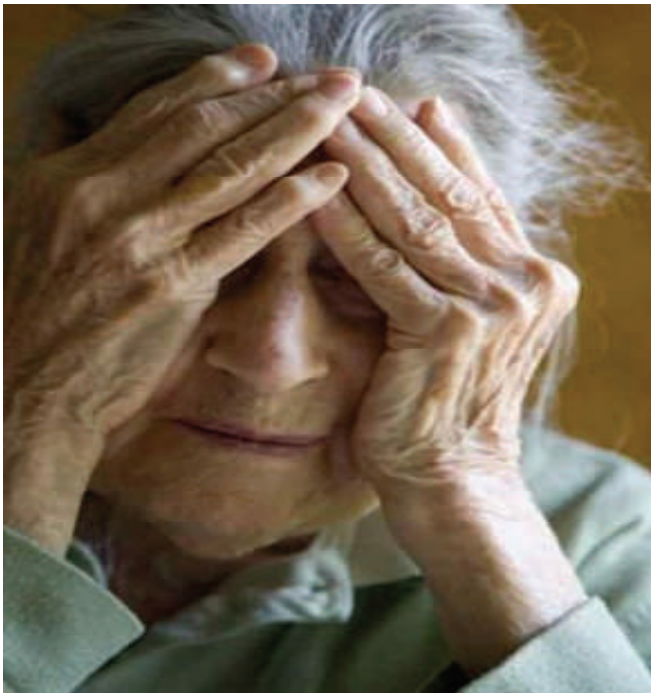
Caring for Residents with Dementia:

A Guide for Behavior Management and Evidence-Based Medication Use

A Toolkit



This project is funded by the Agency for Healthcare Research and Quality (AHRQ).

This toolkit was created by researchers at the University of Massachusetts Medical School, in partnership with Qualidigm.

UMASS University of Massachusetts Medical School

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Introduction

This toolkit contains information, tools, and resources that can help you and others in your nursing home care for people with dementia. Patients with dementia are sometimes prescribed medications, called atypical antipsychotics. One important goal of this toolkit is to increase awareness of the issues surrounding the use of these medications for behavior management.

The tabs mark sections specifically designed to meet the needs of the different people who work in nursing homes.

For example, direct care staff will find the materials in Section 3 helpful, as they include resources and tools for managing challenging behaviors. Many of the pages in this toolkit are intended to be copied and shared with others in your nursing home.

Too often we underestimate the power of a touch, a smile, a kind word, a listening ear, an honest compliment, or the smallest act of caring, all of which have the potential to turn a life around. ~Leo Buscaglia

There is no tool to help with one of the most important things to remember when caring for your residents with dementia: the ability to "walk a mile in the shoes" of these residents. Imagine how it would feel to have difficulty remembering things or to be unable to think clearly. How would you behave if you could not communicate your needs or problems with others? What if you could no longer take care of yourself and were dependent on strangers to feed, bathe, and help you in the bathroom? How would you like to be treated?

There are a number of links to additional tools and materials included in this toolkit. Additionally, this toolkit is available online at www.qualidigm.org.

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- Use of an antipsychotic should be justified by a target symptom that is thought to present a danger to the patient or others.
- If a patient develops delirium or has new challenging behaviors, a careful medication review is recommended.
- When choosing the most appropriate antipsychotic, consideration should be given to the type of dementia present as safety and efficacy of medications may vary.
- Follow dosing guidelines, do not expect an immediate response, and do not increase doses too quickly.
- Monitor for adverse effects and be familiar with how drug choice may impact the occurrence of side effects.
- To meet federal regulations, establish standardized tapering practices in your facility based on suggestions from the literature. Be sure to document all tapering trials and their results as well as establishing plans for subsequent trials and frequency.

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- Growing evidence shows increased risk of death and stroke from antipsychotics.
- Atypical antipsychotics provide at best minimal benefits for treatment of symptoms of dementia.

Section 4 – Best Practices for Prescribing – "WEIGH THE RISKS, MONITOR THE EFFECTS, AND TAPER WHEN POSSIBLE" (P. 41-76)

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Section 5 – Implementing Change – "IS YOUR FACILITY READY?" (P. 77-102)

- To successfully implement change, you will need to assess your organization's readiness for change.
- A plan to implement change in antipsychotic use should reflect your organization's readiness for change.
- The implementation team should include nursing home administrators, consultant pharmacists, nurses, and direct-care staff.

Section 6 – Resources for NH Culture Change & Person Centered Care Programs (P. 103-105)

- Caring for Residents with Dementia for RNs and LPNs
- Caring for Residents with Dementia for CNAs

Section 7 – Office of the Inspector General Report (P. 106-155)

- Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs.

- Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label indications.
- Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards.

If you are a nurse educator go to…

<u>Section 6</u> – Resources for NH Culture Change & Person Centered Care Programs (P. 103-105)

- Caring for Residents with Dementia for RNs and LPNs
- Caring for Residents with Dementia for CNAs

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SUMMARY OF SECTIONS

	LEADERSHIP	PRESCRIBER	NURSE EDUCATOR	RN/LPN	CNA
Section 2 – Raising Awareness	X	X		X	
Section 3 – Person-Centered Behavior Management		X		X	X
Section 4 – Best Practices for Prescribing	X	X		X	
Section 5 – Implementing Change	X				
Section 6 – Resources for NH Culture Change & Resident Centered Care Programs	X		X		
Section 7 – Office of Inspector General Report	X		X		

Section 2- Raising Awareness

What is this section about?

This section explains the risks of atypical antipsychotics for residents with dementia.

What can you do?

- Raise awareness about the risks
- Think of ways to reduce antipsychotic use where you are
- Know the evidence

How can you use this section?

- Read it
- Share it with others
- Post it where others can see

Contents:

Take Away Points

- Antipsychotics are widely used in the nursing home setting.
- Growing evidence shows increased risk of death and stroke from antipsychotics.
- Atypical antipsychotics provide at best minimal benefits for the treatment of symptoms of dementia.
- Awareness is the first step towards change. You can help make others aware of the risks of antipsychotics.

ANTIPSYCHOTIC RESEARCH

The following document is a collage of current and relevant research articles about antipsychotic medications and dementia

How can you use it?

READ • SHARE • POST

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Atypical Antipsychotic Drugs and the Risk of Sudden Cardiac Death

Wayne A. Ray, Ph.D., Cecilia P. Chung, M.D., M.P.H., Katherine T. Murray, M.D., Kathi Hall, B.S., and C. Michael Stein, M.B., Ch.B.

BACKGROUND

Users of typical antipsychotic drugs have an increased risk of serious ventricular arrhythmias and sudden cardiac death. However, less is known regarding the cardiac safety of the atypical antipsychotic drugs, which have largely replaced the older agents in clinical practice.

CONCLUSIONS

Current users of typical and of atypical antipsychotic drugs had a similar, dose-related increased risk of sudden cardiac death.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Risk of Death in Elderly Users of Conventional vs. Atypical Antipsychotic Medications

Philip S. Wang, M.D., Dr.P.H., Sebastian Schneeweiss, M.D., Jerry Avorn, M.D., Michael A. Fischer, M.D., Helen Mogun, M.S., Daniel H. Solomon, M.D., M.P.H., and M. Alan Brookhart, Ph.D.

BACKGROUND

Recently, the Food and Drug Administration (FDA) issued an advisory stating that atypical antipsychotic medications increase mortality among elderly patients. However, the advisory did not apply to conventional antipsychotic medications; the risk of death with these older agents is not known.

CONCLUSIONS

If confirmed, these results suggest that conventional antipsychotic medications are at least as likely as atypical agents to increase the risk of death among elderly persons and that conventional drugs should not be used to replace atypical agents discontinued in response to the FDA warning.

Annals of Internal Medicine

ARTICLE

Antipsychotic Drug Use and Mortality in Older Adults with Dementia

Sudeep S. Gill, MD, MSc; Susan E. Bronskill, PhD; Sharon-Lise T. Normand, PhD; Geoffrey M. Anderson, MD, PhD; Kathy Sykora, MSc; Kelvin Lam, MSc; Chaim M. Bell, MD, PhD; Philip E. Lee, MD; Hadas D. Fischer, MD; Nathan Herrmann, MD; Jerry H. Gurwitz, MD; and Paula A. Rochon, MD, MPH

Objective: To examine the association between treatment with antipsychotics (both conventional and atypical) and all-cause mortality.

Conclusions: Atypical antipsychotic use is associated with an increased risk for death compared with nonuse among older adults with dementia. The risk for death may be greater with conventional antipsychotics than with atypical antipsychotics.

Ann Intern Med. 2007;146:775-786. www.annals.org

MEDICAL NEWS & PERSPECTIVES

Questionable Antipsychotic Prescribing Remains Common, Despite Serious Risks

Bridget M. Kuehn

JAMA, April 28, 2010—Vol 303, No. 16 (Reprinted)

CLINICAL REVIEW CLINICIAN'S CORNER

Pharmacological Treatment of Neuropsychiatric Symptoms of Dementia

A Review of the Evidence

Kaycee M. Sink, MD
Karen F. Holden, MD
Kristine Yaffe, MD

Objective To evaluate the efficacy of pharmacological agents used in the treatment of neuropsychiatric symptoms of dementia.

Conclusions Pharmacological therapies are not particularly effective for management of neuropsychiatric symptoms of dementia. Of the agents reviewed, the atypical antipsychotics risperidone and olanzapine currently have the best evidence for efficacy. However, the effects are modest and further complicated by an increased risk of stroke. Additional trials of cholinesterase inhibitors enrolling patients with high levels of neuropsychiatric symptoms may be warranted.

JAMA. 2005;293:596-608 www.jama.com

Efficacy and Comparative Effectiveness of Atypical Antipsychotic Medications for Off-Label Uses in Adults

A Systematic Review and Meta-analysis

Alicia Ruelaz Maher, MD
Margaret Maglione, MPP
Steven Bagley, MD
Marika Suttorp, MS
Jian-Hui Hu, MPP
Brett Ewing, MS
Zhen Wang, MS
Martha Timmer, MS
David Sultzer, MD
Paul G. Shekelle, MD, PhD

Objective To perform a systematic review on the efficacy and safety of atypical antipsychotic medications for use in conditions lacking approval for labeling and marketing by the US Food and Drug Administration.

Conclusions Benefits and harms vary among atypical antipsychotic medications for off-label use. For global behavioral symptom scores associated with dementia in elderly patients, small but statistically significant benefits were observed for aripiprazole, olanzapine, and risperidone. Quetiapine was associated with benefits in the treatment of generalized anxiety disorder, and risperidone was associated with benefits in the treatment of obsessive-compulsive disorder; however, adverse events were common.

JAMA. 2011;306(12):1359-1369 www.jama.com

“WHY A TOOLKIT FOR CHANGING HOW WE THINK ABOUT ANTIPSYCHOTIC PRESCRIBING IN THE NURSING HOME?”

The following document introduces the major components of the toolkit and explains why antipsychotic prescribing is an important issue to address.

How can you use it?

READ • SHARE

Why Change How We Think about Antipsychotic Prescribing in Nursing Home Setting?

Currently: Antipsychotics are widely used in nursing homes. These drugs have become the leading treatment for management of behavioral symptoms for residents with dementia.

Mostly for unapproved indications: Up to 80% of antipsychotics prescribed in Nursing Homes are for off-label uses (prescribed to treat a condition that is not among the reasons the drug was originally approved by the FDA). Management of the behavior associated with advanced dementia is not an approved indication.[1-4]

Risk: Growing evidence shows an increased risk of death and stroke from antipsychotics.[5-8] A January 2007 Agency for Healthcare Research and Quality (AHRQ) report found that **all of these drugs increase the risk of death for elderly persons with dementia.**

FDA[9] black box warnings call for greater limits in antipsychotic prescribing because of the risk of death.

Black Box Warning

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with atypical antipsychotics drugs are at increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 and 1.7 times seen 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 varied, most deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infections (e.g., pneumonia) in nature. [This drug] is not approved for the treatment of patients with dementia-related psychosis.

Little benefit: Atypical antipsychotics provide at best minimal benefits for treatment of behavioral and psychological symptoms of dementia. [1, 6]

Federal Regulations: Centers for Medicare and Medicaid Services (CMS) requires that nursing home residents who have not previously taken antipsychotic drugs, including atypical antipsychotic drugs, **not be given these drugs unless the drug therapy is necessary** to treat a specific condition as diagnosed and documented in the medical record[10] (See Section 7 of this Toolkit for additional information). CMS also requires that nursing homes administering antipsychotic drugs ensure that the residents receive gradual dose reductions and behavioral interventions in an effort to discontinue these drugs unless such measures are clinically contraindicated.[11, 12]

What can you do?

Action Steps

- Learn about your facility's level of antipsychotic prescribing for off-label uses.
- Raise awareness of the risks and limited efficacy of antipsychotic use for behavioral symptoms of dementia.
- Conduct in-service sessions reviewing the risks and limited efficacy of these medications and learn how a team approach can help physicians prescribe antipsychotics only when appropriate.
- Understand what alternatives can be used in place of these medications (individualized care planning, anticipating needs and addressing unmet needs, engaging patient strengths).
- If you have a leadership role, consider identifying one unit where behavior challenges are the most intense or where staff are most enthusiastic about making changes to behavioral management approaches. Form a work group or committee to address how changes can be made. Ask staff for their opinions and ideas.
- Assess your facility's readiness for change (see Section 5)

Tools in this Toolkit

1. Summary of the Facts About Antipsychotics
    a. The AHRQ Comparative Effectiveness Summary Resource Guide on atypical antipsychotics (Section 2)
2. Person-Centered Behavior Management (Section 3)
3. Best Practices for Prescribing (Section 4)

Toolkit Online

Available March 1, 2012 at www.Qualidigm.org

REFERENCES

1. Lee PE, Gill SS, Freedman M, Bronskill SE, Hillmer MP, Rochon PA. Atypical antipsychotic drugs in the treatment of behavioural and psychological symptoms of dementia: systematic review. *BMJ.* Jul 10 2004;329(7457):75.

2. Crystal S, Olfson M, Huang C, Pincus H, Gerhard T. Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges. *Health Aff (Millwood).* Sep-Oct 2009;28(5):w770-781.

3. Chen Y, Briesacher BA, Field TS, Tjia J, Lau DT, Gurwitz JH. Unexplained variation across US nursing homes in antipsychotic prescribing rates. *Arch Intern Med.* Jan 11 2010;170(1):89-95.

4. Briesacher BA, Limcangco MR, Simoni-Wastila L, et al. The quality of antipsychotic drug prescribing in nursing homes. *Arch Intern Med.* Jun 13 2005;165(11):1280-1285.

5. Jeste DV, Blazer D, Casey D, et al. ACNP White Paper: update on use of antipsychotic drugs in elderly persons with dementia. *Neuropsychopharmacology.* Apr 2008;33(5):957-970.

6. Schneider LS, Tariot PN, Dagerman KS, et al. Effectiveness of atypical antipsychotic drugs in patients with Alzheimer's disease. *N Engl J Med.* Oct 12 2006;355(15):1525-1538.

7. Schneider LS, Dagerman KS, Insel P. Risk of death with atypical antipsychotic drug treatment for dementia: meta-analysis of randomized placebo-controlled trials. *JAMA.* Oct 19 2005;294(15):1934-1943.

8. Maher AR, Maglione M, Bagley S, et al. Efficacy and comparative effectiveness of atypical antipsychotic medications for off-label uses in adults: a systematic review and meta-analysis. Jama 2011;306:1359-69.

9. Public Health Advisory April 2005: Death with antipsychotics in elderly patients with behavioral disturbances (online). http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/UCM053171. Accessed January 25, 2011.

10. 42 CFR § 483.25(l)(2)(i).

11. 42 CFR § 483.25(l)(2)(ii).

12. CMS, State Operations Manual (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, §483.25(l) Unnecessary Drugs (describing circumstances under which gradual dose reduction is clinically contraindicated).

13. Chartbook: Medicaid Pharmacy Benefit Use and Reimbursement in 2006. In: Institute MPR, ed. *Total Annual Medicaid reimbursement for top 10 drug groups among dual beneficiaries, 2006*: Centers for Medicare and Medicaid Services; 2010.

“IS IT SAFE TO GIVE ATYPICAL ANTIPSYCHOTICS TO PATIENTS WITH DEMENTIA?”

The following document is a one-page highlight of the more detailed Comparative Effectiveness Review Summary Guide that follows.

How can you use it?

READ • SHARE • POST

Is it Safe to Give Atypical Antipsychotics to Patients with Dementia?

Atypical antipsychotics have serious side effects.

No atypical antipsychotic has FDA approval for the treatment of behavioral problems in older adults with dementia.

Know the research findings. This can help you weigh the **risks** and **efficacy**.

The Evidence of Risks

Death

Atypical antipsychotics increase the risk of death for elderly people with dementia. Of every 100 patients treated with an atypical antipsychotic, 1 died due to treatment with the antipsychotic (NNH=100)[+] during the 10- to 12-week trials of these medications.

Stroke

Risperidone is associated with an increased risk of stroke (NNH=34)[+].

Cardiovascular events

Both risperidone (Risperdal®) (NNH=53)[+] and olanzapine (Zyprexa®) (NNH=48)[+] are associated with an increased risk of cardiovascular events.

Extrapyramidal symptoms (EPS) - Parkinsonian-type symptoms

In elderly adults, EPSs are common with risperidone (Risperdal®) (NNH=20)[+] and olanzapine (Zyprexa®) (NNH=10)[+].

[+] NNH = Number needed to harm. If this number of patients were treated with an antipsychotic, we would expect that 1 patient would be harmed because of the drug.

The Evidence of Efficacy

There is evidence for a **very small*** improvement in behavioral symptoms of dementia for:

- Aripiprazole (Abilify®)
- Olanzapine (Zyprexa®)
- Risperidone (Risperdal®)
- Quetiapine (Seroquel®)

* The effect sizes are <0.2 standard deviations of difference between treatment and control groups.

Bottom Line

Atypical antipsychotics provide at best minimal benefits for the treatment of behavioral and psychological symptoms of dementia. Adverse effects offset advantages in the efficacy of atypical antipsychotic drugs for the treatment of psychosis, aggression, or agitation in patients with Alzheimer's disease.

New England Journal of Medicine 2006; 355:1525-1538

For more information please visit:

http://www.effectivehealthcare.ahrq.gov/ehc/products/150/1193/off_lab_ant_psy_clin_fin_to_post.pdf

July 2012

“OFF-LABEL USE OF ATYPICAL ANTIPSYCHOTICS”

The Agency for Healthcare Research and Quality (AHRQ) created a series of Comparative Effectiveness Summary Review Guides (CERSG) on health related topics. The following document is the summary guide on the off-label use of atypical antipsychotic drugs. This summary guide is based on systematic review of over 100 research publications.

How can you use it?

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ABSTRACT:

“Efficacy and comparative effectiveness of atypical antipsychotic medications for off-label uses in adults: a systematic review and meta-analysis.”

The following document is the publicly available abstract of a systematic review recently published in JAMA, comparing the effectiveness of atypical antipsychotic for off-label use in adults.

How can you use it?

READ • SHARE • POST

JAMA. 2011 Sep 28;306(12):1359-69.

Efficacy and comparative effectiveness of atypical antipsychotic medications for off-label uses in adults: a systematic review and meta-analysis.

Maher AR, Maglione M, Bagley S, Suttorp M, Hu JH, Ewing B, Wang Z, Timmer M, Sultzer D, Shekelle PG.

Source

RAND Health, Southern California Evidence-Based Practice Center, 1776 Main St, Santa Monica, CA 90401, USA. Alicia.Ruelaz@cshs.org

Erratum in

- JAMA. 2012 Jan 11;307(2):147.

Abstract

CONTEXT:

Atypical antipsychotic medications are commonly used for off-label conditions such as agitation in dementia, anxiety, and obsessive-compulsive disorder.

OBJECTIVE:

To perform a systematic review on the efficacy and safety of atypical antipsychotic medications for use in conditions lacking approval for labeling and marketing by the US Food and Drug Administration.

DATA SOURCES AND STUDY SELECTION:

Relevant studies published in the English language were identified by searches of 6 databases (PubMed, EMBASE, CINAHL, PsycInfo, Cochrane DARE, and CENTRAL) from inception through May 2011. Controlled trials comparing an atypical antipsychotic medication (risperidone, olanzapine, quetiapine, aripiprazole, ziprasidone, asenapine, iloperidone, or paliperidone) with placebo, another atypical antipsychotic medication, or other pharmacotherapy for adult off-label conditions were included. Observational studies with sample sizes of greater than 1000 patients were included to assess adverse events.

DATA EXTRACTION:

Independent article review and study quality assessment by 2 investigators.

DATA SYNTHESIS:

Of 12,228 citations identified, 162 contributed data to the efficacy review. Among 14 placebo-controlled trials of elderly patients with dementia reporting a total global outcome score that includes symptoms such as psychosis, mood alterations, and aggression, small but statistically significant effects sizes ranging from 0.12 and 0.20 were observed for aripiprazole, olanzapine, and risperidone. For generalized anxiety disorder, a pooled analysis of 3 trials showed that quetiapine was associated with a 26% greater likelihood of a favorable response (defined as at least 50% improvement on the Hamilton Anxiety Scale) compared with placebo. For obsessive-compulsive disorder, risperidone was associated with a 3.9-fold greater likelihood of a favorable response (defined as a 25% improvement on the Yale-Brown Obsessive Compulsive Scale) compared with placebo. In elderly patients, adverse events included an increased risk of death (number needed to harm [NNH] = 87), stroke (NNH = 53 for risperidone), extrapyramidal symptoms (NNH = 10 for olanzapine; NNH = 20 for risperidone), and urinary tract symptoms (NNH range = 16-36). In nonelderly adults, adverse events included weight gain (particularly with olanzapine), fatigue, sedation, akathisia (for aripiprazole), and extrapyramidal symptoms.

CONCLUSIONS:

Benefits and harms vary among atypical antipsychotic medications for off-label use. For global behavioral symptom scores associated with dementia in elderly patients, small but statistically significant benefits were observed for aripiprazole, olanzapine, and risperidone. Quetiapine was associated with benefits in the treatment of generalized anxiety disorder, and risperidone was associated with benefits in the treatment of obsessive-compulsive disorder; however, adverse events were common.

http://www.ncbi.nlm.nih.gov/pubmed/21954480

Section 3- Person-Centered Behavior Management

What is this section about?

This section is about managing difficult behaviors. It focuses on identifying and assessing triggers of difficult behaviors, offers examples and suggestions for behavior management techniques, and provides guides to help caregivers respond to residents with dementia exhibiting difficult behaviors

What can you do?

- Raise awareness about managing difficult behaviors with drugs
- Get to know your residents as individuals
- Know the evidence about behavior management

How can you use this section?

- Read it
- Make copies to use
- Share it with others
- Post it where others will see it

Contents:

Take Away Points

- In order to successfully manage difficult behaviors it is important to understand what is causing or "triggering" the behavior. Using a step-by-step approach to behavior management encourages resident centered care.

“FACT SHEET: Ten Tips for Talking with a Person with Dementia”

The following fact sheet uses information from the Family Caregiver Alliance in cooperation with California’s statewide system of Caregiver Resource Centers.

How can you use it?

READ • SHARE • POST

FACT SHEET: Ten Tips for Talking with a Person with Dementia

We aren't born knowing how to talk with a person with dementia—but we can learn. Improving your skills will help make caregiving less stressful. These skills will also help you to handle the difficult behavior you may encounter as you care for a person with dementia.

1. Set a positive mood for interaction. Your attitude and body language express your feelings and thoughts stronger than your words. Set a positive mood by speaking in a pleasant and respectful manner. Use facial expressions, tone of voice and physical touch to help convey your message.

2. Get the person's attention. Turn off the TV or move to quieter surroundings. Before speaking, make sure you have her attention. Address her by name, identify yourself by name, and use nonverbal cues and touch to help keep her focused. If seated, get down to her level and maintain eye contact.

3. State your message clearly. Use simple words and sentences. Speak slowly, clearly and in a comforting tone. Do not raise your voice higher or louder; instead, pitch your voice lower. If she doesn't understand the first time, use the same wording to repeat your message or question. If she still doesn't understand, wait a few minutes and rephrase the question.

4. Ask simple, answerable questions. Ask one question at a time; those with yes or no answers work best. Refrain from asking open-ended questions or giving too many choices. For example, ask, *"Would you like to wear your white shirt or your blue shirt?"* Better still, show her the choices—visual prompts and cues also help clarify your question and can guide her response.

5. Listen with your ears, eyes and heart. Be patient in waiting for a reply. If she is struggling for an answer, it's okay to suggest words. Watch for nonverbal cues and body language, and respond appropriately. *Always strive to listen for the meaning and feelings that underlie the words.*

6. Break down activities into a series of steps. This makes many tasks much more manageable. You can encourage residents to do what they can, gently remind him of steps he tends to forget, and assist with steps he's no longer able to accomplish on his own. Using visual cues, such as showing him with your hand where to place the dinner plate, can be very helpful.

7. When the going gets tough, distract and redirect. When a resident becomes upset, try changing the subject or the environment. For example, ask him for help or suggest going for a walk. *It is important to connect with the person on a feeling level, before you redirect.* You might say, *"I see you're feeling sad—I'm sorry you're upset. Let's go get something to eat."*

8. Respond with reassurance. People with dementia often feel confused, anxious and unsure of themselves. Further, they often get reality confused and may recall things that never really occurred. *Avoid trying to convince them they are wrong.* Stay focused on the feelings they are demonstrating (which are real) and respond with verbal and physical expressions of comfort, support and reassurance.

9. Remember the good old days. Remembering the past is often a soothing and affirming activity. Many people with dementia may not remember what happened 45 minutes ago, but they can clearly recall their lives 45 years earlier. Therefore, *avoid asking questions that rely on short-term memory*. Instead, try asking general questions about the person's distant past—this information is more likely to be retained.

10. Maintain your sense of humor. *Use humor whenever possible, though not at the person's expense.* People with dementia tend to retain their social skills and are usually delighted to laugh along with you.

“FACT SHEET: Ten Tips for Caring for a Person with Dementia”

From the Loddon Mallee Regional Dementia Management Strategy website

How can you use it?

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FACT SHEET: Ten Tips for Caring for a Person with Dementia

STOP- Think about what you are about to do and consider the best way to do it.

PLAN AND EXPLAIN- Who you are; what you want to do; why.

SMILE- The person who takes their cue from you will mirror your relaxed and positive body language and tone of voice.

GO SLOW- You have a lot to do and you are in a hurry but the person isn't. How would you feel if someone came into your bedroom, pulled back your blankets and started pulling you out of bed without even giving you time to wake up properly?

GO AWAY- If the person is resistive or aggressive but is not causing harm to themselves or others, leave them alone. Give them time to settle down and re-approach later.

GIVE THEM SPACE- Any activity that involves invasion of personal space increases the risk of assault and aggression. Every time you provide care for a person you are invading their space.

STAND ASIDE- Always provide care from the side not the front of the person where you are an easy target to hit, kick etc.

DISTRACT THEM- Talk to the person about things they enjoyed in the past. Give them a face cloth or something to hold while you are providing care.

KEEP IT QUIET- Check noise level and reduce it. Turn off the radio and TV.

DON'T ARGUE- They are right & you are wrong. The demented brain tells the person they can't be wrong.

BRAINSTORM AND DEBRIEF- How can you and your team best meet the physical, environmental and psychological needs of the people in your care?

“FACT SHEET: How to Handle Troubling Behavior”

The following fact sheet uses information from the Family Caregiver Alliance in cooperation with California’s statewide system of Caregiver Resource Centers.

How can you use it?

READ • SHARE • POST

FACT SHEET: How to Handle Troubling Behavior

Some of the greatest challenges of caring for a person with dementia are the personality and behavior changes that often occur. You can best meet these challenges by using creativity, flexibility, patience and compassion. It also helps to not take things personally and maintain your sense of humor.

To start, consider these ground rules:

We cannot change the person. The person you are caring for has a brain disorder that shapes who he has become. When you try to control or change his behavior, you'll most likely be unsuccessful or be met with resistance. It's important to:

- *Try to accommodate the behavior, not control the behavior*.
- *Remember that we **can** change our behavior or the physical environment.* Changing our own behavior will often result in a change in our resident's behavior.

Check with the nurse or doctor. Behavioral problems may have an underlying medical reason: perhaps the person is in pain, is sick, or experiencing an adverse side effect from medications.

Behavior has a purpose. People with dementia typically cannot tell us what they want or need. They might do something, like take all the clothes out of the closet on a daily basis, and we wonder why. It is very likely that the person is fulfilling a need to be busy and useful. *Always consider what need the person might be trying to meet with their behavior—and, when possible, try to accommodate them.*

Behavior is triggered. It is important to understand that all behavior is triggered—it doesn't occur out of the blue. It might be something a person did or said that triggered a behavior or it could be a change in the physical environment. *The root to changing behavior is to change the patterns that we create.* Try a different approach.

What works today, may not tomorrow. The many things that influence troubling behaviors and the natural course of the disease process means that solutions that are work today may need to be changed tomorrow—or may no longer work at all. The key to managing difficult behaviors is being creative and flexible in your plan to address a given issue.

“FACT SHEET: Agitation”

The following fact sheet uses information from the Family Caregiver Alliance in cooperation with California’s statewide system of Caregiver Resource Centers.

How can you use it?

READ • SHARE • POST

FACT SHEET: Agitation

Agitation refers to a range of behaviors associated with dementia, including:

- Irritability or being in a bad temper
- Sleeplessness
- Verbal or physical aggression or anger

Often these types of behavior problems progress with the stages of dementia, from mild to more severe. Agitation may be triggered by a variety of things, including environmental factors, fear and being tired. Most often, agitation is triggered when the person experiences "control" being taken from him.

Suggestions that may be useful in managing agitation

- Reduce caffeine intake, sugar and junk food.
- Reduce noise, clutter or the number of persons in the room.
- Maintain structure by keeping the same routines.
- Keep personal objects and furniture in the same places. Familiar objects and photographs offer a sense of security and can suggest pleasant memories.
- Try gentle touch, soothing music, reading or walks to quell agitation. Speak in a reassuring voice. Do not try to restrain the person during a period of agitation.
- Keep dangerous objects out of reach.
- Allow the person to do as much for himself as possible—support his independence and ability to care for himself.
- Acknowledge the confused person's anger over the loss of control in his life. Tell him you understand his frustration.
- Distract the person with a snack or an activity. Allow him to forget the troubling incident. Confronting a confused person may increase anxiety.

“FACT SHEET: Sleeplessness and Sundowning”

The following fact sheet uses information from the Family Caregiver Alliance in cooperation with California’s statewide system of Caregiver Resource Centers.

How can you use it?

READ • SHARE • POST

FACT SHEET: Sleeplessness and Sundowning

Restlessness, agitation, disorientation and other troubling behavior in people with dementia often get worse at the end of the day and sometimes continue throughout the night. Experts believe this behavior, commonly called *sundowning,* is caused by a combination of factors, such as exhaustion from the day's events and changes in the person's biological clock that confuse day and night.

Suggestions that may be useful in managing sleeplessness

- Increase daytime activities, particularly physical exercise.
- Discourage inactivity and napping during the day.
- Watch out for dietary culprits, such as
    - Sugar
    - Caffeine
    - Junk food.

  Eliminate or restrict these types of foods and beverages to early in the day.
- Plan smaller meals throughout the day, including a light meal, such as half a sandwich, before bedtime.
- Plan for the afternoon and evening hours to be quiet and calm; however, *structured, quiet activity is important*. Perhaps take a stroll outdoors, play a simple card game or play soothing music together.
- Turning on lights well before sunset and closing the curtains at dusk will minimize shadows and may help diminish confusion.

“FACT SHEET: Bathing”

The following fact sheet uses information from the Family Caregiver Alliance in cooperation with California’s statewide system of Caregiver Resource Centers.

How can you use it?

READ • SHARE • POST

FACT SHEET: Bathing

People with dementia often have difficulty remembering "good" hygiene, such as brushing teeth, toileting, bathing and regularly changing their clothes. From childhood we are taught these are highly private and personal activities; to be undressed and cleaned by another can feel frightening, humiliating and embarrassing. As a result, bathing often causes distress for the person with dementia.

Suggestions that may be useful in managing bathing

- Find out from family members about preferences–
    - Did she prefer baths or showers?
    - Mornings or nights?
    - Did she have her hair washed at the salon or do it herself?
    - Was there a favorite scent, lotion or talcum powder she always used? Adopting—as much as possible—her past bathing routine may provide some comfort. Remember that it may not be necessary to bathe every day—sometimes twice a week is sufficient.

  Adopting—as much as possible—her past bathing routine may provide some comfort.
- Respect residents feeling of dignity and modesty. Enhance that feeling by making sure doors and curtains are closed. Whether in the shower or the bath, keep a towel over her front, lifting to wash as needed. Have towels and a robe or her clothes ready when she gets out.
- Be mindful of the environment, such as the temperature of the room and water (older adults are more sensitive to heat and cold) and the adequacy of lighting. Remember—people are often afraid of falling. Help them feel secure in the shower or tub.
- Never leave a person with dementia unattended in the bath or shower. Have all the bath things you need laid out beforehand. If giving a bath, draw the bath water first. Reassure the person that the water is warm—perhaps pour a cup of water over her hands before she steps in.
- If hair washing is a struggle, make it a separate activity. Or, use a dry shampoo.

“FACT SHEET: Feeding”

The following fact sheet uses information from the Alzheimer’s Society.
http://www.alzheimers.org.uk/site/index.php

How can you use it?

READ • SHARE • POST

FACT SHEET: Feeding

A person with dementia may develop a poor appetite or lose interest in food. This can cause weight loss and a dip in their overall well-being.

A poor appetite may develop for numerous reasons, for example,

- A change in food preference
- Difficulties chewing and swallowing
- Coordination problems affecting eating and drinking
- Depression

People with dementia may need to be reminded to eat and drink.

Suggestions that may be useful in managing feeding

- Make certain that there isn't a treatable cause of appetite loss, such as acute illness, depression or denture pain
- Try and avoid confusion between foods by encouraging the person to finish one food before moving on to the next
- Serve foods that are familiar
- Demonstrate chewing if this seems to be the problem, and eat with the person so that they can copy you
- If they're having difficulty with cutlery, encourage finger foods
- Make sure that they get enough fluids
- Help to build a healthy appetite through daily activities such as walking or spending time in the garden.
- Make food and meals look good enough to want to eat. Colorful food such as a bowl of chopped fruit is attractive and eye-catching.
- Try not to overload the plate with too much food - offer small portions at frequent intervals throughout the day and have gaps between courses.
- Be flexible and make the most of 'good eating' times. Some people eat better at certain times of the day, whether this is at breakfast or later in the day at teatime.
- It is easy to lose interest in food once it has gone cold. If someone has difficulty with co-ordination or swallowing, their food is more likely to go cold. Serve half portions and keep the remainder warm until the first portion has been eaten.
- Use a microwave to reheat food during the meal.
- Offer positive encouragement and gentle reminders to eat and describe the food offered to build the person's interest.

http://www.alzheimers.org.uk/site/index.php Alzheimer's Society-Food for Thought

“CARING FOR PEOPLE WITH DEMENTIA AND CHALLENGING BEHAVIORS”

The following materials were adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center, Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

READ • SHARE • POST

Caring for People with Dementia and Challenging Behaviors

A Step-by-Step Approach to Behavior Management and Appropriate Prescribing

Managing challenging behaviors associated with dementia begins with the evaluation and treatment of common causes utilizing **non-pharmacologic approaches.** Medications such as atypical antipsychotics have serious side effects, including death and stroke. They provide at best minimal efficacy for treatment of behavioral and psychological symptoms of dementia.

1. Identify and Assess Triggers

Clearly **characterize the behavior** or symptom, including frequency and severity.
Consider **environmental factors** and triggers.
Are they modifiable?

↓

Perform **medical evaluation** (delirium, medical conditions, pain, depression, drugs).
Address these causes if they are identified.

↓

Discuss with family history that may help explain or manage the behavior;
patient habits, preferences, life history, activities they enjoy.

Common Causes of Challenging Behaviors

Physical:	*Medical:*	*Psychological:*	*Environmental:*
- Pain - Hunger - Constipation - Fatigue	- Dehydration - Infections - Blood sugar abnormalities - Medication side effects	- Anxiety, Fear - Depression - Boredom - Autonomy/privacy	- Caregiver approaches - Institutional expectations and demands - Misinterpretation of events/setting - Over/under-stimulation

2. Try Behavioral Management

If the resident is…TRY

***Agitated/Irritable* → Calm, soothe, distract**

***Resistive to Care* → Identify source of threat**

***Wandering/Restless/Bored* → Engage and distract**

***Disruptive Vocalization* → Distract and engage**

***Apathetic/Withdrawn* → Stimulate and engage**

***Depression/Anxiety* → Reassure and engage**

EXAMPLES

- Cognitive stimulation therapy
- Social interaction
- Therapeutic touch
- Simple pleasures interventions
- Individualized activity
- Validation therapy
- Physical exercise
- Outdoor activities
- Wheelchair biking
- Music or white noise
- Aromatherapy
- Multisensory stimulation
- "Rest stations" in pacing path
- Adapt environment to reduce exit-seeking
- Check physical comfort, vision, hearing
- Pet therapy
- Presence therapy: audio or video tapes of family
- Adjust routines to fit long-standing habits
- PRN analgesics to promote physical comfort
- Slow down, communicate clearly

3. Assess Risk and Severity

If the behavior poses a risk to themselves or others (including staff) AND behavior management fails AND medication work-up does not reveal another cause THEN consider drug therapy targeted at behaviors

Section 4- Best Practices for Prescribing

What is it?

This section presents best practices for antipsychotic prescribing.

What can you do?

- Familiarize yourself with appropriate and inappropriate antipsychotic treatment targets
- Learn how to monitor and document adverse effects
- Review literature on antipsychotic tapering and documentation

How can you use this?

- Read
- Share
- Discuss

Contents:

10. **"Is the Antipsychotic Hurting the Resident? Monitoring Movement Side Effects with the Abnormal Involuntary Movement Scale (AIMS)"** The AIMS can be used to identify tardive dyskinesia (TD) in patients receiving antipsychotic medications. The test is both to detect the presence of TD and to track the severity of a patient's symptoms over time. We include materials describing the AIMS examination procedure as well as the actual tool. (p. 70-72)
11. **"Is the Antipsychotic Hurting the Resident? Monitoring Delirium Using The Confusion Assessment Method (CAM)"** The CAM provides a standardized method to identify delirium quickly and accurately. The short version (included) uses the four features that were found to have the greatest ability to distinguish delirium from other types of cognitive impairment. Along with background information, the instrument and diagnostic algorithm are also included. (p. 74-76)

Take Away Points

- Use of an antipsychotic should be justified by a treatment target symptom that is thought to present a danger to the patient or others.
- If a patient develops delirium or has new challenging behaviors, a careful medication review is recommended.
- When choosing the most appropriate antipsychotic, consideration should be given to the type of dementia present as safety and efficacy of medications may vary.
- Follow dosing guidelines, do not expect an immediate response, and do not increase doses too quickly.
- Monitor for adverse effects as indicated and be familiar with how drug choice may impact presence of side effects.
- To meet federal regulations, establish standardized tapering practices in your facility based on suggestions from the literature. Be sure to document all taper trials and results as well as establishing guidelines for subsequent trials and frequency.

C.A.R.E TO BEHAVE

The following document provides information regarding the appropriate and inappropriate use of antipsychotics.

How can you use it?

READ • SHARE • POST

QUALIDIGM

C.A.R.E. for Behaviors

Check for
Appropriateness and Weigh the
Risks Against the
Efficacy

IMPROVE CARE FOR ELDERLY PEOPLE WITH DEMENTIA

Atypical antipsychotic medications are **not** FDA-approved for behavior management in elderly people with dementia.

A systematic review of more than 100 controlled research trials evaluating atypical antipsychotic medications shows an increased risk of death and stroke in elderly people with dementia.

Prescribing of atypical antipsychotics for unapproved indications remains very common.

So:

What is the evidence of efficacy & risk in elderly people with dementia?

When are atypical antipsychotics appropriate?

Produced by the Meyers Primary Care Institute at the University of Massachusetts Medical School with funding by the Agency for Healthcare Research and Quality (AHRQ)

Is it Safe to Give Atypical Antipsychotics to Patients with Dementia?

Atypical antipsychotics have serious side effects.

No atypical antipsychotic has FDA approval for the treatment of behavioral problems in older adults with dementia.

Know the research findings. This can help you weigh the **risks** and **efficacy**.

The Evidence of Risk

Death

Atypical antipsychotics increase the risk of death for elderly people with dementia. Of every 100 patients treated with an atypical antipsychotic, 1 died due to treatment with the antipsychotic (NNH=100)[+] during the 10- to 12- week trials of these medications.

Stroke

Risperidone is associated with an increased risk of stroke (NNH=34)[+].

Cardiovascular events

Both risperidone (Risperdal®) (NNH=53)[+] and olanzapine (Zyprexa®) (NNH=48)[+] are associated with an increased risk of cardiovascular events.

Extrapyramidal symptoms (EPS) – Parkinsonian-type symptoms

In elderly adults, EPSs are common with risperidone (Risperdal®) (NNH=20)[+] and olanzapine (Zyprexa®) (NNH=10)[+].

[+] NNH = Number needed to harm. If this number of patients were treated with an antipsychotic, we would expect that 1 would be harmed because of the drug.

The Evidence of Efficacy

There is some evidence for a **very small*** improvement in behavioral symptoms of dementia for:

- Aripiprazole (Abilify®)
- Olanzapine (Zyprexa®)
- Risperidone (Risperdal®)
- Quetiapine (Seroquel®)

* The effect sizes are <0.2 standard deviations of difference between treatment and control groups

Updated July 2012

Bottom Line

Atypical antipsychotics provide at best minimal benefits for the treatment of behavioral and psychological symptoms of dementia. Adverse effects offset advantages in the efficacy of atypical antipsychotic drugs for the treatment of psychosis, aggression, or agitation in patients with Alzheimer's disease.

New England Journal of Medicine 2006; 355:1525-1538

Just Ask Why

Make a commitment to "***Ask Why***"

At every new start and at every new resident admission:

Why is this person receiving an antipsychotic medication?

Is the indication appropriate?

Appropriate indications include:

- Aggressive behavior (resident is a danger to self and/or others)
- Hallucinations or delusions (if these behaviors cause impairment in functional capacity)

For all persons receiving an antipsychotic (regardless of indication):

✓ Reassess the need for therapy

✓ Evaluate the safety and efficacy data (see page 2 of this handout)

✓ Attempt taper to minimal effective dose

✓ Include resident centered behavioral management strategies (see Section 3 of the toolkit)

INAPPROPRIATE USE OF ANTIPSYCHOTICS:

The patient has dementia with the following behavioral issues <u>that do not present a danger to themselves, a danger to others (including staff)</u>, or interfere with staff's ability to provide care:

Anxiety	**Paranoia Not Impairing Functional Capacity**
Anxiety due to Medical Condition	**Insomnia**
Verbally Aggressive/Threatening	**Sexual Aggression**
Continuous Pacing Not Impairing Functional Capacity	**Substantial Difficulty Receiving Care**
Continuous Crying Out, Screaming and/or Yelling Not Impairing Functional Capacity	**Hallucinations Not Impairing Functional Capacity**
Disrobing	**Delusions Not Impairing Functional Capacity**
Throwing food items	**Biting**
Combative	**Kicking**
Spitting	**Hitting/Striking out**
Scratching	

ANTIPSYCHOTICS MAY BE APPROPRIATE FOR:

Atypical Psychosis	**Psychotic mood disorders**
Delusional Disorder (DSM-IV criteria)	**Schizo-affective Disorders**
Huntington's Disease	**Schizophrenia**
Acute psychotic episodes	**Schizophreniform Disorder**
Brief reactive psychosis	**Tourette's Disorder**

Short term use (7 days) for nausea and vomiting

Organic mental syndromes including dementia with associated psychotic and/or agitated features as defined by:

- **Specific behaviors which cause the resident to present a danger to themselves or others**
- ***Continuous* crying out, screaming, yelling, or pacing if these specific behaviors cause an impairment in functional capacity**
- **Psychotic symptoms (hallucinations, paranoia, delusions)**

HCFA Interpretive Guideline: 483.25 (1) (2) (l) for U.S. Nursing Homes

Just Ask Why

CHECKLIST FOR APPROPRIATE USE OF ANTIPSYCHOTICS

The patient has one of the following diagnosis (check all that apply):	
□ Atypical Psychosis	□ Psychotic mood disorders (including mania and depression with psychotic features)
□ Delusional Disorder (DSM-IV criteria)	□ Schizo-affective Disorders
□ Huntington's Disease	□ Schizophrenia
□ Acute psychotic episodes	□ Schizophreniform Disorder
□ Brief reactive psychosis	□ Tourette's Disorder
□ Short term use (7 days) for nausea and vomiting	
□ Organic mental syndromes (including dementia with associated psychotic and/or agitated features as defined by:	
□ Specific behaviors as quantitatively (number of episodes) and objectively (e.g., biting, kicking, and scratching) documented by the facility which cause the resident to: - Present a danger to themselves - Present a danger to others (including staff) - Actually interfere with staff's ability to provide care □ *Continuous* crying out, screaming, yelling, or pacing if these specific behaviors cause an impairment in functional capacity and if they are quantitatively (e.g., periods of time) documented by the facility □ Psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as specific behaviors listed in (a) and (b) above, if these behaviors cause *impairment in functional capacity*.	

Make a commitment to "Ask Why" the person is receiving antipsychotics at:

- **Every new start**
- **Every new resident admission**

Just Ask Why

CHECKLIST FOR INAPPROPRIATE USE OF ANTIPSYCHOTICS

The patient has dementia with the following behavioral issues that do not present a danger to themselves, a danger to others (including staff), or interfere with staff's ability to provide care (check all that apply):	
□ Anxiety	□ Paranoia Not Impairing Functional Capacity
□ Anxiety due to Medical Condition	□ Insomnia
□ Verbally Aggressive/Threatening	□ Sexual Aggression
□ Continuous Pacing Not Impairing Functional Capacity	□ Substantial Difficulty Receiving Care
□ Continuous Crying Out, Screaming and/or Yelling Not Impairing Functional Capacity	□ Hallucinations Not Impairing Functional Capacity
□ Disrobing	□ Delusions Not Impairing Functional Capacity
□ Throwing food items	□ Biting
□ Combative	□ Kicking
□ Spitting	□ Hitting/Striking out
□ Scratching	
Antipsychotic medications are not FDA-approved for the management of behavioral disturbances in adults with dementia. The Centers for Medicare and Medicaid Services requires that NH residents need to have mandatory drug cessation attempts at least every six months in the absence of documented psychosis or approved indication. [Nursing Home Reform Amendments of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), F329]	

Make a commitment to "Ask Why" the person is receiving antipsychotics at:

- **Every new start**
- **Every new resident admission**

ANTIPSYCHOTIC PRESCRIBING AND DOCUMENTATION GUIDE:

APPROPRIATE TARGETS

The following document provides information and step-by-step directions to guide antipsychotic prescribing. Appropriate and inappropriate antipsychotic treatment targets are identified. The "Overall Approach to Documentation and Monitoring" was adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center , Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

READ • SHARE • DISCUSS

OVERALL APPROACH TO DOCUMENTATION AND MONITORING

BEFORE DECIDING ON AN ANTIPSYCHOTIC

1. **Rule out reversible causes of challenging behaviors or other target symptoms (medical disorders, drugs, modifiable stressors, etc.)**
2. **Try non-drug management strategies first.**
   Continue non-drug strategies even if antipsychotics are used
3. **Clearly document treatment targets (symptoms) before and after a strategy or drug is tried.**
   Document frequency, severity, time and day, and environment or other triggers.
4. **Justify use of an antipsychotic. The treatment target symptom must present a danger to the patient or others, or cause the patient to experience one of the following:**
   - **Inconsolable or persistent distress**
   - **A significant decline in function**
   - **Substantial difficulties receiving needed care**
5. **Only use antipsychotics for appropriate treatment target symptoms**
   Exceptions to this rule are rare. Please refer to "Checklist for Appropriate Use of Antipsychotics" for detailed information (p. 52).
6. **If an antipsychotic is needed, consider the impact of side effects on patient comorbidities when choosing the drug.**
7. **Monitor! If the drug doesn't help, stop it (see MONITORING FOR RESPONSE AND ADVERSE EFFECTS).**

CHECKLIST FOR APPROPRIATE USE OF ANTIPSYCHOTICS

The patient has one of the following diagnosis (check all that apply):	
□ **Atypical Psychosis**	□ **Psychotic mood disorders (including mania and depression with psychotic features)**
□ **Delusional Disorder (DSM-IV criteria)**	□ **Schizo-affective Disorders**
□ **Huntington's Disease**	□ **Schizophrenia**
□ **Acute psychotic episodes**	□ **Schizophreniform Disorder**
□ **Brief reactive psychosis**	□ **Tourette's Disorder**
□ **Short term use (7 days) for nausea and vomiting**	
□ **Organic mental syndromes (including dementia with associated psychotic and/or agitated features as defined by:** □ **Specific behaviors as quantitatively (number of episodes) and objectively (e.g., biting, kicking, and scratching) documented by the facility which cause the resident to:** **- Present a danger to themselves** **- Present a danger to others (including staff)** **- Actually interfere with staff's ability to provide care** □ ***Continuous*** **crying out, screaming, yelling, or pacing if these specific behaviors cause an impairment in functional capacity and if they are quantitatively (e.g., periods of time) documented by the facility**	
□ **Psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as specific behaviors listed above, if these behaviors cause *impairment in functional capacity*.**	

HCFA Interpretive Guideline: 483.25 (1) (2) (l) for U.S. Nursing Homes

CHECKLIST FOR INAPPROPRIATE USE OF ANTIPSYCHOTICS

The patient has dementia with the following behavioral issues that do not present a danger to themselves, a danger to others (including staff), or interfere with staff's ability to provide care (check all that apply):

□ Anxiety	□ Paranoia Not Impairing Functional Capacity
□ Anxiety due to Medical Condition	□ Insomnia
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□ Continuous Pacing Not Impairing Functional Capacity	□ Substantial Difficulty Receiving Care
□ Continuous Crying Out, Screaming and/or Yelling Not Impairing Functional Capacity	□ Hallucinations Not Impairing Functional Capacity
□ Disrobing	□ Delusions Not Impairing Functional Capacity
□ Throwing food items	□ Biting
□ Combative	□ Kicking
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Antipsychotic medications are not FDA-approved for the management of behavioral disturbances in adults with dementia. The Centers for Medicare and Medicaid Services requires that NH residents need to have mandatory drug cessation attempts at least every six months in the absence of documented psychosis or approved indication. [Nursing Home Reform Amendments of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), F329]

DRUGS THAT MAY CAUSE DELIRIUM OR BEHAVIORS: STOP THE OFFENDING DRUG

The following document lists the major drug classes and some of the most common drugs that may cause delirium or contribute to challenging behaviors in people with dementia. It was adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center, Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

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DRUGS THAT MAY CAUSE DELIRIUM OR CHALLENGING BEHAVIORS

Listed below are some of the more common drugs that may cause delirium or contribute to challenging behaviors. This is not a complete list.

This does not always mean the drugs should not be used.

If a patient develops delirium or exhibits new challenging behaviors, a careful medication review is warranted.

Be especially mindful of new medications.

ANTICHOLINERGICS

Commonly used examples:

Antihistamines
- Chlorpheniramine (Chlor-Trimeton)
- Diphenhydramine (Benadryl)

Bladder Antispasmodics
- Oxybutynin (Ditropan)
- Tolterodine (Detrol)

GI Medications
- H2 antagonists (Zantac, Tagamet)
- GI antispasmodics (Levbid)

Meclizine

ANTICONVULSANTS

All anticonvulsants can cause delirium

Examples:
- Levetiracetam (Keppra)
- Valproic acid (Depakote)
- Carbamazepine (Tegretol)

PAIN

Narcotics (i.e. opiates)
All can cause delirium if the dose is too high or titrated up too quickly.
NSAIDS (occasionally)

PSYCHIATRIC

All psychiatric medications should be reviewed as possible causes. Effects are unpredictable.

Notable offenders include:

Benzodiazepines
- Alprazolam (Xanax)
- Clonazepam (Klonopin)

Sleep Medications
- Zolpidem (Ambien)

Tricyclic Antidepressants
- Amitripytiline (Elavil)
- Doxepin (Sinequan)
- Nortriptyline (Pamelor)

Antipsychotics
- Aripiprazole (Abilify)
- Olanzapine (Zyprexa)
- Risperidone (Risperal)
- Quetiapine (Seroquel)
- Ziprasidone (Geodon)
- Chlorpromazine (Thorazine)

Methylphenidate (Ritalin)

PARKINSON'S/RESTLESS LEGS

All can cause psychosis

Levodopa (Sinemet)
Pramipexole (Mirapex)
Ropinrole (Requip)
Selegiline (Anipryl)

ANTIBIOTICS/ANTIVIRALS

Fluoroquinolones
- Levofloxacin
- Ciprofloxacin

Metronidazole (Flagyl)
Vancomycin
Antivirals
- Acyclovir (Zovirax)
- Valacyclovir (Valtrex)

Others may contribute as well.
It may be difficult to separate from effects of infection

STEROIDS

Corticosteroids
- Prednisone

Testosterone

CARDIAC MEDICATIONS

Antihypertensives (rare)
Antiarrhythmics
Digoxin

CHOOSING THE APPROPRIATE ANTIPSYCHOTIC

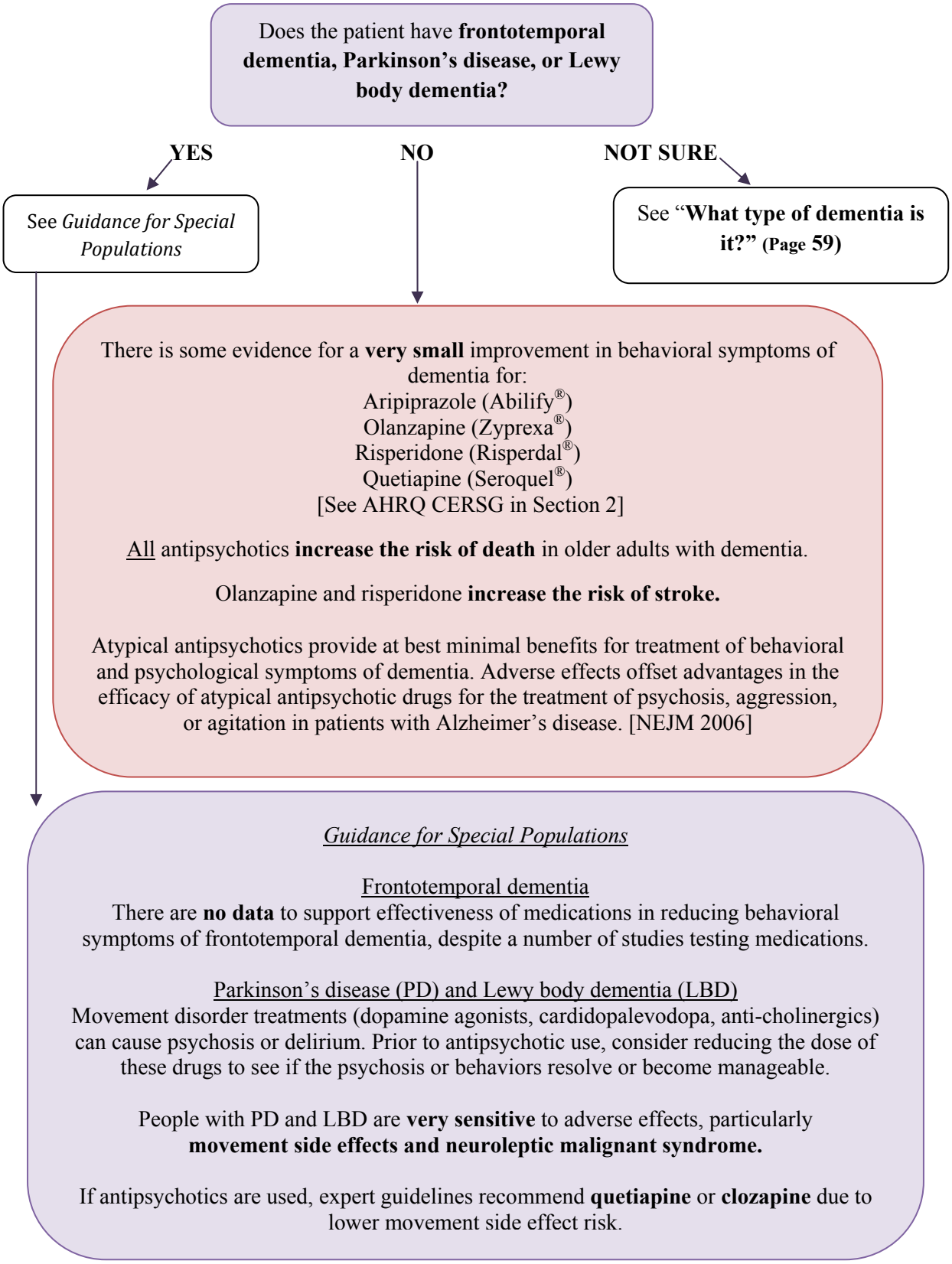
The following document is a schematic guide that can be used to help identify the most appropriate antipsychotic choice in the event that an antipsychotic is thought to be necessary. Guidance for special populations is also included. It was adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center, Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

READ • SHARE • DISCUSS

Choosing the Appropriate Antipsychotic

If an antipsychotic is thought to be necessary, follow these steps:



WHAT TYPE OF DEMENTIA IS IT?

DIAGNOSTIC CRITERIA

The following document can help determine what type of dementia the patient may have. Knowing the type of dementia will help to guide appropriate medication choices and minimize adverse drug effects.

How can you use it?

READ • SHARE • DISCUSS

DIAGNOSTIC CRITERIA AND IMPLICATIONS

Syndrome	Onset	Cognitive Domains, Symptoms	Motor Symptoms	Progression	Drug Choice Issues
Mild cognitive impairment	Gradual	Primarily memory	Rare	Unknown, 12% per year proceed to Alzheimer's disease	
Alzheimer's disease	Gradual	Memory, language, visuospatial	Rare early, apraxia later	Gradual (over 8-10 yr)	
Vascular dementia	May be sudden or stepwise	Depends on location of ischemia	Correlates with ischemia	Gradual or stepwise with further ischemia	
Lewy body dementia (LBD)	Gradual	Memory, visuospatial, hallucinations, fluctuating symptoms	Parkinsonism	Gradual, but faster than Alzheimer's disease	Expert guidelines recommend **quetiapine** or **clozapine** due to lower movement side effect risk
Frontotemporal dementia	Gradual age <60 yr	Executive, disinhibition, apathy, language, +/- memory	None	Gradual, but faster than Alzheimer's disease	There is **no data** to support effectiveness of medications in reducing behavioral symptoms of frontotemporal dementia
Parkinson's disease (PD)	Gradual	Cognitive slowing, executive dysfunction, impairment in memory retrieval	Abnormal motor signs of resting tremor, slowness and poverty of movement, muscular rigidity and loss of associated movements	Gradual	Expert guidelines recommend **quetiapine** or **clozapine** due to lower movement side effect risk

Adapted from: Pacala JT, Sullivan GM, eds. *Geriatrics Review Syllabus: A Core Curriculum in Geriatric Medicine.* 7th ed. New York: American Geriatrics Society; 2010.

ANTIPSYCHOTIC DOSING

The following document provides general guidelines for some of the more common atypical antipsychotics. Starting doses and maintenance doses are discussed, as well as dosage forms and monitoring for response. It was adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center, Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

READ • SHARE • DISCUSS

DOSING

Antipsychotics are most often given at night.

Beware of sedation-related adverse events if given earlier than bedtime.

	Starting Dose	Max Maintenance Dose*
Aripiprazole (Abilify®)	2.5-5 mg/day	10 mg/day
Haloperidol (Haldol®)	0.25 mg/day	2 mg/day
Olanzapine (Zyprexa®)	2.5-5 mg/day	7.5 mg/day
Quetiapine (Seroquel®)	12.5-25 mg/day	150 mg/day
Risperidone (Risperdal®)	0.25-0.5 mg/day	2 mg/day

*Per CMS regulations for long-term care facilities. Doses for acute treatment sometimes exceed maintenance doses.

DOSAGE FORMS

Tablets can be crushed and mixed with food if needed.

Some liquids and rapidly dissolving tablets are also available.

IM antipsychotics used **only in emergencies** when oral is refused.

Topical forms (e.g. compounded creams) not recommended.
No evidence to guide proper dosing.
Absorption is unknown and unpredictable.

MONITORING FOR RESPONSE AND ADVERSE EFFECTS

The following two tables give information on monitoring atypical antipsychotics. It was adapted from tools created by Ryan Carnahan Pharm.D., M.S., B.C.P.P. Clinical Assistant Professor, Department of Epidemiology, Associate Director, Health Effectiveness Research Center, Assistant Director, University of Iowa Center for Education and Research on Therapeutics, at the University of Iowa.

How can you use it?

READ • SHARE • DISCUSS

Monitoring for Response

Clearly document treatment target symptoms.
If the drug does not help, discontinue the drug.
These symptoms may also change over time, with or without drug treatment.

Do not expect an immediate response.
Sedation may explain much of any immediate effect that is seen.

Do not increase doses too quickly if the patient doesn't respond right away.
It take 5-7 drug half lives (up to several days) to reach steady state blood levels of the drug.

Increased doses lead to increased side effects.

MONITORING FOR ADVERSE EFFECTS

Side Effect	Monitoring Method	Frequency
Movement Side Effects	Observation	Continuous
	Abnormal Involuntary movement scale (AIMS) – see AIMS tab	Baseline, every 6 months, or if movement side effects are suspected
Central Nervous System		
Sedation	Observation	Continuous
Confusion, delirium, or other cognitive worsening	Observation	Continuous
	Delirium screening tool, e.g. Confusion Assessment Method (CAM) See CAM tab	If delirium is suspected
Psychotic symptoms	Observation	Continuous
Cardiovascular/Metabolic		
Orthostatic hypotension	Signs of dizziness or falls	Continuous
	Orthostatic blood pressure	Monthly or if signs of dizziness occur, more frequent on initiation or after dose increase
Edema	Observation	Continuous
Weight gain	Weight	Monthly. Possibly weekly for 1 month in overweight patients
Hyperglycemia	Blood glucose	In diabetics, or if mental status or other change occurs
Triglyceride ↑	Blood lipid panel	In patients with cardiovascular disease risk factors, e.g. obesity diabetes, hyperlipidemia

TAPERING GUIDELINES

Use these forms to document and monitor taper trials.

How can you use it?

READ • SHARE • DISCUSS

Clinical Pharmacologic Approach to Tapering Antipsychotics

While studies have used different approaches to tapering antipsychotics, clinical pharmacologic principles of pharmacokinetics suggest an alternative approach.

For patients on antipsychotics chronically, a slow taper is advised based on the half life (t ½) of the specific drug. Recall that there is a log-dose response curve and that it takes time to move from one steady state to another. We recommend that patients be allowed time to acclimate to the new steady state before proceeding with further tapers.

Outline of approach

- Taper dose by 50% then wait 5-7x t ½ to get to steady state
- When at steady state, wait 1 week for resident to adjust
- Then proceed with another cut of 50% (or same fraction as initial taper), wait until steady state, wait 1 week, and repeat

  (See last column in table below for time between dose reductions)

  - **Table 1. Suggested taper schedule for each drug: Atypical Antipsychotics**

- Monitor outcomes
  - Subtle changes are not detected on behavioral measurement scales used in research studies – follow the family and staff knowledge of patient behavior to judge outcome of tapering

Table 1. Suggested taper schedule for each drug: Atypical Antipsychotics

Generic/Brand	t1/2*	Adjustment to t ½ for elderly (multiple t ½ by 1.5 ; if age > 90, multiple by 2)	Calculated time to steady state (adjusted t ½ x 5-7days)	Time to next taper (leave at steady state for ~ 7 days)
aripiprazole/Abilify®	Parent: 75hrs Act.Metab:94hrs	Parent: 83hrs Act.Metab:141hrs	41 days (based on active metabolite)	48 days
asenapine/Saphris®	Parent: 24hrs	Parent: 36hrs	36 days (based on parent)	43 days
clozapine/Clozaril®	Parent: 8-12hrs	Parent: 12-18hrs	3.5-5 days	10.5-12 days
iloperidone/Fanapt®	Parent:18-33hrs P88:26-37hrs P95:23-31hrs	Parent:27-40hrs P88:39-56hrs P95:35-47hrs	Parent: 8 – 12 days P88: 11—16 days P95: 10-14 days	Parent: 15 – 19 days P88: 18—24 days P95: 17-21 days
lurasidone/Latuda®	Parent: 18hrs	Parent: 27hrs	8 days	15 days
olanzapine/Zyprexa®	Parent:21-54hrs	Parent:32-81hrs	9 – 24 days	16-31 days
paliperidone/Invega®	Parent:23hrs, varies with renal impairment(24-51hrs)	Parent:35hrs, varies with renal impairment(36-77hrs)	10 days, varies with renal impairment (11-22 days)	17 days, varies with renal impairment (18-29 days)
quetiapine/Seroquel®	Parent: IR:6hrs ER:7hrs	Parent: IR:9hrs ER:11hrs	Parent: IR: 2.5 days ER: 3 days	Parent: IR: 9.5 days ER: 10 days
risperidone/Risperdal®	Parent:3-20hrs Act.Metab.:21-30hrs	Parent:4-30hrs Act.Metab.:32-45hrs	Parent: 1–9 days Act.Metab.: 9 – 13 days	Parent: 8-16 days Act.Metab.: 16-20 days
ziprasidone/Geodon®	Parent:7hrs	Parent:11hrs	Parent: 3 days	Parent: 10 days

* Goodman and Gilman

STUDIES SHOW THAT

ANTIPSYCHOTICS CAN BE SUCCESSFULLY TAPERED

The following document is a review of some of the literature on antipsychotic tapering. As of yet, best practices for antipsychotic tapering have not been identified.

How can you use it?

READ • SHARE • DISCUSS

Do Residents Have Increased Behaviors After an Antipsychotic Taper Trial?

Five studies reporting result of tapering of antipsychotic (atypical and typical) medications

Citation	Full Reference	Study Design	Outcomes
Van Reekum 2002	Van Reekum R, Clarke D, Conn D, et al. A randomized, placebo-controlled trial of the discontinuation of long-term antipsychotics in dementia. International Psychogeriatrics. 2002; 14:197-210	Randomized, double-blind, controlled trial	**No difference in worsening behavior.** There was a non-statistically significant trend where "…subjects in the intervention group were more likely to be withdrawn from the study because of worsening behavior."
Ballard 2004	Ballard CG, Thomas A, Fossey J, et al. A 3-month, randomized, placebo-controlled, neuroleptic discontinuation study in 100 people with dementia: The neuropsychitratric inventory median cutoff is a predictor of clinical outcome. J Clin Psychiatry 2004; 65: 114-119.	Randomized, double-blinded, controlled trial	**No difference in behavioral deterioration.** "There were no significant differences between groups in the change on the NPI total score or the key psychiatric/behavioral factors of agitation, mood, and psychosis." There were 6 (13%) withdrawals in control and 5 (9%) withdrawals in intervention group for behavioral deterioration (p=0.55)
Ballard 2008	Ballard CG, Lana MM, Theodoulou M, et al. A randomized, blinded, placebo-controlled trial in dementia patients continuing or stopping neuroleptics (The DART-AD Trial) PLoS 2008; 5:-587-599	Randomized, double- blinded, controlled trial	**No difference in behavioral scores.** "There was no significant difference between the continue treatment and placebo (discontinue) groups in the estimated mean change in SIB scores between baseline and 6 months…"
Monette 2008	Monette J, Champoux N, Monette M, et al. Effect of an interdisciplinary educational program on antipsychotic prescribing among nursing homes residents with dementia	Pre-post study	**The frequency of disruptive behaviors decreased significantly over the 6 month period ($p<0.001$).** "No significant changes were found in the use of other psychotropics, the use of restrains, or in the number of stressful events experienced by nursing staff and personal care attendants."
Ruths 2008	Ruths S, Straand J, Nygaard HA et al. Stopping antipsychotic drug therapy in demented nursing home patients: a randomized, placebo-controlled study – The Bergen District Nursing Home Study (BEDNURS) Int J Geriatr Psychiatry. 2008; 23: 889-895.	Double-blind, controlled trial	**Behavioral symptoms remained stable or improved.** "By study completion, 23 of the 27 intervention group patients were still off antipsychotics. Symptom scores (NPI) remained stable or even improved…"

IS THE ANTIPSYCHOTIC HURTING THE RESIDENT?

MONITORING MOVEMENT SIDE EFFECTS WITH ABNORMAL INVOLUNTARY MOVEMENT SCALE (AIMS)

The AIMS can be used to identify tardive dyskinesia (TD) or involuntary movements in patients receiving antipsychotic medications. The test is both to detect the presence of TD and to track the severity of a patient's symptoms over time. We include materials describing the AIMS examination procedure as well as the actual tool.

How can you use it?

READ • SHARE • DISCUSS

IS THE ANTIPSYCHOTIC HURING THE RESIDENT?

MONITORING DELIRIUM USING THE CONFUSION ASSESSMENT METHOD (CAM)

The CAM provides a standardized method to identify delirium quickly and accurately. The short version (included) uses the four features that were found to have the greatest ability to distinguish delirium from other types of cognitive impairment. Along with background information, the instrument and diagnostic algorithm are included.

How can you use it?

READ • SHARE • DISCUSS

Confusion Assessment Method (CAM)

(Adapted from Inouye et al., 1990)

Patient's Name: _____ Date: _____

Instructions: Assess the following factors.

Acute Onset

1. Is there evidence of an acute change in mental status from the patient's baseline?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Inattention

(*The questions listed under this topic are repeated for each topic where applicable.*)

2A. Did the patient have difficulty focusing attention (for example, being easily distractible or having difficulty keeping track of what was being said)?

_____ Not present at any time during interview

_____ Present at some time during interview, but in mild form

_____ Present at some time during interview, in marked form

_____ Uncertain

2B. (*If present or abnormal*) Did this behavior fluctuate during the interview (that is, tend to come and go or increase and decrease in severity)?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

2C. (*If present or abnormal*) Please describe this behavior.

_____

_____

Disorganized Thinking

3. Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable, switching from subject to subject?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Altered Level of Consciousness

4. Overall, how would you rate this patient's level of consciousness?

_____ Alert (*normal*)

_____ Vigilant (*hyperalert, overly sensitive to environmental stimuli, startled very easily*)

_____ Lethargic (*drowsy, easily aroused*)

_____ Stupor (*difficult to arouse*)

_____ Coma (*unarousable*)

_____ Uncertain

Disorientation

5. Was the patient disoriented at any time during the interview, such as thinking that he or she was somewhere other than the hospital, using the wrong bed, or misjudging the time of day?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Memory Impairment

6. Did the patient demonstrate any memory problems during the interview, such as inability to remember events in the hospital or difficulty remembering instructions?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Perceptual Disturbances

7. Did the patient have any evidence of perceptual disturbances, such as hallucinations, illusions, or misinterpretations (for example, thinking something was moving when it was not)?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Psychomotor Agitation

8A. At any time during the interview, did the patient have an unusually increased level of motor activity, such as restlessness, picking at bedclothes, tapping fingers, or making frequent, sudden changes in position?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Psychomotor Retardation

8B. At any time during the interview, did the patient have an unusually decreased level of motor activity, such as sluggishness, staring into space, staying in one position for a long time, or moving very slowly?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Altered Sleep-Wake Cycle

9. Did the patient have evidence of disturbance of the sleep-wake cycle, such as excessive daytime sleepiness with insomnia at night?

___ YES ___ NO ___ UNCERTAIN ___ NOT APPLICABLE

Scoring:

For a diagnosis of delirium by CAM, the patient must display:

1. Presence of acute onset and fluctuating discourse

AND

2. Inattention

AND EITHER

3. Disorganized thinking

OR

4. Altered level of consciousness

Source:

Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the confusion assessment method. A new method for detection of delirium. *Ann Intern Med*. 1990;113(12):941-948.

Confusion Assessment Method (CAM) Diagnostic Algorithm

Feature 1: Acute Onset and Fluctuating Course

This feature is usually obtained from a family member or nurse and is shown by positive responses to the following questions: Is there evidence of an acute change in mental status from the patient's baseline? Did the (abnormal) behavior fluctuate during the day; that is, did it tend to come and go, or increase and decrease in severity?

Feature 2: Inattention

This feature is shown by a positive response to the following question: Did the patient have difficulty focusing attention; for example, being easily distractible, or having difficulty keeping track of what was being said?

Feature 3: Disorganized Thinking

This feature is shown by a positive response to the following question: Was the patient's thinking disorganized or incoherent, such as rambling or irrelevant conversation, unclear or illogical flow of ideas, or unpredictable switching from subject to subject?

Feature 4: Altered Level of Consciousness

This feature is shown by any answer other than "alert" to the following question: Overall, how would you rate this patient's level of consciousness? (alert [normal], vigilant [hyperalert], lethargic [drowsy, easily aroused], stupor [difficult to arouse], or coma [unarousable])

Source:

Inouye SK, van Dyck CH, Alessi CA, Balkin S, Siegal AP, Horwitz RI. Clarifying confusion: the confusion assessment method. A new method for detection of delirium. *Ann Intern Med*. 1990;113(12):941-948.

Section 5- Implementing Change

What is it?

This section will discuss how to bring about change in your nursing home. It focuses on how to incorporate behavior management techniques and reduce inappropriate prescribing. Several methods are provided to help with assessing readiness for change including figures, questions to ask nursing home leadership, and outside resources. In addition, details are provided on developing a plan for change and the steps necessary to implement best practices for antipsychotic use.

What can you do?

- Consider your nursing home's readiness to change

How can you use this?

- Read
- Share
- Discuss

Contents:

1. **"Assessing your Organization's Readiness for Change"** This document summarizes how to assess the current readiness at your institution to improve antipsychotic prescribing including action steps and a link to the AHRQ Toolkit for improving quality and care. (p. 79)
2. **AHRQ Nursing Home Survey on Patient Safety** – Use this survey to help understand where your facility stands. (p. 81-86)
3. "**Is your Nursing Home Ready for Change?**" This figure helps you identify where your nursing home is on the stages of change model for reducing antipsychotic use. (p. 88)
4. **"The Stages of Culture Change"** Outlines the stages that lead to nursing home culture change. (p. 90)
5. "**Implementation of Best Practices**" Outlines the steps necessary to implement best practices for antipsychotic use in the NH setting. (p. 93-103)

Take Away Points

- To successfully implement change, you will need to assess your organization's readiness for change.
- A plan to implement change in antipsychotic use should reflect your organization's readiness for change.
- The implementation team should include nursing home administrators, consultant pharmacists, nurses, and direct care staff.

ASSESSING YOUR ORGANIZATION'S READINESS FOR CHANGE

This document summarizes how to assess the current readiness at your institution to improve antipsychotic prescribing including action steps and a link to the AHRQ Toolkit for improving quality and care.

How can you use it?

READ • SHARE • DISCUSS

Assessing your Organization's Readiness for Change

Do you see a need to change how your nursing home cares for patients with dementia?

Do others in your organization see a need for change?

WHAT CAN YOU DO?

Action Steps

- Point to where you think your organization is on the stages of change steps.
- Complete the AHRQ Nursing Home Survey on Patient Safety – understand where your facility stands.
- Identify the reasons serving as the impetus for reducing antipsychotic use and implementing the behavior management program in your health care organization. If they are general and not specific to your NH, you may want to find cases or examples that will help bring the issue home to your facility.
- Determine your facility leadership's interests and needs in this area, and assess how much effort will be needed to obtain and sustain their support.
- Talk with other people (from various levels, roles, and clinical areas) who support reducing antipsychotic use and implement a behavior management program.
- Gather their input and begin to clarify the reasons for needed change.
- Develop consensus on reason this program needs to move forward.
- Consider identifying one unit where behavioral challenges are the worst or where staff are most enthusiastic about changes to behavior management approaches. These staff are most likely to understand why change is needed, so find out what they think.

Tools

A tool for measuring readiness to change can be found in AHRQ's Toolkit for Improving Quality and Care. While this resources targets pressure ulcers, it can help you develop an assessment for your facility's ability to improve behavior management.

www.ahrq.gov/research/ltc/pressureulcertoolkit/putool7.htm#TooloneB

AHRQ NURSING HOME SURVEY ON PATIENT SAFETY

Use this survey to help understand where your facility stands.

How can you use it?

READ • SHARE • DISCUSS

Nursing Home Survey on Patient Safety

In this survey, **"resident safety"** means preventing resident injuries, incidents, and harm to residents in the nursing home.

This survey asks for your opinions about resident safety issues in your nursing home.
It will take about 15 minutes to complete.

To mark your answer, just put an X or a √ in the box: [x] or [√].

If a question does not apply to your job or you do not know the answer, please mark the box in the last column. If you do not wish to answer a question, you may leave your answer blank.

SECTION A: Working in This Nursing Home

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. Staff in this nursing home treat each other with respect	☐1	☐2	☐3	☐4	☐5	☐9
2. Staff support one another in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
3. We have enough staff to handle the workload	☐1	☐2	☐3	☐4	☐5	☐9
4. Staff follow standard procedures to care for residents	☐1	☐2	☐3	☐4	☐5	☐9
5. Staff feel like they are part of a team	☐1	☐2	☐3	☐4	☐5	☐9
6. Staff use shortcuts to get their work done faster	☐1	☐2	☐3	☐4	☐5	☐9
7. Staff get the training they need in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
8. Staff have to hurry because they have too much work to do	☐1	☐2	☐3	☐4	☐5	☐9
9. When someone gets really busy in this nursing home, other staff help out	☐1	☐2	☐3	☐4	☐5	☐9
10. Staff are blamed when a resident is harmed	☐1	☐2	☐3	☐4	☐5	☐9

SECTION A: Working in This Nursing Home (continued)

	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
11. Staff have enough training on how to handle difficult residents	☐1	☐2	☐3	☐4	☐5	☐9
12. Staff are afraid to report their mistakes	☐1	☐2	☐3	☐4	☐5	☐9
13. Staff understand the training they get in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
14. To make work easier, staff often ignore procedures	☐1	☐2	☐3	☐4	☐5	☐9
15. Staff are treated fairly when they make mistakes	☐1	☐2	☐3	☐4	☐5	☐9
16. Residents' needs are met during shift changes	☐1	☐2	☐3	☐4	☐5	☐9
17. It is hard to keep residents safe here because so many staff quit their jobs	☐1	☐2	☐3	☐4	☐5	☐9
18. Staff feel safe reporting their mistakes	☐1	☐2	☐3	☐4	☐5	☐9

SECTION B: Communications

How often do the following things happen in your nursing home?	Never ▼	Rarely ▼	Some-times ▼	Most of the time ▼	Always ▼	Does Not Apply or Don't Know ▼
1. Staff are told what they need to know before taking care of a resident for the first time	☐1	☐2	☐3	☐4	☐5	☐9
2. Staff are told right away when there is a change in a resident's care plan	☐1	☐2	☐3	☐4	☐5	☐9
3. We have all the information we need when residents are transferred from the hospital	☐1	☐2	☐3	☐4	☐5	☐9
4. When staff report something that could harm a resident, someone takes care of it	☐1	☐2	☐3	☐4	☐5	☐9
5. In this nursing home, we talk about ways to keep incidents from happening again	☐1	☐2	☐3	☐4	☐5	☐9

SECTION B: Communications (continued)

	Never ▼	Rarely ▼	Some-times ▼	Most of the time ▼	Always ▼	Does Not Apply or Don't Know ▼
6. Staff tell someone if they see something that might harm a resident	☐1	☐2	☐3	☐4	☐5	☐9
7. Staff ideas and suggestions are valued in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
8. In this nursing home, we discuss ways to keep residents safe from harm	☐1	☐2	☐3	☐4	☐5	☐9
9. Staff opinions are ignored in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
10. Staff are given all the information they need to care for residents	☐1	☐2	☐3	☐4	☐5	☐9
11. It is easy for staff to speak up about problems in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9

SECTION C: Your Supervisor

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. My supervisor listens to staff ideas and suggestions about resident safety	☐1	☐2	☐3	☐4	☐5	☐9
2. My supervisor says a good word to staff who follow the right procedures	☐1	☐2	☐3	☐4	☐5	☐9
3. My supervisor pays attention to resident safety problems in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9

SECTION D: Your Nursing Home

How much do you agree or disagree with the following statements?	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
1. Residents are well cared for in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
2. Management asks staff how the nursing home can improve resident safety	☐1	☐2	☐3	☐4	☐5	☐9
3. This nursing home lets the same mistakes happen again and again	☐1	☐2	☐3	☐4	☐5	☐9

SECTION D: Your Nursing Home (continued)

	Strongly Disagree ▼	Disagree ▼	Neither Agree nor Disagree ▼	Agree ▼	Strongly Agree ▼	Does Not Apply or Don't Know ▼
4. It is easy to make changes to improve resident safety in this nursing home	☐1	☐2	☐3	☐4	☐5	☐9
5. This nursing home is always doing things to improve resident safety	☐1	☐2	☐3	☐4	☐5	☐9
6. This nursing home does a good job keeping residents safe	☐1	☐2	☐3	☐4	☐5	☐9
7. Management listens to staff ideas and suggestions to improve resident safety	☐1	☐2	☐3	☐4	☐5	☐9
8. This nursing home is a safe place for residents	☐1	☐2	☐3	☐4	☐5	☐9
9. Management often walks around the nursing home to check on resident care.....	☐1	☐2	☐3	☐4	☐5	☐9
10. When this nursing home makes changes to improve resident safety, it checks to see if the changes worked	☐1	☐2	☐3	☐4	☐5	☐9

SECTION E: Overall Ratings

1. I would tell friends that this is a safe nursing home for their family.
   - ☐ a. Yes
   - ☐ b. Maybe
   - ☐ c. No

2. Please give this nursing home an overall rating on resident safety.

Poor ▼	Fair ▼	Good ▼	Very good ▼	Excellent ▼
☐1	☐2	☐3	☐4	☐5

SECTION F: Background Information

1. What is your job in this nursing home? Check ONE box that best applies to your job. If more than one category applies, check the highest level job.

☐ a. **Administrator/Manager**

Executive Director/Administrator
Medical Director
Director of Nursing/Nursing Supervisor
Department Head
Unit Manager/Charge Nurse
Assistant Director/Assistant Manager
Minimum Data Set (MDS) Coordinator/
Resident Nurse Assessment
Coordinator (RNAC)

☐ b. **Physician (MD, DO)**

☐ c. **Other Provider**

Nurse Practitioner
Clinical Nurse Specialist
Physician Assistant

☐ d. **Licensed Nurse**

Registered Nurse (RN)
Licensed Practical Nurse (LPN)
Wound Care Nurse

☐ e. **Nursing Assistant/Aide**

Certified Nursing Assistant (CNA)
Geriatric Nursing Assistant (GNA)
Nursing Aide/Nursing Assistant

☐ f. **Direct Care Staff**

Activities Staff Member
Dietitian/Nutritionist
Medication Technician
Pastoral Care/Chaplain
Pharmacist
Physical/Occupational/Speech/
Respiratory Therapist
Podiatrist
Social Worker

☐ g. **Administrative Support Staff**

Administrative Assistant
Admissions
Billing/Insurance
Secretary
Human Resources
Medical Records

☐ h. **Support Staff**

Drivers
Food Service/Dietary
Housekeeping
Laundry Service
Maintenance
Security

☐ i. **Other** (Please write the title of your job):

_____

2. How long have you worked in this nursing home?

☐ a. Less than 2 months
☐ b. 2 to 11 months
☐ c. 1 to 2 years
☐ d. 3 to 5 years
☐ e. 6 to 10 years
☐ f. 11 years or more

3. How many hours per week do you usually work <u>in this nursing home</u>?

☐ a. 15 or fewer hours per week
☐ b. 16 to 24 hours per week
☐ c. 25 to 40 hours per week
☐ d. More than 40 hours per week

SECTION F: Background Information (continued)

4. When do you work most often? Check ONE answer.
   - ☐ a. Days
   - ☐ b. Evenings
   - ☐ c. Nights

5. Are you paid by a staffing agency when you work for this nursing home?
   - ☐ a. Yes
   - ☐ b. No

6. In your job in this nursing home, do you work directly with residents most of the time? Check ONE answer.
   - ☐ a. YES, I work directly with residents most of the time.
   - ☐ b. NO, I do NOT work directly with residents most of the time.

7. In this nursing home, where do you spend most of your time working? Check ONE answer.
   - ☐ a. Many different areas or units in this nursing home / No specific area or unit
   - ☐ b. Alzheimer's / Dementia unit
   - ☐ c. Rehab unit
   - ☐ d. Skilled nursing unit
   - ☐ e. Other area or unit (Please specify): _____

SECTION G: Your Comments

Please feel free to write any comments about resident care and safety in this nursing home.

THANK YOU FOR COMPLETING THIS SURVEY.

HOW READY IS YOUR NURSING HOME FOR CHANGE?

This figure can help you identify where your nursing home is on the stages of change model for reducing antipsychotic use.

How can you use it?

READ • SHARE • DISCUSS

IS YOUR NURSING HOME READY FOR CHANGE?

Where is your nursing home on the stages of change model for reducing antipsychotic use?

NEW BEHAVIOR REINFORCED

MAINTENANCE

Change has been made and work is being done to sustain change

Continual oversight is maintained

Outcomes are continually being measured

HAVE A "KICK-OFF" EVENT

ACTION

Team has begun to implement a plan

Staff are receiving trainings about the planned change and building skills

Have a plan to assess how change is progressing and address barriers/problems

FIND THOSE WHO CAN HELP

PREPARATION

Are preparing a plan with outcomes

Have identified a team leader

Assembling a committee

INCREASE AWARENESS OF PROBLEM

CONTEMPLATION

Thinking about change and exploring concerns

Weighing the pros and cons of making change

Beginning to build consensus

PRECONTEMPLATION

Unaware that there is a problem and see no need to change

Business as usual

Respond to crisis as they happen

THE STAGES OF CULTURE CHANGE

Outlines the stages that lead to nursing home culture change.

How can you use it?

READ • SHARE • DISCUSS

The Stages of Culture Change

- *Stage 1—Institutional model* is a traditional medical model organized around a nursing unit without permanent staff assignment.

- *Stage 2—Transformational model* is the initial phase when awareness and knowledge of culture change spreads among direct care workers and the leadership team.

- *Stage 3—Neighborhood model* breaks up traditional nursing units into smaller functional areas and introduces resident-centered dining.

- *Stage 4—Household model* consists of self-contained living areas with 25 or fewer residents who have their own fully functional kitchen, living room, and dining room. Staff work in multi-disciplinary self-directed work teams.

IMPLEMENTATION OF BEST PRACTICES

Outlines the steps necessary to implement best practices for antipsychotic use in the NH setting.

How can you use it?

READ • SHARE • DISCUSS

1) How do we implement best practices for anti-psychotic use in the Nursing Home setting

a) Create an Implementation team (IT)

The makeup of the implementation team (IT) is purposeful and important. Membership is designed to include employees with authority to access and distribute resources and who have knowledge about the organization, direct care practices, and the work environment. IT membership is also designed to encourage commitment from all corners of the organization. Consider the following: **If the implementation team only includes representatives from management, how will frontline staff be empowered?** If the IT is only representative of nursing, how can cross-discipline collaboration occur? **If the IT includes only long-term, experienced staff, how can new ideas and energy in your organization be tapped?** If the IT includes only frontline workers, how can the organization change be expected?

Identify a Change Facilitator

Facilities should consider designating a **change facilitator** to oversee implementation activities. This person is at the hub of the action, staying connected on a daily basis to every aspect of the change initiative by linking all teams in the facility. The change facilitator assists with creating and sustaining teams, working with members of teams to identify and prepare for carrying out pre- and post-module implementation plans and assisting teams to work effectively with each unit. The facilitator also will work with department and management representatives to develop support and accountability systems for implementation purposes. The facilitator requires an individual who is a savvy organizational worker. Some of the activities the change facilitator may be engaged in include:

1. Identifying the skills and knowledge that teams and individual team members need to be successful;
2. Arranging for opportunities to gain any missing skills and knowledge;
3. Promoting a supportive environment for team activities;
4. Preparing staff with clear information from the leadership team;
5. Serving as a liaison between the leadership team and the care team;
6. Managing the logistics of staffing teams.

When you designate a current employee to be the facilitator, consider how they will manage other duties. You will want to assure this person has time to do an adequate job of coordinating activities across the facility. While some facilities have joined together to hire a new position to undertake these duties, it may not be necessary or feasible in every facility. **Consider your staff resources and how you can reallocate work to allow for the asset of a facilitator.**

b) Roles and Responsibilities

i) Leadership

The Leadership Team (LT) – "Leading the change"

A team of **leaders** to **shape the direction** of the projects or **change within** the facility, be a **primary information source**, and establish **a firm link to administration.**

The administrator and other management staff must be **directly** involved with implementation if change is to succeed. This greater involvement often requires altering communication systems and information flow, decision-making processes, and accountability systems. Additionally, the top management team members, including the administrator, will likely need to learn more about **direct-care processes** to assist supervisors in becoming leaders in the implementation effort in their specific areas and to alter authority structures to be more consistent with an **empowered staff model.**

Possible members

- CEO/Administrator
- Director of Nursing
- Director of Dietary
- Human Resources
- Director of Staff Development/Education
- Director of Housekeeping
- Director of Maintenance/Engineering
- Change Facilitator
- Medical Director

The Mission

The LT will, at a minimum:

- Set the **strategic direction** for change at the facility;
- Be a strong **resource** for staff;
- Define a uniform stance on how they **envision change** taking shape at the facility;
- Assure **clear communication** of implementation **vision**, **tasks**, and **progress** to all staff in the facility;
- **Listen** to staff comments and concerns, taking time to consider all feedback and respond;
- Perform **assessments** and gather necessary data related to the proposed changes, such as performing surveys, interviews, and staffing trends; looking at MDS data; and reviewing budget structures;
- Set **benchmarks** for the organization as a whole in **meeting change goals**;
- Define imperative **support structures** (teams, information sources) that need to be in place for change implementation; and
- Create formal **accountability** systems for implementation of changes.

Challenges to Change

The LT could address common barriers to change implementation including:

- **Insufficient awareness** across the facility about the change in philosophy or practice;
- **Uncertainty** of administrative and supervisory staff about their roles in the operation and implementation of new philosophy or practices;
- **Inconsistent implementation** across units and departments;
- Difficulty in creating and sustaining teams;
- **Lack of accountability**;
- **Challenges** related to team implementation ideas (too costly, unrealistic, etc.);
- Inability of team members to access or understand facility data sources; and
- Communication and information flow that is inconsistent with the needs of teams, staff, families, and residents.

It is critically important to understand that **no organization can be transformed by outsiders**. When organizations rely on outside consultants, educational programs, and/or the introduction of specific structures to change their organization, the implementation is less likely to be successful. The facility LT will have a lead role in **preparing an assessment of the organization and identifying things to be done to make the organization fertile ground for the changes being implemented**

Assessment work by the LT will include:

- Ease of staff access to relevant data;
- Effectiveness of communication and targeted information flow;
- Focus of performance evaluations and link to desired behaviors;
- Link between staff development and care outcomes;
- Work environment quality; and
- Resident quality of life.

Responsibilities

Many have underestimated the importance of **regular, prescheduled meetings** in implementing major changes within organizations. LT members are seen as the **primary staff resource** for all change information, as well as **role models**. Having consistent, frequent meetings will assure the LT has current information at their fingertips and **energy** is sustained. Frequent meetings will help **"keep the ball rolling"** and will serve as a model to other teams in your facility. You will want to set up meetings well in advance to avoid scheduling conflicts. **Decide** early in the process how you will **support attendance** via backup staff or possibly a reward system. If conflicts should arise, it is important to decide how to handle those. If one person is absent, consider passing on careful notes, with tailored messages to that individual. If multiple people are absent, decide how to update other

members of the LT about change activities in each department over the recent time period and any pressing issues that need to be dealt with immediately.

One **barrier** that teams frequently encounter is pushing off starting tasks because all team members are not present. A suggested strategy:

1. Create a plan to start the task without that team member's input, but do not yet move ahead with that plan
2. Engage one present LT member as a liaison for the absent member
3. Have that person meet privately with the absent member as soon as possible to discuss the task and proposed plan and gather input
4. Require immediate report of the results of that communication to the whole LT
5. Decide if, given the input, you can all move forward with the plan or if you will need to revisit it at the next LT meeting

ii) Direct Care Staff

The Care Team (CT) – "Bringing organizational change to the frontline"

A team connected to frontline care, linking initiatives directly to resident care.

The care team (CT), is a generic term used to describe any team that is primarily concerned with linking project implementation directly to the frontline. It is not indicative of a particular model but is a team to consider assembling for the purpose of engaging important staff and assuring projects link to resident care.

The collaboration that is required for change implementation across organizational levels and creating a decision-making structure that engages frontline workers, mid-level managers, and upper management is what leads to a sense of worker **empowerment**. As collaborative decision-making proceeds, it becomes apparent that each worker has a vital part to play in both identifying the problems and devising solutions to those problems. This will clearly help **link change** activities to frontline work.

Possible members

- Change Facilitator
- Director of Staff Development/Education
- Director of Nursing
- Dietary Aide
- Housekeeper
- Unit Nurse
- CNA
- Social Worker

- Activities Facilitator
- Pharmacist

The Mission

The purpose of the CT is to work collaboratively to:

- Identify problems in a particular area of resident care;
- Determine the source(s) of these problems;
- Select problems to address;
- Define the problems clearly;
- Identify the people who need to be involved;
- Develop a plan to address the problem (you may want to create a separate team to work on the issue);
- Mobilize the resources need to carry out the plans;
- Anticipate and address any organizational challenges to implementing the plans; and
- Evaluate whether and how well the plans ultimately worked

The efforts required to manage a facility's CT and its effective engagement in the organization are considerable. The change facilitator (described under "Implementation Team" above) could be designated to manage the CT.

Responsibilities

The CT should allow ample time for communication via meetings, yet also have time to progress with projects. Many have found that a biweekly meeting structure can accomplish these two goals. Meeting less frequently often dilutes the impact of the team and puts them in a position to catch up or put out fires, rather than being proactive. This also allows time for the change facilitator to share and disseminate communication between the LT and CT. You will want to set clear expectations for participation because floor staff might find it difficult to get away from their work. Try scheduling meetings when team members are not expected to be on the floor and work to minimize interruptions.

Given that many CT members do not have an administrative component to their jobs, administration may need to clarify to the team members and their colleagues the necessary time commitment, and provide support to colleagues who might be short-staffed. Additionally, the team member participating in the CT might feel guilt or fear of not being on the floor. Verbal support that person from administration and other CT member sand the support of their colleagues remaining on the floor cannot be overlooked.

iii) Facilitating linkage of the Direct Care Team with the Leadership Team

Linking the Care Team to the Leadership Team

It is important to integrate change structures and processes with the rest of the organization. A change facilitator plays a significant role in linking all the teams; however, leadership team (LT) members need to engage in other team membership within the facility. This engagement keeps managers informed about and connected to the changes that are taking place, preventing managers from unknowingly undermining what CT members are attempting to do. In some culture-change initiatives, managers were making decisions that were counter to what a CT had decided to move forward with. This can result in frustration of the CT members and create needless tension between managers and staff. This is most likely to occur when managers make decisions in the complete absence of knowledge about what the CTs are doing and how the managers' decisions might affect the team's plans. This can be avoided when the managers are familiar with the CT's plans and the logic and thinking behind the plans. It is important to move forward together.

Managers involved in culture change expressed concern that any involvement on their part might disempower CT members. To the contrary, evidence supports the importance of ongoing involvement of managers. It is important to remember that empowerment cannot occur when frontline staff are simply left alone to make decisions and carry out plans. This is a mistaken perception that can seriously undermine any change initiative. Empowerment requires information and resources. This will only happen when managers who are knowledgeable about the organization and the systems and processes within the organization are involved.

c) How to make change

Introducing change

As an initial step to implementing change in your facility, it is important to create a general awareness about what the key philosophy is and why you have decided to embark on the changes. Based on conversations with many care staff and managers involved in change, this initial step is not always done as carefully as it could be. Reasons for this seem to include lack of clarity on the part of the managers about just what the philosophy and changes are, and inadequate planning for facility-wide inclusion in the startup process. This has important consequences. When there is insufficient awareness about the program, staff may be left wondering what the new initiative is all about, or worse, not knowing about it at all. Being clear that there is a commitment from the top of the organization, and that the program is neither short-term nor confined to isolated areas of the organization is necessary for staff in the organization to take change seriously. Unless this is done carefully, there is a risk that most staff will see the program as "someone else's concern" or "just a passing fad."

Anticipating questions from staff

Successful implementation seems to be dependent on creating a facility-wide belief that organizational change is everyone's concern and that, importantly, there is a role for everyone to play in its implementation. Promoting the belief that everyone has a role to play relies on a clear understanding of just what those roles are. It is crucial for the facility Leadership Team (LT) to have a clear understanding of these roles and to be able to describe them in a way that staff, across the organization, can see themselves in the program. Questions from staff that the LT can expect and must be prepared to respond to include:

- What exactly are we trying to achieve?
- What is wrong with the way we are currently doing things?
- Does this mean I will have additional responsibilities?
- What are the systems that will be used to communicate as the program is implemented?
- What exactly will be different for me?
- Will this ultimately make the care we provide here better? If so, how?
- Will this affect my relationships with coworkers? If so, how?
- What if I don't have the skills or knowledge to do this?
- Will I relate differently to those above and below me in the organization? If so, in what ways?
- Will I or others be held accountable? If so, how?

These are questions that the LT must think carefully about and be prepared to discuss as the changes are initiated. It is assumed that the LT will engage in considerable discussion about these questions before presenting the changes to the organization. It is not necessary that the LT be able to answer each of these questions for every worker in great detail, particularly in the early phase of introducing commitment to change. However, it is vital that these questions be addressed and considered and that the LT understands that, eventually, these questions need to be addressed for all workers in the organization. Otherwise, organizational change will be seen as something "extra" to do, something that is added to—rather than integrated into—daily work. When change is viewed by facility staff, and especially direct-care workers, as something that is "added on," it has little chance of being successfully implemented or sustained.

Strategies to introduce changes

Some strategies that can be used for introducing new philosophies and changes include:

Public discussions and educational sessions about the need for changes in care delivery and hoped-for outcomes. Discussions must be held at multiple times and in multiple places to be effective. This means all three shifts, each unit and department, resident and family councils, and any formal gatherings of staff, residents, and family. It might also be helpful to include physicians, medical directors, and nurse practitioners who attend to residents in your nursing home. Physicians and nurse practitioners can be an important source of information regarding the impact of implementation on resident outcomes. They can also provide insight into the quality and comprehensiveness of reports and documentation on resident conditions, which should be positively influenced by the implementation of the changes.

Scheduled forums to discuss expected changes in staff roles and relationships. Such forums could be used to make expectations clear, while also allowing staff to ask questions and make suggestions about the evolution of their roles. This will be slightly different in each organization and will likely evolve over time.

Regular reporting from the Leadership Team on findings from its ongoing organizational assessments. Success of implementation relies heavily on the accuracy of data about resident outcomes and staff work environment, the effective use of information about the organization, and how well the staff is able to use data about resident care outcomes. It is important to remember that the work of the LT must be integrated with the evolution of the organizational change. This means the LT's findings must be made available to staff, and the implications of its findings must be discussed, at a minimum, with those who will be using the information.

Examine the systems of communication used in the organization. Assess whether and how these systems will serve the implementation plan, and identify places where these systems need to be modified. In particular, this should include discussions about what information is needed, by whom, and when, so that systems are established that will automatically do what needs to be done (rather than relying on an individual staff to remember). Points at which information flow is blocked or tends to be delayed should be identified and addressed. It is helpful to create a checklist or information flow chart whenever long-established communication systems are being examined or altered.

Create a system to determine whether follow-through on each of the above areas is occurring. There is often a significant difference between perception and reality on how well goals are being achieved and how well staff are following through. This is true for both direct care and organizational practices. Objective accountability systems that provide actual evidence for degree of follow-through are extremely helpful to identify.

Can you identify clear and convincing evidence that what you perceive is occurring in your facility related to communication and follow-through actually is occurring? If you are able to do this, the likelihood of successfully implementing change in your facility increases significantly.

Prior to engaging in organizational assessments

Undertaking major organizational change, implementing successfully, and transforming your organization will require your organization and its staff to work hard. Assessing items within your organization will require significant commitment on the part of the LT. Prior to conducting an organized assessment, your LT members must be familiar with challenges associated with long-term care quality, particularly with regard to the following areas:

- **Ability of CNAs to participate in care planning.** Probably the most consistent research finding is that CNAs feel left out of care planning for the residents they care for. CNAs and other staff seem to have different views about what it means to "participate in care planning." Nurses often point to the important information that is brought to them by CNAs and how that information is important for care planning. This is viewed as "participating in care planning." CNAs on the other hand do not see this as adequate. Providing information for someone else to make a decision is not the same as being involved in the decision. This is an important distinction that, unfortunately, is often not appreciated by unit nurses and other managers.
    - **Questions for the LT to consider:** In addition to providing information to the nurses, how are the CNAs in your facility participating in the resident care planning process? Do they feel as if they are true participants? How do you know?
- **Effectiveness of communication across shifts.** Cross-shift communication is a challenge in almost every health care environment. In long-term care settings, lack of effective communication across shifts is a source of anxiety and frustration for families and residents and undermines carefully designed clinical interventions. Families and residents frequently report that important information about their loved one, as well as simple requests made to staff, are not transferred from one shift to the next. These "simple" things are often important quality-of-life issues for residents and family members. Vital information about clinical practice interventions frequently suffers the same fate, leading to interruptions and delays in care.
    - **Questions for the LT to consider:** What is done to prevent such information from being lost? If information related to a family member or resident request or related to clinical practice change were given to someone on the staff and you tracked what happened to it for three days, what would you expect to find?
- **Care provider access to and use of data about unit level outcomes.** Staff are quite good at describing what has happened to a particular resident in a particular care area. However, most staff would not be able to say how their unit is doing overall or over time in any of several care

areas. This would include an inability to describe trends over time on their unit in functional ability, continence, weight gain, or participation in activities. It is important to appreciate the distinction between understanding an individual resident and understanding the resident population on a unit.

What happens to an individual resident can always be explained by particular circumstances, idiosyncrasies of one resident, or staffing problems that occur during a particular time. When confronted with data indicating a poor outcome for a particular resident, staff often see this situation as "unusual." They will often say (and believe) that the situation has been corrected or that it is so unusual as not to merit any corrective action. Not seeing the proverbial forest leads to inaction, while allowing the staff to maintain the belief that nothing needs to be done. For this reason, it is vital to provide staff with data about how their local environment (unit/shift/department) is doing and how the residents receiving care in that local area are faring. It is quite difficult to dismiss data that shows trends over time, that defies what may appear to be the case and that cannot be explained away by unusual circumstances or residents.

    - **Questions for the LT to consider:** Can staff on a selected unit tell you what trends have been over the last month? Last year? What about trends in weight loss for low-risk residents? What about depression without treatment? What about other care outcomes? Can they tell you how they compare to other units? To the United States as a whole?

- **Unit nurses' supervisory skills.** For 25 years, research in long-term care has suggested that the supervisory skills of the unit nurses are crucial determinants of CAN work life quality. Despite this, there has been little attention paid to this important area. While some nursing homes have attended to the development of supervisory skills in their RNs, most facilities have neither assessed nor promoted this area of skill development. The collective wisdom of available research would suggest that this may be the single most important factor in frontline staff turnover.

    - **Questions for the LT to consider:** What training have nurses in your facility had on supervision, delegation, collaboration and leadership? How important do nurses think these skills are in the work life quality of CNAs? Do nurses in your facility enjoy supervising? Are they comfortable with it? Are they evaluated, in part, on their effectiveness as supervisors? Do they have mentors to help them develop these skills?

- **Link between actual work and staff development.** Frontline staff have identified their lack of preparation in several areas as a source of frustration and work stress. While in-service programs are often interesting and sometimes helpful, frontline staff often find little or no link between what they are learning and what they need to know to do their work. Sometimes this is as simple as making the link more explicit. Many times, it also involves assisting the frontline worker to develop new care approaches that would allow them to integrate the new learning. Changing

approaches to care would, necessarily, involve others who also care for the same resident. Only with collaborative decision-making and a change in the way the group approaches care can new skills and knowledge be put to use. CNAs have identified the inability to use new skills and knowledge as a negative aspect of their work.

- **Questions for the LT to consider:** What happens on each unit or each department when a frontline worker—or other worker—returns from an in-service program? What, if anything, is done beyond information sharing? Are the implications for care delivery routinely discussed? What does the department head or supervisor do, explicitly, to promote the integration of new learning into the care or service? How successful has this been?

Many care quality and work life quality problems can be prevented. Unfortunately, the quality systems necessary to do this are often not in place. The questions above were provided in an effort to get LT members thinking about the quality systems that currently exist, or are lacking, in your facility. Interestingly, research continues to identify the same issues (like those above) as obstacles to quality in long-term care. The good news is that the apparent obstacles are largely limited to a set of issues that is well recognized. The bad news is that we have done little about these issues in the 30 years since they were first documented.

Section 6 – Resources for NH Culture Change & Resident Centered Care Programs

What is it?

This section contains sample training programs that your institution could use to improve resident centered care.

What can you do?

- Explore these training programs online
- Consider whether these training programs can be utilized by your nursing home
- Ask leadership to train their staff in a resident centered culture program

How can you use this?

- Read
- Share
- Discuss

Contents:

Take Away Points

- Training programs exist; you do not need to reinvent the wheel.
- Nursing homes successfully use these programs to maximize resident care delivery.

Caring for Residents with Dementia for RNs and LPNs

A unique curriculum designed to assist licensed staff in dealing with everyday needs and challenges of today's long-term care population.

How can you use it?

READ • SHARE • DISCUSS

If you would like to receive copies of these training materials for use in your nursing home, please contact the project manager:

Celeste Lemay

Email: Celeste.Lemay@umassmed.edu

Phone: 508-791-7392

Fax: 508-595-2200

Caring for Residents with Dementia for CNAs

A unique curriculum designed to assist direct care staff in dealing with everyday needs and challenges of today's long-term care population.

How can you use it?

READ • SHARE • DISCUSS

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Section 7- Office of Inspector General Report

What is it?

This section contains a recent report released by the Department of Health and Human Services, Office of the Inspector General.

What can you do?

- Understand that federal regulators are concerned about the overuse and abuse of atypical antipsychotics for behavior management in dementia
- Raise awareness of your colleagues that federal scrutiny is increasing

How can you use this?

- Read
- Share
- Discuss

Contents:

1. **"Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents"**- Report by the Department of Health and Human Services, Office of the Inspector General (p. 106-155)

Take Away Points

- Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs.
- Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label indications.
- Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards.

“MEDICARE ATYPICAL ANTIPSYCHOTIC DRUG CLAIMS FOR ELDERLY NURSING HOME RESIDENTS”

REPORT BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL

How can you use it?

READ • SHARE • DISCUSS

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE ATYPICAL ANTIPSYCHOTIC DRUG CLAIMS FOR ELDERLY NURSING HOME RESIDENTS

Daniel R. Levinson
Inspector General

May 2011
OEI-07-08-00150

EXECUTIVE SUMMARY

OBJECTIVES

To determine the extent to which, from January 1 through June 30, 2007:

1. nursing home residents aged 65 and older had Medicare claims for atypical antipsychotic drugs,
2. Medicare claims for atypical antipsychotic drugs for nursing home residents aged 65 and older were associated with off-label conditions and/or the condition specified in the Food and Drug Administration's (FDA) boxed warning,
3. claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria, and
4. claimed atypical antipsychotic drugs were administered in accordance with Centers for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes.

BACKGROUND

Senator Charles Grassley requested that the Office of Inspector General (OIG) evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs and the associated cost to Medicare. Senator Grassley expressed concern about atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions (i.e., conditions other than schizophrenia and/or bipolar disorder) and/or for residents with the condition specified in the FDA boxed warning (i.e., dementia).

FDA has approved the use of eight atypical antipsychotic drugs for the treatment of schizophrenia and/or bipolar disorder. Side effects associated with these drugs include increased risk of death in elderly persons with dementia. Medicare requires that drugs be used for medically accepted indications supported by one or more of three compendia to be eligible for reimbursement. CMS sets standards to ensure that nursing home residents' drug therapy regimens are free from unnecessary drugs, such as drugs provided in excessive doses or for excessive durations.

We used Medicare claims data from Part B and Part D and the Minimum Data Set to identify Medicare claims and payments for atypical antipsychotic drugs for elderly (i.e., aged 65 and older) nursing

home residents from January 1 through June 30, 2007. Using medical record documentation, medical reviewers completed a medical record review instrument to determine the extent to which these drugs were provided to residents diagnosed with conditions that were off-label and/or specified in the boxed warning and whether Medicare erroneously paid for these drugs. Based on medical reviewers' responses, we also determined whether drugs associated with these claims were provided in compliance with CMS standards for drug therapy in nursing homes.

FINDINGS

Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs. Of the 2.1 million elderly nursing home residents, 304,983 had at least 1 Medicare claim for an atypical antipsychotic drug from January 1 through June 30, 2007. Claims for elderly nursing home residents accounted for 20 percent of the total 8.5 million claims for atypical antipsychotic drugs for all Medicare beneficiaries during the review period. Claims for these residents amounted to $309 million.

Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions; 88 percent were associated with the condition specified in the FDA boxed warning. Using medical reviewers' responses, we determined that, during the review period, almost 1.4 million atypical antipsychotic drug claims were for elderly nursing home residents diagnosed with conditions that were off-label and/or were specified in the boxed warning. Physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of the condition(s) specified in the FDA boxed warning.

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.

Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes. For the 6-month review period, we determined using medical record review that 317,971 Medicare claims ($63 million) were associated with atypical antipsychotic drugs that were not administered according to CMS standards for drug regimens in nursing homes. Nursing homes' noncompliance with these standards (e.g., providing drugs in excessive doses or for excessive durations) does not cause Medicare payments for these drugs to be erroneous because the payments are made on behalf of the residents, not the nursing homes. However, failure to comply with CMS standards may affect nursing homes' participation with Medicare.

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.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on the draft report, CMS shared the concern of OIG and Congress over whether atypical antipsychotics and other drugs are being appropriately prescribed for elderly nursing home residents. CMS concurred with the second, third, and fourth recommendations; however, CMS did not concur with the first recommendation and expressed several general concerns with the report.

In response to the second recommendation, CMS concurred and stated that it has already assessed and made improvements to the survey and certification process. However, CMS acknowledged that other efforts are needed in combination with onsite surveys to achieve the progress desired to safeguard nursing home residents against unnecessary antipsychotic drug use.

Regarding the third recommendation, CMS concurred but did not believe the examples provided in the report to be practicable (excluding provider education). CMS stated that it continues to explore alternative strategies within its statutory authority that more directly address the financial incentives in contractual agreements among drug manufacturers, long term care (LTC) pharmacies, LTC facilities, and consultant pharmacists in nursing homes.

Regarding the fourth recommendation, CMS concurred and will consider what appropriate actions need to be taken when the claims data are received from OIG.

In response to the first recommendation, CMS did not concur, stating that diagnosis information is not a required data element of pharmacy billing transactions nor is it generally included on prescriptions. OIG recognizes that the industry has not developed a standardized way of collecting diagnosis information for prescription drugs. However, without access to diagnosis information, CMS cannot determine the indications for which drugs were used. For this reason, CMS is unable, absent a medical review, to determine whether claims meet payment requirements.

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INTRODUCTION

OBJECTIVES

To determine the extent to which, from January 1 through June 30, 2007:

1. nursing home residents aged 65 and older had Medicare claims for atypical antipsychotic drugs,
2. Medicare claims for atypical antipsychotic drugs for nursing home residents aged 65 and older were associated with off-label conditions and/or the condition specified in the Food and Drug Administration's (FDA) boxed warning,
3. claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria, and
4. claimed atypical antipsychotic drugs were administered in accordance with Centers for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes.

BACKGROUND

Senator Charles Grassley requested that the Office of Inspector General (OIG) evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs. For this evaluation, we are using the term "atypical antipsychotic drugs" for second-generation antipsychotic drugs developed to treat psychoses and/or mood disorders. Senator Grassley was specifically concerned about atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions (i.e., conditions other than schizophrenia and/or bipolar disorder) and/or for residents with the condition specified in the FDA boxed warning (i.e., dementia). Moreover, Senator Grassley was concerned about whether Medicare is paying for drugs that may not be in the best interest of elderly nursing home residents.

Atypical antipsychotic drug use by elderly nursing home residents has also been an issue in law enforcement activities. For example, in November 2009, the United States reached a $98 million settlement with Omnicare, Inc. (a long-term care (LTC) pharmacy), to resolve allegations that it received kickbacks to recommend drugs, including Risperdal (an atypical antipsychotic), for use in nursing homes. In January 2010, the Department of Justice filed suit against the manufacturer of Risperdal and two subsidiaries alleging that the

companies paid kickbacks to Omnicare, Inc., to induce it to purchase and recommend Risperdal and other drugs for use in nursing homes.[1] The United States has entered into settlements with the manufacturers of several other atypical antipsychotic drugs to resolve allegations that the manufacturers promoted their drugs for uses that were not approved by FDA and were not reimbursable under Federal health care programs. The marketing of atypical antipsychotic drugs was outside the scope of this evaluation.

The OIG mission is to protect the integrity of Department of Health & Human Services (HHS) programs and the health and welfare of the beneficiaries of those programs. In fulfilling this mission, OIG has conducted numerous studies examining the correctness of Medicare payments and the care of program beneficiaries residing in nursing homes. This study supports the OIG mission in that it seeks to identify vulnerabilities, detect waste and abuse, and promote efficiency and effectiveness in HHS programs. More specifically, this study addresses ongoing concerns regarding claims for atypical antipsychotic drugs prescribed for elderly nursing home residents for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning. Further, this study seeks to address OIG-identified top management challenges for HHS with regard to the integrity of Federal health care program payment methodologies and quality of care by seeking to identify claims for atypical antipsychotic drugs that were paid in error or not in accordance with standards regarding their use in nursing homes.

FDA Drug Approval, Including Atypical Antipsychotic Drugs

FDA has approved eight atypical antipsychotic drugs: Aripiprazole, Clozapine, Olanzapine, Olanzapine/Fluoxetine, Paliperidone, Quetiapine, Risperidone, and Ziprasidone.[2] At the time of our review, FDA had approved all of these drugs for use in the psychiatric treatment of schizophrenia and/or bipolar disorder.[3]

All drugs have benefits and risks. Risks can range from less serious (e.g., an upset stomach) to permanent and potentially life threatening

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[1] United States ex rel. Lisitza and Kammerer v. Johnson & Johnson, et al., Civil Action Nos. 07-10288-RGS and 05-11518 RGS (D. Mass.).

[2] These are the generic names for these drugs.

[3] FDA, *Drug Approvals List*. Accessed at http://www.fda.gov on February 22, 2008. At the time of our review, one of the eight atypical antipsychotic drugs was also approved to treat autism.

(e.g., liver damage).[4] If FDA determines that a drug's health benefits for its intended use outweigh its known risks, then FDA approves the drug for marketing for that use.[5]

Risks associated with the use of atypical antipsychotic drugs that apply to all persons and are included in product labeling include, but are not limited to: neuroleptic malignant syndrome, a life-threatening nervous system problem; tardive dyskinesia, a movement problem; high blood sugar and diabetes; and low blood pressure resulting in dizziness and possibly fainting. For a complete description of approved uses and risks of the eight FDA-approved atypical antipsychotic drugs at the time of our review, see Appendix A.

Off-Label Drug Use

After FDA approves a drug to be marketed for a specific use, physicians are permitted to prescribe that drug for other uses. This is commonly referred to as off-label use.

Off-label use is not uncommon. A 2006 study in the *Archives of Internal Medicine* found that off-label uses accounted for 21 percent of prescriptions written in 2001.[6] Specific to atypical antipsychotic drugs, a 2007 Agency for Healthcare Research and Quality (AHRQ) report listed the most common off-label uses: the treatment of agitation in dementia, depression, obsessive-compulsive disorder, posttraumatic stress disorder, personality disorders, Tourette's syndrome, and autism.[7] Additionally, a 2009 study examining antipsychotic drug use among patients in the Department of Veterans Affairs health care system found that 60.2 percent of the individuals who received an antipsychotic drug had no record of a diagnosis for which these drugs are FDA approved (i.e., the drug was used off-label).[8]

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[4] FDA, *Side Effects: Questions and Answers*. Accessed at http://www.fda.gov on November 12, 2009.

[5] FDA, *Approved Drugs: Questions and Answers*. Accessed at http://www.fda.gov on December 30, 2009.

[6] D.C. Radley, S.N. Finkelstein, and R.S. Stafford, "Off-Label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine*, Vol. 166, 2006, pp. 1021–1026.

[7] AHRQ, *Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics* (07-EHCOO3-EF), January 2007.

[8] D.L. Leslie, S. Mohamed, and R.A. Rosenheck, "Off-Label Use of Antipsychotic Medications in the Department of Veterans Affairs Health Care System," *Psychiatric Services,* Vol. 60, No. 9, 2009, pp. 1175–1181.

FDA's Boxed Warning

If drug manufacturers and/or FDA determine during the approval process or after a drug has been approved for marketing that the drug may produce severe or life-threatening risks, FDA requires that drug manufacturers include a boxed warning (also referred to as a black-box warning) on the product's labeling to warn prescribers and consumers of these risks.[9, 10] Physicians are not prohibited from prescribing a drug in the presence of the condition(s) specified in the boxed warning.

In April 2005, FDA issued a public health advisory for atypical antipsychotic drugs.[11] FDA required manufacturers of these drugs to include a boxed warning regarding the increased risk of mortality when these drugs are used for the treatment of behavioral disorders in elderly patients with dementia. See Figure 1 for an example of a boxed warning.

Figure 1. Example of a Boxed Warning

WARNING

Increased Mortality in Elderly Patients with Dementia-Related Psychosis — Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials (modal duration of 10 weeks) in these patients revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen 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. [this drug] is not approved for the treatment of patients with dementia-related psychosis.

Boxed warning taken from an FDA-approved atypical antipsychotic drug label.
For the purposes of this report, OIG removed the name of the drug in this boxed warning.

Additionally in 2006, FDA revised its patient information sheets specific to each of the eight atypical antipsychotic drugs. These patient information sheets summarize the most important information specific

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[9] In 2006, FDA revised its regulations governing the content and format of labeling for drugs. 71 Fed. Reg. 3922 (Jan. 24, 2006). For categories of drugs described under 21 CFR § 201.56(b)(1), see the section entitled "boxed warnings" at 21 CFR § 201.57(c)(1) and the implementation schedule at 21 CFR § 201.56(c). For categories of drugs described under 21 CFR § 201.56(b)(2), see the section entitled "warnings" at 21 CFR § 201.80(e).

[10] FDA, *An FDA Guide to Drug Safety Terms*. Accessed at http://www.fda.gov on December 29, 2009.

[11] FDA noted that mortality for elderly demented patients with behavioral disorders treated with atypical antipsychotics increased 1.6–1.7 times compared to mortality for those treated with a placebo. FDA, *Public Health Advisory: Deaths With Antipsychotics in Elderly Patients With Behavioral Disturbances,* April 2005. Accessed at http://www.fda.gov on February 22, 2008.

to each drug, including risks and potential side effects. Among the risks and potential side effects listed for all eight atypical antipsychotic drugs is the increased chance of death in elderly persons. See Appendix B for an example of a patient information sheet for one of the eight atypical antipsychotic drugs.

Medicare Reimbursement Criteria for Drugs

Atypical antipsychotic drugs that are provided to Medicare beneficiaries, including those residing in nursing homes, are covered by both the Medicare Part D and Part B programs. Since January 1, 2006, most outpatient prescription drugs for Medicare beneficiaries and dually eligible beneficiaries (i.e., beneficiaries eligible for both Medicare and Medicaid) have been covered through Medicare Part D, which was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[12]

For drugs to qualify for Medicare Part D reimbursement, the Medicare *Benefit Policy Manual* and the *Prescription Drug Benefit Manual*[13] require that drugs be used for medically accepted indications.[14, 15]

These indications include both the uses approved by FDA and those uses, including off-label, supported by one or more of three compendia: (1) the American Society of Health System Pharmacists, Inc.'s, *American Hospital Formulary Service Drug Information*; (2) the *United States Pharmacopeia-Drug Information* (or its successor publications);

[12] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 (Dec. 8, 2003).

[13] CMS, *Medicare Benefit Policy Manual* (Internet-Only Manual), Pub. 100-02, ch. 15, § 50.4. CMS, *Medicare Prescription Drug Benefit Manual* (Internet-Only Manual), Pub. 100-18, ch. 6, § 10.6.

[14] CMS, State Medicaid Director Letter, *Release #141*, May 4, 2006.

[15] Medicare reimbursement criteria regarding medically accepted indications apply to all Part D drugs with the exception of anticancer drugs. The Medicare Improvements for Patients and Providers Act, or MIPPA, expanded the definition of medically accepted indications for anticancer drugs, effective January 1, 2009, to include drugs used in an anticancer chemotherapeutic regimen even if supported solely by peer-reviewed medical literature.

and (3) Thomson Reuters' *DrugDEX Information System*.[16,17] Hereinafter these are collectively referred to as the compendia.

For drugs to qualify for Medicare Part B reimbursement, the Medicare *Benefit Policy Manual*[18] specifies conditions for coverage of drugs that are administered in an outpatient setting (e.g., physician's office).

CMS Standards Regarding Drug Use in Nursing Homes

As a condition for participation in Medicare, nursing homes must comply with Federal nursing home quality and safety standards.[19] State agencies ensure that these standards are met through the State survey and certification process. For more information regarding the State survey and certification process, see Appendix C.[20, 21] One standard requires that nursing home residents' drug regimens be free from what CMS terms unnecessary drugs.[22] CMS defines unnecessary drugs as those that are used:

- in excessive dose,
- for excessive duration,
- without adequate monitoring,
- without adequate indications for use, and/or

[16] The Social Security Act (the Act) § 1927(g)(1)(B)(i). 42 U.S.C. 1396r-8(g)(1)(B)(i). The compendia described at the Act § 1927(g)(1)(B)(i) are incorporated into the Part D definition of "medically accepted indication" through the Act § 1860D-2(e)(4)(A)(ii), 42 U.S.C. 1395w-102(e)(4)(A)(ii), which refers to the Act § 1927(k)(6), which, in turn, refers to the Act § 1927(g)(1)(B)(i).

[17] Thomson Reuters' *DrugDEX Information System* is hereinafter referred to as *DrugDEX*.

[18] CMS, *Medicare Benefit Policy Manual* (Internet-Only Manual), Pub. 100-02, ch. 15, § 50.

[19] 42 CFR § 488.3(a)(2) (incorporating 42 CFR p.t. 483).

[20] The Act § 1864(a), 42 U.S.C. 1395aa, directs the Secretary of HHS to use the help of State health agencies or other appropriate agencies when determining whether health care entities meet Federal standards.

[21] CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(l), Unnecessary Drugs.

[22] 42 CFR § 483.25(l)(1).

- in the presence of adverse consequences[23] that indicate that the dosage should be reduced or discontinued.[24]

Nursing homes' failure to comply with Federal standards regarding unnecessary drugs may affect their participation in Medicare because they would not be meeting their conditions for participation.[25] However, Medicare drug reimbursement policy does not consider payments erroneous when claimed drugs are administered by nursing homes that fail to comply with standards regarding unnecessary drug regimens (e.g., providing drugs in excessive doses or for excessive durations), because drug claims are paid by or on behalf of individual residents, not nursing homes.[26]

CMS requires that nursing home residents who have not previously taken antipsychotic drugs, including atypical antipsychotic drugs, not be given these drugs unless the drug therapy is necessary to treat a specific condition as diagnosed and documented in the medical record.[27] CMS also requires that nursing homes administering antipsychotic drugs ensure that the residents receive gradual dose reductions and behavioral interventions in an effort to discontinue these drugs unless such measures are clinically contraindicated.[28, 29]

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[23] An adverse consequence is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities.

[24] 42 CFR § 483.25(l)(1).

[25] Generally, see 42 CFR Part 488. More specifically, see 42 CFR § 488.406 listing available remedies in addition to termination of the provider agreement and 42 CFR § 488.414 describing actions that must be taken when there are repeated surveys with "substandard quality of care," as defined in CFR § 488.301.

[26] Medicare prescription drug insurance covers both brand-name and generic prescription drugs. As in other insurance policies, beneficiaries generally pay a monthly premium, which varies by plan, and a yearly deductible. Beneficiaries also pay a part of the cost of prescriptions, including a copayment or coinsurance. Everyone with Medicare is eligible for this coverage, regardless of income and resources, health status, or current prescription expenses. *Prescription Drug Coverage: Basic Information*, April 2, 2009. Accessed at http://www.medicare.gov on May, 10, 2010.

[27] 42 CFR § 483.25(l)(2)(i).

[28] 42 CFR § 483.25(l)(2)(ii).

[29] CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, §483.25(l) Unnecessary Drugs (describing circumstances under which gradual dose reduction is clinically contraindicated).

Related Studies

A 2001 OIG study assessed the extent and nature of psychotropic drug use in nursing homes; that study included four of the eight atypical antipsychotic drugs.[30] The study determined that psychotropic drug use in nursing homes was generally appropriate according to CMS guidelines.

A January 2007 AHRQ report assessed the off-label use of atypical antipsychotic drugs. AHRQ found that all of these drugs increase the risk of death for elderly persons with dementia.[31]

Additionally, CMS issued a data analysis brief in June 2009 reporting that 3 of the top 10 drugs paid for by Medicare Part D in 2006 were atypical antipsychotic drugs. The brief cautioned that Part D data do not provide information about the diagnosis associated with the claimed drug, only that a pharmacy indicated that the drug was dispensed.[32]

METHODOLOGY

Scope

This study included nursing home residents aged 65 or older, hereinafter referred to as elderly nursing home residents, with claims for atypical antipsychotic drugs billed to Medicare Part D and/or Part B from January 1 through June 30, 2007. This study excluded payments for atypical antipsychotic drugs provided under the Medicare Part A Prospective Payment System for short-term stays in skilled nursing facilities.[33]

We included elderly nursing home residents eligible for Medicare services, either as Medicare-only residents or those eligible for both Medicare and Medicaid services (i.e., dually eligible residents). Although we included dually eligible residents, we did not review Medicaid claims for atypical antipsychotic drugs. Elderly nursing home

[30] OIG, *Psychotropic Drug Use in Nursing Homes* (OEI-02-00-00490), November 2001.

[31] AHRQ, *Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotics* (07-EHCOO3-EF), January 2007.

[32] CMS, *Data Analysis Brief: Medicare Part D Utilization Trends for Atypical Antipsychotics: 2006–2008*, June 2009. Accessed at http://www.cms.hhs.gov on November 9, 2009.

[33] For skilled nursing facility stays of 100 days or less, prescription drug costs are included in the case-mix adjusted per diem Prospective Payment System rates covered by Part A. These costs were excluded from our analysis because they are not individually quantifiable based on claims data.

residents not eligible for Medicare benefits (i.e., Medicaid-eligible-only residents or those covered solely by private pay) were excluded from this study.

Further, while this study evaluated the extent to which claims for atypical antipsychotic drugs met Medicare reimbursement criteria and determined whether these drugs were provided in accordance with CMS standards regarding unnecessary drug use, this study did not evaluate the medical decisions used to determine each resident's treatment. This study did not evaluate the conduct of drug manufacturers and/or LTC pharmacies with regard to atypical antipsychotic drugs. This study also did not evaluate nursing home survey and certification processes, including those used to review nursing homes' compliance with standards regarding unnecessary drug use.

Data Sources

Identifying atypical antipsychotic drug claims. From CMS, we obtained Medicare Part D Prescription Drug Event (PDE) data and Part B program data containing only final action claims for the period January 1 through June 30, 2007.[34] We used drug codes[35] associated with atypical antipsychotic drugs from these data to identify claims for atypical antipsychotic drugs.

From each of these claims, we matched the Health Insurance Claim Number to the Medicare Enrollment Database to identify Social Security numbers (SSN) for all Medicare beneficiaries with claims for these drugs. Medicare allowed 8.5 million claims for atypical antipsychotic drugs for all Medicare beneficiaries from January 1 through June 30, 2007.

Identifying elderly nursing home residents with antipsychotic drug claims. From CMS, we obtained 2007 Minimum Data Set (MDS) data for all nursing home residents. We used the nursing home admission and discharge dates in the MDS to identify beneficiaries residing in nursing homes at any time during our 6-month review period. We then identified elderly nursing home residents by date of birth. We

[34] PDE records may be amended or deleted up to 6 months after the end of the payment year. After that point, CMS considers them to be final action claims. Final action claims data include all adjustments.

[35] Drug codes included in Part D are National Drug Codes and drug codes included in Part B are Healthcare Common Procedure Coding System codes. See Appendix D for detailed methodology regarding drug codes.

determined that 2,158,801 elderly beneficiaries resided in nursing homes at some time during our study period.

To identify elderly nursing home residents with atypical antipsychotic drug claims, we matched the SSNs from the data match described above when identifying atypical antipsychotic drug claims against the SSNs in MDS data. We identified 1,678,874 Part D and Part B claims for atypical antipsychotic drugs for elderly nursing home residents during the review period.[36]

Data Stratification and Sample Selection

We used available diagnosis codes[37] to identify diagnoses for each elderly nursing home resident with claims for atypical antipsychotic drugs.[38] Using these data, we stratified claims based on whether the data indicated that the beneficiaries lacked an FDA-approved condition[39] for the drug associated with each claim (i.e., the drug was used off-label) and/or whether the beneficiaries had been diagnosed with dementia (i.e., the drug was used in the presence of the condition specified in the boxed warning).

The four strata are as follows:

- an FDA-approved condition and no dementia (i.e., the drug was used neither for an off-label condition nor in the presence of the condition specified in the boxed warning);
- an FDA-approved condition and dementia (i.e., the drug was used in the presence of the condition specified in the boxed warning only);
- no FDA-approved condition and no dementia (i.e., the drug was used for an off-label condition only); and
- no FDA-approved condition and dementia (i.e., the drug was used for both an off-label condition and in the presence of the condition specified in the boxed warning).

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[36] We identified 1,678,441 Part D and 433 Part B claims for atypical antipsychotic drugs.

[37] Because Part D data do not include diagnosis codes, we used the following claims data from 2006 and 2007 to identify the diagnoses: MDS data; Medicare Part B physician and outpatient claims; and Medicare Part A home health, hospice, inpatient, and skilled nursing facility claims. See Appendix D for a more detailed methodology regarding diagnosis codes.

[38] We matched the beneficiaries' Health Insurance Claim Numbers and SSNs across MDS and Part A and Part B claims data to identify diagnosis codes.

[39] For the purposes of this report, an FDA-approved condition is a medical indication for which the FDA had approved the use of a drug at the time of our review period.

The intent of this stratification was to enable us to determine whether the presence or absence of the conditions indicated in the strata affected compliance with Medicare reimbursement criteria and CMS standards regarding unnecessary drug use in nursing homes.

We selected a random sample of 175 claims from each of the 4 strata, for a total of 700 claims. This included oversampling by 100 claims (25 in each stratum) to account for nursing homes we might choose not to contact because of ongoing OIG investigations and nonrespondent nursing homes. Table D-1 in Appendix D shows the sample size and corresponding population of claims for each stratum.

Medical Record Review and Data Analysis

We consulted with a medical record review contractor to select board-certified psychiatrists knowledgeable in the prescribing of atypical antipsychotic drugs for the elderly (hereinafter referred to as medical reviewers). The contractor hired the medical reviewers to review requested documentation from residents' medical records and complete a medical record review instrument for each record.

We developed a letter to request documentation from the nursing home in which each resident lived at the time of the sampled claim.[40] The contractor sent this letter to each nursing home up to three times at predetermined intervals to obtain the requested documentation. For information about the specific documentation requested, see Appendix D.

We instructed the medical record review contractor to provide to the medical reviewers the first 150 complete records received for each stratum, for a total of 600 records.[41] Therefore, our projections are based only on those claims for which medical review was conducted (600 of the 700 sampled claims) and will not equal the known universe of claims (1.7 million) during the study period. Although a nonresponse analysis showed statistically significant differences between the types of nursing homes from which claims were and were not reviewed, additional analysis found no statistically significant evidence that the results presented in our findings were biased because of nonresponse (see Appendix E).

[40] Nursing home contact information was obtained through MDS and Online Survey Certification and Reporting data.

[41] Appendix D explains requirements for a medical record to be considered complete.

Using the medical record documentation, medical reviewers completed a medical record review instrument for OIG to determine whether the claimed drug was used for an off-label condition and/or in the presence of the condition specified in the boxed warning, and whether the claim met Medicare reimbursement criteria. Based on medical reviewer responses, we also determined whether claimed drugs were administered in accordance with CMS standards regarding unnecessary drug use in nursing homes. We determined claims for drugs to be erroneously paid if they were undocumented[42] or did not meet Medicare reimbursement criteria regarding medically accepted indications supported by the compendia. For detailed information regarding the use of the compendia in this study, see Appendix D. Medicare claims for drugs not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes were not considered erroneously paid.

In many cases, medical reviewers determined that documentation from the medical records supported diagnoses that were different from those listed in the data sources we used for stratification. For the purposes of our analyses and findings in this report, we used the diagnoses determined by medical reviewers and not the diagnoses indicated in claims data. See Table D-2 in Appendix D. Although we found no statistically significant differences in error rates among the strata, we did find differences in error rates among the diagnosis groups identified by medical reviewers. Appendix D explains these differences and error rates.

Limitations

Medical reviewers reviewed only the documentation provided by nursing homes. Medical reviewers did not conduct in-person observations of the residents, interview the residents or clinical staff, or conduct a pharmacist's medication regimen review.[43]

[42] Claims were undocumented if the medical record documentation provided by the nursing facility did not support the resident's receipt of the drug associated with the sampled claim.

[43] A pharmacist's medication regimen review is a thorough evaluation of a beneficiary's medication regimen, with the goal of promoting positive outcomes and minimizing adverse consequences associated with drugs. CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(l), Unnecessary Drugs.

DrugDEX is an electronically created and maintained system in which quarterly updates replace older versions. We consulted several sources to obtain historical copies of *DrugDEX*, including CMS, FDA, the Library of Congress, and the National Institutes of Health, but none of these sources possessed a version that covered our review period. Therefore, we used the 2008 version of *DrugDEX*, which was the version we could access that most closely covered our review period.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

Fourteen percent of elderly nursing home residents had Medicare claims for atypical antipsychotic drugs

From January 1 through June 30, 2007, 304,983 (14 percent) of the 2.1 million elderly nursing home residents had at least 1 Medicare claim for an atypical antipsychotic drug. Claims for elderly nursing home residents accounted for 20 percent (1,678,874) of the 8.5 million atypical antipsychotic drug claims for all Medicare beneficiaries during the review period. Table 1 provides an overview of the number of Medicare claims and dollar amounts for elderly nursing home residents by atypical antipsychotic drug from January 1 through June 30, 2007.

Table 1: Number of Medicare Claims and Amount for Each Atypical Antipsychotic Drug (January 1 through June 30, 2007)

Generic Drug Name	Claims	Amount
Quetiapine	627,661	$85,847,131
Risperidone	536,600	$87,161,507
Olanzapine	356,695	$94,055,067
Aripiprazole	83,756	$29,565,887
Ziprasidone	44,681	$10,067,477
Clozapine	27,294	$1,691,718
Olanzapine/Fluoxetine	1,521	$431,799
Paliperidone	666	$207,731
Total	**1,678,874**	**$309,028,317**

Source: OIG analysis of Medicare Part B and Part D claims data, 2009.

The total dollar amount for atypical antipsychotic drug claims for elderly nursing home residents during the review period was $309 million, with an average dollar amount of $184 per claim. The average dollar amount for a 1-day supply of these drugs was $7.26. Dollar amounts ranged from $4.53 to $13.28 per claimed drug, depending on the drug. Further, 17 percent of elderly nursing home residents with claims for atypical antipsychotic drugs had claims for more than one of these drugs during the review period.

Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions; 88 percent were associated with the condition specified in the FDA boxed warning

For the 6-month review period, we determined through medical record review that 83 percent (1,197,442) of atypical antipsychotic drug claims were for elderly nursing home residents diagnosed with conditions for which the drugs' use was not approved by FDA (i.e., the drugs were used off-label). Eighty-eight percent (1,263,641) of the drug claims were for residents diagnosed with dementia (the condition specified in the FDA boxed warning). In total, 95 percent (nearly 1.4 million) of Medicare claims for atypical antipsychotic drugs were for elderly nursing home residents diagnosed with off-label conditions and/or the condition specified in the boxed warning. Physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of the condition(s) specified in the boxed warning.

Table 2 provides an overview of the number and percentage of Medicare claims for atypical antipsychotic drugs used for off-label conditions and/or in the presence of the condition specified in the boxed warning. For point estimates and confidence intervals for selected statistics, see Appendix F.

Table 2: Number and Percentage of Medicare Claims for Atypical Antipsychotic Drugs (January 1 Through June 30, 2007)

Indication for Use of Claimed Drug	Number of Claims	Percentage of Reviewed Claims
For off-label conditions	1,197,442	83.1%
In the presence of the condition specified in the FDA boxed warning	1,263,641	87.7%
For off-label conditions and in the presence of the condition specified in the FDA boxed warning	(1,088,260)	(75.5%)
For off-label conditions and/or in the presence of the condition specified in the FDA boxed warning	1,372,823	95.3%
Neither for off-label conditions nor in the presence of the condition specified in the FDA boxed warning	68,277	4.7%
Total reviewed (net)	**1,441,100***	**100.0%**
Records not reviewed	237,744	n/a
Total claims	**1,678,874**	**n/a**

Source: OIG medical record review analysis, 2009.

*Projection is based only on reviewed records for reviewed claims and will therefore not equate with the population size listed in Table 1.

Medical reviewers determined that elderly nursing home residents who were prescribed atypical antipsychotic drugs for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning commonly had mental health conditions that required treatment, such as depression, dementia, psychosis not otherwise specified, and/or Alzheimer's disease. Additionally, 89 percent (1,216,823) of these residents exhibited symptoms that presented one or more of the following: a danger to themselves or others, significant inconsolable or persistent distress, a significant decline in functioning, or substantial difficulty in receiving needed care. Medical reviewers also expressed that it is not uncommon for atypical antipsychotic drugs to be used in nursing homes off-label for troublesome emotions or behaviors (e.g., anxiety, depression, complaining, or mild agitation) that may also exist in normal life.

Fifty-one percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were erroneous, amounting to $116 million

For the 6-month review period, we determined using medical record review that over 726,000 of the 1.4 million claims for atypical antipsychotic drugs did not comply with Medicare reimbursement criteria. The claimed drugs were either not used for medically accepted indications as supported by the compendia (50.2 percent of claims) or not documented as having been administered to elderly nursing home residents (0.3 percent of claims). Using the results of the medical record review, we evaluated only the extent to which claimed drugs met Medicare reimbursement criteria; we did not evaluate the clinical appropriateness of these drugs. Table 3 outlines the number and percentage of Medicare claims with dollar amounts for atypical antipsychotic drugs paid in error.

Table 3: Erroneous Medicare Claims for Atypical Antipsychotic Drugs (January 1 Through June 30, 2007)

Reason for Error	Number of Claims	Percentage of Claims	Amount
Claimed drug not documented*	3,808	0.3%	$559,333
Claimed drug not for medically accepted indications	722,975	50.2%	$115,919,685
Total errors	**726,783**	**50.5%**	**$116,479,018**

Source: OIG medical record review analysis of nursing home records, 2009.

*Undocumented claims are included only for the purposes of completing the table. There were only three undocumented claims in the sample, which is too few to calculate a 95-percent confidence interval for the projections.

Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes

For the 6-month review period, we determined from medical record review that 317,971 of the 1.4 million claims were associated with drugs that were not administered according to CMS standards for drug therapy in nursing homes, which CMS terms unnecessary drug use. Claims for these drugs represent approximately $63 million. Nursing homes' failure to comply with CMS standards for drug therapy in nursing homes may affect their participation in Medicare. However, nursing homes' noncompliance with these standards does not cause Medicare payments for these drugs to be erroneous. Forty-two percent of claimed drugs did not comply with CMS standards for more than one reason (e.g., the drug was in an excessive dose and for an excessive duration). Table 4 outlines the number and percentage of Medicare claims with dollar amounts for atypical antipsychotic drugs that did not meet CMS standards.

Table 4: Medicare Claims for Atypical Antipsychotic Drugs Determined Unnecessary According to CMS Standards (January 1 Through June 30, 2007)

Reason Drug Did Not Meet CMS Standards	Number of Claims	Percentage of Claims	Amount
In excessive dose	150,106	10.4%	$36,050,851
For excessive duration	135,199	9.4%	$29,369,213
Without adequate indication(s) for use	115,818	8.0%	$21,396,226
Without adequate monitoring	110,949	7.7%	$18,150,616
In the presence of adverse consequences that indicate that the dosage should be reduced or discontinued	67,923	4.7%	$11,479,869
Total (gross)*	**579,994**	**40.2%**	**$116,446,775**
(Overlapping)	(262,023)	(18.2)%	($53,251,792)
Total (net)*	**317,971**	**22.1%**	**$63,194,984**

Source: OIG medical review analysis of nursing home records, 2009.

*Totals may not sum exactly because of rounding.

Medical reviewers noted that some nursing homes that failed to comply with CMS standards regarding unncecessary drugs may not adequately ensure nursing home residents' health and safety. For example, a medical reviewer noted the following for a beneficiary who received an atypical antipsychotic drug without adequate indications for use: "It clearly seems like [the antipsychotic drug] was ineffective in treating her agitation. Since her agitation was associated with infection and pain, more efforts could have been placed on treating those conditions."

RECOMMENDATIONS

We evaluated Medicare claims for atypical antipsychotic drugs from January 1 through June 30, 2007, and found that 14 percent of the 2.1 million elderly nursing home residents had at least 1 claim for these drugs. We determined through medical record review that 83 percent of claims were associated with atypical antipsychotic drugs used for off-label conditions and 88 percent with those used in the presence of the condition specified by the FDA boxed warning. While physicians are not prohibited from prescribing drugs for off-label conditions or in the presence of conditions specified in an FDA boxed warning, Medicare will pay only for drugs that are used for medically accepted indications approved by FDA or supported by the compendia. Using medical record review, we also determined that 50 percent of claims did not meet these conditions, amounting to $116 million. We further determined through medical record review that 22 percent of the atypical antipsychotic drugs associated with the sampled claims did not comply with CMS standards regarding unnecessary drugs in nursing homes, amounting to $63 million. Nursing homes' failure to comply with these standards may affect their participation in Medicare. However, nursing homes' noncompliance with these standards does not cause Medicare payments for the individual drug claims to be erroneous.

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

Enhanced claims data could improve CMS's ability to enforce criteria for Medicare drug coverage and reimbursement and to determine whether a drug is covered by Medicare. For Part D claims, expansion of the required data elements to include diagnosis codes could help drug plan sponsors and CMS ensure that a drug meets the definition of a Part D-covered drug (i.e., is used for an FDA-approved indication or a medically accepted indication supported by the compendia). CMS should also consider what other claims data enhancements would facilitate ensuring accurate claims processing and program oversight.

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

If any survey and certification processes are determined ineffective, CMS should develop improved mechanisms to ensure that all elderly nursing home residents are protected from unnecessary drugs.

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

Possible methods include provider education and incentive programs. Moreover, CMS should consider strategies to prevent Medicare payments for drugs by the Part D program and beneficiaries when those drugs were administered in violation of Federal standards. For example, CMS may want to consider making nursing homes responsible for reimbursing the Part D program when claimed drugs violate the CMS standards regarding unnecessary drug use.

Take appropriate action regarding the claims associated with erroneous payments identified in our sample

We will forward information on these claims to CMS in a separate memorandum.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its written comments on the draft report, CMS shared the concern of OIG and Congress over whether atypical antipsychotics and other drugs are being appropriately prescribed for elderly nursing home residents. CMS concurred with the second, third, and fourth recommendations; however, CMS did not concur with the first recommendation and expressed several general concerns with the report.

In response to the second recommendation, CMS concurred and stated that it had already assessed and made improvements to the survey and certification process. However, CMS acknowledged that other efforts are needed in combination with onsite surveys to achieve the progress desired to safeguard nursing home residents against unnecessary antipsychotic drug use, including efforts to address the financial incentives for unnecessary drug use. OIG recognizes CMS's previous efforts to improve the detection of unnecessary drug use through the survey and certification processes; however, OIG recommends that CMS

use its authority through the survey and certification processes to hold nursing homes accountable when unnecessary drug use is detected.

Regarding the third recommendation, CMS concurred but did not believe the examples provided in the report to be practicable (excluding provider education). CMS stated that although it can improve provider education in this area, establishing incentive programs and preventing Medicare drug payments and nursing home reimbursement are beyond its statutory authority. However, CMS stated that it continues to explore alternative strategies within its statutory authority that more directly address the financial incentives in contractual agreements among drug manufacturers, LTC pharmacies, facilities, and consultant pharmacists in nursing homes. OIG suggests that CMS either use its existing authority or seek new statutory authority to prevent payment and hold nursing homes responsible for submitting claims for drugs that are not administered according to CMS's standards regarding unnecessary drug use in nursing homes.

Regarding the fourth recommendation, CMS concurred and will consider what appropriate actions need to be taken when the claims data are received from OIG.

In response to the first recommendation, CMS did not concur, stating that diagnosis information is not a required data element of pharmacy billing transactions nor is it generally included on prescriptions. OIG recognizes that the industry has not developed a standardized way of collecting diagnosis information for prescription drugs. However, without access to diagnosis information, CMS cannot determine the indications for which drugs were used. For this reason, CMS is unable, absent a medical review, to determine whether claims meet payment requirements.

CMS also expressed a number of concerns regarding the report background and findings. Specifically, CMS was concerned about the nature of the contractual arrangements involving LTC facilities, LTC pharmacies, LTC consultant pharmacies, and drug manufacturers and/or distributors and the incentives such arrangements provide for inappropriate prescribing practices that may adversely affect the health and safety of LTC residents. CMS expressed the opinion that the report's combining of off-label uses cited in the compendia and uses in contraindication of the boxed warning overstates inappropriate use of atypical antipsychotic drugs. Finally, CMS requested that Part D

formulary policies relating to antipsychotic medications be included in the final report.

In response, although we evaluated the extent to which atypical antipsychotic drugs were prescribed for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning, we did not examine the medical decisionmaking regarding why elderly nursing home residents were prescribed these drugs. Our report is based on a medical record review. We did not examine the influence of arrangements between various actors in the nursing home market on the use of atypical antipsychotic drugs. Therefore, our report cannot comment on the relationship, if any, between atypical antipsychotic drug use and contractual agreements involving LTC facilities, LTC pharmacies, LTC consultant pharmacies, and drug manufacturers and/or distributors. However, based on CMS's comments, we did add background information regarding law enforcement issues with atypical antipsychotic drugs.

In regard to CMS's concern that the report was overstating inappropriate drug use, the report states that off-label prescribing is permissible and not uncommon and that evaluating the medical appropriateness of prescribed drugs was outside the scope of this study. The report does not make any statements regarding inappropriate drug use, although it does identify erroneous payments for atypical antipsychotic drug claims that were erroneous because the claims did not comply with the Medicare payment policy (i.e., claimed drugs were not used for medically accepted indications as supported by the compendia or were not documented as having been administered to elderly nursing home residents). Specifically in response to the congressional request, we included data regarding drugs prescribed for off-label conditions and/or in the presence of the condition specified by the FDA boxed warning. In response to CMS's concern, we changed the finding statement to separately address those atypical antipsychotic drug claims associated with off-label conditions and those associated with the condition specified in the FDA boxed warning. We still present the combined total in the text of the finding.

Lastly, we did not include Part D formulary requirements in the report because we do not believe this information is germane to the report's criteria and methodology.

The full text of CMS's comments can be found in Appendix G.

APPENDIX A

Food and Drug Administration-Approved Atypical Antipsychotic Drugs

Descriptions of each atypical antipsychotic drug listed below are drawn from the Food and Drug Administration's approved labels at the time of our review. The most common side effects listed are those that were considered to be reasonably associated with the use of the drug.

Aripiprazole (Abilify). Indicated for the treatment of schizophrenia and acute manic and mixed episodes associated with bipolar disorder. Side effects include, but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; increased body temperature; and difficulty swallowing. The most common side effects (incidence ≥10%) in adult patients in clinical trials were nausea, vomiting, constipation, headache, dizziness, akathisia, anxiety, insomnia, and restlessness.

Clozapine (Clozaril). Indicated for the treatment of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia and for reducing the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for experiencing suicidal behavior. Side effects include, but are not limited to: increased chance of death in elderly persons, agranulocytosis, seizures, heart problems including myocarditis, lowering of blood pressure, neuroleptic malignant syndrome, tardive dyskinesia, high blood sugar and diabetes, fever, blood clots in the lung, increased blood sugar, and liver disease. The most common side effects (incidence ≥5%) in clinical trials were: central nervous system complaints, including drowsiness/sedation, dizziness/vertigo, headache, and tremor; autonomic nervous system complaints, including excessive salivation, sweating, dry mouth, and visual disturbances; cardiovascular findings, including tachycardia, hypotension, and syncope; gastrointestinal complaints, including constipation and nausea; and fever.

Olanzapine (Zyprexa). Indicated for the treatment of schizophrenia, acute mixed or manic episodes associated with bipolar I disorder, and agitation associated with schizophrenia and bipolar I mania. Side effects include, but are not limited to: increased chance of death in elderly persons, neuroleptic malignant syndrome, tardive dyskinesia, high blood sugar and diabetes, strokes, low blood pressure seen as dizziness and possibly fainting, cardiac irregularities, seizures, liver problems, increased body temperature, and difficulty swallowing. The most common side effects (incidence ≥5% and at least twice that for placebo) include: weight gain, dizziness, postural hypotension, constipation, personality disorder, akathisia, dry mouth, dyspepsia, increased appetite, somnolence, and tremor.

Olanzapine/Fluoxetine (Symbyax). Indicated for the treatment of depressive episodes associated with bipolar disorder. Side effects include, but are not limited to: suicidal thoughts or actions; increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; bleeding problems; sexual problems; mania; weakness, confusion, or trouble thinking caused by low salt levels in the blood; low blood pressure seen as dizziness and possibly fainting; cardiac irregularities; seizures; liver problems; increased body temperature; and difficulty swallowing. The most common side effects (incidence ≥5% and at least twice that for placebo) include: disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, tremor, blurred vision, and weight gain.

Paliperidone (Invega). Indicated for the acute and maintenance treatment of schizophrenia. Side effects include, but are not limited to: increased chance of death and strokes in elderly patients with dementia; QT prolongation; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; dizziness and fainting caused by a drop in blood pressure; impaired judgment, thinking, or motor skills; overheating and dehydration; seizures; difficulty swallowing; suicidal thoughts or actions; persistent erection; fever; and bruising. The most common side effects (incidence ≥5% and at least twice that for placebo) include: extrapyramidal symptoms, tachycardia, akathisia, somnolence, dyspepsia, constipation, weight gain, and nasopharyngitis.

Quetiapine (Seroquel). Indicated for the treatment of schizophrenia and both depressive episodes associated with bipolar disorder and acute manic episodes associated with bipolar I disorder. Side effects include, but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; cataracts; seizures; low thyroid; elevated cholesterol or triglycerides; liver problems; persistent erection; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence ≥5% and at least twice that for placebo) in adults include: somnolence, dizziness, dry mouth, constipation, increase in alanine aminotransferase, weight gain, and dyspepsia.

Risperidone (Risperdal). Indicated for the treatment of schizophrenia and short-term treatment of acute manic or mixed episodes associated with bipolar I disorder. Side effects include but are not limited to: increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; strokes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; persistent erection; thrombotic thrombocytopenic purpura; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence ≥10%) include: somnolence, increase in appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, excessive saliva, constipation, fever, Parkinsonism, dystonia, abdominal pain, anxiety, nausea, dizziness, dry mouth, tremor, rash, akathisia, and dyspepsia.

Ziprasidone (Geodon). Indicated for the treatment of schizophrenia and acute agitation in people with schizophrenia. Side effects include, but are not limited to: dangerous problems with heart rhythm; increased chance of death in elderly persons; neuroleptic malignant syndrome; tardive dyskinesia; high blood sugar and diabetes; low blood pressure seen as dizziness, cardiac irregularities, and possibly fainting; seizures; persistent erection; increase or decrease in body temperature; and difficulty swallowing. The most common side effects (incidence ≥5% and at least twice that for placebo) include: somnolence, respiratory tract infection, extrapyramidal symptoms, dizziness, akathisia, abnormal vision, asthenia, and vomiting.

APPENDIX B

Example of the Food and Drug Administration Atypical Antipsychotic Drug Patient Information Sheet

Patient Information Sheet

[Generic drug name]
(marketed as [brand name])

This is a summary of the most important information about [drug name]. For details, talk to your healthcare professional.

What Is [drug name]?

- [Drug name] is in a class of medications called atypical antipsychotics. Antipsychotic medicines are used to treat symptoms of schizophrenia that may include hearing voices, seeing things, or sensing things that are not there, mistaken beliefs or unusual suspiciousness.
- [Drug name] is used to treat mixed or manic episodes in adults who have a condition called Bipolar I disorder. Bipolar disorder is a mental illness that causes extreme mood swings.

What Are The Risks?

The following are the risks and potential side effects of [drug name] therapy. However, this list is not complete.

- ***Increased chance of death in elderly persons.*** Elderly patients treated with atypical antipsychotics, such as [drug name], for dementia had a higher chance for death than patients who did not take the medicine. [Drug name] is not approved for dementia.
- ***A life-threatening nervous system problem called neuroleptic malignant syndrome (NMS).*** NMS can cause a high fever, stiff muscles, sweating, a fast or irregular heart beat, change in blood pressure, and confusion. NMS can affect your kidneys. NMS is a medical emergency. Call your healthcare professional right away if you experience these symptoms.
- ***A movement problem called tardive dyskinesia (TD).*** Call your healthcare professional right away if you get muscle movements that cannot be stopped.
- ***High blood sugar and diabetes.*** Patients with diabetes or who have a higher chance for diabetes should have their blood sugar checked often.
- ***Strokes*** have happened in older patients treated for mental illness from dementia. [Drug name] is not approved for this use.
- ***Other serious side effects*** with [drug name] may include low blood pressure seen as dizziness, increased heart beat and possibly fainting, seizures; increased body temperature; and difficulty swallowing.
- ***The most common side effects*** may include headache, weakness, nausea, vomiting, constipation, anxiety, problems sleeping, lightheadedness (dizziness), sleepiness, restlessness and rash.

What Should I Tell My Healthcare Professional?

Before you start taking [drug name], tell your healthcare professional if you:

- have or had heart problems
- have or had seizures
- have or had diabetes or increased blood sugar
- are trying to become pregnant, are already pregnant, or are breast-feeding
- drink alcohol

Are There Any Interactions With Drugs or Foods?

Because certain other medications can interact with [drug name] review all medications that you are taking with your healthcare professional, including those that you take without a prescription.

Your healthcare professional may have to adjust your dose or watch you more closely if you take the following:

- blood pressure medicines
- ketoconazole
- quinidine
- carbamazepine
- fluoxetine or paroxetine

Avoid drinking alcohol while taking [drug name].

Is There Anything Else I Need to Know?

- [Drug name] may impair judgment, thinking, or motor skills. You should be careful in operating machinery, including automobiles, until you know how [drug name] affects you.
- It is important to avoid overheating and dehydration lower while taking [drug name]. [Drug name] may make it harder to lower your body temperature

[Drug name] FDA Approved 2002
Patient Information Sheet Revised 09/2006

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570
Druginfo@fda.hhs.gov

APPENDIX C

Survey and Certification and Examples of Nursing Home Noncompliance Related to Unnecessary Drugs

To determine a nursing home's compliance with the unnecessary drug requirement, the Centers for Medicare & Medicaid Services (CMS) completes a review for unnecessary drugs through the nursing home's survey and certification process. The objectives of this review are to determine whether (1) each resident is administered only those drug(s) that are clinically indicated in the dose and for the duration to meet the resident's assessed needs; (2) nonpharmacological approaches or alternatives are used when clinically indicated; and (3) gradual dose reduction is attempted, unless clinically contraindicated. This review should also determine whether the nursing home, in collaboration with a drug's prescriber, is monitoring the effectiveness of drug(s) by identifying the parameters for drug monitoring or drug combinations that could pose a risk of adverse consequences. The review should also determine whether the nursing home, in collaboration with a drug's prescriber, recognizes and evaluates the onset or worsening of signs or symptoms or a change in condition to determine whether these effects may be related to a drug regimen and follows up as necessary.

Examples of noncompliance related to unnecessary drugs in nursing homes drawn from CMS's *State Operations Manual* are listed below:[44]

Excessive Dose (Including Duplicate Therapy). Examples of noncompliance related to excessive dose include, but are not limited to: giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition without a documented clinically pertinent rationale; failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication (i.e., gradually reducing the dose); and failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

Excessive Duration. Examples of noncompliance related to excessive duration include, but are not limited to: (1) continuation beyond the manufacturer's recommended timeframes, the stop date or duration

[44] CMS, *State Operations Manual* (Internet-Only Manual), Pub. 100-07, Appendix PP: Guidance to Surveyors for Long Term Care Facilities, F329, § 483.25(l), Unnecessary Drugs.

indicated on the medication order, facility-established stop order policies, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or current standards of practice without documented clinical justification; and (2) continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit.

Inadequate Monitoring. Examples of noncompliance related to inadequate monitoring include, but are not limited to: failure to monitor the responses to or effects of a drug and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal or the emergence of an adverse consequence; failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines; and failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences.

Inadequate Indications for Use. Examples of noncompliance related to use of a medication without adequate indications include, but are not limited to: failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using drug(s) for a specific resident; failure to provide a clear clinical rationale for continuing a drug that may be causing an adverse consequence; and initiation of an antipsychotic drug to manage distressed behavior without considering a possible underlying medical cause (e.g., urinary tract infection, congestive heart failure) or environmental or psychosocial stressor.

Adverse Consequences. Examples of noncompliance related to adverse consequences include, but are not limited to: failure to act (i.e., discontinue a drug, reduce the dose, or provide clinical justification for why the benefit outweighs the adverse consequences) upon a report of the risk for or presence of clinically significant adverse consequence(s).

Use of Antipsychotic Medications Without Gradual Dose Reduction and Behavioral Interventions Unless Clinically Contraindicated. Examples of noncompliance related to this requirement include, but are not limited to: failure to attempt gradual dose reduction in the absence of identified and documented clinical contraindications, prolonged or indefinite antipsychotic use without attempting gradual dose reduction, and failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

APPENDIX D

Detailed Methodology

Data Sources

Identifying Atypical Antipsychotic Drug Claims. We obtained final action claims for Medicare Part D program Prescription Drug Event (PDE) and Part B program data. The PDE data are not the same as individual drug claim transactions; they are summary extracts that document the final adjudication of a dispensing event using the Centers for Medicare & Medicaid Services-defined standard fields. However, because these data contain claim-level information, we refer to the PDE and Part B records collectively as claims for the purposes of this study.

Additionally, the Food and Drug Administration (FDA) identifies a drug product by using a National Drug Code (NDC), which is a unique, universal three-segment numerical product identifier for human drugs. NDCs are listed directly in PDE data and crosswalked through Healthcare Common Procedure Coding System (HCPCS) codes in Part B data. At the time of our review, 909 NDC and 11 HCPCS codes were associated with the 8 atypical antipsychotic drugs. We calculated dollar amounts for claims by adding the ingredient cost, dispensing fee, and sales tax for Part D claims and using the allowed payment amount for Part B claims.

Identifying Elderly Nursing Home Residents With Atypical Antipsychotic Drug Claims. We analyzed Medicare Part A inpatient and skilled nursing facility claims data to determine whether a beneficiary's nursing home stay was interrupted by an admission to a different medical facility (i.e., hospital) during our 6-month review period. If these data indicated that a resident was not in the nursing home as identified through the Minimum Data Set (MDS) data at the time of a drug claim, we excluded that beneficiary from our universe of elderly nursing home residents.

Identifying Elderly Nursing Home Residents' Diagnoses for Stratification. For purposes of this report, we identified diagnoses of interest (bipolar disorder, schizophrenia, and dementia) using the following indicators:

- ten fields for International Statistical Classification of Diseases and Related Health Problems (ICD-9) codes listed in Part A home health, hospice, inpatient, and skilled nursing facility claims and Part B outpatient claims;
- two fields for ICD-9 codes in Medicare Part B physician data;

- five fields for ICD-9 codes in MDS data; and
- one specific data field in MDS data for each of the following: dementia, Alzheimer's disease, schizophrenia, and manic depression (i.e., bipolar disorder).

Requesting Medical Records. Documentation requested from nursing homes for each sampled elderly nursing home resident included:

- the first mental health or medical evaluation upon admission to the facility if the beneficiary was already receiving the drug at the time of admission, or
- the hospital discharge summary or evaluation if the drug was first administered during a hospital stay, or
- the evaluation immediately preceding the initiation of the drug if the drug was initiated at the facility.

Additional information requested included documentation for the 6 months prior to and after the date of the sampled claim: pharmacy review documents/drug utilization review forms; daily Medication Administration Records; resident care plans; history and physical notes; physician orders, progress notes, evaluations, and consults; nurses' progress notes; behavior monitoring notes/logs; social services records/notes; and MDS/Resident Assessment Protocol assessments.

A medical record was considered complete and forwarded to medical reviewers if (1) the nursing home provided the resident's date of admission to the facility and information regarding when the drug associated with the sampled claim was first administered to the resident and (2) all requested documents were received or the reason(s) for any missing requested documents were provided.

Identifying Medically Accepted Indications for Use of Atypical Antipsychotic Drugs. We identified the medically accepted indications from each of the three statutorily named compendia for the use of the eight atypical antipsychotic drugs included in our review.[45] If an indication was noted in

[45] At the time of our review, the three statutorily named compendia were: (1) the *American Hospital Formulary Service Drug Information*, (2) the *United States Pharmacopeia-Drug Information* (or its successor publications), and (3) *the DrugDEX Information System*. Prior to our review period, the *American Medical Association Drug Evaluations* was included in the list of statutorily named compendia but was incorporated into the *United States Pharmacopeia-Drug Information* in 1994 and discontinued in 1996.

any of the three compendia for a drug, we included that indication on that drug's list of accepted indications.[46] Medically accepted indications identified from each compendium included both FDA-approved and off-label uses.

Data Analysis

Identifying Claimed Drugs That Met Medicare Reimbursement Criteria. We used the diagnosis determined by medical reviewers for each resident to determine whether the claimed drug met Medicare reimbursement criteria. We matched the resident's diagnosis to the list of medically accepted indications for the claimed drug that each resident received. If the resident's diagnosis was not found on the claimed drug's list of medically accepted indications, then the claimed drug did not meet Medicare reimbursement criteria. We determined claims for drugs to be erroneously paid if they were undocumented or did not meet Medicare reimbursement criteria.

Sampling Frame and Strata.
We stratified claims based on whether the data indicated that the claimed drug was used off-label and/or in the presence of the condition specified in the boxed warning (see Table D-1).

Table D-1: Original Sampling Frame and Number of Claims in Each Stratum

Stratum	Stratum Definition (Diagnoses)	Claims (Population)	Claims (Sample)
1	FDA-approved condition* and no dementia	149,301	175
2	FDA-approved condition and dementia	510,725	175
3	No FDA-approved condition and no dementia	77,795	175
4	No FDA-approved condition and dementia	941,053	175
Total**		**1,678,874**	**700**

Source: Office of Inspector General (OIG) analysis of 2008 MDS and Medicare Part A, Part B, and Part D claims data.
*For the purposes of this report, an FDA-approved condition is a medical indication for which FDA had approved the use of a drug at the time of our review period.
**The population figures are based on diagnosis data in the Medicare Part A and Part B claims and MDS system.

[46] We used the versions of the compendia published closest to our review period. We used the 2007 versions of *American Hospital Formulary Service Drug Information* and *United States Pharmacopeia-Drug Information*. We used the 2008 version of *DrugDEX*; see the Limitations section of this report for more information.

Medical reviewers determined that elderly nursing home residents' diagnoses in the medical record were sometimes different from the diagnoses in the data sources we used for sample stratification (see Table D-2).

Table D-2: Sampling Frame With the Number of Claims in Each Diagnosis Group After Medical Reviewers Determined Diagnoses

Stratum	FDA-Approved Condition and No Dementia	FDA-Approved Condition and Dementia	No FDA-Approved Condition and No Dementia	No FDA-Approved Condition and Dementia	Claims (Medical Review)
1	54	19	50	27	150
2	6	49	5	90	150
3	2	1	76	71	150
4	0	3	4	143	150
Total	**62**	**72**	**135**	**331**	**600**

Source: OIG medical review analysis of nursing home records, 2009.

Determining Relationship of Diagnosis Groups to Error Rates. Our analysis identified differences in rates of payment error among the four diagnosis groups (see Table D-2 above). Because FDA-approved conditions are medically accepted indications, claims for atypical antipsychotic drugs prescribed to elderly nursing home residents diagnosed with such conditions were not considered errors. For the claimed drugs that were determined to be used off-label, 62 percent did not have medically accepted indications and were therefore in error.

Our analysis also identified differences in rates of compliance with CMS standards regarding unnecessary drugs among the diagnosis groups. The 34 percent of claims for drugs prescribed for residents who were not diagnosed with dementia were significantly more likely to comply with CMS criteria regarding unnecessary drugs than the 21 percent of claims for drugs prescribed for residents who were diagnosed with dementia (i.e., the condition specified in the FDA boxed warning).[47]

[47] All references to error rates are statistically significant at the 95-percent confidence level.

APPENDIX E

Nonresponse Analysis

We examined the potential for effects of nonresponse bias on key statistics. We analyzed how nonresponse of the 100 sampled claims for which medical review was not conducted may have affected our estimates used in this report.

For the purposes of this analysis, we considered all records that were not reviewed as nonrespondents. A total of 100 sampled claims did not receive medical review because 1 nursing home was under investigation, 39 provided the requested documentation after 150 records had already been received for the corresponding stratum, 21 did not provide sufficient records for review, 3 indicated that the beneficiary was not a resident at the time of the sampled claim, and 36 did not respond to our record request.

We compared reviewed claims to nonreviewed claims according to the following six variables: type of nursing home ownership, whether the nursing home was part of a chain, the nursing home's total number of beds, beneficiary age, beneficiary gender, and beneficiary race. We determined whether reviewed and nonreviewed claims differed statistically at the 95-percent confidence level on these variables and found only two statistically significant differences. Claims for residents in for-profit nursing homes were less likely to have been reviewed (83.1 percent) compared with not-for-profit (92.8 percent) and government (90.1 percent) nursing homes. Also, claims for residents in nursing homes that were part of a chain were less likely to have been reviewed (81.8 percent) compared with all other claims (90.0 percent).

Because claims for residents in for-profit nursing homes and in chain nursing homes were underrepresented in our sample, we investigated whether this might bias our results. To do this, we first classified the reviewed claims into six categories corresponding to the ownership and chain variables. Then we assigned the average of reviewed values to nonreviewed claims within the same ownership and chain categories. Finally, we determined whether estimates based on both reviewed actual values and nonreviewed imputed values differed significantly from the estimates based only on the reviewed values. Based on this analysis, we found no statistical evidence that our results were biased because of nonresponse.

APPENDIX F

Point Estimates and Confidence Intervals for Selected Statistics

Description	Sample Size (n)	Point Estimate	95-Percent Confidence Interval
Percentage of claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (net)	600	95.3	94.0–96.5
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (net)	600	1,372,823	1,354,910–1,390,736
Percentage of claims for drugs used for off-label conditions	600	83.1	80.3–85.9
Claims for drugs used for off-label conditions	600	1,197,442	1,157,389–1,237,495
Percentage of claims for drugs used in the presence of the condition specified in the FDA boxed warning	600	87.7	85.6–89.8
Claims for drugs used in the presence of the condition specified in the FDA boxed warning	600	1,263,641	1,233,783–1,293,500
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (gross)	600	2,461,083	2,409,185–2,512,981
Total claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (overlapping)	600	1,088,260	1,043,144–1,133,377
Percentage of claims for drugs used for off-label conditions and/or in the presence of the condition specified in the FDA boxed warning (overlapping)	600	75.5	72.4–78.6
Percentage of claims for drugs used neither for off-label conditions nor in the presence of the condition specified in the FDA boxed warning (net)	600	4.7	3.5–6.0
Total claims for drugs neither off-label nor in the presence of the condition specified in the FDA boxed warning (net)	600	68,277	50,364–86,190
Total claims for which records were reviewed	700	1,441,100	1,379,118–1,492,003
Total claims for which records were not reviewed	700	237,774	186,871–299,756
Percentage of claims for elderly nursing home residents who exhibited symptoms that presented one or more of the following: a danger to themselves or others, inconsolable or persistent distress, a significant decline in functioning, and/or substantial difficulty in receiving needed care	535	88.6	85.3–91.9
Number of claims for elderly nursing home residents who exhibited symptoms that presented the conditions listed above	535	1,216,823	1,171,381–1,262,265
Total errors: percentage (net)	600	50.4	45.5–55.3
Total errors: dollar amount (net)	600	$116,479,018	$100,800,390–$132,157,646
Total errors: claims (net)	600	726,782	655,956–797,608
Number of claims for undocumented drugs	600	3,807	0–9,668
Percentage of claims for undocumented drugs	600	0.3	0.0–0.7
Dollar amount for claims for undocumented drugs	600	$559,333	$0–$1,318,866
Number of claims for drugs without medically accepted indication	600	722,975	652,242–793,706
Percentage of claims for drugs without medically accepted indication	600	50.2	45.3–55.1
Dollar amount for claims for drugs without medically accepted indication	600	$115,919,685	$100,243,543–$131,595,827

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APPENDIX F

Description	Sample Size (n)	Point Estimate	95-Percent Confidence Interval
Percentage of claims for drugs that did not comply with CMS* standards regarding unnecessary drug use in nursing homes (net)	600	22.1	17.8–26.3
Total claims for drugs that did not comply with CMS standards regarding unnecessary drug use in nursing homes (net)	600	317,971	257,214–378,729
Dollar amount for claims for drugs that did not comply with CMS standards regarding unnecessary drug use in nursing homes (net)	600	$63,194,984	$48,933,121–$77,456,846
Percentage of claims for drugs determined to be unnecessary for more than one reason	149	42.4	31.7–53.3
Number of claims for drugs taken in excessive dose	600	150,106	107,499–192,713
Percentage of claims for drugs taken in excessive dose	600	10.4	7.4–13.4
Dollar amount for claims for drugs taken in excessive dose	600	$36,050,851	$24,142,398–$47,959,303
Number of claims for drugs taken for excessive duration	600	135,199	91,706–178,692
Percentage of claims for drugs taken for excessive duration	600	9.4	6.4–12.4
Dollar amount for claims for drugs taken in excessive duration	600	$29,369,213	$17,510,089–$41,228,337
Number of claims for drugs taken without adequate indications for use	600	115,818	75,136–156,500
Percentage of claims for drugs taken without adequate indications for use	600	8.0	5.2–10.8
Dollar amount for claims for drugs taken without adequate indications for use	600	$21,396,226	$13,220,119–29,572,334
Number of claims for drugs taken without adequate monitoring	600	110,949	69,948–151,950
Percentage of claims for drugs taken without adequate monitoring	600	7.7	4.8–10.5
Dollar amount for claims for drugs taken without adequate monitoring	600	$18,150,616	$10,772,976–$25,528,257
Number of claims for drugs taken in the presence of adverse consequences	600	67,923	36,021–99,824
Percentage of claims for drugs taken in the presence of adverse consequences	600	4.7	2.5–6.9
Dollar amount for claims for drugs taken in the presence of adverse consequences	600	$11,479,869	$6,088,283–$16,871,455
Total claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	579,994	437,574–722,414
Percentage of claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	40.2	30.4–50.1
Dollar amount for claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (gross)	600	$116,446,775	$84,276,682–$148,616,869
Total claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	262,023	161,822–362,163
Percentage of claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	18.2	11.2–25.1
Dollar amount for claims for drugs that did not comply with CMS's standards regarding unnecessary drug use in nursing homes (overlapping)	600	$53,251,792	$32,241,106–$74,262,477

Source: Office of Inspector General medical review analysis of nursing home records, 2009.
*CMS is the Centers for Medicare & Medicaid Services, and FDA is the Food and Drug Administration.

APPENDIX G

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: MAR 1 1 2011

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, MD /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," (OEI-07-08-00150)

Thank you for the opportunity to review and comment on the subject draft report "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents." The OIG study examined claims for the period January 1 through June 30, 2007. Specifically, the study determined the extent to which:

- Nursing home residents aged 65 and older had Medicare claims for atypical antipsychotic drugs;
- Medicare claims for atypical antipsychotic drugs for nursing home residents aged 65 and older were associated with conditions off-label and/or specified in the Food and Drug Administration's (FDA) boxed warning;
- Claimed atypical antipsychotic drugs for nursing home residents aged 65 and older complied with Medicare reimbursement criteria; and
- Claimed atypical antipsychotic drugs were provided in accordance with Center for Medicare & Medicaid Services (CMS) standards regarding unnecessary drug use in nursing homes.

The concern over whether atypical antipsychotics and other drugs are being appropriately prescribed to elderly nursing home residents is one we share with the OIG and Congress. In particular, we are very concerned about the nature of the contractual arrangements involving long-term care (LTC) facilities, LTC pharmacies, LTC consultant pharmacists, and pharmaceutical manufacturers and/or distributors, and the incentives such arrangements provide for inappropriate prescribing practices that may adversely affect the health and safety of LTC residents. Based on the November 2009 Omnicare settlement, the OIG identified these contractual relationships as the cause of the inducement to over-utilize antipsychotics in nursing

homes, and we strongly believe this should be referenced in this report. We are very concerned that if an official OIG report ignores the causative behavior of the LTC pharmacies, and instead suggests that the problem is limited to a Medicare Part D claims payment issue, the issuance of this report may be used as a defense of the practice, and may seriously interfere with any future efforts of OIG, Department of Justice, and CMS to correct the fundamental problem.

Below is CMS response to the OIG recommendations and additional general comments:

General Comments on OIG Findings

The CMS has additional comments with regard to other study findings. The OIG found that 95 percent of Medicare claims associated with atypical antipsychotic drugs used off-label and /or against the FDA black-box warning. Although a member of Congress requested that the OIG evaluate the extent to which elderly nursing home residents receive atypical antipsychotic drugs, the off-label uses that are cited in the compendia are still considered by law to be medically accepted indications. We believe that reporting these uses together with uses against the boxed warning incorrectly overstates inappropriate use.

The CMS requests that Part D formulary policies relating to antipsychotic medications be included in the final report. With few exceptions (such as brand/generic substitution), all antipsychotics must be on all Part D formularies. Further, Part D sponsors may not impose step therapy or prior authorization requirements for beneficiaries who are taking the drug. Part D sponsors are required to perform retrospective drug utilization reviews and are able to identify non-medically accepted uses through this mechanism.

OIG Recommendation

CMS facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.

CMS Response

We do not concur with OIG's recommendation. Currently, diagnosis information is not a required data element on pharmacy billing transactions nor is it generally included on prescriptions. As such, this information is not readily available to dispensing pharmacists.

The industry has not developed a standardized process to collect diagnosis related information as part of the prescription drug claim. Until such time as state boards of pharmacy require that this information be included on prescriptions, and the industry agrees upon an industry standard for reporting diagnosis-related information as part of the claim, CMS will not add any new data fields to the prescription drug event (PDE) elements until such data is useful and can be used to determine if Part D reimbursement was appropriate.

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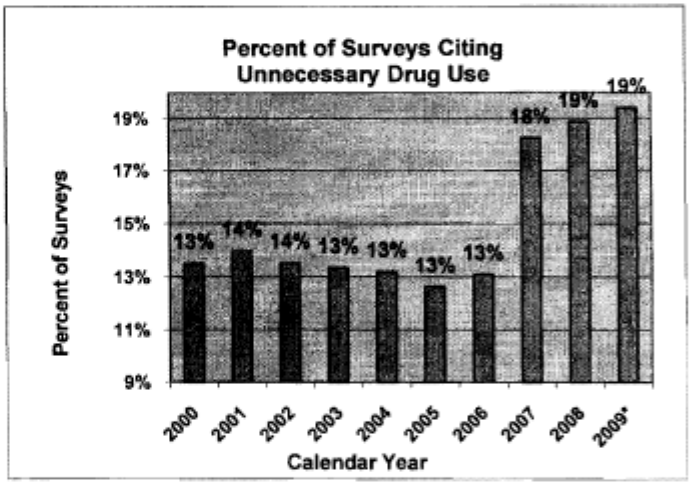
OIG Recommendation

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

CMS Response

We concur and have already assessed the survey & certification process and made improvements.

We have assessed survey & certification processes and in late 2006 implemented substantial improvements to the CMS onsite surveys, as described below. One result was a substantial increase in the number of deficiencies cited for unnecessary drug use. As shown in the following graph, the percent of onsite surveys in which the facility was cited for unnecessary drug use increased from 13 percent in 2003-2006 to 18 percent in 2007 and 19 percent in 2008-2009. We noted that the level of deficiencies identified through onsite surveys did not decrease after the reforms were implemented in late 2006, despite the added scrutiny and enforcement that CMS put in place. We therefore concluded that the survey process is pushing against very strong counter-forces, such as financial counter-forces, that require other actions to address the financial incentives for unnecessary drug use.



In September 2006, CMS released S&C Memorandum 06-29 which provided much more information regarding the Issuance of Revised Surveyor Guidance for Unnecessary Medications (F329) and the entire Pharmacy Services section at §483.60. We combined current regulatory language into three tags (F425, F428, and F431) in Appendix PP of the State Operations Manual, as well as medication related revisions in Appendix P Task 5 and Sub-Tasks 5A, 5C, and 5E. The memo identified not only the changes to the guidelines and survey process, but also included information regarding training surveyors regarding these changes.

The CMS entirely revised interpretive guidelines for F329 (Unnecessary Medications), including clarifications of several aspects of medication management and a new medication table that includes medications that are problematic to the nursing home population. We provided an Investigative Protocol that also covers both Medication and Medication Regimen Review issues and severity guidance for F329. This guidance was developed with experts in the area of medications and with survey agency, nursing home advocates and nursing home provider input.

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For Pharmacy Services at §483.60, we combined regulatory guidance Tags F425-431 into three tags, F425 Pharmacy Services, F428 Drug Regimen Review, and F431 Labeling and Storage of Drugs and Biologicals. The guidance addresses the provision of pharmaceutical services for the entire distribution system, from ordering and acquisition to administration and disposal of medications to assure a safe system for each resident. In addition, we provided severity guidance for each of these F Tags. The guidance is available on the CMS Website - http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf at CFR 483.25(l) F329 – Unnecessary Drugs and CFR 483.60, F425 – F431 Pharmacy Services.

Training materials on these revisions were provided through various methods:

- Power point training materials;
- Two, two-day train-the-trainer sessions in Baltimore in November 2006; and
- A satellite presentation on F329 on December 15, 2006.

We believe that the surveyor guidelines and protocols provide effective direction for surveyors in determining the presence of an unnecessary medication, but that other efforts are needed in combination with onsite surveys to achieve the progress desired to also address the financial incentives for unnecessary drug use.

OIG Recommendation

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

CMS Response

CMS concurs with this recommendation, but do not believe the examples provided in the report are practicable (excluding provider education). The report recommendations suggest CMS adopt (1) provider education and incentive programs, (2) strategies to prevent Medicare payments, and (3) requirements for nursing homes to reimburse for claims not meeting CMS standards. Although CMS can identify opportunities to improve provider education in this area, the remaining recommendations (incentive programs, prevention of payment, and nursing home reimbursement) are beyond our statutory authority. CMS is, however, continuing to explore alternative strategies within our statutory authority that more directly address the financial incentives in contractual arrangements among pharmaceutical manufacturers, LTC pharmacies, facilities and consultant pharmacists that are responsible for the increased and unnecessary use of atypical antipsychotics by patients in nursing homes.

OIG Recommendation

CMS should take appropriate action regarding the claims associated with erroneous payments identified in the OIG's sample.

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CMS Response

CMS concurs and will consider what appropriate actions need to be taken when the claims data are received from the OIG.

Thank you for the opportunity to review and comment on the draft report.

ACKNOWLEDGMENTS

This report was prepared under the direction of Brian T. Pattison, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Deborah K. Walden, Deputy Regional Inspector General.

Amber Meurs served as the project leader for this study. Other principal Office of Evaluation and Inspections staff from the Kansas City regional office who contributed to the report include Julie Dusold and Rae Hutchison; central office staff who contributed include Robert Gibbons, Sandy Khoury, and Julie Taitsman.

Office of Inspector General

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