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Hagen, Brad F.

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Antipsychotic drug use in Canadian long-term care facilities: prevalence, and patterns following resident relocation

Brad Hagen,1 Chris Armstrong Esther,1 Roland Ikuta,2 Robert J. Williams,1 Carole-lyne Le Navenec3 and Morgan Aho
1 School of Health Sciences, The University of Lethbridge, Alberta, Canada
2 Senior’s Health, The Chinook Health Region, Lethbridge, Alberta
3 School of Nursing, The University of Calgary, Alberta, Canada

ABSTRACT

Background and aims: Data on antipsychotic use were collected in two Canadian long-term care (LTC) facilities. During the one-year study, residents in one facility were relocated to a new facility, allowing examination of the changes in antipsychotic use associated with relocation.

Method: A comparative descriptive design was used. Pharmacy and chart data on antipsychotic use were gathered for three separate one-month periods during one year. Data were collected both in a facility experiencing relocation of all residents to a new facility, and in a facility not undergoing relocation. The three one-month data collection periods covered a one-month period before the relocation, immediately after the relocation, and six months after the relocation.

Results: In the facility not experiencing relocation, an average of 31.3% of all residents were receiving antipsychotics. Residents in this facility received antipsychotics for an average length of 0.81 years, and 20.8% of all antipsychotic prescriptions reflected dose reductions within six months of the start of the prescription. Only 8.1% of prescriptions had accompanying documentation on the behavioral indication for the use of antipsychotics. A total of 73.4% of all antipsychotics were ‘atypical’ antipsychotics, and 13.5% of all antipsychotic prescriptions were written as ‘p.r.n.’ (as needed). While the use of antipsychotics remained relatively constant in the non-relocation facility (between 30.3% and 33.1% of all residents), the percentage of residents receiving antipsychotics in the facility experiencing a relocation climbed significantly; from 21.5% six
Conclusion: These findings, when compared with the U.S. standards on antipsychotic use (OBRA), suggest the need for additional research on antipsychotic use in Canadian LTC facilities.

Key words: Long-term care, antipsychotic agents, aged, dementia, skilled nursing facilities, nursing homes, drug utilization review, relocation, Parkinson's disease

Background

Although antipsychotic drugs were first developed in the early 1950s to treat schizophrenia, they have become widely used in long-term care (LTC) facilities to manage behavioral disturbances and agitation associated with dementia. Both typical and atypical antipsychotics, though differing in their side-effect profiles, have side-effects, including sedation, orthostatic hypotension, falls and hip fractures, anticholinergic effects, cardiac complications, weight gain, metabolic complications, neuroleptic malignant syndrome and cognitive decline (Hagen and Armstrong-Esther, 1999). Due in large part to these side-effects, there has been increasing concern over the last 30 years about the widespread use of antipsychotics in nursing homes. Several studies conducted in the U.S.A during the 1970s and 1980s found that close to 40% of nursing home residents were receiving antipsychotics (Avorn et al., 1989; Buck, 1988; Ray et al., 1980). The widespread use and growing perceptions that antipsychotics were being used as chemical restraints prompted the U.S. Congress to introduce the Omnibus Budget Reconciliation Act of 1987 (OBRA), that legislated numerous standards for nursing home care, including the use of psychotropic drugs.

The OBRA regulations, implemented in the 1990s, appear to have been effective, with use of antipsychotics in nursing-home residents declining by approximately one-third (Garrad et al., 1991; Lantz et al., 1996; Semla et al., 1994). Recent U.S. research on the use of antipsychotics in nursing homes has found rates of usage in approximately the mid-teens (Garrad et al., 1991; Hughes et al., 2000; Llorente et al., 1998), a rate similar to that of European countries (Hughes et al., 2000; McGrath and Jackson, 1996; Ruth et al., 2001; Sorenson et al., 2001). However, there are very few studies on the use of antipsychotics in Canadian nursing homes. One Western Canadian study found a rate of 17% (Earth y et al., 2000) and another Eastern Canadian study found a rate of 29.8% (Conn et al., 1999). More Canadian research is needed, particularly since Canada, unlike the U.S.A, has no mandatory regulations limiting the use of antipsychotics in nursing homes. In addition, although relocation can be a stressful experience for long-term care residents, and one often associated with
an increase in behavioral problems (Anthony et al., 1987; Castle, 2001), there are no published studies on changes in antipsychotic use associated with resident relocation.

**Aims**

There were two aims for this study. The first aim was to collect data on the overall prevalence and nature of antipsychotic use in a typical LTC facility \((N=118)\). The second aim was to monitor changes in the use of antipsychotic drugs in a similar group of residents \((N=214)\) who were experiencing physical relocation from two older LTC facilities into a new facility.

**Research questions**

1) Overall, what percentage of LTC residents are receiving antipsychotics?
2) What is the average length of time over which LTC residents are prescribed antipsychotics?
3) What percentage of antipsychotic prescriptions in LTC demonstrate attempts at dose reductions within a six month period of the prescription being written?
4) What percentage of antipsychotic prescriptions in LTC are written as regular dosing vs. ‘p.r.n.’ \((pro\;re\;nata/as\;needed)\) dosing?
5) What percentage of prescriptions in LTC are for typical vs. atypical antipsychotics?
6) What percentage of antipsychotic prescriptions in LTC have corresponding documentation on the behavioral indications for these medications and what are the most common indications?
7) What changes in antipsychotic prescribing and administration practices will be associated with the relocation of LTC residents?

**Methods**

**Research design**

The study was a comparative descriptive design, whereby pharmacy and chart data on antipsychotic drug use by residents in a typical LTC facility were gathered for one-month periods on three separate occasions during one calendar year. For comparison purposes, data were also collected, during the same three time periods, on LTC residents who were being moved from two older LTC facilities into a new larger LTC facility. The three one-month data collection periods took place 1) six months before the move 2) immediately after relocation and 3) six months later. Figure 1 provides an overview of the study design.
Sample and setting

Three LTC facilities in Western Canada participated in the study. Facility A was a 118-bed private-sector facility with a stable physical environment and staffing throughout the course of the study, and represented a typical LTC facility in this part of Canada. Residents from two older public sector LTC facilities (N = 103 beds and N = 111), designated Facility B and C respectively, underwent a major relocation to a new 190-bed, single-site integrated facility under the same management. The new unit was intended to provide a home for similar kinds of residents as the two former facilities, but was also designed to provide a more social, and less clinical, atmosphere. A third LTC facility existed in the same city, but declined to participate due to a large renovation project they were undergoing. All LTC facilities within the province in which this study was conducted have similar legislation and accreditation standards, and all provide services to the same kind of LTC resident.

Table 1 summarizes information on the characteristics of residents in facility A and B at Time 1 (six months before relocation). This information pertains only to residents receiving antipsychotic medications, and not all residents. The residents receiving antipsychotics were similar in many regards, with the exception of five characteristics which reached levels of statistical significance. The general similarity in residents between facilities was not unexpected, given that all local LTC admissions are co-ordinated through a central placement office from a waiting list, placing persons to facilities based primarily upon when beds become available.
Table 1. Initial characteristics (Time 1) of study residents receiving antipsychotic medications

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>“MOVE” FACILITY RESIDENTS</th>
<th>“NO MOVE” FACILITY RESIDENTS</th>
<th>SIGNIFICANCE OF DIFFERENCE BETWEEN FACILITY RESIDENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years</td>
<td>83.73 (N=178)</td>
<td>85.08 (N=111)</td>
<td>t = −1.38, p = 0.17 (2-tailed)</td>
</tr>
<tr>
<td>Percent with residents with diagnosis of dementia</td>
<td>71.3% (N=127)</td>
<td>73.0% (N=81)</td>
<td>X^2 (1, N=289) = 0.089, p = 0.77</td>
</tr>
<tr>
<td>Percent of residents with diagnosis of schizophrenia</td>
<td>14.6% (N=26)</td>
<td>19.8% (N=22)</td>
<td>X^2 (1, N=289) = 1.34, p = 0.25</td>
</tr>
<tr>
<td>Percent of residents with diagnosis of depression</td>
<td>15.2% (N=27)</td>
<td>20.7% (N=23)</td>
<td>X^2 (1, N=289) = 1.47, p = 0.23</td>
</tr>
<tr>
<td>Percent of residents with diagnosis of Parkinson’s disease</td>
<td>13% (N=23)</td>
<td>6.3% (N=7)</td>
<td>X^2 (1, N=288) = 3.27, p = 0.071</td>
</tr>
<tr>
<td>Percent of residents with diagnosis of stroke</td>
<td>9.6% (N=17)</td>
<td>10.8% (N=12)</td>
<td>X^2 (1, N=289) = 0.12, p = 0.73</td>
</tr>
<tr>
<td>Percent of residents on special care unit</td>
<td>4.5% (N=8)</td>
<td>27% (N=30)</td>
<td>X^2 (2, N=289) = 152.96, p = 0.00*</td>
</tr>
<tr>
<td>Percent of residents with hearing/vision problems</td>
<td>3.9% (N=7)</td>
<td>14.4% (N=16)</td>
<td>X^2 (1, N=289) = 10.25, p = 0.001*</td>
</tr>
<tr>
<td>Percent of female residents</td>
<td>63.3% (N=112)</td>
<td>84.7% (N=94)</td>
<td>X^2 (1, N=288) = 15.35, p = 0.00*</td>
</tr>
<tr>
<td>Percent of residents receiving psychogeriatric consult</td>
<td>42.0% (N=74)</td>
<td>76.6% (N=85)</td>
<td>X^2 (1, N=287) = 32.85, p = 0.00*</td>
</tr>
<tr>
<td>Mean length of stay (weeks)</td>
<td>114.53 (N=178)</td>
<td>M = 181.13 (N=111)</td>
<td>t = −3.10, p = 0.002 (2-tailed)*</td>
</tr>
</tbody>
</table>

*Difference significant at p < 0.050.

Data collection

Data collection from pharmacy records and resident charts was undertaken over one year for three one-month periods using the following time sequence: six months before the relocation of Facility B and C’s residents, immediately after the relocation, and six months after the relocation. Data collection from both the typical facility (Facility A) and the relocated residents (Facilities B and C) occurred concurrently (see Figure 1). Data collection followed a two-stage process in all facilities. Initially, computerized pharmacy records were searched by drug class to identify the residents receiving antipsychotics. Using these records, the researchers were able to collect the following data: (1) the overall percentage of residents receiving antipsychotic medications, (2) the average number of different antipsychotic medications that were prescribed.
for each resident, (3) the percentage of antipsychotic prescriptions ordered as a ‘regular’, as opposed to p.r.n. administration, (4) the average length of time residents had been receiving antipsychotic medications, (5) the percentage of antipsychotic prescriptions that were for typical vs. atypical antipsychotics, (6) evidence of attempts to reduce dosages of antipsychotic medications and/or antipsychotic drug holidays. Next, the individual charts of those residents having been identified as having received antipsychotics were reviewed to obtain the following data: (1) the reason (if given) for beginning the administration of the antipsychotic, and (2), the number of p.r.n. doses that were administered.

Results

Data analysis

Due to the nature of the comparative descriptive design, descriptive statistics were used predominantly. Initially, t-tests for independent samples (two-tailed) and Pearson $X^2$ tests were used to identify any statistically significant differences between the characteristics of the residents receiving antipsychotics at the two facilities at Time 1 (Table 1). Due to the nominal measurement nature of the majority of the resident characteristics, a regression analysis to test the effect of any of these differences on antipsychotic was not viable. Where appropriate, and depending upon the level of measurement, $t$-tests and ANOVA were used to determine differences between residents of the two facilities on selected measurements of antipsychotic drug utilization.

Percentage of residents receiving antipsychotics

Residents in Facility A (‘non-move’), and the percentage receiving antipsychotics remained fairly constant between Time 1 (30.3%), Time 2 (30.5%) and Time 3 (33.1%), with an average rate of 31.3%. For the relocated residents (Facilities B and C), antipsychotic use rose from 21.5% before the move, to 32.6% immediately after the move, to 36.9% six months post-move (See Figure 2).

For all facilities at all sampling times, the average number of different concurrent antipsychotic prescriptions each resident was receiving was 1.38, although a handful of residents had as many as four concurrent prescriptions. There was a statistically significant main-effect difference between the average number of different concurrent prescriptions for the move facilities (1.46) and the non-move facility (1.25), $F(1,286) = 6.57, p < 0.011$.

Average length of time receiving antipsychotics

The average length of time that residents in all facilities had been receiving antipsychotic medications was 45.4 weeks, or 0.87 years. There was a difference
of three weeks between the move facility (46.5 weeks) and the non-move facility (43.6 weeks) in terms of their average length of time for residents receiving antipsychotic medications, but this difference was not statistically significant, $t(285) = 0.47, p < 0.64$.

### Percentage of prescriptions demonstrating dose reductions within six months

Overall, only 15.7% (20.8% non-move and 12.4% move) of all antipsychotic prescriptions demonstrated evidence of efforts to make an attempt at dose reduction within six months of the prescription being written.

### Regular vs. as needed (p.r.n.) dosing

A total of 24.5% ($N=71$) of prescriptions, for all facilities at all sampling periods, were written as p.r.n. Of these, 73.1% ($N=52$) had a dose limit indicated on the p.r.n. order. The average total number of p.r.n. antipsychotic doses that were given to each of the residents during each of the one-month data-collection periods was quite low, at 2.1 p.r.n. antipsychotic doses per one-month period. However, while the majority of residents with p.r.n. antipsychotic prescriptions actually received no p.r.n. doses during the sampling period, a handful of residents received as many as 90 doses per month, revealing a wide range of p.r.n. administration. Furthermore, the average number of p.r.n. doses administered for all time periods per resident varied considerably between the move facility (3.03) and the non-move facility (0.72), a difference that was statistically significant, $t(286) = 1.97, p < 0.05$. 

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**Figure 2.** Percentage of residents on antipsychotic medications
Typical vs. atypical antipsychotic use

In all facilities at all times, the most commonly prescribed antipsychotics were risperidone (42.4%), loxapine (28.0%), olanzapine (20.4%) and quetiapine (10.6%). In total, atypical antipsychotics represented 73.4% of all prescriptions, and overall atypical antipsychotic use was higher in the non-move facility (80.8% of all prescriptions) than the move facilities (62.7% of all prescriptions).

Indication for antipsychotic use

For all facilities at all time periods, just under a third of the prescriptions for antipsychotics (29.0%, \(N=84\)) had a reason given for their use by the prescribing physician, in either the progress notes or the prescription itself. By far the most common (63.74%) reason was “continuation of previous prescription.” The other indications were for “agitated or aggressive behavior” (29.7%), “delusional” (4.4%) and “yelling or calling out” (2.2%). If the relatively non-descript “continuation of previous prescription” reason was removed from the calculations, only 11.4% of all prescriptions had a behavioral reason given for the prescription.

Changes in antipsychotic use associated with resident relocation

Figure 2 demonstrates that while the use of antipsychotics in the non-move facility remained constant throughout the course of the study, use of antipsychotics in the move facilities nearly doubled over the course of the year-long study. While such a dramatic change in the relocated facilities compared to the non-relocated facility is obviously clinically significant, these data could not be tested for statistical significance on a comparative bases due to: (1) the repeated-measures dependent variable in question (percentage of residents receiving neuroleptics) was a categoric (discrete) variable (i.e., “yes” the residents received an antipsychotic, or “no” they did not), and (2) there are no available tests for the analysis of repeated measures of categorical variables, particularly when comparing two groups (Pett, 1997). However, it was possible to perform Pearson \(X^2\) statistics on the repeated measures data for each of the two separate facilities. The results from these \(X^2\) tests indicated that the substantial change in residents receiving antipsychotics in the facilities experiencing the move was statistically significant (\(X^2 = 12.4, p = 0.002\)), whereas the small change in the non-move facility was not statistically significant (\(X^2 = 0.26, p = 0.88\)).

Diagnosis of Parkinson’s disease

While this was not one of our original research questions, a serendipitous finding related to the number of residents who had a chart diagnosis of Parkinson’s
disease. Thirty out of the 288 available records, or 10.4% of the residents, had this diagnosis.

**Discussion**

**Limitations**

As with many other studies using descriptive or comparative descriptive designs, this study had a number of limitations. A principal limitation was the inability to ensure that the two LTC facilities were identical in all regards other than the primary difference of having (or not having) their residents experience relocation to a new facility. We utilized a comparison facility (as similar as circumstances allowed) not experiencing a move, to compare and contrast any changes in antipsychotic drug use in the facility residents experiencing relocation. However, this kind of comparative descriptive design does not control for the many potentially confounding differences that could exist between facilities, such as differences in physical layout, individual physician prescribing practices, and so forth. Indeed, some differences between resident facilities at Time 1 reached a level of statistical significance (such as the percentage of female residents).

A second important limitation was to be the small number of facilities in the study, and the resulting uncertainty over whether these facilities are indeed “typical” LTC facilities. Canada is a vast country with varied provinces and regions, and more research on psychotropic drug use in Canadian long-term care facilities would give a more precise picture. In partial response to this need, the authors are now conducting a much larger two-year randomized clinical trial involving 24 nursing homes in Western Canada, evaluating the effects of physician- and nursing-staff education on the use of antipsychotic and benzodiazepine medication use in LTC.

**Results**

The results of this study indicate that the rates both for overall rate of antipsychotic prescriptions for all long-term care residents in this study (30.8%) – and just those in the non-move facility (31.3%) – are generally higher those that found in comparable studies in Europe or the U.S.A. (Hughes et al., 2000; McGrath and Jackson, 1996; Ruth et al., 2001; Sorensen et al., 2001) and the much lower rate of 7.5% for Japan (Hughes et al., 2000). Our rates are also approximately double of most U.S. rates (approximately 15%) since the introduction of OBRA federal regulations (Garrad et al., 1991; Hughes et al., 2000; Llorente et al., 1998), and approximately double the rate of 17% found in one other Canadian study (Earthly et al., 2000).
Our rates are similar, however, to the rates of 28.8% (Snowdon et al., 1995) and 30.7% (Snowdon and Vaughan, 1997) found in Australia, and the rate of 29.8% found in another Canadian study (Conn et al., 1999). Taken together, our study and the Conn et al. (1999) study suggest that Canadian rates of antipsychotic use in LTC facilities may be among the highest in the developed world, and close to the high rates found in the U.S.A. before the introduction of the OBRA legislation limiting antipsychotic use (Avorn et al., 1989; Ray et al., 1980). Regardless of the many potential reasons that may contribute to these comparatively high rates found in this and the Conn et al. (1999) study – and whether one sees these figures as evidence that laws and legislation are the most effective way to improve medical and nursing practice in nursing homes (Hughes, 2000) – these initial results highlight the need for more Canadian research. Furthermore, the findings are suggestive of the potential need for Canadian nursing homes to monitor more carefully the appropriate use of antipsychotic medications and/or consider the use of educational programs for physicians and nursing staff on the use of antipsychotics in LTC (Rovner et al., 1996).

Other findings also highlight the concern not only of potentially high usage of antipsychotics in nursing homes, but also concerns around consistency of use. The overall rate of 30.8% found in our study is not only comparatively high, but the percentage of residents on antipsychotics in our study varied considerably from both facility to facility, and time to time, with a range from 21.5% to 36.9%. These variations between facilities and times have been mirrored in other studies (Oborne et al., 2002; Ruth et al., 2001), suggestive of a lack of consistency in antipsychotic prescribing practices within nursing homes.

This study afforded the unique opportunity to monitor changes in antipsychotic use associated with a potentially major stressor to long-term care residents, that of being relocated to a new facility. While the comparison (no move) facility’s use of antipsychotics remained relatively constant throughout the study, the use of antipsychotics in the move facilities rose from 21.5% before relocation, to 32.6% immediately afterwards. Whether this increase in antipsychotics was more of a anticipatory or preventative measure – i.e. trying to prevent behavioral disturbances associated with the move – or a response to an actual increase in behavioral disturbances, was not clear. The existing literature suggests that stress such as relocation can lead to psychological changes and behavior problems, and careful planning and interventions are needed to facilitate the transition (Anthony et al., 1987; Castle, 2001; Johnson and Hlava, 1994). Importantly, even six months after relocation – after the residents had been through the most stressful period of the move— antipsychotic use, rather than subsiding, actually continued to climb, to 36.9%. This finding highlights what many clinicians in long-term care have noted; that once a resident is placed on antipsychotics, there is a tendency to keep that resident on antipsychotic medication.
This tendency to keep long-term residents on antipsychotics for long periods is also reflected in the data on the overall length of time for antipsychotic prescriptions. The average length of time study residents were on any given prescription for antipsychotics was 0.87 years, with a range from less than a week, to 6.9 years. This tendency to keep residents with behavior problems on antipsychotics for long periods is understandable, particularly for nursing staff, who may have been the recipients of physical aggression, and are fearful of a recurrence. There are several problems with this approach, however. The risk of side-effects from antipsychotics – such as falls, tardive dyskenesia, akathesia orthostatic hypotension and cardiac complications – rises dramatically over time with older persons (Jeste et al., 1999a; Thapa et al., 1995; Woerner et al., 1998), although the risk of tardive dyskensia may be lower for atypical antipsychotics compared with typical antipsychotics (Jeste et al., 1999b). Several studies have demonstrated that the majority of long-term care residents receiving antipsychotics for behavior problems can have their antipsychotic medications safely and effectively withdrawn without an increase in difficult behaviors (Bridges-Parlet et al., 1997; Thapa et al., 1994).

It is considered good practice – and explicitly made law in the U.S. OBRA federal regulations – that attempts be made to reduce the doses of LTC residents receiving antipsychotics, within a six-month period of the prescription being initiated (Levenson, 1998; Semla et al., 1994). It was therefore disappointing to find that only 15.7% of all prescriptions in this study reflected any evidence of attempts to make dose reductions within the specified time-frame. If the OBRA U.S. regulations were applied to the LTC centers involved in this study, 84.3% of the prescriptions could be deemed to be inappropriate, due to the lack of timely efforts to reduce the amount of antipsychotic medications received.

The newer atypical antipsychotics accounted for 73.4% of all prescriptions, with the most common being risperidone (42.4% of all prescriptions). This finding is supported by many guidelines on the treatment of behavioral disturbances in LTC (Gurvich and Cunningham, 2000; Patterson et al., 1999). Nevertheless, while these atypical antipsychotics are generally considered to be safer than their typical counterparts, they do have side-effects of their own, are no more effective than typical antipsychotics and are much more expensive. (Dewa and Goering, 2001). Furthermore, as good data on the long-term safety of the newer atypical neuroleptics for use in the elderly are difficult to find (Jeste et al., 1999c), it is premature to view the use of these medications as a problem-free solution to the issues surrounding the use of traditional antipsychotics.

Our finding that 24.5% of all prescriptions were written as p.r.n. is similar to the rate of 25% rate in the other Canadian study providing this kind of data (Earthly et al., 2002), a rate half that of the 53% rate found in a recent U.K. study (Oborne et al., 2002). Our rate is encouraging, given that it is often advocated
to minimize antipsychotic prescriptions written as p.r.n., due to concerns over the variability with which the antipsychotics may be administered, (Earthy et al., 2000; Semla et al., 1994). Also encouraging is the finding that 73.1% of all the antipsychotic prescriptions written during our study had an upper dose-limit indicated, thereby preventing unlimited administration. By comparison, only 23% of the antipsychotic prescriptions in the Oborne et al. (2002) U.K. study had a maximum frequency of administration and/or dose limit indicated.

Only 11.4% of prescriptions had any accompanying documentation on the behavioral problems in residents that were necessitating antipsychotics. This figure is considerably less than the 52%–87% documentation rate found in the Earthy et al. (2000) Canadian study, or the 38% documentation rate found in the Oborne et al. (2002) U.K. study. The lack of documentation in this study makes it impossible to know whether the drugs were being used for appropriate reasons. Furthermore, such lack of documentation on the reasons for using antipsychotics would by itself be a violation of OBRA regulations, which require that the behavioral problems warranting antipsychotic use be documented.

Finally, it is noteworthy that 10.4% of the residents in our study had a diagnosis of Parkinson’s disease. Previous research has identified rates of Parkinson’s disease of 2.6% for the old-old in the community (de Rijk et al., 2000), and 5.2% for the old-old in nursing homes (Lapane et al., 1999). Our sample’s rate of 10.4% is at least double that expected. While it is possible that our sample simply did have Parkinson’s disease at twice the rate of other studies, another equally plausible explanation might be that due to the comparatively large percentage of residents receiving antipsychotic medications, medical and nursing staff might be missing one of the extrapyramidal side-effects of these medications – pseudoparkinsonsim – and misdiagnosing it as Parkinson’s disease (Caligiuri et al., 1998).

Conflict of interest

None.

Description of authors’ roles

BH: Co-principal investigator of study; co-author of grant application; designed study, supervised data collection, analysis and research assistants. Main author of article.

CAE: Co-principal investigator of study; co-author of grant application; co-designed study; consultant on data collection and analysis; provided substantial reviews and contributions to article.
R I: Geriatrician, and primary medical consultant and supervisor for study; primary physician liaison to family physicians and long-term care administrators in study; consultant for study design and data collection; provided detailed review of article.

RW: Primary statistical consultant for study, also consultant for design methodology; provided substantial reviews and contributions to article.

CLN: Co-author of grant application; considerable assistance with design of study; provided substantial reviews and contributions to article.

MA: Involved with data entry and analysis; provided substantial contributions to literature review for article, and editing and reviews of article.

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