The Impact of OBRA-87 on Psychotropic Drug Prescribing in Skilled Nursing Facilities

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Objectives: **This study examined the impact of regulations established by the Omnibus Budget Reconciliation Act of 1987 (OBRA-87) on prescriptions for psychotropic drugs, and on research on their use in nursing homes.** ***Methods:*** **Data were collected on drugs prescribed for residents of 39 skilled nursing facilities over the four-year period from 1989 to 1992, bracketing the implementation of OBRA-87 in the fall of 1990. Changes in prescribing patterns were analyzed by drug class, specific target medications and doses, number of drugs prescribed, and multidrug combinations. To determine the effect of OBRA-87 on research, peer-reviewed journals were searched for the number and content of publications on psychotropic drug use in skilled nursing facilities between 1980 and 1996.** ***Results:*** **The number of prescriptions for antipsychotics, sedative antihistamines, and sedative-hypnotics decreased significantly, while prescribing of anxiolytics increased. Qualitative, but not quantitative, shifts occurred in prescriptions for antidepressant drugs, the most frequently used psychotropic medications in all years. Rates of psychotropic polypharmacy remained stable. The number of data-based publications on psychotropic drug use in nursing homes increased after implementation of OBRA-87, but few were related to the effectiveness of drug treatment.** ***Conclusions:*** **Implementation of OBRA-87's nursing home regulations was associated with reductions in use of drugs specifically targeted by this legislation and was a potent stimulus to research, an unanticipated benefit of legislative action. Increased use of anxiolytics, persistent prescribing of anticholinergic antidepressants, enthusiastic adoption of new agents despite a limited research database involving frail patients, and the paucity of new studies reporting data on clinical effectiveness suggest a need for targeted research on treatment outcomes to improve the care of this population. (*Psychiatric Services* 48:1289–1296, 1997)**

Concern over misuse and overuse of psychoactive drugs played a major role in the nursing home reforms incorporated into the Omnibus Budget Reconciliation Act of 1987 (OBRA-87) (1). At particular issue was the unregulated chronic use of antipsychotic drugs, singled out during the OBRA debates because of their well-known risk for causing functional disability and potentially irreversible neurologic side effects, the propensity to overuse them to quiet difficult patients, and their inconsistent efficacy among elderly patients suffering from behavioral and psychiatric complications of dementia. OBRA-87 established a precedent for regulation of treatment strategy as well as drug use, directing consideration of dose reduction trials and potentially less risky, nonpharmacologic approaches to management of psychiatric problems prevalent in the nursing home setting.

In early 1989 the first drafts of the interpretative guidelines governing the use of antipsychotic drugs were published (2), and revised guidelines were implemented nationally in the fall of 1990. Briefly, these regulations spelled out a requirement to limit the psychiatric use of antipsychotic drugs for patients with a diagnosed psychotic disorder or delirium or dementia with intractable, functionally impairing, and dangerous agitation.

In 1992 basic standards were set for allowable doses of individual drugs and for p.r.n. use. These standards required dose reduction trials unless they were clinically contraindicated. New guidelines were introduced governing indications, dosage, and selection of specific anxiolytic and sedative-hypnotic drugs (3) due to concern over possible substitution of these drugs for antipsychotics (1) and awareness of their potential adverse effects. Short-acting agents were preferred over long-acting agents such as clonazepam. A general warning discouraged the practice of psychotropic polypharmacy, targeting use of two or more agents with similar effects, such as sedative or anticholinergic effects.

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Several studies have demonstrated a probable impact of OBRA-87 on rates of antipsychotic drug prescribing (1,4–6). Three studies found no evidence for substitution of benzodiazepine anxiolytics, based on overall prescribing rates, or for changes in antidepressant use (4–6). Psychotropic polypharmacy, known to elevate risk for an array of functional toxicities in elderly persons (7–9), did not change in the one study in which this phenomenon was examined (6).

We have previously shown that a pharmacist-led educational intervention for nursing staff aimed at reducing facility-wide neuroleptic prescribing, initiated three years before implementation of OBRA-87, effected a dramatic decline in 36 nursing homes and achieved the lowest rates reported in any study (10).

Based on these results, we carried out the longitudinal investigation of prescribing patterns reported here to determine whether implementation of OBRA-87 had further impact on antipsychotic use and to extend the scope of inquiry to other major classes of psychotropic drugs. We hypothesized that new reductions in the use of antipsychotics would be associated with increased prescribing of other drugs such as anxiolytics, sedative-hypnotics, or antidepressants with antiagitation effects for patients with dementia, and that warnings about the use of sedative and anticholinergic drugs, long-acting benzodiazepines, and possibly psychotropic polypharmacy would be associated with diminished use. We expected no effect on antidepressant prescribing rates. We speculated that OBRA regulations would stimulate new research on psychotropic drug use in nursing homes, a relatively neglected focus of mental health services research.

Methods

Setting

Thirty-nine skilled geriatric care facilities in or near urban centers of western Washington State that were served by a single pharmaceutical provider constituted the sample for this study. Eighty-seven percent were for-profit, compared with 74 percent of U.S. nursing homes in 1991 (11). The mean number of residents per facility was 125, with a range from 44 to 240, slightly larger than the national mean of 106 (11), and several of the facilities had special care units for severely demented patients with Alzheimer's disease. The total number of residents varied by less than 2 percent from year to year, and this number represented about 20 percent of all nursing home residents in Washington during the sampling periods.

Over the course of the study, the percentage of residents receiving any scheduled psychotropic drug declined by 14 percent.

Data collection

Data on current use of psychotropic drugs—antipsychotics, anxiolytics, sedative-hypnotics, antihistamines used for behavior control purposes, and antidepressants that were available before February of 1992—were gathered by experienced consultant pharmacists for all residents (N≈ 4,850) of all 39 nursing homes during the same month, September, of four sequential years (1989–1992). Drug names and doses were abstracted from residents' charts separately for scheduled and p.r.n. orders, and these data were grouped by drug class.

Data were not collected on use of anticonvulsant drugs for psychiatric indications; the demographic characteristics of the nursing home residents; diagnoses, problems, or the clinical appropriateness of drug choice for individual patients; duration of drug use or actual ingestion of p.r.n. medications; variation in drug use by specific patients; or changes made as part of a mandatory dosage reduction trial. Medication orders are reported as cross-sectional point prevalences for all facilities combined.

Publications in peer-reviewed journals related to psychotropic drug prescribing in nursing homes were identified through a MEDLINE search using a wide-search protocol that included a variety of key words and subject headings related to medication types, behavioral problems, and psychiatric diagnoses. Papers reporting research data on drug use were counted for each half-decade between 1980 and 1995 and for January 1996.

Data analysis

For each of the four sampling points, the proportion of all residents using each drug was calculated. Frequency distributions of psychotropic usage were calculated for each drug and class, and observations in successive years were assumed to be independent. Percent change between year 1 and year 4 was calculated for individual drugs and classes, and the significance of this change was evaluated by z test (12), where z=[the proportion in year 1 – the proportion in year 4] divided by the standard error of the difference. Chi square analysis was used to test differences in rates of polypharmacy over time. Total numbers of residents sampled varied slightly in different analyses due to missing data.

Twenty-seven of the 39 facilities had participated in our previous staff intervention. Separate analysis of data from those facilities and the remaining 12 facilities disclosed rates of antipsychotic use that were initially higher in the nonparticipant settings, but the rates in nonparticipant settings fell more rapidly, such that the rates were equivalent for the two groups at the end of the study. Data were combined for the remainder of the analysis and may therefore underestimate rates of change in facilities that lacked clinical pharmacy consultation or other management enrichments.

Table 1

Residents of 39 skilled nursing facilities in western Washington State who received scheduled psychotropic medications before and after implementation of the Omnibus Budget Reconciliation Act of 1987 (OBRA-87) in 1990[1]

Medication[2]	1989 (N=4,857) N	%	1990 (N=4,850) N	%	1991 (N=4,942) N	%	1992 (N=4,848) N	%	% change 1989–1992	z	p
Any psychotropic drug	1,967	40.5	1,717	35.4	1,799	36.4	1,687	34.8	-14.0	5.75	<.001
Any antipsychotic	832	17.1	642	13.2	629	12.7	541	11.2	-34.8	8.44	<.001
Haloperidol	438	9.0	321	6.6	312	6.3	289	6.0	-33.8	5.71	<.001
Thioridazine	207	4.3	150	3.1	159	3.2	150	3.1	-27.3	3.04	.024
Any antidepressant	947	19.5	914	18.9	982	19.9	973	20.1	3.1	0.74	.459
Doxepin	255	5.2	193	4.0	205	4.1	192	4.0	-24.5	3.02	.003
Amitriptyline	220	4.5	157	3.2	145	2.9	135	2.8	-38.4	4.57	.001
Trazodone	166	3.4	147	3.0	157	3.2	173	3.6	4.6	0.42	.674
Nortriptyline	95	2.0	139	2.9	181	3.7	198	4.1	109.1	6.15	<.001
Fluoxetine	45	0.9	148	3.1	159	3.2	166	3.4	270.1	8.47	<.001
Any anxiolytic, excluding buspirone	248	5.1	220	4.5	274	5.6	276	5.7	11.7	1.30	.194
Any anxiolytic	266	5.5	299	6.2	384	7.8	394	8.1	48.6	5.21	<.001
Lorazepam	159	3.3	148	3.1	195	4.0	171	3.5	7.9	0.70	.484
Alprazolam	36	0.7	27	0.6	25	0.5	40	0.8	11.5	0.48	.631
Buspirone	18	0.4	79	1.6	110	2.2	118	2.4	557.7	8.68	<.001
Diazepam	17	0.4	7	0.1	8	0.2	16	0.3	-5.6	0.16	.873
Clonazepam	9	0.2	18	0.4	36	0.7	43	0.9	368.0	4.74	<.001
Any sedative-hypnotic	178	3.7	102	2.1	89	1.8	53	1.1	-70.1	8.34	<.001
Triazolam	134	2.8	69	1.4	62	1.2	19	0.4	-85.8	9.40	<.001
Temazepam	24	0.5	22	0.4	15	0.3	25	0.5	4.5	0.15	.881
Psychiatric antihistamine	125	2.6	137	2.8	118	2.4	74	1.5	-40.6	3.63	.001
Diphenhydramine	112	2.3	112	2.3	99	2.0	61	1.3	-45.4	3.90	.001
Any cerebral stimulant	17	0.4	12	0.2	14	0.3	14	0.3	-17.4	0.53	.596
Methylphenidate	12	0.2	7	0.1	7	0.1	13	0.3	8.7	0.21	.834
Lithium carbonate	41	0.8	21	0.4	28	0.6	31	0.6	-24.1	1.17	.242

[1] Guidelines established by OBRA-87 for use of antipsychotic medication in nursing home settings were implemented in the fall of 1990.

[2] Not all drugs or classes are shown; number and percentage of residents in a medication category may differ from the sum of those listed.

Results

Impact on drug use

The number and percentage of residents for whom psychotropic drugs were prescribed are shown by drug class and for selected individual drugs in Table 1 (for scheduled orders) and Table 2 (for p.r.n. orders). Figure 1 graphically displays changes for each class over time as a function of phases of OBRA implementation. Over the course of the study, the percentage of residents receiving any scheduled psychotropic drug declined by 14 percent, stabilizing at about 35 percent of all residents two years after mandatory adoption of prescribing guidelines. Overall p.r.n. prescriptions fell more dramatically, to 60 percent of initial values over the term of data collection. Only 15 percent of residents had prescriptions for any p.r.n. psychotropic by 1992. Distinctive prescribing patterns were observed between and within individual drug classes.

Decline in prescribing. Antipsychotic prescribing declined significantly for both scheduled and p.r.n. use, falling to 65 percent of the levels previously effected by pharmacy consultation alone (10). The bulk of this reduction took place before formal implementation of OBRA guidelines, with more gradual change in subsequent years.

Haloperidol and thioridazine were the two most frequently prescribed antipsychotics, used daily by 9 percent and 4.3 percent of all residents, respectively, in 1989 and by 6 percent and 3 percent, respectively, in 1992. No significant change in antipsychotic drug choice was observed. Sixty percent of residents who were taking any antipsychotic received haloperidol in 1989, compared with 53 percent in 1992; 25 percent of residents who were taking antipsychotics received thioridazine in 1989, compared with 28 percent in 1992.

The mean dose of haloperidol, 3 mg per day, was stable over the study period, and the dose of thioridazine declined modestly from 82 to 61 mg per day. Doses for both drugs generally fell within the range recommended by OBRA guidelines for antipsychotics but were higher than levels suggested by others (13) as triggers for concern about overuse.

Dramatic reductions in p.r.n. antipsychotic prescriptions occurred during the study period, falling from 13 percent in 1988 (10) and 11 percent in 1989 to only 2 percent in 1992.

About 10 percent of all residents had a routine or p.r.n. prescription for a sedative-hypnotic drug at baseline, dropping significantly to about 3 percent in year 4. This change was mainly due to reduced use of triazolam, an ultra-short-acting drug with significant potential hazards for cognitive and neurological functioning (14). This change was clinically significant, as 115 elderly persons (6

Table 2

Residents of 39 skilled nursing facilities in western Washington State with p.r.n. prescriptions for psychotropic medications before and after implementation of OBRA-87 in 1990

Medication[1]	1989 (N=4,873) N	%	1990 (N=4,860) N	%	1991 (N=4,938) N	%	1992 (N=4,855) N	%	% change 1989–1992	z	p
Any psychotropic drug	1,228	25.2	904	18.6	790	16.0	738	15.2	–39.7	18.40	<.001
Any antipsychotic	545	11.2	194	4.0	138	2.8	101	2.1	–81.4	18.37	<.001
Haloperidol	432	8.9	138	2.8	98	2.0	72	1.5	–83.3	16.68	<.001
Thioridazin	65	1.3	34	0.7	22	0.4	21	0.4	–67.6	4.76	<.001
Chlorpromazine	16	0.3	10	0.2	6	0.1	2	0.04	–87.5	3.30	.001
Thiothixene	16	0.3	6	0.1	4	0.08	3	0.06	–81.1	2.98	.003
Fluphenazine	8	0.2	2	0.04	2	0.04	0	0.00	–100.0	—	—
Trifluoperazine	4	0.1	2	0.04	3	0.06	0	0.00	–100.0	—	—
Any anxiolytic	391	8.0	410	8.5	447	9.0	497	10.3	27.5	3.79	<.001
Lorazepam	265	5.5	325	6.7	359	7.3	424	8.8	60.5	6.34	<.001
Any sedative-hypnotic	299	6.2	192	4.0	155	3.1	109	2.2	–63.4	9.63	<.001
Triazolam	232	4.8	134	2.8	82	1.7	33	0.7	–85.7	12.48	<.001
Temazepam	37	0.8	28	0.6	48	1.0	63	1.3	70.8	2.63	.01
Flurazepam	18	0.4	18	0.4	14	0.3	6	0.1	–66.6	2.43	.015
Psychiatric antihistamines	128	2.6	171	3.5	110	2.2	97	2.0	–24.0	2.07	.038
Diphenhydramine	106	2.2	144	3.0	100	2.0	86	1.8	–18.6	1.44	.15

[1] Not all drugs or classes are shown; number and percentage of residents in a medication category may differ from the sum of those listed.

percent of all residents) were protected from these risks after implementation of OBRA. Prescriptions for other sedative-hypnotics, including temazepam, which is preferred under the OBRA guidelines, did not increase, suggesting that much of the use observed during the first year of the study may have been unnecessary.

Scheduled use of antihistamines—primarily diphenhydramine—for management of behavior, including sleep, declined by nearly half, and p.r.n. orders also declined. This change followed explicit OBRA recommendations to avoid use of these anticholinergic agents for treatment of anxiety and insomnia (3). Nevertheless, by the end of the study, more than 1 percent of all residents were still receiving daily diphenhydramine for psychiatric symptoms.

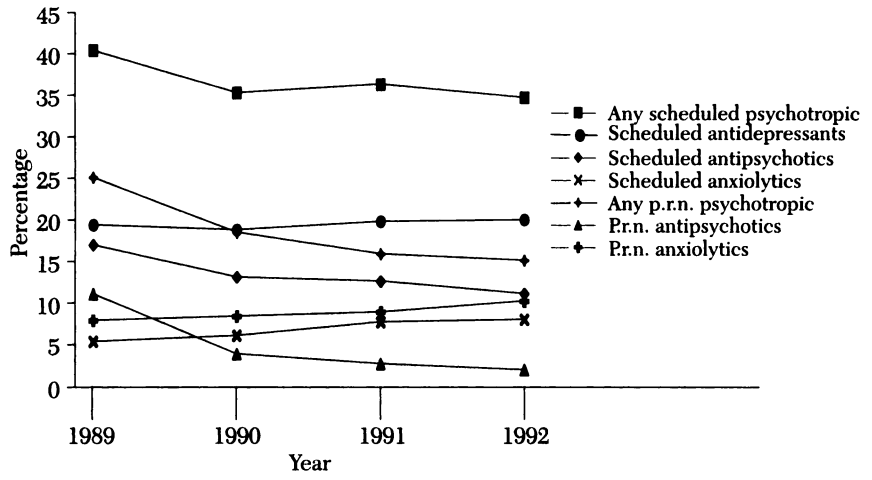
Stability in prescribing. Antidepressants were the most frequently prescribed drugs, prescribed for about 20 percent of residents in each study year. No change in mean daily dose was observed for individual drugs. Doxepin and amitriptyline together accounted for 50 percent of all antidepressant prescriptions in 1989, dropping to 34 percent in 1992. For these most frequently prescribed antidepressants—each used by 4 to 5 percent of residents at the start of data collection and 3 to 4 percent at the end of the study period—mean doses were within the range suggested for elderly patients of 50 to 60 mg per day for doxepin and 40 mg per day of amitriptyline (15).

Small but statistically significant reductions occurred in the frequency of use of strongly anticholinergic and sedative drugs, generally considered poorer choices for older persons (15), while the use of fluoxetine and better-tolerated tricyclics such as nortriptyline, which are effective for many depressed older patients with diverse comorbidities (16), increased.

Fluoxetine use increased sharply. In 1992, four years after its introduc-

Figure 1

Percentage of residents of 39 skilled nursing facilities in Washington State for whom selected classes of psychotropic medication were prescribed before and after implementation of OBRA-87 in 1990[1]



[1] All data were collected in September of each study year. Draft OBRA guidelines were circulated in early 1989, revised guidelines were implemented in the fall of 1990, and further revisions were implemented in the spring of 1992.

tion, fluoxetine was prescribed for nearly 4 percent of residents and accounted for 17 percent of all antidepressant orders. The mean dose of fluoxetine was stable over the study period at 18 to 20 mg per day.

Use of nortriptyline increased significantly over the study period. Nortriptyline was prescribed for 4 percent of all residents and accounted for 20 percent of all antidepressant orders by 1992, and the mean dose of 40 mg per day was at or below the generally recommended range for elderly patients.

Trazodone prescriptions did not change, suggesting that this agent was not substituted for antipsychotics for indications such as agitation in demented patients. The use of other drugs for mood disorders, including lithium carbonate and psychostimulants, remained stable at 1 percent or less of the population.

Increase in prescribing. Total prescriptions for scheduled anxiolytics increased from 5.5 percent to 8 percent over the course of the study, a change attributable entirely to increased use of buspirone. This drug, although available as early as 1986, became the second most frequently used anxiolytic by the end of the study period and was prescribed for 2.4 percent of all residents in 1992. Use of scheduled benzodiazepine anxiolytics remained roughly constant at 5 to 6 percent, with the short-acting drug lorazepam, in a mean dose of 1 to 2 mg per day, leading the group. No statistically significant change in dose was observed for any drug in this class.

The absolute number of residents receiving scheduled long-acting benzodiazepine anxiolytics, such as clonazepam and diazepam, shown in Table 1, and chlordiazepoxide, not shown, increased from 35 to 65 patients. Long-acting drugs took an increasing share, from 15 percent to 23 percent, of all benzodiazepine prescriptions, due to more frequent prescribing of clonazepam. The frequency of p.r.n. orders for benzodiazepine anxiolytics also increased significantly, due to more liberal prescribing of lorazepam.

Polypharmacy. The number of scheduled and p.r.n. psychotropic drugs prescribed for each year is shown in Table 3. Routine prescription of multiple psychotropic drugs was minimally affected; the proportion of residents for whom two or more psychotropic drugs were routinely prescribed was 8.4 percent before implementation of OBRA and 7.4 percent in the third year after implementation. This rate was much lower than in most earlier, pre-OBRA reports (17) but similar to that reported in a large recent survey of drug use (6).

The most common combinations were an antipsychotic with an antidepressant, for about 3 percent of all residents; an antidepressant with an anxiolytic, for 1 to 2.5 percent; and an antipsychotic with an anxiolytic, for 1 to 2 percent. A significant increase in the frequency (data not shown) of prescriptions for buspirone with an antipsychotic (50 percent over base rates), for a benzodiazepine with an antidepressant (50 percent increase), and for buspirone with an antidepressant (87 percent increase) may reflect a secondary impact of reduced use of sedative antipsychotics and antidepressants.

These upward trends were balanced by fewer combinations that included antihistamines and sedative-hypnotics, a change supported by OBRA guidelines that discouraged use of these medications for behavior management. For p.r.n. orders, the frequency of multidrug combinations showed a small downward trend, but agents selected for these combinations included several that had no accepted p.r.n. uses such as amitriptyline, nortriptyline, imipramine, desipramine, fluoxetine, and buspirone.

Impact on research. Between 1980 and 1984, before serious legislative concern with nursing home prescribing practices, only six data-based papers on psychotropic drug use in nursing homes appeared in peer-reviewed journals, an average of 1.2 per year. Most of those papers dealt with antipsychotics. Between 1985 and 1989, during drafting and finalization of OBRA regulations, 13 articles appeared (2.6 per year). Publication rates tripled during the next half-decade, for a mean of 7.8 papers per year between 1990 and 1994, and seven more papers appeared in 1995–1996.

The bulk of this recent research has been explicitly directed at outcomes of the implementation process itself, with two important exceptions: a study reporting widespread neurologic toxicity in nursing home residents taking even modest doses of neuroleptic drugs (18) and a controlled trial of a multifocal intervention showing reductions in behavioral problems despite less use of an-

Table 3

Number of psychotropic drugs prescribed to residents of 39 skilled nursing facilities in western Washington State before and after implementation of OBRA-87 in 1990

	1989 (N=4,857)		1990 (N=4,845)		1991 (N=4,940)		1992 (N=4,837)	
Number of drugs	N	%	N	%	N	%	N	%
Scheduled drugs[1]								
None	2,890	59.5	3,130	64.6	3,142	63.6	3,154	65.2
One	1,555	32.0	1,349	27.8	1,364	27.6	1,332	27.5
Two	366	7.5	301	6.2	357	7.2	299	6.2
Three or more	46	0.9	67	1.4	78	1.6	56	1.2
P.r.n. drugs[2]								
None	3,629	74.7	3,943	81.3	4,151	84.0	4,103	84.8
One	1,082	22.3	815	16.8	721	14.6	668	13.8
Two or more	146	3.0	89	1.8	69	1.4	70	1.4

[1] Significant difference in numbers of drugs between 1989 and 1990 (χ^2=34.4, df=3, p=.001) and between 1989 and 1992 (χ^2=36.5, df=38, p<.001)

[2] Significant difference in numbers of drugs between 1989 and 1990 (χ^2=77.5, df=2, p<.001), between 1990 and 1991 (χ^2=12.3, df=2, p=.002), and between 1989 and 1992 (χ^2=153.7, df=2, p<.001)

tipsychotics and restraints in severely demented patients (19). Notably underrepresented were outcome studies contributing new knowledge about the clinical effectiveness of psychotropic drugs.

Discussion and conclusions

In general, the changing prescribing patterns we found have at least limited support from clinical investigations and secondary analyses of existing studies. For neuroleptics, a meta-analysis of placebo-controlled trials involving patients with dementia found decisive benefit in only 18 percent of patients when symptom relief, behavior change, and side effects were factored into an overall appraisal of effectiveness (20). A growing literature supports selective trials of nonneuroleptic agents for behavioral disturbances associated with dementia; those agents include mood-stabilizing anticonvulsants and modulators of serotonergic function such as buspirone, trazodone, and selective serotonin reuptake inhibitors (21–27).

Although it is widely accepted that minimizing neuroleptic drug use is a desirable epidemiological outcome, individual patients will continue to require antipsychotic pharmacotherapy (28,29). Novel antipsychotics with different modes of action and side effect profiles may prove preferable to neuroleptics for some patients, but published data are lacking. For sedative-hypnotic drugs, the reductions in use that we found positively reflect the existing consensus among researchers (7,8,30–33).

For antidepressants, interpretation of the data is more complex. The use rates we report were higher than those reported by most other investigators (17), even before implementation of OBRA. The high prevalence, underrecognition, undertreatment, and adverse health outcomes of depression in nursing home patients (34) led to the inclusion of a screen for depression in OBRA's Minimum Data Set, which is to be used when staff suspect that a resident has a change in mood. However, we found no apparent effect of this innovation in this study.

Changes in drug choice, favoring less frequent selection of first-generation tricyclics, are in keeping with the evolving preference of geriatric psychiatrists to limit the use of sedative and anticholinergic agents. The spectrum of indications for serotonin-selective antidepressants has not been adequately studied in frail elderly populations (35). Small studies have suggested unique hazards in old people at risk for weight loss (36) and impaired balance and gait (37); other studies have suggested that these agents may have lower efficacy in treating melancholic depression (38). These preliminary findings require testing in larger samples of patients.

The strategy adopted by OBRA-87 for altering patterns of psychotropic drug use in nursing homes holds the facilities themselves, rather than the prescribing physicians, accountable for monitoring drug use.

The increase in anxiolytic prescribing we observed poses a conundrum. Benzodiazepines with long elimination half-lives gained an increasing share of prescriptions over the course of the study, contrary to predictions of decreased use as a result of OBRA implementation, an outcome supported by most of the clinical literature (14,33). A recent large case-control study reconfirmed the known association of benzodiazepines with hip fractures related to falls, but found that total dose and rate of dosage increase contributed more to risk than did elimination half-life (39). As long-acting agents may have clinical advantages for patients who experience repeated cycles of withdrawal and increased anxiety with short-acting drugs, and who are therefore at risk for dose escalation and increased functional toxicity, it is unclear whether OBRA guidelines are appropriate as written.

Buspirone use increased dramatically over time in the study reported here. This medication has been found to be safe and preferable to a short-acting benzodiazepine (alprazolam) in short-term trials involving healthy geriatric outpatients with anxiety (40,41). However, its cost and known side effects of nausea and weight loss, headache, and agitation call for formal comparison trials with benzodiazepines in the nursing home setting. The increased use of buspirone in combination with antipsychotics and antidepressants found in this study suggests that buspirone may be employed to offset reductions in use of more sedating agents and the anxiogenic effects of fluoxetine. It is unclear whether such combinations are superior to the drugs they may replace.

The continued use of highly anticholinergic and sedative medications in several drug classes—including thioridazine, amitriptyline, doxepin, and diphenhydramine, which together comprised 32 percent of all regularly scheduled psychotropic drug prescriptions—requires further investigation. The dose-related cognitive and functional toxicities of these agents in elderly persons have been well described (42–44), and their use more than doubles the risk of chronic constipation in nursing home residents (44). However, low cost, familiarity to practitioners, and lack of propensity to cause weight loss may make them useful in nursing home practice, provided these potential advantages are matched by efficacy and safety in relatively low doses. Neither has been established in large samples of patients.

Psychotropic polypharmacy regimens continue to place 5 to 10 percent of nursing home residents in this sample at potentially increased risk for falls, fractures, psychiatric toxicity, impaired cognitive function, and other adverse outcomes due to

additive drug effects. In addition, we found that several agents with no p.r.n. indications still appear as part of "as needed" polypharmacy regimens. Patients for whom such regimens are ordered are a logical and practical focus for future outcome studies.

The strategy adopted by OBRA-87 for altering patterns of psychotropic drug use in nursing homes sets an important precedent for health care reform. This strategy holds the facilities themselves, rather than prescribing physicians, accountable for monitoring drug use. This approach is well suited to the realities of nursing home practice, which demand that nursing staff who care for residents around the clock, not doctors who often visit infrequently and briefly, must be the primary monitors of their patients' welfare and the gatekeepers for appropriate detection and management of psychiatric problems.

OBRA may also stimulate enhanced efforts by other providers, such as consultant pharmacists, to monitor drug use. However, previous work by us (10) and others (45,46) indicates that the specific role of the pharmacist is important. Pharmacist-led educational programs for nonphysician primary caregivers influence physicians' prescribing behavior, at least with respect to antipsychotics, while purely administrative review of prescriptions has no effect (1).

All available data, including those reported here, suggest that OBRA legislation has had a significant effect on patterns of prescribing that had been relatively stable, in some cases for more than a decade. These patterns of drug use changed only after the stirrings of legislative reform began to be felt and then to prompt active interventions and new practice-based research (4-6,10,13,18,19, 28,29,31,44–46). Our data suggest that the prescribing frequency for drugs that are not specifically regulated has remained relatively unchanged, as in the case of antidepressants and psychotropic polypharmacy, or increased, as in the case of buspirone. Based on the anticipatory changes in antipsychotic drug use we observed, trials of educational interventions aimed at improving recognition of depression, anxiety, and drug interactions and knowledge of their appropriate treatments could be a valuable mechanism for further improvements in prescribing practices.

Influences not directly related to the provisions of OBRA legislation, such as better training of nursing home staff in mental health management and pharmaceutical advances leading to the introduction of new proprietary drugs (fluoxetine and buspirone, in this study), occurred during the study period and undoubtedly also contributed to the observed changes in prescribing patterns.

Since the completion of this study, several new and more expensive antidepressant and antipsychotic medications, including sertraline, paroxetine, venlafaxine, nefazodone, clozapine, and olanzapine, have entered the market. These medications have been powerfully promoted on the basis of their distinctive modes of action and side effect profiles compared with the older drugs they are meant to replace. Efforts to comply with OBRA guidelines may indirectly stimulate their use, precisely because of these differences. To avoid the hazardous side effects of older drugs recognized in OBRA's legislative language, new drugs may be enthusiastically adopted in the absence of clear scientific data about their impact in nursing home populations. In this way, legislative mandates can interact with shifts in nonpharmacologic practice, and with changes in the range of drugs available for use, to alter choice of medications and prescribing frequencies. Our data offer limited support for such an effect.

In future years, the higher dollar cost of newer psychopharmacologic agents is likely to become an increasingly important issue in nursing homes, as these facilities, like managed care organizations, begin to consider price-based administrative constraints on drug choice. These economic pressures may help to stimulate badly needed comparative drug trials that are anchored in clinical treatment outcomes.

The apparent vitalizing effect of OBRA-87 on drug treatment research in long-term care has had little impact on stimulating such comprehensive outcome research thus far. Much of the effort has been directed at identifying treatment hazards, lending empirical validity to Kane's argument (1) that a major intent of regulating nursing home practice is "to avoid catastrophes rather than to encourage good care." This is not a bad place to start—the heterogeneous psychiatric presentations and comorbidities encountered in nursing home residents often challenge the most experienced physicians and are partly to blame for the slow development of the types of research that are needed to develop positive, as well as negative, practice guidelines.

Nursing homes require a unique research agenda that reflects their continued role as the largest group of psychiatric facilities still functioning today (47), caring for seven times the number of patients in all mental hospitals combined (48). Paradigms for research in these settings are necessarily complex; they must combine global functional outcomes with appraisal of symptoms, disease, disability, quality of life, physiologic measures, and impact on caregivers, and they must take into consideration both psychiatric disorders and prevalent medical disorders and their treatments (49). A strategy similar to that successfully implemented in large, multisite studies of primary care patients, such as the Medical Outcomes Study (50), would be a decisive step in improving management of psychiatrically impaired patients in long-term care. ♦

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