Mental Health Legal Advisors Committee
Navigating the Clinical and Legal Choices of Elders with Mental Health Issues - February 27, 2015
Nursing Home Hot Topics Panel

Misuse of Antipsychotics and Other Psychoactive Drugs

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Problem

I am discussing the misuse of psychoactive drugs with nursing home residents, in particular, elderly residents with dementia, since this population represents the majority of nursing home residents. But please know that the inappropriate use of these drugs can happen to any patient of any age in any healthcare setting.

The major classes of psychoactive medications include antipsychotics, anti-anxiety drugs, anti-depressants, and sedative-hypnotics"[1]. While these drugs have positive outcomes when used appropriately, they can have a devastating effect when misused as a chemical restraint.

"…For decades, psychoactive drugs have been used to sedate and control elderly residents, especially those with dementia, rather than to diagnose and treat their underlying medical conditions, and to understand and meet their social needs. Residents who are unable to communicate with caregivers about "infections, dehydration, dental pain, or other physical or emotional conditions" can exhibit anxiety, aggression or other behaviors that become diagnosed as symptoms of dementia. When residents are inappropriately treated with psychoactive drugs that further thwart their efforts to communicate their needs, undiagnosed conditions put them at risk of developing even more serious medical problems…"[2] It's important to note that in 2005, the FDA cautioned health care professionals that there is no approved drug for the treatment of dementia-related psychosis. [3]

The Federal Government has been concerned about the overuse and misuse of psychoactive drugs with nursing home residents dating back 40 years to 1975 when the Senate Special Committee on Aging issued a report called "Drugs in Nursing Homes: (their) Misuse, High Costs, and Kickbacks". The 1987 Nursing Home Reform Act addressed these injustices, but unfortunately, even this landmark legislation did not completely eliminate the problems. And over the decades, there have been additional Senate hearings and numerous studies.

Most recently, the spotlight has been on antipsychotics, since the misuse of these drugs reached crisis proportions in nursing homes across the nation. Antipsychotics are meant to treat severe mental illnesses like schizophrenia. However, a 2011 report by the OIG [Office of Inspector General] found that "…88% of the antipsychotics prescribed in nursing homes were for elderly patients with dementia, a population the FDA has warned faces an increased risk of death from this class of drugs…"[4] As a matter of fact, the FDA has issued its most dire warning, called a 'black box' warning, against using any antipsychotic with elderly people who have dementia[5]. Serious side effects include strokes, heart attacks, diabetes, pneumonia, and dizziness which can lead to falls and further injury.[6]

Resident-Centered Care & Initiatives

It's been a long battle, and sadly, there are still serious and widespread problems. However, I'd like to give you some news on current efforts.

Central to eliminating the misuse of antipsychotics is resident-centered care, an approach that looks at the resident as an individual to better understand a person's history, their likes and

dislikes, and their daily living patterns. Resident-centered care is key to understanding individuals who cannot communicate due to dementia or other reason; and to developing non-pharmacologic approaches, instead of using drugs.

In 2012, some promising federal and state initiatives were implemented to address the antipsychotic crisis by training staff to use resident-centered care approaches:

- The national CMS initiative [*National Partnership to Improve Dementia Care in Nursing Homes*] includes training for facilities and surveyors. CMS also started reporting antipsychotic drug use by nursing home on its website *Nursing Home Compare*. However, the level of drug usage did not affect the nursing home's rating. That is until last week, when CMS raised the bar on its rating system to include this measurement and other factors.[7]
- In 2012, two initiatives[8] were also launched in MA to train nursing home staff in resident-centered approaches. Within the next couple of years, nearly all MA nursing homes will have participated in these specialized trainings.

These efforts are laudable, and we are making progress. But progress is slow. The National campaign set a goal of reducing the misuse of antipsychotics with nursing home residents by 15% by the end of 2012. However, this goal was not reached until the end of 2013. The next goal is a 30% reduction by the end of 2016, nearly 5 years since the beginning of this effort.

In MA, it's good that we reduced antipsychotic usage from 26% in 2011 to 20% in 2014. But this means that about 1 out of every 5 residents is still receiving these drugs inappropriately, and 20% ranks us as having the 16th highest rate of antipsychotic usage in the nation. So we still have a long way to go.

Other Efforts

Another concern about these national and state efforts is that they are not mandated, so they do not help all nursing home residents. Therefore, from an advocate's perspective, much work still needs to be done. Eliminating chemical restraints in nursing homes requires many solutions, such as mandating written informed consent, safe staffing levels, better training, expanded use of consistent staff assignments, stronger enforcement, and meaningful independent pharmacist regulations.

Written informed consent

Ensuring that people have a voice in their own care is the most basic step to eliminate the misuse of psychoactive drugs. I'm happy to report that last July, MA passed a law mandating written informed consent before the administration of any psychoactive drug in nursing homes, rest homes, and other long term care facilities [Outside Section 140 FY15 Budget]. Granted, informed consent is already a right. Nevertheless, important information is not always provided, and consent is not always received, before administering these mind-altering drugs. The written process guarantees that critical information is communicated and that consent is verified. We are currently in discussions with DPH to develop a meaningful informed consent process.

Safe staffing levels

As you can understand, staffing levels have a major impact on quality of care. However, federal regulations only require "sufficient" staffing, with no specific guidance, leaving it up to the states to decide staffing levels. However, a federal study done about 15 years ago determined that it takes at least 4 hours of care from CNAs and nurses for each resident, each day, just to

prevent avoidable medical and emotional problems[9]. MA only requires a minimum of about 2 ½ hours of care each day.

The National Consumer Voice for Quality Long Term Care is running a 2 year staffing campaign to change federal law to the recommended minimum of 4 hours of care per day. If you'd like to support the Campaign --- the Consumer Voice is collecting signatures to submit to Congress, and please sign one of their postcards on the resource table and drop it in the box.

DSCU

Regulations for the MA law establishing Dementia Special Care Units went into effect a year ago. The law promotes resident-centered care and will help reduce the use of psychoactives.

The DSCU law closes a loophole that allowed nursing homes to advertise specialized dementia care units without maintaining standards. The new law sets standards for dementia care training, a meaningful activities program, and specifications for a safe environment[10]. However, it is not mandatory to establish a DSCU. To-date, about 100, or 25%, of MA nursing homes have a DSCU. It should also be noted that the dementia care training requirements apply to all MA nursing homes, not only DSCU facilities.

A DSCU facility is reauthorized annually by submitting a Disclosure Form to DPH. The form contains important information, such as staffing ratios by shift, and are available to the public. So if your client lives in a DSCU, you should ask for a copy.

Other Resources

I have 3 more resources to discuss briefly, and I just wanted to mention that links to these and additional resources are in our handout.

The CMS State Operations Manual [Appendix PP, Guidance to Surveyors for Long-Term Care Facilities] includes guidance to surveyors to help them determine a facility's compliance with federal regulations. November 2014 updates address regulations for Quality of Care [FTag309 483.29] and Unnecessary Drugs [FTag329 483.25(l)][11]. The guidance provides valuable information on standards to hold nursing homes accountable for quality dementia care and the responsible use of psychoactive drugs. You can use the CMS Manual as guidelines to do the same.

Another resource is a report entitled *Federal Requirements and Regulatory Provisions Relevant to Dementia Care & the Use of Antipsychotic Drugs*. This is a great document that gives you a kind of one-stop-shopping that targets about 30 regulations with helpful commentary. Even the table of contents is useful as a quick reference.

One more resource is a handbook published by the California Advocates for Nursing Home Reform to help protect long-term care consumers from the misuse of psychoactives. It includes valuable questions to ask before the drug is given, as well as helping you focus on major issues for follow-up[12] [13].

In closing, I want thank you for the opportunity to spread the word on ways to protect our nursing home residents from the misuse of psychoactive drugs.

[1] *Toxic Medicine, What You Should Know to Fight the Misuse of Psychoactive Drugs in California Nursing Homes*, CANHR, 2010, pg. 5

[2] Statement for 10/22/13 MA Joint Committee on Mental Health and Substance Abuse Hearing on H1804 (written informed consent before administration of psychoactive drug), Janet C. Wells

[3] The danger of atypical antipsychotic drug use on the elderly with dementia is addressed in the FDA's *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances*, US Food and Drug Administration (April 11, 2005). http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. FDA warning linking atypical and conventional antipsychotics with an increased risk of death in elderly patients treated for dementia-related psychosis. FDA also cautions that there is no approved drug for the treatment of dementia-related psychosis: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm

[4] *Overmedication of Nursing Home Patients Troubling,* Daniel R. Levinson, Inspector General, Department of Health and Human Services, May 9, 2011 https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp

[5] The danger of atypical antipsychotic drug use on the elderly with dementia is addressed in the FDA's *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances*, US Food and Drug Administration (April 11, 2005). http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm. FDA warning linking atypical and conventional antipsychotics with an increased risk of death in elderly patients treated for dementia-related psychosis. FDA also cautions that there is no approved drug for the treatment of dementia-related psychosis: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm

[6] Ibid.

[7] **2/20/15 – Nursing Home Compare:** CMS's fact sheet, click here and a summary of the changes follows:

- Include long & short stay residents antipsychotic quality measures, respectively, to the 5-star calculations. Antipsychotic medication use had previously not been calculated into the rating;
- Raising bar for performance on quality measures by increasing the number of total quality measure points needed to achieve each star rating;
- Conducting specialized onsite surveys of a sample of facilities nationwide to assess accuracy of the resident assessment information used to calculate quality measures; and
- Adjusting how number of stars awarded for staffing is determined. Up to this time, facility could have 3 stars for RN staffing and 3 stars for total nursing staff hours and receive four stars for overall staffing. Under new system, facility must have at least 4 stars in either RN staffing or total nursing staff hours to be awarded 4 stars.

[8] ***Statewide Initiative to Safely Reduce the Off-Label Use of Antipsychotics*** **[OASIS]** – about 200 nh, with another 100 planned; and Alzheimer's Assoc. training in habilitation therapy – about 100 nh.

[9] CMS Report to Congress December 2001: Appropriateness of Minimum Nurse Staffing Ratios in Nursing homes, Phase II Final Report. The report also concludes that it takes nursing assistants a minimum of 2.8 to 3.2 hours per day just to provide essential services such as dressing and grooming, exercising, feeding, toileting, changing wet clothes, and repositioning.

[10] Examples: Secured outdoor recreation space; dedicated activities director and also provide a minimum of 8 hrs of activities per day, 7 days per week. 6 hrs for scheduled activities and 2 hours of individualized activities. Activities must also be available during night hours based upon the needs of individual residents.

[11] 11/26/14 revisions to Appendix PP guidelines and protocols for state nursing home surveyors, including F309/§483.25 Quality of Care and F329/§483.25(l) Unnecessary Drugs: Revisions to State Operations Manual (SOM), Appendix PP – "Guidance to Surveyors for Long Term Care Facilities" F309 & F329 extracted by LTCCC from the CMS revision: Changes to quality of care guidelines.

[12] What specific, documented behaviors or symptoms prompted the need for a psychoactive drug? (for instance, are there delusions or is the resident simply agitated?)

Have all possible medical or environmental causes been ruled out? (e.g., pain, dehydration, infection, sleep disruptions)

Has the doctor recently physically examined the resident to determine the need for the drug?

What alternative treatments have been tried? Are other options still available?

Will the resident start on the lowest possible dose of medication?

When and how often will the need for the drug be reassessed? Is the proposed drug duplicating other current medications?

[13] When antipsychotic drugs are given, are gradual dose reductions and behavioral interventions in place in an effort to discontinue the drug, unless clinically contraindicated?

42 CFR 483.25(l)(2):

Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.