

‘Boxed in’ or ‘boxed out’?

Prescribing atypicals for dementia

Dear Dr. Mossman:

Some of my older patients with dementia develop severe behavioral disturbances, and when other treatments don't work, I sometimes use second-generation anti-psychotics (SGAs) to help them cope better. But I worry about the liability I might face because of the “black-box” warning about prescribing SGAs to these patients. How can I minimize the legal risks of doing this?

Submitted by “Dr. K”

“Black-box” warning. The phrase *sounds* scary, and it's meant to frighten you—or at least get your attention.

However, the FDA has put boxed warnings on all antidepressants and many other psychotropic drugs. This doesn't mean you should quit practicing psychopharmacology. Instead, the FDA just wants you to hesitate and be careful when you prescribe certain drugs in certain situations. One such situation is using SGAs to address behavioral problems that often occur in older persons with dementia.

When it comes to prescribing SGAs for patients with dementia, you can respond to your fear of the “black box” with something that isn't scary at all: doing what's best for your older patient. In this article, we'll explain how, as we cover:

- the scope of the clinical problem
- what a “black-box” warning is
- the significance of the boxed warning for SGA use for dementia-related behavioral disturbances

Box

Regulatory definition of ‘boxed warning’

Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box on the drug's prescribing information. The box must contain, in uppercase letters, a heading inside the box that includes the word “WARNING” and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the “Contraindications” or “Warnings and Precautions” section for more detailed information.

Source: Reference 7

- how to minimize medicolegal liability when prescribing SGAs.

Aging boomers

As the “baby boom” generation enters its 7th and 8th decades, psychiatrists should expect to treat many older individuals who have dementia and behavioral problems. In the United States, approximately 4 million individuals age >60 have dementia,¹ and this number will rise rapidly in the next few years.² Rates of dementia-related agitation and aggression range from 20% to 80%.^{3,4} Such behavior—always distressing to patients, family members, and caregivers—can lead to physical injuries, increased caregiver burden, premature institutionalization, physical restraint, and over-medication.



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DO YOU HAVE A QUESTION ABOUT POSSIBLE LIABILITY?

- Submit your malpractice-related questions to Dr. Mossman at douglas.mossman@qhc.com.
- Include your name, address, and practice location. If your question is chosen for publication, your name can be withheld by request.

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continued

Clinical Point

Despite the ‘black-box’ warning, SGAs commonly are prescribed to cognitively impaired older persons

Table 1

Questions to ask before starting SGAs for dementia-related behavioral problems

Questions	Comments
Is the behavior dangerous?	Nonviolent behavior (eg, foul language, inappropriate voiding, hoarding, or refusing to bathe) can be addressed with nonpharmacologic interventions
What about treatable medical problems?	A demented person’s behavioral outbursts may stem from pain (ingrown toenail, acid reflux), misinterpretations caused by hearing or vision problems, delirium from infections or drug interactions, etc
Would a nonpharmacologic approach work?	Possibilities include eliminating environmental stressors, increasing interpersonal attention, more frequent reorientation, or music or art therapy

SGAs: second-generation antipsychotics

Source: References 9,10

Table 2

Essentials of informed consent

Elements	Patient has the capacity to consent, has received adequate information about the proposed treatment, and has not been coerced
Information to disclose about the proposed treatment	Expected benefits, risks (common and serious side effects), alternatives, and expected outcomes of treatment and no treatment

Source: Reference 13

No medication has received FDA approval for treatment of dementia-related agitation. Currently, doctors try a variety of medications, such as memantine, cholinesterase inhibitors, anticonvulsants, and selective serotonin reuptake inhibitors.⁵ Nearly one-third of nursing home residents with dementia receive antipsychotic drugs.⁶ Thus, despite the “black-box” warning, SGAs commonly are prescribed to cognitively impaired older persons for behavioral agitation and/or psychosis.

What’s a ‘black-box’ warning?

Almost every prescription drug has dozens of possible adverse effects. “Black-box” warning is a colloquialism that refers to the FDA’s format for describing particularly important potential complications or precautions necessary when prescribing a drug. (For the official definition of a “boxed warning,” see *Box, page 77*).⁷

Understanding the warning

In April 2005, the FDA mandated a boxed warning for SGAs after placebo-controlled studies showed a significantly higher death rate—mostly from cardiovascular accidents or infections—in geriatric patients who received SGA treatment for dementia-related psychoses.⁸ The warning does not forbid you from using SGAs when treating older patients with dementia—but you must think carefully about this off-label treatment (ie, prescribing SGAs for an indication that is not FDA-approved).

In patients with dementia, medical conditions may be expressed as behavioral problems that should be addressed with behavioral therapies or appropriate medical therapy (*Table 1*).^{9,10} You can feel better about starting SGA therapy if a thorough medical, cognitive, and functional work-up has ruled out nonpsychiatric reasons for disruptive behavior.^{9,11,12} The workup should look for cardiovascular, cerebrovascular, pulmonary, and metabolic risk fac-

tors, along with medication side effects.

If medical and situational problems are ruled out, or if aggressive, assaultive, or disruptive behavior threatens the physical safety of patients or others, careful consideration of therapeutic alternatives may show that SGAs are the best treatment choice. Once this decision is reached, clinicians can minimize legal liabilities in several ways.

Informed consent: A process

Informed consent is an essential feature of most medical treatment (*Table 2*).¹³ Informed consent is especially important when—as with using SGAs for behavioral disturbances in dementia—you want to prescribe a drug off-label in a context for which the FDA has required a boxed warning.

Patients in early stages of dementia may retain their decision-making capacity and ability to give informed consent.¹⁴ If the opportunity presents itself, this is an ideal time to discuss the possible future need for SGAs and to make sure the patient has designated a proxy decision-maker who can make treatment choices if the patient loses capacity. If a patient's decision-making capacity is questionable, obtain consent from a surrogate (often a relative).

Informed consent is a process, not a printed form. It involves taking time to be sure that the patient or surrogate decision-maker understands and accepts the risks associated with a proposed treatment. Thinking of informed consent as a process facilitates communication, acceptance of treatment, and trust between prescribers and recipients of care.

Involving family

When appropriate, include a patient's family in informed consent and treatment planning processes. Providing written material, such as *Treatment of dementia and agitation: a guide for families and caregivers*,¹⁵ can help educate persons whose loved ones suf-

Table 3

What to document

Your reasons for starting treatment with SGAs
Other treatments that were tried unsuccessfully
Other treatments that were considered but deemed inappropriate
The patient's baseline medical, physical, cognitive, and functional status, including consideration of cardiovascular, cerebrovascular, pulmonary, and metabolic risk factors
How and when you will monitor side effects
For a patient who resides outside a nursing home, send a letter to the primary care provider stating that the patient is on SGA therapy and requesting assistance in monitoring for medical problems
For a patient who resides in a nursing home, describe the monitoring system for identifying adverse events (eg, regular EKGs, pulmonary exams, and lab tests)
Collect and keep copies of literature supporting your treatment choice
SGAs: second-generation antipsychotics
Source: Adapted from reference 20

fer from dementia. These resources often improve care and build relationships with family members that sustain treatment alliances when adverse outcomes occur. Also, well-engaged and informed families are less likely to initiate malpractice lawsuits when adverse events occur.¹⁶

Monitor for side effects

Older patients are especially vulnerable to physical harm during agitated or aggressive behavior, but they're also quite vulnerable to medication side effects. Before starting SGAs, note the patient's alertness, activities of daily living, movement abnormalities, and EKG abnormalities. Knowing this "baseline" helps you assess the effects of medication and monitor for side effects. Brief assessment scales—such as the Montreal Cognitive Assessment Test,¹⁷ the Abnormal Involuntary Movement Scale,¹⁸ and the Instrumental Activities of Daily Living Scale¹⁹—can help you quantify

Clinical Point

Before starting SGAs document your patient's baseline medical, physical, cognitive, and functional status

Drug Brand Name

Memantine - Namenda

Disclosure

The authors report no financial relationship with any company whose products are mentioned in this article or with manufacturers of competing products.

baseline functioning, monitor symptom response, and detect adverse effects.

For patients receiving SGA therapy, reassess benefits and risks at least every 3 months, and preferably more often.¹¹ In geriatric patients, titrate dosages slowly, maintain medications at the lowest effective levels, and discontinue them once they are no longer necessary. When doubt arises about the effectiveness of SGA therapy, stop the drug.¹²

Remember to document

Because older patients have high rates of medical problems and medication side effects, negative outcomes always are a risk. Good documentation is a key risk management strategy that can help if a bad outcome requires you to defend your treatment plan in court (*Table 3, page 79*).²⁰

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Clinical Point

For patients receiving SGA therapy, reassess benefits and risks at least every 3 months

Bottom Line

When prescribing second-generation antipsychotics for older patients with dementia is clinically appropriate, you can lower your liability risk by judicious dosing, obtaining informed consent, having a monitoring system for detecting adverse events, coordinating care with other providers, and documenting reasons that justify your treatment choice.