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The Use of Antipsychotic Medications in Nursing Home Residents—Questions and Answers

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What are antipsychotic medications?

Antipsychotic medications belong to a broader category of medicines called psychopharmacologic medications. Psychopharmacologic medications are designed to affect mood, mental function, or behavior. Psychopharmacologic medications include antidepressants, antianxiety medicines, hypnotic medicines (to treat insomnia), and antipsychotic medicines. Antipsychotic medicines are approved by the U. S. Food and Drug Administration for treatment of schizophrenia and bipolar disorder in adults, among other conditions.

Physicians are free to prescribe any prescription medication, including antipsychotics, for other uses that go beyond the ones officially approved by the FDA. This is referred to as "off-label" use and is quite common. In addition to the official indications, antipsychotics are also frequently used to treat symptoms of psychosis, which involve hallucinations or delusions, including paranoia.

What are antipsychotic medicines used to treat in nursing home residents?

The Centers for Medicare & Medicaid Services, which issues regulations and is responsible for oversight of nursing facilities, recognizes three primary uses for antipsychotic medications. The first type of use is treatment of residents with "psychiatric diagnoses," including schizophrenia, Huntington's chorea, Tourette Syndrome and certain other psychiatric conditions. A second use is for treatment of psychotic symptoms, such as hallucinations and delusions, which often accompany conditions such as delirium and dementia. This type of use is often short-term. The third type of use is for management of behavioral and psychological symptoms in residents with Alzheimer's disease or other dementia-related disorders.

Some antipsychotic medications are also approved by the FDA for treatment of bipolar disorder and adjunctive treatment of major depressive disorder. The American Society of Consultant Pharmacists has a Web page with resources and links to additional information about the use of antipsychotic medications in nursing home residents. The link is: http://www.ascp.com/antipsychotic

Are behavioral symptoms common in patients with dementia?

Over one-half of nursing home residents have a diagnosis of Alzheimer's disease or another form of dementia. The prevalence of behavioral symptoms in community-dwelling patients with dementia is 76%, and is as high as 90% among nursing-home residents. Among patients with Parkinson's disease, 15-40% experience symptoms of delusions or hallucinations.[1,2]

Agitated behaviors are among the most common of behavior disturbances in nursing-home residents. In one study, agitation was displayed by 60% of residents. Agitation may be the most troubling and challenging of the behavioral

symptoms in demented long-term care residents as it commands significant attention from family and staff. Much understanding and creativity are required in dealing successfully with such problems.[2]

How is agitation defined?

Agitation may be defined as psychomotor activity with disruptive physical or vocal behavior. Agitated behaviors can be further subdivided into four categories: (1) aggressive behaviors, (2) physically nonaggressive behaviors, (3) verbally agitated behaviors, and (4) hiding or hoarding behavior. Though each of these types can be challenging, aggressive behavior often is given highest priority by staff at long-term care facilities because of the risk of physical harm to the patient and others. Examples of aggressive behavior include cursing, verbal aggression, hitting, grabbing, tearing things, pushing, biting, and spitting.[2]

How should behavioral and psychological symptoms of dementia (BPSD) be managed?

Generally speaking, strategies for managing BPSD can be divided into non-pharmacologic strategies and pharmacologic (drug) strategies. The generally recognized consensus is that non-pharmacologic approaches to management of BPSD are preferred as initial therapy.[3,4] These approaches can be effective and avoid exposing the patient to the potential risks of drug therapy.

As a first step, it is important that behavioral manifestations be recognized as symptoms, rather than as a distinct problem. All behavior is purposeful. Problem behaviors, such as hitting, require thorough evaluation to investigate an underlying cause. The explanation may be a physical problem, such as a toothache or fecal impaction in a demented person who is unable to communicate verbally. In other cases, the problem may be a manifestation of an adverse reaction from a medication. For this reason, older adults who exhibit behavioral symptoms should always be evaluated for possible physical, as well as psychological, causes of underlying problem behaviors.

Behaviors may be periodic and repetitive, episodic, or seemingly random. A thorough assessment should not only attempt to identify the underlying cause but also the event or precipitating factors that trigger the behaviors.

Once the underlying cause and triggers are identified, a behavioral intervention plan can be developed and implemented. In some cases, the behavior can be controlled or prevented simply by removing the trigger. An example would be a female resident who becomes agitated when a male nurse assists her with dressing. Another example is a resident who becomes agitated when left sitting alone. It may be possible to devise specific programs or interventions to address the underlying causes of the behavior.

Other non-pharmacologic approaches have been used. Music, for example, has been shown to reduce agitation, and music therapy can reduce anxiety and agitation through stress reduction. Although controlled studies are lacking, art therapy, pet therapy, spiritual activities, massage therapy, and aromatherapy are used for patients with BPSD.[5]

Environments can alleviate or intensify BPSD. Attention to colors, lighting, identification of one's room, noise levels, and temperature are all important variables.[5]

Teri and Logsdon[6] have used the following non-pharmacologic approach to behavior management:
1. Identify the target symptoms.
2. Determine when the symptoms are most likely to occur.
3. Determine events that may precipitate or contribute to the symptoms.
4. Set up a planned intervention.
5. Continue to evaluate and alternate treatment approaches as necessary.

What is the evidence to support non-pharmacologic management of BPSD?

Clinical trials of non-pharmacologic therapy have been mixed and of limited value.[7] Because of funding limitations, these trials tend to be small in size and extrapolation of the results may not be appropriate. It is also difficult to randomize patients to a blinded study because the nature of the interventions require that participants (including facility staff) be aware of the interventions.

In the nursing home setting, limitations on number and training of facility staff, along with high turnover of personnel, serve as barriers to use of non-pharmacologic interventions. These interventions require trained staff, can be time-consuming to employ, and must be individualized to the needs and nature of the resident problems.

Nursing homes have evolved to the point where the vast majority of residents have one or more mental health problems, yet few nursing homes have staff with specialized training in psychology or behavior management. The result is that medications have become the dominant approach to management of BPSD.

What is the evidence that supports the use of antipsychotic medications for treatment of PBSD?

Almost a century ago, Alzheimer described a patient who had not only loss of cognitive functioning but also hallucinations, delusions of sexual infidelity, paranoia, agitation, and physical aggression. Despite his salient case description, for most of the rest of the century little attention was paid to the psychotic and other behavioral and psychologic symptoms of the illness that bears his name.[5]

It wasn't until the late 1980s that measurements and scales were developed to study BPSD. The Cohen-Mansfield Agitation Inventory, which studied abnormal behaviors in people with dementing illness, was published in 1986. The BEHAVE-AD, which combined behavior with anxiety, depression, and psychotic symptoms, was published in 1987. These scales provided the basis for conducting research in this neglected area.[5]

As late as 1990, a meta-analysis revealed that only seven double-blind placebo-controlled studies had been conducted in elderly patients using antipsychotic medication.[1] Only one trial had been conducted in nursing home residents. Clinical trials have been conducted, with mixed results, on a variety of classes of medications for these symptoms.[7,8] These drug classes include:

- Antipsychotics (typical and atypical subtypes)
- Antiepileptic medications
- Antidepressant medications
- Cholinesterase inhibitors
- Analgesics (for presumed pain as a cause of symptoms)
- Buspirone
- Propranolol

As of the end of 2011, the U. S. Food and Drug Administration has still not approved any medicines to treat BPSD. Canada has approved risperidone, an atypical antipsychotic, for this indication.[9]

The Agency for Healthcare Research and Quality evaluated the off-label use of atypical antipsychotic agents in 2011.[10] They found "moderate or high" evidence of efficacy for risperidone to treat psychosis and agitation in older adults with dementia, and some evidence to support use of olanzapine and aripiprazole for these purposes.

In April 2011, the American Geriatrics Society released a Guide to the Management of Psychotic Disorders and Neuropsychiatric Symptoms of Dementia in Older Adults.[11]

The American Psychiatric Association issued practice guidelines for the treatment of patients with Alzheimer's disease and other dementias in 2007.[12] The use of antipsychotics is supported in this guideline when non-pharmacologic strategies are inadequate. The guideline concludes, "On the basis of good evidence, antipsychotic medications are recommended for the treatment of psychosis in patients with dementia and for the treatment of agitation. These medications have also been shown to provide modest improvement in behavioral symptoms in general."

The Centers for Medicare & Medicaid Services (CMS) issues a State Operations Manual (SOM) with regulations and guidance for surveyors of health care

facilities. Appendix PP of this manual addresses nursing facilities.[13] This CMS manual recognizes that "distressed behaviors" of nursing facility residents should be managed with non-pharmacological interventions when possible, and provides guidelines when medication use is needed for this purpose (tag F329).

When residents with dementia manifest behavioral symptoms, CMS guidelines call for:

- Comprehensive assessment of the resident to identify potential underlying causes, including physical problems
- Identifying the specific problem behavior(s), such as hitting, kicking, etc.
- Quantifying the number of episodes of problem behaviors and tracking over time
- Evaluating results of any non-pharmacologic or pharmacologic interventions on the number of episodes of behavioral symptoms

In the case of antipsychotic use for BPSD, the CMS guidelines further call for:

- 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
- Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs

What additional provisions are in place to protect nursing facility residents?

Nursing facilities certified to participate in the Medicare/Medicaid programs must comply with federal regulations and are surveyed at least annually based on those regulations and the interpretive guidelines set forth by the Centers for Medicare & Medicaid Services (CMS) in the CMS State Operations Manual.[13] Tag F-329 discusses the facility's responsibility to ensure that residents do not receive unnecessary medications, including antipsychotics.

This manual also includes other protections for residents, including:

- Facilities are required to have a consultant pharmacist review the drug regimen of every resident monthly
- Facilities are required to have a medical director
- Facilities are required to have a Quality Assessment and Assurance Committee to oversee quality of care provided to residents
- Licensed nurses administer medications to residents and monitor for potential adverse effects

More details about these regulations and survey guidance can be found in Appendix A of this document.

What is the role of the consultant pharmacist with respect to medication use in nursing facility residents?

Regulations from the Centers for Medicare & Medicaid Services require that every nursing home resident have a monthly medication regimen review performed by a pharmacist. The CMS State Operations Manual includes specific guidance on medication use for nursing home residents, and the consultant pharmacist uses this CMS guidance to help ensure that drug therapy for residents conforms to these CMS standards and other appropriate clinical standards.

Consultant pharmacists help to advise physicians and nursing facility staff on appropriate use of antipsychotics and other psychotherapeutic medications. The American Society of Consultant Pharmacists has a variety of policy documents that relate to these responsibilities of the consultant pharmacist, including:

- ASCP Code of Ethics[14]
- ASCP Statement on Use of Antipsychotic Medications in Nursing Facility Residents[15]

What factors have resulted in higher utilization of antipsychotic medicines among nursing facility residents?

Nursing home residents today are much more acutely ill, both physically and mentally, than nursing home residents were 10 or 20 years ago. The growth of assisted living has resulted in less acute older adults moving to alternative settings, so that nursing homes are now getting the most seriously ill older adults.

In addition, the number of psychiatric and long-term mental health hospitals has declined in recent years. Patients who formerly would have resided in one of these facilities now reside in nursing facilities. Therefore, antipsychotic use for true long-standing psychiatric illnesses is more common in nursing facilities today than it was in the past.

Antipsychotic medicines are frequently initiated during a hospital stay, often inappropriately. Once begun in the hospital, it may take weeks or months for the nursing home resident to be tapered gradually from these medicines. The past medical history of new nursing home admissions is often murky, and physicians may be reluctant to change medicines that a patient has been taking previously from another physician.

High turnover of facility staff, lack of staff training in behavior management, lack of adequate staff, and the culture of the nursing facility can all contribute to overuse of medicines, including antipsychotics. Implementation of non-pharmacologic strategies is more challenging when the number or training of staff is less than adequate.

Are antipsychotic medicines overused in nursing home residents?

Approximately 25% of nursing home residents receive an antipsychotic medicine, according to 2012 data from CMS, and the use of these medicines has been stable in recent years. Significant variation exists when state-level data from the CMS Online Survey Certification and Reporting (OSCAR) database is reviewed. The proportion of nursing home residents receiving an antipsychotic medication ranges from a low of 12.4% in Hawaii to a high of 33.5% in Louisiana.[16]

A recent study found unexplained variation across U.S. nursing homes in antipsychotic prescribing rates.[17] The authors found significant facility-level variation in antipsychotic drug use. Their study provides evidence that "antipsychotic prescribing varies by nursing homes, independent of residents' clinical characteristics, and nursing homes' antipsychotic prescribing culture may be an important component to explain such variations." The authors call for additional research to explore this issue.

By the standards of experts in mental health care of nursing home residents, non-pharmacologic strategies should be more widely used in nursing homes so that medicines would be used less. If medicines are used, however, the antipsychotic class of medicines has the most robust evidence base for efficacy.[1,7] On the safety side, antipsychotics are known to increase the risk of mortality in older adults with dementia, and the Food and Drug Administration requires a boxed warning on the product labeling with this information. First generation antipsychotics (e.g. haloperidol) have a greater risk of mortality than second generation antipsychotics (e.g. risperidone).[18]

Fewer studies have been conducted with other classes of medicines. Although evidence of efficacy is more limited than with antipsychotics, a medicine from another class may be preferred in certain cases due to safety considerations. Treatment of BPSD is generally by trial and error, no matter which medicine is used, because each patient may respond differently (or not at all) to different medicines.

What policy changes are needed to improve management of BPSD in nursing home residents?

More research is definitely needed to explore strategies, pharmacologic and non-pharmacologic, for management of BPSD. These behavioral symptoms vary widely in type and severity from patient to patient, so research can be challenging to perform. Much more needs to be known, however, about how to manage patients with these symptoms.

Other policy changes are needed as well. Nursing facility staff need better training in managing behavioral symptoms in residents with dementia, and

facilities need adequate reimbursement and strategies to help recruit and retain adequate staff to implement behavior management programs.

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Appendix A

Nursing Facility Regulations and Survey Guidance on Antipsychotic Medications

Nursing facilities certified to participate in the Medicare/Medicaid programs must comply with federal regulations and are surveyed at least annually based on those regulations and the interpretive guidelines set forth by the Centers for Medicare & Medicaid Services (CMS). These regulations and interpretive guidelines can be found in the CMS State Operations Manual. Appendix PP of the State Operations Manual contains the regulations and interpretive guidelines for long-term care facilities.

In that appendix, section F-329 discusses the facility's responsibility to ensure that residents do not receive unnecessary medications. This section of the regulations also discusses appropriate use of antipsychotics. It is important to note that this is the only specific class of medication mentioned in the nursing facility regulations.

The regulations pertaining to antipsychotics are listed below:

> **F329, Unnecessary Drugs**
> 42 CFR §483.25(l)
>
> Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:
>
> (i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and
>
> (ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

In addition to the specific requirements above regarding antipsychotics, there is also a requirement for consultant pharmacist services. Consultant pharmacists are tasked with oversight of antipsychotics and all other drugs and biologics used by residents in the nursing facility. These services are also mandated by regulation and accompanying guidelines, as seen below:

> ***F425, Pharmacy Services***
> 42 CFR §483.60
>
> The facility must employ or obtain the services of a licensed pharmacist who--

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility

F428, Drug Regimen Review
42 CFR §483.60(c)

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and these reports must be acted upon.

As seen above, the critical role of the pharmacist is written into the regulations governing nursing facility participation in the Medicare and Medicaid programs. Pharmacists provide needed expertise in pharmacotherapy and the unique medication-related needs of the senior population in order to improve quality of care and quality of life. In so doing, pharmacists assist the facility to meet their obligations under the Federal requirements for participation in the Medicare and Medicaid programs. Consultant pharmacists assist nursing facilities in developing and implementing comprehensive strategies to reduce the inappropriate use of antipsychotic medications.

In addition to regulatory oversight, the comprehensive assessment tool mandated for all Medicare/Medicaid-certified nursing facilities also plays an important role in tracking and monitoring residents taking antipsychotics. The assessment tool, called the Minimum Data Set (MDS), is part of the Resident Assessment Instrument. These questionnaires and care planning tools provide a comprehensive assessment of each resident's functional capabilities and help nursing facility staff identify residents' health problems.

The MDS data also feed into the facility's Quality Measure (QM) and Quality Indicator (QI) reports. The QM reports are made available to the public through the Nursing Home Compare Web site. The QI reports are used by surveyors during the survey process. The MDS collects information about each resident's behaviors and antipsychotic use upon admission and on a quarterly and annual (and more frequently, if needed) basis.

Among the MDS-based Quality Indicators used by surveyors to identify potential care issues prior to surveys, one indicator measures the prevalence of antipsychotic use in the absence of a psychotic disorder or related condition. A facility that scores high on this indicator could be depending on medications as their primary strategy for managing behavioral symptoms rather than individualizing strategies based upon the needs of each resident. This could indicate that additional training or assistance is needed for facility staff in effective management of behavioral symptoms.