DRUG FORMULARIES: REAL OPPORTUNITIES TO IMPROVE MCO EFFICIENCY

Approximately 20,000 biomedical journals now publish more than three million articles each year.¹ This is worrisome for those who subscribe to the paradigm of evidence-based medicine and practice policies.² We must evaluate study design, methodology, sample size, induction criteria, and a host of other factors for each article, as well as judge relevance for our organization and the managed care operating environment.

It helps to be able to rely on the integrity of the peer-review process to sort through the avalanche of articles. For me, *The New England Journal of Medicine* (NEJM) anchors one end of the spectrum of integrity in medical journalism. Yet, NEJM itself was rocked recently when two authors who wrote a review article about dexfenfluramine turned out to have a financial consulting relationship with the pharmaceutical companies that produced and marketed the drug. The editors and some of the readers of NEJM understandably were stunned by the experience, and NEJM tightened up the language in its disclosure-exclusion policy to prevent a repeat occurrence.³ Specifically, NEJM found it necessary to leave no opportunity for a reviewer to interpret a direct conflict of interest.

The development of practice policies based on "evidence" is a noble goal. However, there are some potentially useful data and

information developed in studies other than those involving randomized, clinical trials (RCTs). And much of the "evidence" in medicine, particularly in pharmacotherapy, involves placebo-controlled RCTs or bacterial eradication rates that have little or no application in the real-world environment of managed care. So what can we do?

In March, 1996, a new journal published a report that was written by Susan Horn, Ph.D. and associates and sponsored by the National Pharmaceutical Council (NPC), representing many brand-name pharmaceutical manufacturers.^{4,5} The journal declares in its masthead that it is "The Forum for Peer-Reviewed Literature on Healthcare Outcomes." The premise of Dr. Horn's report, developed in discussions with NPC representatives dating back to 1990 or before, was that prescription drug formularies can be shown to increase total system costs, a claim that is difficult for anyone who actually has worked in formulary development or management to accept. However, a closer look at the two articles by Horn et al. reveals much information for those skeptical of the assertion that prescription drug formularies increase total health system costs. First, to the ambitious premise that drug formularies somehow are associated with higher medical system costs, Horn and NPC applied a one-time, non-equivalent

group study design and used regression analysis to proclaim causative effects. There is no weaker "research" design for this purpose. And even the most casual "peer reviewer" would not permit an author of a manuscript to use a one-time, non-equivalent study design to conclude, "In the case of limited formularies, we found the unintended consequence of increased utilization of healthcare resources."⁶

Second, Horn et al. applied an artificial measure of "formulary restrictiveness" for the principal independent variable. By itself, this may not startle readers, but Horn was apprised of the invalidity of this measure in a meeting in 1994—a more valid and reliable measure of the degree to which MCO members actually were restricted access to various prescription drugs would require counting the number and type of drugs actually used by the patients in the sample Horn et al. studied. Admittedly, the authors stated, "Formulary limitation generally did not result in absolute exclusion of unlisted entities from use."⁷ But the authors went on to discount this important measure of actual reduced access to non-formulary drugs by making statements unsubstantiated by any data or statistics: "However, listed entities were prescribed much more frequently than nonlisted entities, and the breadth and composition of the formulary determined the identity and mix of the most

frequently used drugs."⁸

Third, Horn et al. put forth their conclusions despite the absence of data on actual MCO prescription drug costs and other missing information such as prescription drug copayment:

"...drug copayment information was missing for 28% to 35% of the patients by disease group and all drug copayment data were missing from one site."⁹ And, "for some sites, only incomplete data were available for some potentially significant resources (e.g., laboratory tests and diagnostic tests)."¹⁰

Fourth, Horn et al. blame the absence of actual drug cost data and their use of AWP cost calculations on a fictitious excuse: "We used AWP because four of the study sites were forbidden by their contracts to reveal whether they received discounts from pharmaceutical manufacturers."¹¹ As most readers know, price contracts with pharmaceutical manufacturers do not and cannot prohibit disclosure of the existence of these contracts, but can and do, with fair reason, prohibit disclosure of specific terms of these agreements. Moreover, all prescription drug data bases contain the actual drug cost, a mandatory data element in drug claims payment data in the standards set forth by the National Council on Prescription Drug Programs (NCPDP). For any study sites that employed staff pharmacy

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Figure 1. Arthritis Drugs Horn et al. "Study"

operations, actual drug cost data could be obtained if the Horn study was truly "supported in part by the six health maintenance organizations,"⁵ and the "participating HMOs were required to have computerized information systems capable of merging data from drug claims, visits, emergency department (ED) visits, and hospitalizations at the patient level."⁵

The Horn "study" and published reports on their own warrant little if any response. But NPC hired a public relations firm to publicize this "important study" that showed that aspects of managed care are misguided. Worse, bills have appeared in California and Virginia to limit or eliminate effective drug formularies including therapeutic selection. Today, NPC continues to produce and distribute information about the Horn reports.

The graphical presentation of the precious little data that can be extracted from

the "secret" Horn et al. study suggest how the "statistically significant" regression results were obtained. Figures 1 and 2 were prepared directly from table data presented at multiple points in the two reports by Horn et al. In both figures, the Utah HMO site (number 4) is a dramatic outlier on the x-axis of "drug formulary limitation" and has the lowest score on the y-axis, "severity-adjusted mean office visits." Figures 3 and 4 were developed from a review of the actual drug formulary in place at the Utah HMO site (number 4) in 1992, the period of the "study." Table 1 shows the actual count of drugs on the Utah HMO formulary in its Spring 1992 edition.

If this information does not incite JMCP readers, we have become too complacent about drug company promotion masquerading as science. Harvard's Steve Soumerai, MD, referred to the "heroic statistical manip-

Figure 2. Hypertension Drugs Horn et al. "Study"

Figure 3. Arthritis Drugs Horn et al. "Study"—site 4 actual data

ulations" employed by Horn et al. to overcome the inability to control for pre-existing differences among the study sites. I demonstrated that the Utah site in the Horn reports was not an HMO, but one multispecialty medical group that provided care to many

payors.⁷ Champions of drug formulary systems have demonstrated cost savings, particularly dramatic in many staff and group-model HMOs⁸ where pharmaceutical manufacturers can be made to compete on price. We need more of the inves-

Figure 4. Hypertension Drugs Horn et al. "Study"—site 4 actual data

Table 1. Summary Data from Horn et al. "Study"—revised with actual data from site no. 4

Hypertension				Arthritis		
Site no.	# drugs	limit.%	office visits	# drugs	limit %	office visits
5	27	62.0%	7.23	18	55.0%	7.69
6	29	59.2%	6.60	21	47.5%	8.48
3	32	54.9%	7.84	15	62.5%	9.05
2	34	52.1%	5.42	17	57.5%	5.36
1	37	47.9%	6.81	23	42.5%	8.93
4	30	57.7%	4.20	17	57.5%	4.90
Total drugs available		71			40	

tigative work displayed by Ralph King in the *Wall Street Journal* regarding last year's sabotage of a report on the bioequivalence of Levoxyl, two generic levothyroxine and the much higher-cost Synthroid.⁹ MCO pharmacists armed with reliable data can successfully apply the managed care model of preferred provider (product) contracting to lower drug costs while maintaining or improving care outcomes. A tremendous injustice would be perpetrated by state legislatures that are persuaded to mandate open formularies based on the seemingly endless hype produced by NPC and its PR firm regarding the Horn reports. This subject should leave no MCO pharmacists as casual observers.

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