The Diffusion of New Antipsychotic Medications and Formulary Policy

by Marisa Elena Domino, Richard G. Frank, and Robert Rosenheck

Abstract

Spending on antipsychotic medications continues to escalate as new products such as atypicals are increasingly used to treat schizophrenia and other conditions. Given that per person spending on behavioral health benefits is shrinking while spending on pharmaceutical products is increasing, the psychotropic portion of mental health expenditures is likely to continue to increase in the future. The diffusion of these new behavioral health technologies, or the rate at which these products have spread through the market, has been very uneven. Differences in adoption and diffusion rates of psychotropic medications across insurance settings, geographic regions, or subpopulations defined by age, gender, or racial or ethnic groups have important implications for the quality of care received by persons with mental illnesses. This article reviews the evidence on the diffusion of antipsychotic medication and discusses the implications of formulary policies on diffusion, addressing the health care service and administrative context in which the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) project is being conducted and which it is intended to inform.

Keywords: Antipsychotic, diffusion, formulary design.


The past decade has witnessed unprecedented growth in new technologies in mental health treatment. The availability of new pharmacological agents has had an enormous impact on the treatment of mental health disorders, enabling patients to experience relief from many symptoms and improve their functioning and quality of life.

Spending on psychotropic medications accounts for a substantial portion of total behavioral health dollars. In 1997, psychotropic medications composed an estimated 13 percent of total mental health expenditures (Coffey et al. 2000). Antipsychotic medications are currently the 13th-highest drug category ranked by total retail sales in the United States in 2001 (NIHCM 2002). Novartis reports that average annual spending per health maintenance organization (HMO) member on antipsychotics is $4.21 (2000). As per person spending on behavioral health benefits is shrinking while spending on pharmaceutical products increases (Hay Group 1998; Coffey et al. 2000), the psychotropic portion of mental health expenditures is likely to continue to increase.

Psychotropic medications are also a significant expense in the Medicaid program. Antipsychotic agents ranked first for the number of prescriptions covered by Medicaid in 1998 (Novartis 1999). Medicaid covers more than 50 percent of the prescriptions in the $1.5 billion antipsychotic market (Novartis 1999). This therapeutic class of drugs also ranks in the top five for total spending in MediCal, California’s Medicaid program (Frank et al. 1999).

Spending on prescription drugs for mental health and substance abuse has continued to increase. Average annual spending on psychotropic medications is growing at a rate of 9.3 percent per year, adjusted for inflation, faster than the real growth rate for nonpsychotropic medications at 8.3 percent per year (Coffey et al. 2000). The same study found an increase of over 5 percent per year in the number of psychotropic drugs prescribed during outpatient office visits. Psychotropic drug products, however, are considered underused in mental health care. Wells and Sturm (1996) note that increases in appropriate use of these medications could improve the cost-effectiveness of care.

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across insurance settings, geographic regions, or subpopulations defined by age, gender, or racial or ethnic groups have important implications for the quality of care received by persons with mental illnesses. Failure to recognize mental illness in primary care patients precludes treatment; thus, these differences in diagnosis across subpopulations will lead to differential rates of psychotropic drug diffusion.

To advance models of best practice, it is important to understand the factors that underlie these varying rates of diffusion. Knowledge concerning the diffusion process would be of particular help to State Medicaid programs, for many are experimenting with components of behavioral health insurance without fully understanding the consequences for spending and outcomes. This article reviews the evidence on the diffusion of antipsychotics and other types of psychotropic medication and discusses the implications of formulary policies on diffusion.

Factors Affecting Drug Diffusion

What causes mental health providers to select one antipsychotic treatment option over another? Greater effectiveness of one product over others in the therapeutic class, the minimization of side effects and toxicity, and lower costs of treatment are all reasons commonly cited in the literature on treatment selection for medical disorders (Berndt et al. 1995, 1996; Ellison et al. 1997). Patient requests and characteristics, and provider characteristics and familiarity with certain products, can also play an important role (Weiss et al. 1990; Peay and Peay 1994; Crystal et al. 1995; Hellerstein 1998; Stern and Trajtenberg 1998; also see Hemminki 1975; Christensen and Bush 1981; Bradley 1991 for literature reviews). Another source of variation is the relative contribution of the new product to the existing treatment class; new “breakthrough” drugs that are substantial improvements on existing technologies may enter the market more strongly than “me-too,” or imitator, products. A substantial amount of the variance in prescribing patterns still remains unexplained.

Studies investigating the relative weights of deterministic factors have shed some light on medical treatment decisions. In a study by Segal and Hepler (1985), physicians gave the highest value ranking to pharmaceutical features reflecting clinical control of the disease, patient compliance, and side effects. A similar study (Denig et al. 1988) found that the highest values were given to efficacy, personal experience, and side effects. Conspicuously low on the value list for both of these studies was the cost of the medication prescribed, which ranked fifth of 7 outcomes in the Segal and Hepler study, fourth of 10 outcomes in the 1988 Denig et al. study for a less harmful dis-order, and the last of 9 outcomes for a more severe disorder. This branch of the literature has had moderate success in predicting physician choice of pharmaceutical products, estimating the elicited responses correctly in 45 to 87 percent of cases. However, these studies do not specifically examine psychotropic medications and are based on patient vignettes, which may not accurately represent decision making in a real-world setting.

Influence of Drug Characteristics on Diffusion

Drug characteristics such as effectiveness, efficacy, dosing, and side effects have been found in a variety of studies to have important influences on the rate of use (Berndt et al. 1996, 1997a, 1999; Domino and Salkever 2001). In the past 14 years, five new antipsychotic medications have been released that have been referred to as “atypical antipsychotics” because they have been consistently shown to have fewer extrapyramidal side effects than older agents (Kane et al. 1988; Kerwin 1994; Marder and Meibach 1994; Tollefson et al. 1997; Geddes et al. 2000; Csernansky et al. 2002). While these medications have been found more effective in reducing symptoms than standard medications in many (Kane et al. 1988; Marder and Meibach 1994; Rosenheck et al. 1997; Tollefson et al. 1997; Csernansky et al. 2002) but not all studies (Essock et al. 2000), the magnitude of their advantage is generally modest (Geddes et al. 2000). Several randomized controlled trials conducted in the early 1990s examined the cost-effectiveness of these medications, especially clozapine, and indicated that they generate savings that are of sufficient magnitude to offset their greater initial expense, at least in patients who have made extensive use of expensive inpatient services (Rosenheck et al. 1997; Essock et al. 2000). However, recent studies among outpatients have not demonstrated such savings (Viale et al. 1997; Luchins et al. 1998).

Recent work, especially by Ernst Berndt, has demonstrated the influence of pharmaceutical marketing activities on the diffusion of H2-antagonists for the treatment of ulcers and heartburn (Berndt et al. 1995, 1997a, 1999). These studies have shown that price, minutes of detailing, journal pages of advertising, direct-to-consumer marketing efforts, and whether any H2 antagonist had U.S. Food and Drug Administration (FDA) approval for gastroesophageal reflux disease affected the growth of the entire H2 ANTAGONIST market, while relative shares garnered by the individual H2 ANTAGONIST brand-name drugs depended on order of entry, relative prices, relative marketing efforts, and relative number of adverse interactions with other drugs.
Influence of Insurance on Diffusion

The strong proliferation of pharmaceutical insurance either as a benefit in medical or behavioral health insurance plans, or as a separate policy, as is the case with some Medi-gap policies targeted at Medicare recipients, has reduced the price sensitivity of consumers receiving prescription drugs (Leibowitz et al. 1985; Phelps 1997). Using IMS America national data, Berndt et al. (1998) report that by the end of 1996, 57 percent of all prescriptions dispensed by retail drugstores were paid for at least in part by private third party insurers, 11 percent by Medicaid, and 32 percent by cash.

It is likely that the insurance setting under which individual physicians practice may play an important role in explaining variations in prescribing. Until 1993, consumer out-of-pocket payments accounted for more than 50 percent of total spending on prescription drugs; this percentage has been declining steadily since 1960. The managed care era has ushered in a more generous pharmacy benefit for enrollees, but with it, a greater degree of restrictions on choices of treatment, especially among expensive new products. These changes have likely altered the selection of treatments for many disorders and thus the diffusion patterns of many pharmaceuticals.

The Department of Veterans Affairs (VA) is another large purchaser of antipsychotic medications. While the single-payer nature of the VA and the specialized population of service users likely affect many aspects of provider behavior, several studies have found few differences between prescribing patterns of VA and non-VA providers (Rosenheck et al. 2000; Leslie and Rosenheck 2002).

As the tools of managed care increasingly permeate behavioral health insurance, the diffusion of new antipsychotic products into existing treatment options is likely to be strongly affected. The direction of this effect is ambiguous because of the complexity and differing incentives inherent in these tools. Managed care insurers promote treatment in an ambulatory setting, thus favoring ancillary services such as pharmaceutical products over more expensive substitutes such as hospitalization. The lower out-of-pocket prices for physician office visits often present in managed care plans may increase prescription opportunities. However, once contact with a specialist is initiated, there is some evidence that enrollees have fewer visits with their specialty provider (e.g., Norquist and Wells 1991). This may affect the diffusion of psychotropic medications if prescription opportunities are decreased. While a competing explanation is that increased psychotropic drug use substitutes for greater provider contact, increased medication switches have been shown to be associated with greater outpatient contact (Sernyak et al., submitted).

Managed care is associated with an increase in the amount of insurance coverage for drugs (Lyles and Palumbo 1999). In 1997, one study estimated that 94 percent of persons in HMO commercial or group plans had coverage for pharmaceutical expenses (Novartis 1998). As out-of-pocket expenses decrease, consumers have been shown to demand more and higher priced pharmaceuticals. Results from the RAND health insurance experiment indicate that consumers faced with lower out-of-pocket payments for physician visits and pharmaceuticals are more likely to use prescription drugs (Leibowitz et al. 1985), but because the study design held the copayment rate for drugs equal to that for office visits, it is not clear which effect was driving this result.

There is very little evidence on what impact, if any, managed care has on the use of newer drug products, especially antipsychotics; somewhat more is known about the use of antidepressants. Weiner et al. (1991) found no difference between managed care physicians and their fee-for-service counterparts in terms of the use of new drugs. Domino and Salkiver (in press), however, found that managed care providers in a Medicaid program were more likely than their colleagues in a gatekeeper fee-for-service model to use the new class of antidepressants, selective serotonin reuptake inhibitors (SSRIs), once they decided to prescribe an antidepressant product. Managed care enrollees were also found to be much less likely to receive a pharmaceutical treatment, indicating an overall negative association between managed care and newer antidepressant products. Berndt et al. (1997b) also found that preferred provider organizations and mental health carveouts have lower spending on SSRIs as a percentage of all antidepressant spending than do fee-for-service indemnity plans.

Intertwined with changes in the medical marketplace brought about by the introduction of managed care are changes in mental illness treatment settings. Discussed above were the associated shifts out of inpatient-based treatment to outpatient care. In addition, changes in the type of outpatient treatments and providers have occurred (Domino et al. 1998; Pincus et al. 1998), with the primary care system increasingly serving as an entry point for mental health care (Wells 1991). Coupled with physician characteristics, such as age and managed care involvement, these changes have been observed to affect the types of treatments received by patients. For example, Pincus et al. (1998) found that while both primary care physicians and psychiatrists experienced a 100 percent increase in the number of visits for depression from 1985 to 1993–1994, only psychiatrists changed their likelihood to prescribe psychotropic medications. This is consistent with a study by Meredith et al. (1994), which found a significantly higher rate in the use of antidepressants by mental health...
specialists over primary care physicians, despite a similarity in reported preferences for use by these two provider types. In addition, in line with the traditional sociological view of diffusion, Escarce (1996) found that other physician characteristics, such as exposure to colleagues who quickly adopted new medical innovations, influence the rate at which these innovations are adopted.

Behavioral Health Carveouts. A newer facet of managed behavioral health care is a mental health/substance abuse carveout, found in both the public and the private sectors. Insurers taking a carveout approach contract all mental health and, frequently, substance abuse services to a secondary insurer, which is often paid on a capitated basis and arranges with a provider network to provide care. Forty-two States used mental health and/or substance abuse carveouts in their public programs in 1999 (SAMHSA 2000). This approach is also common among private insurers, with 56 percent of plans reporting use of behavioral health carveouts in a recent survey (Novartis 1998).

Mental health carveouts have been shown to have a strong effect on the patterns of care received, shifting care from more costly inpatient care to less expensive outpatient substitutes, and often using different types of outpatient services (Grazier et al. 1999). In most cases, prescription drugs are not included in carveout arrangements and are covered instead under the primary (general) insurance policy. Novartis (1998) reports that only 26 percent of behavioral health carveouts include prescription drugs in coverage. It is likely that new psychotropic medications are adopted much more readily under carveout arrangements, as providers shift patients onto pharmaceutical care for which the carveout vendor is at not at risk.

Influence of Market Characteristics on Diffusion

Market or local area characteristics are likely to influence differences in the diffusion of drug products across geographic or market areas. For example, personal income has been shown to influence spending on medical care, with a 10 percent increase in individual income associated with a 10 percent increase in expenditures on medical care; in economic terms, this translates to an income elasticity of 1.0 for overall medical spending (Phelps 1997). At the market level, this may translate into an influence of per capita income on product demand. Gresenz et al. (2000) found that per capita income and HMO penetration affect access to specialty mental health care and behavioral health care, respectively. Other local area characteristics that are hypothesized to influence psychotropic drug diffusion are relevant public resources, insurance characteristics, such as managed care penetration or percent of the population with any insurance coverage, as discussed above; and the physician/population ratio.

Influence of Sociodemographic and Treatment Characteristics on Diffusion

Sociodemographic characteristics such as age, race, education, and income have been shown to affect mental health treatments received (Snowden and Thomas 2000; Young et al. 2001; Domino and Salkever, in press). Other characteristics, such as the perception of stigma, have been shown to affect compliance with treatment (Sirey et al. 2001), a factor that certainly affects diffusion, through decreased consumption. This difference in treatments received is partly due to differential effectiveness and side effects of pharmaceutical products in subpopulations such as the elderly but may also be due to differences in product selection and dosing in racial and ethnic minority populations (Walkup et al. 2000). Patient comorbidities, such as the presence of a substance abuse disorder or comorbid depression with anxiety, may also affect the use of psychotropic medications (Meredith et al. 1997; Olson et al. 2000; Leslie and Rosenheck 2001).

Older patients, men, and African-Americans have been observed to be less likely to fill a prescription for atypical antipsychotic medication, although some studies have found no effect of age, gender, or education on the use of atypicals (Covell et al. 2002). People with a comorbid mental health diagnosis and those with a prior psychiatric hospitalization have also been found to be more likely to use atypicals (Leslie and Rosenheck 2001). However, the recent Mount Sinai Conference on the Pharmacotherapy of Schizophrenia recommended that “in terms of efficacy considerations there is no evidence that personal or demographic characteristics should guide drug selection” (Marder et al. 2002). Contributions to the cost-effectiveness literature have concurred with this result; for example, Rosenheck et al. (1998) showed no clear advantage of clozapine over haloperidol for any subgroup defined by age, race, clinical status, or comorbidity.

Treatment characteristics, especially a diagnosis of schizophrenia or schizoaffective disorder, have an obvious effect on the use of antipsychotic medication, although considerable off-label prescribing still exists. In a study in a VA setting, Rosenheck et al. (2001) found that only 57.2 percent of people on atypical antipsychotics had received a diagnosis of schizophrenia. While inadequate diagnostic information on medical records likely accounts for some of this difference, this represents considerable off-label use. Other treatment characteristics, such as the level of inpatient hospital use, have been shown to be differentially associated with the demonstrated cost-effectiveness of antipsychotic medications (Rosenheck et al. 1999).
The factors that may affect the diffusion of antipsychotic medications are many and complex. Penetration of managed care plans is probably a major influence on drug diffusion, through increased use of formularies (including preferred drug formularies) and increased access to outpatient services, but the direction of the effect is not obvious. In addition, the increased use of treatment guidelines and algorithms has influenced drug prescriptions. Other factors, such as drug characteristics, marketing effects, and individual and physician characteristics, are hypothesized to have important effects but are inadequately studied in the current literature on the use of psychotropic drug products.

Formularies and Changing Patterns of Diffusion

Participants in the Mount Sinai Conference (Marder et al. 2002) recommended the use of several of the atypical medications in new cases of schizophrenia, while reserving the use of conventional antipsychotics for those who have already successfully tried them without substantial realized side effects. This recommendation agrees with much of the evidence from the cost-effectiveness literature. This growing body of research has largely found that although the medication costs for atypicals are much higher than those for conventional antipsychotics, the newer products demonstrate greater cost-effectiveness when total treatment or, better, societal costs are considered, at least in high-cost inpatients (e.g., Rosenheck et al. 1997; Essock et al. 2000). While the incentives may not be aligned for insurers to minimize societal costs, programs such as Medicaid and the VA should use information on societal costs, such as quality of life, labor market participation, and costs of caregiving by family members or friends, in their formulary decisions. In cases where there are no significant differences in cost-effectiveness of two or more antipsychotic medications, medication costs may be the driver in choosing between them.

Many managed care organizations use drug lists called formularies, which specify which drugs are reimbursable under the plan (called a "closed" formulary) or which drugs are not reimbursable (a "negative" formulary [Lyles et al. 1997]). The purpose of a formulary is at least threefold: to obtain discounts from pharmaceutical manufacturers in exchange for the increased use of the manufacturer's products in lieu of competing products, to provide information to physicians on the relative benefits and costs of the various treatment options, and to align the consumers' incentives with those of the plan by encouraging selection of the least costly or most cost-effective products. In a recent study, the Congressional Budget Office found that discounts to HMO plans average as much as 18 percent off the average retail price of drugs and vary with the degree of competition in the therapeutic class (CBO 1998).

Formularies can be used to improve diffusion patterns to be more closely aligned with treatment recommendations, but the net effect of formularies on the use of new drug products is difficult to determine (CBO 1998). While brand-name manufacturers that successfully negotiate admittance to an insurer's formulary can expect to receive an increase in the utilization of their products over other products that are excluded from the formulary, these brand-name products also face intense competition from lower priced generic products that are members of the same therapeutic class.

In addition, formularies are updated on a periodic, rather than continual, basis, delaying the introduction of new drug products to insured persons subject to a formulary. Often, formulary committee members rely on drug information obtained from peer-reviewed literature (CBO 1998), which further increases this delay because of lags in publication. For example, a recent survey found that only 20 percent of HMOs included new drugs in their formularies immediately after FDA approval (Novartis 1998). However, formularies may increase the flow of information to physicians in participating plans and thus speed changes in prescribing behavior (T. McGuire, personal communication, 2001).

Although the VA formulary for atypical antipsychotic medications is not restricted, several VA administrators have implemented prescription review policies that encourage use of the less expensive atypicals (risperidone and quetiapine) before olanzapine, which is almost twice as expensive, in the absence of patient-specific indications for olanzapine. Although this procedure generated intense protestations from the manufacturer of olanzapine (Rogers 2002), a review of evidence by the U.S. General Accounting Office found this procedure to be justified and sound, and further analysis of VA data showed reduced use of olanzapine in regions that implemented this policy and several million dollars in savings (Rosenheck and Leslie, in press).

Comparison of Diffusion Rates in Different Settings

In this section, we present information on the diffusion of antipsychotic medications in three different populations and settings: the Medicaid program, the VA, and long-term care facilities.

Diffusion in the Medicaid Program. Rudimentary analyses on aggregate Medicaid data indicate considerable differences in the diffusion patterns of the number of pre-
scriptions filled for antipsychotic drugs by State. After its Medicaid debut, New York's olanzapine consumption increased fifteenfold by the end of 1998, as compared to a ninefold increase in Pennsylvania, an elevenfold increase in Ohio, and an almost fourfold increase in Florida (figure 1). Note that these figures are not adjusted for the size of the enrollee population, the size of the prescriptions in terms of number of daily doses, or any State or program characteristics that may be important in explaining these differences.

Diffusion in the VA. Examining data on the use of antipsychotic medications by regions, or Veterans Integrated Service Networks (VISNs), in the VA, we find considerable differences in prescribing patterns. Table 1 demonstrates these results for 2 years, 1999 and 2001. The average VISN used conventional antipsychotics for 46 percent of its clients with schizophrenia in 1999, dropping to 34 percent in 2001. Within atypicals, some VISNs prescribe particular drug products more than five times the rate of other lower prescribing VISNs. For all four atypicals on the market in 1999, the difference in diffusion rates decreases over time.

Diffusion in Long-Term Care Facilities. Figure 2 shows the pattern of diffusion of the four top-selling atypical antipsychotics in the long-term care (LTC) market from 1995 to 2000 (2000 data were based on first quarter 2000 data). Risperidone originally accounted for almost 50 percent of sales to LTC facilities in 1995, dropping to less than 40 percent of sales in 2000. Use of olanzapine increased dramatically during this time frame, while the share of sales of clozapine dropped substantially. Most of these drugs increased their market share in terms of the percentage of antipsychotic prescriptions during this period, with only clozapine remaining at a constant 11 to 12 percent of sales. By the first quarter of 2000, drugs other than these four atypicals represented less than 4 percent of total antipsychotic sales to LTC facilities, but almost 30 percent of total prescriptions.

Evidence From Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE)

Differential cost-effectiveness of antipsychotic medication in these populations could be instrumental in making formularies more effective, by allowing plans to use different first line agents for the treatment of schizophrenia based on personal characteristics. To date, this information is sparse, but studies like CATIE that are examining multiple antipsychotics, with a large enough sample size to do subgroup analyses, would provide important information to...
**Table 1. Differences in antipsychotic use rates across VA regions (VISNs)**

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<th>1999 (%)</th>
<th>2001 (%)</th>
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<tr>
<td>Maximum percent of veterans in VISN on conventional antipsychotics</td>
<td>57.9</td>
<td>41.9</td>
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<td>Minimum percent of veterans in VISN on conventional antipsychotics</td>
<td>37.0</td>
<td>26.4</td>
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<tr>
<td>Maximum percent of veterans in VISN on atypical antipsychotics</td>
<td>67.7</td>
<td>78.9</td>
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<tr>
<td>Minimum percent of veterans in VISN on atypical antipsychotics</td>
<td>45.9</td>
<td>66.0</td>
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*Note.*—VA = Department of Veterans Affairs; VISN = Veterans Integrated Service Network.

Source: Leslie and Rosenheck 2002.

**Figure 2. Diffusion of atypical antipsychotics in the LTC market**

*Note.*—LTC = long-term care.

Source: IMS Health.

this end. In addition to treatment costs, CATIE researchers are collecting labor market information on study participants, which will provide improved estimates of the influence of treatment on an important societal (and personal) cost.

The final phase of CATIE will also provide important insights into the treatment selection process. In that part of the trial, physicians can choose among several alternatives for their treatment-refractory patients, rather than having them randomly assigned. Data from this phase of the study can be analyzed to determine which, if any, physician or patient factors guide treatment selection in this subpopulation.

**Conclusions**

The uneven diffusion of antipsychotic medication is troubling in light of recent treatment guidelines that offer no differential recommendations on antipsychotic medication selection for subpopulations based on age, race, gender, or other personal characteristics. Factors such as provider and patient preferences, cost differentials, insurance characteristics, and market characteristics likely affect the diffusion process, but little is known about the complex influence of these factors. We present evidence on the diffusion process of atypical antipsychotic medications in three different settings—the Medicaid program, the VA, and LTC facilities—and find very different rates of diffusion, even across regions with similar program characteristics. Further research is needed to help explain the factors that affect the diffusion of new psychotropic medications. Studies like those being conducted in the CATIE project can provide a rich starting point.

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