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A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

SEPTEMBER 2014

Survey Solutions

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

F 329: Avoid Unnecessary Deficiencies by Avoiding Unnecessary Drugs

The concepts are so simple and straightforward: make sure your resident really needs the drugs you are administering, give the lowest dose possible for the least amount of time, monitor the drug to make sure it's working and not causing intolerable side effects, and pay special attention to antipsychotics (a class of drugs when used in certain residents offers little benefit but carry significant risk). Why then were 1 in 5 nursing homes cited for providing deficient care at F329 in 2013? Given the highly anticipated quality assurance / performance improvement (QAPI) regulations set to be released by CMS in the near future, now is the perfect time for facilities to take a proactive look and determine if "unnecessary" drugs exist in their residents' medication profiles. Below are listed some common clinical situations which increase the risk of medication mismanagement, as well as suggestions on how to mitigate that risk:

- **Transitions in care:** When residents move, be it to/from a hospital, a room change inside the nursing home or even an afternoon outing with a family member, staff should take the opportunity to critically review medications. For new admissions, especially those that have complex medication regimens, consider involving your Consultant Pharmacist in a brief review by phone.
- **Coordinating laboratory results:** When administering medications, the nursing staff is expected to have a clear understanding of the resident's current status which includes knowledge of relevant laboratory results. Consider promptly adding the most recent drug level, INR, hematocrit, etc., to the MAR to avoid the inappropriate administration of a drug (consider discussing this function with your EHR vendor).
- **Monitoring protocols:** Part of medication management includes monitoring drugs for effectiveness as well as

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Please do not hesitate to contact your Remedi Consultant Pharmacist or Account Manager if you have any questions or concerns.

The Battle Against Polypharmacy

Prepared by: Erin M. Foti, PharmD, CGP, Clinical Consultant Pharmacist

In the health care system today, we are finding that more and more of our elderly residents have lengthy medication regimens. The term polypharmacy is defined as the use of more medications than are clinically indicated, or when a medication regimen contains at least one unnecessary drug. (Claudene J. George, 2011) In long term care, polypharmacy comes with its own F-tag, F329. F329 states that each resident's drug regimen must be free from unnecessary drugs. This may include but not be limited to drugs used in excessive dose, excessive duration, without adequate monitoring, no indication for use, or being used in the presence of drug related side effects. (CMS, 2006) Now, with the average life span reaching record highs in the upper seventies and into the eighties, we are seeing residents with compounding comorbidities. Therapeutic polypharmacy is a term used when a resident is on multiple medications that are justified to treat someone's numerous conditions, such as an admission with COPD, Diabetes, Hypertension, Dementia, and Renal Insufficiency. Risk factors for polypharmacy are included in three different categories: Patient specific, Physician specific and Health care system specific. Patient specific risk factors would entail increased age, poor health, multiple medical conditions, education level, and the use of 9 or more medications. Physicians can contribute to this issue by having unfamiliarity with geriatric pharmacology, a reluctance to stopping a medication, and also willingness to prescribe. The health care industry then compounds the worsening situation by having multiple physicians treat one patient, availability of pharmacies, and an increased number of drugs on the market. (Claudene J. George, 2011)

The approach that health care providers should initiate to reduce the incidence of polypharmacy is systematic. All medications that a patient is receiving should be documented, including any over the counter or herbal products. If a patient sees more than one physician, this list should be shared among the various providers in order to avoid unnecessary prescribing and duplication of therapy. Medications should be matched to known conditions or diagnoses of the individual and excess medications should be discontinued. Any medication that is causing the individual side effects or does not have a known benefit should be stopped. We need to be vigilant and avoid what is known as the prescribing cascade. This is where one drug is added in order to treat the side effect of another, such as prescribing an overactive bladder medication for someone on a diuretic. If a resident is experiencing a new complaint, we should question whether it's a drug they are currently taking before adding another. Another way to avoid polypharmacy would be to simplify the regimen by reducing the amount of doses in 24 hours, such as switching to longer acting products and assuring that dosage is appropriate for renal or hepatic dysfunction.

With the growing number of prescription drugs available, both brand name and generic, and over the counter and herbal therapies, the health care team needs to be consistent with evaluating what are geriatric population is receiving. Medications should always have an indication for use and if they are not beneficial or providing the patient with optimal results discontinued. Careful thought and consideration should be given whenever a medication is initiated or discontinued. Health care providers should be able to discuss alternative forms of treatment, such as non-pharmacological interventions prior to initiating medication management. Physicians, pharmacists, and nurses all play an important role when it comes to consistently reviewing medication regimens to ensure that our aging population is receiving the most ideal therapeutic approach.

References

Claudene J. George, M. R. (2011). Polypharmacy. In D. W.-B. Victor Hirth, Case Based Geriatrics A Global Approach (pp. 431-439). New York: McGraw Hill Medical.

CMS. (2006, December 15). F329 Unnecessary Drugs. Retrieved from http://www.ncdhhs.gov/dhsr/nhlcs/pdf/tag_329.pdf

Nurse of the Month

KAM MCCORMICK, LPN
Country Club Retirement Center V in Delaware, Ohio

CONGRATULATIONS TO Kam McCormick, LPN at Country Club Retirement Center V in Delaware, OH for being chosen as the Remedi **"Nurse of the Month!"** Kam was nominated by her former DON Linda Pfizenmayer and Kristie Mazzocca RN, Corporate Clinical Specialist for Holland Management. Per Linda, "Kam is a very positive force in this building. She is always cheerful and loves her job. Kam takes care of business and you can count on her to do her job to the best of her ability." Per Kristie: "Kam was brought on when Holland Management took over ownership. She worked full time and went to RN school while pregnant and only took off 4 weeks for delivery of her new baby and returned to the building full time. Kam promotes Holland standards in our building and leads by example to show resident care is above all else. She works with the team in excelling towards meeting above regulatory standards."

Email your "Nurse of the Month nomination(s)" no later than the 30th of the month to Rebecca.Ogden@Remedirx.com. Nurses Rock!!

Update and Review on Sedatives/Hypnotics

Prepared by: Maureen Gearhart, PharmD, CGP, Clinical Consultant Pharmacist

Insomnia is a common complaint in the elderly. This can be the result of age-related changes in sleep patterns, underlying illness, or medication side effects. Possibly, our requirement for sleep becomes less as we age. The sedative/hypnotic drug class is often used for insomnia in the long term care settings. The most recent updated data reported from the CASPER program indicate a utilization rate of 6.7% nationally in those nursing homes reporting. The most widely prescribed medications in this class include the non- benzodiazepine group including, Ambien, Lunesta, Intermezzo, Sonata, and the benzodiazepine, Restoril. Recently, the FDA has made recommendations on dose reductions due to safety concerns. In May 2014, the FDA recommended the starting dose of Lunesta be reduced from 2 mg to 1 mg. This is a result of studies indicating "severe next-morning psychomotor and memory impairment". One study showed impairment in memory and coordination up to 11 hours after the dose was taken. This would be of great concern to our elderly population who have already been diagnosed with dementia, Parkinson's and other disease states affecting their sense of orientation and gate.

In January 2013, the FDA informed the manufacturers that the recommended dose of zolpidem for women should be lowered from 10 mg to 5 mg for immediate-release products (Ambien, Edluar, and ZolpiMist) and from 12.5 mg to 6.25 mg for extended-release products (Ambien CR). The FDA also informed the manufacturers that, for men, the labeling should recommend health care professionals consider prescribing the lower doses—5 mg for immediate-release products and 6.25 mg. The dose reductions were all based on study results showing "next morning impairment". The recommended dose is lower in women because women metabolize the drug more slowly than men which can lead to higher blood levels and increase risk of central nervous system side effects. The FDA urges health care professionals to caution all patients (men and women) who use these zolpidem products about the risks of next-morning impairment for activities requiring complete mental alertness. Monitoring of our elderly residents on these medications should be done because of the increased risk of falls, confusion and other CNS side effects (sleep walking has been reported). Data show the risk for next-morning impairment is highest for patients taking the extended-release forms of these drugs (Ambien CR and generics). Again, women appear to be more susceptible to this risk because they eliminate zolpidem from their bodies more slowly than men.

The safety of this medication class in the elderly population has been further investigated specifically in nursing home residents. One study evaluated residents who had been on one of the non benzo medications (Ambien, Lunesta, Sonata) and the incidence of hip fractures in these residents. The authors concluded that the risk of hip fracture was increased in nursing home patients who were prescribed a nonbenzodiazepine hypnotic within 30 days prior to the fracture. Caution should be used when using these agents in all nursing home residents.

In addition to the increased incidence of hip fractures, the nonbenzodiazepine hypnotics have also been associated with a number of rare effects. These include anaphylaxis, angioedema, and a number of complex sleep-related behaviors such as sleep-driving, sleep-eating, and making phone calls during sleep. Although the actual incidence of these adverse sleep behaviors is rare, they are serious and must be kept in mind. Complex sleep related behaviors may occur when nonbenzodiazepine hypnotics are concurrently used with alcohol and when they are taken and the patients/residents do not immediately go to bed. Both the benzodiazepine and non benzo classes are included in the Beers list for inappropriate medications for the elderly. The concerns with both classes include an increased risk of cognitive impairment, delirium, unsteady gate and falls.

Benzodiazepine receptor agonists (a.k.a. Z-drugs):

- Eszopiclone (Lunesta) 1 mg
- Zaleplon (Sonata) 5 mg
- Zolpidem (Ambien, generics; Ambien CR) 5 mg, 6.25 mg CR

Benzodiazepines

- Temazepam (Restoril, generics) 7.5 mg
- "Z drugs" have less rebound insomnia, hangover, tolerance, and dependence, and less effect on sleep cycle
- Triazolam (a benzo not listed above, is not a first-line agent due to rebound insomnia and anxiety, and anterograde amnesia
- Temazepam has an intermediate half-life and may cause hangover

The first step in treating insomnia is the identification and management of exacerbating factors such as pain, SOB, angina and GI related disorders. Non drug therapies for insomnia include avoidance of nicotine, alcohol, and caffeine; increasing daytime exercise and light exposure; limiting napping; and improving the sleep environment. Certain medications can also contribute to insomnia. Examples include levodopa, beta-blockers, diuretics, bupropion, SSRIs, SNRIs, theophylline, corticosteroids, pseudoephedrine, cimetidine, and phenytoin. A medication evaluation should be done to make sure medications are not contributing to insomnia. Alternatives to both the benzo and non benzo drug classes include melatonin, low dose trazodone or doxepin and ramelteon (Rozerem) which is a melatonin receptor agonist.

The sedative/hypnotic medications are one drug class reported in the CASPER program and the information is available to surveyors. Facilities should be aware of their residents on this type of medication, especially long term, and how their facility compares to both the state and national average. Residents on long term therapy could be evaluated by the surveyors on the documentation of need (diagnosis), appropriate dose, duration of use, monitoring and side effects. (F329) In addition, any resident with a fall and prescribed one of these medications should have documentation for the continued use

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Update and Review on Sedatives/Hypnotics

of the med. Both benzos and nonbenzos can cause rebound insomnia when stopped abruptly so if the decision is made to discontinue the sedative/hypnotic, it should be reduced slowly to avoid withdrawal symptoms.

In summary, the first step in the treatment of insomnia is optimizing the therapy of contributing medical conditions. Consider eliminating, or changing the dose or timing of, contributing medications. Targeted sleep hygiene measures are preferred to pharmacotherapy, and should be continued even if pharmacotherapy is needed. Although nonbenzodiazepine hypnotics were once considered to be safer than benzodiazepines, recent evidence suggests that these agents are also associated with serious adverse effects and dose reduction recommendations have been made by the FDA on both Ambien and Lunesta. If a sedative/hypnotic is necessary, a nonbenzodiazepine hypnotic is preferred before a benzodiazepine hypnotic for most elderly patients. Keep in mind, all sedatives should be used cautiously in the elderly and should be at the lowest effective dose for short term.

References

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6. CMS CASPER Data: March 27th, 2014

SURVEY SOLUTIONS:

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adverse consequences. While F 329 includes a requirement to monitor drug therapy, it does not mandate specific approaches. Resist the "one size fits all" mentality when it comes to drug monitoring, but instead meet the individual needs of each resident. More is not always better when it comes to blood pressures, finger-sticks, INRs and behavioral assessments (to name just a few).

- **Change in condition:** "Any symptom in an elderly patient should be considered a drug side effect until proved otherwise."[1] Incorporating this principle into your daily practice can have a profoundly positive effect on the health of your residents and improve the regulatory "health" of your facility. When notifying the attending physician of a resident's change in condition, make sure current drug therapy is discussed and note any recently discontinued drugs as well.
- **Dementia related behaviors:** The use of antipsychotics to treat behaviors associated with dementia is problematic on two fronts. First, the evidence is clear that the use of this class of drugs in this specific population increases the risk of death and secondly, the evidence is lacking regarding their overall effectiveness.[2] While no drug is inherently bad or good, this risk/benefit analysis put a heavy burden on providers to justify the use of antipsychotics. Consider adding a second layer of review by your Medical Director, consulting Psychiatrist and/or Consultant Pharmacist when an antipsychotic is initiated or undergoes a dosage increase to address dementia related behaviors. (Note: the use of antipsychotics in residents with a clearly diagnosed mental illness such as schizophrenia would not necessarily require this level of review).
- **End of life care:** A terminally ill resident or one who is not terminal but has an end stage condition, such as advanced dementia, may have different goals of care than other residents in your facility. Drug therapy should promote those goals while maintaining compliance with the various mandates contained in F 329. Focusing on the unique needs of these residents will enable you to justify the use of atypical doses of drugs, employ unique approaches to drug monitoring and even confidently forgo drug treatment of existing conditions.

Ultimately, drug therapy management, like all care provided in nursing homes, should be based on solid evidence, a thorough risk/benefit analysis and should always involve the resident or surrogate decision maker. Compliance with F 329 should not be the focus of your efforts but rather the result of them.

[1] Gurwitz et al. Long-Term Care Quality Letter, Brown University, 1995

[2] http://www.todaysgeriatricmedicine.com/archive/012312p32.shtml

NOTE: Bill was the former Chief Nurse for the State of Maryland and also a Maryland State Surveyor for nearly 15 years.