

FINDING REAL SOLUTIONS FOR BEHAVIORAL HEALTH NEEDS IN PERSONS WITH DEMENTIA

Kelly Bagby and Sue Renz

Housekeeping & Logistics

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Advocating Against The Illegal and Excessive Use of Psychotropic Drugs with People with Dementia

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Impact of Psychotropic Drugs

Psychotropic drugs affect mental activity, emotion, and behavior (e.g., antipsychotics, antidepressants, mood stabilizers)

- Side effects can be very harmful; lower quality of life
- increased vulnerability to infections
- excessive sedation, lethargy, dizziness and unsteadiness which can lead to increased falls and injuries, increased risk of bed sores
- parkinsonism (tremors and rigidity), body restlessness
- reduced well-being, loss of appetite, social withdrawal
- accelerated cognitive decline

Antipsychotics, Approved Uses

FDA has approved the use of 10 atypical antipsychotic drugs for the treatment of schizophrenia and/or bipolar disorder.

Source: FDA Website, last accessed on April 11, 2017, at <http://goo.gl/oy1kR>.

What is a Black Box Warning Drug??

A boxed warning (sometimes "black box warning", colloquially) is a type of warning that appears on the **package insert** for certain prescription drugs, so called because the U.S. Food and Drug Administration specifies that it is formatted with a 'box' or border around the text.

Drugs With Black Box Warning

Risperdal (Risperidone)
Zyprexa (Olanzapine)
Seroquel (Quetiapine Fumarate)
Geodon (Ziprasidone Hydrochloride; Ziprasidone Mesylate)
Abilify (Aripiprazole)
Invega (Paliperidone; Paliperidone Palmitate)
Haldol (Haloperidol Decanoate; Haloperidol Lactate; Haloperidol)
Moban (Molindone Hydrochloride)
Navane (Thithixene)
Orap (Pimozide)
Symbyax (Fluoxetine Hydrochloride; Olanzapine)
Clozaril (Clozapine)
Fazaclo (Clozapine)

Content of Label

Warning Label - Geodon

“Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at **an increased risk of death.**”

“Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group [and] **most of the deaths appeared to be either cardiovascular...in nature.**”

Warning Label - Seroquel

“Antipsychotic drugs are **associated with an increased risk of death...**[and Seroquel] is not approved for elderly patients with Dementia-Related Psychosis.”

Off-Label Uses in Nursing Facilities

- **Despite known dangers**, antipsychotic (sometimes called psychotropic) drugs are commonly prescribed to elderly nursing facility residents for uses not approved by the FDA
- To **control unwanted/challenging behavior** caused by dementia
- To **avoid increased staffing and training** for non-pharmacological interventions to modify these behaviors
- Doctors are allowed to prescribe Rx for off-label uses
- Serious concerns that the risks and alternative interventions are NOT given appropriate consideration and consent not obtained

Kickbacks and Other Illegal Inducements

FOR IMMEDIATE RELEASE

Monday, October 17, 2016

Nation's Largest Nursing Home Pharmacy to Pay Over \$28 Million to Settle Kickback Allegations

The nation's largest nursing home pharmacy, Omnicare Inc., has agreed to pay \$28.125 million to resolve allegations that it solicited and received kickbacks from pharmaceutical manufacturer Abbott Laboratories in exchange for promoting the prescription drug, Depakote, for nursing home patients....

“Every day, elderly nursing home residents suffering from dementia rely on the independent judgment of our nation's healthcare professionals for their personal care and their medical treatment,” said Principal Deputy Assistant Attorney General Benjamin C. Mizer, head of the Department of Justice's Civil Division. “Kickbacks to entities making drug recommendations compromise their independence and undermine their role in protecting nursing home residents from the use of unnecessary drugs.”

Abbott Laboratories Paid \$1.5 Billion for Promoting Depakote Be Used on Elderly Patients With Dementia

“Abbott’s off-label promotion of Depakote was multifaceted. The company entered into contracts that provided long-term care pharmacy providers with payments of rebates based on increases in the use of Depakote in nursing homes serviced by the providers. In addition to using its sales force to promote the drug to health care providers and employees of nursing homes, Abbott created programs and materials to train the pharmacy providers’ consultant pharmacists about the off-label use of Depakote to encourage them to recommend the drug for this unapproved use. Under these contracts, Abbott paid millions of dollars in rebates to the pharmacy providers.”

--2012 Press Release from DOJ

Kickbacks and Other Illegal Inducements

- Johnson & Johnson guilty plea for promoting Risperdal to treat dementia-related behavior while downplaying deadly risks, criminal and civil fines totaling \$2.2 billion. Source: FDA Office of Criminal Investigations, <http://goo.gl/NExp55>.
- Eli Lilly took a criminal plea and paid \$1.45 billion to resolve several cases alleging off-label promotion of Zyprexa to elderly people in nursing facilities. Notwithstanding the above, Zyprexa is still commonly administered in nursing facilities to people with dementia and despite the potentially fatal consequences.

Non-Pharmacological Interventions

Preferred, Safer

Clinical guidelines:

- assess the scope and severity of the behavior
- identify any environmental triggers for the behavior
- determine if behavioral symptoms are associated with another medical condition, such as under-treated arthritis pain, constipation, or dehydration
- use drugs **only** when other, non-pharmacological attempts to ameliorate the behaviors have failed; AND
- the individual poses a threat to themselves or to others

Antipsychotics or Not, Who Decides?

- There is no FDA-approved psychotropic drug treatment for dementia-related behaviors
- No evidence showing significant differences in behavior attributable to atypical antipsychotic drugs as compared to non-pharmacological interventions.

*See Clinical Guidelines, The Society for Post-Acute and Long-Term Care Medicine (AMDA), reviewing clinical studies.

Levine v. Ventura Convalescent Hospital

Devastation from the Drugs was Quick and Complete

Ms. Levine believed that the drugs turned her mother into a person with little cognitive function who would babble nonsense at all hours of the night, too confused and sleepy to even participate in the physical therapy that had been the purpose of her admission to the facility.

Once her mother was discharged, her doctor tried in vain to wean her off the powerful medications. Within a few weeks, her mother died.

Legacy of Levine (in materials)

- In July 2014, the AARP Bulletin ran a Special Report entitled, “Prescription for Abuse: Antipsychotics in Nursing Homes,” in which this litigation and the issue of inappropriate medications in nursing facilities was described in detail. The response to the Bulletin article has been overwhelming from members nationwide whose families suffered similar horrible experiences.
- AARP Foundation was contacted by dozens of people who had suffered terrible losses from the exact kind of scenarios as Ms. Levine and her mom.
- AARP Letter to CMS and FDA

Negligent Monitoring after Drugs are Administered

Many facilities administer the drugs and do not monitor the consequences:

Somnolence

Confusion

Restlessness

Shuffling

Falls

Loss of appetite

Dysphasia

Parkinsonian reactions

Thank you!!

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Finding Real Solutions for Behavioral Needs in Persons with Dementia

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December 16, 2020

Dementia and Long-Term Care

- Home health agencies (4,742,500)
 - 31.4%
- **Nursing Homes (1,383,700)**
 - **50.4%**
- Hospice (1,244,500)
 - 44.7%
- Residential Care Facilities (713,300)
 - 39.6%
- Adult Day Service Centers (273, 200)
 - 29.9%

Behavioral and Psychological Symptoms of Dementia

- Disturbed perception, thought content, mood or behavior
- Occur in up to 90% of patients with dementia over the course of illness
- Impacts the caregiver burden
- Typically cause more distress than the hallmark cognitive symptoms inherent to dementia
- Often contribute to admission to long-term care institutions

Behavioral and Psychological Symptoms of Dementia

How does memory impairment lead to behavioral problems?

Example: Patient is able to dress himself, but can't remember where his clothes are kept



Walks around naked

Behavioral and Psychological Symptoms of Dementia

How does impaired recognition (agnosia) lead to behavioral problems?

Example: Patient can maneuver to pull down his pants, but can't recognize that a toilet is a receptacle for urination.



Urinate on floor

Behavioral and Psychological Symptoms of Dementia

How does impairment in performance of motor tasks (apraxia) lead to behavioral problems?

Example: Patient is continent of bladder, but cannot unzip or unbutton to pull down her pants.



Wets her clothing

BPSD Symptom Spectrum

Behavioral

- Physical/Verbal
 - Restlessness
 - Wandering/Pacing
 - Hitting/scratching/biting
 - Throwing things
 - Social inappropriateness
 - Physical sexual advances
 - Screaming/cursing
 - Temper outbursts

Psychological

- Depression/Anxiety
- Apathy
- Sleep disturbances
- Psychosis
 - Hallucinations
 - Delusions

Evaluation of Symptoms

Identify underlying cause of agitation or aggression

- Delirium
- Medications
- Sensory deficits
- Cognitive/language deficits
- Pain
- Sleep issues
- Depression/anxiety/apathy/psychosis
- Unmet needs
- Environmental triggers

Nonpharmacological Management

- Shown to reduce agitation and anxiety in dementia
- Techniques should be individualized

Incorporates:

- Behavioral Interventions
- Caregiver education and training
- Sensory techniques

Nonpharmacological Management: Behavioral Intervention

Avoid Triggers

- Ensure a consistent routine and environment
- Sudden changes can precipitate confusion and subsequently agitation
- Determine/anticipate unmet needs (pain, thirst, hunger, etc.)
- Language and memory deficits can hinder communication of what is needed
- “Person-centered” care

Nonpharmacological Management: Caregiver Education

- Communication skills training
- Provide calm, reassuring communication when patients seem anxious
- Use redirection and distraction techniques

Nonpharmacological Management: Sensory Techniques

- Aromatherapy
- Music therapy
- Massage and touch therapy
- Exercise
- Pet therapy

Nonpharmacological Management

- “Correct the correctables”
- Monitor closely
- Stop non-essential medications (drug toxicity or drug induced delirium common)
- Reduce psychiatric symptoms
- Provide cognitive structure/emotional support
- Maintain function

Medications

Use of Antipsychotics

- Increased mortality when used for dementia- related psychosis
- Increased risk of stroke, MI, and death
- Reserved for symptoms that are severe, debilitating, or pose safety risks
- Agitation/aggression
- Psychosis
- Should NOT be used routinely and should be regularly reassessed
- No clear evidence indicating benefit of 1st generation antipsychotics in dementia

Indications for antipsychotics

- Poses a danger to self or others
- Uncontrolled agitation despite non-pharmacological interventions
- Anxiety in the presence of agitation and/or hallucinations
- Need to decrease agitation for diagnostic or clinical intervention

Indications for antipsychotics

New FDA Warning Added to Antipsychotic Labeling

- Antipsychotics cause falls and fractures as the result of:
 - Somnolence
 - Postural hypotension
 - Motor and sensory instability
- Recommends a fall risk assessment
 - When initiating antipsychotics
 - Recurrently for long-term use

Summary

- A wide range of behavioral and psychological symptoms can occur with dementia.
- It is important to identify the underlying cause of agitation and aggression.
- Some symptoms may be related to chronic illness.
- Many symptoms of BPSD can be managed by nonpharmacological methods and caregiver education.
- Antipsychotics should only be used when safety is an issue, or when a resident has severe or debilitating symptoms that cannot be managed using other interventions.
- Antipsychotics should not be used routinely.



Avoiding Drugs As



Chemical Restraints

Changing the Culture of Care

A CONSUMER EDUCATION CAMPAIGN

The National Consumer Voice for Quality Long-Term Care & AARP Foundation

<https://theconsumervoice.org/stop-chemical-restraints>

Avoiding Drugs as Chemical Restraints

CONSUMER FACT SHEET

Everyone who enters a nursing home has a right to individualized, person-centered care. Some nursing facilities, however, are giving residents antipsychotic drugs, not to treat a medical diagnosis, such as Schizophrenia or Bipolar Disorder, but rather to control the resident's behavior or for the staff's convenience. When used this way as a chemical restraint, these drugs pose special risks for older people and increase the risk of death in persons with dementia.

Signs of Someone at Risk for Chemical Restraints

When individuals, including residents with medical conditions such as dementia, are unable to express themselves using words, they express themselves through actions. For example, a resident may repeatedly moan to show they are in pain. These actions should not be dismissed. Instead, they should be evaluated to identify what the resident is trying to communicate. Other examples of behavioral communication that require further evaluation include:

- Anger, Distress, Agitation
- Screaming, Swearing, Spitting
- Hitting, Lashing out
- Confusion, Paranoia, Delusions
- Crying, Sadness, Fear
- Continuous wandering, Repetitive actions, Failure to cooperate

These actions or behaviors
are signals that something
is wrong!

Signs that A Resident May Have Been Chemically Restrained

Negative effects often associated with chemical restraints can also be the result of other factors such as illness or adverse effects of other drugs. However, if a resident has the following symptoms, raise questions and ask that their drug regimen be reviewed.

- Sedation (difficulty waking the resident to eat or for a visit)
- Disordered thinking, delirium, depression, hallucinations, delusions
- Distress
- Dry mouth
- Decreased appetite
- Tardive Dyskinesia (repetitive, involuntary movement of the head, tongue, and sometimes the trunk, fingers, and toes)
- Parkinsonian symptoms



Avoiding Drugs as Chemical Restraints: Consumer Fact Sheet

A CONSUMER EDUCATION PODCAST

PURSuing QUALITY LONG-TERM CARE



Know Your Drugs & Know Your Rights

Questions to ask your care provider
and a list of drugs often used
as chemical restraints



Medications can be helpful if they are treating an illness. It is important to be aware of whether a drug is being used for treatment or as a restraint. You should be told about any drug before it is given to you so you can decide if you consent or want to refuse it.

Questions to ask your healthcare provider about medications that have been prescribed for you or a loved one:

- 1 Why was this drug ordered? What symptoms or behavior prompted it?
- 2 Could an illness be causing these symptoms?
- 3 Is this medication specifically for the cause/symptoms?
- 4 What are our non-drug options?
- 5 What was done to treat or eliminate the cause/symptoms before resorting to this medication? Was enough time given to figuring out the causes?
- 6 Is the drug one of those with a black box warning?
- 7 What are the side effects/risks of the medication?
- 8 Why do you believe the benefits outweigh those risks?
- 9 What possible interactions will it have with other drugs?
- 10 What is your plan for monitoring the use of the drug and weaning off/stopping it?

Avoiding Drugs As Chemical Restraints

Changing the Culture of Care

A CONSUMER EDUCATION PROGRAM

By Michael Gorman, Director of Health Care Quality, The Consumer Voice

If you need help or have questions about your long-term care,
contact your Long-Term Care Ombudsman Program at:
https://theconsumerveoice.org/get_help