:

- If no adverse event is found, the reviewer should move on and look for other triggers in the record. Reviewers will find many positive triggers, but will identify many fewer triggers associated with adverse events.
- Some triggers (e.g., new infections) are also adverse events by definition. However, a positive trigger often is not an adverse event in itself; rather, the trigger is simply a clue that an event *may* have occurred.
- Occasionally, reviewers may discover an adverse event without a trigger while looking for triggers or other details in the record. These events should be included on the worksheet when recording findings, regardless of whether a trigger led the reviewer to identifying the adverse event.
- An adverse event that is POA to the SNF should be recorded, provided that it meets the criteria of harm related to medical care. To differentiate such an event from harm related to SNF care, it should be designated as a preadmission event.

## Step 6: Describing the Harm Event

Once an adverse event has been identified, the primary reviewers should describe the harm event in a data collection instrument (DCI). Using a DCI facilitates the structured collection of data from multiple reviewers and ensures that key questions are answered about each identified event.

The DCI should include questions (or data elements) that ask the reviewer to briefly describe the event, the clinical history of the patient, the evidence for the event, and the intervention needed to ameliorate the harm caused by the event. The DCI should ask the reviewer to note the severity of the harm caused by the event using a predetermined harm scale. The following is a list of data elements that should be included in the DCI, with guidance to reviewers on how to complete the data elements.

- Description: Brief description of the adverse event
- Background: Short summary of the clinical history of the resident
- Evidence for the Adverse Event: Lab values, staff actions, or other documented evidence for the event

- **Intervention:** Brief description of the care intervention needed to ameliorate the harm caused by the event
- **Severity of Harm:** Level of harm (E through I) as defined by the harm scale (see Table 2 below)

**Table 2. Categorizing the Level of Harm Caused by Adverse Events in SNFs**

<b>E Level</b>	Harm occurred that required intervention but did not cause lasting harm. <i>Note: Some intervention is required for a harm to be considered an E Level event.</i>
<b>F Level</b>	Harm occurred that prolonged the SNF stay or led to a transfer to a different SNF or other post-acute facility and/or hospitalization (i.e., admission to a hospital observation unit, emergency department, or inpatient care). <i>Note: Prolongation of the SNF stay, emergency department transfer, or rehospitalization qualifies.</i>
<b>G Level</b>	Harm occurred that contributed to or resulted in permanent resident harm. <i>Example: A fall associated with a medication that resulted in a hip fracture.</i>
<b>H Level</b>	Harm occurred that required intervention to sustain the resident's life. <i>Note: Experienced reviewers have found it helpful to define "lifesaving intervention" as that which must be provided in one hour or less in order to prevent death. For example, a resident who develops severe respiratory depression and arrest from a narcotic requires immediate intervention, such as a narcotic reversal agent. In this case, failure to provide the narcotic reversal agent immediately would lead to death.</i>
<b>I Level</b>	Harm occurred that may have contributed to or resulted in resident death. <i>Note: The event needs only to be contributory to the death.</i>

Source: OIG's 2014 modified version of the *NCC MERP Index for Categorizing Medication Errors* (February 2001)

### **A Note on Determining Harm for SNF Residents Readmitted to Hospitals**

Rehospitalization discharge summaries, history and physical forms, consultant dictations, or emergency department (ED) notes may be required to establish the severity of harm incurred by the resident. For example, a resident aspirates resulting in difficulty breathing and is transferred to the ED and subsequently hospitalized. This is considered an F Level harm event. However, if this harm contributed to the hospitalized patient's death, then it would likely be categorized an I Level harm event.

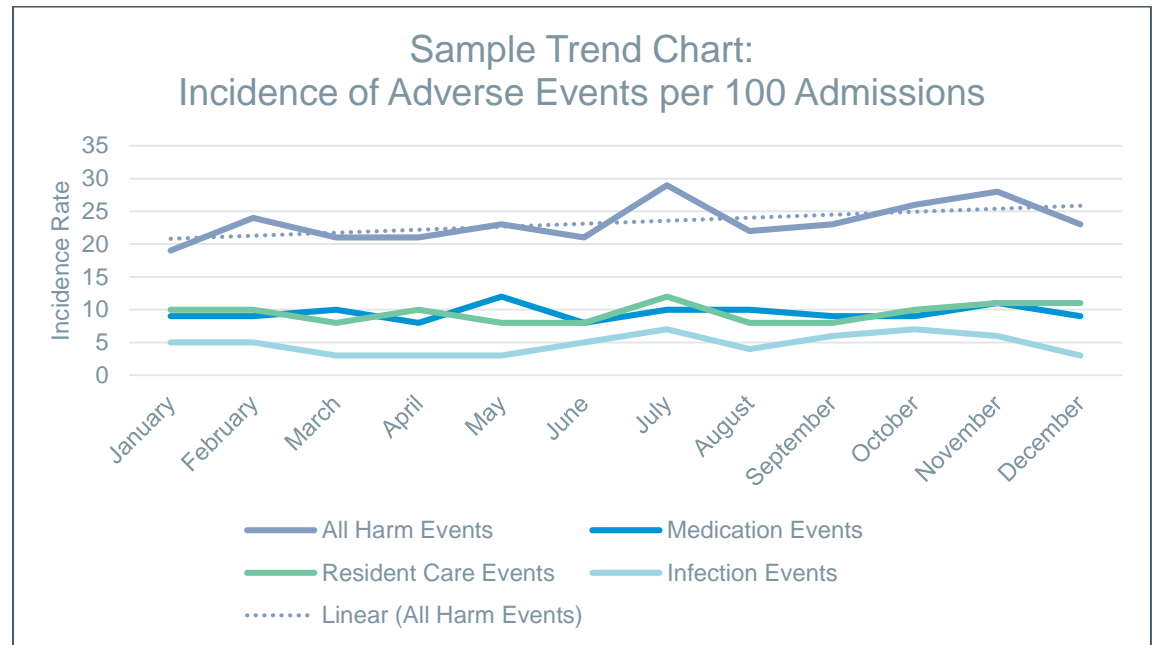
## **Step 7: Analyzing Trigger Tool Review Data**

Data from Trigger Tool reviews can be presented using trend, run, or control charts to depict trends in incidence in adverse events over time. One method for displaying data over time is to plot the overall incidence rate from each review as a single data point (i.e., one data point per month). The incidence rate can be presented in two ways:

- Adverse events per 100 SNF admissions
- Adverse events per 1,000 resident days **of review**

The trend chart in Figure 1 provides an example of how the incidence of events can be plotted to show trends over time. See IHI's website for resources on run charts.<sup>10</sup>

**Figure 1. Sample Trend Chart: Incidence of Adverse Events per 100 SNF Admissions**



In addition to tracking incidence of adverse events over time, we recommend that facilities analyze events by harm level, category, or other attribute. For example, SNFs may classify events using predefined descriptive categories (e.g., falls due to medication, internal bleeding due to anticoagulants, aspiration pneumonia) to estimate the relative frequency of these events within the facility. See Appendix A for examples and descriptions of adverse events in SNFs, or refer to the OIG report on adverse events in SNFs.<sup>2</sup>

# Skilled Nursing Facility Triggers and Definitions

The IHI SNF Trigger Tool organizes all triggers into three modules: Care Module Triggers, Medication Module Triggers, and Resident Care Module Triggers. This section provides a description of each trigger and considerations for determining the presence of an adverse event.

## Care Module Triggers

C1	Acute mental status change	C15	Insertion or use of urinary catheter
C2	Aspiration/spontaneous pneumonia	C16	Significant Change in Status Assessment (SCSA)
C3	Call to physician or family members	C17	Resident incident or accident
C4	Code or Emergency Medical Services (EMS)	C18	Pressure ulcer
C5	Death	C19	ED visit
C6	Drop in hemoglobin/hematocrit	C20	Transfer to acute care hospital or observation unit
C7	Studies for emboli, PE, or DVT	C21	Restraint use
C8	Fall	C22	Rising serum creatinine
C9	Family complaint	C23	Urinary retention
C10	Any infection	C24	New onset diarrhea
C11	New or increased diuretics	C25	Prolonged constipation
C12	High or low body temperature	C26	Diagnostic radiology or imaging studies
C13	In (SNF) stroke or TIA	C27	Care-Other
C14	New onset of incontinence		

### C1–Acute mental status change

Medication toxic effects and drug-related problems can cause profound medical and safety consequences in geriatric residents (e.g., delirium caused by narcotic analgesics) and are considered adverse events. Review progress notes (e.g., nurse, physician/allied health, interdisciplinary) and scan the information derived from the Minimum Data Set/Confusion Assessment Method (MDS/CAM) evaluations for mental status change such as lethargy, increasing confusion, or oversedation. In elderly residents, an increase in confusion is often a signal to consider a urinary or respiratory tract infection as the source.



Also review vital signs; the medication administration record and prescriber orders (e.g., analgesics, muscle relaxants, psychoactive medications), especially for new or changed dosages; and mental health provider documentation. Note a change in ability to participate in physical therapy or new or worsening wandering behavior. Treatment that results in intentional oversedation is not considered an adverse event (e.g., comfort measures).

### **C2–Aspiration/spontaneous pneumonia**

Aspiration of foreign material into the airway may be the result of abnormal swallowing or other contributory events. All harm resulting from aspirations (such as aspiration pneumonia, bronchitis, or acute respiratory distress) while the resident is under the care of the SNF are considered adverse events regardless of whether they are preventable. Spontaneous pneumonias may also occur due to subclinical aspiration while in the SNF and may be avoided through increasing mobility and positioning of the resident.

### **C3–Call to physician or family members**

Telephone calls to physicians or family members regarding unanticipated deterioration of the resident’s clinical status should be reviewed for potential harm events.

### **C4–Code or Emergency Medical Services (EMS)**

All “codes,” calls for an emergency response (e.g., EMTs), and cardiac or pulmonary arrests need to be carefully reviewed because they may have been caused by an adverse event. Reviewers should check for medication-related issues. Not all codes/arrests/emergency responses are adverse events, as some may be related to progression of a disease process. For example, sudden cardiac arrhythmia resulting in cardiac arrest may not be an adverse event, but rather related to underlying cardiac disease (unless related to a medication adverse event that resulted in cardiac toxicity).

### **C5–Death**

Resident deaths in SNFs are not adverse events but should be reviewed to determine if an adverse event contributed to or resulted in the death. Advanced directives and “Do Not Resuscitate” orders do not mean a death should not be reviewed to determine whether an adverse event contributed to the resident’s death.

### **C6–Drop in hemoglobin/hematocrit**

A significant drop in hemoglobin or hematocrit (H&H) or evidence of blood loss should be investigated for documented vital sign changes or symptoms from any medical intervention, particularly if the decrease occurs within a short period of time (e.g., 72 hours or less). Significant decreases in H&H are considered an adverse event if they are the unintended result of a medical treatment (e.g., ASA, NSAIDs, anticoagulants) or a procedure. Clinical judgment is key to determining what constitutes a “significant” decrease; reviewers may use a 25 percent decrease in H&H as a general parameter.

### **C7–Studies for emboli, PE, or DVT/VTE**

Development of a deep vein thrombosis (DVT) or pulmonary embolism (PE) during a SNF stay should be considered an adverse event unless clearly related to an underlying disease process (e.g., prostate cancer or clotting disorders). Rare exceptions may be those related to disease processes such as cancer or clotting disorders. However, in most patients this is considered harm related to medical care, even if all appropriate preventive measures appear to have been taken. If the hospitalization occurs due to a DVT or embolism, look for causation prior to admission that could be attributed to medical care such as a prior surgical procedure. The lack of prophylaxis with no DVT or PE is not an adverse event; it is an error of omission.

**C8–Fall**

Any fall in the care setting that causes injury, regardless of cause, is an adverse event; a fall without injury is not an adverse event. A fall in a care setting represents a failure of care and may be the result of medications, equipment failure, or failure of adequate staffing. Documented injuries might include fracture, lacerations, pain, and/or hematoma. The majority of falls will not represent an adverse event, but review for adverse events in all falls is necessary.

**C9–Family complaint**

Complaints for medical care issues or due to an unexpected deterioration in the resident's status should be reviewed for an adverse event. Family complaints are most likely documented in social worker notes.

**C10–Any infection**

Generally, resident harm associated with this trigger and attributable to the SNF will include infections diagnosed 48 hours or more after admission, such as bloodstream line infections, *Clostridium difficile* infection, sepsis associated with a device, catheter-associated urinary tract infections, or any other SNF-associated infection. Infections that began within the first 48 hours of the SNF stay may be POA. A positive blood culture at any time during the SNF stay must be investigated as an indicator of an adverse event. If a resident does not have a medical intervention preceding sepsis or septicemia, this likely is not an adverse event (such as urinary tract infections in residents without a Foley catheter progressing to sepsis).

Note: Generally, a positive urine culture without signs/symptoms (i.e., asymptomatic bacteriuria) is not considered an adverse event unless bacteremia and urine have the same culture. For example, the resident has an indwelling urinary catheter within seven days of a positive urine culture that is 100,000 organisms per cc. This type of colonization without signs or symptoms (asymptomatic bacteriuria) is typically not be considered an adverse event in the absence of symptoms such as pain or fever, even if physician documentation is present.

**C11–New or increased diuretics**

An introduction or increased dosing of diuretic are triggers for a potential fluid overload. Respiratory distress, increased leg edema, or weight change may indicate the presence of an adverse event.

Note: Decompensated heart failure in SNFs is likely the result of the progression of underlying cardiac disease and not an adverse event. However, heart failure because of unintentional fluid overload is considered an adverse event.

**C12–High or low body temperature**

Elderly residents in SNFs with infections may not generate a typical febrile response. Rather, infected residents may present with fever or as afebrile or even hypothermic. Hypothermia and fever are triggers that should result in a review of the medical record for a SNF-associated infection.

**C13–In (SNF) stroke or TIA**

Stroke or transient ischemic attack (TIA) is often due to an underlying disease process. However, these conditions may also result from anticoagulation excess (e.g., in residents with atrial fibrillation) or as a result of intracranial bleeding related to a medication intervention (an act of commission).

### **C14–New onset of incontinence**

New or worsening bladder or bowel incontinence are triggers that may lead to the detection of an adverse event resulting from medications or infections. Incontinence leading to dehydration and electrolyte abnormalities may result in triggers captured by trigger C1 or trigger C8.

### **C15–Insertion or use of urinary catheter**

Incontinent residents are frequently catheterized for many reasons. Both short- and long-term catheter use may result in adverse events (infections, falls, and urethra injuries) or changes in mental status due to oversedation. Insertion or use of a urinary catheter may be a trigger for an adverse event that has already occurred, or may also be a marker of a resident likely to experience harm.

### **C16–Significant Change in Status Assessment (SCSA)**

SCSAs are unscheduled MDS assessments performed when necessary as part of SNF Resident Assessment and Care Screening. Reviewers should determine if the SCSA for a deterioration of resident status is due to an adverse event.

### **C17–Resident incident or accident**

All resident incidents or accidents, including unexplained trauma and other injuries, should be reviewed for an adverse event. Examples include abuse, neglect, assault, restraint injuries, and suicide. Review the resident record for the cause of any injury.

### **C18–Pressure ulcers**

The diagnosis or documentation of Stage 1 pressure ulcers can be variable based on skin tone, injury, or state of evolution. If a resident has light-toned skin with non-blanching redness resembling the picture of Pressure Ulcer Stage 1 on the skin assessment chart, then this is a confirmed adverse event. Inability to determine the stage due to dark-toned skin or insufficient documentation may require a discussion between the reviewer and physician to appropriately assess the stage of the ulcer, and determine if an adverse event occurred.

Note: Pressure ulcers that advance in stage while the resident is in the SNF's care are recorded as adverse events. For example, a pressure ulcer that is Stage 1 on arrival that escalates to Stage 3 during the SNF stay is considered an adverse event. Refer to the National Pressure Ulcer Advisory Panel (NPUAP) staging guidelines.<sup>11</sup>

### **C19–ED visit**

SNF residents transferred from the SNF to an emergency department (ED) and then returned to the SNF should be reviewed to determine if an adverse event occurred. When such events occur, they are considered to be an F Level of harm, at a minimum.

Note: ED referrals are not always the result of an adverse event; such referrals may instead be due to a new diagnosis or exacerbation of an underlying condition.

### **C20–Transfer to acute care hospital or observation (OBS) unit**

Transfers to an acute care hospital, either through the emergency department or as a direct admission, must be reviewed. Transfers may be the direct result of an adverse event or due to the deterioration of a resident secondary to an adverse event.

When investigating a resident transfer, first try to obtain records from the hospital. Look for the reasons for the transfer. For example, in the case of a transfer to the ED following respiratory arrest and intubation, determine if the respiratory arrest was a natural progression of an exacerbation of chronic obstructive pulmonary disease (COPD). If so, then it is not considered an

adverse event. If respiratory arrest was likely the result of oversedation from a medication, it is considered an adverse event.

**C21–Restraint use**

Whenever physical and/or chemical (use of medication to control behavior) restraints are used, review the documented reasons and evaluate the possible relationship between the use of restraints and confusion from drugs or complications such as falls that may result from the use of restraints, which indicates an adverse event. Restraint use without associated harm is not considered an adverse event for the SNF Trigger Tool because it doesn't meet the definition of an adverse event (i.e., no harm or injury), but this type of event is still subject to applicable federal and state laws.

**C22–Rising serum creatinine**

Review laboratory records for asymptomatic or symptomatic rising levels of serum creatinine. If a change of two times greater than baseline levels is found, review medication administration records for medications known to cause acute kidney injury. To determine serum creatinine baseline, it may be helpful to review laboratory tests, if available, from preceding hospitalization or within the resident's discharge summary, history and physical, or SNF records. Glomerular filtration rate (GFR) from serum creatinine in adults can be determined using the Modification of Diet in Renal Disease (MDRD) calculator.<sup>12</sup>

Prior to determining if an adverse event occurred, consider pre-existing disease by reviewing physician progress notes and the history and physical for other causes of renal failure, such as pre-existing renal disease. These residents may be at greater risk for renal failure, and this would not be considered an adverse event, but rather the progression of disease. Events may also be due to a medical intervention (e.g., aminoglycosides, diuretics, NSAIDs) or dehydration.

**C23–Urinary retention**

Urinary retention is the inability to empty the bladder. Acute urinary retention is usually an emergent condition. With chronic urinary retention, a SNF resident may have trouble starting a stream or emptying their bladder completely. Acute and chronic urinary retention due to underlying resident condition (e.g., prostate enlargement) is not considered an adverse event. However, retention associated with medical interventions (e.g., medications or post-Foley catheter withdrawal) would be considered an adverse event. Please note that SNF residents with urinary retention are at greater risk for falls, infections, and mental status changes.

**C24–New onset diarrhea**

Acute diarrhea (new onset) is defined as three or more loose or watery stools per day, usually liquid (taking the shape of the container). The most common causes are infections (e.g., *Clostridium difficile* infection) and medications (e.g., Milk of Magnesia). Review the SNF medication administration record (MAR), orders, laboratory tests, and clinician notes.

**C25–Prolonged constipation**

Prolonged constipation that results in symptoms (e.g., abdominal pain, bloating, significant discomfort, rectal bleeding from straining) or that is attributable to diagnostic evidence of obstruction is considered an adverse event. Constipation alone without signs and symptoms is not considered an adverse event. Obstipation is chronic constipation, often with signs or symptoms of severe and intractable constipation that may lead to obstruction. SNF residents are prone to constipation due to age, bed rest, and medications; however, residents typically respond to a daily bowel care treatment program. Residents may progress to obstipation or evidence of obstruction; review the record for medications associated with prolonged constipation (commission). Note that elimination difficulties are associated with increased likelihood of falls.

**C26–Diagnostic radiology or imaging studies**

Review any unplanned radiology study ordered during a resident’s SNF stay for a potential adverse event such as fall with injury or SNF-acquired respiratory infection.

**C27–Other**

Use this trigger for care-related adverse events that are detected but not related to one of the Care triggers listed above.

**Medication Module Triggers**

M1	Abnormal electrolytes	M10	Sodium polystyrene administration
M2	Abrupt medication stop	M11	Abnormal drug levels
M3	Anti-emetic use	M12	Thrombocytopenia
M4	Diphenhydramine use	M13	Total WBC < 3000
M5	Elevated INR	M14	Vitamin K administration
M6	Epinephrine use	M15	Antibiotics started in SNF
M7	Glucose <50mg/dL, glucagon or dextrose supplement	M16	Increasing pain medication needs
M8	Abrupt onset hypotension	M17	Administration of parenteral fluid
M9	Naloxone use	M18	Medication-Other

**M1–Abnormal electrolytes**

In general, for example, the resident develops hypokalemia or hyponatremia (above or below lower limits of laboratory) without signs and symptoms such as lightheadedness, confusion, EKG changes, low blood pressure, or decrease in urinary output or difficulty breathing are not considered adverse events. Exceptions that may be considered adverse events based on lab values, even without signs or symptoms, are rising serum creatinine and hyperkalemia (see trigger M14).

**M2–Abrupt medication stop**

Although the discontinuation of medications is a common finding in the record, abruptly stopping medications is a trigger that requires further investigation for cause. A sudden change in resident condition requiring adjustment of medications is often related to an adverse event. This trigger is most useful when many medications are suddenly stopped, suggesting something dramatic has occurred to the resident. “Abrupt” is best described as an unexpected stop or deviation from typical ordering practice; for example, discontinuation of an intravenous antibiotic to switch to oral is not unexpected.

**M3–Antiemetic use**

Nausea and vomiting commonly are the result of drug administrations both in surgical and non-surgical settings. Antiemetics are commonly administered. Nausea and vomiting that interferes with feeding or delayed discharge suggests an adverse event. One or two episodes treated

successfully with antiemetics would not suggest an adverse event. Reviewer judgment is needed to determine whether harm occurred.

**M4–Diphenhydramine use**

Diphenhydramine is frequently used for allergic reactions to drugs, but can also be ordered as a sleep aid or for seasonal allergies. If the drug has been administered, review the record to determine if it was ordered for symptoms of an allergic reaction to a drug administered during the SNF stay. This would indicate an adverse event. Also diphenhydramine use in the elderly may result in adverse events due to its anticholinergic side effects (i.e., delirium, constipation, urinary retention, and hallucinations).

**M5–Elevated INR**

An elevated International Normalized Ratio (INR) laboratory test is not considered an adverse event unless the elevated INR is associated with signs and symptoms of bleeding. Look for evidence of bleeding due to medications to determine if an adverse event has occurred. Any value above the laboratory normal should be reviewed.

**M6–Epinephrine use**

Epinephrine use on a SNF resident with a severe allergic (i.e., anaphylactic) reaction is considered an adverse event, regardless of whether it was preventable.

**M7–Glucose <50mg/dL, glucagon or dextrose supplement given**

Review for symptoms such as lethargy and shakiness documented in nursing notes, and the administration of glucose, orange juice, or other intervention. In addition, an abnormal lab result with no symptoms is considered an adverse event if glucose <50mg/dL because most residents have physiologic changes that may not be documented or recognized by the resident due to cognitive disorders. If symptoms are present, or blood glucose <50mg/dL, review diabetic flow sheets, glucose monitoring flow sheets, nursing notes, laboratory tests orders, and medication administration record for symptoms, laboratory value, and associated use of insulin or oral hypoglycemic.

**M8–Abrupt onset hypotension**

Abrupt onset hypotension, defined as systolic blood pressure less than 90mmHg, may be due to the resident's underlying condition, but often may be related to an adverse event secondary to medications, including muscle relaxants, pain medications, sedatives, or diuretics. Review for symptoms such as resident feeling like he/she is going to pass out, has weakness, or has a lack of coherence. Look for actions such as paging the physician, flattening the bed, or starting IVs.

**M9–Naloxone use**

Naloxone is a powerful narcotic antagonist. Usage likely represents an adverse event since excess narcotic administration may result in a spectrum of clinical signs and symptoms, ranging from oversedation to respiratory failure.

**M10– Sodium polystyrene administration**

Sodium polystyrene sulfonate is used in the treatment of hyperkalemia and aids in the removal of excess potassium from the body. Look for the reason for hyperkalemia and whether the resident had been receiving potassium. Administration of sodium polystyrene may be in response to an overdose of potassium, which is considered an adverse event. Hyperkalemia should be considered an adverse event for any potassium (K<sup>+</sup>) greater than or equal to ( $\geq$ ) 6.5, regardless of whether there are associated signs and symptoms.

**M11–Abnormal drug levels**

If laboratory tests are sub-therapeutic (below therapeutic limit) or supra-therapeutic (above upper therapeutic limit), review the SNF record progress notes for documentation of a potential adverse event. Examples include inadequate seizure medication, serum drug levels leading to a seizure, or an elevated aminoglycoside serum drug level that leads to acute kidney injury.

**M12–Thrombocytopenia**

Certain medications can cause platelet counts in the blood to drop, placing residents at greater risk for bleeding. Look for adverse events related to bleeding such as strokes, hematomas, and hemorrhage requiring blood transfusions. Look for information about why the platelet count decreased to see if it was as a result of a medication. Usually, a platelet transfusion is an indication that the resident has a low platelet count. Events related to transfusions or bleeding may indicate that an adverse drug event may have occurred.

**M13–Total WBC count <3,000 (or >12,000)**

Follow the white blood cell (WBC) counts throughout the admission and see if the resident becomes symptomatic due to infection. An elevated WBC count may indicate a new infection or progression of an existing infection. In some cases, a low WBC count will occur in response to drug administration (and is not considered an adverse event, in this case). Infection is most likely to occur if the Absolute Neutrophil Count is less than 1,000. Intentional decrease in leukocyte count as part of planned chemotherapy is also not an adverse event. If a decrease in WBC count occurs in the absence of medications that may cause this, an adverse event related to drugs has not occurred; for example, when due to bone marrow infiltration by cancer, this is not considered an adverse event.

**M14–Vitamin K administration**

If Vitamin K was used as a response to a prolonged prothrombin time or elevated INR levels, it may signal an adverse event. If either lab value is high, review the resident record for evidence of bleeding. Look in the lab reports for a decrease in hematocrit or for guaiac-positive stools. Check the progress notes for evidence of excessive bruising or gastrointestinal bleeding. Less likely, a hemorrhagic stroke or other internal bleeding may have occurred. If any of these is found, it is likely that an adverse event has occurred.

**M15–Antibiotics started in SNF**

Review the SNF record for documentation of a SNF-acquired healthcare-associated infection or other signs or symptoms from unintentional medication side effects such as nausea, vomiting, diarrhea, elevated serum creatinine, or allergic reactions (e.g., a rash).

**M16–Increasing pain medication needs**

Increases in pain medications may be required to control SNF residents' pain. However, increases may also signal an adverse event such as a fall with injury, procedural or post-operative complication, prolonged constipation, or worsening pressure ulcers.

**M17–Administration of parenteral fluid**

SNF residents may require administration of parenteral fluid if unable to maintain oral intake or if they develop dehydration or hypotension. These conditions may develop because of medications or infection (e.g., catheter-associated urosepsis). Dehydration may lead to mental status changes and increased likelihood of falls.

**M18–Other**

Use this trigger for drug-related adverse events that are detected but not related to one of the Medication triggers listed above.

## Procedure Module Triggers

P1	Postoperative/post-procedure complication
P2	Procedure reintubation/BiPAP/new CPAP
P3	Procedure-Other

### **P1–Postoperative/post-procedure complication**

A complication resulting from any procedure is an adverse event, even if informed consent is provided. Intravenous infiltrates are considered adverse events when there are symptoms (such as redness, swelling, or pain) that require intervention, including compresses or elevation.

Procedure notes rarely indicate complications, especially if they occur hours or days after the procedure note has been dictated. Review resident records for complications that are present on admission as noted in the intake SNF assessment or, if available, the hospital discharge summary.

Deep tissue or prosthesis infections post-surgery should be considered POA events. Superficial site infections that occur two calendar days after admission to the SNF should be attributed to the SNF and not considered POA events.

### **P2–Procedure re-intubation/BiPAP/new CPAP**

Sedatives or pain medications can result in respiratory depression requiring the use of BiPAP/CPAP or a code requiring emergency responders who may perform an intubation. If the resident is on a ventilator, an adverse event related to re-intubation is dependent on the resident's care plan. For example, re-intubation following planned extubation as a trial for self-breathing or a planned transition to BiPAP generally are not considered adverse events. Alternatively, unplanned extubation with subsequent acute respiratory failure is always considered an adverse event, and an associated re-intubation or BiPAP is considered a life-sustaining intervention. Complications associated with any re-intubation (e.g., aspiration, anoxic encephalopathy) are always considered adverse events.

### **P3–Other**

Use this trigger for procedure-related adverse events that are detected but not related to one of the Procedure triggers listed above.



# Frequently Asked Questions (FAQs)

The additional guidance below is intended to improve consistency among reviewers using the IHI SNF Trigger Tool methodology. This guidance was created from information provided in the IHI Global Trigger Tool and modified based on the experiences of the nurse and physician reviewers who participated in the OIG's study of adverse events in SNFs. However, each SNF is encouraged to create its own FAQs or modify rules as needed to establish consistency among their own record reviewers.

## 1. Should the reviewer include adverse events that occurred prior to arrival at the SNF facility or campus?

Yes, if the adverse events comply with the definition of harm caused by medical care. These events should be designated as "POA events" (i.e., present on admission) in the data collection system (e.g., a database used to track the results of the Trigger Tool review) so they can be easily separated from events attributable to the SNF in any analysis. The benefit of tracking POA events is that facilities will be able to identify sources of harm affecting the residents that enter their facility.

Examples of POA events:

- Complications from a procedure performed during a preceding hospitalization that were recognized upon admission and treated adequately by the SNF
- Pressure ulcers that developed in an acute care hospital prior to the SNF stay
- Complications from medications taken in the hospital that began before the SNF stay
- Patient with a complication that began at a hospital or different SNF and is now admitted/transferred to the SNF for the index stay
- Patient admitted to the SNF for a pressure ulcer that developed at the hospital prior to the SNF stay

## 2. What's the difference between adverse events of commission and omission?

The difference is attributable to the primary cause of the event.

**Adverse events of commission** occur because of a problem associated with the active delivery of care. Such events can often be associated with a clearly defined action such as administering an incorrect medication to a resident.

Example of adverse events related to commission:

- Patient with a known penicillin allergy receives penicillin and has an allergic reaction
- Patient is on a beta blocker that results in heart block requiring a pacemaker

**Adverse events associated with an omission of care** can be more difficult to identify, but represent serious and often preventable events. Per the OIG's report, errors of omission are frequent in the SNF setting. The primary causes of events related to omission are substandard care (e.g., using an outdated treatment plan), a lack of monitoring, or an omission of evidence-based treatments.

Examples of adverse events related to an omission of care:

- Failure to identify a patient's progressive weakness, which ultimately leads to a significantly decreased functional status

- Delayed diagnosis of pneumothorax and inadequate monitoring, which leads to significant worsening of condition characterized by life-threatening difficulty breathing
- Fatal pulmonary embolus with hospitalization due to inadequate resident monitoring
- Delay in treatment for pleural effusion, which leads to worsening of hypoxia (inadequate oxygen in blood) that requires transfer to hospital for a chest tube, drainage, and intubation

### **3. Should an adverse event associated with an omission of care be included in the SNF Trigger Tool review?**

When beginning a SNF Trigger Tool review program in your facility, we suggest that reviewers focus on identifying events resulting from acts of **commission**. During the OIG reviews of adverse events in SNFs, the reviewers found that identifying and describing complex events associated with an omission in care were time consuming and costly. Once facilities gain experience with the Trigger Tool review methodology, they may choose to progress to include the more complex **errors of omission** (e.g., exacerbations of preexisting disease due to failure to adequately treat).

Facilities should, to the extent possible, try to refer events related to an omission of care that are identified during review to others in the facility for further investigation, or record them in any data collection instrument or database as “omission events.” By designating these events as omission events, these events can be easily separated from the more systematically captured commission events in any analysis.

### **4. What is a “cascade” event?**

A cascade event is an instance where an initial adverse event causes a series of additional, related events for the same patient. Always assign the highest level of harm (Level I) for the cascade event.

An example of a cascade event follows: A patient receives a central venous catheter, which is followed by sepsis, shock, hypotension, acute kidney injury, respiratory failure, and intubation, leading ultimately to patient death. This cascade is considered a single adverse event, categorized as Level I harm.

If a clinical non-physician record reviewer is unsure about whether multiple events should be combined into a single cascade event, the reviewer should ensure that all events are clearly identified and documented in the review — either separately or within the cascade — and ask the physician reviewer to determine whether a cascade event has occurred.

### **5. When are aberrant lab values in the absence of signs or symptoms considered patient harm?**

Generally speaking, abnormal lab results with no symptoms are not considered harm (see FAQ 6 for exceptions), even if documented by a physician as harm.

For example, consider a patient that has an indwelling urinary catheter within seven days of a positive urine culture that is 100,000 organisms per cc and was diagnosed and treated in the SNF as having a CAUTI. This sort of colonization without signs or symptoms (asymptomatic bacteriuria) is typically not considered to be an adverse event in the absence of signs or symptoms such as pain or fever or altered mental status. See FAQ 25 on CAUTIs.

**6. Are asymptomatic cases of abnormal electrolytes (e.g., hyponatremia, hypokalemia, hyperkalemia) considered harm?**

Generally, no. Abnormal electrolytes should be considered as a potential risk for harm but are not necessarily harm, with some exceptions. Patients should be symptomatic before reviewers consider abnormal electrolytes harm. A patient may have a 3.4 mEq K<sup>+</sup> from a diuretic and require replacement, but this is most likely potential risk and not harm. The degree of electrolyte abnormality will drive symptoms. Minor abnormalities will have no symptoms.

**Exceptions:** Asymptomatic laboratory test exceptions that are considered patient harm include rising serum creatinine (two times baseline), elevated Liver Function Tests (three to five times baseline), hypoglycemia (<50mg/dL), and hyperkalemia (>6.5 mEq).

**7. How do you define Level F harm for the SNF Trigger Tool review?**

Level F harm is any prolongation of the SNF stay or unplanned transfer to another post-acute setting for higher-level care, and/or hospitalization, including admission to an observation unit, emergency department, or inpatient care. These circumstances elevate a temporary event (Level E) to at least a category of Level F harm. An event is at least Level F harm if it causes the patient's SNF stay to be extended.

If an event results in unplanned transfer to another post-acute care setting or a hospital, it may be difficult to determine the extent of the harm caused by the adverse event beyond Level F unless post-SNF records are available for review.

**8. When are expected side effects considered to be adverse events?**

In general, expected side effects are considered to be adverse events when they are more severe or prolonged than normal and require intervention. Harm from complications is still considered an adverse event even when the complication was explained during informed consent.

Examples where clinical judgment is required to determine adverse events and assign a harm category:

- For patients demonstrating effect(s) of narcotic pain medication, judgment is required to determine if clinically significant enough to call an adverse event such as prolonged SNF stay or significant intervention. Ambulation status, feeding, fluids, bowel agents, and drugs all impact prolonged constipation and ileus.
- Nausea and vomiting are considered adverse events when the episode is prolonged or requires significant intervention (see specific guidance in FAQ 19).

**9. Is a patient fall in a SNF without a known precipitating cause considered an adverse event?**

Yes, remembering that a fall in the SNF is only an adverse event if there is documented injury (such as fracture, laceration, pain, significant skin tear, or hematoma) and requires an intervention.

**10. What are the rules for contamination of blood cultures?**

Skin contaminants in blood cultures may lead to false positives for bloodstream infections and are not necessarily considered an adverse event. If a common contaminant is found in a single blood culture, this is not considered an adverse event. It is helpful if the second blood culture is positive prior to a skin contaminant to be considered an adverse event. Some common skin contaminants include:

- Diphtheroids [*Corynebacterium* spp.]
- *Bacillus* [not *B. anthracis*] spp.
- *Propionibacterium* spp.
- Coagulase-negative staphylococci [including *S. epidermidis*]

**11. At what threshold is low blood glucose considered harm in the absence of signs or symptoms?**

A blood glucose below 50mg/dL should be flagged as a trigger and an adverse event. It is important for the physicians to review significant hypoglycemia laboratory results, even in the absence of documented signs or symptoms. For example, patients sedated on a ventilator or in a coma will be unlikely to exhibit usual signs or symptoms related to their hypoglycemia.

**12. Is it possible for harm to result from glycemic control with blood glucose above 50mg/dL?**

Yes; for example, a blood glucose in the 200s with a sudden drop to 60mg/dL with documented signs and symptoms of low blood glucose is considered an adverse event with associated harm.

Low blood glucose for patients experiencing low blood flow states (i.e., severe hypotension or code situations) may be inaccurate if identified through finger-stick. Reviewers should confirm these potential events by checking serum/plasma glucose level. Concern is that reliance on flawed technology may lead to over-identifying glycemic control adverse events.

**13. Can failing to administer a medication (error of omission) that causes harm be considered an event?**

No, failure to provide care that results in harm is an act of omission, not commission. As a reminder, if the SNF decides to capture omissions in its reviews, these events should be flagged as such in the database and separated from the incidence reporting.

**14. Is an abrupt stop of medication due to hypotension an adverse event?**

The abrupt stop of medication is considered only a trigger that may indicate an adverse event has possibly occurred. Patients should be symptomatic (i.e., lightheadedness, dizziness, confusion, fainting) to define as harm. It does not require an abrupt drop in blood pressure; however, that is helpful to know. The caveat is if the patient is restrained and bedridden, it is difficult to judge symptoms with a very low blood pressure.

Hypotension is a relative finding. Without some evidence of symptoms, there is no harm. Reviewers should be careful not to call normal low blood pressure an adverse event because elderly patients may have systolic blood pressure of 80-90 mmHg when prone. Reviewers should look for symptoms and evidence that the low blood pressure was associated with care (e.g., medications).

**15. Is administration of diphenhydramine for itching likely to be considered an adverse event?**

Drug-induced itching is considered an adverse event. Itching may be due to other medical interventions; however, drugs are the most likely culprits. Pruritus not associated with a medical intervention is considered an underlying condition rather than an adverse event.

**16. What are the specific medication issues in the geriatric population that might be considered adverse events?**

Medication toxic effects and drug-related problems are likely to cause profound medical and safety consequences in geriatric patients (e.g., delirium caused by opioids or benzodiazepines). Atypical antipsychotic medications require an indication and judicious use in SNF patients since they may lead to adverse events (see FAQ 18). Potential examples of side effects include movement disorders, sedation, postural hypotension cardiac arrhythmia, and sudden cardiac death.

**17. Is intertrigo or thrush while on an antibiotic considered an adverse event?**

If the intertrigo or thrush is due to a yeast infection, such as *Candida*, this is considered an adverse event (i.e., unintentional side effect of the medication).

**18. What if the patient is on any atypical antipsychotic drugs?**

Check mental health records (e.g., psychiatrist, psychologist, psychiatric social worker) for any documentation of change in mental status due to medication. In the patient record, review the pharmacist drug regimen assessment.

**19. When are nausea and vomiting considered adverse events?**

Some conditions and treatments, such as chemotherapy, are known to cause increased nausea and vomiting. To make a determination of an adverse event, focus on the length of time and the extent of the intervention.

Examples that are considered adverse events:

- Administration of anti-emetics at least 6 times during a 24-hour period
- Associated signs/symptoms such as projectile vomiting, dehydration, and/or hypotension

**20. Is prolonged obstipation considered an adverse event, such as a patient who experienced five days of obstipation with discomfort and possibly signaling inadequate bowel prep?**

Yes, this would be considered an adverse event if symptomatic (i.e., discomfort) and it requires intervention.

**21. When is constipation considered an adverse event?**

Constipation is considered an adverse event when it is prolonged and leads to significant symptomatic discomfort (i.e., pain, bloating, rectal bleeding from strain). Many SNF patients will have some constipation and require bowel care protocols (e.g., senna tablets, mobility, hydration, stool softeners) but without significant symptomatic discomfort, it is likely not an adverse event.

**22. Is diarrhea due to constipation agents an adverse event?**

Diarrhea is defined as three or more watery (takes the shape of a container) stools per day. However, calling this an adverse event depends on degree and clinical context. Reviewers should try to determine whether the patient was dehydrated, required an intervention, cause of diarrhea, and the frequency of the diarrheal stools.

**23. Are pressure ulcers that were present on arrival but increased in stage during the indexed SNF stay considered an adverse event?**

Yes, pressure ulcers that increase in stage while the resident is in the SNF's care count as adverse events. For example, a pressure ulcer that is Stage 1 on arrival but increases to Stage 3 during the

indexed SNF stay. (NOTE: All pressure ulcers are considered adverse events if present on admission.) We recommend reviewers indicate the stage of pressure ulcers based on medical record documentation in their description of the adverse event.

#### 24. What are the definitions for septicemia, sepsis, SIRS, and bacteremia used in the SNF Trigger Tool?

- **Septicemia:** Systemic disease associated with the presence of pathological microorganisms or toxins in the blood, which can include bacteria, viruses, fungi, or other organisms.
- **Sepsis:** SIRS due to infection.
- **SIRS:** The systemic inflammatory response syndrome (SIRS) is the systemic response to infection or trauma; symptoms include fever, tachycardia, tachypnea, and leukocytosis.
- **Bacteremia:** The presence of bacteria in the blood. It can also be defined as a positive blood culture without signs and symptoms of illness.

#### 25. How do we determine UTIs in patients who may have had catheters during a preceding hospitalization?

Symptomatic catheter-associated urinary tract infection (CAUTI) is considered an adverse event up to 48 hours post-discontinuation. The following two scenarios, based on a modified Centers for Disease Control and Prevention (CDC) definition, are considered CAUTIs for the SNF Trigger Tool:

- **Symptomatic CAUTI:** Patient had an indwelling urinary catheter in place at the time of specimen collection *and* at least one of the following signs or symptoms with no other recognized cause: fever ( $>38^{\circ}\text{C}$ ), suprapubic tenderness, or costovertebral angle pain or tenderness *and* a positive urine culture of  $\geq 10^5$  colony-forming units (CFU)/ml with no more than two species of microorganisms. Or, patient had indwelling urinary catheter removed within the 48 hours prior to specimen collection *and* at least one of the following signs or symptoms with no other recognized cause: acute mental status change, fever ( $>38^{\circ}\text{C}$ ), urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness *and* a positive urine culture of  $\geq 10^5$  colony-forming units (CFU)/ml with no more than two species of microorganisms.
- **Asymptomatic Bacteremic CAUTI:** Patient with or without an indwelling urinary catheter *has no signs or symptoms* (i.e., no fever ( $>38^{\circ}\text{C}$ ) for patients  $\leq 65$  years of age\*; and for any age, patient has no acute mental status change, urgency, frequency, dysuria, suprapubic tenderness, or costovertebral angle pain or tenderness, *and a positive urine culture of  $\geq 10^5$  CFU/ml with no more than two species of uropathogen microorganisms\*\* and a positive blood culture with at least one matching uropathogen microorganism to the urine culture.*
  - \*Fever is not diagnostic for UTI in  $>65$  years of age and therefore fever in this age group does not disqualify from meeting the criteria of an ABUTI.
  - \*\*Uropathogen microorganisms are: Gram-negative bacilli, *Staphylococcus* spp., yeasts, beta-hemolytic *Streptococcus* spp., *Enterococcus* spp., *G. vaginalis*, *Aerococcus* *urinae*, and *Corynebacterium* (urease positive).
- Many patients in the SNF experience cognition impairment and acute mental status change (i.e., increasing confusion). This is added to the CDC Guidelines as an acceptable symptom in considering CAUTI diagnosis (Infectious Disease Society Guidelines).

**26. If a PORT, PICC, or Peripheral IV implanted for chemotherapy, or other permanent port, is clotted or has to be removed within a brief period of time, is that an adverse event?**

Yes, a device that was supposed to be “permanent” (e.g., a permanent or totally implanted vascular access device, such as a PORT implanted for chemotherapy) but has become clotted or otherwise defective is considered an adverse event, even in the absence of signs or symptoms.

Determinations of harm resulting from clotted vascular access devices depend on whether the device is non-permanent, permanent, or totally implanted.

A non-permanent vascular access device, such as PICC line or peripheral IV, that is clotted or removed and reinserted should be considered a quality issue and not an adverse event unless there is other resulting patient harm such as a hematoma, vein thrombosis with associated signs and symptoms (e.g., pain, swelling), or infection.

**27. Is a minor skin injury (e.g., bruising, skin tears) an adverse event?**

Such types of skin injury will require clinical judgment.

- Falls with injury (skin tears, bruises) are defined as adverse events.
- Skin tears without documentation of a fall or other injury require clinical judgment to determine whether or not an adverse event has occurred.
- Multiple skin tears in a non-frail patient with normal skin on admission to the SNF may be an adverse event. However, as an example, a few minor skin tears in a fragile elderly patient are most likely not an adverse event.
- Even with a fall, a very minor skin abrasion needs to be evaluated carefully. Many elderly have fragile skin; therefore, this will be an issue of degree and requires clinical judgment.
- Steroids causing major skin changes (e.g., superficial infections or requiring special treatments) could be an event.

**28. For imaging for PE/DVT, a patient had a clot in the right heart by CT and was referred to the thrombophilia clinic. Is the clot considered an adverse event or simply related to disease?**

No, if the patient’s clot in the right heart was due to thrombophilia and not due to a medical intervention (e.g., Swan Ganz catheter) it is considered an underlying disease of the patient and is not harm.

**29. Should we consider an infection that develops within the first 48 hours of a SNF stay as a SNF-attributable adverse event?**

No; however, these are considered POA events and should be recorded as POA events in any data collection system.

- A potential *exception* to the 48-hour rule is a CAUTI when the Foley is inserted the day of SNF admission and the patient develops symptomatic UTI within 48 hours. This is categorized as an adverse event attributable to the SNF.
- Deep wound tissue infections are almost always attributable to the surgery during the preceding hospitalization, and are thus counted and categorized as POA events.

## Appendix A: Examples of Adverse Events in Skilled Nursing Facilities

The following tables include select descriptions of the adverse events, as identified by the OIG in their 2014 review of resident harm events in SNFs,<sup>13</sup> organized by the three modules in the IHI SNF Trigger Tool: Care Module, Medication Module, and Procedure Module. We suggest reviewing the events listed in the table and using them as examples of the harm that reviewers are likely to find in SNF records.

Please note that because the OIG's methodology included identifying events caused by an omission of care, some events may not apply to facilities targeting only events of commission.

**Table A1. Adverse Events Related to Resident Care**

Event Type	Description
<b>Acute kidney injury or insufficiency secondary to fluid maintenance</b>	Acute kidney insufficiency and confusion due inadequate hydration therapy resulting in hospitalization
	Acute kidney injury due to poor monitoring of hydration and inadequate diuretic therapy complicated by antipsychotics used to treat associated delirium
	Cascade event in which inadequate hydration led to acute kidney insufficiency, hypotension, and obtundation
	Cascade in which acute kidney injury due to inadequate hydration led to high potassium and uremia characterized by significant lethargy resulting in hospitalization
	Life-threatening acute kidney injury characterized by severe hyperkalemia due to inadequate monitoring of electrolytes and serum creatinine resulting in hospitalization
	Acute kidney injury due to progressive dehydration resulting in hospitalization and finally contributing to the resident's death
<b>Electrolyte disorders</b>	Cascade event in which failure to recognize postoperative delirium led to poor oral intake, hyperkalemia, and hypernatremia resulting in hospitalization
	Change in mental status due to electrolyte disorder caused by multiple free water gastrostomy tube flushes in a resident with a recent history of syndrome of inappropriate antidiuretic hormone secretion (SIADH)
	Hyponatremia with increased lethargy and change in mental due to free-water gastrostomy tube flushes resulting in hospitalization
	Severe hypernatremia due to inadequate hydration resulting in hospitalization



**Table A1. Adverse Events Related to Resident Care (continued)**

Event Type	Description
<b>Electrolyte disorders (continued)</b>	Significant dehydration due to inadequate hydration resulting in hospitalization
	Cascade event in which failure to adequately hydrate resident with dysphagia led to life-threatening hypovolemia, hyponatremia (electrolyte abnormality characterized by high sodium), hypotension, paroxysmal atrial tachycardia, need for cardioversion, non-STEMI myocardial infarction, and acute kidney injury resulting in transfer to hospital intensive care unit
	Cascade event in which insufficient monitoring of ileostomy led to leaking, excoriation around insertion site, significant dehydration, acute kidney injury, and high potassium
	Cascade event in which substandard monitoring of resident with known obstructive kidney disease resulted in progressive kidney failure, hyperkalemia (electrolyte abnormality characterized by high potassium), and finally cardiac arrest which contributed to the resident's death
<b>Exacerbations of preexisting conditions resulting from an omission of care</b>	Failure to properly assess resident in SNF and in preceding hospital stay, which led to delay in recognizing hip fracture that required hospitalization
	Failure to provide appropriate intervention for increasing hypothyroidism and monitoring of increasing heart failure, which led to episode of exacerbated heart failure that required hospitalization
	Hydronephrosis due to delay in needed post-hospital follow-up care for resident with significant urinary tract obstruction
	Jaundice, low hemoglobin, and lethargy due to a delay in recognition of acquired autoimmune hemolytic anemia resulting in hospitalization
	Suicide attempt by resident at risk for suicide characterized by self-inflicted cuts on wrists that required hospitalization due to inadequate compliance with a care plan that was not sufficient for the resident
	Reduction in diuretics and failure to adequately monitor increased weight gain (anasarca) associated with congestive heart failure and cirrhosis resulting in hospitalization and finally contributing to the resident's death
<b>Excessive bleeding related to resident care</b>	Excessive bleeding around wound vacuum pump site resulting in hospitalization
	Excessive bleeding from infection site resulting in hospitalization
	Hematuria secondary to Foley catheter resulting in hospitalization

**Table A1. Adverse Events Related to Resident Care (continued)**

Event Type	Description
<b>Fall or other trauma with injury associated with resident care</b>	Fall from motorized wheelchair resulting in multiple scrapes and abrasions
	Fall resulting in abrasions on face and elbow
	Fall resulting in elbow fracture
	Fall resulting in multiple skin tears on appendages and bruising on head
	Multiple falls resulting in skin tear on hand and elbow
	Trauma while in bed characterized by abrasions on temple and elbow
	Ankle fracture due to unwitnessed trauma in SNF
	Fall resulting in effusion and hematoma on knee resulting in hospitalization
	Fall resulting in hematoma on head resulting in hospitalization
	Fall resulting in multiple skin tears
	Fall with large hematoma on head resulting in hospitalization
<b>Hypotension related to resident care</b>	Cascade event in which dehydration due to inadequate monitoring led to hypotension, sinus tachycardia, and atrial fibrillation resulting in hospitalization
	Hypotension and hematuria due to inadequate monitoring of Foley catheter resulting in hospitalization
<b>Other resident care events</b>	Cascade event in which failure to provide adequate skin care caused a skin friction abrasion that progressed to a stage II pressure ulcer and developed cellulitis resulting in hospitalization
	Omission of care, which led to progressive weakness and decreased bowel and overall functional status resulting in hospitalization
	Significant constipation resulting in hospitalization
	Substandard urinary catheter care, which led to urinary retention resulting in hospitalization

**Table A1. Adverse Events Related to Resident Care (continued)**

Event Type	Description
<b>Other resident care events (continued)</b>	Cascade event in which pulmonary overload led to decreased oxygenation, life-threatening respiratory failure, atrial flutter, and significant lethargy resulting in hospitalization
	Acute kidney injury secondary to inadequate monitoring of urinary retention
	Acute urinary retention
	Blistering caused by medical tape
	Cascade event in which inadequate monitoring led to severe dehydration with associated confusion leading to falls with minor injuries
	Failure to monitor resident, which led to dislodged enteral feeding tube requiring multiple replacement attempts
	Hypotension due to inadequate hydration therapy
	Multiple-day delay in appropriate treatment of excessive swelling in a resident recovering from a hip fracture, which resulted in difficulty breathing
<b>Pressure ulcers</b>	Multiple Stage 1 pressure ulcers on heels, elbow, scapula, and toe
	Progression of pressure ulcer on buttocks from Stage 1 to Stage 2
	Progression of Stage 1 pressure ulcer to a Stage 2 pressure ulcer
	Progression of Stage 1 pressure ulcer to Stage 2
	Progression of Stage 1 pressure ulcers on coccyx and heels to Stage 2 ulcers
	Stage 1 pressure ulcer
	Stage 1 pressure ulcer on coccyx
	Stage 1 pressure ulcer on heel
	Stage 1 pressure ulcers on buttocks and heel
	Stage 1 pressure ulcers on heels
	Stage 2 pressure ulcer on buttocks

**Table A1. Adverse Events Related to Resident Care (continued)**

Event Type	Description
<b>Pressure ulcers (continued)</b>	Stage 2 pressure ulcers on thigh and Stage 1 pressure ulcers on buttock and coccyx
	Stage 3 pressure ulcer on hand
	Unstaged pressure ulcer on left heel
	Unstaged pressure ulcer on right heel
<b>Respiratory issues (other than infections)</b>	Cascade event in which delay in treatment for pleural effusion led to worsening of hypoxia (inadequate oxygen in blood) that required transfer to hospital for a chest tube, drainage, and intubation
	Delay in diagnosis of pneumothorax and inadequate monitoring, which led to significant worsening of condition characterized by life-threatening difficulty breathing resulting in hospitalization
	Failure to provide adequate tracheostomy care resulted in life-threatening acute respiratory failure
	Hypoxia and life-threatening respiratory distress due to insufficient pulmonary suction resulting in hospitalization
<b>Skin tear, abrasion, or breakdown</b>	Abrasion on forearm caused by collision with railing
	Multiple skin breakdowns above the coccyx
	Multiple skin excoriations
	Pressure wound on leg associated with cast
	Skin tear on elbow
	Skin tear on leg
	Skin tear on right forearm
	Skin tears on arm and leg
<b>Stage 3 or 4 pressure ulcers</b>	Stage 3 pressure ulcer on sacrum and Stage 2 pressure ulcer on buttocks
	Stage 3 pressure ulcer on heel

**Table A1. Adverse Events Related to Resident Care (continued)**

Event Type	Description
<b>Venous thromboembolism, DVT, or pulmonary embolism related to resident monitoring</b>	Delay in recognition of pneumothorax resulted in hospitalization
	DVT and pulmonary embolism due to inadequate monitoring resulting in hospitalization
	DVT due to a failure to provide adequate DVT monitoring and prophylaxis resulting in hospitalization
	Significant DVT due to failure to provide sufficient DVT monitoring and prophylaxis resulting in hospitalization
	DVT due to insufficient DVT prophylaxis led to hospitalization and finally resulted in a fatal pulmonary embolus
	Fatal pulmonary embolus with hospitalization due to inadequate resident monitoring

**Table A2. Adverse Events Related to Medication**

Event Type	Description
<b>Allergic reactions to medications (e.g., rash, itching)</b>	Rash in groin area due to immunosuppressant (methotrexate)
	Allergic reaction to medication (fluoroquinolone antibiotic) characterized by pruritis
	Pruritus associated with narcotics
	Skin rash on abdomen and legs associated with medication
<b>Anemia and other blood count problems secondary to medication</b>	Anemia due to inadequate administration of epoetin alfa (anemia medication) in resident with chronic kidney failure resulting in hospitalization
	Cascade event in which provision of antibiotics led to pancytopenia, angina, and pneumonia resulting in hospitalization
<b>Constipation, obstipation, and ileus</b>	Significant constipation secondary to pain medication (opioids) and inadequate bowel care
	Significant constipation secondary to pain medication (opioids)

**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Constipation, obstipation, and ileus (continued)</b>	Abdominal distention with ileus secondary to opiates
	Inadequate bowel care led to significant constipation secondary to opiates resulting in hospitalization
	Severe constipation due to pain medications (opioids)
	Significant constipation secondary to opiates resulting in hospitalization
	Significant ileus secondary to narcotics resulting in hospitalization
	Significant ileus secondary to opiates and inadequate bowel care resulting in hospitalization
<b>Excessive bleeding due to medication</b>	Coumadin toxicity led to gastrointestinal bleeding resulting in hospitalization
	Gastrointestinal bleeding due to anticoagulation treatment (aspirin) resulting in hospitalization
	Gastrointestinal bleeding secondary to anticoagulants resulting in hospitalization
	Anticoagulant overdose led to headache, nausea, vomiting, and subdural hematomas, which resulted in life-threatening hematemesis
	Cascade event in which anticoagulant (warfarin) toxicity led to life-threatening hematemesis (gastrointestinal bleeding) with kidney insufficiency and resultant hypotension resulting in hospitalization
	Life-threatening epistaxis (significant bleeding through nose) due to anticoagulant (warfarin) resulting in hospitalization
	Cascade event in which hematemesis (gastrointestinal bleeding) from an anticoagulant (warfarin) led to aspiration, which resulted in death
	Cascade event in which hemoptysis (coughing up blood) associated with anticoagulant led to aspiration, cardiac arrest, anoxic encephalopathy, and finally contributing to the resident's death
<b>Fall or other trauma with injury associated with medication</b>	Delirium and disorientation secondary to opiates for pain (oxycodone) resulting in multiple falls without injury
	Fall associated with anti-anxiety medications (lorazepam and escitalopram) and inappropriately prescribed atypical antipsychotic medication (risperidone) resulting in abrasion

**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Fall or other trauma with injury associated with medication (continued)</b>	Fall associated with inappropriately prescribed anti-anxiety medication (clonazepam) resulting in injury to head
	Fall associated with inappropriately prescribed anticholinergic medication (amitriptyline and perphenazine) resulting in skin tear on forearm
	Fall associated with poor diabetes management (multiple episodes of hypoglycemia and hyperglycemia) resulting in abrasions
	Fall associated with psychotropic medications (alprazolam and risperidone) resulting in abrasions
	Multiple falls associated with inappropriately prescribed antidepressant (fluoxetine) and anti-anxiety medications (selective serotonin reuptake inhibitor and lorazepam) resulting in multiple skin tears and abrasions
	Fall associated with appropriately prescribed antipsychotic medication (haloperidol decanoate) resulting in injury to hand
	Fall associated with appropriately prescribed atypical antipsychotic (olanzapine) and antidepressant (escitalopram) resulting in hip fracture resulting in hospitalization
	Fall associated with inappropriately prescribed antipsychotics (haloperidol decanoate and risperidone) resulting in hematoma
	Fall associated with inappropriately prescribed atypical antipsychotic (quetiapine) resulting in femur fracture resulting in hospitalization
	Fall associated with inappropriately prescribed opiates for pain (hydromorphone, hydrocodone/APAP, tramadol) resulting in rib fracture
	Fall associated with atypical antipsychotic (quetiapine) resulting in right hip fracture resulting in hospitalization
	Cascade event in which hypoglycemic episode characterized by blood glucose of 53 resulted in a resident fall
<b>Hypoglycemic episodes (e.g., low or significant drop in blood glucose)</b>	Hypoglycemic episode characterized by a significant drop in blood glucose
	Fall associated with inappropriately prescribed atypical antipsychotic (quetiapine) resulting in femur fracture resulting in hospitalization
	Hypoglycemic episode characterized by blood glucose of 32

**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Hypoglycemic episodes (e.g., low or significant drop in blood glucose) (continued)</b>	Hypoglycemic episode characterized by blood glucose of 43
	Hypoglycemic episode characterized by blood glucose of 49 and diaphoresis (excessive sweating)
	Hypoglycemic episode characterized by blood glucose of 59 and lethargy
	Hypoglycemic episode characterized by shaking and heart palpitations
	Hypoglycemic episode characterized by significant drop in blood glucose from baseline
	Hypoglycemic episodes characterized by significant drop in blood glucose and trembling
	Multiple hypoglycemic episodes characterized by blood glucose of 54 and 48
	Multiple hypoglycemic episodes characterized by blood glucose of 55 and unresponsiveness
	Multiple hypoglycemic episodes characterized by blood glucoses of 30, 35, 30 and, 20
	Multiple hypoglycemic episodes characterized by lowest blood glucose of 24
	Multiple hypoglycemic episodes characterized by lowest blood glucose of 66 and diaphoresis
	Life-threatening hypoglycemic episode characterized by blood glucose of 31
	Hypoglycemic episode characterized by a blood glucose of 20 resulting in hospitalization and finally contributing to the resident's death
	Hypoglycemic episode characterized by blood glucose of 38 resulting in hospitalization and finally contributing to the resident's death
<b>Hypotension secondary to medication</b>	Hypotension secondary to ACE inhibitor resulting in hospitalization
	Syncope with atrial fibrillation and hypotension secondary to overdose of levothyroxine and liothyronine resulting in hospitalization



**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Ketoacidosis, hyperosmolar coma, and other complications of diabetes related to insulin management</b>	Diabetic ketoacidosis due to insufficient administration of insulin resulting in hospitalization
	Failure to provide adequate insulin care led to diabetic ketoacidosis resulting in hospitalization
	Cascade event in which hyperosmolar diabetic coma characterized by somnolence and vomiting led to aspiration resulting in hospitalization and finally contributing to the resident's death
<b>Medication-induced delirium or other change in mental status</b>	Confusion and anxiety secondary to opioid pain medication (oxycodone)
	Confusion secondary to pain medication (opioids)
	Delirium and hallucinations due to pain medication (opioid)
	Delirium and hallucinations secondary to polypharmacy
	Delirium secondary to pain medication (hydrocodone)
	Delirium secondary to pain medication (opioid) caused resident to pull IV tube
	Episode of diaphoresis and dizziness due to pain medication (oxycodone and paracetamol)
	Light-headedness and vertigo due to pain medication (opioids)
	Acute change in mental status secondary to medication
	Acute mental status due to inadequate hydration therapy that was exacerbated by multiple medications
	Cascade event in which confusion and somnolence secondary to medications led to dehydration because of decreased fluid intake
	Cascade in which disorientation and hallucinations due to multiple medications (acetaminophen and hydrocodone, cyclobenzaprine, and lorazepam) led to a fall with resultant skin tear and rib fracture, which led to pneumonia requiring a hospitalization
Confusion secondary to beta blocker (metoprolol) characterized by sinus bradycardia	

**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Medication-induced delirium or other change in mental status (continued)</b>	Confusion, delusions, and continuing episodes of disorientation secondary to pain medication (opioids and benzodiazepines) resulting in hospitalization
	Delirium and agitation secondary to psychotropic and pain medications resulting in hospitalization
	Delirium secondary to multiple pain medications (opioids) resulting in hospitalization
	Delirium secondary to psychiatric medications (hydrocodone/APAP)
	Delirium, disorientation, and hallucinations secondary to inappropriately prescribed anti-anxiety medication (lorazepam) and other medications (acetaminophen and hydrocodone, cyclobenzaprine)
	Delirium, hallucinations, and respiratory failure secondary to pain and anti-anxiety medications (opioids and benzodiazepines) resulting in hospitalization
	Episode of unresponsiveness secondary to psychiatric medication (lithium)
	Lethargy and altered mental status secondary to medication
<b>Medication-induced allergic reaction</b>	Cascade event in which antibiotics (levofloxacin) given for an infected incision site caused an unanticipated allergic reaction characterized by pruritic rash over most of resident's body
	Rash secondary to antibiotic
	Rash secondary to anticoagulant
<b>Nausea and vomiting secondary to medication</b>	Digoxin toxicity led to nausea
	Nausea and vomiting secondary to antibiotic
<b>Thrush and other nonsurgical infections related to medication</b>	Candida vaginitis and oral thrush secondary to antibiotics
	Candida vaginitis secondary to antibiotics
	Oral and pharyngeal thrush secondary to antibiotic
	Oral thrush secondary to antibiotics
	Pharyngeal thrush secondary to antibiotic

**Table A2. Adverse Events Related to Medication (continued)**

Event Type	Description
<b>Other medication events</b>	Seizure in resident with history of seizures during period of inadequate levels of anti-epileptic (phenytoin)
	Significant and unanticipated diarrhea secondary to laxative
	Seizure secondary to inadequate monitoring of antiepileptic medication resulting in hospitalization
	Stroke because of a failure to provide anticoagulants which required hospitalization
	Life-threatening acute kidney injury due to inadequate diuretic therapy characterized by hyperkalemia resulting in hospitalization
	Life-threatening hyperkalemia and severe dehydration due to ACE inhibitor (lisinopril) resulting in hospitalization

**Table A3. Adverse Events Related to SNF-Associated Infections**

Event Type	Description
<b>Aspiration pneumonia and other respiratory infections</b>	Aspiration pneumonia due to failure to monitor resulting in hospitalization
	Aspiration pneumonia due to inadequate aspiration precautions and monitoring of resident with history of dysphagia
	Aspiration pneumonia resulting in hospitalization
	Cascade event in which dysphagia and vomiting led to aspiration pneumonia, associated with hyperglycemia (with diabetic ketoacidosis or hyperosmolar coma) and hyponatremia, resulting in hospitalization
	Emesis associated with lung infiltrate resulting in hospitalization
	Recurrence of pneumonia due to incomplete treatment of prior pneumonia resulting in hospitalization
	Several episodes of emesis, which led to aspiration pneumonia resulting in hospitalization
	Cascade event in which aspiration pneumonitis led to life-threatening respiratory failure resulting in hospitalization

**Table A3. Adverse Events Related to SNF-Associated Infections (continued)**

Event Type	Description
<b>Aspiration pneumonia and other respiratory infections (continued)</b>	Cascade event in which aspiration pneumonitis led to life-threatening respiratory failure, which exacerbated residents COPD resulting in hospitalization for needed BIPAP treatment
	Aspiration pneumonia characterized by tachypnea, dyspnea, and chest congestion resulting in hospitalization and finally contributing to the resident's death
<b>Catheter-associated urinary tract infection</b>	Multiple catheter-associated urinary tract infections secondary to multiple catheterizations
	Recurrent urinary tract infections associated with urinary catheter
	Urinary tract infection associated with urinary catheter
	Cascade event in which urosepsis led to dehydration, hypotension, and paroxysmal supraventricular tachycardia (PSVT)
	Cascade in which a partial obstruction due to Foley catheter placement led to a urinary tract infection
	Urinary tract infection associated with urinary catheter
	Urinary tract infection associated with urinary catheter characterized by acute change in mental status resulting in hospitalization
	Urinary tract infection associated with urinary catheter resulting in hospitalization
	<i>Clostridium difficile</i> infection following treatment with broad spectrum antibiotic
	<i>Clostridium difficile</i> infection
	<i>Clostridium difficile</i> infection associated with significant weight loss resulting in hospitalization
	<i>Clostridium difficile</i> infection resulting in hospitalization
<b>Sepsis</b>	Failure to provide adequate care for urinary tract infection, which led to sepsis resulting in hospitalization
	Urinary tract infection associated with urinary catheter characterized by acute change in mental status and somnolence resulting in hospitalization
	Life-threatening sepsis due to progression of inadequately treated pneumonia resulting in hospitalization

**Table A3. Adverse Events Related to SNF-Associated Infections (continued)**

Event Type	Description
<b>Soft tissue or other nonsurgical infection</b>	Bacterial conjunctivitis
	Blepharitis (swelling of the eyelids)
	Conjunctivitis on eye
	Fungal skin infection on abdomen
	Cellulitis on legs resulting in hospitalization
	Progressive infection characterized by rash, sloughing, and necrosis resulting in hospitalization
<b>Surgical site infection attributable to wound care</b>	Cellulitis at surgical site
	Superficial infection at surgical incision site
	Superficial infection at surgical incision site for a lower leg fracture
	Superficial infection at surgical incision site for recent knee replacement
	Cellulitis at PEG tube placement site resulting in hospitalization
	Cellulitis at site of skin graft resulting in hospitalization
	Cellulitis at surgical site resulting in hospitalization
	Superficial infection around surgical incision site for recent knee arthroplasty
	Superficial infection around surgical incision site for recent toe resection resulting in hospitalization
	Superficial infection around surgical incision site on hip
	Superficial infection around surgical incision site on leg resulting in hospitalization
	Superficial infection around surgical incision site on lower back

**Table A3. Adverse Events Related to SNF-Associated Infections (continued)**

Event Type	Description
<b>Vascular-catheter associated infection (e.g., PICC line, central line)</b>	Cascade event involving DVT and catheter-associated central line infection
	Infection (MRSA) around dialysis insertion site resulting in hospitalization
	Port site infection resulting in hospitalization
<b>Other infections</b>	Aspiration pneumonia
	Sepsis resulting from urinary tract infection

## Appendix B: Comparison of Adverse Event Review Methodologies

The table below provides descriptions of the differences between IHI's methodology for conducting reviews in acute care hospitals using the IHI Global Trigger Tool (GTT) methodology; the OIG's methodology described in the report, *Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries* (OEI-06-11-00370); and the IHI Skilled Nursing Facility (SNF) Trigger Tool methodology.

	IHI Global Trigger Tool for Acute Care Hospitals	OIG Study of Adverse Event Incidence in SNFs	IHI Skilled Nursing Facility Trigger Tool
<b>Primary objectives</b>	For a single hospital, determine the: 1) incidence per 100 admissions 2) incidence per 1,000 patient care days 3) percent of patients with 1 or more harms and 40 scope of harm	For a sample of Medicare beneficiaries who stayed in SNFs, determine the: 1) incidence rate of adverse events 2) preventability of observed events 3) costs of adverse events to Medicare	For a single SNF, determine the incidence of events per 100 admissions or per 1000 resident care days reviewed.
<b>Setting</b>	Acute care hospitals	SNFs	SNFs
<b>Include POA events?</b>	Yes – record as POA event	No	Yes – record as POA event in any database, but don't include them in SNF-based incidence rate
<b>Systematically include omission of care events?</b>	No	Yes	No – Facilities may refer omission events to others or mark them as such in any database, but do not include them in SNF-based incidence rate
<b>Distinguish between adverse events and temporary harm events?</b>	No	Yes	No
<b>Random sample?</b>	Yes	Yes	Yes
<b>Limit sample to closed records?</b>	Yes	Yes – Stays less than 35 days	No – Include all stays in sample that began (i.e., had a date of admission) during the defined observation period
<b>Sample records based on length of stay?</b>	No	Yes	No
<b>Sample frequency</b>	Every two weeks until 24 data points, then 1x per month	One-time sample	Every two weeks until 24 data points, then 1x per month
<b>Random sample size</b>	20	650	20
<b>Observation period</b>	One month or every two weeks	One month	One month or every two weeks

## Appendix C: IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events Worksheet

	Care Module Triggers	Event Description and Harm Level (E-I)		Medication Module Triggers	Event Description and Harm Level (E-I)
C1	Acute mental status change		M1	Abnormal electrolytes	
C2	Aspiration		M2	Abrupt medication stop	
C3	Call to physician or family members		M3	Anti-emetic use	
C4	Code or Emergency Medical Services (EMS)		M4	Diphenhydramine use	
C5	Death		M5	Elevated INR	
C6	Drop in hemoglobin/hematocrit		M6	Epinephrine use	
C7	Studies for emboli, PE or DVT		M7	Glucose <50mg/dL, glucagon or dextrose supplement given	
C8	Fall		M8	Abrupt onset hypotension	
C9	Family complaint		M9	Naloxone use	
C10	Any infection		M10	Sodium polystyrene administration	
C11	New or increased diuretics		M11	Abnormal drug levels	
C12	High or low body temperature		M12	Thrombocytopenia	
C13	In (SNF) stroke or TIA		M13	Total WBC < 3,000	
C14	New onset of incontinence		M14	Vitamin K administration	
C15	Insertion or use of urinary catheter		M15	Antibiotics started in SNF	
C16	Significant Change in Status Assessment		M16	Increasing pain medication needs	
C17	Resident incident or accident		M17	Administration of parenteral fluid	
C18	Pressure ulcer		M18	Rising ALT/AST liver function test	
C19	ED visit		M19	Medication-Other	
C20	Transfer to acute care hospital or observation (OBS) unit			Procedure Module Triggers	Event Description and Harm Level (E-I)
C21	Restraint use		P1	Postoperative/post-procedure complication	
C22	Rising serum creatinine		P2	Procedure reintubation/BiPAP/new CPAP	
C23	Urinary retention		P3	Procedure-Other	
C24	New onset diarrhea		<b>Notes</b>		
C25	Prolonged constipation				
C26	Diagnostic radiology or imaging studies				
C27	Care-Other				
Patient Identifier _____		Total Events _____	Total LOS _____	Complete data fields on reverse for each identified event	



### Appendix C: IHI Skilled Nursing Facility Trigger Tool for Measuring Adverse Events Worksheet (continued)

Data Collection Instrument	Event 1 (if applicable)	Event 2 (if applicable)	Event 3 (if applicable)
<b>Description:</b> (Brief description of the event)			
<b>Background:</b> (Short summary of the clinical history of the resident)			
<b>Evidence:</b> (Lab values, staff actions, or other documented evidence for the event)			
<b>Intervention:</b> (Brief description of the care intervention needed to ameliorate the harm caused by the event)			
<b>Harm Level:</b> (Level E-I)			
<b>Date of Harm:</b>			
<b>Other Notes:</b>			

## References

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- <sup>4</sup> Centers for Medicare & Medicaid Services. “Quality Assurance and Performance Improvement (QAPI) Resources.” <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/qapiresources.html>
- <sup>5</sup> Handler SM, Hanlon JT, Perera S, et al. Consensus list of signals to detect potential adverse drug reactions in nursing homes. *Journal of the American Geriatric Society*. 2008 May;56(5):808-815.
- <sup>6</sup> National Coordinating Council for Medication Error Reporting and Prevention. “Types of Medication Errors” (February 2001). <http://www.nccmerp.org/types-medication-errors>
- <sup>7</sup> Institute for Healthcare Improvement. “Sampling Tool.” <http://www.ihl.org/resources/Pages/Tools/Sampling.aspx>
- <sup>8</sup> This is a departure from the methodology the OIG used in their review. The OIG tested the SNF Trigger Tool on a population limited to SNF residents with a length of stay of less than 35 days. For Version 1 of the SNF Trigger Tool, we recommend this alternate methodology to reduce the complexity of the sample selection methodology and to include all SNF residents.
- <sup>9</sup> Limiting to the first 30 days of records will capture the majority of SNF stays but will necessarily limit all findings to the first 30 days of all stays. Any analysis of the data should note this as well as any other limitations of the data. SNFs interested in identifying events that occur during longer stays may wish to start a second Trigger Tool review that focuses on SNF stays longer than 30 days.
- <sup>10</sup> Institute for Healthcare Improvement. “Run Chart Tool.” <http://www.ihl.org/resources/Pages/Tools/RunChart.aspx>
- <sup>11</sup> National Pressure Ulcer Advisory Panel. “Pressure Ulcer Category/Staging Illustrations.” <http://www.npuap.org/pr2.htm>
- <sup>12</sup> National Institute of Diabetes and Digestive and Kidney Diseases. “Glomerular Filtration Rate (GFR) Calculators: Modification of Diet in Renal Disease (MDRD) Calculators.” <http://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/lab-evaluation/gfr-calculators/Pages/gfr-calculators.aspx>
- <sup>13</sup> Office of Inspector General. *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*. OEI-06-11-00370. February 2014:48-58. [Note: Some redundant events were deleted.]

**Potentially Preventable Events Related to Medication**

1. Change in mental status/delirium related to use of opiates and psychotropic medication
2. Hypoglycemia related to use of antidiabetic medication
3. Ketoacidosis related to use of antidiabetic medication
4. Bleeding related to use of antithrombotic medication
5. Thromboembolism related to use of antithrombotic medication
6. Prolonged constipation/ileus/impaction related to use of opiates
7. Electrolyte imbalance (including dehydration and acute kidney injury ) related to use of diuretic medication
8. Drug toxicities including: acetaminophen, digoxin; levothyroxine; ACE inhibitors; phenytoin; lithium; valproic acid; antibiotics
9. Altered cardiac output related to use of cardiac/blood pressure medication

**Potentially Preventable Events Related to Resident Care**

1. Falls, abrasions/skin tears, or other trauma related to care
2. Electrolyte imbalance (including dehydration and acute kidney injury/insufficiency) associated with inadequate fluid maintenance
3. Thromboembolic events related to inadequate resident monitoring and provision of care
4. Respiratory distress related to inadequate monitoring and provision of tracheostomy/ventilator care
5. Exacerbations of preexisting conditions related to inadequate or omitted care
6. Feeding tube complications (aspiration, leakage, displacement) related to inadequate monitoring and provision of care
7. In-house acquired/worsened stage pressure ulcers, and unstageable/suspected deep tissue injuries
8. Elopement

**Potentially Preventable Events Related to Infections**

1. Respiratory infections
  - a. Pneumonia
  - b. Influenza
2. Skin and wound infections
  - a. Surgical Site Infections (SSIs)
  - b. Soft tissue and non-surgical wound infections
3. Urinary tract infections (UTIs)
  - a. Catheter associated UTIs
  - b. UTIs
4. Infectious diarrhea
  - a. Clostridium difficile
  - b. Norovirus

Medication class:		Oral Anticoagulants
		<p><b>List of available categories:</b></p> <ul style="list-style-type: none"> <li>• Vitamin K Antagonists (Warfarin)</li> <li>• NOACs (Novel Oral Anticoagulants; Apixaban, Argatroban, Bivalirudin, Dabigatran, Desirudin, Edoxaban, Eteplixate, Fondaparinux, Rivaroxaban)</li> </ul>
<b>1. Key Benefits</b>	<i>Indication(s):</i>	<ul style="list-style-type: none"> <li>◆ Prevention and treatment of VTE and embolic CVA, and other systemic embolic events <i>See Chest guidelines (2012 Guideline and 2016 Update) for detailed information on indications, intensity and monitoring</i></li> </ul>
	<i>Diagnosis(es):</i>	<ul style="list-style-type: none"> <li>◆ Atrial fibrillation</li> <li>◆ DVT/PE</li> <li>◆ Prosthetic valves</li> <li>◆ Post-operative orthopedic and pelvic surgery</li> <li>◆ Cancer</li> </ul>
<b>2. Key Risks</b>	<i>Safety concern(s):</i>	<ul style="list-style-type: none"> <li>◆ Bleeding, extremely frequent falls, recent CVA</li> <li>◆ Drug-drug, drug-disease, drug dietary/supplements interactions while using warfarin</li> <li>◆ Verify additional safety concerns on structured product label (<a href="#">DailyMed</a>)</li> </ul>
<b>3. Risk/Benefit Ratio</b>	<i>Goals of care:</i>	<ul style="list-style-type: none"> <li>◆ Prevent and/or treat VTE</li> <li>◆ Prevent stroke or other embolic events</li> <li>◆ Consideration of patient and family preferences and care plan goals</li> </ul>
	<i>Non-pharmacological Alternatives:</i>	<ul style="list-style-type: none"> <li>◆ Compression (may not be practical in PA/LTC)</li> <li>◆ IVC filters when anticoagulation is contraindicated(not a definitive treatment)</li> <li>◆ Encourage mobility</li> <li>◆ Cardioversion for AFIB</li> </ul>
	<i>Pharmacologic Alternatives:</i>	<ul style="list-style-type: none"> <li>◆ Antiplatelet agents (Aspirin, Aspirin/Dipyridamole, Cangrelor, Cilostazol, Clopidogrel, Prasugrel, Ticagrelor, Ticlopidine, Vorapaxar)</li> <li>◆ Heparin (unfractionated)</li> <li>◆ Low Molecular Weight Heparin (Dalteparin, Enoxaparin, Nadroparin, Tinzaparin)</li> </ul>
<b>4. Safe Prescribing</b>	<i>Medication use:</i>	<ul style="list-style-type: none"> <li>◆ For warfarin management: <ul style="list-style-type: none"> <li>◆ Required dose of warfarin to achieve therapeutic INR decreases with advancing age and the usual starting dose is in the range of 2-5mg/d for those &gt;70 or who are undernourished, debilitated, or have heart failure or liver disease</li> <li>◆ Avoid the use of loading doses as they do not help achieve steady state faster</li> <li>◆ Do not increase dose by more than 15% at any given interval</li> <li>◆ To reduce risk of medication errors, avoid alternating/variable daily doses and don't use discontinuation rather than hold orders</li> <li>◆ For patients taking warfarin with INRs between 4.5-10 and with no evidence of bleeding do not use Vitamin K <i>See Chest guidelines (2012 Guideline and 2016 Update) for detailed information</i></li> <li>◆ When non-rapid reversal is needed, use Vitamin K 2.5-5 mg PO (not SQ or IM)</li> </ul> </li> <li>◆ NOACs <ul style="list-style-type: none"> <li>◆ Weigh risks/benefits of warfarin vs. NOACs when deciding on treatment regimen Use lower dose in older patients and others with impaired renal function</li> <li>◆ Idarucizumab is available for Dabigatran reversal when appropriate</li> </ul> </li> <li>◆ Consider avoiding use of the following <a href="#">Beers list 2015</a> medications: Aspirin &gt;325 mg/d (↑ bleeding), Dabigatran (↑ bleeding in CKD), Dipyridamole (without aspirin), Prasugrel (↑ bleeding in older adults), and Ticlopidine (safer alternatives exist)</li> <li>◆ Note: Consider checking with pharmacist upon initiation and any addition/subtraction of a medication or other useful resources such as AMDA's Antithrombotic Therapy in the Long-Term Care Setting or Atrial Fibrillation in the Long-Term Care Setting</li> </ul>
	<i>Duration:</i>	◆ Concomitant with indication <i>See Chest guidelines (2012 Guideline and 2016 Update) for detailed information</i>
	<i>Age-related:</i>	◆ Lower dose NOACS in older patients based on renal function.
	<i>Interactions:</i>	<ul style="list-style-type: none"> <li>◆ Drug-Drug (DDI): Multiple, for warfarin, see key risks above and consider using drug-drug interaction checking software and the Top 10 Particularly Dangerous DDIs (<a href="#">AMDA Top 10</a>)</li> <li>◆ Drug-Disease: drug with CHF, liver disease, uncontrolled hypertension</li> </ul>

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		<ul style="list-style-type: none"> <li>◆ Drug-Diet: Multiple for warfarin</li> <li>◆ NOACs: calcium channel blockers, antifungals, amiodarone, fibrates, statins, antibiotics</li> </ul>
	<i>Box warning:</i>	◆ Verify additional safety concerns on structured product label ( <a href="#">DailyMed</a> )
	<i>Duplication:</i>	<ul style="list-style-type: none"> <li>◆ Brand/name confusion</li> <li>◆ Additive risk of bleeding with concurrent use of aspirin, NSAIDs, clopidogrel, heparin(s)</li> </ul>
	<i>Drug history:</i>	<ul style="list-style-type: none"> <li>◆ Recent starting/stopping of medications affecting INR (warfarin)</li> <li>◆ Any previous adverse reactions to these drugs</li> <li>◆ Use of herbal supplements/OTC and other non-prescription medications especially with warfarin</li> </ul>
<b>5. Monitoring/ Effectiveness</b>	<i>Physiologic:</i>	<ul style="list-style-type: none"> <li>◆ Organ damage</li> <li>◆ Skin necrosis (Warfarin)</li> </ul>
	<i>Symptom:</i>	<ul style="list-style-type: none"> <li>◆ Signs and symptoms of bleeding</li> <li>◆ Anemia</li> </ul>
	<i>Lab:</i>	<ul style="list-style-type: none"> <li>◆ Order INR at time of warfarin drug initiation (q2-3 days until goal achieved), any change in dose, prescribing of any interacting drug particularly antibiotics plus with repeat INR in 3-4 days, and regular fixed intervals (e.g., monthly) once steady state is achieved</li> <li>◆ Steady state is achieved in 5-7 days on a fixed dose so avoid more frequent monitoring of INRs or dosing changes for warfarin</li> <li>◆ Changes in other drugs or acute conditions may require more frequent lab monitoring of warfarin</li> <li>◆ Consider centralization of warfarin management (i.e., warfarin clinics)</li> <li>◆ NOAC: none, check renal function prior to prescribing</li> <li>◆ Consider baseline and periodic monitoring of hemoglobin for development or worsening of anemia</li> </ul>
<p>AFIB= atrial fibrillation; CHF= congestive heart failure; CKD= chronic kidney disease; CVA= cerebrovascular accident; DVT= deep vein thrombosis; IVC= inferior vena cava filter; PE= pulmonary embolism; VTE= venous thromboembolism.</p>		

References to include:

1. Beers 2015 Criteria: <http://www.ncbi.nlm.nih.gov/pubmed/26446832>
2. Bleeding risk and anticoagulation:
  - a. <http://www.ncbi.nlm.nih.gov/pubmed/23479259>
  - b. <http://www.ncbi.nlm.nih.gov/pubmed/22840664>
  - c. <http://www.ncbi.nlm.nih.gov/pubmed/18334606>
3. Chest Guidelines
  - a. <http://journal.publications.chestnet.org/article.aspx?preview=true&articleid=2479255> (2016 update)
  - b. <http://journal.publications.chestnet.org/issue.aspx?journalid=99&issueid=23443&direction=P> (2012 guideline)
4. Quality measures and anticoagulation (Time in therapeutic range and INR variability):  
<https://www.qualitymeasures.ahrq.gov/content.aspx?id=32739>

Medication class:		Diabetes Treatment
<ul style="list-style-type: none"> <li>Alpha – glucosidase inhibitors</li> <li>Biguanides</li> <li>DPP-IV Inhibitors</li> </ul>		<ul style="list-style-type: none"> <li>GLP1 agonists</li> <li>Insulins</li> <li>Meglitinides</li> <li>SGLT 2 Inhibitors</li> <li>Sulfonylureas</li> <li>Thiazolidinediones (TZDs)</li> </ul>
<b>I. Key Risks</b>	<i>Safety concern(s):</i>	<ul style="list-style-type: none"> <li>Hypoglycemia and its consequences, including;               <ul style="list-style-type: none"> <li>Falls/falls with injury</li> <li>Change in mental status/delirium</li> <li>Worsening co-morbidities (dementia, CV complications)</li> </ul> </li> </ul>
<b>II. Appropriate use</b>	<i>Indication:</i>	Treatment of hyperglycemia due to Type 1 and 2 diabetes Decrease morbidity from microvascular complications (retinopathy, neuropathy, nephropathy)
	<i>Diagnoses:</i>	Type 1 DM, Type 2 DM
<b>III. Risk/ Benefit Ratio</b>	<i>Goals of care:</i>	Minimize morbidity/mortality due to diabetes and/or its treatment Patient-centered based on life expectancy, function, cognition, and co-morbidities Patient/family preference
	<i>Non-pharmacological management:</i>	<ul style="list-style-type: none"> <li>Regular diet (consistent caloric diet) and weight management if appropriate</li> <li>Physical activity promotion</li> </ul>
<b>IV. Safe Prescribing</b>	<i>Medication use:</i>	<ul style="list-style-type: none"> <li>Don't use sliding scale insulin for long-term glucose management (link to <a href="http://www.choosingwisely.org/clinician-lists/amda-sliding-scale-insulin-for-long-term-diabetes-management/">Choosing Wisely</a> campaign - <a href="http://www.choosingwisely.org/clinician-lists/amda-sliding-scale-insulin-for-long-term-diabetes-management/">http://www.choosingwisely.org/clinician-lists/amda-sliding-scale-insulin-for-long-term-diabetes-management/</a>)</li> <li>Switch from sliding scale to basal insulin (long-acting) or oral agent and decrease daily multiple glucose checks.</li> <li>Do not hold basal insulin if FBG is normal, and the patient will be eating</li> <li>Adjust basal insulin dose dependent on AM glucose level</li> <li>Simplify multiple-dose insulin regimens; in addition to basal, add mealtime insulin to the main meal initially, then to subsequent meals if goals are not achieved</li> <li>Link ultra short acting insulin administration to actual meal intake</li> <li>Avoid long-acting sulfonylureas</li> <li>Reduce dose of metformin if GFR is less than 60; stop if GFR is less than 30</li> <li>Don't use TZDs in patients with heart failure</li> <li>Ensure hydration if SGLT2 inhibitors are used</li> <li>Avoid GLP1 agonists if GFR is below 30 mL/min</li> <li>Reconcile the pre-hospitalization orders for diabetes to nursing home admission orders; oral medications may have been stopped in the hospital or not on formulary</li> </ul>
	<i>Age-related:</i>	<ul style="list-style-type: none"> <li>Decline in renal and hepatic function interferes with sulfonylurea and insulin metabolism, and increases their hypoglycemic effects</li> </ul>
	<i>Interactions:</i>	<ul style="list-style-type: none"> <li>Avoid combinations of sulfonylureas and insulins/meglitinides</li> <li>Recognize potential effects of steroids, thiazides, beta blockers, and atypical antipsychotics to increase blood glucose levels</li> <li>Impact of additional "stress" such as concurrent infection</li> </ul>
	<i>Drug history:</i>	<ul style="list-style-type: none"> <li>Obtain history of prior response, reactions and preferences</li> </ul>
	<i>Duplication:</i>	<ul style="list-style-type: none"> <li>Document that the benefit exceeds the risk of prescribing more than one diabetic agent to achieve desired goals.</li> <li>Avoid use of basal insulins with intermediate-acting insulins</li> </ul>
	<i>Potential for error:</i>	<ul style="list-style-type: none"> <li>Name confusion (sound alike/look alike) related to insulin products</li> <li>Inappropriate timing of medication in relation to meals</li> <li>Need to address change in therapy when intake is altered</li> <li>Repeated injections in same site or use of insulin before exercise</li> <li>Errors in order transcription</li> <li>Use of outdated insulin vials, dosing error (minimized with insulin pens)</li> <li>Need for caution when prescribing concentrated Insulins (regular U-500, glargine</li> </ul>

		U-300 (Toujeo) , degludec U-200 (Tresiba), Humalog U-200)
<b>V. Monitoring/ Effectiveness</b>	<i>Physiologic</i>	<ul style="list-style-type: none"> <li>◆ Caloric intake and activity mismatch</li> <li>◆ Inappropriate caloric restriction</li> </ul>
	<i>Symptom:</i>	<ul style="list-style-type: none"> <li>◆ Hypoglycemia signs and symptoms may be atypical</li> </ul>
	<i>Monitoring:</i>	<ul style="list-style-type: none"> <li>◆ Avoid A1C values less than 7.5%; may be higher based on patient characteristics/health status/life expectancy /goals <a href="http://www.choosingwisely.org/clinician-lists/american-geriatrics-society-medication-to-control-type-2-diabetes/">http://www.choosingwisely.org/clinician-lists/american-geriatrics-society-medication-to-control-type-2-diabetes/</a> <a href="http://care.diabetesjournals.org/cgi/content/abstract/39/2/308?ct doi: 10.2337/dc15-2512">http://care.diabetesjournals.org/cgi/content/abstract/39/2/308?ct doi: 10.2337/dc15-2512</a></li> <li>◆ Re-evaluate role and appropriateness of SMBG (self-monitoring of blood glucose)</li> <li>◆ Review patterns and trends of glucose values in a timely fashion</li> <li>◆ Minimize glucose checks in stable patients (AMDA CPG Diabetes Management)</li> <li>◆ Optimize facility response to and prompt practitioner notification for hypoglycemia</li> </ul>
<b>VI. De-Prescribing</b>	<i>Indications:</i>	<ul style="list-style-type: none"> <li>◆ Recurrent hypoglycemic episodes</li> <li>◆ Change in patient care goals and/or risk/benefit</li> </ul>
	<i>Caveats</i>	<ul style="list-style-type: none"> <li>◆ Adverse events: hyperglycemia, dehydration, urinary incontinence, confusion, hyperosmolar state</li> </ul>

**References:**

UK Prospective Diabetes Study (UKPDS) Group. (1998). *Intensive Blood-Glucose Control with Sulphonylureas or Insulin Compared with Conventional Treatment and Risk of Complications in Patients with Type 2 Diabetes*. (UKPDS 33). Lancet. pp.352:837–853.

American Diabetes Association (ADA); (January 2016) *Diabetes Care* 39:Suppl. 1; S81-85 at [www.Diabetes.Org/Diabetes Care](http://www.Diabetes.Org/Diabetes Care)

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Medication class: <b>Opioid Analgesics</b>	
<p><b>Strength Categories (WHO):</b></p> <ul style="list-style-type: none"> <li>• <b>Weak:</b> codeine, tramadol</li> <li>• <b>Strong:</b> buprenorphine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine sulfate, oxycodone, oxymorphone, pentazipine</li> </ul>	
<b>I. Key Benefits</b>	<p><i>Indication:</i></p> <ul style="list-style-type: none"> <li>◆ Acute and chronic persistent moderate to severe pain not controlled by other strategies</li> <li>◆ End of life care</li> <li>◆ Dyspnea</li> </ul>
<b>II. Key Risks</b>	<p><i>Safety concern(s):</i></p> <ul style="list-style-type: none"> <li>◆ Constipation/urinary retention</li> <li>◆ Delirium and mental status changes</li> <li>◆ Drug diversion</li> <li>◆ Falls</li> <li>◆ Nausea/vomiting</li> <li>◆ Overdose</li> <li>◆ Respiratory depression</li> </ul>
<b>III. Risk/ Benefit Ratio</b>	<p><i>Goals of care:</i></p> <ul style="list-style-type: none"> <li>◆ Relief of pain</li> <li>◆ Relief of respiratory distress</li> <li>◆ May improve ADLs and Quality of Life</li> <li>◆ Shortens recovery time after surgery</li> </ul>
	<p><i>Non-pharmacological alternatives:</i></p> <ul style="list-style-type: none"> <li>◆ Physical modalities: e.g., heat, ultrasound, cold, biofeedback, massage, acupuncture,</li> <li>◆ Invasive procedures to manage pain: e.g. epidural injections, nerve blocks, surgical repair/replacement</li> <li>◆ TENS units/ electrical stimulation</li> </ul>
	<p><i>Pharmacologic alternative:</i></p> <ul style="list-style-type: none"> <li>◆ Acetaminophen, NSAIDs, anti-convulsants, anti-depressants, steroids, topical anesthetics, opioid-like medicines; capsaicin ; topical NSAIDS</li> </ul>
<b>IV. Safe Prescribing</b>	<p><i>Medication Use:</i></p> <ul style="list-style-type: none"> <li>◆ Complete accurate pain assessment and medical diagnosis in order to select the appropriate agent for the type of pain</li> <li>◆ Utilize non opioids and non pharmacologic interventions prior to initiating opioids particularly for chronic pain</li> <li>◆ Start low, go slow, and reevaluate frequently. Use lowest effective dose. Fentanyl is contraindicated in opioid-naïve patients.</li> <li>◆ For initiation of opioids, use short-acting first, then consider conversion to long-acting agent for persistent pain. When titrating utilize the same medication for short and long acting</li> <li>◆ Do not write time ranges for doses (i.e. every 4-6 hours)</li> <li>◆ Do not abbreviate morphine sulfate</li> <li>◆ If more than one pain medication ordered be clear on what type of pain and severity of pain in the orders</li> <li>◆ Start laxative regimen to avoid constipation when opioids started</li> <li>◆ Do not start methadone unless experienced in its use</li> <li>◆ Avoid/discontinue long-term orders for PRN opioids that are not being used</li> <li>◆ Appropriate use of equi-analgesic dosing</li> <li>◆ Adjust dosing for renal insufficiency and use in hepatic impairment</li> <li>◆ Pentazocine, meperidine, indomethacin, and ketorolac are Beers High Risk Medications <a href="http://geriatricscareonline.org/toc/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CLO01">http://geriatricscareonline.org/toc/american-geriatrics-society-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/CLO01</a></li> <li>◆ When prescribing Morphine Sulfate oral concentrate 20 mg/1 ml, include strength and volume to be administered</li> <li>◆ Consider the inclusion of naloxone in emergency medication supplies in facility</li> </ul>
	<p><i>Age-related:</i></p> <ul style="list-style-type: none"> <li>◆ Physiologic changes may prolong duration of effectiveness</li> <li>◆ Consider dose reduction when GFR less than 50 for many agents</li> </ul>



QUALITY PRESCRIBING FORM

	<i>Interactions:</i>	Other CNS-active drugs <a href="http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf">http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf</a>
	<i>Route:</i>	◆ Preferably oral
	<i>Duplication:</i>	◆ Multiple narcotics
	<i>Drug history:</i>	◆ Prior use and effectiveness of narcotics ◆ Use of other pharmacologic and non-pharmacologic alternatives ◆ Prior adverse events ◆ Prior or current history of substance abuse
	<i>Box warning:</i>	◆ Fentanyl patch use with opioid-naïve patients; <a href="http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges/ucm113224.htm">http://www.fda.gov/Safety/MedWatch/SafetyInformation/Safety-RelatedDrugLabelingChanges/ucm113224.htm</a> ◆ Trans mucosal Fentanyl requires certification <a href="https://www.tirfremssaccess.com/TirfUI/remss/home.action">https://www.tirfremssaccess.com/TirfUI/remss/home.action</a> ◆ Extended Release-Long Acting Opioid Analgesics <a href="http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm396503.htm">http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm396503.htm</a>
<b>V. Monitoring/ Effectiveness</b>	<i>Physiologic:</i>	◆ Pain response ◆ Monitor bowel function ◆ Monitor mood and physical functional status ◆ Monitor for sedation and respiratory depression
	<i>Symptom:</i>	◆ Pain control matched to care goals and patient preference ◆ When using PRN, very clear indications on parameters (mild/moderate/severe pain and frequency) ◆ Use short-acting for breakthrough pain, convert to increased long-acting dose as needed. ◆ Reassessment with each dose for effectiveness
<b>VI. De-Prescribing and Diversion</b>	<i>Caveats:</i>	◆ Monitor for withdrawal symptoms when tapering or discontinuing opioids ◆ Participate in Prescription Drug Monitoring Programs (PDMPs) where required <a href="http://www.cdc.gov/drugoverdose/pdmp/">http://www.cdc.gov/drugoverdose/pdmp/</a>

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VA/DOD. (2010). **Veterans Administration /DoD CLINICAL PRACTICE GUIDELINE FOR MANAGEMENT OF OPIOID THERAPY FOR CHRONIC PAIN.** [http://www.healthquality.va.gov/guidelines/Pain/cot/COT\\_312\\_Full-er.pdf](http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf). 160 pages used by VAH

**CDC Guideline for Prescribing Opioids for Chronic Pain.** <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>

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