Antipsychotics and the Nursing Home

Lisa M. O’Hara, PharmD, CGP
Corporate Director of Clinical Services
The State Operations Manual

Part 1: F329 – Unnecessary Drugs
Medication Management Defined

- Helps promote or maintain mental, physical, and psychosocial well-being
  - Indication
  - Monitoring
  - Dose (including duplicate therapy)
  - Duration
  - Gradual dose reductions/Tapering
  - Prevention, identification, and response to adverse consequences
Medication Evaluation Triggers

- Admission or re-admission
- Clinically significant change in condition
- New, persistent, or recurrent clinically significant symptom or problem
- Worsening of existing problem
- Unexplained decline in function or cognition
- New medication order or renewal or orders
- Irregularity identified by the consultant pharmacist
Unnecessary Drugs Defined

- In excessive dose
- For excessive duration
- Without adequate monitoring
- Without adequate indications for use
- In the presence of adverse effects that signify the need to reduce the dose or discontinue the drug
- In any combination of the above
Monitoring Defined

- An ongoing collection and analysis of information (observations and test results)
  - Comparison to baseline
    - Evaluate response to therapy
      - Meeting target or goal of therapy
  - Detect complications
    - Potential adverse consequences
    - Adverse consequence prediction
  - Support treatment decisions
Surveyor Goals

- Guidance (F329) intended to help surveyors determine if medication promotes mental, physical, or psychosocial well-being:
  - Risk vs. Benefit was addressed
  - Signs and symptoms evaluated (Indication)
  - Appropriate doses and duration
    - Tapering and gradual dose reductions
      - Rationale for contraindication
  - Non-pharmacological interventions
  - Monitoring efficacy and adverse outcomes
    - Progress towards therapeutic goals
    - Recognition, evaluation, reporting, management by facility, action of prescriber
Keep this Handy!

- The surveyor’s review of medication use is not intended to constitute the practice of medicine.
  - However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.
F329 and Antipsychotics
“Typical” or “First Generation” Antipsychotics

- Chlorpromazine (Thorazine)
- Fluphenazine (Prolixin)
- Haloperidol (Haldol)
- Loxapine (Loxitane)
- Molindone (Moban)
- Perphenazine (Trilafon)
- Thioridazine (Mellaril)
- Thiothixene (Navane)
- Trifluoperazine (Stelazine)
“Atypical” or “Second Generation” Antipsychotics

- Aripiprazole (Abilify)
- Asenapine (Saphris)*
- Clozapine (Clozaril)
- Iloperidone (Fanapt)*
- Lurasidone (Latuda)*
- Olanzapine (Zyprexa)
- Paliperidone (Invega)*
- Quetiapine (Seroquel)
- Risperidone (Risperdal)
- Ziprasidone (Geodon)
Indication for Use

- DSM Criteria
  - Schizophrenia
  - Schizoaffective disorder
  - Delusional disorder
  - Mood disorders (mania, bipolar disorder, depression with psychotic features, major depressive disorder)
  - Schizophreniform disorder
  - Psychosis NOS
  - Atypical psychosis
  - Brief psychotic disorder
  - Dementing illness with associated behavioral symptoms
  - Medical illnesses or delirium with manic or psychotic symptoms and/or treatment related psychosis or mania (thyrotoxicosis, neoplasms, high dose steroids)
Criteria for Use

- Facilities must ensure that:
  - 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**
  - Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.
Criteria for Use - “OR”

- Diagnosis alone do not warrant use; clinical condition must also meet the following:
  - (A) Symptoms are due to mania or psychosis OR
  - (B) Behavioral symptoms present a danger to the resident or to others OR
  - (C) Symptoms are causing one or more of the following: inconsolable or persistent distress, a significant decline in function and/or major difficulty in receiving needed care
Criteria for Routine Use - “AND”

- Additional requirements for enduring psychiatric conditions must meet the previous requirements for use AND the behavior must be identified and monitored objectively and quantitatively to ensure the symptoms:
  - Not due to a underlying medical condition or problem that can be expected to resolve as the medical condition resolves; AND
  - Persistent or likely to reoccur without continued treatment; AND
  - Not sufficiently relieved by non-pharmacological interventions, AND
  - Not due to environmental stressors that can be addressed; AND
  - Not due to psychological stressors, anxiety, or fear due to misunderstanding related to cognitive impairment that can be expected to resolve as the situation is addressed
Criteria for PRN Use – “AND”

- Additional requirements for acute psychiatric situations must meet the previous requirements for use and **ALL** of the following:
  - Acute treatment period of $\leq 7$ days; **AND**
  - Evaluation and documentation within 7 days, identifying and addressing any contributing and underlying causes and verifying continued need for treatment; **AND**
  - Pertinent non-pharmacological interventions **must** be attempted, unless contraindicated, following the resolution of the acute situation.
Inadequate Indications for Antipsychotics

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

- Nervousness
- Uncooperativeness
- Inattention/indifference to surroundings
- Verbal expressions and/or behaviors that do not present danger to the resident or to others
Monitoring of all Psychoactives

- Review continued need at least quarterly
- Document rationale for continuing
  - Resident’s target symptoms
  - Effects of the medication(s)
    - Benefit vs. Risk
  - Changes in resident’s function
  - Medication-related adverse consequences
Monitoring: Antipsychotics May be Considered Unnecessary When in the Presence of Side Effects

- Anticholinergic effects
- Akathisia (internal restlessness)
- Neuroleptic malignant syndrome
  - Delirium, hypertensive crisis, raised WBC, raised CPK, rhabdomyolysis
- Falls
- Lethargy/Excessive sedation
- Parkinsonism
- Tardive dyskinesia (repetitive, involuntary, purposeless movements)
- Increased total cholesterol and triglycerides
- Increased blood sugar
- Orthostatic hypotension
- Cardiac arrhythmias
- Cerebrovascular event (stroke, TIA in elderly with dementia)
Gradual Dose Reduction (GDR)

- Stepwise dose reduction used to determine if symptoms, conditions, or side effects can be managed by a lower dose or if the medication can be discontinued
- Determines benefit and appropriate dose
- Necessary even when condition has improved or stabilized
- Often the only way to determine continued benefit and need by the resident
Antipsychotics

- GDR required for use of antipsychotics, unless clinically contraindicated
- Attempted within the 1st year of admittance to the facility or initiation of an antipsychotic by the facility in 2 separate quarters, with at least 1 month in between attempts
- After the 1st year, a GDR must be attempted annually
Clinical Contraindications for GDR

- In residents with behavioral symptoms related to dementia, if:
  - Symptoms return or worsen after most recent GDR attempt AND
  - Clinical reasoning is documented by the physician explaining why a GDR would be inappropriate at that time
Clinical Contraindications for GDR

- In residents being treated for conditions other than behavioral symptoms related to dementia, if:
  - Continued use is within current practice guidelines and the physician has documented why a GDR attempt would be inappropriate OR
  - Symptoms returned or worsened during most recent GDR attempt and the physician has documented why a GDR would be inappropriate at that time
Example Note: Clinically Contraindicated

- Resident has had recurrent behaviors with previous dose reduction (date). Behaviors are aggressive (explicitly what are they) in nature and do not allow for assisted self-care (which care is affected) essential for this resident’s well-being. Resident is without side-effects of therapy and these continue to be monitored per facility protocol.

Benefit > Risk.
When and Why the Scrutiny Started

Part Two: FDA Warnings
Risperdal (risperidone) Dear Healthcare Professional Letter Apr 2003

This is the text of a letter from Janssen Pharmaceutica Inc. Contact the company for a copy of any referenced enclosures.


JANSSEN PHARMACEUTICA INC.

IMPORTANT DRUG INFORMATION

16-April-2003

Dear Healthcare Provider,

Janssen Pharmaceutica Products, L.P., would like to inform you of important changes regarding Risperdal (risperidone). The Risperdal prescribing information has been updated with the addition of the following information:

WARNINGS

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia

Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with risperidone compared to patients treated with placebo. Risperdal has not been shown to be safe or effective in the treatment of patients with dementia-related psychosis.

This update is based on data from 4 placebo-controlled trials conducted in elderly patients with dementia (N=1230). Additional information on these and other clinical trials conducted in elderly patients can be obtained by calling 1-800-JANSSEN (600-526-7736). We remind you that, like all other antipsychotics, Risperdal is not indicated for the treatment of dementia.

Janssen Pharmaceutica Products, L.P., remains committed to providing you with the most current product information available for the management of your patients. Please refer to the enclosed package insert for full prescribing information. As always, we request that serious adverse events be reported to Janssen at 1-800-JANSSEN (6026-7736) or to the FDA MedWatch program by phone 1-800-FDA-1088, by fax (1-800-FDA-0176), or by email (www.fda.gov/medwatch). For additional medical information about Risperdal or any other Janssen product, please call 1-800-JANSSEN (526-7736) from 9AM to 5PM EST, Monday through Friday.

Sincerely,

Christine Cole, MD
Vice President, Medical Affairs
Janssen Pharmaceutica Inc.
Risperdal (risperidone) Dear Healthcare Professional Letter Aug 2004

The following information is from Janssen Pharmaceutica, Inc. Contact the company for a copy of any referenced enclosures.

Dear Health Care Provider,

Janssen Pharmaceutica, Inc. would like to inform you of important labeling changes regarding Risperdal® (risperidone). The FDA has asked all manufacturers of atypical antipsychotic medications, including Janssen Pharmaceutica, Inc. to add a Warnings statement describing the increased risk of hyperglycemia and diabetes in patients taking these medications, including Risperdal.

Accordingly, the Risperdal Prescribing Information has been updated with the addition of the following information:

WARNINGS

Hyperglycemia and Diabetes Mellitus

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including Risperdal. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycemia-related adverse events in patients treated with atypical antipsychotics are not available. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control.

Patients with risk factors for diabetes mellitus (eg, obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.

If you have any questions regarding this important safety information, please contact Janssen Medical Affairs at 1-800-JANSSEN. Please refer to the full prescribing information for RISPERDAL included with this letter. As always, we request that serious adverse events be report to Janssen at 1-800-JANSSEN or to the FDA MedWatch program by phone (1-800-FDA-0186), by fax (1-800-FDA-0178), or by e-mail (www.fda.gov/medwatch).

Sincerely,

Ramy A. Mahmoud, MD, MPH
Vice President, CNS
Janssen Medical Affairs, LLC
Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances

The issues described in this communication have been addressed in product labeling (see Drugs@FDA).

4/11/2005

The Food and Drug Administration has determined that the treatment of behavioral disorders in elderly patients with dementia with atypical (second generation) antipsychotic medications is associated with increased mortality. Of a total of seventeen placebo controlled trials performed with olanzapine (Zyprexa), aripiprazole (Abilify), risperidone (Risperdal), or quetiapine (Seroquel) in elderly demented patients with behavioral disorders, fifteen showed numerical increases in mortality in the drug-treated group compared to the placebo-treated patients. These studies enrolled a total of 5,106 patients, and several analyses have demonstrated an approximately 1.6-1.7 fold increase in mortality in these studies. Examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

The atypical antipsychotics fall into three drug classes based on their chemical structure. Because the increase in mortality was seen with atypical antipsychotic medications in all three chemical classes, the Agency has concluded that the effect is probably related to the common pharmacologic effects of all atypical antipsychotic medications, including those that have not been systematically studied in the dementia population. In addition to the drugs that were studied, the atypical antipsychotic medications include clozapine (Clozaril) and ziprasidone (Geodon). All of the atypical antipsychotics are approved for the treatment of schizophrenia. None, however, is approved for the treatment of behavioral disorders in patients with dementia. Because of these findings, the Agency will ask the manufacturers of these drugs to include a Boxed Warning in their labeling describing this risk and noting that these drugs are not approved for this indication. Symbyax, a combination product containing olanzapine and fluoxetine, approved for the treatment of depressive episodes associated with bipolar disorder, will also be included in the request.

The Agency is also considering adding a similar warning to the labeling for older antipsychotic medications because the limited data available suggest a similar increase in mortality for these drugs.
Antipsychotic Black Box Warning

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in drug-treated patients of between 1.6 to 1.7 times the risk of death in placebo-treated patients. 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. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Observational studies suggest that, similar to atypical antipsychotic drugs, treatment with conventional antipsychotic drugs may increase mortality. The extent to which the findings of increased mortality in observational studies may be attributed to the antipsychotic drug as opposed to some characteristic(s) of the patients is not clear. RISPERDAL® (risperidone) is not approved for the treatment of patients with dementia-related psychosis.
Information on Conventional Antipsychotics

FDA ALERT [6/16/2008]: FDA is notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis.

In April 2005, FDA notified healthcare professionals that patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death. Since issuing that notification, FDA has reviewed additional information that indicates the risk is also associated with conventional antipsychotics.

Antipsychotics are not indicated for the treatment of dementia-related psychosis.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this when additional information or analyses become available.

- Conventional Antipsychotic Drugs:
  - Compazine (prochlorperazine)
  - Haldol (haloperidol)
  - Loxitane (loxapine)
  - Mellaril (thioridazine)
  - Moban (molindone)
  - Navane (thithixene)
  - Orap (pimozide)
  - Prolinx (fluphenazine)
  - Sletazine (trifluoperazine)
  - Thorazine (chlorpromazine)
  - Trilafon (perphenazine)

To report any serious adverse events associated with the use of these drugs, please contact the FDA MedWatch program using the contact information at the bottom of this sheet.
Nursing Home Antipsychotic Rate

Increased 36% since 1998

Increased 9% since 2003
Expected Decline Failed to Occur

Part Three: OIG Involvement Nursing Facilities Underperform
Office of Inspector General (OIG)

Medicare Atypical Antipsychotic Drug Claims For Elderly Nursing Home Residents

Daniel R. Levinson
Inspector General

May 2011
OEI-07-08-00150
OIG Report – May 2011

- January 1 – June 30, 2007
- Elderly (age 65 and older) nursing home residents
- Reviewed Medicare Part D and/or B claims for atypical antipsychotic drugs (1.4M claims)
- Medical record reviewed for: (700 records)
  - Off-label use
  - Use in the presence of dementia
  - Meeting Medicare reimbursement criteria
  - Meeting CMS standards for drug use
OIG Report – May 2011

- 14% of residents had Medicare claims for Atypical Antipsychotics
- 83% of those claims were for off label-use
- 88% of those claims were associated with Dementia
- 51% of these drug claims were erroneous amounting to about $116 million  
  Averaging ~ $166 per script.
- 22% were not administered in accordance with CMS standards amounting to about $63 million  
  Averaging ~ $205 per script.
Fifty-one percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were erroneous, amounting to $116 million. For the period of January 1 through June 30, 2007, we determined from medical record review that over 726,000 of the 1.4 million atypical antipsychotic drug claims for elderly nursing home residents did not comply with Medicare reimbursement criteria. The claimed drugs were either not used for medically accepted indications as supported by the compendia or not documented as having been administered to the elderly nursing home residents.
Medicare Claims Considered Unnecessary According to CMS Standards

<table>
<thead>
<tr>
<th>Reason</th>
<th>No. Claims</th>
<th>% Claims</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive Dose</td>
<td>150,106</td>
<td>10.4%</td>
<td>$36,050,851</td>
</tr>
<tr>
<td>Excessive Duration</td>
<td>135,199</td>
<td>9.4%</td>
<td>$29,369,213</td>
</tr>
<tr>
<td>Without Indication</td>
<td>115,818</td>
<td>8.0%</td>
<td>$21,396,226</td>
</tr>
<tr>
<td>Without Monitoring</td>
<td>110,949</td>
<td>7.7%</td>
<td>$18,150,616</td>
</tr>
<tr>
<td>In the Presence of Adverse Events</td>
<td>67,923</td>
<td>4.7%</td>
<td>$11,479,869</td>
</tr>
</tbody>
</table>
RECOMMENDATIONS
To ensure that payments for atypical antipsychotic drugs are correct and that elderly nursing home residents are free from unnecessary drugs, we recommend that CMS:

Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.

Assess whether survey and certification processes offer adequate safeguards against unnecessary antipsychotic drug use in nursing homes.

Explore alternative methods beyond survey and certification processes to promote compliance with Federal standards regarding unnecessary drug use in nursing homes.

Take appropriate action regarding the claims associated with erroneous payments identified in our sample.
Office of Inspector General (OIG)

Nursing Facility Assessments And Care Plans For Residents Receiving Atypical Antipsychotic Drugs

Daniel R. Levinson
Inspector General

July 2012
OEI-07-08-00151
OBJECTIVE

To determine the extent to which nursing facilities follow Federal assessment and care plan requirements designed to ensure quality of care for elderly residents receiving atypical antipsychotic drugs.

Graphic 1: Quality of Care Pathway

1. Assessment
2. Decisionmaking
3. Care Plan Development
4. Care Plan Implementation
Phase One: Assessment
- Comprehensive assessments
- Quarterly assessments

Phase Two: Decisionmaking
- Triggered conditions
- Resident Assessment Protocols (RAP)
OIG Report – July 2012

- Phase Three: Care Plan Development
  - Seven days
  - Physician, Registered Nurse, Others

- Phase Four: Care Plan Implementation
  - Physical, medical, and psychosocial objectives
  - Interventions
  - Goal evaluation
Interpretive guidelines state that nursing facilities must ensure that each resident “obtains optimal improvement or does not deteriorate” within the limits of the normal aging process.
# Overall Results

<table>
<thead>
<tr>
<th>Federal Requirements Not Documented</th>
<th>Records (n=375)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resident Assessments</td>
<td>125</td>
<td>33.3%</td>
</tr>
<tr>
<td>Decisionmaking (Consideration of RAP for psychotropic drug use)</td>
<td>15</td>
<td>4.0%</td>
</tr>
<tr>
<td>Care Plan Development</td>
<td>371</td>
<td>98.9%</td>
</tr>
<tr>
<td>Care Plan Implementation</td>
<td>67</td>
<td>17.9%</td>
</tr>
<tr>
<td>Overlapping</td>
<td>(205)</td>
<td>(54.6%)</td>
</tr>
<tr>
<td><strong>Total (net)</strong></td>
<td><strong>373</strong></td>
<td><strong>99.5%</strong></td>
</tr>
</tbody>
</table>

Source: OIG analysis of nursing facility records, 2011.
OIG Report – July 2012
Phase Two: Decisionmaking (4%)

- 15 of 375 – RAP for psychotropic drug use not considered
- 277 of 375 – Staff intended to develop care plan interventions
  - 39 of 277 (14%) – Not actually done
- 98 of 375 – Staff did NOT intend to develop care plan interventions
  - 53 of 98 (54%) – Actually done
### OIG Report – July 2012

**Phase Three: Care Plan (99%)**

<table>
<thead>
<tr>
<th>Federal Requirements Not Met</th>
<th>Records (n=375)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No care plan documentation was provided</td>
<td>23</td>
<td>6.1%</td>
</tr>
<tr>
<td>Care plans were not developed timely</td>
<td>35</td>
<td>9.3%</td>
</tr>
<tr>
<td>Care plans did not include evidence of resident/family/representative involvement or documentation as to why it was impracticable</td>
<td>221</td>
<td>58.9%</td>
</tr>
<tr>
<td>Care plans were not developed by interdisciplinary team (physician and RN)</td>
<td>363</td>
<td>96.8%</td>
</tr>
<tr>
<td>Overlapping</td>
<td>(271)</td>
<td>(72.2%)</td>
</tr>
<tr>
<td><strong>Total (net)</strong></td>
<td>371</td>
<td><strong>98.9%</strong></td>
</tr>
</tbody>
</table>

Source: OIG analysis of nursing facility resident records, 2011.
OIG Report – July 2012
Phase Four: Care Plan Implementation (18%)

- Intervention for psychotropic drug use
  - Monitoring for side-effects
  - Monitoring for effectiveness
  - Attempting gradual dose reductions
    - 18% contained interventions but records contained no evidence of occurrence
    - 23% contained no interventions
    - 41% contained no indication interventions occurred
OIG Report – July 2012

- Recommendations:
  - Improve detection of noncompliance with Federal requirements for resident assessments and care plans
  - Take appropriate action to address noncompliance with Federal requirements for resident assessments and care plans
  - Provide methods for nursing facilities to enhance the development and usefulness of resident assessments and care plans for residents receiving antipsychotic drugs
Making Sense of the Data

Part 4: AHRQ 2011 Report
Current, Concise, Complete
Agency for Healthcare Research and Quality (AHRQ)

Effective Health Care Program

Comparative Effectiveness Review
Number 43

Off-Label Use of Atypical Antipsychotics: An Update
Executive Summary

AHRQ Pub. No 11-EHC087-1
www.effectivehealthcare.ahrq.gov/reports/final.cfm
Agency for Healthcare Research and Quality (AHRQ)

Antipsychotic medicines studied in the research for this summary include:

- Aripiprazole (Abilify®)
- Olanzapine (Zyprexa®)
- Quetiapine (Seroquel®)
- Risperidone (Risperdal®)
- Ziprasidone (Geodon®)
# Agency for Healthcare Research and Quality (AHRQ)

## Table 1: Summary of Evidence for Efficacy of Atypical Antipsychotics in Dementia

<table>
<thead>
<tr>
<th></th>
<th>Aripiprazole (Abilify®)</th>
<th>Olanzapine (Zyprexa®)</th>
<th>Quetiapine (Seroquel®)</th>
<th>Risperidone (Risperdal®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia overall</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Dementia psychosis</td>
<td>+</td>
<td>+/-</td>
<td>+/-</td>
<td>++</td>
</tr>
<tr>
<td>Dementia agitation</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>++</td>
</tr>
</tbody>
</table>

**Note:**
- ++ = moderate or high evidence of efficacy
- +  = low or very low evidence of efficacy
- +/- = mixed results
<table>
<thead>
<tr>
<th>Condition</th>
<th>What benefit?</th>
<th>Which medicine?</th>
<th>How likely is the benefit?</th>
</tr>
</thead>
</table>
| Dementia   | Improved symptoms such as aggression, delusions (believing things that are not true or logical), or hallucinations (seeing things or hearing voices that are not there) Did NOT improve problems with thinking or memory | - All antipsychotics included in this summary, except for ziprasidone (Geodon®)  
- There are not enough studies on ziprasidone (Geodon®) to know if it improves symptoms | Although doctors may see small improvements in tests that score symptoms, there is not enough research to know how many are likely to see the same result. |
### Agency for Healthcare Research and Quality (AHRQ)

1.7 Million seniors reside in nursing facilities
25.2% (429,000) receive antipsychotics

<table>
<thead>
<tr>
<th>What side effect or risk?</th>
<th>Which medicine?</th>
<th>How likely is the side effect or risk?</th>
</tr>
</thead>
</table>
| Death in elderly* people with dementia | - All antipsychotics included in this summary, except for ziprasidone (Geodon®)  
- There are not enough studies on ziprasidone (Geodon®) to know if it has this side effect | For every 100 people taking one of these medicines, 1 had this side effect. |

1.7 Million seniors reside in nursing facilities
25.2% (429,000) receive antipsychotics

4,290 Annual Deaths!
Agency for Healthcare Research and Quality (AHRQ)

<table>
<thead>
<tr>
<th>What side effect or risk?</th>
<th>Which medicine?</th>
<th>How likely is the side effect or risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke in the elderly*</td>
<td>Risperidone (Risperdal®)</td>
<td>For every 34 people taking this medicine, 1 had this side effect.</td>
</tr>
</tbody>
</table>

12,600 Strokes Annually!
Agency for Healthcare Research and Quality (AHRQ)

<table>
<thead>
<tr>
<th>What side effect or risk?</th>
<th>Which medicine?</th>
<th>How likely is the side effect or risk?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncontrollable movements, such as tremors or tics</td>
<td><strong>In the elderly</strong>:  - Olanzapine (Zyprexa®)  - Risperidone (Risperdal®)</td>
<td><strong>In the elderly</strong>:  - For every 10 people taking olanzapine (Zyprexa®), 1 had this side effect.  - For every 20 people taking risperidone (Risperdal®), 1 had this side effect.</td>
</tr>
<tr>
<td></td>
<td><strong>In adults ages 18 to 64</strong>:  - Aripiprazole (Abilify®)†  - Quetiapine (Seroquel®)†  - Ziprasidone (Geodon®)†</td>
<td><strong>In adults ages 18 to 64</strong>:  - For every 11 people taking aripiprazole (Abilify®), 1 had this side effect.  - For every 36 people taking quetiapine (Seroquel®), 1 had this side effect.  - For every 24 people taking ziprasidone (Geodon®), 1 had this side effect.</td>
</tr>
</tbody>
</table>

21,450 to 42,900 develop tremors or tics
**What side effect or risk?** | **Which medicine?** | **How likely is the side effect or risk?**
--- | --- | ---
Weight gain | - All antipsychotics included in this summary, except for ziprasidone (Geodon®)†<br>- People taking olanzapine (Zyprexa®) had the greatest risk of gaining weight | - **Olanzapine (Zyprexa®):** For every 3 people taking this medicine, 1 had this side effect.<br>- **All other antipsychotics included in this summary, except ziprasidone (Geodon®):** For every 25 people taking one of these medicines, 1 had this side effect. |
<table>
<thead>
<tr>
<th>Drug Brand Name (daily dose range)</th>
<th>Aripiprazole Abilify (2-10 mg)</th>
<th>Haloperidol Haldol (0.25-2 mg)</th>
<th>Olanzapine Zyprexa (2.5-7.5 mg)</th>
<th>Quetiapine Seroquel (12.5-150 mg)</th>
<th>Risperidone Risperdal (0.25-2 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement Side Effects¹</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
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<tr>
<td>Central Nervous System</td>
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<tr>
<td>Sedation</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■</td>
</tr>
<tr>
<td>Confusion, delirium, cognitive worsening</td>
<td>■</td>
<td>0</td>
<td>■</td>
<td>■</td>
<td>■</td>
</tr>
<tr>
<td>Worsening psychotic symptoms</td>
<td>0</td>
<td>0</td>
<td>■</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cardiovascular/Metabolic</td>
<td></td>
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<tr>
<td>Orthostatic hypotension</td>
<td>■?</td>
<td>■</td>
<td>■</td>
<td>■?</td>
<td>■?</td>
</tr>
<tr>
<td>Edema</td>
<td>■?</td>
<td>0</td>
<td>■</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Weight gain/glucose ↑</td>
<td>0</td>
<td>■?</td>
<td>■</td>
<td>■?</td>
<td>0</td>
</tr>
<tr>
<td>Triglyceride ↑</td>
<td>0</td>
<td>0</td>
<td>■</td>
<td>■?</td>
<td>0</td>
</tr>
<tr>
<td>Urinary incontinence, UTI</td>
<td>■</td>
<td>■</td>
<td>■</td>
<td>■?</td>
<td>■</td>
</tr>
</tbody>
</table>

■ = more boxes indicates greater risk. Colors are darker with increasing risk.
■? = evidence poor in dementia, but evidence in other conditions indicates some risk
0 = no clear evidence that the drug causes this side effect in a clinically important way, or very rarely
¹ Movement side effects = parkinsonism, akathisia (restlessness), dystonia, tardive dyskinesia
Agency for Healthcare Research and Quality (AHRQ)

- **Summary:** Atypical Antipsychotics and Dementia
  - Moderate to strong evidence of efficacy for only a few of the drugs within class
    - Aripiprazole (Abilify)
    - Olanzapine (Zyprexa)
    - Quetiapine (Seroquel)
    - Risperidone (Risperdal)
  - Newly approved agents lack supportive clinical trials
    - Asenapine (Saphris)
    - Iloperidone (Fanapt)
    - Lurasidone (Latuda)
    - Paliperidone (Invega)
Head-to-head comparisons of atypical antipsychotic drugs for off-label uses are few, and evidence from placebo-controlled trials for off-label use suggests that efficacy differs between drugs, meaning that the assumption of a “class effect” for atypical antipsychotics may be unwarranted. This means that each drug requires its own evaluation of efficacy for each off-label indication, which is a large task; drugs demonstrated to be efficacious will need to be compared in head-to-head in trials.
CMS Initiative
5/30/2012

Part Five: CMS National Partnership to Improve Dementia Care: Rethink, Reconnect, Restore
CMS Initiative
5/30/2012

- Public-private partnership and a multi-dimensional approach to Dementia care
  - Raise Public Awareness
  - Strengthen Regulatory Oversight
  - Provide Technical Assistance and Training
  - Improve Public Reporting
  - Increase Transparency
  - Conduct Research
CMS Initiative
5/30/2012

3.5% absolute reduction (25.2% to 21.7%)

15%

428,400 vs. 369,000 = 59,400 fewer residents receiving antipsychotics

600 fewer deaths due to treatment each year
CMS Initiative
5/30/2012

- Enhanced Training
  - Hand in Hand
    - Emphasis on Person Centered Care
    - Prevention of Abuse
    - High Quality Care

- Alternatives to Antipsychotics
  - Non-pharmacological Approaches
    - Consistent Staff Assignments
    - Increased Exercise and Time Outside
    - Monitoring and Managing Pain
    - Individualized Activities
Increased Transparency:

Each Nursing Home’s Antipsychotic Drug Use Available on Nursing Home Compare

Starting July 2012
Percent of short-stay residents who newly received an antipsychotic medication. *Lower percentages are better.*

Percent of long-stay residents who received an antipsychotic medication. *Lower percentages are better.*
Ready, Set, Go!

Part 6: Where to Start
Know Your Statistics

- % new admits receiving an antipsychotic without an approved indication and discontinued within facility at 30, 60, 90 days, etc.
- % new admissions with newly started antipsychotics at the facility within the first 90 days
Know Your Statistics

- % residents > 100 day stay, on an antipsychotic without approved indication
- The number of days since the last person was started on an antipsychotic
  - Post this number in your facility!
Non-Pharmacological Approaches to BPSD
(Behavioral and Psychological Symptoms of Dementia)

Part 7: Must Have Algorithm

https://www.healthcare.uiowa.edu/igec/iaadapt/
BPSD IA-ADAPT Algorithm

Algorithm for Treating Behavioral and Psychological Symptoms of Dementia (aka Problem Behaviors)

STEP 1: IDENTIFY, ASSESS, AND TREAT CONTRIBUTING FACTORS
- Determine and document frequency, duration, intensity, and characteristics of each problem behavior
- Identify, assess, treat or eliminate ANTECEDENTS and TRIGGERS

Unmet physical needs?
- Pain
- Infection/illness
- Dehydration/nutrition
- Sleep disturbance
- Medication side effects
- Sensory deficits
- Constipation
- Incontinence/retention

Unmet psychological needs?
- Loneliness
- Boredom
- Apprehension, worry, fear
- Emotional discomfort
- Lack of enjoyable activities
- Lack of socialization
- Loss of intimacy

Environmental causes?
- Level/type of stimulation: noise, confusion, lighting
- Caregiver approaches
- Institutional routines, expectations
- Lack of cues, prompts to function & way-find

Psychiatric causes?
- Depression
- Anxiety
- Delirium
- Psychosis
- Other mental illness

Monitor outcomes to assure full treatment response
- If problem behavior persists after antecedents are adequately treated, use NON-DRUG INTERVENTIONS
Medications that can Precipitate or Worsen BPSD

IA-ADAPT Pocket Guide

<table>
<thead>
<tr>
<th>Drugs that May Cause Delirium or Problem Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Psychiatric</strong></td>
</tr>
<tr>
<td>All psychiatric medications should be reviewed as possible causes, as effects are unpredictable. Notable offenders include:</td>
</tr>
<tr>
<td>Benzodiazepines ±-E</td>
</tr>
<tr>
<td>Abamectin - Klovax</td>
</tr>
<tr>
<td>Clonazepam - Klonopin</td>
</tr>
<tr>
<td>Lorazepam - Ativan</td>
</tr>
<tr>
<td>OxAZepam - Xanax</td>
</tr>
<tr>
<td><strong>Anticholinergics</strong></td>
</tr>
<tr>
<td>Anticholinergic - those on this side of the card may impair cognition and cause psychosis. Drugs available over-the-counter marked with *</td>
</tr>
<tr>
<td>Triyclic Antidepressants</td>
</tr>
<tr>
<td>Amtriptyline - Elavil</td>
</tr>
<tr>
<td>Clomipramine - Anafranil</td>
</tr>
<tr>
<td>Desipramine - Norpramin</td>
</tr>
<tr>
<td>Doxepin - Sinequan</td>
</tr>
<tr>
<td>Imipramine - Tofranil</td>
</tr>
<tr>
<td>Nortriptyline - Aventyl, Pamelor</td>
</tr>
<tr>
<td><strong>Antihistamines / Allergy / Cough &amp; Cold Medicines</strong></td>
</tr>
<tr>
<td>Chlorpheniramine - Chlor-Trimeton</td>
</tr>
<tr>
<td>*Chlorpheniramine - Chlor-Trimeton</td>
</tr>
<tr>
<td>*Clemastine - Tavist</td>
</tr>
<tr>
<td>*Cyproheptadine - Periactin</td>
</tr>
<tr>
<td>*Doxylamine - Sinequan</td>
</tr>
<tr>
<td>*Triptolide - Triac-E</td>
</tr>
<tr>
<td><strong>Antibiotics/Immunosuppressants</strong></td>
</tr>
<tr>
<td>Aztreonam / cefepine / meropenem / imipenem / gentamicin / amikacin / tobramycin / vancomycin / teicoplanin</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
</tr>
<tr>
<td>Glipizide - Tarahalene, etc.</td>
</tr>
<tr>
<td>Nateglinide - DextroPro, etc.</td>
</tr>
<tr>
<td>Dapagliflozin - Farxiga, etc.</td>
</tr>
<tr>
<td><strong>Cardiac Medications</strong></td>
</tr>
<tr>
<td><strong>Antihypertensives</strong></td>
</tr>
<tr>
<td>*Amlodipine - Norvasc</td>
</tr>
<tr>
<td>*Candesartan - Atacand</td>
</tr>
<tr>
<td>*Captopril - Kapostil</td>
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<tr>
<td>*Enalapril - Vasotec</td>
</tr>
<tr>
<td>*Hydralazine - Apresoline</td>
</tr>
<tr>
<td>*Losartan - Coza</td>
</tr>
<tr>
<td>*Metoprolol - Toprol-XL</td>
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<tr>
<td>*Nifedipine - Adalat</td>
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<tr>
<td>*Verapamil - Calan, Isoptin</td>
</tr>
<tr>
<td><strong>Movement Disorders</strong></td>
</tr>
<tr>
<td>Benztropine -Cogentin</td>
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<tr>
<td>Trihexyphenidyl - Artane</td>
</tr>
</tbody>
</table>

| Bladder Anti-spasmodics                           |
| *Bentolax - Profenex |
| *Flavoxate - Unisop |
| Oxybutynin - Ditropan |
| Solifenacin - VESIcare |
| Tolterodine - Detrol |
| Triprolidine - Sancure |

| Insomnia / Sleep                                  |
| *Dihydroxyamine - Serotonin, Tylenol PM, others |
| *Zolpidem - Ambien, Medi-Sleep |

| Laxer and Reflux                                  |
| *Cetirizine - Zyrtec |
| *Glycopyrrolate - Robeclol |
| *Metoclopramide - Pantopon |

| GI Anti-spasmodics                                |
| Atropine - Sal-Tracine, Atropin |
| Belladonna Alkaloids - Dramamine, Belladonna S, Bell-Tale, B&O suppositories |
| Clidinium - Librax |
| Diphenoxylate - Butadine |
| Hyoscymine - Levof, Anaspine, Cymotrop |
| Methscopolamine - Pansine, Pansine Forte |
| Propranolol - Pro-Bantril |

<p>| Anticholinergic Antipsychotics                    |
| Chlorpromazine - Thorazine |
| Clorazapine - Zyprexa |
| Clozapine - Lostrane |
| Clozapine - Zyprexa |
| Minocycline - Orap |
| Quetiapine - Serque |
| Thorazine - Mellaril |</p>
<table>
<thead>
<tr>
<th>Feature</th>
<th>Delirium</th>
<th>Dementia</th>
<th>Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset</td>
<td>Usually sudden. Often at twilight.</td>
<td>Chronic and generally insidious.</td>
<td>Often abrupt and coinciding with life changes.</td>
</tr>
<tr>
<td>Duration</td>
<td>Hours to &lt; one month. Rarely longer</td>
<td>Months to years.</td>
<td>Months to years.</td>
</tr>
<tr>
<td>Progression</td>
<td>Abrupt</td>
<td>Slow but even</td>
<td>Variable and uneven</td>
</tr>
<tr>
<td>Memory</td>
<td>Impaired. Sudden *immediate memory loss may be noticeable.</td>
<td>Impaired</td>
<td>Selective or patchy</td>
</tr>
<tr>
<td>Thinking</td>
<td>Disorganised, slow, incoherent.</td>
<td>Scarcity of thought, poor judgement; words hard to find.</td>
<td>Intact with themes of hopelessness.</td>
</tr>
<tr>
<td>Sleep</td>
<td>Nocturnal confusion.</td>
<td>Often disturbed; nocturnal wandering</td>
<td>Early morning wakening.</td>
</tr>
<tr>
<td>Awareness</td>
<td>Reduced</td>
<td>Clear</td>
<td>Clear</td>
</tr>
<tr>
<td>Alertness</td>
<td>Fluctuates; lethargic or hypervigilant</td>
<td>Generally normal</td>
<td>Normal</td>
</tr>
<tr>
<td>Attention</td>
<td>Impaired, fluctuates</td>
<td>Generally normal</td>
<td>Minimal impairment but easily distracted.</td>
</tr>
<tr>
<td>Common target problems and behaviours observed in elderly people in residential care.</td>
<td></td>
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<td>----------------------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>- calling out</td>
<td></td>
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<td></td>
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<tr>
<td>- aggression</td>
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<td></td>
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<tr>
<td>- agitation</td>
<td></td>
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<td></td>
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<tr>
<td>- hallucinations and illusions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- delusions</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- wandering</td>
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<td></td>
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<tr>
<td>- depression</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- elevated mood</td>
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<tr>
<td>- “sundowning”</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- extreme anxiety</td>
<td></td>
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<td></td>
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<tr>
<td>- resistance or unease towards carers</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- intrusive behaviours</td>
<td></td>
<td></td>
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<tr>
<td>- inappropriate sexual behaviour</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- inappropriate urination or defaecation</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- other inappropriate social behaviours</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- day / night reversal</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- insomnia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- apathy / motivational failure</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 2: SELECT AND APPLY NON-DRUG INTERVENTIONS

- Select interventions based on the TYPE of problem and ASSESSMENT of retained abilities, preferences, and resources
  - Cognitive level
  - Physical function level
  - Long-standing personality, life history, interests/abilities
  - Preferred personal routines and daily schedule
  - Personal/family/facility resources
- Train staff to use selected interventions appropriately/following best practice and evidence-based guidelines
- Tailor intervention to individualized needs, combining approaches and interventions to promote comfort & function
- Monitor outcomes using rating scales to quantify behaviors
Adjust caregiver approaches

- **Personal approach:** cue, prompt, remind, distract (treats, activities); focus on person’s wishes, interests, concerns; use/avoid touch as indicated; avoid trying to reason, teach new routines, or ask to “try harder”
- **Daily routines:** simplify, sequence tasks; offer limited choices; use long-standing history & preferences to guide
- **Communication style:** simple words and phrases; speak clearly; wait for answers; make eye contact; monitor tone of voice/other nonverbal messages

Unconditional positive regard: do not confront, challenge or “explain” misbeliefs (hallucinations, delusions, illusions); accept belief as “real” to the person; reassure, comfort, and distract
- **Involvement/Engagement:** tailor activities to increase involvement/reduce boredom; individualize social and leisure activities

Change the environment

- **Eliminate misleading stimuli:** clutter, TV, radio, noise, people talking; reflections in mirrors/dark windows; misunderstood pictures/decor
- **Reduce environmental stress:** caffeine; extra people; holiday decorations; public TV
- **Adjust stimulation:** reduce noise, activity, confusion if over-stimulated; increase activity/involvement if under-stimulated (bored)
- **Enhance function:** signs, cues, pictures to promote way-finding; increase lighting to reduce misinterpretation
- **Involve in meaningful activities:** personalized program of 1:1 and small group vs. large group

Adapt the physical setting:
- secure outdoor areas; decorative tactile objects; home-like features; smaller, segmented recreational and dining areas; natural and bright light; spa-like bathing facilities; signage to promote way-finding

Use evidence-based interventions

- **Agitated/Irritable:** Calm, soothe, distract
  - Individualized music
  - Aromatherapy (e.g., lavender oil)
  - Simple Pleasures
  - Pet therapy
  - Physical exercise/outdoor activities
- **Resistant to care:** Identify source of threat; change routines and approaches
- **Wandering/Restless/Bored:** Engage, distract
  - “Rest stations” in pacing path
  - Adapt environment to reduce exit-seeking
  - Physical exercise/outdoor activities
  - Simple Pleasures
- **Disruptive vocalization:** Distract, engage
  - Individualized music: Nature sounds
  - Presence therapy: tapes of family
- **Apathetic/Withdrawn:** Stimulate, engage
  - Individualized music
  - Simple Pleasures
- **Repetitive questions/mannerisms:** Reassure, address underlying issue, distract
  - Validation therapy/therapeutic lying
  - Simple Pleasures
- **Depression/Anxiety:** Reassure, engage
  - Physical exercise
  - Pleasant activities
  - Cognitive stimulation therapy
  - Wheelchair biking
STEP 3: MONITOR OUTCOMES AND ADJUST COURSE AS NEEDED

- Quantify behavioral symptoms using rating scale(s)
- Assure adequate “dose” (intensity, duration, frequency) of interventions
- Provide/reinforce staff training and development activities to assure full understanding and cooperation in daily care
- Adapt/add interventions as needed to promote optimal outcomes
- Consider antipsychotics for persistent and severe cases that meet criteria for use. See Antipsychotic Prescribing Guide.
BPSD IA-ADAPT Algorithm Pocket Guide

**Non-Drug Management of Problem Behaviors and Psychosis in Dementia**

**Step 1: Assess & Treat Contributing Factors**
- **FOCUS on one behavior at a time**
  - Note how often, how bad, how long, & document specific details.
  - Ask: What is really going on? What is causing the problem behavior? What is making it worse?

- **IDENTIFY what leads to or triggers problems**
  - Physical: pain, infection, hunger/thirst, other needs?
  - Psychological: loneliness, boredom, nothing to do?
  - Environment: too much/too little going on; lost?
  - Psychiatric: depression, anxiety, psychosis?

- **REDUCE, ELIMINATE things that lead to or trigger the problems**
  - Treat medical/physical problems
  - Offer pain medications for comfort or to help cooperation
  - Address emotional needs: reassure, encourage, engage
  - Offer enjoyable activities to do alone, 1:1, small group
  - Remove or disguise misleading objects
  - Redirect away from people or areas that lead to problems
  - Try another approach; try again later
  - Find out what works for others; get someone to help

- **DOCUMENT outcomes**
  - If the behavior is reduced or manageable, go to Step 3
  - If the behavior persists, go to Step 2

**Step 2: Select & Apply Interventions**
- **CONSIDER retained abilities, preferences, resources**
  - Cognitive level
  - Physical functional level
  - Long-standing personality, life history, interests
  - Preferred personal routines, daily schedules
  - Personal/family/facility resources

- **DEVELOP a Person-Centered plan**
  - Adjust caregiver approaches
  - Adapt/change the environment
  - Select/use best evidence-based interventions tailored to the person’s unique needs/interests/abilities

**Step 2: Select & Apply Interventions, continued**
- **ADJUST your approach to the person**
  - Personal approach: cue, prompt, remind, distract; focus on person’s wishes, interests, concerns; use/avoid touch as indicated. Do not try to reason, teach new routines, or ask to “try harder.”
  - Daily routines: simplify tasks and put them in a regular order; offer limited choices; use long-standing patterns & preferences to guide routines & activities
  - Communication style: simple words and phrases, speak in short sentences, speak clearly; wait for answers; make eye contact; monitor tone of voice and body language
  - Unconditional positive regard: do not confront, challenge or explain misbeliefs (hallucinations, delusions, illusions); accept belief as real to the person; reassure, comfort, and distract

- **ADAPT or CHANGE the environment**
  - Eliminate things that lead to confusion: clutter, TV, radio, noise, people talking; reflections in mirrors/dark windows; misunderstood pictures or decor
  - Reduce things that cause stress: caffeine; extra people; holiday decorations, public TV
  - Adjust stimulation: if overstimulated—reduce noise, activity, and confusion; if under-stimulated (bored)—increase activity and involvement
  - Help with functioning: signs, cues, pictures help way-finding; increase lighting to reduce misinterpretation
  - Involve in meaningful activities: personalized program of 1:1 and small group or large group as needed
  - Change the setting: secure outdoor areas; decorative objects; objects to touch and hold; homelike features; smaller, divided recreational and dining areas; natural and bright light, spa-like bathing facilities; signs to help way-finding

- **SELECT and USE evidence-based Interventions**
  - Work with the team to fill the intervention to the person
  - Check care plan for additional information
  - Contact supervisor with problems/issues

**Step 3: Monitor Outcomes & Adjust Course as Needed**
- **Track behavior problems using rating scale(s)**
  - Assess adequate “dose” (intensity, duration, frequency) of interventions
  - Adapt/add interventions as needed to get the best possible outcomes
  - Make sure all people working with the person understand and cooperate with the treatment plan and are trained as needed
Behavior management might involve removing rewards for attention seeking behavior or giving rewards for increased social activity.
The problem is an expression of an un-met need – a communication that challenges you to understand.
Antipsychotic Withdrawal

Part 8: Federal Regulation vs. Clinical Standards
Gradual Dose Reduction (GDR)

- Stepwise dose reduction used to determine if symptoms, conditions, or side effects can be managed by a lower dose or if the medication can be discontinued
- Determines benefit and appropriate dose
- Necessary even when condition has improved or stabilized
- Often the only way to determine continued benefit and need by the resident
Antipsychotics

- GDR required for use of antipsychotics, unless clinically contraindicated
- Attempted within the 1st year of admittance to the facility or initiation of an antipsychotic by the facility in 2 separate quarters, with at least 1 month in between attempts
- After the 1st year, a GDR must be attempted annually
Clinical Contraindications for GDR

- In residents with behavioral symptoms related to dementia, if:
  - Symptoms return or worsen after most recent GDR attempt AND
  - Clinical reasoning is documented by the physician explaining why a GDR would be inappropriate at that time
Clinical Contraindications for GDR

- In residents being treated for conditions other than behavioral symptoms related to dementia, if:
  - Continued use is within current practice guidelines and the physician has documented why a GDR attempt would be inappropriate OR
  - Symptoms returned or worsened during most recent GDR attempt and the physician has documented why a GDR would be inappropriate at that time
Clinically Acceptable Withdrawal

- BPSD symptoms are often temporary
  - When stable, reduce
  - Reduce Q3months
  - Most patients do not worsen behaviorally
Clinically Acceptable Withdrawal

- Reduce gradually
  - Never more than 50% of dose Q2weeks
  - The longer the medication prescribed, the slower the withdrawal
    - Reduction to quickly leads to emergence of symptoms (drug withdrawal ≠ BPSD)
Reduced Yesterday and Treatment Failure Today?

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Half-Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole</td>
<td>Abilify</td>
<td>75 hours</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>Zyprexa</td>
<td>30 hours</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>Seroquel</td>
<td>6 hours</td>
</tr>
<tr>
<td>Risperidone</td>
<td>Risperdal</td>
<td>20 hours</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>Geodon</td>
<td>7 hours</td>
</tr>
</tbody>
</table>
Alternatives to Antipsychotics

Part 9: Road Blocks

Alternatives to Antipsychotics
Acetylcholinesterase Inhibitors

- Donepezil (Aricept)
- Galantamine (Razadyne)
- Rivastigmine (Exelon)
Glutamate (NMDA) Receptor Antagonist

- Memantine (Namenda)
Selective Serotonin Reuptake Inhibitors (SSRIs)

- Citalopram (Celexa)
- Escitalopram (Lexapro)
- Fluoxetine (Prozac)
- Paroxetine (Paxil)
- Sertraline (Zoloft)
- Vilazodone (Viibryd)
Other Clinically Useful Antidepressants

- Bupropion (Wellbutrin)
- Desvenlafaxine (Pristiq)
- Duloxetine (Cymbalta)
- Mirtazapine (Remeron)
- Trazodone (Desyrel)
- Venlafaxine (Effexor)
Mood Stabilizers

- Carbamazepine (Tegretol)
- Lamotrigine (Lamictal)
- Oxcarbazepine (Trileptal)
- Valproic Acid (Depakote)
Anxiolytics

- Short Acting
  - Alprazolam (Xanax)
  - Lorazepam (Ativan)
  - Oxazepam (Serax)
  - Temazepam (Restoril)
Anxiolytics

- Long Acting
  - Chlordiazepoxide (Librium)
  - Clonazepam (Klonopin)
  - Clorazepate (Tranxene)
  - Diazepam (Valium)
  - Flurazepam (Dalmane)
Final Review of Antipsychotics

Part 10: When All Else Fails…
Atypical Antipsychotics

- Aripiprazole (Abilify)
- Asenapine (Saphris)*
- Clozapine (Clozaril)
- Iloperidone (Fanapt)*
- Lurasidone (Latuda)*
- Olanzapine (Zyprexa)
- Paliperidone (Invega)*
- Quetiapine (Seroquel)
- Risperidone (Risperdal)
- Ziprasidone (Geodon)
Appropriate Antipsychotic Targets

- Aggressive behavior (esp. physical)
- Hallucinations (if distressing)
- Delusions (different from memory problems)
- Severe distress
  - Danger to self or others
    - Inconsolable or persistent distress
    - A significant decline in function
    - Substantial difficulty receiving needed care
Inappropriate Antipsychotic Targets

- Wandering
- Unsociability
- Poor self-care
- Restlessness
- Nervousness
- Fidgeting
- Mild Anxiety
- Impaired memory

- Uncooperative without aggression
- Inattention or indifference to surroundings
- Verbal expressions or behaviors that do not represent danger to self or others
Dementia Antipsychotic Prescribing Guide

General Guidelines:
1. Rule out reversible causes prior to using a drug.
2. Try non-drug management strategies first.
3. Clearly document treatment targets (symptoms) before and after a treatment strategy is tried.
4. Justify use of an antipsychotic. The treatment target symptom must present a danger to the person or others, or cause the patient to experience one of the following:
   - intractable or persistent distress
   - a significant decline in function
   - substantial difficulty receiving needed care
5. See Guidance for Special Populations, if the patient has frontotemporal dementia, Parkinson’s disease, Lewy body dementia, renal impairment, or hepatic impairment.
6. Consider the impact of side effects on comorbidities when choosing a drug, and start with a low dose.
7. If the drug doesn’t help, stop it (use appropriate tapering).

Appropriate antipsychotic treatment targets:
- Aggressive behavior (especially physical)
- Hallucinations (if disturbing)
- Delusions (note: memory problems are often mistaken for delusions, e.g., thinks people are stealing lost items)
- Severe distress as described above in #4 General Guidelines

Inappropriate antipsychotic treatment targets:
- Wandering
- Unsociality
- Poor self-care
- Restlessness
- Uncooperativeness without aggressive behavior
- Inattention or indifference to surroundings
- Verbal expressions or behaviors that do not represent a danger to the resident or others

*According to CMS regulations for long-term care facilities
Antipsychotics May be Considered Unnecessary When in the Presence of Side Effects

- Anticholinergic effects
- Akathisia (internal restlessness)
- Neuroleptic malignant syndrome (NMS)
- Falls
- Lethargy/Excessive sedation
- Parkinsonism
- Tardive dyskinesia
- Increased total cholesterol and triglycerides
- Increased blood sugar
- Orthostatic hypotension
- Cardiac arrhythmias
- Cerebrovascular event (stroke, TIA in elderly with dementia)
<table>
<thead>
<tr>
<th>Drug Brand Name (daily dose range)</th>
<th>Aripiprazole Abilify (2-10 mg)</th>
<th>Haloperidol Haldol (0.25-2 mg)</th>
<th>Olanzapine Zyprexa (2.5-7.5 mg)</th>
<th>Quetiapine Seroquel (12.5-150 mg)</th>
<th>Risperidone Risperdal (0.25-2 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Movement Side Effects(^1)</td>
<td>■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sedation</td>
<td>■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
<tr>
<td>Confusion, delirium, cognitive worsening</td>
<td>■</td>
<td>0</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
<tr>
<td>Worsening psychotic symptoms</td>
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<td>0</td>
<td>■■■■</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cardiovascular/Metabolic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthostatic hypotension</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
<tr>
<td>Edema</td>
<td>■■■■</td>
<td>0</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
<tr>
<td>Weight gain/glucose ↑</td>
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<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>0</td>
</tr>
<tr>
<td>Triglyceride ↑</td>
<td>0</td>
<td>0</td>
<td>■■■■</td>
<td>■■■■</td>
<td>0</td>
</tr>
<tr>
<td>Urinary incontinence, UTI</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
<td>■■■■</td>
</tr>
</tbody>
</table>

■ = more boxes indicates greater risk. Colors are darker with increasing risk.
■? = evidence poor in dementia, but evidence in other conditions indicates some risk
0 = no clear evidence that the drug causes this side effect in a clinically important way, or very rarely
\(^1\) Movement side effects = parkinsonism, akathisia (restlessness), dystonia, tardive dyskinesia