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## Statistical Assessment of a Conflict of Interest

In December 1991, the House of Delegates of the American Medical Association unanimously approved a report from its Council on Ethical and Judicial Affairs on the issue of physician ownership of diagnostic facilities. The central tenet of that report is summarized in the following excerpt:

However others may see the profession, physicians are not simply business people with high standards. Physicians are engaged in the special calling of healing, and, in that calling, they are the fiduciaries of their patients. They have different and higher duties than even the most ethical business person. . . . There are some activities involving their patients that physicians should avoid whether or not there is evidence of abuse.

This report is part of a continuing debate within the medical community, government agencies and state and federal legislative bodies on *self-referral*: a physician's referral of patients to an outside facility in which the physician has a financial interest but no professional responsibility. These arrangements are sometimes called *joint ventures*. Self-referral is but one aspect of the growing commercialization of medicine and the larger concern over the increasing cost of health care.

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This reading was prepared by Professor Paul Glasserman based on articles in the *New England Journal of Medicine*, *The New York Times* and *The Wall Street Journal*.

Six months after approving this report, the AMA's House of Delegates reversed itself and adopted instead a weaker resolution declaring self-referral to be ethical provided the patient is informed about the physician's stake in the facility. Proponents of the new policy argued that a ban on joint ventures would, in some areas, limit patient access to health services and would penalize even those physicians who act ethically. The second argument raises the question of whether it is ever possible for a physician to avoid a conflict of interest while maintaining a financial interest in a facility to which he or she refers patients.

For the AMA, and the medical community in general, concerns about self-referral rest on the profession's vision of its role in society; one might argue that the profession also has a pragmatic interest in preserving the good will of its customers. For government agencies (such as the Department of Health and Human Services, which administers Medicare and Medicaid) and for the population at large, the primary concerns are the effect of joint ventures on costs and quality of care.

### The Growth in Self-Referrals

As major health-care insurers, most notably Medicare, have moved to control costs, physicians have found their opportunities for revenue growth through traditional means increasingly limited. For most office visits and routine procedures (such as X-rays and cardiograms), Medicare specifies an allowable fee and then reimburses physicians for 80% of that fee. The fee specified by Medicare may be substantially less than what physicians would otherwise charge. In addition, as a practical matter physicians must often accept the 80% paid by Medicare as full payment: aggressive collection practices are generally incompatible with the patient-doctor relationship most physicians try to foster, and elderly patients unable to pay the 20% "Medigap" may simply change doctors until they find one willing to accept Medicare payments. Physicians cannot disregard these patients, as they make up a large fraction of the customer base — partly because of the aging of the population, but also because older people tend to require more medical attention.

Limitations on fees for standard billable activities have led many physicians in private practice to seek alternative sources of revenue. At the same time, for-profit diagnostic centers and health care services have moved aggressively in soliciting investments from physicians who can refer patients to them. This has led to a growth in joint ventures, which some critics have described as disguised kick-back schemes.

## Justification and Concerns

Defenders of joint ventures argue that they may increase access to important services in underserved areas, especially rural and inner-city areas. (One interpretation of this argument is that facilities will not operate in such areas without special opportunities for profit, in this case arising from self-referrals.) Another argument in favor of joint ventures is that they may improve the quality of services provided to patients, either through greater physician involvement in the facility or by providing physicians with a greater incentive to maintain quality. It has also been suggested that joint ventures may provide needed financing for patients otherwise unable to afford services.

The overriding ethical issue in self-referral is aptly summarized by the following excerpt from an editorial in the *New England Journal of Medicine* (Nov. 1992, pp.1522-1524):

Physicians are trusted to act as medical purchasing agents for their patients. A doctor who thinks there should be no concern about self-referral as long as it is disclosed and the referrals are monitored is analogous to a purchasing agent for a large corporation who discloses to the CEO that he has a vested interest in certain vendors with whom he does business, and who thinks that this disclosure, plus careful surveillance of his purchases by management should assuage the CEO's concerns. Obviously, it would not do so. In fact, the CEO would probably fire the purchasing agent on the spot. Why should physicians want to apply a lower standard of fiduciary responsibility to themselves than is generally accepted in business?

Underlying this view is a widely accepted principle that positions of major responsibility bring with them an obligation to avoid all possible conflicts of interest. This not merely a matter of keeping up appearances. The more fundamental issue is that one's judgement may be subtly — even unconsciously — affected by conflicting interests and that no degree of monitoring can insure against the consequences of such conflicts.

Motivated more by concerns for costs than ethical principles, various government bodies have moved to limit self-referrals. Since 1972, it has been illegal under federal law for physicians to receive kickbacks for referrals of Medicare and Medicaid patients. Thirty-six states have anti-kickback laws that apply as well to privately insured patients. Based on a new interpretation of anti-kickback statutes,

in September 1991 the Department of Health and Human Services issued restrictions on self-referrals for patients covered by Medicare and Medicaid. Congress may move to enact an outright ban on the practice. The Federal Trade Commission, which previously supported self-referrals as enhancing competition, now opposes the practice on the grounds that it limits the referring physician's choices and keeps prices high.

## The Role of Statistics

In light of the concerns of both sides of the debate on self-referrals, it is evidently important to determine the actual impact of the practice. Does self-referral lead to higher costs for services? Does it lead to unnecessary use of services? Have joint ventures increased the availability of services in rural or inner-city areas? Do they provide higher quality service?

These questions and the broader issue of a possible conflict of interest are difficult to answer by looking at individual physicians or facilities. Many medical decisions are subjective and accepted practices leave room for differences of opinion in specific cases. It is thus difficult to conclude that a specific referral by a physician reveals a conflict of interest. Indeed, the influence on a physician's judgement of a financial stake in a facility may be subtle, and in each specific instance a physician may find a sound basis for a self-referral.

The effect of self-referrals is, then, best assessed through an examination of aggregate behavior. Do physicians in joint ventures use special facilities at a higher rate than other physicians, *as a group*? Do these facilities command higher prices *overall*? A careful statistical analysis can address these questions though, of course, it can never determine the motives behind the actions of individual physicians.

In the rest of this reading, we discuss two studies, one in California (Swedlow et al., *NEJM*, Nov.1992, pp.1502-1506) and one in Florida (Mitchell and Sunshine, *NEJM*, Nov.1992, pp.1497-1501). We discuss their procedures, analysis and conclusions.

## The California Study

This study is based on 6581 claims filed with a large insurance company through the California worker's compensation system. Cost and frequency of usage were compared in two groups of physicians: those with a financial interest in the facility to which a patient was

referred (the self-referral group) and those with no such financial interest (the independent-referral group). Three types of high-cost services were studied: psychiatric evaluations, magnetic resonance imaging (MRI) and physical therapy. Self-referrals were identified by matching tax identification numbers of the primary and referral service or by identifying common owners of both entities; commercially available databases listing officers, stockholders and partners of facilities were searched to identify common ownership. If no match was identified, physicians were contacted directly to confirm independent referral.

Differences found between the self-referral and independent referral groups could potentially be attributable to differences in their patient mix. To correct for this, the three types of services were further broken down into specific categories for which costs and usage should be roughly equal in the two groups.

Physical therapy accounts for 56% of all outpatient procedures and 34% of all outpatient costs for the treatment of injured workers in California. Injured workers typically receive a prescription for physical therapy from a physician and are referred to a therapist for treatment. Among the primary specific categories of ailments are back problems, tendonitis, wound or fracture of an arm, and trauma to finger or toes. The two groups of physicians were compared in each of these categories.

In the worker's compensation system, psychiatric services are most often initiated as a result of back problems, minor injuries, unscheduled crises and a category called "other mental disturbances." Fees for specific tests are set by the State of California and are thus the same in both groups; however, there are opportunities for differences in the number of tests administered per case.

Almost all requests for MRI scans follow back problems or strain of an arm or shoulder. In addition to cost and frequency of usage, the study compared the frequency of inappropriate referrals from the two groups. The California worker's compensation system requires precertification for MRI: all requests for scans are referred to a national, independent firm for review. The review determines if the request is appropriate.

Results of the study are summarized in Table 1. For the underlying statistical analysis, we quote from the report:

*Statistical Analysis:* Continuous variables are presented as means  $\pm$ SD and were compared by two-tailed t-tests. The proportion of cases in each group was assessed by the chi-square test. For all analyses, a P value of less than 0.05 was considered to indicate statistical significance.

		Phys. Therapy	Psych. Svcs.	MRI
CASES	Self-Ref.	68%†	155	38%§
	Indep. Ref.	30%	65	28%
	Ratio	2.3	–	1.4
COSTS	Self-Ref.	404±102‡	2,056±1,063‡	976±226
	Indep. Ref.	440±167‡	1,680±578‡	990±170
	Ratio	0.9	1.2	1.0

Table 1: Frequency of use and cost per case in the two groups. †Proportion of cases in which physical therapy was ordered differed significantly ( $P < 0.01$ ) by chi-square test. ‡Mean cost per case differed significantly ( $P < 0.01$ ) by t-test. §Proportion of cases in which MRI scans were found inappropriate differed significantly ( $P < 0.05$ ) by chi-square test.

Table 1 gives the percentage of all injuries in which patients were referred to physical therapy by the two groups of physicians. The percentage in the self-referral group (68%) is significantly higher than in the independent group (30%). A separate analysis (not displayed here) shows that the mix of patient categories in the two groups is not significantly different. The cost per case is lower in the self-referral group, but the increased rate of usage leads to higher costs overall.

For psychiatric services, results in the table indicate that the cost per case is significantly higher in the self-referral group. Since the fee per test is fixed, the difference is attributable to an increased number of tests per case.

Finally, Table 1 shows that the percentage of inappropriate MRI requests is significantly higher (38% vs. 28%) in the self-referral group, though the cost per scan is not significantly different in the two groups.

The study concludes that self-referral does indeed lead to increased costs in all three services, though by different mechanisms. Increased physical therapy costs come from a higher rate of referral; increased psychiatric-evaluation costs come from a higher number of tests per patient; and increased MRI costs come from a higher rate of inappropriate requests for scans.

## The Florida Study

This study looked exclusively at free-standing facilities providing radiation therapy. It analyzed differences in cost and usage, and also examined some of the arguments used to support joint ventures: in-

creased access to services, better quality of care, and increased financing opportunities for patients. The study compared data for Florida, where 44% of free-standing radiation-therapy facilities are joint ventures, with data for the rest of the country, where only 7% are joint ventures.

In the study, a joint venture indicates ownership or investment by a referring physician in the facility providing the service. Since radiation oncologists (doctors specializing in radiation therapy) only treat patients referred to them by other physicians, a facility wholly owned by such specialists was not deemed a joint venture.

The following aspects were considered in the study:

*Access:* Both geographical and economic access were evaluated. Geographical classification of facility locations into metropolitan and non-metropolitan areas was based on census data. Economic access was evaluated by comparing percentages of revenues from high-paying and poorly paying sources. Managed care programs, Blue Cross and commercial insurers were considered high-paying. Medicaid reimbursements averaged between 5 and 10 percent of full charges, Medicare reimbursements approximately 70%. These were classified as poorly paying sources because patients covered by these plans rarely made up the difference.

*Use:* The treatment of cancer through radiation therapy follows standardized programs; thus, a physician cannot increase the level of use by requesting greater treatment for individual patients, only by increasing the number of patients receiving treatment. Usage was compared through a market-area approach; that is, the use of radiation therapy per Medicare beneficiary in Florida and the rest of the country were compared. The incidence of cancer requiring radiation therapy was found to be no different in Florida than in the rest of the country, so no correction was needed for this possible source of bias.

*Costs:* Costs were compared based on Medicare claims and include both the physician's time and the use of laboratory equipment.

*Quality of care:* Two comparisons were made as rough measures of quality: the time spent with the patient by the radiation physicist (in joint ventures and independent facilities) and the overall lethality of cancer (in Florida and the rest of the country).

For comments on the statistical analysis, we quote the report:

*Statistical Analysis:* Percentages of revenue from high-paying sources and physicists' time spent per patient were compared by two-tailed t-tests. Since the sample of radiation therapy facilities represented a large percentage of

	Florida	Rest of U.S.	Excess
Procedures	139	88	58%
Charges submitted	13,290	9,328	42%
Charges allowed	9,572	6,556	46%
Lethality rate	54.4	52.8	3%

Table 2: Number of procedures and charges are per 1000 Medicare enrollees. Submitted and allowed charges are reimbursements requested and paid by Medicare. Lethality rate, reported per 1000 elderly, equals death rate divided by incidence rate.

the total number, we applied the usual finite-population correction factor to adjust the standard errors of these variables. The Medicare data represented the entire population, rather than a sample. In such cases, the usual view of statisticians is that tests of significance are not required, because all differences found are real.

Table 2 compares data for Florida and the rest of the U.S. The results of the study indicate higher costs and rate of use in Florida along with a slightly higher lethality rate.

The study found that none of the joint ventures in Florida is located in an inner-city neighborhood or a rural area. In contrast, one free-standing center that is not a joint venture is located in a rural county and 39 hospital-based facilities are located in inner-city areas. Joint ventures derive 39% of their revenues from high-paying sources compared with 31% for free-standing facilities that are not joint ventures. Hence, the argument that joint ventures increase access is not supported. Moreover, radiation physicists at joint ventures were found to spend 4.78 hours per patient compared with 5.82 hours for other facilities, raising questions about the comparative quality of care.

### Concluding Remarks

The studies summarized here paint a statistical picture of differences in practice between physicians involved in self-referral and those that are not. Of course, neither the data collected in the studies nor its analysis can determine whether any individual has acted ethically or not. Nevertheless, the results of these studies and others like them clearly have important implications for health care policy as dictated both by the government and the medical profession itself.

## Questions

1. How do the methods for comparison differ in the California and Florida studies? How does the difference affect the statistical analysis?
2. How might differences in patient population affect the comparison of self-referrals and independent referrals in the California study? How might population differences affect the comparison in the Florida study?
3. Are the results of the study compelling? Might the observed differences be due to factors not considered?