Antipsychotics in LTC: UPDATES FROM THE FIELD

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Objectives

Define the updated regulatory guidance for appropriate use and gradual dose reductions of antipsychotic medications

Evaluate a case study for clinical and process-related failures

Discuss current issues surrounding Dementia Care and Antipsychotics use in LTC among the peer group.
Misadventures with Haldol
A Regulatory Case Review
92 Year Old Female

Diagnoses

- Dementia
- Depression
- HTN
- Hypothyroidism
- History of falls
- Hard of hearing
“Increased confusion today …. bed and chair alarms on due to fall risk … despite alarms resident found on floor in bathroom with stool in diaper … states she is getting ready to go to a wedding”

MD contacted and gave the following orders:

- Stools x 3 for C diff (why?)
- Flagyl x 10 days (why? … see above?)
- Haldol 5 mg now and q 12 hours PRN
The facility must ensure that residents are:

“… not given these drugs unless necessary to treat a specific condition as diagnosed and documented in the clinical record …”
June 17, 2010

PRN order placed into the record

9 PM: Haldol 5 mg administered

10:30 PM: Resident sleeping
Nursing Note:

• “Resident expressed that she wanted to go to Kmart to buy nylons and a raincoat for roommate … calm but confused … PRN Haldol given … effective, resident stopped preparing to go to Kmart”
(~ 1 month post order)

Nursing Note:
• “PRN Haldol given for agitation [not described] … effective results noted”
“A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided ...”

- SOM Interpretive Guidelines
  § 483.75(l)(1)
Pharmacist medication regimen review:

• “No irregularities noted”
Irregularity refers to any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services or that impedes or interferes with achieving the intended outcomes of those services.”

- State Operations Manual
August 2, 2010 at 1:30 AM

(~ 6 weeks post order)

Nursing Note:

• “Resident agitated [not described] … PRN Haldol given … resident now sleeping”
(~ 6 weeks post order)

Nursing Note:

“Nursing assistant reported that resident was packing up her room to go home … resident requested shopping bag to give pictures on window sill to the person they belong to … PRN Haldol given … effective, resident no longer wants to go home … “

2nd dose of Haldol 5 mg administered < 24 hours
August 2, 2010 at 6:30 PM

(~ 2 hrs after 2nd dose)

Nursing Note:

• “Resident noted with muscle spasms of neck and clenching of teeth intermittently … this is a new finding …”
“Any symptom in an elderly patient should be considered a drug side effect until proved otherwise.”

Gurwitz et al. Long-Term Care Quality Letter, Brown University, 1995
Nursing Note:

• “Resident noted with muscle spasms of neck and clenching of teeth intermittently … this is a new finding … MD called, Haldol discontinued … give Benadryl 25 mg x 1 dose for possible dyskinesia ..”
August 3, 2010

(∼ 6 weeks post order)

Seen by MD, ordered Cogentin 1 mg bid for “cogwheeling and dyskinesia”

Symptoms resolved within 24 hours
Let's Review: “Indication” for Haldol

June 17: Confused, fall in bathroom, wanted to go to a wedding
June 23: Wanted to go to Kmart
July 19: Agitation (not described)
August 2: Agitation (not described)
August 2: Wanted to go home
If this happens in your facility, you should anticipate an uncomfortable discussion with the surveyor!

If you can’t explain it **simply**, you don’t understand it well enough.

– Albert Einstein
Do the regs allow for PRN use of Haldol?

What if any discipline(s) are deficient in this case?

What is the scope and severity of the deficiency or deficiencies?
Actual Deficiencies Cited

F 281 (Professional Standards of Practice)
  • Nurses knew or should have known Haldol was not indicated

F 329 (Unnecessary Drugs) = Actual Harm
  • Without adequate indication for use
  • Excessive dose

F 385 (Physician Services)

F 428 (Drug Regimen Review)
  • Failure to note and act upon a drug irregularity
Sanctions

Directed plan of correction

Civil money penalty ($10,000.00)
Informal Dispute Resolution

Facility attendees:

• Admin., DON, Medical Director x 2, Consulting Psychiatrist, Attending Physician, Pharmacist

• Noticeably absent: Nursing staff directly involved in assessing the resident / administering Haldol
Facility’s position:

- Attending physician knew the resident well (provided care x years)
- In the past her behavior escalated without the use of antipsychotics (not evident in the record)
- “Agitation” was extreme
- Benefit outweighed the risk
- Pharmacist → not an irregularity
- Yes, poor documentation … but no harm
- Attending physician will leave LTC if this is not reversed!
Informal Dispute Resolution Result
Other Considerations

- Care plans?
- Chemical restraints?
- Immediate jeopardy?
- What about informed consent?
Clinicians must have sound rationale for the use and monitoring of all medications

Facilities should structure procedures to help clinicians (including the prescriber) “get it right”

Get two birds with one stone … antipsychotics in the context of QAPI
Antipsychotics have now joined a long list of regulatory “priorities” (restraints, decubitus, tube feeding, side rails, etc) – so focus on the process

When all the safety nets fail (physician, multiple nurses, pharmacist) the regulatory risk increases dramatically
Regulations for Antipsychotic Use in Long Term Care

CMS State Operations Manual

Appendix PP - Guidance to Surveyors for Long Term Care Facilities
Pharmacological Management

When control is needed to prevent harm and to allow evaluation and treatment, psychotropic medications may be required.

**Indications for pharmacologic treatment:**

- Aggression
- Agitation
- Risk of harm to self or others
- Hallucinations
- Inconsolable or Persistent Distress
  
  *(e.g., fear, continuously yelling, screaming, distress associated with end-of-life, or crying)*

- Significant decline in function

**Must seek the underlying cause of distressed behavior before or while treating the symptom.**
In Addition……..

- The symptoms are identified as being due to mania or psychosis OR
- The behavioral symptoms present a danger to the resident /others OR
- The symptoms are significant enough that the resident is experiencing one or more of the following:
  - Inconsolable or persistent distress
  - Significant decline in function
  - Substantial difficulty receiving needed care
- Must help stabilize or improve a resident’s outcome, quality of life and functional capacity

Consider utilizing this language when documenting justification for antipsychotic use
Inadequate Indications for Antipsychotic Use

Antipsychotics should not be used if the only indication is one or more of the following:

- Wandering
- Poor self-care
- Restlessness
- Impaired memory
- Mild anxiety
- Insomnia
- Unsociability

- Inattention or indifference to surroundings
- Fidgeting
- Nervousness
- Uncooperativeness
- Verbal expressions
- Behaviors that do not represent a danger to the resident or others
Requirements for Enduring Use of Antipsychotics

- Target behavior must be clearly and specifically identified and monitored objectively and qualitatively.

Ensure the behavioral symptoms are:

- A. Not due to a medical condition or problem that can be expected to improve or resolve.
- B. Persistent or likely to reoccur without continued treatment; and
- C. Not sufficiently relieved by non-pharmacological interventions; and
- D. Not due to environmental stressors that can be addressed to improve the psychotic symptoms or maintain safety.
- E. Not due to psychological stressors or anxiety or fear stemming from misunderstanding related to his or her cognitive impairment.

*Behavioral symptoms must be reevaluated periodically to determine the effectiveness of the antipsychotic and the potential for reducing or discontinuing.*
Gradual Dose Reduction: Antipsychotics

Seek an appropriate dose and duration for each medication, and minimize the risk of adverse consequences

Within the first year in which a resident is admitted and taking an antipsychotic medication, the facility must attempt a GDR:

- In 2 separate quarters, (at least 1 month between attempts)
- After the first year, GDR must be attempted annually
- GDR attempts can be omitted if they are clinically contraindicated

“Often the only way to know whether a medication is needed indefinitely and whether the dose remains appropriate is to try reducing the dose and to monitor the resident closely for improvement, stabilization, or decline.”
New Admissions to Skilled Nursing Facility

When a resident is admitted to a SNF from hospital/community and are already on an antipsychotic:

- *Facility must re-evaluate antipsychotic medication at the time of admission and/or within two weeks of admission*

- *PASRR screening (F285) - evaluation for mental illness and/or intellectual disability*
Acute Situations/Emergency

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

- Acute treatment period limited to 7 days
- Clinician and IDT must reevaluate and document situation within 7 days, and define continuing need
- Non-drug therapies are attempted beyond the emergency period
Non-Drug Therapy Requirements

Part of all medication treatment = Non-pharmacological approaches

Examples of non-pharmacological interventions may include:
• Identifying, addressing, and eliminating or reducing underlying causes of distressed behavior
• Developing interventions that are specific to resident’s interests, abilities, strengths and needs
• Minimize distractions or overstimulated environment
• Using sleep hygiene techniques and individualized sleep routines
• ↑ exercise or therapy
• Massage, hot/warm or cold compresses
• Enhancing the taste and presentation of food
• Music therapy
Surveyors are instructed to review the clinical record to determine if it reflects the following elements:

- Indication
- Non-pharmacological interventions
- Dose
- Duration
- Tapering/Gradual Dose Reduction documentation
- Monitoring and reporting for efficacy and adverse consequences
- Adverse consequence identification, evaluation, and actions by physician and facility
Dementia Care Principles:

1. **Person–Centered Care**
   Recognizing individual needs and preferences

2. **Quality and Quantity of Staff**
   To meet the needs of residents

3. **Thorough Evaluation of New or Worsening Behaviors**
   IDT to identify and address treatable factors

4. **Individualized Approaches to Care**
   Understanding behavior as communication

Dementia Care Principles:

5. **Critical Thinking Related to Antipsychotic Drug Use**
   - Using medications only when necessary
   - F222 - 483.13(a) Right to be Free From Chemical Restraints

6. **Interviews with Prescribers**
   - Understanding the reasoning

7. **Engagement of Resident /Representative in Decision-Making**
   - Ensure judicious use of medication therapy

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.

1. Recognition and Assessment
   • Nature, frequency, severity, and duration of both usual and dementia-related behaviors and patterns
   • Risks of those behaviors

2. Cause Identification and Diagnosis
   • Potential underlying causes
   • Potentially remediable causes

3. Development of Care Plan
   • Baseline and ongoing details
   • Specified goals
   • Rational and monitoring plan for medications
   • Environmental and other approaches
4. Individualized Approach and Treatment
   • Identify and document target behaviors and desired outcomes
   • Appropriate person-centered interventions to meet the person’s needs
   • Communicate and consistently implement the Care Plan

5. Monitoring, Follow-up and Oversight
   • Effectiveness of interventions documented
   • Adjusts interventions as needed
   • Concerns or declines are addressed timely

6. Quality Assessment and Assurance (QAA)
   • Policies reflect a clear process for dementia care
   • Facility compliance with policies
   • Training of Staff
   • Collection/Analyzing data
   • Consultant Pharmacist reviews and responses
Surveyor Investigation - Areas of Focus

- **PRN orders** for antipsychotic medications
- Describe how the facility provides *individualized care and services* for residents with dementia
- Provide **policies** related to the use of antipsychotic medications in residents with dementia
- Resident/families/representatives **involvement**
- Identify and document specific **target behaviors**
- **Communicate** consistently
Tales from the Field…

- GDR on antidepressants and anxiolytics
- PRN use of antipsychotics
- PRN use of other psychoactives
- Order and indication of PRNs used for behavioral problems
- Behavior monitoring forms – target behaviors, incomplete
- Hospice and antipsychotics
- Off-label use of medications

- Facility ‘over-response’ to surveyor comments
What have you done differently in your facility surrounding dementia care and antipsychotic medication use?

- Tools or Programs
- Success stories and Best Practices
- Survey encounters
- Barriers
Questions?

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