Reducing Antipsychotic Drug Use in Long Term Care

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Goals and Objectives
• Understand the history of Antipsychotics in LTC
• Understand the prevalence of use
• Define CMS goals for reduction
• Consider appropriate documentation of behaviors
• Identify non-pharmacologic alternatives
• Identify alternate pharmacological interventions
• Resources

History
• 1950’s – Introduction of first generation antipsychotics
• 1987 – OBRA / Nursing Home reforms
• 1993 – Risperdal introduced to the market / First of the 2nd generation or atypical antipsychotics
• 2003 – Reports of increased risk in elderly
• 2005 – Black Box warnings
• 2011 – OIG report
• 2012 – CMS Commitment to reduce utilization
The Antipsychotic Boxed Warning

- ALL antipsychotics carry the following Boxed Warning specifically addressing their use in patients with dementia-related psychosis:

  “Warning: Increased Mortality in Elderly Patients With Dementia-Related Psychosis

  Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (most duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. Over the course of a typical 10 week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. DRUGNAME is not approved for the treatment of patients with dementia-related psychosis.”

Prevalence of Use – OSCAR data

<table>
<thead>
<tr>
<th>Year</th>
<th>National</th>
<th>Missouri</th>
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<tbody>
<tr>
<td>1998</td>
<td>18.6%</td>
<td>18.3%</td>
</tr>
<tr>
<td>2002</td>
<td>24.1%</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>26.1%</td>
<td>27.3%</td>
</tr>
<tr>
<td>2009</td>
<td>25.5%</td>
<td>27.3%</td>
</tr>
<tr>
<td>2012</td>
<td>25.2%</td>
<td>28.4%</td>
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OIG recommendations

To ensure that Medicare correctly pays for atypical antipsychotic drugs and that elderly nursing home residents are free from unnecessary drugs, we recommend that CMS

1. facilitate access to information necessary to ensure accurate coverage and reimbursement determinations
2. assess whether survey and certification processes offer adequate safeguards against unnecessary antipsychotic drug use in nursing homes
3. explore alternative methods beyond survey and certification processes to promote compliance with Federal standards regarding unnecessary drug use in nursing homes
4. take appropriate action regarding the claims associated with erroneous payments identified in our sample.
Dr. Jonathan Evans, geriatrician and Vice-President of the American Medical Directors Association:

"I do not prescribe antipsychotic drug for the treatment of agitation or other behaviors in patients with dementia, and I know that the leadership of AMDA acknowledges the use of these medications in patients with dementia only as a last resort, and only when all else has been tried and failed, which is rare. There should be 'near zero' use of antipsychotics for persons with dementia"

CMS Commitment

- Partnership to Improve Dementia Care in Nursing Homes
  - Launched March 29, 2012
  - Includes Leading Age, ASCP, AMDA, AHCA, Patient Advocacy groups and many others
- Baseline
  - Determined from MDS data submitted in the last three quarters of 2011 (April – December)
  - 22.3% National Average
- Goal
  - 15% reduction in overall antipsychotic use in Nursing Homes
  - 20.3% by end of 2012
- 2013 goals will be set at the end of 2012

New Nursing Home Quality Measures

- Percentage of short-stay residents that are given an antipsychotic medication after admission to the nursing home
- Percentage of long-stay residents that are receiving an antipsychotic medication

- Posted on Nursing Home Compare
  - Not included in the Five Star Quality rating at this time
- Prevalence of antipsychotic Medication Use—3 exclusions (Long Stay)
  - Numerator
    - Long-stay residents with a selected target assessment where the following condition is true: antipsychotic medications received.
  - Denominator
    - All long-stay residents with a selected target assessment, except those with exclusions.
- Exclusions
  - Any of the following related conditions are present on the target assessment
    - 2.1. Schizophrenia (I6000 = [1]).
    - 2.2. Tourette's Syndrome (I5350 = [1]).
    - 2.3. Tourette's Syndrome (I5350 = [1]) on the prior assessment if this item is not active on the target assessment and if a prior assessment is available.
    - 2.4. Huntington's Disease (I5250 = [1]).
Missouri

• Antipsychotic Utilization in Long Stay
  • 26%

• Goal for end of 2012
  • 22.1%

• Have we reduced our Antipsychotic utilization by 15% in our facilities to help meet the state goal?

F-tag 329: Unnecessary medications

1. General. Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

   (i) In excessive dose (including duplicate therapy); or
   (ii) For excessive duration; or
   (iii) Without adequate monitoring; or
   (iv) Without adequate indications for its use; or
   (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
   (vi) Any combinations of the reasons above.

F 329: Unnecessary medications

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.
Although "Dementing illnesses with associated behavioral symptoms" is listed as one of the 10 conditions/diagnoses for which antipsychotics may be used, additional requirements must be met:

- the symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions [paranoia, grandiosity]); OR
- the behavioral symptoms present a danger to the resident or others; OR
- The symptoms are significant enough that the resident is experiencing one or more of the following: inconsolable or persistent distress (e.g., fear, continuously yelling, screaming, distress associated with end-of-life, or crying); a significant decline in function; and/or substantial difficulty receiving needed care (e.g., not eating resulting in weight loss, fear and not bathing leading to skin breakdown or infection).
Partnership to Improve Dementia Care in Nursing Homes
State Coalition Provider Question Worksheet (Self-Assessment Tool)

Direct Caregivers

1. How does staff address behavioral responses by persons with dementia in your facility, such as anxiety or aggressiveness?
2. Do you know if your facility has policies and procedures in place that you are supposed to follow when a resident with dementia exhibits certain behaviors, or those behaviors worsen?
3. What training have you received about how to care for persons with dementia?
   a. Who provides the training?
   b. Do you know what materials are used?
   c. Does the training give you a chance to practice how you would respond?
4. When a resident with dementia demonstrates certain behaviors such as anxiety or aggression, is he or she given a medication to treat them?
   a. Do you know whether the team at your facility is trying to reduce the use of these drugs?
5. Are residents and families given information about care options for persons with dementia, including those that do or do not use medications?

Leadership (Nursing Home Administrator, Director of Nursing, Medical Director)

1. How will your facility measure success in improving dementia care and reducing or optimizing antipsychotic drug use?
2. What do you see as the major barriers to accomplishing this?
3. Are you currently reviewing data related to antipsychotic drug use for all residents, including residents that are returning or were recently discharged from an acute care setting?
4. Are there tools/resources/support that would assist you in analyzing and interpreting data? For example, telephone or in-person support from:
   a. A member of your state nursing home association;
   b. A consultant;
   c. A quality improvement organization;
   d. Other state-based nursing home specialist?
Partnership to Improve Dementia Care in Nursing Homes
State Coalition Provider Question Worksheet (Self-Assessment Tool)

5. If your facility is part of a corporation, does the corporation provide educational materials, clinical support or data analysis related to dementia care and/or antipsychotic drug use?

6. Is staff in all departments educated on person-centered care for individuals with dementia?

7. How is the Consultant Pharmacist involved in the overall care of residents? For example, does the Consultant Pharmacist routinely engage in:
   a. Data analysis;
   b. Staff education;
   c. Routine interaction with residents and/or families?

8. How is the Medical Director involved in the overall care of residents with dementia?

http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare
Self Assessment Action Plan

- Identify three areas where we need to begin our focus on Improving Dementia Care
  - Education
  - Policies and Procedures
  - Role playing
  - Utilization trends
  - Interdisciplinary Team involvement
  - Consultant Pharmacist involvement
  - Medical Director involvement
What Is A “Behavior”?

• A form of communication
• A reaction to frustration or boredom
• A reaction to stimuli (internal, e.g., pain, constipation; external, e.g., sounds, physical surroundings, people)
• A sign of an underlying condition (e.g., depression, insomnia)

What Are The Symptoms Of “Agitation”

• Walking aimlessly, pacing
• Psychomotor agitation/general restlessness (which could be akathisia, a movement side effect from antipsychotic drugs)
• Repetitive actions (dressing/undressing)
• Sleep disturbances
• Excessive worrying (e.g., about toileting, etc.)

PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES
Questions to Consider in Interdisciplinary Team Review

• If the behavioral symptoms represent a change or worsening, was a medical work up performed to rule out underlying medical or physical causes of the behaviors, if appropriate?
  ➢ Medical – infection, delerium, depression, dehydration, hypothyroidism, hypoglycemia
  ➢ Physical – pain, constipation, GI distress

• If a medical cause (e.g., UTI) was identified, was treatment (if indicated) initiated in a timely manner?

http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare
Pharmacologic Approaches to Agitation: Appropriate Pain Management

• Study from September 2011: “Efficacy of treating pain to reduce behavioral disturbances in residents in nursing homes with dementia: cluster randomised clinical trial”

• 352 nursing home residents with moderate to severe dementia and clinically significant behavioral disturbances randomized to receive either a stepwise protocol for pain treatment for 8 weeks or usual care

• Stepwise pain protocol included acetaminophen, morphine, transdermal buprenorphine, or pregabalin

• Primary outcome measure was agitation, while secondary outcomes were aggression, pain, ADL’s and cognition.

Study Results

• Agitation was significantly reduced compared to control group at 8 weeks
• Significant benefit for aggression, overall severity of neuropsychiatric symptoms, and pain
• No significant differences in ADL’s or cognition

Conclusion

“A systematic approach to the management of pain significantly reduced agitation in residents of nursing homes with moderate to severe dementia. Effective management of pain can play an important part in the treatment of agitation and could reduce the number of unnecessary prescriptions for psychotropic drugs in this population”

Questions to Consider in Interdisciplinary Team Review

• Were current medications considered as potential causes of the behaviors?
  ➢Anticholinergic side effects
  ➢Benzodiazepines
  ➢H2 receptor antagonists
  ➢Zolpidem
  ➢Corticosteroids

http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare
PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES
Questions to Consider in Interdisciplinary Team Review

• If medical causes were ruled out, did the staff attempt to establish the root causes of the behaviors, using a careful and systematic process and individualized knowledge about the resident when possible? Were family caregivers or others who knew the resident prior to his/her dementia consulted about prior life patterns, responses to stress, etc.?
  – Sleep / wake cycle
  – Routines – reading paper, taking a walk, chores
  – Stress response

http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare

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PARTNERSHIP TO IMPROVE DEMENTIA CARE IN NURSING HOMES
Questions to Consider in Interdisciplinary Team Review

• Were non-pharmacologic, person-centered interventions tried before medications (other than in an emergency)?

• Were the results documented?

http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare

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Drugs with Strong Anticholinergic Properties (Table) – 2012 Beers Criteria

- Anticholinergics
  - Benztropine
  - Cogentin
- Benzodiazepines
  - Lorazepam
  - Tempeprazine
- Calcium channel blockers
  - Nifedipine
- Antidepressants
  - Amoxapine
  - Desipramine
- Antipsychotics
  - Haloperidol
  - Thiothixene
- Tricyclic antidepressants
  - Amitryptiline
  - Imipramine
- Others
  - Dimenhydrinate
  - Diphenhydramine
  - Meclizine
  - Prochlorperazine
Reducing the behavior via sedation with psychoactive medication can be detrimental because it robs people with dementia of the very limited resources they have in either expressing or attending to their needs, and thereby diminishes the ability of caretakers to detect and address the true underlying need.

From "Dementia Beyond Drugs"

Nonpharmacologic Approaches to Behavior Management

Examples of nonpharmacologic treatment categories and strategies:

- Sensory: music therapy, massage, light therapy
- Environmental: adequate space, reduction in disruptive stimuli
- Behavioral: positive reinforcement, redirection, avoid reality orientation
- Communication: use short sentences, give adequate time for response, awareness of non-verbal communication

Don’t be limited – think outside the box

General Approach For Residents with Dementia: “Approach Is Almost Everything”

- Display a positive, comforting demeanor (smile, calm/non-threatening voice and body language; praise often)
- Treat resident with respect
- Be aware of resident’s need for personal space, and historical way of doing things (“my way”)
- Care must be individualized
- Wandering – what are they looking for?

- Everyone wants to be acknowledged, recognized, respected. If we aren’t how would we feel?
### Questions to Consider in Interdisciplinary Team Review

- Were specific target behaviors identified and desired outcomes related to those behaviors documented? Were caregivers aware of the target behaviors and desired results of the medication?

<table>
<thead>
<tr>
<th>Agitation</th>
<th>versus</th>
<th>Continuously yelling out</th>
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<tbody>
<tr>
<td>Anxiety</td>
<td></td>
<td>Fear</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repetitive questioning</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Restlessness</td>
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<tr>
<td></td>
<td></td>
<td>Worried expression</td>
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<td></td>
<td></td>
<td>Physical aggression</td>
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<tr>
<td></td>
<td></td>
<td>Verbal aggression</td>
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</tbody>
</table>

- Was the resident or appropriate legal representative consulted about the decision to use an antipsychotic medication and was that discussion documented?

- If a drug is continued for more than a few weeks, is the original clinical indication still valid (are the behaviors still present)?

- Is appropriate monitoring in place and is the team aware of the potential side effects?

- If new symptoms or changes in condition occurred after an antipsychotic medication was started, was medication use considered as a potential cause of a change or symptom?

- If on a medication, did the pharmacist perform a medication regimen review and identify related signs and symptoms, or did the staff inform the pharmacist if symptoms occurred after the last pharmacist visit?
Psychopharmacologic Interdisciplinary Medication Review

- Initiation
- Quarterly (minimum)
- Change in Condition

Facility Approach To Residents Receiving Antipsychotics For Dementia-Related Behaviors

- Establish a protocol for re-assessment within the first 3 days to determine if appropriate (especially if started in an “emergent” situation).

- Carefully review each resident receiving antipsychotics for behaviors on at least quarterly basis

- Review should consist of analysis of documented behaviors that have occurred since last review, any trends related to these behaviors, and what non-pharmacologic interventions have been tried (and which have worked and not worked; those approaches that have worked need to be documented for other caregivers to follow!!!)

Facility Approach To Residents Receiving Antipsychotics For Dementia-Related Behaviors (cont’d)

- Care team members to include in this review: nursing, nursing assistants, activities, social services, consultant pharmacist. Team can make recommendations to prescriber regarding potential reduction or discontinuation of antipsychotic therapy, and other recommendations

- Have a NON-PHARMACOLOGIC contingency plan for each resident if behaviors recur - be creative and don’t “knee jerk” to increasing or re-starting the antipsychotic unless the behavior is potentially harmful to the resident and/or others
Are Antipsychotics Actually Effective For Behaviors Associated With Dementia?

Landmark Clinical Trial: "CATIE-AD Trial" (cont’d)

Results
- No significant differences among treatment groups with regard to time to discontinuation or improvement on the CGIC scale
- 63% treatment discontinuation rate at 12 weeks; 82% at 36 weeks
- Significantly higher percentage of patients discontinued antipsychotic treatment due to intolerability versus placebo

Conclusions
- Adverse effects offset advantages in the efficacy of atypical antipsychotic drugs for the treatment of psychosis, aggression, or agitation in patients with Alzheimer’s disease

Algorithm for Reducing or Eliminating Antipsychotics for Residents with Behavioral Symptoms of Dementia

Can Residents Receiving Antipsychotics For Behaviors Be Successfully Taken Off Them?

“A Randomised, Blinded, Placebo-Controlled Trial in Dementia Patients Continuing or Stopping Neuroleptics” (The “DART-AD Trial”)
- 12 month study in nursing home or residential home patients receiving antipsychotics for behavioral or psychiatric disturbances in dementia for at least 3 months
- Patients randomised equally to either continue receiving antipsychotic or switch to placebo

Results
- At both 6 and 12 months, no overall differences in cognitive decline or change in neuropsychiatric symptoms (NPS) were seen between groups
- Patients with severe NPS at baseline did better on antipsychotic vs. placebo, but this was not statistically significant
- Significant decline in verbal fluency in those who continued antipsychotics
Can Residents Receiving Antipsychotics For Behaviors Be Successfully Taken Off?
(cont’d)

DART-AD Conclusions

• for most patients with Alzheimer’s disease, withdrawal of antipsychotics had no overall detrimental effect on functional and cognitive status

• Antipsychotics, with their known safety issues, should not be used as first-line treatment of agitation or aggression


Sample Psychotropic Medication Policy and Procedure

Mrs. Jones

• Mrs. Jones has lived at the nursing home for several years. She recently started yelling out at various times. It usually takes the form of “Ya, Ya, Ya” and gets louder over time. If staff talks to her, she quiets but as soon as they walk away she starts again. It is starting to bother the other residents.
  – What would you assess for medically?
  – What types of non-medication interventions would you try?
  – What if her history included rheumatoid arthritis, but she is not receiving therapy and she says no when asked if she is in pain?
Friends

• Know each other’s history
• Do things together (spontaneous, not always planned)
• Communicate
• Build self-esteem
• Laugh often
• Are equals
• Work at the relationship

Resources

• LeadingAge
• Advancing Excellence in America’s Nursing Homes
  – http://www.田qualitycampaign.org/star_index.aspx?control= dementiaCare
• American Medical Directors Association (AMDA)
  – Psychopharmacologic Interdisciplinary Medication Review
  – Sample Psychotropic Medication Policy
  – AMDA’s Clinical Practice Guidelines
  – http://www.amda.com/advocacy/brucbs.cfm
• The Consumer Voice
  – http://www.theconsumervoice.org/advocate/antipsychotic-
    drugs
• Department of Veterans Affairs
• The Eden Alternative
  – The Eden Alternative has created a webpage that
    summarizes new groundbreaking educational offerings
    designed to introduce providers to fundamental and
    advanced techniques in person-directed care proven to
    reduce the off-label use of antipsychotic drugs.
  – http://www.edenalt.org/how-we-solve/reduce-the-use-of-
    antipsychotic-medications-in-people-living-in-long-term-care-
    settings
• National Gerontological Nursing Association (NGNA)
  – http://www.ngna.org
• The National Long-Term Care Ombudsman Resource Center
  – Person-centered Care Planning
  – http://www.田ombudsman.org/ombudsman-
    support/training/Training_Programs_and_in-services