Editorial

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It's Time To Require Written Informed Consent When Using Antipsychotics in Dementia

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The prevalence of behavioural symptoms in dementia is well known. Patients may exhibit outright psychotic features (delusions, hallucinations) and commonly experience a host of symptoms such as screaming, hitting, agitation, and wandering. The patient often appears to be upset and suffering, and whether the symptom is the cause of that distress, or a result of some inner discord, is unknown. Clearly, these behaviours are upsetting to the patient's family, loved ones, and their caregivers. Physicians are driven to attempt to reduce the suffering of patients and support the family and other professional caregivers. Hence, medications are often the first approach to dealing with such problems. Given the similarity between these symptoms and those seen in patients with schizophrenia, antipsychotics are often the first choice. As a result, nearly 1 in 4 elderly nursing home residents in the United States are given antipsychotic drugs[1].

Unfortunately, they are not very effective. Schneider, in an extensive review of the efficacy of antipsychotics found an effect size of only 18% favouring these drugs over placebo[2]. But much more worrisome are the potentially lethal, or permanently disabling, side-effects. A meta-analysis of 15 randomized controlled trials evaluating dementia patients with behavioural and psychological symptoms concluded that there was an overall increase in the risk of death (odds ratio 1.54, 95% CI 1.06–2.23; p = 0.02) when atypical antipsychotics were compared to placebo[3]. This means that for every 9 to 25 persons helped in these trials, there possibly will be 1 death due to the treatment itself. Older "typical" antipsychotics may not be any less risky. A comedian once commented, "I don't consider 'death' a side-effect, I think it's a primary effect!" In addition, the risk of the patient acquiring the permanent though not lethal side-effect of tardive dyskinesia is higher in older patients than younger ones. Finally there are other serious potential adverse affects such as falls, confusion, and weight gain or increased risk of diabetes.

Some have written that using antipsychotics in dementia is "off label" prescribing, a term which is usually reserved for the use of a drug for which there has been little study but presumed efficacy based on clinical experience. However, the "Black Box Warning" on the use of antipsychotics in dementia is non-ambiguous: these drugs are "not approved for dementia-related psychosis." Yet one company, Eli Lilly, incurred a $1.4 billion fine from the FDA for marketing Zyprexa (Olanzapine) in the use of dementia related psychosis.

Clinical guidelines by both Canadian and American interests have clearly described these risks and suggest that antipsychotics be used only as a last resort[4,5]. Searching for a treatable medical problem, ranging from a serious condition such as pneumonia, to a painful irritation like an ingrown toenail, is the first step. But perhaps most importantly, providing a caring, nurturing and non-stressful environment is likely to be most helpful[6]. The work of Tom Kitwood in defining the problematic behaviours of caregivers which may increase dementia-related agitation is refreshing[7]. Unfortunately, few long term care programs have provided for this type of caregiver training. Other interventions, such as music therapy, caregiver support, and caregiver stress reduction may be helpful but have not been extensively studied[8]. So what's the clinician to do if an antipsychotic medication is to be used "as a last resort?"

For the patient's protection and to reduce medical-legal risks, I believe that a formal informed consent process should be initiated. Such a process should entail adequate description of the risks of the treatment, the potential benefits, and the plan for further monitoring and adjustments to the treatment course. As in any informed discussion, it should include the alternatives available, along with the risks and benefits of each alternative. Finally, it should include a discussion of what is likely to happen if no pharmacologic treatment is provided. In most cases, these discussions will necessarily be conducted with the surrogate decision-maker (usually a family member), given the occurrence of psychotic symptoms later in the course of dementia when decision-making capacity is usually severely impaired.

The key elements of the discussion, including open and specific disclosure of the risks, should be documented in written form and entered into the patient's medical record. An example of such documentation is in Appendix 1. Some clinicians with whom I have discussed this idea have responded that the caregivers would not be likely to approve the use of medications if these risks were so openly discussed. My response is simple – the ethical thing to do is always to inform the patient (or his or her surrogate) before initiating treatment. If that leads to a reduction in the use of these drugs, I would not be unhappy.

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Appendix 1

Consent for Use of Antipsychotic Medication

Indications: Antipsychotic medications are sometimes used to treat behavioral symptoms in patients with dementia. These symptoms include delusions (fixed beliefs that are not real), hallucinations (seeing or hearing things that are not real), and others. The Federal Drug Administration (FDA) has approved the use of antipsychotic medications in the treatment of schizophrenia and other mental conditions. While the FDA has not approved these medications in treatment of behavioral symptoms of dementia, physicians may use them for "off-label" purposes if it is believed they well help the patient.

These medications should be used as a last resort to help patients with dementia who are suffering behavioral symptoms. Other "treatments" include changing the person's environment, getting them more involved in activities, making sure there are no medical problems causing the symptoms (like pain), and making sure other medications the patient is taking have not caused the symptoms. If the patient is not suffering from the symptoms (that is, they are not bothered by them) and they do not prevent the caregivers from giving good and safe care, then it is best not to give them medications for the symptoms.

These types of medications have two very serious potential side-effects, which is why it is important that you know both the risks and the benefits of using them.

Recommended medication: _____

Dose: _____

Frequency: _____

Anticipated duration of use: _____

Alternatives: Sometimes other medications, like sedatives, are used if the patient is anxious. But they also have side-effects and may not help the severe behavior problems and usually do not help delusions and hallucinations. Another alternative is to keep trying the non-medicine interventions described above. The final alternative is to give no treatment and just live with the symptoms. As the person's dementia gets worse over time, the symptoms do usually go away. But that may take some time.

Expectations of Treatment: If the medication is used, we expect the person with dementia to have less suffering. The patient should be calmer and feel less distressed. The hallucinations and/or delusions may not go completely away, but they should be less bothersome to the patient. Caregiving should be more accepted by the patient. Hopefully, the patient will not experience any side effects but many patients do have some side effects so it is important to report any change that may be due to the medication.

Side effects and complications include but are not limited to:

1. The most serious concern is that older patients with dementia who are given these medications have an increased risk of death compared to patients given placebos (sugar-pills). That risk is about 1.7 times the risk of using the placebo. Most of the deaths were due to heart problems or pneumonia.
2. The second most serious concern is the development of a permanent side-effect called "tardive dyskinesia." It is an uncontrolled movement of the face and mouth. This occurs in about 25% of patients who take the medication for a long time. Rarely, it can occur even in patients who only take a few doses of the medication.
3. Neuroleptic malignant syndrome – a rare but potentially fatal side effect with fever, blood pressure problems, and irregular pulse.
4. Increased blood sugar, diabetes, and weight gain
5. Sleepiness
6. Falls
7. Low blood pressure
8. Confusion
9. Stiffness, walking problems, tremor (Parkinson's-like symptoms)
10. Liver problems
11. Seizures (epileptic fits)

Contraindications: These medications should not be used if you or your loved-one has an allergy to them. A history of having bad reactions to this medication (or ones similar to this medication) is also a concern and should be discussed with the doctor.

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I understand the above, and have had the risks, benefits, and alternatives explained to me. I have had an opportunity to ask questions about the recommended treatment. I understand that no guarantees about results have been made. I give my informed consent for the use of _____.

_____ _____

Patient Signature Date

_____ _____

Witness Surrogate Signature (if the patient does not have decision-making capacity)