



To: OMH Facility, Clinical, and Nursing Directors
Directors of OMH Licensed Programs

From: Lloyd I. Sederer, MD, Medical Director
Leslie Citrome, MD, MPH, Nathan Kline Institute for Psychiatric Research
Lewis Opler, MD, Director, Adult Psychopharmacology

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Re: FDA Advisory on Antipsychotic use in Dementia

While antipsychotics (APs) are the treatment of choice for positive symptoms like hallucinations and delusions in patients with schizophrenia, **antipsychotics are not approved by the FDA for the treatment of dementia-related psychosis**. This is the case for both first and second generation antipsychotics (FGAs and SGAs). In particular, the use of APs to treat dementia is problematic because of medical risks, including death, associated with their use.

OMH cautions against the use of FGAs and SGAs in elderly patients treated for dementia-related psychosis or dementia-related behavioral disturbances. *If a physician chooses to treat a behavioral disturbance or psychosis in an elderly patient with dementia with an AP, a risk/benefit analysis should be provided and the health status of the recipient needs be closely monitored.*

The OMH position is consistent with practice guidelines as well as with recent FDA advisories. Specifically, on June 16, 2008, the FDA issued a Public Health Advisory that typical antipsychotics (FGAs such as haloperidol, perphenazine and chlorpromazine) are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. This supplements their advisory from April 11, 2005, that atypical antipsychotics (SGAs such as risperidone, olanzapine, and aripiprazole) are associated with an increased risk of mortality in elderly patients treated for dementia-related behavioral disturbances.

Because of these findings, the FDA is requiring a **Boxed Warning** in antipsychotic product labeling describing this risk and noting that these drugs are not approved for the treatment of psychosis in elderly patients with dementia.

Additional reasons why antipsychotics may be contraindicated in treating dementia are:

1. Antipsychotics have side effects that can make dementia worse. Sedation, primarily mediated by blockade of histamine receptors, can lead to greater confusion, potentially making agitation worse in persons with dementia. Additionally, all of the antipsychotics have some degree of intrinsic anticholinergic activity, which can interfere with memory.
2. Antipsychotic side effects can add to health problems, particularly in the elderly. In addition to the concerns raised by the FDA, anticholinergic activity can lead to constipation and bowel obstruction, as well as decreased sweating which can contribute to heat-related illness in the summer.

Additional information can be obtained at
http://www.fda.gov/cder/drug/InfoSheets/HCP/antipsychotics_conventional.htm

<http://www.fda.gov/cder/drug/advisory/antipsychotics.htm>

