Evidence-Based Best Practices - Antipsychotic Medications

Overview

Antipsychotic medications are generally prescribed to manage psychosis (including delusions, hallucinations, paranoid thoughts), primarily in people with schizophrenia. They may also be used to treat other psychotic disorders and as an adjunct in the treatment of bipolar disorder. When used to treat these disorders, their clinical benefits are widely accepted.

Antipsychotic medications have been frequently used "off-label" in Alzheimer's disease and other dementia-related disorders where the effectiveness of the treatment can show mixed results. The off-label use of antipsychotic medications for dementia-related illnesses is unsupported in the literature.

The U.S Food and Drug Administration (FDA) has issued black box warnings of increased mortality in older adults with dementia who take antipsychotic medications. Significant risks - including higher blood glucose and lipid levels, weight gain, increased risk of falls, and decreased cognition - also are associated with the use of antipsychotics. These complications can lead to the worsening of other primary diagnoses.

In 2023, the FDA approved the use of the antipsychotic Rexulti® to treat agitation related to Alzheimer's disease. The physician must consider the risks versus benefits before prescribing this medication, and non-pharmacological interventions should be the first-line treatment in these situations. Rexulti® retains the black box warning, despite the new FDA approval for Alzheimer's-related agitation.

Both psychosis and agitation greatly contribute to caregiver burden and depression in the community setting and are frequently cited as factors for nursing facility (NF) placement. Drug-first treatment approaches often carry over from the community and hospital settings into NFs. However, antipsychotic medications should not be considered a first-line therapy except in circumstances of extreme distress or harm.

The Centers for Medicare and Medicaid Services (CMS) long-stay quality measure for antipsychotics uses data from the Minimum Data Set (MDS) to evaluate the use of antipsychotic medications in NFs. It reports the percentage of people living in the NF who received antipsychotics in the 7-day period leading to the MDS target

assessment date. The quality measure is included in the Five-Star Quality Rating System and is reported for each facility on the Care Compare website. People with an active diagnosis of schizophrenia, Tourette's Syndrome or Huntington's disease are excluded from the measure. There have been concerns that these exclusions have led to inappropriate diagnoses of schizophrenia in older adults with dementia to avoid the need for dosage reductions and to lessen the impact on the quality measure. A 2022 study published by the U.S. Department of Health and Human Services Office of the Inspector General found that between 2015 through 2019, "there were increases in both MDS reporting of schizophrenia and the numbers of residents who lacked a corresponding schizophrenia diagnosis in Medicare claims and encounters." CMS continues to audit schizophrenia coding in NFs, and if erroneous coding is found, adjusts the quality measures for the facilities whose audits revealed inaccurate coding. During the audits, issues CMS has identified include:

- Absence of comprehensive psychiatric evaluations and behavior documentation
- Sporadic behaviors documented in the medical record, usually related to dementia rather than schizophrenia

Texas Administrative Code §554.1207 requires that a person receiving antipsychotic or neuroleptic medications provide written consent. Written consent can also be given by someone authorized by law to consent on the person's behalf. Consent for antipsychotic and neuroleptic medications **must** be documented on the Texas Health and Human Services Commission Form 3713.

Assessing for Underlying Issues

Input from an established interdisciplinary team (IDT) of clinicians, nursing staff, and others involved in caregiving can have a great influence on how antipsychotics are prescribed. One study found that more than one third of people living in NFs lacked a clinical indication for the appropriate use of an antipsychotic. People who were newly admitted to NFs with high percentages of antipsychotic use were more likely to receive an antipsychotic, than those admitted to facilities with lower percentages. This study suggests that prescribing rates are greatly influenced by facility level factors.

Before initiating an antipsychotic, a detailed assessment should be completed to identify any treatable causes of the behavioral and psychological symptoms of dementia (BPSD) such as infections, delirium, pain, depression, or sleep disorders.

Any person with dementia who develops psychological symptoms or uncharacteristic behaviors which cause significant distress should be evaluated at

the earliest opportunity to establish the likely factors that may trigger, aggravate, or lead to such behaviors. A comprehensive assessment includes:

- The person's physical health
- Depression screening
- Evaluations for undetected pain or discomfort
- Review of medication regimen and potential adverse effects
- The person's biography, including spiritual beliefs and cultural identity factors
- Emotional and psychosocial predispositions
- Physical, functional, and environmental factors
- Social and cognitive factors
- Interpersonal relationship issues

Family members can offer a great deal of information regarding the person's life-long routines and habits, their preferences, and the things they dislike. Structure person-centered non-pharmacological interventions and therapeutic approaches through discussions with the family. Additionally, commonly used alternative methods which are valid yet unfamiliar to the lay person should also be discussed to educate family members/representatives.

Stabilization of a person with dementia may be a primary concern, with considerations of secondary risk factors. For example, with palliative care and hospice. A careful assessment should evaluate the person's remaining life expectancy and goals of care. Close to the end of life, sedation may be a desirable effect and may be the reason to choose an older (typical) antipsychotic agent over a newer (atypical) one. Towards the end of life, goals of care will shift to maintaining comfort; at this stage antipsychotics can show an increased benefit over risk. Yet even in palliative care, the principle of "start low and go slow" still applies.

The focus should be on the risk versus benefit of these medications, along with alternative non-pharmacological methods. Clinicians and caregivers may wish to develop policies which are focused on improving quality of life to limit inappropriate treatments. Algorithms can be very helpful with implementing these policies.

Alternatives to Antipsychotic Medications

Non-pharmacological interventions are considered the first-line approach toward managing uncharacteristic behaviors. Antecedents of behavior are seldom discussed

with the IDT, and are rarely documented by the nursing staff, but can suggest the possible triggers or root causes for the behaviors.

- What was happening just before the behavior occurred?
- What is the reason for the behavior?
- What is the description of the behavior?
- What are the consequences of the behavior?

Simply documenting generalized interventions (such as "re-direct") is generally not enough. More specifics as to "how" the staff can approach the person, allow for time to communicate, offer care, etc. are needed. Specify the likes and dislikes of the person, as well as their usual routines and habits to tailor meaningful activities to avoid uncharacteristic behaviors or triggers.

Psychosis can be part of the disease process but does not always need to be treated with an antipsychotic medication. Unless the hallucinations or delusions are causing the person distress or causing harm to others, non-pharmacological approaches are appropriate.

- Do not argue with the person about these delusions or hallucinations, try to deflect and comfort him/her.
- Educate staff and family about validation techniques, to accept the beliefs of the person so that medications can be avoided for as long as possible.
- Provide clear documentation if the psychosis causes distress or harm. This can substantiate evidence that antipsychotic treatment is necessary to stabilize the person.
- Document the result of the distressing or harmful psychosis (e.g., person is refusing food because they believe they are being poisoned)

Management techniques work best when "appropriate" behaviors are strengthened.

- Use low-toned slow speech and simplified statements
- Use positive statements - avoid negative speak, don't argue, deflect by asking questions that make the person converse, change location
- Don't wait until behaviors escalate
- Use the four Rs
    - **R**epeat (verbally prompt)
    - **R**edirect (introduce pleasant stimuli such as important life events, prayers, poems, hobbies, interests, photographs, music of the person's choice)

    - **R**einforce (assist the resident by maintaining the person's independence and try to enhance physical ability)
    - **R**eassure (defuse the situation, offer comfort, address emotional needs

Specific interventions should be based not only on the person's needs and deficits, but also his/her strengths, preferences, life-long routines, and dislikes.

- Simplify tasks
- Don't overestimate the person's ability to complete or engage in tasks
- Allow rest between stimulating events
- Provide cues or reminders routinely
- Scheduled toileting and prompted voiding to reduce urinary incontinence (if this is a specific problem with the person)
- Music (individualized playlists)
- Audio relaxation tapes (the beach, the outdoor sounds, etc.)
- Aromatherapy
- Walking & light exercise
- Pet therapy to improve socialization
- Reminisce therapy
    - Old photo albums for recall of the past
    - Audiotapes of family members
    - Videotapes of family members
    - Videotapes which recall former occupation or hobby (e.g., farming or fishing)
- Consider repositioning, hand massage, backrub, or other relaxation techniques
- Conduct pain assessments when behaviors occur (behaviors could be a sign of discomfort and/or pain)
- Offer any security items, religious trinkets, the need for a blanket or shawl, or a particular item of apparel (e.g., favorite hat or scarf)
- Document and offer the person's favorite beverage or snack (unless there are specific restrictions)

A successful behavior management program may require changes in facility policies, procedures, and nursing care practices. All staff should be trained on behavior management techniques.

Reducing Unnecessary Antipsychotic Medications

The Centers for Medicare and Medicaid Services (CMS) guidelines state that people should not be given antipsychotic drugs unless medically necessary to treat a specifically diagnosed condition which is documented in the clinical record. People with dementia who are on antipsychotics must receive gradual dose reductions and behavioral interventions (unless clinically contraindicated by the attending physician) in an effort to discontinue the drug's use.

When a person is admitted or re-admitted into the NF from a hospital, another NF, or a community setting with an antipsychotic drug, the receiving facility is responsible for seeking out and verifying why the drug was started. The facility must then evaluate the necessity for use of the antipsychotic and determine whether a medication reduction (tapered or discontinued) will take place.

If an antipsychotic is deemed clinically necessary, initial doses are started low and then slowly titrated upwards to maintain the highest level of functioning with the lowest effective dose. Dosages must be monitored regularly with considerations of adverse reactions while evaluating the person's response and level of functioning. The medication should be used at the lowest possible effective dose, for the shortest possible time, ideally less than 12 weeks.

The necessity of the antipsychotic medication should be reviewed routinely, with at least quarterly considerations of gradual dosage reductions. The nursing staff can review the data gathered from the behavior monitoring system to identify decreasing trends in behavior. These dosage considerations be discussed and documented with the IDT. The information gathered is used in determining if a lower dose may have the same outcome. Dosage reductions are conducted slowly, unless clinically contraindicated, with the ultimate goal of drug discontinuation. Downward titration is best started when behaviors have greatly diminished, and the person is at a stable baseline and continued behavior management techniques are in place.

When stabilization is reached and the targeted behavior is re-directed with continued behavioral techniques, gradual dosage reductions are attempted.

- Dosage titrations downward usually occur at 1-to-2-week intervals.
- The staff must be aware of the step down in dose, to ensure that protocols of the non-pharmacological approaches are still in place.
- At the end of each 1-to-2-week interval, notations of clinical outcomes are documented in the clinical record.
- Longer intervals (at 3 to 4 weeks) between adjustments may be considered if behaviors are deemed to be of negative consequence. Keep the dose at a standstill and continue to implement non-pharmacological interventions.

Medical directors, psychiatrists, other behavioral health consultants, administrative staff, consultant pharmacists, and nursing staff need to be aware of the percentage of people in their NF receiving an antipsychotic medication without a CMS approved diagnosis (schizophrenia, Huntington's disease, or Tourette's syndrome).

Start by reviewing the NF's Quality Measure for long-stay antipsychotic use. Is the facility's percentage higher than the national or state average? **Note:** The CMS Quality Measure does not exclude FDA approved diagnoses of bipolar-related diagnoses or major depressive disorder (MDD).

Run an internal report to identify people currently receiving antipsychotics, whether on a routine and as-needed (PRN) basis.

- Review the diagnoses of the people on antipsychotics.
- Was the person already receiving an antipsychotic at the time of admission to the NF from the hospital, other NF, or from a residential setting?
- Consider the total length time since initiation of drug (caution: the order date may not be a good indicator due to re-admittance).
- Did the person ever receive hospice care where an antipsychotic drug was initiated? Did the person improve to the point of discontinuation from hospice without consideration of an antipsychotic dose reduction?
- Review the necessity of the current dosage. Have changes in condition such as frailty, weight loss, dehydration, increased age, co-morbid diagnoses, or the addition of other psychoactive drugs warranted a decrease in antipsychotic dosage?

Address the benefits of changing the NF's culture to one of person-centered care. Identify and try to resolve barriers which may be present or may arise over time.

Behavior Monitoring

Behavior monitoring is an on-going process to evaluate a person's distressed behaviors, including:

- Physically aggressive behaviors – hitting, kicking, pushing, pinching
- Verbally aggressive behaviors – screaming, cursing, insults
- Sexually aggressive behaviors – sexual comments, inappropriate touching
- Wandering
- Taking, touching, or rummaging through another person's belongings

Monitoring of the targeted behavior can help NF staff quickly identify an escalation of behavior and determine the effectiveness of any interventions that have been

implemented. Behaviors to be monitored should be specifically identified; terms such as "agitated" or "aggressive" are vague. What, specifically, is the person doing or saying that constitutes a distressed or uncharacteristic behavior?

Basic Guidelines for Behavior Monitoring

Initiate behavior monitoring and documentation with the start of an antipsychotic medication or upon admission with antipsychotic medications.

Behavior monitoring occurs with antipsychotics, antianxiety medications, sedative hypnotics, and other psychotropic medications used to alter mood or behaviors (e.g., Depakote for behaviors, Provera in men, etc.). A drug-specific behavior monitoring system should be used for each psychotropic category of medication prescribed (including PRN medications).

Combining all medications together without separate distinction in the behavior monitoring system is not considered a best practice. A combined system can make it difficult to determine the necessity and/or continued need of each psychotropic medication ordered.

At least one individualized behavior must be clearly linked with each antipsychotic, antianxiety medication, sedative hypnotic, and other psychotropic medications used to alter mood or behaviors. These targeted behaviors should be linked within the behavior monitoring system in such a way that anyone (staff, physicians, medical consultants, family members, regulatory, and etc.) can clearly see the specific targeted behavior(s) treated with each medication prescribed.

Targeted behaviors **are not** the diagnosis for using the medication, but the actual undesirable/unwanted or uncharacteristic behavior that occurs because of the medical condition. The behavior(s) may change over time, and new target behaviors may need to be linked with the treatment of specific drugs within the monitoring system.

At least daily (or preferably shift-by-shift) monitoring of the specific targeted behaviors should be documented within this system, and not solely noted within the nurse's notes. Staff observations must be documented within this monitoring system so that data can be easily reviewed and determinations (i.e., benefit vs. risk) made as to the continued need of each psychoactive drug (including PRN doses).

Non-pharmacological behavioral interventions and therapeutic approaches need to be listed within the monitoring system with additional space provided to note person-centered approaches taken when applicable. The staff should note the attempted interventions used when behavioral disturbances occur to identify the techniques that work best.

The absence of behaviors should be indicated with a zero in the appropriate row and column of the monitoring system. Don't leave these spaces blank, as this indicates monitoring did not occur. Additionally, monitoring by exception only (i.e., noting behaviors or side effects only when they occur) is not a best practice since it can lead to underreporting and a lack of trust in the monitoring system.

Monitoring for Adverse Effects

Side effect monitoring is necessary for each of the four most common psychoactive categories (i.e., antipsychotics, antianxiety medications, sedative hypnotics, and antidepressants). At least daily (or preferably shift-by-shift) monitoring of the specific targeted side effects should be documented within this system, and not solely noted within the nurse's notes. The absence of side effects should be indicated with a zero in the appropriate row and column of the monitoring system.

Common side effects that are appropriate to each category of psychoactive medication ordered need to be listed within the side effect monitoring system. The staff should have a list of the most common side effects pertaining to each class of drug (i.e., antipsychotics, antianxiety, hypnotics, and antidepressants) used by the individual clearly listed. Class specific listings can provide better recognition of adverse reactions, especially when multiple psychotropic drug classes are being administered to an individual. Less common side effects can be added to the monitoring list if they are observed with a specific person.

All side effects that occur are be recorded in the monitoring system, regardless of whether they happen regularly or infrequently, with included documentation of the specific adverse reaction(s) observed.

Laboratory and Diagnostic Monitoring

Some drug classes or specific medications carry recommendations for laboratory or other diagnostic monitoring. The NF should work with their medical director and consultant pharmacist to develop processes for addressing these recommendations. General recommendations for antipsychotic monitoring include:

- Fasting glucose and/or HbA1c
- Fasting lipids
- Potassium and magnesium levels

Quarterly Medication Evaluation and Effectiveness of Non-Pharmacological Interventions

A formal documented comprehensive psychotropic evaluation should be performed at least quarterly and involve input from all members of the IDT. Each psychotropic drug should be discussed and reviewed independently. Grouping all psychotropic medications together on one quarterly evaluation form defeats the purpose of reviewing the necessity of each drug's effectiveness or lack thereof. A preprinted psychotropic evaluation form can be utilized for this process so that the discussions are not off the cuff and haphazardly written down.

Elements of a proper comprehensive evaluation include at a minimum:

- Review the diagnoses associated with the use of the drug
- Changes to the dosage and/or frequency of administration
- A list of all targeted behaviors linked with the treatment of the drug
- Review of the behavior monitoring system discussing the approximate number of episodes of targeted behavior(s)
- Review of other potential underlying causes or triggers for the behavior
- An overview of the non-pharmacological interventions attempted for the targeted behaviors
    - Review the outcomes noted on the behavior monitoring system (whether each intervention was effective or ineffective)
- An overview of medication side effects, potential risk factors, or changes of condition which may be indirectly related to the use of the drug
- An overview of the previous dosage reductions (when attempted and what was the result)
- An overview of the effectiveness of the medication on the targeted behavior
- Determination of the benefit versus risk for continuing the use of the drug
- Review the need for care plan updates, and comments on changes which must be addressed

Even when psychotropic drugs are utilized within CMS approved guidelines (e.g., schizophrenia, generalized anxiety disorder, parasomnias, etc.) medication dosages should always be at the lowest effective dose and frequency. Changes in condition (acute or chronic), hospitalization, comorbidities, increasing age, and abnormal lab work can all contribute to drug dosage considerations or alternate dosage forms (e.g., liquids or patches) and should be noted during quarterly evaluations.

When prescribed outside of CMS approved guidelines, the focus is to lessen the number of psychotropic agents utilized as potential chemical restraints, so that the person can maintain their highest level of functioning.

NF staff must take into consideration the cumulative effect of the psychotropic drugs on the central nervous system, the anticholinergic burden, any extrapyramidal reactions, and the cardiovascular effects they may have on a specific person.

When medication therapies are necessary, drugs which can provide added benefits for other diagnoses or lessen potential risk factors should be discussed to limit the total number of medications within a drug regimen. For example: duloxetine used for depression and for neuropathy; trazodone used for depression and sleep instead of adding a hypnotic drug; sertraline used for depression and anxiety

Review the MARs at least quarterly to determine if PRNs are being utilized appropriately by the nursing staff. Frequent use of PRNs may not be the intent of the prescribing physician. Additionally, frequent use of psychotropic PRNs could be a sign of an underlying condition which may need to be addressed.

Resources

PharMerica Psychotropic Medication Prescribing Guidelines: February 2023

Superior Health Quality Alliance Antipsychotic Medication Safety Decision Tool

Great Plains QIN Reducing Antipsychotic Medication Use: The Resident Prioritization Tool

Deprescribing.org Deprescribing Guidelines and Algorithms

Deprescribing.org Deprescribing in Ontario Long-Term Care Framework

Comagine Health Psychotropic Medication Management Tool

TMF Health Network Antipsychotic Medication Tracking Form

TMF Network Antipsychotic Medication Reference

CMS Adverse Drug Event Trigger Tool

American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia

Iowa Geriatric Education Center Improving Antipsychotic Appropriateness in Dementia Patients (IA-ADAPT)

Health Quality Innovation Network (HQIN) Algorithm for Treating BPSD