Improving Care and Quality of Life for Patients with Dementia in LTC:
Using and Reducing Antipsychotics

Marc E. Agronin, MD
Vice President, Behavioral Health and Clinical Research
Miami Jewish Health Systems
Key Questions

• Why do we use antipsychotic medications?
• What are the relatives benefits and risks?
• Why is there a drive to reduce antipsychotic use?
• Are there safe and effective alternatives?
• What is the best, evidence-based approach?
How Common Is Agitation and Psychosis?

• Up to 90% of dementia patients demonstrate agitation at some point

1 Int Psychogeriatr Assoc. Int Psychgeriatr 2000, 12 (suppl 1): 1 -424

• The Cache County Study found 24% of dementia patients were agitated or aggressive in the last month and the five-year prevalence ranged from 13% - 24%


• Between 30% and 50% of individuals with dementia experience psychotic symptoms at some point

Agitation and Psychosis Can:

- Accelerate disease progression
- Lead to disproportionate reductions in function and well-being
- Increase costs of caregiving
- Increase the risk of self-injury, injury to others
- Increase the risk of institutionalization
- Increase mortality
- Negatively impact caregiver stress and overall burden which can, in turn, further exacerbate symptoms
Assessment and Treatment Flowchart

Identify, Document, Analyze Behaviors [Review ABC’s]

Identify Potential Causes
- Medical
- Psychiatric
- Environmental
- Behavioral

Address Readily Reversible Causes

Select Appropriate Target Symptoms

Re-evaluate if no response:
- Correct target symptoms?
- Untreated causes?
- Revise, retry behavioral approach
- Try alternate medication or augmentation

Consider Low-dose Pharmacologic Agent to Match Symptoms

Implement Behavioral Approaches, including Therapeutic Programs
When Are Medications Needed?

- Dangerous or severe symptoms
- Underlying psychiatric disorder (e.g. bipolar disorder)
- Behavioral approaches are not working
- Psychotic symptoms
Types of Psychotropic Medications

- Anti-anxiety / benzodiazepines
- Antipsychotics
- Antidepressants
- Mood stabilizers
Antipsychotic Medications

All antipsychotics are believed to work by blocking the effects of dopamine. Second generation agents also alter effects of serotonin. Most commonly antipsychotics in LTC settings:

- Haldol (haloperidol)
- Risperdal (risperidone)
- Zyprexa (olanzapine)
- Seroquel (quetiapine)
- Abilify (aripiprazole)
REASONS TO USE ANTIPSYCHOTICS

- Schizophrenia and other chronic psychotic disorders
- Bipolar disorder
- Augmentation for Major Depression
- Delirium
- Dementia with psychosis
- Dementia with agitation

= FDA Indication  
= NO FDA Indication
Pharmacological Treatment Dilemmas

- There is no universally recognized or FDA-designated indication for agitation and psychosis in dementia
- All psychotropic medication use is thus “off-label”
- Most studies are of short duration, use small samples, multiple instruments, variable definitions, limited samples, are not always controlled and have high placebo responses
- Clinical trials have not always consistently established significant efficacy of psychotropic medications for dementia related behavioral disruption

### Clinical Trials of Atypical Antipsychotics in Dementia Patients

<table>
<thead>
<tr>
<th>Antipsychotic</th>
<th>Trial</th>
<th>N</th>
<th>Mean Age (y)</th>
<th>Duration (wk)</th>
<th>Efficacy Results (vs Placebo)</th>
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<td><strong>RISPERIDONE</strong></td>
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<td>238</td>
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<td></td>
<td>Zhong et al</td>
<td>333</td>
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<th>Duration (wk)</th>
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<td>ARIPIPRAZOLE</td>
<td>Streim et al</td>
<td>256</td>
<td>83</td>
<td>10</td>
<td>No difference in symptoms of PAD. Clinically meaningful reduction of behavioral symptoms approaching 10 mg</td>
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<td></td>
<td>Breder et al</td>
<td>487</td>
<td>83</td>
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<td>Improved symptoms of PAD at 10 mg. Agitation reduced at 5 and 10 mg</td>
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<td></td>
<td>De Deyn et al</td>
<td>208</td>
<td>82</td>
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<td>Inconsistent. Aripiprazole 10 mg/d was effective on BPRS-psychosis vs placebo.</td>
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<td>16</td>
<td>cases</td>
<td>cases</td>
<td>“Beneficial” in cases of treatment-resistant agitation</td>
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ANTIPSYCHOTICS

ADVANTAGES
• Treat comorbid psychosis
• Rapid-acting
• Potent
• Versatile preparations
• Available data on efficacy and dosing

DISADVANTAGES
• Sedating
• Risk of EPS and TD
• Metabolic effects
• Cognitive toxicity
• Anticholinergic
• Black Box warning on increased mortality

EPS, extrapyramidal side effects; TD, tardive dyskinesia
The Controversy Over Antipsychotics

• Senator Grassley requested that the Office of Inspector General (OIG) evaluate the use of antipsychotics in nursing homes due to concerns about off-label use

• According to the OIG report from May 2011: 83% of Medicare claims were for off-label indications, and 88% of residents using them had dementia

• AN OIG report from 2012 found that 99% of charts “failed to meet one or more Federal requirements for resident assessment and/or care plans” with respect to antipsychotics.

• CMS recommended a 12% reduction in nursing homes

Antipsychotics: Mortality Warning

FDA Black Box Warning Concerning the Potential Increased Mortality in Elderly Patients with Dementia-Related Psychosis Treated with Antipsychotic Agents:

• Affects elderly patients with dementia-related psychosis treated with any atypical antipsychotic agent
• Analyses of 17 placebo controlled trials (average 10 weeks) revealed risk of death in drug-treated patients between 1.6 and 1.7 times that seen in placebo-treated patients
• Rate of death 4.5% in drug-treated group versus 2.6% in placebo group. Most deaths cardiovascular (e.g., heart failure, sudden death) or infectious (pneumonia) in nature
• Differential affects of individual antipsychotics not reported
• No study showed a statistically significant difference in mortality, but trend of increased mortality appeared in 15 / 17 studies
Some Important Caveats

- There are NO FDA-approved medications for agitation and psychosis in dementia
- It is not clear that other medications work better or are safer
- Nonpharmacologic approaches do not necessarily work better and may delay treatment
- Bipolar disorder is an FDA indication for antipsychotic use but not always recognized as such in the rush to reduce
- The lack of FDA indication does NOT mean a lack of evidence or lack of ability to use (40% of non-psychotropic use is “off-label”)
- There are many situations in which medications are necessary and useful
- There are many non-psychiatric medications that pose safety risks as well
Unintended Effects

- Clinicians switch to non-antipsychotic medications which have less efficacy and equal side effect issues
- Clinicians skip or minimize medications and do not adequately treat the symptoms
- Clinicians stop antipsychotics used for diagnoses such as schizophrenia and bipolar disorder
- Politicians consider draconian, selective consent forms which threaten to limit access to care to vulnerable elders with dementia
- Antipsychiatry forces jump on board

Consider the double standard: how many politicians are calling for draconian measures to limit “dangerous” cardiac medications? Or antibiotics?
Recommendations from the American Association for Geriatric Psychiatry, 2015

- More clinicians need to be trained in the proper recognition, assessment and management of behavioral problems associated with dementia
- More research is needed for both behavioral and non-pharmacologic approaches
- An algorithmic approach to agitation should always be used
- When used, antipsychotic medications should be monitored closely, used judiciously, and discontinued when no longer needed
Suggestions on Reducing Use

• Do not reduce or stop antipsychotics when used for schizophrenia, bipolar disorder, chronic psychosis, or successful augmentation for recurrent depression
• When used for agitation and psychosis due to dementia, follow OBRA guidelines for proper use and regular attempts at reduction
• Develop behavioral specialists and a team to first provide optimal care BEFORE rushing to reduce
A FINAL NOTE

• The main goal is to provide effective, safe and evidence-based care for individuals suffering from agitation and psychosis

• Reducing antipsychotic use depends upon having this care in place first

• A rush to reduce without understanding the use of antipsychotics and without providing proper care can evolve into providing no care
Questions & Discussion
IMPROVING CARE AND QUALITY OF LIFE FOR PATIENTS WITH DEMENTIA IN LONG-TERM CARE

Rick Foley, PharmD, CPh, CGP, FASCP, BCPP
Consultant Pharmacist - Omnicare
Clinical Professor of Geriatrics - UF College of Pharmacy
President, Florida Chapter American Society of Consultant Pharmacists
THE PHARMACIST’S PERSPECTIVE

- First do no harm
- The regulations
- Trends in the field
- Recognizing prescribing patterns that lead to antipsychotic (AP) use
EPS
- 1 in 10 pts taking olanzapine, 1 in 20 w/ risperidone

CVA
- 1 in 34 patients taking risperidone

During 10-12 week trials, 1 out of every 100 patients taking an atypical AP died

Conventional and atypical antipsychotics appear to increase the risk of hospitalization for femur fracture in a population of institutionalized elderly patients. These medications should be used with caution, especially among patients with a high risk of falls.


Atypical antipsychotic drugs may be associated with a small increased risk for death compared with placebo.


increase the risk of hospitalization

The studies have also shown, however, a greater risk of mortality and adverse cerebrovascular events with several of these agents than with placebo in individuals with dementia.


Our findings suggest that many older people with Alzheimer's dementia and NPS can be withdrawn from chronic antipsychotic medication without detrimental effects on their behaviour.


greater risk of mortality

Among patients continuing phase 1 treatment at 12 weeks, there were no significant differences between antipsychotics and placebo on cognition, functioning, care needs, or quality of life.

New concept - May 2013

"Individualized, person-centered approaches that may help reduce potentially distressing or harmful behaviors and promote improved functional abilities and quality of life for residents"

Bottom line - AP’s can only be used after ALL other causes of behavior have been ruled out
Requirements when using APs

- Diagnosis
- Target behaviors - quantitative documentation each shift; specific guidance on TBs
- Dose limitations, unless documented rationale is present
- Daily monitoring of side effects
- Assessment of movement side effects at least every 6 months
- GDR twice within first year, in two separate quarters and separated by at least 1 month
- Contraindication requires significant rationale
National Partnership for the Treatment of Dementia

- Initial AP use reduction set at 15%
- National average reduction 15.1%
  - Florida -17.1%
- New goal set to reduce by 25% by the end of 2015 and 30% by the end of 2016
- Reinforces the concept of non-pharmacologic approaches
- ALL regions achieved goal

As of Q1-2015, Florida ranks 39th of 50 states + D.C. at 20.3%; Louisiana 51st at 24.9%
- Hawaii #1 at 10.9%

**TRENDS IN THE FIELD**

- **Microdosing of Quetiapine**
  - Potent binding and antagonism of H\(^1\) and α-1 receptors
    - Sedation, orthostasis, weight gain
  - Side effects may be enhanced at low doses
    - 25mg QHS for “dementia” -- *sleep*?
    - 25mg QHS and my patient is falling!

- **Blanket contraindication statements**
  - Preprinted progress notes

- **Staff pushback on GDR despite documentation**
New resident w/ “dementia”

“agitated”

MD called

Given 3x PRN Xanax

Resident is now disinhibited and falls

Midodrine ordered TID

Resident naps due to sedation

“GDR clinically CI”

Psychiatry consulted

Behaviors become constant, patient moved to locked unit

Pt develops tremor - PD diagnosed - Sinemet ordered

New order for risperidone for BPSD

3 weeks of behaviors

Sxs worsen

Risperdal increased

Postural HA

Behaviors become constant, patient moved to locked unit
Limited information for practitioners
Assuming disease manifestation
Broad strokes with “blank check” orders
Underestimation of drugs’ side effect potential and severity - anticholinergic load
Overestimation of efficacy of “behavior” meds prescribed
Lack of “zero-budgeting” drug regimen evaluation

A method of prescribing in which medications must be justified for each new period. Zero-based budgeting starts from a “zero base” and every treatment, goal of therapy, and expected and realistic patient-focused outcome, is analyzed for its appropriateness and risk-benefit profile.
NON PHARMACOLOGIC APPROACHES TO BEHAVIORS

- Avoid confrontation
- Remove environmental triggers
- Create calm, quiet environment (offer gentle help)
- Structure daily routine
- Address pain, discomfort
- Use aromatherapy
- Use scheduled or prompted toileting

AMDA Multidisciplinary Medication Management Manual, American Medical Directors Association, March 2011
Management of Dementia Related Behaviors Using Non-pharmacological Interventions

Maria Vazquez, Ph.D.
Clinical Psychologist
Orlando VAMC Community Living Center
Alzheimer’s Association
Definition of Dementia

• “Dementia is a general term for a decline in mental ability severe enough to interfere with daily life.”

• Dementia is NOT a specific disease but rather a term used to describe a wide range of symptoms.
First Signs of Dementia

The individual may appear intact but have difficulty with Instrumental Activities of Daily Living (IADL’s)

- Driving
- Cooking
- Paying bills
- Managing medication
- Housework
- Using the computer or telephone
Dementia

In order to diagnose a dementia related disorder there must be impairment in at least \textit{two} of the following areas:

- Memory
- Communication and language
- Ability to focus/pay attention
- Reasoning and judgment
- Visual perception
Some Types of Dementia

- Alzheimer’s Dementia
- Vascular Dementia
- Frontotemporal Dementia
- Lewy Body Dementia
- Parkinson’s Dementia
- Dementia due to other medical conditions. i.e. TBI, HIV
- Mixed Dementia
Life Enhancement for People with Dementia

- Improve quality of life
- Allow for maximum independence and functioning
- Maintain stable cognition, mood, and behaviors for as long as possible
- Safety (minimize risk of danger to self and others)
- Socialization (enjoyable, pleasant, stimulating or calming depending on the need)
Developmental Stages and Dementia

FAST Scale

• Stage 1: No difficulty, either subjectively or objectively
• Stage 2: Complains of forgetting location of objects; subjective work difficulties
• Stage 3: Decrease job functioning evident to coworkers; difficulty in traveling to new locations
• Stage 4: Decreased ability to perform complex tasks (e.g., planning dinner for guests, handling finances)
• Stage 5: Requires assistance in choosing proper clothing
• Stage 6: Decreased ability to dress, bathe and toilet independently
  o Sub Stage 6a: Difficulty putting clothing on properly
  o Sub Stage 6b: Unable to bathe properly; may develop fear of bathing
  o Sub Stage 6c: Inability to handle mechanics of toileting (i.e., forgets to flush, does not wipe properly)
  o Sub Stage 6d: Urinary incontinence
  o Sub Stage 6e: Fecal incontinence
• Stage 7: Loss of speech, locomotion and consciousness
  o Sub Stage 7a: Ability to speak limited (1 to 5 words a day)
  o Sub Stage 7b: All intelligible vocabulary lost
  o Sub Stage 7c: Non-ambulatory
  o Sub Stage 7d: Unable to sit up independently
  o Sub Stage 7e: Unable to smile
  o Sub Stage 7f: Unable to hold head up

http://dementia.americangeriatrics.org/
## Changing Negative perspectives to Positive

<table>
<thead>
<tr>
<th>Can’t do</th>
<th>VS</th>
<th>Can do</th>
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</thead>
<tbody>
<tr>
<td>Unable to choose proper clothing</td>
<td>Able to dress themselves</td>
<td></td>
</tr>
<tr>
<td>Wanders</td>
<td>Able to ambulate</td>
<td></td>
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<tr>
<td>Unable to feed self</td>
<td>Able to eat finger foods</td>
<td></td>
</tr>
<tr>
<td>Unable to hold a conversation</td>
<td>Able to say a few words, and respond to stimuli</td>
<td></td>
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</table>
Causes of Behavioral issues

• **Physical discomfort** - pain, neuropathy, UTI, URI, hearing and/or visual impairment

• **Environmental Concerns** - Over stimulating environment, loudness, clutter, time of day for activities, sun downing

• **Poor communication** - Are questions easy to understand? Are you asking too many questions or making too many demands at once? Is the person picking up on caregiver stress or emotions?

• **Realization of the memory and functional impairments** - Especially in the earlier stages, the person may get frustrated, angry, and depressed when they realize that they are forgetting things and are not able to do the things that they used to do.
Behaviors in person’s with Dementia

Aggressive Behaviors

• May be **verbal** or **physical**.
• Can be sudden or seem to appear for no apparent reason.

**Note:** There is a **reason** for the person’s actions. Do not take it personal. Their actions are not deliberate. We must look at our approach.
Pharmacological Interventions

• There is **No** known cure for Dementia.
  o Medications are used to treat symptoms of Dementia
  o Medications should be used **as a last resort** when all other non-pharmacological interventions have been tried

• Medications are not full-proof
Physical Threat or Physically Aggressive Behavior

- Know your Veteran and their triggers
- Look in CPRS for flags and ask familiar staff for tips on how to work with Veteran if unfamiliar
- Assess any situation for safety, both yours and the Veterans
- If the Veteran is agitated try to calm the person down (distraction, redirection). If that doesn’t work, leave the Veteran alone for ~5 to 10 minutes and re-approach.
- If you feel unsafe in any way get out of the room and notify your supervisor immediately
- If you are in a room and cannot get out call for help
- Give the person space and time to calm down when safe to do so
- Call the VA Police if situation becomes more unsafe or violent behavior is exhibited.
Non-pharmacological Interventions

If a behavior occurs try to understand what happened and how to prevent it in the future. Use your ABC’s.

• **A** means **Antecedent**: Events that happen before an upsetting event
• **B** means **Behavior**: Any upsetting or aggressive behavior done by the person who has dementia
• **C** means **Consequence**: Events that happen after the behavior.

Use your ABC’s to help formulate treatment plans
Non-pharmacological Interventions

- Reassurance - offer support
- Distraction
- Maintain routines
- Structured activities (Bingo, singing, groups)
- Unstructured activities (walking, sorting objects)
- Music
- Exercise
- Therapies (Bright light, Snoezelin, Get well-network programming)
- Touch Therapy - (hand massages, gentle touches for reassurance)
- Pet Therapy
- Specific Individualized Behavior Interventions
- One to one therapy
- Ongoing monitoring and make changes as needed
- Allow for private or alone time.
- Avoid over stimulating situations
Communication

MESSAGE

- M Maximizing Attention
- E Expression & Body Language
- S Support the Conversation
- S Simple
- A Assistance with visual aids
- G Get their message
- E Encourage & engage
Maximizing Attention

**Key Points**
- Attract attention
- Avoid distraction

**Examples**
- Always identify yourself
- Make sure that the person can see you
- Call the person by preferred name
- Only one person speaking to the patient at a time
Expression & Body Language

Key points
• Be Relaxed and Calm
• Show interest

Examples
• Use positive friendly facial expressions and tone of voice
• Ask for assistance from co-workers (or someone familiar with the patient) if you're feeling frustrated
• Treat the person with dignity and respect
Key Points
• Adjust your approach to the person’s cognitive status (don’t assume)
• Offer Clear Choices

Examples
• Avoid Elder speak in patients with mild cognitive impairment
• Use short, simple and familiar words in patients with severe cognitive impairment
• Offer simple choices (No more than 1 or 2 at a time)
• Turn questions into answers. “Your dinner is right here” as opposed to “Do you want to eat?”
• Ask 1 question or request that they perform 1 task at a time.
• Avoid confusing or vague statements.
• Avoid using “it” or “that” and sayings such as “Do you have to use the potty?”
Support the Conversation

Key Points
• Give the person time to respond (15-30 Seconds)
• Find the word if they are having trouble
• Repeat then rephrase
• Give reminders of the topic

Examples
• Repeat questions and use cues as needed.
• Wait for a response. If no response ask again. Give them about 15-30 seconds to respond.
• Don’t argue or try to correct the person
Assistance with Visual Aids

Key Points
• Gestures and Actions
• Objects and Pictures

Examples
• Give visual cues- demonstrate, point, or touch the item you want the individual to use
• For those who are able to follow written reminders. Assist with written reminders (Calendars, clocks, labels)
Get their message

Key points
• Listen, watch, and help them to work it out
• Look for behavior and non-verbal clues

Examples
• Help when they have difficulty finding the right words.
Encourage and engage

Key points

• Interesting and familiar topics
• Give opportunities to talk

Examples

• Use positive statements. Instead of telling the person “you can’t go there.” You can say “let’s go here.
• Reminisce but don’t quiz. Don’t say “Do you remember when...?” If the person remembers or shares a memory show interest
Behavior Rounds

• In many long term care facilities there is a need to increase the utilization of non-pharmacological interventions with regard to the treatment of Dementia related behaviors.

• The use of interdisciplinary teams for behavior rounds has been gaining momentum in the literature (Chapman and Toseland, 2007). Although there is still a need for more research in this area, behavior rounds that include input from multiple disciplines including medicine, nursing, dietary, psychology, recreation therapy, and physical therapy have been shown to be effective in decreasing agitation and pain in patients diagnosed with dementia related disorders (Chapman and Toseland, 2007).
Behavior Rounds

- Interdisciplinary behavior rounds resumed at the Orlando VAMC Community Living Center in April 2015.
- Team meets on a weekly basis and reviews patients on two units each week.
- Members include Medical Director, Psychologist, Dietician, Pharmacist, Social Workers, Unit Nurses, CNA staff, and Recreation Therapists.
- Members review behavioral issues and come up with individualized plan to address behavioral issues.
Efficacy of Behavior Rounds

Dr. Maria Vazquez completed a QI project for the national VA Geriatric Scholars Program in June 2015.

Utilization of Behavior Rounds for the Implementation of Non-Pharmacological Interventions for Veterans Exhibiting Dementia Related Behaviors.

- A total of 16 Veterans with dementia related diagnoses between the ages of 42 and 93 were reviewed during a two month period (April and May 2015).

- Of the group of sixteen Veterans, five were selected because they were in the facility longer than six months.

- The number of Nursing Behavior Management notes for the five Veterans selected were reviewed from November 2014 to March 2015 when behavior rounds did not occur to see if the number of behavior notes written by the nursing staff decreased in April and May 2015 when behavior rounds were conducted.

- In addition, the impact of the behavior rounds was assessed using a brief survey where the nursing staff was asked about the usefulness of the behavior rounds.
Results of Intervention

Although a small subset of the Veterans screened during behavior rounds in April and May 2015 were used for comparison over six months, the table below shows a trend toward decreasing the number of behavior notes written by the nursing staff for the Veterans reviewed in April and May 2015 as compared to the previous four months. The Team would assemble on the units. Nursing staff would identify Veterans for review. There was a case discussion including a chart review. Non-pharmacological interventions were suggested for inclusion in the Veteran’s care plan. The cases were reviewed again for efficacy in one to two weeks by the team in order to determine if interventions were effective and adjustments to the treatment plans were made as needed.

<table>
<thead>
<tr>
<th>Month</th>
<th>Veteran 1</th>
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Behavior Notes
Sixteen nursing staff which included RNs, LPNs, and CNAs participated in a survey about the usefulness of the Interdisciplinary Behavior Rounds. Fourteen of them said the behavior rounds were "very useful" and two of them said the behavior rounds were "Useful." No staff selected the other options which included "Not Useful At All", "Somewhat Useful", or "Neutral". The chart below outlines the survey results.
Conclusions:

• Although there are limitations to this QI project based on time factors and number of Veterans reviewed, there was a slight decrease in the number of Nursing Behavior Management notes written for the months the Interdisciplinary Behavior rounds took place for the Veterans reviewed.

• There was additional support from the nursing staff for Interdisciplinary Behavior Rounds based on the survey results. As part of the survey, the nursing staff were also asked in an open ended question about what is going well with the behavior rounds. The responses to this question included the perception of more positive outcomes for the Veterans, more immediate interventions, increased utilization of team approaches, addressing individual needs in a timely manner, alerting team to changes in residents condition, staff being kept up to date on the status of the Veterans, closer monitoring of the Veterans, enhancing Veteran safety, preventing injuries/incidents, more direct contact with interdisciplinary team providers, increased nursing input and involvement, improve relationships with Veterans, and improve their overall quality of life.

• The staff were also asked about how behavior rounds can be improved. Some of the feedback included more CNA involvement, selecting a day when more staff are present, meetings where the three shifts can participate, inclusion of Veterans who are able to participate, staff trainings on specialized related areas including hospice and rehab, and access to the team when a situation arises where consultation is needed.
References


Video

Experience 12 Minutes In Alzheimer's Dementia

http://www.youtube.com/watch?v=LL_Gq7Shc-Y
Video

Through Our Eyes – A Life With Dementia

http://www.youtube.com/watch?v=lpuUoX0RwAk
Video


http://www.youtube.com/watch?v=laB5Egej0TQ
Improving Care and Quality of Life for Patients with Dementia in Long Term Care

Presented by:
Polly Weaver, Assistant Deputy Secretary, Health Quality Assurance
Agency for Health Care Administration
Roadmap to Quality – Ahead of the Curve of the Unnecessary Drug Review
F309
§483.25 Quality of Care

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Surveyors use this guidance for a resident with dementia. If the resident is receiving one or more psychopharmacological agents, also review the guidance at F329, Unnecessary Drugs.
F309
§483.25 Quality of Care

• If a concern is identified during a survey that an antipsychotic medication may potentially be administered for discipline, convenience and/or is not being used to treat a medical symptom, consider reviewing F222 - 483.3(a) Restraints, for the right to be free from any chemical restraints.
F309
§483.25 Quality of Care

• Facilities should be able to identify how they have involved residents/families in discussions about potential approaches to address behaviors.

• Potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings).
It is expected that the resident’s record reflects the implementation of a systematic care processes:

- Recognition and Assessment (MDS)
- Cause Identification and Diagnosis;
- Development of Care Plan;
- Individualized Approaches and Treatment;
- Monitoring, Follow-up and Oversight; and
- Quality Assessment and Assurance (QAA).
F329
§483.25(I) Unnecessary Drugs

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

  • In excessive dose (including duplicate therapy); or
  • For excessive duration; or
  • Without adequate monitoring; or
  • Without adequate indications for its use; or
  • In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
  • Any combinations of the reasons above.
F329
§483.25(l) Unnecessary Drugs

• Antipsychotic Drugs.

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

• 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

• Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
F329 §483.25(I) Unnecessary drugs

• The intent of this requirement is that each resident’s entire drug/medication regimen be managed and monitored to achieve the following goals:

  • Promote or maintain the resident’s highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;

  • Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident’s assessed condition(s);
F329 Unnecessary drugs

Goals continued

• Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;

• Clinically significant adverse consequences are minimized; and

• The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.
F329 Unnecessary drugs

The surveyor’s review of medication use is not intended to constitute the practice of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

**NOTE:** This guidance applies to all categories of medications including antipsychotic medications.
Unnecessary Medications
Investigative Protocol

• Surveyors use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.
F329
Investigative Protocol

Not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

Was there a failure in the care process related to considering and acting upon an adverse consequence related to medications?

The surveyor may need to contact the attending physician or consultant pharmacist regarding questions related to the medication regimen.
F329
Investigative Protocol

DETERMINATION OF COMPLIANCE
6 aspects to the unnecessary medication requirement. The facility must assure medication therapy is based upon:

• An adequate indication for use;

• Use of the appropriate dose;

• Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
F329
Investigative Protocol

• Use for the appropriate duration.

• Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and

• Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.
F329
Investigative Protocol

• Potential Tags for Additional Investigation
  Notification of Change – F157
  Notice of Rights and Services, and Free Choice – F154, F155
  Comprehensive Assessment – F272
  Comprehensive Care Plans – F279, F280
  Decline if ADL – F310
  Urinary Incontinence – F315
  Mental and Psychosocial functioning – F319, F320
  Nutritional Parameters – F325
  Hydration – F327
  Physician Supervision &/or Physician visits – F385, F386
  Medication Regimen Review – F428
F329
Investigative Protocol

DEFICIENCY CATEGORIZATION

• Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

• Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

• The immediacy of correction required.
F329
Unnecessary Drugs

• Severity Level 4: Immediate Jeopardy to Resident Health or Safety

• Severity Level 3: Actual Harm that is Not Immediate Jeopardy

• Severity Level 2: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

• Severity Level 1: No Actual Harm with Potential for Minimal Harm
F329 Unnecessary Drugs

• **Severity Level 1: No Actual Harm with Potential for Minimal Harm**

• The failure of the facility to provide appropriate care and services to manage the resident’s medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement
Tapering/GDR

Tapering of a Medication Dose/Gradual Dose Reduction (GDR)

- Considerations Specific to Antipsychotics. The facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a GDR must be attempted annually, unless clinically contraindicated.

- Tapering Considerations Specific to Sedatives/Hypnotics. For as long as a resident remains on a sedative/hypnotic that is used routinely and beyond the manufacturer’s recommendations for duration of use, the facility should attempt to taper the medication quarterly unless clinically contraindicated.
Considerations Specific to Psychopharmacological Medications (Other Than Antipsychotics and Sedatives/Hypnotics). During the first year in which a resident is admitted on a psychopharmacological medication (other than an antipsychotic or a sedative/hypnotic), or after the facility has initiated such medication, the facility should attempt to taper the medication during at least two separate quarters (with at least one month between the attempts), unless clinically contraindicated. After the first year, a tapering should be attempted annually, unless clinically contraindicated.
Contact Information

Polly Weaver
850-412-4491
Polly.Weaver@ahca.myflorida.com