

# PSYCHOTROPIC MEDICATIONS WORK GROUP

## BACKGROUND

### ***Discussion of challenging behaviors***

In Phase Two of the Alzheimer’s Challenging Behaviors Task Force, the Psychotropic Medications Work Group discussed several issues related to the pharmacologic treatment of challenging behaviors. First and foremost, the Work Group emphasized that non-pharmacologic approaches are preferable and should always be the starting point in treating challenging behaviors. The Work Group also agreed that each case is different; there is no “one size fits all” in terms of when it is appropriate to use medications or which specific medications to use.

For the purposes of our Task Force, the term “challenging behaviors” was selected because it reflects not only the behaviors that may be exhibited by a person with dementia, but also because these behaviors are challenging to address by everyone associated with the person, including family members, paid caregivers, and health care personnel. In the context of medicine, the behaviors exhibited by the person with dementia are categorized as Behavioral and Psychological Symptoms of Dementia (BPSD).

*According to the Alzheimer’s Association, Individuals living with dementia may experience behavioral and psychotic symptoms (BPSD) during the course of their disease due to the alteration in processing, integrating and retrieving new information that accompanies dementia. Studies have found that more than 90 percent of people with dementia develop at least one BPSD with a significant percentage of these individuals having serious clinical implications. Depression, hallucinations, delusions, aggression, agitation, wandering and “sun downing” are hallmark behavioral and psychotic symptoms of dementia, commonly manifested in moderate- to severe stages of disease. These symptoms cause considerable caregiver stress, and frustration is often the breaking point prior to institutionalization in long-term care facilities. Many of these (BPSD) are also the impetus to falls, weight loss, infection and incontinence in individuals with dementia.<sup>1</sup>*

### ***Psychotropic medications***

As defined in Wisconsin state statutes, a “psychotropic medication refers to a prescription drug that is used to treat or manage a psychiatric symptom or challenging behavior. Some psychotropic medications fall into specific medication classes like antipsychotics or antidepressants. In other cases, the medications may be primarily used for other diseases but have been found effective in controlling behaviors thus making that specific use a psychotropic medication.”<sup>2</sup>

### ***Potential underlying reasons for challenging behaviors***

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<sup>1</sup> Alzheimer’s Association National Board of Directors, “Challenging Behaviors” statement, approved September 2011 [http://www.alz.org/documents\\_custom/statements/challenging\\_behaviors.pdf](http://www.alz.org/documents_custom/statements/challenging_behaviors.pdf), accessed October 8, 2012.

<sup>2</sup> Psychotropic Medications as defined in Chapter 55.01 of State of Wisconsin Statutes <[www.dhs.wisconsin.gov/rl\\_dsl/.../psychMeds.pdf](http://www.dhs.wisconsin.gov/rl_dsl/.../psychMeds.pdf)> accessed on October 1, 2012.

Many practitioners have come to understand that challenging behaviors are a form of communication, especially for those who have lost their ability to communicate and regulate their emotions. The American Geriatrics Society cites three categories of potential triggers for challenging behaviors: physiologic, environmental, and caregiver communication. It is also possible that current medications (including over-the-counter) can exacerbate challenging behaviors. According to the Alzheimer's Society (UK), more than ninety-percent (90%) of people with dementia will experience BPSD as part of their illness.<sup>3</sup> The organization also notes that, "Sudden emergence of BPSD often has a physical trigger."<sup>4</sup>

### ***About delirium***

Delirium is a relatively common condition among older adults, and one that is highly co-morbid with dementia. According to the American Geriatrics Society, delirium is found in one-third of hospitalized medical patients over age 70 and in one-third of patients over age 70 presenting to emergency department.<sup>5</sup> Delirium is diagnosed when the following characteristics are present, using the Confusion Assessment Method rating scale<sup>6</sup>

1. Acute change in mental status and fluctuating course.
  2. Inattention
  3. Disorganized thinking
  4. Altered level of consciousness
- (note: the diagnosis requires that both characteristics 1 and 2 are present and either 3 or 4)*

Delirium is worth special attention because of its prevalence in people undergoing a "care transition", i.e., a move from one setting to another, such as from a hospital to a skilled nursing facility. The condition is often treated with psychotropic medication, and the Work Group's concern is twofold: 1) that these medications are often prescribed unnecessarily, i.e., before non-pharmacologic interventions are used, and 2) that people remain on these medications beyond their usefulness, putting people at risk for complications. The Work Group is singling out the treatment of delirium as a critical area where we need to "change the practice default", looking first at non-pharmacologic interventions and in cases where these are ineffective or when a person exhibits severe aggression or psychosis that place them and those caring for them at risk of imminent harm, using psychotropic medications with gradual dose reduction.

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<sup>3</sup> Alzheimer's Society (UK) "Optimising treatment and care for people with behavioural and psychological symptoms of dementia" A best practice guide for health and social care professionals. United Kingdom: July 2011.

<sup>4</sup> Alzheimer's Society, 10.

<sup>5</sup> *Geriatrics Evaluation and Management: DELIRIUM, Developed by the American Geriatrics Society (AGS) 2012* < [http://www.srfmr.org/uploads/patient\\_education/1337971806-4133ee54e69a34787/GEM%20-%20Delirium.pdf](http://www.srfmr.org/uploads/patient_education/1337971806-4133ee54e69a34787/GEM%20-%20Delirium.pdf) > Accessed September 10, 2012.

<sup>6</sup> Mittal, Vikrant. MMuralee, Sunanda. Williamson, Deena. McEnery, Nicole. Thomas, Jennifer. Cash, Mary, Tampi, Rajesh R. "Review: Delirium in the Elderly: A Comprehensive Review, American Journal of Alzheimer's Disease and Other Dementias 2011, 26." < <http://aja.sagepub.com/content/26/2/97> > Accessed September 10, 2012.

Another area of concern is the need to assess the underlying cause(s) of delirium. In *Review: Delirium in the Elderly: A Comprehensive Review by Mittal et al (2011,)* the authors conclude,

*Although not fully understood, it appears that delirium develops due to a complex interplay between various predisposing and precipitating factors... Increasing age and pre-existing cognitive deficit are thought to be the 2 most common predisposing factors for delirium.*

*A study by Inouye demonstrated that a simple predictive model based on 4 predisposing factors—vision impairment, severe illness, cognitive impairment, and BUN/creatinine ratio—can identify at admission older persons at greatest risk for delirium.*

*Inouye and Charpentier identified 5 independent precipitating factors for delirium in the elderly: use of physical restraints, malnutrition, more than 3 medications added, use of bladder catheter and any iatrogenic event.”<sup>7</sup>*

Young et al, summarizing recommendations from the National Institute for Health and Clinical Excellence (NICE), lists the following interventions in order to prevent delirium<sup>8</sup>,

*Within 24 hours of admission, assess people at risk for the following clinical factors that might precipitate delirium:*

- *Cognitive impairment, disorientation, or both*
- *Dehydration, constipation, or both*
- *Hypoxia*
- *Immobility or limited mobility*
- *Infection*
- *Multiple medications*
- *Pain*
- *Poor nutrition*
- *Sensory impairment*
- *Sleep disturbance*

When the use of a psychotropic medication is warranted, NICE recommendations call for short-term use, defined as one week or less, starting at the lowest dose possible and titrating cautiously.

### ***Pharmacologic approaches to treating BPSD: psychotropic medications in general***

An alert issued in 2008 by the Food and Drug Administration warned that, “Antipsychotics are not indicated for the treatment of dementia-related psychosis...both conventional and atypical

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<sup>7</sup> Ibid

<sup>8</sup> Young, John. Murthy, Lakshmi. Westby, Maggie. Akunne, Anayo. O’Mahony, Rachel. “Diagnosis, prevention, and management of delirium: summary of NICE guidance, BMJ, July 31, 2011, 341. <http://www.bmj.com/content/341/bmj.c3704> Accessed September 4, 2012.

antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis.”<sup>9</sup>

Current efforts by CMS address the inappropriate use of *antipsychotics* in nursing homes. Antipsychotics are the top-selling class of drugs in the US, generating revenues of \$14.6 billion.<sup>10</sup> Reducing the use of these medications in nursing homes will result in significant savings for the Medicare program. Our work group, however, believes that inappropriate medication use should be addressed across a broader spectrum of **psychotropic** medications that includes benzodiazepine, antidepressant and anti-anxiety medications in addition to antipsychotics; these classes of medications have their own set of potential problems and side effects. One of our concerns is that as the use of antipsychotics decreases, the use of other psychotropic medications may increase. This explains the need to address the inappropriate use of all psychotropic medications and the importance of non-pharmacologic approaches as the first step in addressing challenging behaviors. The Work Group cautions that while this summary frequently cites information related to the use of antipsychotics, it is primarily due to an abundance of data about this class of medications, and should not be construed as the primary focus of our recommendations.

### ***Pharmacologic approaches to treating BPSD: antipsychotic medications in particular***

In addition to the treatment of harmful behavioral and psychological symptoms associated with dementia, antipsychotics are typically used to treat such conditions as schizophrenia, bipolar disorder, and the treatment of psychotic symptoms such as delusions and hallucinations.<sup>11</sup> According to the American Geriatrics Society, possible side effects of antipsychotics in treating older people with dementia include increased mortality, cerebrovascular events or metabolic syndrome.<sup>12</sup> “Typical” antipsychotics, e.g., haloperidol (Haldol®), traditionally were used to control behavioral disturbances in older people; however side effects such as increased morbidity and increased likelihood of falls led more physicians to the use of second generation or “atypical” antipsychotics. Atypical antipsychotics are associated with an increased risk of stroke and death in older adults with dementia, in addition to other side effects such as tardive dyskinesia, weight gain, diabetes, insomnia, sedation, Parkinsonism, and cognitive difficulties.

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<sup>9</sup> “Information on Conventional Antipsychotics”, FDA Alert 6/16/2008  
<[www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM107211.htm](http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM107211.htm). Accessed September 11, 2012.

<sup>10</sup> Duff Wilson, “Side Effects May Include Lawsuits,” *The New York Times* (October 3, 2010)  
<[www.nytimes.com/2010/10/03/business/03psych.html?scp=1&sq=%22Side%20Effects%20May%20Include%20Lawsuits%22&st=cse](http://www.nytimes.com/2010/10/03/business/03psych.html?scp=1&sq=%22Side%20Effects%20May%20Include%20Lawsuits%22&st=cse). Accessed July 11, 2012.

<sup>11</sup> American Society of Consultant Pharmacists “Antipsychotic Medication Use in Nursing Facility Residents,”  
[www.ascp.com/articles/antipsychotic-medication-use-nursing](http://www.ascp.com/articles/antipsychotic-medication-use-nursing) 2012.

<sup>12</sup> American Geriatrics Society “A guide to the Management of Psychotic Disorders and Neuropsychiatric Symptoms of Dementia in Older Adults,” April 2011.

<b>Atypical antipsychotics</b>	
<i>Generic name</i>	<i>Brand name</i>
Aripiprazole	Abilify®
Asenapine	Saphris®
Clozapine	Clozaril®
lloperidone	Fanapt®
Lurasidone	Latuda®
Olanzapine	Zyprexa®
Paliperidone	Invega®
Quetiapine	Seroquel®
Risperidone	Risperdal®
Ziprasidone	Geodon®

After the FDA approves a medication to be marketed for a specific use, physicians are permitted to prescribe that medication for other uses. This is commonly referred to as off-label use, which is how psychotropic medications are used to treat BPSD. The FDA has issued a “black box” warning that requires physicians who prescribe antipsychotics to older patients with dementia-related psychosis to discuss the risk of increased mortality with their patients, patients’ families or their legal representatives. In addition to the known side effects of antipsychotics, the work group has also noted that the use of other psychotropic medications in older people with dementia can result in sedation and a diminished quality of life.

<p>Alzheimer’s Challenging Behaviors Task Force  Work Group Report  <b>Psychotropic Medications</b></p>
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**Co-chairs:** Joseph Goveas, MD, Medical College of Wisconsin and Cary Kohlenberg, MD, IPC Research

**Original Charge to the Work Group and Short Chronicle of Activities**

One of the recommendations from Phase 1 of the Alzheimer's Challenging Behaviors Task Force was to, "establish a work group to reduce the inappropriate use of antipsychotic medications for residents with dementia and promote alternate approaches to behavior management." The Psychotropic Medications Work Group met on two occasions at the end of 2011 (November 9<sup>th</sup> and December 8<sup>th</sup>), and on four more dates in 2012 (January 12, March 8, June 4, and August 21<sup>st</sup>).

The Work Group members included Waukesha and Milwaukee County geriatricians, geriatric psychiatrists, nurse practitioners, and other medical providers with representation from each of the major health systems in southeastern Wisconsin. Other members included social work staff from skilled nursing and assisted living facilities, staff from the Alzheimer's Association of Southeastern Wisconsin, the State of Wisconsin's Consultant Pharmacist, and other representatives from the Wisconsin Department of Health Services/Division of Quality Assurance (DQA).

Work Group members reviewed literature on the topic, shared experiences from their practices, analyzed data from the State's Division of Quality Assurance, and arrived at a set of recommendations by consensus.

### **Key Findings**

The first action taken by the Work Group was to expand the scope of charge from the inappropriate use of *antipsychotic* medications to the inappropriate use of *all psychotropic* medications. Since the prescribing practices and beliefs about the efficacy of medications varied among the work group members, there was no agreement on specific medications that should/should not be used.

The Work Group agreed to the following key findings.

- Psychotropic medications are often prescribed as a default for challenging behaviors, and are thereby used inappropriately.
- Non-pharmacologic approaches to challenging behaviors should always be attempted before psychotropic medications are prescribed.
- The medical community needs to do a better job in monitoring use and gradual dose reduction strategies of psychotropic medications in individuals with dementia.

### **Psychotropic medication use: Local and National Data**

#### **National Data**

Despite black box warnings regarding the dangers in prescribing antipsychotic medications for older adults, it is estimated that up to one-third of nursing home residents receive these medications, mostly for the treatment of behavioral disturbances.<sup>13</sup> Data from the Center for Medicare and Medicaid Services (CMS) indicates that over 17% of nursing home patients had *daily doses exceeding recommended levels* in 2010.<sup>14</sup> In May 2011, the Office of the Inspector General of the US Department of Health And Human Services issued a report with the following key findings.<sup>15</sup>

- Fourteen percent of elderly nursing home residents had Medicare claims for *atypical* antipsychotic drugs.
- Eighty-three percent (83%) of Medicare claims for *atypical* antipsychotic medications for elderly nursing home residents were associated with off-label indications; 88 percent were associated with the condition specified in the Food and Drug Administration (FDA) boxed warnings.
- Forty-one percent (41%) of Medicare *atypical* antipsychotic medication claims for elderly nursing home residents were erroneous, amounting to \$116 million.
- Twenty-two percent (22%) of the *atypical* antipsychotic medications claimed were not administered in accordance with CMS standards regarding unnecessary medication use in nursing homes.

It is important to note that this analysis was limited to the utilization of only the newer generation (i.e., atypical) antipsychotics and did not include the use of first generation or “conventional” antipsychotics, antidepressants, benzodiazepines (or anti-anxiety agents). We believe that the inappropriate use of all groups of psychotropic medications to treat behavioral disturbances in dementia is higher.

### Local data

Local observations on the use of psychotropic medications in adults with dementia mirror the national data. The picture in Wisconsin and specifically in Waukesha and Milwaukee Counties is consistent with

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<sup>13</sup> Huybrechts, Krista F. et al “Comparative Safety of Antipsychotic Medications in Nursing Home Residents” JAGS, 60:420, 2012. The authors cite four separate studies regarding prescribing rates and concluded “up to one-third of all NH [nursing home] residents receive APMs [antipsychotic medications]”.

<sup>14</sup> “CMS Announces Partnership to Improve Dementia Care in Nursing Homes”, press release issued by CMS Media Relations Group, May 30, 2012.

<sup>15</sup> “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, OEI-07-08-00150,” Office of Inspector General, Department of Health and Human Services, May 2011, <<http://oig.hhs.gov/oei/reports/oei-07-08-00150pdf>> Accessed July 11, 2012.

what is being observed nationally as depicted in the State of Wisconsin Department of Health Services/Division of Quality Assurance data presented in Table 1<sup>16</sup>. The work group noted differences in the prescribing rates between Waukesha and Milwaukee counties. For example, while the Waukesha County facilities were noted to have lower rates of administering anti-anxiety medications, there were higher rates of administering antidepressants. The Work Group did not draw any conclusions about these differences, rather emphasized the need for the reduction of the use of *all* psychotropic medications across the board.

Table 1. Statewide and Across Milwaukee and Waukesha Counties By Resident Population Over Age 60, Staff Assigned, Psychotropic Drugs Administered as of June 30, 2012

	Antipsychotics	Anti-Anxiety	Antidepressants
WI average	19.0%	19.1%	52.5%
Milwaukee Co.	18.7%	16.1%	51.5%
Waukesha Co.	20.2%	12.7%	55.5%

### **Possible reasons for the problem**

The Work Group agreed that the differences in prescribing rates among facilities may be due to several factors including but not limited to the staff: resident ratio; mix of residents in terms of health status and age; level of physical, recreational and social activities; access to a geriatric psychiatrist; caregiver education and attitudes about dementia; and non-prescribing or prescribing culture of providers. The work group noted that skilled nursing facilities have significantly decreased their use of physical restraints to control behaviors. However, members expressed the concern that physical restraints have to some extent been replaced by chemical restraints. In addition, lawsuits filed across the country

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<sup>16</sup> "State of Wisconsin, Department of Health Services/Division of Quality Assurance MDS Data Current as of June 30, 2012, compiled by Anthony Reeves, Information Management Section, March 2012.

suggest that the pharmaceutical companies have engaged in illegal off-label marketing of these medications.<sup>17</sup>

According to a handbook published by the Dementia Education and Training Program for the State of Alabama, common reasons that nursing homes have problems with psychotropic medications include:

- No consideration of behavioral management.
- No diagnosis for medication.
- Wrong diagnosis for medication.
- No assessment of medication's side effects.
- No documentation of medication's benefit for resident.
- Unnecessary dose reduction for schizophrenia or bipolar disorder.
- No explanation for continued medication.<sup>18</sup>

### **Importance of non-pharmacologic approaches**

Experts agree that the first step in treating someone with dementia who is exhibiting challenging behaviors should be non-pharmacologic in nature. According to the American Geriatrics Society, "Non-pharmacologic interventions have been shown to be more effective than pharmacologic treatment for dementia-related behavioral problems and therefore should be attempted first."<sup>19</sup> Furthermore, the Alzheimer's Society (UK) notes that many people with BPSD will experience significant improvement or resolution of symptoms over a 4-6 week period.<sup>20</sup> The organization states, "watchful waiting is the safest and most effective therapeutic approach unless there is severe risk of or extreme distress." It defines watchful waiting as "an active process over four weeks involving ongoing assessment of contributing factors and simple non-drug treatments. It does not mean 'doing nothing'."<sup>21</sup>

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<sup>17</sup> Singer, Natasha "Johnson & Johnson Accused of Drug Kickbacks", New York Times, January 16, 2010. The author cites federal charges against other pharmaceutical companies (Omnicare, Eli Lilly) in support of this argument.

<sup>18</sup> Powers RE. Overview of OBRA Guidelines for Psychiatric Care in Nursing Homes, In: A short practical guide for psychotropic medications in dementia patients. Produced by the Dementia Education & Training Program for the State of Alabama Bureau of Geriatric Psychiatry (2008). <http://www.alzbrain.org/pdf/handouts/5021.pdf> Accessed July 11, 2012.

<sup>19</sup> The American Geriatric Society, "A guide to the Management of Psychotic Disorders and Neuropsychiatric Symptoms of Dementia in Older Adults", April 2011.  
<http://dementia.americangeriatrics.org/AGSGeriPsychConsult.pdf>

<sup>20</sup> Alzheimer's Society, UK. "Optimising treatment and care for people with behavioural and psychological symptoms of dementia: A best practice guide for health and social care professionals." p. 11.  
[http://www.alzheimers.org.uk/site/scripts/download\\_info.php?fileID=1163](http://www.alzheimers.org.uk/site/scripts/download_info.php?fileID=1163)

<sup>21</sup> *ibid*

Examples of non-pharmacologic interventions include:

- Music during meals and/or bathing
- Walking or light exercise
- Reducing noise
- Examining environmental stimuli including light and sound not only to prevent challenging behaviors but to help promote overall well-being
- Engaging in meaningful activities, e.g., the TimeSlips program (a research-based creative engagement program for people with dementia)<sup>22</sup>
- Pet therapy
- Person-centered care.

The willingness of residential facilities to approach challenging behaviors using a spectrum of non-pharmacologic approaches varies. The extent to which staff is trained in these approaches is one critical factor. The Training Work Group of the Alzheimer's Challenging Behaviors Task Force is recommending that in choosing a care facility, family members ask questions about the extent of staff training, including what topics are covered under dementia-specific training. To help understand what constitutes "good training", the Work Group has developed a list of "Key Concepts in Dementia Training", building on the work of over 30 national organizations.<sup>23</sup>

- Training family caregivers in preventing challenging behaviors is also critical. The Alzheimer's Association recommends training and education for both professional and family caregivers on psychosocial interventions that might include:  
Routine activity
- Separate the person from what seems to be upsetting him or her
- Assess for the presence of pain, constipation or other physical problem.
- Review medications, especially new medications
- Travel with them to where they are in time
- Don't disagree; respect the person's thoughts even if incorrect
- Physical interaction: maintain eye contact, get to their height level, and allow space
- Speak slowly and calmly in a normal tone of voice. The person may not understand the words spoken, but he or she may pick up the tone of the voice behind the words and respond to that
- Avoid point finger-pointing, scolding or threatening.
- Redirect the person to participate in an enjoyable activity or offer comfort food he or she may recognize and like
- If you appear to be the cause of the problem, leave the room for a while
- Validate that the person seems to be upset over something. Reassure the person that you want to help and that you love him or her
- Avoid asking the person to do what appears to trigger an agitated or aggressive response<sup>24</sup>

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<sup>22</sup> Information about the TimeSlips program can be found at <http://www.timeslips.org>. TimeSlips is licensed by the University of Wisconsin-Milwaukee.

<sup>23</sup> "Summary Report of the Training Work Group of the Alzheimer's Challenging Behaviors Task Force" September 2012. (not yet published) – when this document is published, do not say not yet published, write the page numbers

<sup>24</sup> "Challenging Behaviors Statement". Approved by the Alzheimer's Association National Board of Directors, September 2011. [http://www.alz.org/national/documents/statements\\_antipsychotics.pdf](http://www.alz.org/national/documents/statements_antipsychotics.pdf)

### **When are psychotropic medications necessary?**

According to the Alzheimer's Association, *"If non-drug approaches fail after they have been applied consistently, introducing medications may be appropriate when individuals have severe symptoms or have the potential to harm themselves or others. Medications can be effective in some situations, but they must be used carefully and are most effective when combined with non-drug approaches."*

In its guidelines governing the use of medications issued to nursing home surveyors, the CMS provides indications for the use of antipsychotics in the elderly. In F329 42CFR 483.25(l) it states: *"Based upon 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."*

While the Work Group agreed that reducing the use of psychotropic medications in general is a positive step, they also acknowledged that in some situations, these medications might be indicated. It is not the Group's intention to make it impossible for physicians to prescribe psychotropic medications, rather it is merely to change the practice default.

### **When are psychotropic medications unnecessary?**

According to CMS Regulation F329, 42CFR 483.25(l):

*"Each resident's medication regimen must be free from unnecessary medications. An unnecessary medication is any medication used*

- *In excessive doses (including duplicate therapy); or*
- *for excessive duration; or*
- *without adequate monitoring; or*
- *without adequate indication for use; or*
- *In the presence of adverse consequences which indicate the dose should be reduced or discontinued."*

The Pharmacy Practice Consultant for the Wisconsin Department of Health Services' Division of Quality Assurance, who is a member of the Work Group, suggests that it is important to ask three questions

before considering whether or not to administer a psychotropic medication for a challenging behavior. He asks, “Is the behavior

1. Persistent?
2. Harmful?
3. Caused by other treatable reasons?”<sup>25</sup>

### **Barriers in achieving work group outcomes**

1. Insufficient data on use of psychotropics outside skilled nursing facilities.

While there was interest in addressing the use of psychotropic medications in community and other residential settings aside from skilled nursing facilities, the work group found there was insufficient data to indicate the extent of the problem outside of skilled nursing facilities. It was also noted that people treated in community settings may often see multiple physicians, which makes monitoring and evaluating their medications even more difficult. Given the complexity of the problem and the need for the work group to limit its scope given the amount of time and resources available, the group agreed that recommendations would be general so that they could apply to anyone involved in managing medications, regardless of the setting.

2. Insufficient data on psychotropic use other than antipsychotics.

The current CMS focus on reducing the use of antipsychotics has resulted in numerous studies and data-tracking programs specific to this class of medications; however, we lack comparable information on the use of other psychotropic medications.

3. Insufficient data on prescribing rates and practices

While representatives from the State Division of Quality Assurance worked hard to provide data on the use of psychotropic medications in skilled nursing facilities, use of the Minimum Data Set (MDS 3.0) pointed to data inaccuracies and an incomplete picture as to variables that may be affecting the data, e.g., the work group was unable to draw any conclusions about prescribing rates because of possible variations in resident selectivity or access to a geriatrician/psychiatrist.

### **Work Group recommendations**

1. Psychotropic medications should not be used as a default for treating challenging behaviors associated with dementia.
2. Psychotropic medication should *only* be used after ruling out all possible causes for the behavior and exhausting non-pharmacologic interventions.

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<sup>25</sup> Doug Englebert, R.Ph, Pharmacy Practice Consultant for the Wisconsin Department of Health Services’ Division of Quality Assurance, Alzheimer’s Challenging Behaviors Task Force – Psychotropic Medications Work Group meeting, January 12, 2012.

3. Before prescribing psychotropic medications, current medications should be carefully reviewed. Many medications can worsen the symptoms of dementia and can actually exacerbate challenging behaviors (Refer to 2012 AGS Beers Criteria for a listing, found in the “Resource” section)
4. When psychotropic medications are used, they should be prescribed at the lowest effective dosage possible.
5. A written care plan should be developed to monitor and document the challenging behavior. Documentation should include indication(s) for the medication, side effects, effect on the quality of life of the person with dementia, anticipated duration, and plan for gradual dose reduction over time. (This is often not done and leads to an inability to ascertain whether the treatment is working or is worsening the condition).
6. If a person with dementia moves to a different care setting, written or electronic medication lists should be reconciled to assure accuracy.
7. Written or electronic care plans should be reviewed on at least a quarterly basis with more frequent review for medications prescribed for the onset of new behavioral symptoms.
8. When antipsychotic medications are used to treat delirium related behavioral disturbances, the medications should be tapered and subsequently discontinued after a short period of time (days to weeks) rather than waiting for the quarterly review.

### **Resources identified by the Work Group to share with others**

The Work Group reviewed the literature surrounding practice guidelines and algorithms for the management of BPSD. The Group concluded that the field of psychopharmacy is rapidly changing, and now that the issue of reducing the use of inappropriate psychotropic medication has the attention and resources of CMS, there will likely be new developments. Two of the more useful resources identified by the Work Group are described here.

1. *“Optimising treatment and care for people with behavioural and psychological symptoms of dementia” A best practice guide for health and social care professionals. Alzheimer’s Society (United Kingdom: July 2011)* Available online at [http://www.alzheimers.org.uk/site/scripts/download\\_info.php?fileID=1163](http://www.alzheimers.org.uk/site/scripts/download_info.php?fileID=1163)

This 2011 practice guide developed in the United Kingdom was developed by an advisory group of leading clinicians specializing in dementia for use in all care settings with the exception of acute care hospital stays. The guideline is straightforward and easy-to-follow, utilizing a color-coded traffic light toolkit system. The guide, *“aims to provide evidence-based support, advice and resources to a wide range of health and social care professionals caring for people with dementia.”* The Work Group noted its applicability in treating BPSD in everyday settings and its emphasis on alternatives to medication treatment.

2. *2012 AGS Beers Criteria (Medications to Avoid - Delirium, Dementia, Cognitive Impairment)*

The Beers Criteria, a list of potentially inappropriate medications for older adults, was originally published in 1991 by Mark Beers, MD and colleagues for nursing home residents and subsequently expanded and revised in 1997 and 2003 to include all settings of geriatric care. The criteria were again updated by the American Geriatrics Society and an interdisciplinary panel of experts in 2012.<sup>26</sup> An abridged list can be found in the **Resource** section of this document.

## Success Story **pull out?**

### A residential facility's success story: reducing medications while increasing nonpharmacologic interventions

*Alice, a retired beautician, and her husband, Lenny, enjoy fishing and trips to the cottage. She was 74 years old when she moved into a nursing home. She maintained a very active lifestyle and was still walking independently when she arrived. On the day she moved in, however, Alice's husband was unable to awaken her until 3 p.m. due to her being overly sedated from the clonazepam he had been giving her at home. His physician instructed him to increase the dose when Alice became upset, agitated or had difficulty sleeping. Lenny was only trying to keep her safe and living at home for as long as he could. Alice's family knew that it was time for her to move to a dementia care facility.*

*Alice has been living at the nursing home for almost 2½ years. She seemed to enjoy her new environment. The number of other residents living with her was both overwhelming and exciting. Being a beautician, she loved all the wonderful heads of hair that she could "work" on. Unfortunately, the recipients were not as accepting of this. Some of her peers communicated their dislike by hitting, pushing and yelling at her. Alice, unable to understand, would reciprocate those actions. In response, the staff turned her room into a makeshift beauty shop, with wigs, hair accessories, brushes, clips etc. But this would only hold Alice's attention for a short time. The interactions with her peers continued and become somewhat dangerous as she would often times pull their hair in an attempt to "style" it.*

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<sup>26</sup> American Geriatric Society "The AGS 2012 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults" 2012. Available online at

[http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria\\_JAGS.pdf](http://www.americangeriatrics.org/files/documents/beers/2012BeersCriteria_JAGS.pdf)

*Meanwhile, Alice was also dealing with insomnia. She had sleepless nights and restless days. She started to eat less. Mirtazapine was started in an attempt to increase her appetite (at one time she did need an IV placed for severe dehydration). Several other medications were initiated over the course of this time. Alice's medication regime included the use of clonazepam, divalproex sodium, mirtazapine, and quetiapine, plus Tramadol for pain management.*

*Staff moved Alice to the other side of the facility where her peers were less mobile and there was less chance for confrontation. Family remained very attentive and would come in to assist her with meals and take Alice for walks. As Alice's dementia progressed, her ability to walk independently also declined. She participated in physical therapy and was able to maintain her ability to walk with assistance. Dose reductions in her clonazepam and divalproex sodium were attempted and successful. Gradual reductions in quetiapine were also attempted and successful.*

*During this time, Lenny and Alice's daughter noticed that she was becoming more responsive during their visits, talking more, and overall her mood seemed to be improving. Her appetite also increased greatly (she really liked the donut Lenny would bring her every day) and the mirtazapine was slowly decreased with no adverse effects. Alice is now receiving only trazodone for insomnia, which Lenny agrees should slowly be decreased.*

*Initially, the use of medications helped Alice through a difficult stage of her dementia; however the gradual reductions, along with meaningful, engaging, social situations, have improved her quality of life as she continues her journey with dementia.*

### **Opportunities to move this issue forward**

- Following the May 2011 release of the Inspector General report described on page 8, the United State Senate Special Committee on Aging, chaired by Sen. Herb Kohl, held a hearing in November of 2011 to review the report, receive testimony, and consider possible regulatory or legislative changes that may be needed. Tom Hlavacek, Executive Director of the Alzheimer's Association/Southeastern Wisconsin, provided testimony on our Task Force findings from year one. While no federal legislation or regulatory reform has been advanced so far, it is possible there will be activity in the future, and the hearing provided an opportunity to educate members of Congress on our issues.
- In February, 2012 the American Health Care Association, a non-profit federation of affiliated state health organizations representing more than 10,000 non-profit and for-profit assisted living, nursing facility, developmentally-disabled, and subacute care providers nationally,

announced a new, three year quality initiative to help nursing homes and assisted living facilities improve their delivery of person-centered care. As part of this initiative, the Association set a goal of reducing the off-label use of antipsychotics by 15% by December 2012.<sup>27</sup> (Note: The Wisconsin Health Care Association / Wisconsin Center for Assisted Living Division is a member organization).

- In March of 2012, the federal Centers for Medicaid and Medicare Services (CMS) announced it was launching the Partnership to Improve Dementia Care, a “national initiative to improve behavioral health and reduce antipsychotic use in Nursing Homes”. CMS ‘s goal is to reduce antipsychotic medication use by 15% by December 2012. The Executive Director of the Alzheimer’s Association of Southeastern Wisconsin is currently serving as an Advisory Committee member on the CMS initiative. Four steps already identified to achieve the goal of improved care include:
  1. Enhanced training – CMS had developed “Hand in Hand”, a training series for nursing homes that emphasizes person-centered care, prevention of abuse, and high-quality care for residents. CMS is also providing training focused on behavioral health to state and federal surveyors;
  2. Increased transparency – CMS is making data on each nursing home’s antipsychotic medication use available on its Nursing Home Compare website;
  3. Alternatives to antipsychotic medication – CMS is emphasizing non-pharmacologic alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities.<sup>28</sup>
  4. The establishment of state-level Partnership Coalitions to coordinate and advance these goals. In Wisconsin the first teleconferences related to this coalition took place in the summer of 2012 and more activity is planned.
- The Wisconsin Clinical Resource Center (WCRC) project is jointly sponsored by the Wisconsin Department of Health Services (DHS), Wisconsin Health Care Association (WHCA/WiCal) and LeadingAge Wisconsin (formerly known as Wisconsin Association of Homes and Services for the Aging - WAHSA), through funding from the Wisconsin Department of Health Services (DHS). This project involves the development of the WCRC website, along with access to companion training materials.
- The WCRC website is designed as a user-friendly resource to provide key information about thirteen care areas along with access to companion training materials. The care area modules include challenging behaviors, dementia and distressed behaviors, pain management, and transitions in care, among others. In addition, companion training programs for staff have been developed including Getting to the Root of the Matter: Review of the Care Process; Identifying

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<sup>27</sup> ASCP 1.

<sup>28</sup> CMS Media Relations Group 1.

Change in Resident Condition: Medical Provider Notification; Resident-Directed Care Planning; and Use of Antipsychotic Drugs.

- The State of Wisconsin Office on Aging is developing a state plan to address Alzheimer's disease. The Committee for a Wisconsin Response to Dementia is charged with developing a set of implementable recommendations to expand current resources, make effective service and support programs widely available, enact legislative changes for systems improvements, and identify sources of funding to embed the changes in the system permanently.
- The State of Wisconsin Division of Quality Assurance is actively seeking greater access to Medicare Part D data and data from the Medicare/Medicaid Care Coordination Office, to enhance our understanding of variables affecting prescribing rates on a facility-by-facility basis. The State is also launching Virtual PACE, a managed care program for dual-eligible (Medicare and Medicaid) individuals residing in nursing home settings. Among many other quality indicators, Virtual PACE will focus on medication utilization, including psychotropic medications within this population, many of whom have dementia diagnoses.

### **Our challenge to the community**

As a result of the recent Helen E.F. ruling in Wisconsin that Chapter 51 is not an appropriate vehicle for people with dementia (without a co-occurring mental illness), work group members are concerned that the use of psychotropic medications will increase as a form of chemical restraint for people with challenging behaviors. One community challenge would be to establish a system to monitor the use of all classes of psychotropic medications to ensure that a decrease in one does not lead to an increase in another. Who will take the lead in this effort?

### **Summit Response to the Report of the Work Group on the Use of Psychotropic Medications**

Participants in the Summit praised the report presented by the work group and many expressed their surprise and relief that there are non-pharmacological alternatives and options that can be effective in addressing the challenging behaviors that may be exhibited by those with Alzheimer's disease. Many of the practitioners indicated that they were not aware there was so much overuse of psychotropic medications or that there were counter-indications for their prescription. Recommendations from participants at the Summit included the following:

- Recognize that reducing the use of psychotropic medications must be done in conjunction with an associated increase in behavioral interventions and that these interventions require training, time and funding;

- Train staff and families on the use of non-pharmacological approaches including exercise, music, art therapy and environmental adaptations;
- Engage the resident, doctor and caregiver in reviewing social history and establishing an individualized plan of care which gives preference to behavioral approaches; and
- Establish protocols and parameters that promote an institutional culture so that antipsychotic drugs are used as a last resort, in the smallest effective dose and for the shortest feasible time.