Antipsychotic Medication Reduction for People with Dementia in Nursing Homes and the Revised F-tags 309 and 329

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Why The Concern for Antipsychotic Use?

- Associated with increased risk of stroke, falls, dysphagia and other neurologic risk
- Value of antipsychotics in treatment of behavioral and psychological symptoms of dementia (BSPD unclear)
- CMS’s QM/QI report (July - September 2010) showed 39.4% of nursing home residents nationwide who had cognitive impairment and behavioral problems but no diagnosis of psychosis or related conditions received antipsychotic drugs
- June 2012 OIG report claims only 1% of care plans involving antipsychotics met all care plan development criteria
OIG Concerns: Antipsychotic Use in Nursing Homes

- Legal: DOJ settlements with LTC pharmacy chain and Rx manufacturers re: off label promotion & kick-backs
- 14% of elderly nursing home patients had Medicare claims for atypical antipsychotics in Jan-June 2007
- 83% of these claims were for off label use
- 22% use did not comply with Surveyor guidance on unnecessary drugs
- Elderly NH residents account for 20% (1.7 million) atypical antipsychotic claims ($309 million)

AHRQ: Comparative Effectiveness Off-Label Antipsychotics Use

- Benefits: In elderly patients, benefits included:
  - BPSD: small but statistically significant benefits for aripiprazole, olanzapine, and risperidone.
  - Generalized anxiety disorder: quetiapine, some benefits
  - OCD: risperidone some benefits, but ADE were common.
- Adverse Drug Events: In elderly patients, ADE included:
  - increased risk of death (NNH=87)
  - stroke (risperidone, NNH=53)
  - extrapyramidal symptoms (olanzapine (NNH=10), risperidone (NNH=20)
  - urinary symptoms (NNH= from 16 to 36).
Differential Risk of Death with Specific Antipsychotics

- 6 month risk, 75K NH residents, 2001-2005
- Comparison to risperidone
- Haloperidol had higher risk (HR 2.07)
- Effect strongest shortly after initiation
- No statistically significant difference for others
  - Trend for lower overall risk with quetiapine
  - Less dose response with quetiapine
  - Cerebrovascular risk lowest for aripiprazole

Huybrechts KJ et al, BMJ 2012;344:e977 doi: 10.1136/bmj.e977

Initiatives to Reduce Antipsychotic Use

- The CMS National Partnership to Improve Dementia Care in Nursing Homes set a goal to reduce antipsychotic by 15% in nursing homes by the end of 2012 (4% achieved)
- CMS added two new measures that report a nursing home's use of antipsychotic medications
- CMS released new surveyor guidance on specific and detailed review of antipsychotic and other psychotropic medication use in persons with dementia
Quality Measure Antipsychotic Use

- Started July 2012
- Long term (received) and short term (newly started)
- Previously excluded Schizophrenia, Tourette's syndrome, Huntington's disease, Manic Depression (Bipolar disease), hallucinations, and delusions
- Now excludes only Schizophrenia, Tourette’s syndrome, and Huntington’s disease
- July 2012: chronic measure 23.9%

New Surveyor Guidance

F329 Unnecessary Drugs
F309 Quality of Life

- Released May 24, 2013
- Dovetails with CMS Initiative to Reduce Antipsychotics
- Addresses the “common practice to use various types of psychopharmacological medications in nursing homes to try to address behaviors without first determining whether there is a medical, physical, functional, psychological, emotional, psychiatric, social or environmental cause of the behaviors”
New Surveyor Guidance

Key Principles

- Person Centered Care
- Quantity and Quality of Staff
- Thorough Evaluation of New or Worsening Behaviors
- Individualized Approaches to Care
- Critical Thinking Related to Antipsychotic Drug Use
- Interviews with Prescribers
- Engagement of Resident / RP in Decision Making

Care Process for Dementia Patients

A. Recognition and Assessment;

B. Cause Identification and Diagnosis;

C. Development of Care Plan;

D. Individualized Approaches and Treatment;

E. Monitoring, Follow-up and Oversight; and

F. Quality Assessment and Assurance (QAA).
Recognition and Assessment

- Detailed information about the person – past life, behaviors, preferences, medical condition, pain, cognitive status, abilities and medications
- The record should show evaluation of, but not limited to:
  - How the resident typically communicates needs
  - Usual/current cognitive patterns, mood and behavior, & whether these present a risk to the resident or others;
  - How the resident typically displays personal distress.
- Provides a basis for cause identification (based on knowing the whole person and how the situation and environment may trigger behaviors) and individualized interventions.

- Staff should specifically describe the behavior and related factors in the record with enough detail of the actual situation to permit cause identification and individualized interventions
- Simple descriptions like “violent,” “agitated” or “aggressive” does not identify the specific behavior.
- More specific terms like responds in crowded, busy group activities by yelling or throwing furniture shows both potential safety issue and possible alternative activities to meet needs
Cause Identification & Diagnosis

- Identify the physical, functional, psychosocial, environmental, and other potential causes of behavior and related symptoms
  - Presence of co-existing medical or psychiatric conditions, and/or
  - Adverse consequences related to the resident’s current medications
- Identify/document new / worsening behavioral symptoms
- Attending physician responsible for supervising medical care
- Facility must immediately consult with the resident’s physician when a significant change in resident status occurs
- If change or worsening from the baseline, practitioner and staff are expected to consider potential underlying medical, physical, psychosocial, or environmental causes of the behaviors
- If two or more areas of decline or improvement, including behavior, a Significant Change in Clinical Status Assessment (SCSA) should be considered

- If medical causes are ruled out, establish other root causes of behavior using person centered approach and information from all sources. Consider:
  - Boredom; lack of meaningful activity or stimulation
  - Anxiety related to changes in routines such as shift changes, unfamiliar caregivers, roommate change, inability to communicate;
  - Care routines inconsistent with a person’s preferences;
  - Personal needs not being met
  - Fatigue, lack of sleep or change in sleep patterns
  - Environmental factors, for example noise levels, overhead pages, alarms that could be misinterpretation causing delusions and/or hallucinations.
  - Mismatch between the activities or routines selected and the resident’s cognitive / abilities
Development of Care Plan

- Includes a well-defined problem-statement, outlines the goals of care, with measurable objectives, timetables, and staff responsibilities for interventions. The care plan should reflect:
  - Baseline and ongoing details of common behavioral expressions and expected response to interventions
  - Specific goals for, monitoring interventions effectiveness
  - For medications, rationale for use, dose / duration, target behaviors, expected outcomes, monitoring, GDR plans
  - IDT with patient / family involvement as appropriate determines interventions and regularly reviews
  - Non-pharmacological approaches are required whether or not medication is used. Certain behavior may be anticipated and preventable based on understanding causes and triggers

- Pharmacological interventions: may benefit some cases e.g. inconsolable persistent, frightening delusion despite other approaches
- If a psychopharmacologic medication used, consider:
  - What was the behavior trying to communicate
  - What were the possible reasons for the person's behavior
  - What other approaches / interventions were attempted prior antipsychotic
  - Was the family / representative contacted prior to initiating Rx
  - Was the medication clinically indicated and/or necessary to treat a specific condition and target symptoms as diagnosed and documented in the record;
  - Was the lowest possible dosage used
  - Were gradual dose reductions planned / done
  - Was the IDT / PCP involved in the care planning process
  - How is monitoring done
- If there is a decline in function, worsening behavior, suboptimal improvement, or resident refusal/resistance, the care plan approaches should be reviewed/revised/updated as appropriate
Individual Approaches / Treatment

Correct Care Plan Implementation
- Identify and document specific target behaviors and desired outcomes
- Implement person-centered interventions, document results
- Communicate / consistently implement care plan, across time / shifts

Staffing and Staff Training
- Provide staff (quantity and quality) to meet resident needs. Strive to staff to optimize resident familiarity. Quality staffing includes NA competency in skills / techniques necessary to care for individual dementia needs
- NAs must receive an annual performance review and receive regular in-service education based on outcomes. The facility must provide training in dementia care / behaviors to NAs when hired and annually
- Facilities may have systems to assist staff with caregiver stress.

Involvement of the Medical Team
- The attending physician should be readily available to the IDT and involved in BPSD management. Records must document appropriate psychoactive medication indications
- Surveyors do not evaluate the practice of medicine, only the process of care, including;
  - Communication among the entire IDT
  - P&P to prevent unnecessary medication use
- Surveyors are encouraged to interview the practitioner / IDT members to clarify use Rx / interventions
- Interviewing the medical director with regard to P&P for BPSD / medication use is strongly encouraged.
Monitoring and Follow Up

Monitoring and follow-up includes:
- Staff monitors and documents implementation of the care plan, identifies effectiveness of interventions relative to target BPSD and changes in a resident’s level of distress or emergence of adverse consequences.
- In collaboration with the practitioner, staff adjusts the interventions based on the effectiveness and/or adverse consequences related to treatment
- If concerns are identified related to a resident’s medication regimen, staff must notify the physician and the physician must respond and, as necessary, initiate a change to the resident’s care
- If the physician does not provide a timely and appropriate response to the notification, staff must contact the medical director for further review, and if the medical director was contacted, he/she must respond and intervene as needed

Quality Assessment and Assurance

The QAA committee monitors / oversees:
- If resident care policies reflect the facility’s overall approach to dementia resident care including a clearly outlined processes
- Facility monitoring of individualized interventions for the care of each resident with dementia
- Whether the facility has trained staff in BPSD, and were the initial and annual trainings evaluated for effectiveness
- Whether there is sufficient staff to implement BPSD care plan so that medication is not unnecessarily used
- Whether staff collect and analyze data to monitor the pharmacological & non-pharmacological BPSD interventions
- How the facility monitors responses to MRR issues and concerns
Antipsychotic Use for BPSD

- Only appropriate in a minority of circumstances
- Only after medical, physical, functional, psychological, emotional psychiatric, social and environmental causes have been identified and addressed
- Lowest possible dosage for the shortest period of time
- Subject to gradual dose reduction and re-review
- Not for individual symptoms e.g. wandering, nervousness, insomnia

Criteria for Off-Label Use

- The behavioral symptoms present a danger to the resident or others
  AND one or both of the following:
  - The symptoms are identified as being due to mania or psychosis (such as: auditory, visual, or other hallucinations; delusions, paranoia or grandiosity)
  - Behavioral interventions have been attempted and included in the plan of care, except in an emergency.
Emergent Use of Antipsychotics

Acute onset or exacerbation of symptoms or immediate threat to health or safety of resident or others

- The acute treatment period is limited to seven days or less AND
- A clinician and IDT must evaluate and document the situation within 7 days to identify and address any contributing and underlying causes of the acute condition and verify the continuing need for an antipsychotic medication.
- If the behaviors persist beyond the emergency situation, pertinent non-pharmacological interventions must be attempted, unless clinically contraindicated, and documented following the resolution of the acute psychiatric event.

Criteria for Enduring Use

All four required

- Not due to a medical condition or problem expected to improve / resolve as condition or Rx is addressed
- Not due to environmental stressors alone that can be addressed to improve the symptoms or maintain safety
- Not due to psychological stressors alone, anxiety or fear from cognition-related misunderstandings expected to improve as the situation is addressed
- Persistent despite non-pharmacologic measures and which affects resident quality of life
New Admissions

Facility is responsible for
- Obtaining physician’s orders for the resident’s immediate care.
- Preadmission screening for mentally ill and intellectually disabled individuals. PASRR screening should include appropriate clinical indications for use of antipsychotic.

For residents not requiring PASR & admitted on an antipsychotic, facility must
- re-evaluate antipsychotic use at admission and/or within two weeks of admission (MDS assessment) and
- consider reduction or discontinuation

Monitoring

- Surveyors will monitor not only ongoing effectiveness and potential adverse consequences of antipsychotic but also will evaluate the use of any other psychopharmacological medications (e.g. mood stabilizers, benzodiazepines)
  - Can the facility can explain the rationale for adding, or switching from an antipsychotic to another category of psychopharmacological agents
  - Surveyors should investigate further when more than one antipsychotic agent has been prescribed
  - Will examine when an antipsychotic has been discontinued and a medication such as a mood stabilizer has been added
Effectiveness, Potential ADE

- Must reevaluate antipsychotic - BPSD for efficacy, ADE, potential to reduce / discontinue
  - After initiation or increasing dose
  - At least quarterly
- Must adequately monitor, identify and act on ADE
  - If benefits of drug therapy exceed risk must document and have patient / representative consent

F 329 Immediate Jeopardy Example

- An 89 year old male was re-admitted to the nursing home from the hospital. Admitting diagnoses included pneumonia, CHF, and dementia with moderate cognitive decline and delirium with psychotic features. The history from the hospital indicated the resident was treated with antibiotics, fluid replacement, and was placed on an antipsychotic due to the sudden development, one day after admission, of delirium with psychotic features. The resident had a change in cognition, disorientation and was less alert for prolonged periods and had attempted to remove the IV fluids and crawl out of bed. After the resident’s infection stabilized, he was discharged back to the nursing home.
Four months after NH readmission, the antipsychotic medication was still ordered. Staff was monitoring for the identified target behavior but the resident had none documented for over 3 months. The facility failed to evaluate and/or consider GDR, and no alternative approaches had been tried. The consultant pharmacist had recommended GDR but the physician had continued the medication.

The resident had orthostatic hypotension and a high fall risk. He missed group activities as he was sleeping off and on throughout the day in his recliner. The resident went from ambulatory with one staff at admission to no longer ambulating. The resident developed stage III pressure ulcers on his hips and coccyx. He was losing weight due to decreased food and fluid intake.

When interviewed, staff stated the resident’s decline was related to his dementia. They had not considered reducing the medication and failed to recognize that the medication was used for delirium in the hospital.

Why do we use antipsychotics to excess?

- Lack of clear diagnosis
- Lack of identification of triggers
- Lack of communication
- Lack of documentation
- Lack of involvement of the team
- Lack of staff education
- Inadequate evaluation
- Ease of prescribing versus non-pharmacologic efforts
- Time constraints
Reducing Antipsychotic Use

- Must be able to describe BPSD
- Must be able to identify causes BPSD
- Must be able to prevent BPSD
- Must have a firm diagnosis for use
- Must employ non-pharmacologic measures
- Must have a care plan
- Must be serious about GDR
- Strongly consider a BPSD team

Key Considerations to Help Prevent Behavioral Symptoms

- Effectively communicate:
  - Use calm voice
  - Offer no more than two choices
  - Do not use open-ended questions
  - Keep it simple – do not over explain or discuss events happening in the future
- Attend to resident’s nonverbal communications
  - Grimacing may be a sign of pain
  - Ringing hands may be a sign of anxiety, feelings of insecurity
- Relax the rules - no right or wrong way if safe
- Establish a structured daily routine for resident that is predictable
- Keep resident engaged in activities of interest and that match capabilities
- Use cueing strategies (e.g., touch, verbal directions) to help initiate, sequence, and execute daily activities
- Understand behaviors are not intentional but are an erosion in the person’s ability to initiate or comprehend task or purpose
- Inform physician immediately of changes in behavior as they occur (e.g., sleep disruptions, withdrawal, increased confusion)


- How often did the behavior occur in the past week/month?
- Where does the behavior occur?
  - Is there a particular room/setting within the facility where the behavior occurs (e.g., during activities, in dining room, in person’s own room with daily care routines)?
- Can you recognize any patterns?
  - Does the behavior happen at the same time every day?
- What happens right before the behavior occurs?
- Who is around when the behavior occurs and how do they react?
- What is the environment like where the behavior occurs?
  - Is there a lot of stimulation (television, noise, people)?
- How would you like this behavior to change? When would you consider the problem “solved”?
Describing Behavioral Symptoms

- What is the behavior?
  - Can you describe the behavior?
  - What did he/she do?
  - What did he/she say?
  - What did you do and say?
- Why is this behavior a problem? What about it really gets to you or makes you upset?
- When does the behavior occur?
  - What time of day?
  - What day(s) of the week?

Causes of Behavioral Symptoms

Resident Based Factors

- Altered emotional status (insecurity, sadness, anxiety, loneliness)
- Lack of daily routines
- Sensory deficits (hearing, sight)
- Basic physical needs (hydration, constipation, body temperature)
- Interests and preferences not being met
- Level of stimulation (under or over) not appropriate
- Health issues (underlying infection)
- Impact of other illness or conditions
- Pain
- Medications
- Ambulation and/or difficulty finding one’s way (getting lost)
- Challenges performing daily activities of living
- Sleep cycle disruptions
Caregiver Based Factors

- Communications too complex
- Emotional tone is harsh
- High level of distress
- Lack of availability (staffing issues)
- Poor health status
- Expectations are too high or too low
- Cultural expectations/values/beliefs not good fit with care needs
- Style of caregiving not good fit
- Poor relationship with resident
- Lack of education about disease and behaviors
- Lack of supportive network or system within facility for dementia care
- Limited opportunities for respite
- Strained financial situation influencing work performance
- Employment and other family care responsibilities

Environmental Factors

- Level of physical and/or social stimulation (too much or too little)
- Room arrangements or Amount of clutter
- Needed items are out-of-sight or not in where person can see them
- Lack of appropriate visual cues
- Safety risk
- Too hot or too cold
- Lack of needed adaptive equipment (grab bars in bathroom)
- Poor lighting

Firm Diagnosis for Use

- Only diagnosis excluded from consideration: Schizophrenia, Tourette's syndrome, and Huntington's disease
- Bipolar affective disorder and refractory depression not excluded from quality measure but FDA approved
- All other uses need an underlying diagnosis and specific target symptoms (e.g. dementia with psychotic features) that
  - are refractory to simple management
  - can be quantitated and monitored

Non-Pharmacologic Measures

- Create a predictable, person centered routine
- Ensure familiarity (same staff, own possessions)
- Use simple language, explain actions
- Simplify tasks
- Distract and redirect
- Ensure a safe environment
- Orient (clocks, calendars, etc)
- Moderate lighting in day and night
- Reduce excessive stimulation
- Group and individual activates

More Non-Pharmacologic Measures

- **Physical pain or discomfort?** Medical treatment; nursing intervention; change environment
- **Looking for home?** Make place look/feel more like home
- **Need for social contact?/Restless?** Social interaction (real or simulated); Identify meaningful activities
- **Disturbing others?** Separate people who may trigger negative responses in each other
- **Hallucinations?** Check vision/hearing; try using familiar objects/people
- **Need more control?** Offer choices
- **Refusing help with ADL?** Perform ADL at a different time of a different method
- **Need for stimulation/exercise?** Provide large enclosed environments; safety devices; change locks


More Non-Pharmacologic Measures

- **Apathy** - Activity therapy
- **Agitation / Aggression** - Cognitive/behavior therapy, Therapeutic touch, Music therapy. Multisensory stimulation, Simulated presence
- **Depression** – Cognitive therapy, Cognitive stimulation, Behavioral intervention. Therapeutic activity, Music therapy
- **Psychosis** - Changing medication, Correcting visual and hearing impairment, Improving lighting conditions, Modifying patient environment
- **Wandering** -Management of surroundings, Covering Doors, Visually changing environment
- **Sleep** - Bright-light therapy, Music therapy, Behavior therapy

Care Plan for Reducing Use

- Target symptoms clearly defined
- Measureable objectives
- Timeline for use
- Plans for GDR
- Use of IDT

Getting Firm with GDR

- Strict facility policy of reviewing all antipsychotics
- Include team recommendations with MMR / GDR
- Careful review of response to GDR requests
  - Must include clear and reasonable reason(s) for not doing GDR
  - Suggest medical director / team review refusals to perform GDR
  - ? Family awareness of refusal?
Medical Director Involvement

- Weekly IDT rounds – use of standardized templates
- Targeted letters to practitioners
  - Residents without GDR
  - Residents without proper documentation
  - Reminders to attempt non-pharmacological interventions first when appropriate
- Work with pharmacy to produce physician-specific comparative use reports
- Personal outreach to physicians who refuse to consider antipsychotic alternatives

Alice Bonner, personal communication

Consider a BPSD team

- Reviews all persons with behavior issues
  - New onset / escalating behavior ASAP
  - Admissions within a week
  - Chronic use quarterly
- DON / ADON, floor nurse, CNA, activity therapy
  - Medical director as needed
  - Therapy as indicated
  - Family / RP liberally
  - Consider administrator
- Reviews / tracks GDR
Use State & National Resources

- Changing Antipsychotic Thinking (CAT)
  - Primaris http://www.primaris.org/cat_tips
- MOLANE
  - Missouri chapter of Advancing Excellence campaign
  - dfinley@primaris.org (Deborah Finley)
- Advancing Excellence Campaign
  - http://www.nhqualitycampaign.org/star_index.aspx?controls=dementiaCare