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Maryland Department of Health and Mental Hygiene

Office of Health Care Quality Spring Grove Center 55 Wade Avenue Catonsville, MD 21228

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# It Takes a Village: Anticipating and Managing Medication Side Effects

It takes the entire healthcare team -- from the CNA's to the physicians -- to safely and effectively manage medications. Although medications are an integral part of patient care, all medications have associated risks and dangers. Proper selection and prescribing of medications may improve a patient's outcome, quality of life, and function. But medications can also cause new symptoms, worsen organ function, and may sometimes result in death. The potential benefits of a medication must be weighed against the possible risks for the individual patient. Non-pharmacological and behavioral intervetions should be considered and if appropriate, used instead of or with medications. If after careful consideration, a medication is necessary, the following points must be considered.

Prescribers must be aware of the common, serious, or irreversible side effects of medications, as well as significant drug interactions. Good information comes from many sources, including manufacturers' package inserts, pharmacists, clinical practice guidelines, evidence-based articles, reference books, and journals. Sometimes the FDA requires manufacturers to place statements about serious problems about a drug in a black box on the manufacturer's package insert. The black box indicates a need to more closely monitor the potential benefits and risks of that medication.

A prescriber must consider potential drug interactions, food interactions, a patient's history of allergies or adverse side effects, and the patient's renal and liver function. The prescriber plays a key role in medication management by monitoring and modifying the medication regimen as needed, based on the patient's condition. The prescriber does not act in isolation -- but has input from the patient, caregivers, family members, pharmacists, nurses, and other healthcare professionals and staff. It is the responsibility of the entire healthcare team to monitor for the effectiveness and side effects of medications, and communicate this information to the appropriate team members in a timely manner.

**Case 1:** A 39-year-old man receives residential services funded by the Developmental Disabilities Administration. His diagnoses include moderate mental retardation and a seizure disorder. He has been on Dilantin for many years. His physician orders a blood test to check his Dilantin level. The blood test shows a low level, so the physician increases his dose of Dilantin. Six days later the individual is found on the floor early in the morning. His speech is slurred and he reports, "I slipped." He also reports nausea and one episode of vomiting this morning. His physician is notified and orders a stat Dilantin level. The level comes back high. The physician holds the Dilantin and the individual's symptoms resolve over time. Several days later the Dilantin is restarted at a lower dose.

In this case, the staff had been in-serviced on seizure disorders and possible side effects of medications. When the individual developed new symptoms, an assessment was done and there were immediate interventions. The staff and physician worked together to limit the degree of side effects from the Dilantin, and prevent further harm to the individual. No deficiencies were cited in this case.

Side effects may develop at any time after the medication is initiated. Although an individual may have an unanticipated reaction to a medication, many side effects can be anticipated, minimized, or prevented. Whenever possible the side effects should be anticipated and proactively managed. For instance, it is very likely an individual will develop constipation from around-the-clock opioids. This very common side effect should be anticipated, and may be prevented by prescribing a laxative when the opioids are started. Some drugs, including Coumadin, Dilantin, and Depakote, require blood tests to check the level.

Case #2: An active 75-year-old male in a small assisted living facility is on Coumadin for atrial fibrillation. He gets monthly blood work to see if the Coumadin needs to be adjusted. His INR is 2.9 on May 1st (goal is 2.0 to 3.0). On May 21st he is prescribed Levaguin for a respiratory infection. On May 23th, the staff find bloody tissues in his trash can and in the bathroom. The resident reports that he has had several nose bleeds. There is no further assessment. Two days later he cuts himself shaving and the staff have to apply pressure for 20 minutes to stop the bleeding. Once the bleeding is stopped, there is no further assessment. The following day the resident falls to the ground and hits his head. The staff help him up and he goes on to bingo. In the middle of the bingo game, the resident loses consciousness. 911 is called and he is transported to the hospital. He later dies in the Emergency Room due to bleeding in his brain. The blood work in the Emergency Room shows that his blood is too thin and his INR was 6.9 (qoal was 2.0 - 3.0).

Coumadin is a blood thinner that is used in a variety of healthcare settings. The side effects, drug interactions, and risks of Coumadin are well known. In this case, no one anticipated the well known drug interaction between Levaquin and Coumadin. The assisted living staff missed multiple opportunities to report changes in the resident's condition to the delegating nurse or physician. The assisted living staff failed to report nose bleeds, prolonged bleeding from a cut, and a fall. The end result is that the resident died from a well known side effect and drug interaction, after multiple warning signs were overlooked.

Monitoring medications is an on-going process -- not an isolated event. It involves reevaluation of the goals of the medication and vigilance to monitor for and proactively manage side effects. Ways to avoid,

Continued

## **Clinical Alert**

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reduce, or eliminate potential side effects and drug interactions should be considered. The frequency and duration of monitoring need to be individualized for the patient.

Case #3: An 88-year-old female in a nursing home has chronic constipation and she is on multiple laxatives. Over a one-week period, her psychiatrist recommends Ziprasidone (Geodon) for her worsening psychotic disorder, her urologist recommends Trospium (Sanctura) for her overactive bladder, and her pain management doctor recommends Amitriptyline and Oxycodone for her uncontrolled neuropathic pain. The nursing home calls her primary care doctor's group after each of the visits to confirm the orders. Nine days after these medications are started the primary care doctor is called because the resident is having diarrhea. He was not personally aware of any of these new medications -- his partners had received the evening phone calls. The resident's oral intake has decreased and she is quiet. The nurse practitioner comes to evaluate her. Stool is palpable through the abdominal wall in the intestines, although there is no stool in her rectum. Her abdomen is mildly tender all over. Her blood pressure is 084/48 and her heart rate is 138. She is sent out to the hospital where she is diagnosed with a severe high fecal impaction and ischemic bowel due to mechanical pressure from the hard stool. She undergoes emergency surgery for a bowel resection and gets a colostomy. After a week in the Intensive Care Unit she dies. Her death certificate lists ischemic bowel due to a fecal impaction and constipation as the main cause of her death.

A review of this resident's bowel movements revealed no bowel movements for six days followed by three days of runny diarrhea. The physician and nurse practitioner were not contacted for nine days. The addition of four constipating medications in a resident with chronic constipation warrants close monitoring of her bowel movements, yet no one anticipated or monitored for this common side effect. A review of the chart and interviews with the staff revealed that no member of the healthcare

team considered this expected side effect. Speaking to multiple on-call physicians, and not informing the attending physician of the initiation of four new medications, endangered the resident. Unfortunately, the end result was the resident's death.

The patient's medications should be reviewed on an on-going basis and particularly when there is a/an:

- 1. Admission
- 2. Transfer
- 3. Care transition
- 4. Change in condition
- 5. New, persistent, or recurrent symptom
- 6. Worsening of an existing problem
- 7. Unexplained decline in function or cognition
- 8. New medication order
- 9. Change in diet or enteral feedings
- 10. Irregularity identified by a pharmacist

The patient, caregivers, and healthcare professionals involved in the patient's care must work together to safely manage the patient's medications. Whenever possible, side effects should be anticipated and proactively managed. Prescribers should be aware of common, serious, or irreversible side effects of medications, as well as significant drug interactions. Regardless of the healthcare setting, safe management of a patient's medication regimen must be a primary goal of care.

### **Additional Resources:**

http://cms.hhs.gov/manuals/Downloads/som107ap\_pp\_ guidelines\_ltcf.pdf (Page 299) http://www.fda.gov/ http://www.marylandpatientsafety.org/ http://www.dhmh.state.md.us/ohcq/news\_media/transmittals\_memoranda.htm