

the Remedi Pulse

MANAGING
HIGH-RISK DRUGS



A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

FALL 2016

Survey Solutions

with William Vaughan, BSN, RN
VP of Education & Clinical Affairs

2016 Deficiency Data: Trends and Patterns Regarding High-Risk Medications

One of Benjamin Franklin's more famous quotes declares, "In this world, nothing can be said to be certain, except death and taxes." For providers of nursing home care, "regulatory interest in medication management" could also be added to that list. In July of 2015, with voluminous and long-standing federal regulation already in place, CMS released a memorandum¹ detailing efforts aimed at increasing the scrutiny of medication management in nursing homes. Specifics included an acknowledgement that the mismanagement of high-risk medications can have devastating consequences for residents, the unacceptably high prevalence of adverse events related to such medications, the sharing of a tool developed to assist surveyors in identifying adverse drug events, and the piloting of a new focused survey looking at medication safety systems with an emphasis on high-risk and problem-prone medications.

Given that it's been more than a year since CMS put providers on notice regarding high-risk medications, we thought it would be informative to review what surveyors have cited at F329 (Unnecessary Drugs) year to date. The following is a summary of national deficiencies², cited at a severity level of actual harm ("G") or high under F329, for the period beginning January 1, 2016, and ending September 1, 2016. (Note: as it may take state survey agencies weeks to months to make deficiency data available, the information below likely reflects an under reporting of actual deficiencies cited):

- **Actual Harm (Isolated):** There were a total of fifteen (15) deficiencies cited at this scope/severity level. Six (6) deficiencies involved the drug Coumadin with one death and multiple hospitalizations doc

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"...CMS released a memorandum detailing efforts aimed at increasing the scrutiny of medication management in nursing homes."

Risky Business: High-Risk Drugs

Prepared by Annette Elam., R. Ph., Clinical Consultant Pharmacist

Although Narrow Therapeutic Index (NTI) drugs, such as digoxin and warfarin, are the first to come to mind when discussing drugs that have a high risk of adverse events in the geriatric population, there are numerous other drugs that pose a high risk for adverse events for additional reasons. Opioid, antidiabetics, anticoagulants, and NTI drugs are a current focus for healthcare agencies such as CMS, CDC, and the FDA.

As an example, all opioids can cause changes in mental status, delirium, and respiratory depression. Here are two specific examples of additional adverse effects:

- **Methadone:**

- Methadone has a prolonged action in the body, and can cause profound sedation and life-threatening respiratory depression, especially when used with other sedating drugs such as benzodiazepines.
 - Methadone can also cause QT prolongation alone and that risk increases when used concurrently with other medications that prolong the QT interval, such as antidepressants, antipsychotics, and antibiotics.
 - Patients should routinely be monitored for excess sedation and a corrected QT interval can be calculated from a periodic EKG.

- **Fentanyl Transdermal Patch:**

- Many dangers inherent to fentanyl, outside of the normal opioid side effects, stem from use of the patch. Deaths have occurred from incorrect prescribing and mishandling of the fentanyl patch. Opioid naive patients should not be prescribed fentanyl patches, and nursing must be conscientious when using and disposing the patches.

Antibiotics are also under considerable scrutiny:

- **Antibiotics:**

- The risk for C. diff is increased by antibiotic usage. Many have been linked to causing life-threatening C. diff, an infectious diarrhea which kills more than 14,000 people per year, over 80 percent of whom are above age 65.

- **FDA Warning:**

- Antibiotics have recently become a high profile topic with the FDA. In a memo released in May 2016, the FDA states that the risks associated with fluoroquinolone antibiotics (e.g., ciprofloxacin, levofloxacin) exceeds the benefits of these drugs, and therefore, should no longer be used for common infections such as sinusitis, bronchitis, or uncomplicated UTIs. Serious risks include tendonitis, neuropathy, and other neurological symptoms, such as confusion and hallucinations.

- **Drug Interactions:**

- It is well known that many antibiotics interact with warfarin to increase the risk of bleeding. What is not as well known is the increased risk of QT prolongation potentially leading to dizziness, falls, seizures, and sudden death that can occur with both macrolide antibiotics (e.g., erythromycin, azithromycin) and the fluoroquinolones. This risk is significantly increased when used concurrently with other medications that can cause QT prolongation.

To help providers identify potential adverse events related to medications, CMS has released a detailed “Adverse Drug Event Trigger Tool.” Examples of triggers for potential adverse drug reactions from the tool include:

- Change in mental status/delirium related to opioid use
- Change in mental status/delirium related to psychotropic medication use (including antipsychotics, antidepressants, anxiolytics, and hypnotics)
- Hypoglycemia related to use of antidiabetic medication
- Ketoacidosis related to insulin therapy
- Bleeding related to antithrombotic medication use
- Thromboembolism related to anticoagulant medication use
- Prolonged constipation, ileus, or impaction related to opioid medication use
- Electrolyte imbalance (including dehydration and acute kidney injury) related to diuretic use
- Drug toxicity related to:
 - Acetaminophen
 - Digoxin
 - Levothyroxine
 - ACE inhibitors
 - Phenytoin
 - Lithium
 - Valproic acid

As healthcare providers, our goal is twofold. First, avoid or minimize the risk of drug-related adverse events. Second, safely and effectively manage adverse events when they do occur. While our focus should be on prevention through early detection and monitoring, knowing how to properly manage adverse drug events is equally imperative to the health of our residents.

Resources:

- 1 <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/Adverse-Drug-Event-Trigger-Tool.pdf>
- 2 <http://www.cdc.gov/longtermcare/prevention/antibiotic-stewardship.html>
- 3 <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/NHQAPI.html>

The Thin Line between Therapeutic and Toxic

Prepared by Dave Hicov, R.Ph., MBA, Clinical Consultant Pharmacist

The first lesson drilled into an impressionable pharmacy student's brain is to treat each medication as a dangerous drug. That lesson continues with an important subgroup of medications known as Narrow Therapeutic Index (NTI) drugs.

The therapeutic index of a medication is a comparison of the amount of a therapeutic agent that causes a beneficial, therapeutic effect, compared to the amount that causes toxicity. In other words, NTI drugs are defined by the FDA as drugs where small differences in dose or blood concentration may lead to serious therapeutic failures and/or adverse drug reactions that are life threatening, or result in persistent or significant disability or incapacity. Careful resident monitoring and gradual dose titrations are essential to ensuring safety.

Some examples of medications with a Narrow Therapeutic Index include (but may not necessarily constitute all):

- Carbamazepine (Tegretol)
- Cyclosporine (Neoral, Sandimmune)
- Digoxin (Lanoxin)
- Levothyroxine (Synthroid)
- Lithium (Eskalith)
- Phenytoin (Dilantin)
- Procainamide (Procan)
- Theophylline (Theo-Dur)
- Warfarin (Coumadin)
- Tacrolimus (Prograf)

When evaluating the above list, it should not come as a surprise that residents in our practice setting receive NTI drugs on a daily basis. Warfarin itself can have entire texts written about its pharmacodynamics (e.g., dosing, drug interactions, clearance from the body, frequency of INR draws based on individualized therapy, etc.). Drug and disease-state interactions could result in wide swings in serum concentrations in all of the above medications, thereby, resulting in increased potential for adverse effects or ineffectiveness. There are multiple resources detailing recommended lab draw frequency based on the individual NTI medications. It should be noted, however, that each member of the table should have considerations for routine lab monitoring. Considering the complex histories and comorbidities of residents, it becomes imperative to realize the necessity for proper administration, utilization, and monitoring of these medications. Quite simply, if mistakes are made with NTI drugs, serious adverse effects could be the result.

During the course of surveys in nursing facilities, there are multiple pharmacy related F-Tags that are included in the guidance to surveyors. Errors during the med-pass with NTI drugs can trigger an F333 citation.

Examples of errors with NTI drugs include:

- Omitting administration
- Improper timing of administration
- Inappropriate crushing
- Poor measurement of dose
- Inadequate or missed monitoring
- Variation in taking with food or an empty stomach

The F329 tag refers to unnecessary medications in a resident's medication regimen. Individual components of a regimen should have a clear indication for use, proper dose, proper duration of therapy, GDR if necessary, and adequate monitoring. The components that comprise the parameters of F329 are even more important when NTI medications are involved. Clinicians should be cognizant of the associated relevant lab orders (and recommended frequency of draws), proper dosages based on specific disease-states, symptoms of toxicity, potential for drug and/or disease-state interactions, and the rationale for treating and minimizing toxicity. If a resident experiences a change in condition and is receiving an NTI drug, a level should be checked to rule out toxicity or subtherapeutic dosing as a cause.

Our goals as healthcare providers should always revolve around the safety and well-being of the residents. Understanding the importance of the role of NTI medications in everyday therapy with an eye towards the potential for adverse effects is crucial in ensuring that residents have beneficial clinical outcomes.

Resources:

- 1 <http://www.ncmedsoc.org/nc-board-of-pharmacy-issues-revised-nti-drug-list/>
- 2 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4412688/>
- 3 <https://www.ascp.com/articles/nursing-facility-survey-regulations>
- 4 <http://pharmacologycorner.com/therapeutic-index/>

Remedi Superstar Nurse

TRACY ALFIERI, LPN

Carington Park, Ashtabula, Ohio

CONGRATULATIONS to Tracy Alfieri, LPN, Carington Park, Ashtabula, Ohio, for being chosen as the Remedi Superstar Nurse. Tracy was nominated by her ADON, Bambi Lopez, LPN. Per Bambi, “Tracy joined our team at Carington Park in February 2013, and has been an LPN since 2005. She is a very outstanding nurse. Tracy is always willing to help others and go above and beyond to get her job done. She pays special attention to details and is a team player. I could not ask for a more thorough nurse, and we are very grateful to have such a wonderful employee.”



Email your Superstar Nurse nomination(s) to Rebecca.Ogden@RemediRx.com.

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- **umented.** Antipsychotics were cited in four (4) deficiencies with harm defined by one death, one resident who developed abnormal/involuntary movements, and two residents whose condition declined as evidenced by decreased activity and intake. Each of the five (5) remaining deficiencies involved a single drug or drug class:
 - Digoxin (hospitalization due to Dig toxicity, level = 4.8 ng/mL)
 - Morphine Sulfate (hospitalization in the ICU due to respiratory depression)
 - NSAID (duplicative therapy with resulting GI bleed, Hgb = 5.0 gm/dL)
 - Opioid and sedative (combined administration resulted in over sedation and hospitalization)
 - Narcotic (overdose resulting in hospitalization)
- **Actual Harm (Pattern):** There were three (3) deficiencies cited at this scope/severity level. Two (2) deficiencies involved psychoactive medications with actual harm attributed to weight loss, sedation, and decreased involvement in activities. One (1) deficiency described the mismanagement of Coumadin in multiple residents resulting in hospitalizations.
- **Immediate Jeopardy (Isolated):** A total of eight (8) deficiencies were cited at this scope/severity level. It's important to remember that the citing of a deficiency at an immediate jeopardy (IJ) severity level does not necessarily require a finding of actual harm. If surveyors discover a deficiency that “is likely to cause, serious injury, harm, impairment, or

death to a resident”³ (i.e., a “near miss”), it can be cited at an IJ level. Not surprisingly, seven (7) of the eight (8) deficiencies cited in 2016 under F329 at an IJ level centered on the drug Coumadin. These deficiencies highlight system failures involving prescribers, nurses, and pharmacists who often fail to provide even the most basic of interventions relevant to this high-risk medication. The remaining deficiency involved similar system failures involving the drug Morphine Sulfate.

If you're looking for a QAPI project, the take away from this data is clear. While Coumadin remains the drug most commonly involved in significant deficiencies cited under F329, various other medications increase clinical risk for residents and regulatory risk for facilities when they are poorly managed. By implementing robust and consistent QAPI measures, you can reduce the likelihood that your facility will “contribute” to deficiency data during the remaining months of 2016.

Note: Bill was a surveyor with the Maryland State Survey Agency from 1988 until 2001. He became Chief Nurse of the agency in 2001 and remained in that position until joining Remedi Senior-Care in 2013.

References

- 1 <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-47.pdf>
- 2 <https://data.medicare.gov/data/nursing-home-compare>
- 3 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/so-m107ap_q_immedjeopardy.pdf