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Use of Atypical Antipsychotics in Nursing Homes and Pharmaceutical Marketing

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Abstract

BACKGROUND—Many nursing home (NH) residents are prescribed atypical antipsychotics despite US Food and Drug Administration warnings of increased risk of death in older adults with dementia. Aggressive pharmaceutical marketing has been cited as a potential cause, although data are scarce. The objectives of this study were to describe the current extent and type of pharmaceutical marketing in NHs in one state, and to provide preliminary evidence for the potential influence of pharmaceutical marketing on the use of atypical antipsychotics in NHs.

DESIGN—Nested mixed-methods, cross-sectional study of NHs in a cluster randomized trial.

SETTING—41 NHs in Connecticut.

PARTICIPANTS—NH administrators, directors of nursing and medical directors (n = 93, response rate 75.6%).

MEASUREMENTS—Quantitative data, including prescription drug dispensing data (September 2009–August 2010) linked with Nursing Home Compare data (April 2011), were used to determine facility-level prevalence of atypical antipsychotic use, facility-level characteristics, NH staffing and NH quality. Qualitative data, including semi-structured interviews and surveys of NH leaders conducted in the first quarter of 2011, were used to determine encounters with pharmaceutical marketing.

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Author Contributions: Ms. Pimentel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Dr. Briesacher. Acquisition of data: Ms. Lemay. Analysis and interpretation of data: Ms. Pimentel, Drs. Donovan, Field, Gurwitz, Harrold, Kanaan, Mazor, Tjia, and Briesacher, Ms. Lemay. Drafting of manuscript: Ms. Pimentel. Critical revision of manuscript for important intellectual content: Drs. Donovan, Field, Gurwitz, Harrold, Kanaan, Mazor, Tjia and Briesacher, Ms. Lemay. Statistical analysis: Ms. Pimentel, Dr. Briesacher. Obtained funding: Dr. Gurwitz. Study supervision: Dr. Briesacher.

RESULTS—Leadership at 46.3% of NHs (19/41) reported pharmaceutical marketing encounters, consisting of educational training, written/Internet-based materials and/or sponsored training. No association was detected between the level of atypical antipsychotic prescribing and reports of any pharmaceutical marketing by at least one NH leader.

CONCLUSION—NH leaders frequently encounter pharmaceutical marketing through a variety of ways, although the impact on atypical antipsychotic prescribing is unclear.

Keywords

nursing homes; pharmaceutical marketing; atypical antipsychotics

INTRODUCTION

Despite strong evidence linking atypical antipsychotics with mortality and cardiovascular risk in older adults with dementia,¹⁻³ 22% of the 1.4 million nursing home (NH) residents in the US received these medications in 2010.⁴ While resident sociodemographic and clinical characteristics,⁵⁻⁷ facility-level prescribing practices⁶ and staffing issues^{8,9} have been shown to be associated with antipsychotic use, the role of pharmaceutical industry marketing is understudied. A 2011 report from the US Department of Health and Human Services Office of Inspector General cited overly aggressive marketing by the pharmaceutical industry as a contributing factor in the high use of atypical antipsychotics in NHs,¹ but evidence supporting this assertion is sparse.

Prior studies have consistently shown a strong relationship between marketing efforts by the pharmaceutical industry and physician prescribing behaviors.¹⁰⁻¹² For example, physician participation in educational symposia sponsored by the pharmaceutical industry has been associated with a two- to three-fold increase in the prescription of promoted medications.¹³ Most of the literature is specific to hospitals; however, there is anecdotal evidence of pharmaceutical marketing in NHs in the form of free educational seminars and lunches to licensed nurses and certified nursing assistants (CNAs).¹⁴ There is no study, to our knowledge, linking prescribing patterns in NHs to pharmaceutical marketing.

The objectives of this study were to describe the current extent and type of pharmaceutical marketing in a convenience sample of NHs in one state and to provide preliminary evidence for the potential influence of pharmaceutical marketing on the use of atypical antipsychotics in NHs. We tested our hypothesis that high facility-level use of atypical antipsychotics is associated with pharmaceutical marketing.

METHODS

Study Design and Setting

We conducted a nested cross-sectional study of 41 NHs participating in a cluster randomized controlled trial in Connecticut. The trial evaluated dissemination strategies for an educational intervention to improve evidence-based antipsychotic prescribing ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01347619) Identifier NCT01347619). Detailed information about the study design

and data collection procedures are published elsewhere.^{15,16} Here, we briefly describe the data collection procedures that are relevant to our study.

Data Sources

Data for this study were derived from four linked data sources that comprised the baseline data for 41 NHs participating in the trial. The first was prescription dispensing data (September 2009–August 2010) from a nationwide long-term care pharmacy contracting with all NHs in this study.¹⁷ The second was the Nursing Home Compare database (downloaded April 2011), a publicly-available online report card of NH-reported information required of all Medicare- or Medicaid-certified NHs (www.medicare.gov/NHCompare). The third was semi-structured telephone interviews of 16 NH leaders, including administrators, directors of nursing and medical directors from nine study NHs purposively selected to represent variation across three areas: baseline level of atypical antipsychotic prescribing, for-profit status and NH quality indicators, and described previously elsewhere.¹⁶ The fourth was survey data from a mailed questionnaire sent to NH leaders at 41 NHs (N = 123 individuals), described previously elsewhere.¹⁶ Survey response rates were 87.8% among NH administrators (n = 36), 90.0% among directors of nursing (n = 37) and 48.9% among medical directors (n = 20), for an overall response rate of 75.6% (n = 93). Both the telephone interviews and surveys addressed knowledge of antipsychotic risks, attitudes about caring for residents with dementia, satisfaction with current behavior management training, beliefs about antipsychotic effectiveness, and need for staff training about antipsychotics and behavior management.

Measures

Pharmaceutical Marketing—In both the NH leadership interview and survey we asked, “How do you presently get new information or clinical tools to help you and your staff address challenging behaviors with persons who have dementia?” Respondents indicating pharmaceutical marketing as a source were flagged and their responses assessed for types of encounters. We use the term encounter here to refer to any reported interactions with pharmaceutical company representatives as well as encounters with marketing materials like pamphlets, posters and charts.^{18,19} Types of encounters included conferences, Internet resources, medical literature and professional societies. We categorized NHs as having encounters with pharmaceutical marketing if at least one leader reported any encounter.

Atypical Antipsychotic Use—We computed facility-level prevalence of atypical antipsychotic use as the proportion of residents receiving at least one atypical antipsychotic prescription in the NH in the past year. We categorized NHs according to mean cut-point based on a low to high distribution (range: 7.2–46.5%). Facilities with prevalence of greater than 18.6% were categorized as having above-average atypical antipsychotic prescribing.

Facility-level Characteristics—Nursing home characteristics included number of certified beds, profit status, type of ownership, multi-NH ownership and presence of resident and family councils as reported in Nursing Home Compare.

NH Staff—The NH staffing information was drawn from a two-week period prior to state agency inspections reported in Nursing Home Compare. They include the total number of licensed nursing staff hours per resident per day and by three staff types, i.e., registered nurses, licensed practical/vocational nurses and CNAs. Staffing measures were categorized according to a mean cut-point based on a low to high distribution.

NH Quality—We used the Five-Star Quality Rating System from Nursing Home Compare to measure NH quality. In this system, one star represents a much below average rating and five stars indicates a much above average rating. Ratings are based on overall performance and three subcategories of performance: health inspections, staffing and quality ratings (a composite score based on facility-level performance on 10 resident-level assessments in the Minimum Data Set: change in activities of daily living, change in mobility, high-risk pressure ulcers, long-term catheters, physical restraints, urinary tract infection, delirium, pain and pressure ulcers). Star ratings for the quality measures are risk-adjusted for resident-level covariates prior to reporting on Nursing Home Compare. We collapsed the measures into two levels: average or below (scores of 1–3 stars) and above average (4–5 stars).

Statistical Analysis—We calculated unadjusted means and frequencies with 95% confidence intervals (CI). Multivariable logistic regression was used to test relationships among exposure to pharmaceutical marketing and a dichotomous outcome variable of NH antipsychotic prescribing level. Select facility-level characteristics previously shown to be associated with antipsychotic prescribing were considered for inclusion in the final model based on $P < .25$ in univariate analyses. A two-sided P -value of .05 was considered statistically significant.

Analyses were performed using Stata, version 11.2 (StataCorp LP, College Station, TX). The institutional review board of the University of Massachusetts Medical School approved this study.

RESULTS

Overall, at least one leader in 46.3% of study NHs reported having an encounter with pharmaceutical marketing, either through informational materials or educational tools for the behavioral management of persons with dementia. A comparison between NHs where the leadership reported contact with pharmaceutical marketing and NHs without contacts showed few differences (Table 1). Only the quality rating showed an association: NHs with reported encounters with pharmaceutical marketing were more likely to have above-average overall star ratings than NHs that did not (84.2%, 95% CI: 60.0–96.6% [$n = 16$] vs. 50.0%, 95% CI: 28.2–71.8% [$n = 11$], $P = .021$).

Table 2 characterizes the types of pharmaceutical marketing encounters captured in the leadership interview, organized into four domains. The first domain is in-person training. Several NH leaders received information from pharmaceutical companies through in-service trainings (Quote 1), some of which offered continuing education credits or were facilitated by pharmaceutical company-employed physicians. Examples include lectures on medication side effects or new medications for use among older adults. The second and third domains

are print and Internet-based material, respectively. Some respondents described informational mailings (Quote 2) or Internet-based material from pharmaceutical companies (Quote 3) to learn about efficacy or harmful side effects of medications. The last domain is sponsorship. One medical director reported that he received dementia-related information to assist him in his role as a pharmaceutical company-sponsored speaker (Quote 4).

Association between higher level of atypical antipsychotic prescribing and encounters with pharmaceutical marketing was not statistically significant (unadjusted OR = 0.87, 95% CI: 0.25–3.01; adjusted OR = 1.20, 95% CI: 0.29–4.94, adjusting for CNA hours per resident per day and overall star rating).

DISCUSSION

This mixed-methods study of 41 NHs indicates that administrators, directors of nursing and medical directors frequently encounter pharmaceutical marketing in the NH setting. We found that these encounters occur in a variety of ways, including educational training, written/Internet-based materials or sponsorship of training. How these encounters influence atypical antipsychotic prescribing is yet unclear. Our interviews of NH leaders indicate that pharmaceutical marketing is a main source of information and clinical tools (e.g., resources to support delivery of care) for the behavioral management of NH residents with dementia. Specifically, pharmaceutical companies participate in the education and training of medical, nursing and direct-care staff in the understanding and use of their clinical products. This role may be unduly influential in the NH setting because in-service training for on-site nursing staff—who often consult with off-site prescribers in making medication decisions²⁰—is commonly held in the absence of physicians.¹⁴ To our knowledge, Wengel and colleagues were the first to anecdotally describe the deliberate targeting of licensed nurses and CNAs by pharmaceutical companies operating in long-term care markets.¹⁴ We believe our study is the first to provide empirical evidence toward this question.

Relationships between health care professionals and the pharmaceutical industry have come under increasing scrutiny over the past two decades.^{21–24} As early as 1993, five states (Massachusetts, Minnesota, Vermont, West Virginia and Maine) and the District of Columbia required disclosure of incentives given to hospitals, NHs, health care practitioners and prescribers,²⁵ and Vermont, Massachusetts and Minnesota provide public access to this information.²⁶ As of February 2014, the Patient Protection and Affordable Care Act extends these “sunshine” provisions nationally by requiring that drug and medical device manufacturers that participate in federal health care programs disclose payments and gifts made to physicians and teaching hospitals.²⁷ It is at the discretion of individual NHs to manage activities that do not fall under federal regulation.

This study has important limitations. First, our study may have been underpowered to detect differences between NHs with and without reported exposure to pharmaceutical marketing. The small sample size of this study would have allowed for a minimum detectable OR of 2.88, assuming 80% power, a significance level of $\alpha = 0.05$ and a 22% prevalence of antipsychotic use.⁴ Second, the sample is drawn from a single state. While these facilities are heterogeneous in terms of atypical antipsychotic use, facility-level characteristics and

measures of staffing and quality, the results of our analysis may not be generalizable to NHs in other states. Further, Connecticut ranks in the top quartile of states with respect to prevalence of antipsychotic use among long-stay NH residents.²⁸ Therefore, it is important to study factors potentially associated with prescribing practices in this particular state. Third, we derived data from interviews and surveys of NH leaders who may be removed from direct care of NH residents and less exposed to pharmaceutical marketing efforts. Therefore, future studies would benefit from surveys of direct-care staff and observations of pharmaceutical marketing derived from site visits. Also, since the interview guides and surveys were not designed to collect specific information on pharmaceutical marketing, we were unable to make inferences about the detailed nature of relationships between pharmaceutical companies and NH staff. Fourth, we lacked individual-level data linking resident characteristics to pharmacy dispensing records; therefore, we could not assess facility-level prevalence of on-label versus off-label atypical antipsychotic use. Lastly, we suspect the possibility of reporting bias, with NH leaders from better-performing facilities more accurately reporting pharmaceutical marketing encounters than lower-performing facilities, but the opposite may also be true.

Nevertheless, this study is among the first to attempt to characterize pharmaceutical marketing strategies in the NH setting, focusing specifically on their potential influence on atypical antipsychotic prescribing rates. The use of mixed methods allowed us to first assess that such marketing strategies exist—and may not be rare in the NH setting—and then quantitatively estimate observed associations and patterns.

CONCLUSION

Larger studies across a wider geographic area should continue investigating the possible role of pharmaceutical marketing on overall use and choice of atypical antipsychotics in the NH setting. Additional research is needed to describe and assess the role of pharmaceutical marketing encounters with NH staff, the degree to which NH staff use pharmaceutical company information compared to evidence-based, unbiased sources and the consequences on prescription drug prescribing in NHs.

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Table 1
Nursing Home Characteristics by Receipt of Informational Materials or Educational Tools from Pharmaceutical Marketing (N = 41)

Pharmaceutical Marketing Encounters				
	Total n (%) or mean (± SD)	Yes (n = 19) n (%) or mean (± SD)	No (n = 22) n (%) or mean (± SD)	P-value
Facility-level Characteristics				
Level of antipsychotic prescribing				
Average of below (18.6%)	23 (56.1)	11 (57.9)	12 (54.6)	
Above average (>18.6%)	18 (43.9)	8 (42.1)	10 (45.5)	0.829
Number of beds	132.2 (± 51.5)	119.8 (± 49.0)	142.8 (± 52.2)	0.155
Ownership				
For-profit	29 (70.7)	12 (63.2)	17 (77.3)	
Non-profit/Government	12 (29.3)	7 (36.8)	5 (22.7)	0.322
Type				
Corporation	34 (82.9)	16 (84.2)	18 (81.8)	
Other ^a	7 (17.1)	3 (15.8)	4 (18.2)	0.839
Multi-NH ownership	18 (43.9)	9 (47.4)	9 (40.9)	0.678
Councils				
Resident only	15 (36.6)	8 (42.1)	7 (31.8)	
Resident and family	26 (63.4)	11 (57.9)	15 (68.2)	0.495
Staffing Measures				
RN hours PRPD	0.81 (± 0.29)	0.80 (± 0.23)	0.82 (± 0.34)	0.791
LPN/LVN hours PRPD	0.72 (± 0.21)	0.71 (± 0.22)	0.73 (± 0.20)	0.798
Total licensed staff hours PRPD	1.53 (± 0.32)	1.51 (± 0.24)	1.55 (± 0.39)	0.688
CNA hours PRPD	2.52 (± 0.41)	2.49 (± 0.47)	2.55 (± 0.36)	0.614
Quality Measures ^b				
Overall star ratings				
Average or below	14 (34.2)	3 (15.8)	11 (50.0)	
Above average	27 (65.9)	16 (84.2)	11 (50.0)	0.021
Health deficiencies	6.78 (± 4.05)	5.84 (± 4.03)	7.59 (± 3.98)	0.171

Pharmaceutical Marketing Encounters				
	Total n (%) or mean (± SD)	Yes (n = 19) n (%) or mean (± SD)	No (n = 22) n (%) or mean (± SD)	P-value
Proportion of long-term residents in restraints	1.12 (± 1.40)	1.37 (± 1.74)	0.91 (± 1.02)	0.301

CNA: certified nursing assistant; LPN: licensed practical nurse; LVN: licensed vocational nurse; NH: nursing home; RN: registered nurse; PRPD: per resident per day; SD: standard deviation

^a“Other” includes church, individual, partnership, limited liability and city

^bReported in Nursing Home Compare Five-Star Quality Rating System

Table 2
Representative Quotes from Medical Directors about Exposures to Pharmaceutical Marketing in Nursing Homes

	Type of pharmaceutical marketing	Quote and position title
1	In-person training	"...the pharmaceutical industry does do a good job of in-service on any new product that comes out that might be effective for the geriatric population." – Advanced practice RN (in lieu of medical director)
2	Written material	"It's very kind of erratic the way we receive [new information on clinical tools]. I mean we get a lot of mailings from drug companies, and we sort of sort through that, and if there's anything that brings our attention to problems with prescribed meds, then we'll change the way we prescribe the med...if that's something that's recommended by the pharmaceuticals." – Medical director
3	Internet-based material	"My employer has [new information on clinical tools] available to us, as well as I use [Company Name] and some of the computer-based materials regarding the medications and their efficacy or lack of efficacy for certain issues." – Advanced practice RN (in lieu of medical director)
4	Sponsorship	"I get [new information on clinical tools] because I'm a speaker. It's automatically sent to me, and I attend conferences for speaker training. And then I go to talks that are on dementia that are sponsored by the pharmaceutical companies." – Medical director

RN: registered nurse