

The Inappropriate Use of Imaging Studies: A Report of the 2004 Intersociety Conference

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The participants of the 2004 Intersociety Conference met to discuss the growing problem of self-referral. The United States spends more of its gross national product on health care than other countries, especially Japan and those in Western Europe. Imaging accounts for a large and growing portion of those costs. Despite spending so much on health care, the United States ranks relatively low in measures of national health, including such parameters as infant mortality and even life expectancy. Because the federal government must keep health care expenditures to a "sustainable growth rate," increases in use are likely to be accompanied by decreases in reimbursement per case. Thus, conference participants agreed that the real problem is inappropriate use, which may arise from (1) ignorance of what specific imaging studies are needed when, (2) high public expectations for imaging tests, (3) the fear of liability for a missed diagnosis (defensive medicine), and (4) self-referral. The Stark laws have been largely ineffective in preventing self-referral because there are many loopholes, and the laws are inconsistently enforced. Among the many potential solutions are the education of our clinical colleagues on appropriateness criteria; the education of the public on the costs of inappropriate use; tort reform; and working with third-party payers, especially the private insurance industry, to develop vigorous privileging programs, to require precertification for self-referred studies, or to establish differential payments for self-referred and non-self-referred imaging.

Key Words: Self-referral, appropriate use, Stark laws, sustainable growth rate, reimbursement

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The Intersociety Conference was established by the ACR in 1979 to promote collegiality within radiology, foster and encourage communication among national radiologic societies, and make recommendations on areas of concern. The topic of each meeting of the Intersociety Conference is generated by its executive committee. Fifty-three professional radiology societies participate in the Intersociety Conference, including both diagnostic and interventional radiology, radiation oncology, and radiologic physics.

The Intersociety Conference met July 30 through August 1, 2004, in Quebec City, Canada, to discuss the effect self-referral has on the appropriate use of imaging

examinations and image-guided procedures. Eighty-eight members and executive directors participated in the conference.

HIGH COST OF HEALTH CARE

The United States spends more money on health care than any other country in the world. Even when expressed as a fraction of the country's gross national product (GNP), the United States is clearly the most expensive. In 2001, the United States spent 13.9% of its GNP on health care, compared with 8.5% for the European Union and 7.6% for Japan [1,2]. Furthermore, these health care expenditures have continued to rise. Growth in health care spending has continued to rise at more than twice the rate of growth of the GNP, such that it consumed 14.9% of the GNP in 2002 [3]. The annual growth rate for health care costs is 10%, compared with 4% for wages and only 3% for the GNP. Thus, health care costs as a portion of the GNP continue to rise. By 2003, health care expenditures had grown to 15.3% of GNP and are projected to reach 18.4% in 10 years.

These rising costs for health are passed on to consum-

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ers and to employers. In 2001, aggregate private health insurance premiums rose 10.3%, and they rose 10.9% in 2002 [3]. In the global economy in which we live, American businesses are in direct competition with foreign manufacturers and service providers. High costs for health care put U.S. companies at a competitive disadvantage. Clearly, we cannot continue this growth rate.

The Balanced Budget Act of 1997 requires a target for the annual rate of growth in spending [4]. This “sustainable growth rate” became a way to control Medicare spending. The sustainable growth rate is determined by several factors, but among them are the number of people enrolled in Medicare and the per capita gross domestic product adjusted for inflation. Thus, increases in health care expenditures must be held to about 2% per year. Because the total amount spent on health care is a function of both the payment per case and the number of cases, they are interdependent. If total costs are to remain stable, any increase in use must be accompanied by a decrease in payment per case:

$$\text{number of cases} \times \text{cost per case} = \text{total cost.}$$

The federal government regulates this through the conversion factor used to calculate Medicare payments. This is a particularly important factor, because private payers often take their cue from the Medicare fee schedule.

Despite these enormous expenditures for health care, the United States does not have an enviable record of health statistics. Among the 192 World Health Organization member states, the United States ranks 32nd in infant mortality and 29th in life expectancy [5.] The United States is especially weak in case coordination, medical errors, overall physician ratings, and answering questions from patients.

INAPPROPRIATE USE

Inappropriate imaging use adds to health care costs without improving the quality of health care. According to Fisher *et al.* [6,7], approximately one-third of health care spending is duplicative, unhelpful, or makes patients worse. Not only do these unnecessary imaging studies seldom reveal the cause of a patient’s complaint, but they may reveal abnormalities that do not affect health but require further imaging or interventional procedures to clarify.

Causes of Inappropriate Use

The inappropriate use of imaging tests arises from several causes [8]. Many practicing physicians have not been able to keep up with current indications for imaging tests. Busy with developments in their own fields, these physicians are not aware of changing practice with regard

to imaging. Common abuses include the frequent use of abdominal computed tomography (CT) examinations for abdominal pain, excretory urography for a suspected renal mass, and any imaging for chronic back pain. Physicians responsible for patients with a broad range of potential abnormalities, such as family practitioners or other primary care physicians, may be most prone to order inappropriate imaging tests because of a lack of knowledge [9].

The success of imaging, especially CT and magnetic resonance imaging (MRI), at detecting and often diagnosing a wide range of lesions has led the public to expect such examinations when they encounter the health system. The positive attributes of these cross-sectional imaging modalities are widely reported in the lay press, and patients demand access to them.

The success of our health care system has raised the public’s expectations to the point that an accurate diagnosis and complete recovery are considered the standard of care. This places physicians in the difficult position of making an accurate diagnosis on every patient and missing no significant pathology. Not infrequently, this includes satisfying patients’ expectations for imaging studies. Thus, it is not surprising that referring physicians order imaging tests, even when the indications seem minimal. Fear of liability further contributes to this overuse of imaging tests. An unnecessary examination, even when negative, often reassures a patient. Although the health care costs may be increased, there may be no negative consequence for the ordering physician. On the other hand, failure to order an imaging study risks a malpractice suit should an abnormality that might have been detected by the study be subsequently discovered.

The fourth and most egregious cause of inappropriate use arises when an ordering physician has a financial interest in the entity performing the examination. This “self-referral” is increasingly seen when physicians own imaging equipment or when they refer patients to imaging centers in which they hold equity positions [10]. When a physician interviews and/or examines a patient, he or she may decide that an imaging test is needed to clarify or confirm the diagnosis. Typically, this physician refers the patient to radiology for such testing. However, if the physician elects to perform the examination or procedure rather than referring the patient elsewhere, he or she is practicing self-referral.

The formal definition of self-referral originates in the federal Stark laws, named for their progenitor, Representative Fortney “Pete” Stark of California. Stark I, enacted in 1989, was limited to clinical laboratory services. In 1993, Stark II extended this to other designated health services, including radiology. These laws prohibit a physician from referring a patient to an entity for “designated health services” for which Medicare might otherwise pay

if the physician or an immediate family member has a financial interest in the entity [11]. A financial relationship is defined as ownership or an investment interest in an entity or a compensation arrangement with an entity such as the leasing of space or equipment.

This definition of self-referral would also apply to interventional radiologists when they refer patients to other members of their own groups for imaging procedures. How do we keep interventional radiologists from falling victim to this same temptation? Perhaps the best approach is for primary physicians to make the decision after consulting with specialists. A physician practicing self-referral may have the imaging equipment in his or her office or may be referring patients to an imaging center in which he or she has an investment interest. Beginning with the research by Childs and Hunter [9] in 1972, policy makers have known that a financial interest could be enough to influence a physician's referrals. Not only did nonradiologists having an economic interest in radiologic equipment make heavier use of diagnostic examinations, their patients also experienced relatively larger exposures to radiation than patients of other physicians [9]. In a groundbreaking article in 1990, Hillman and colleagues [12] demonstrated that self-referral results in ordering more imaging tests than when a physician does not stand to gain financially from the performance of an examination. Use by self-referring physicians was 4 to 4.5 times as great, depending on the patient's health condition, compared with that of physicians who referred their patients to radiologists for imaging. Interestingly, the charges for these self-referral examinations were even higher: 4.4 to 7.5 times as high. This same trend was confirmed in a 1992 follow-up study on a broader range of health conditions, including the full range of imaging [13]. Higher rates of procedures by self-referring physicians were reported as early as 1965 [9]. In 1978, Radecki and Steele [14] reported that nonradiologists with imaging facilities on site had 1.2 to 1.7 times higher use rates than those without such facilities. Kouri *et al.* [11] reported that when nonradiologists perform their own imaging, they are 1.7 to 7.7 times more likely to order imaging studies than physicians who do not self-refer. Furthermore, deficiencies such as image quality or patient safety were up to 10 times as common among nonradiologists as among radiologists. Studies on a variety of population subsets have demonstrated similarly increased use arising from self-referral [15,16].

The amount of self-referral has increased significantly in the past 20 to 30 years. Although there was a 3.9% decrease in the noninvasive diagnostic imaging use rate per 100,000 Medicare fee-for-service beneficiaries by radiologists between 1993 and 1999, there was a 25.2% increase in the number of noninvasive diagnostic examinations by nonradiologists in the same period [15]. Ul-

trasound machines, which generate no ionizing radiation, provide a "safe" modality for physicians not trained in radiation safety to place in their private offices. More recently, CT and MRI scanners have proliferated dramatically because of the wealth of diagnostic information they reveal. The relatively high technical fees make them attractive for imaging center investments. Furthermore, they may be exempt from regulation such as certificate-of-need (CON) laws when not placed in a hospital. Because CON laws are state specific, the ability of physicians to own and operate imaging centers, especially those involving expensive technology such as CT and MRI scanners, varies greatly from state to state [17].

Proponents of these self-referral arrangements, especially when an imaging study is performed in a physician's office, argue that it is more convenient for patients. An appointment is not needed, and the patient does not have to drive to another location. They further argue that because physicians are familiar with their patients, they are well equipped to correlate the imaging findings with the clinical concerns [18]. Certainly, these arguments are valid, and if an examination is performed with the same skill, safety, and rate of use, the argument against self-referral would be muted.

OTHERS CONCERNED ABOUT SELF-REFERRAL

The inappropriate use of imaging services affects all segments of our population. The increased costs to consumers of these unnecessary studies add substantially to the cost of health care directly and also increase the frequency of incidental findings. These unexpected abnormalities must be explored, leading to more tests and procedures, with their associated costs, complications, and additional patient anxiety. The morbidity and mortality from chasing incidental findings must be added to the increased costs of the additional tests and procedures themselves. When imaging uses ionizing radiation, especially CT, the adverse effects of this irradiation must be included [9, 19-21].

Equipment manufacturers and drug companies might welcome the increased sales of their products to physicians practicing self-referral, with its associated increased use. However, those industries should also consider the increased cost for health care of their employees associated with these unnecessary procedures. As more scrutiny is applied to the increasing use of imaging by government, industry, health advocacy groups, and insurance companies, equipment manufacturers should be joining forces to ensure the most appropriate use of their products. By taking the high road, these companies will gain sales by demonstrating the ever increasing utility of their products in the hands of those best able to use them

appropriately. Some of these companies have joined with radiologists in the National Coalition for Quality Diagnostic Imaging Services to promote the more appropriate use of imaging to policy makers [22].

The insurance industry needs to carefully monitor the increasing use of imaging, because they are often caught in the middle in the health care financing process. Increases in imaging use may cause expenditures to exceed the payment received for the health policy. Insurers had little interest in trying to contain the cost of diagnostic imaging when it was less than 5% of their medical payments. However, imaging is one of the fastest growing health care services and now accounts for 10% to 15% of health care payments [23]. For some imaging studies, much of this escalation is due to self-referral.

POTENTIAL SOLUTIONS

The many possible remedies to the problem of self-referred imaging may be considered in three categories: legislation, insurance regulation, and tort reform.

Legislation

The federal Stark law was first passed in 1989 and implemented in 1992 and 2004 to address kickbacks in medical reimbursements. In addition, 43 states and the District of Columbia have some type of medical and/or dental anti-self-referral laws. The process of regulatory implementation has been slow and, more important, plagued by exceptions to the law. One solution to reduce inappropriate imaging use is to close the in-office ancillary services loophole. These services are those furnished by a referring physician, another physician in the same group practice, or personally by individuals directly supervised by the physician in the group practice. There are a number of other loopholes in the Stark law that include payment for non-Medicare patients, referral to other physicians in the same group, prepaid plans and employment relationships, health care delivered in rural settings, the lease of office space and equipment, and positron emission tomography (PET) scans. Although all of these exceptions may be difficult to change, the in-office loophole is arguably the greatest contributor to the rapid increase in clinicians' ownership of lucrative imaging equipment.

Other actions that could be considered include higher copayments for imaging performed at a self-referred facility, lower reimbursement for self-referred imaging, and provider credentialing linked to training background.

Alternatively, the federal government could improve quality by mandating the development of informatics to improve efficiency and quality [24]. The government could also expand the updated Mammography Quality

Standards Act that accredits and inspects sites and providers to include other imaging, particularly CT, MRI, and PET. The ACR voluntary accreditation programs for CT and MRI could serve as templates for government mandates [25].

Although unpalatable for many Americans, universal health care coverage would decrease administrative costs and increase access for the more than 40 million people currently without health care insurance. The single-payer system would provide basic coverage, and competitive additional insurance coverage could be purchased.

Linking State Licensure and Training

Although the federal government plays a huge and growing role in medical care reimbursement, state governments control the licensure and certification of health care providers with little federal government oversight. The process of granting a state license has not changed in decades despite the evolution of complex specialty and subspecialty medical practice. Many states grant general licenses to practice medicine that are not linked to a physician's medical training beyond the internship. Therefore, radiologists who have completed an internship and pass the board examination are able to practice virtually any form of medicine outside of a hospital setting. Hospitals have long had more oversight of what services physicians may provide. Many committees review physicians' credentials and performance when granting privileges to practice specific types of care in a hospital. This self-governance of medical practice is lacking or more limited in clinics and physicians' offices.

Health care quality and safety arguments could be made both to policy makers and to insurers to restrict the practice of imaging to those with appropriate training. There are compelling arguments for radiation protection for patients that is a large part of radiology training, unlike all other specialty training programs. Further, many clinicians without subspecialty training may lack knowledge about appropriate imaging. We may improve the quality of care by partnering with them to develop appropriateness guidelines [26], though conformity to practice guidelines may increase the use of services [27].

Thirty-six states and the District of Columbia have CON laws that regulate health care services and equipment purchases. If the CON laws were expanded to include CT, MRI, and PET, they would limit new equipment purchases.

Insurance Regulation

In a series of articles published in *JACR*, Drs. Levin and Rao discussed insurance accreditation and inspection programs for imaging facilities, precertification for self-referred imaging, the auditing of records of physicians who self-refer, and differential payment for self-referred

versus non-self-referred imaging [8, 10, 28-31]. Insurer privileging programs may also reduce inappropriate use by restricting payment to providers with appropriate training.

In many regions and states, large manufacturers and employers have formed groups to decrease their costs of employee health care insurance premiums. These groups have both the political and economic power to pressure insurers, state governments, and local health care systems to reign in costs if the health care system is willing to take steps that will not be popular with those who are benefiting from self-referral practices. One unusual strategy was announced in May 2004 by the California Public Employees' Retirement System, one of the nation's largest health care purchasers, which excluded the most expensive 38 hospitals from its network of approved health care sites for those with its insurance plans [32].

Tort Reform

Defensive medicine, the practice of ordering marginally indicated studies out of fear of malpractice litigation, adds to the cost of our health care system [24,33,34]. Many states are currently facing crises in the cost of medical malpractice insurance [35]. These crises result in more expensive medical care and the potential disruption of health services. We need to look at states not facing these crises and perhaps present those as models for other troubled states. Although there is a cap on malpractice awards that may account for the low malpractice costs, many believe it is more the use of a medical review panel that reduces the number of unwarranted claims. Both federal and state legislation could be used to address the rising cost of malpractice litigation.

BARRIERS

Although many potential solutions exist to decrease inappropriate imaging, there are numerous barriers to any attempt to change the current health care system. All stakeholders will defend any threat to their financial status with vigor. Further, any strategy that is undertaken is likely to have unpredicted effects that will apply to both nonradiologists and radiologists alike. Health care is increasingly complex, and any solution will necessarily be multifaceted. With our limited resources, we must partner with the most promising and willing stakeholders. But there are also barriers from within the radiology profession. We should arrive at a clear understanding of how proposed solutions will affect our profession.

The Legislative Process Is Slow and Fraught with Loopholes

The 2004 presidential election elicited promises from both major candidates to slow the rising costs of health

care insurance, but the discussion was not deep enough to provide real solutions. We spend more and more money on health care for fewer and fewer Americans [24]. Radiologists are rarely involved in insurance and government policy making, yet it is critical that our values and ideas are heard. Reimbursement for new technology will be decided by policy makers, with or without our input.

Stark II took effect in July 2004, 10 years after it was legislated. It was vigorously challenged and resulted in both slow implementation and weaker legislation. The in-office ancillary services loophole was retained. The American Medical Association and many health care stakeholders are likely to continue to oppose any efforts to limit revenue to providers. Similarly, any attempt to change the existing very general licensure that states provide would be strongly fought.

If medical insurers simply pass on these rising costs to patients and their employers by raising premiums and copays, they may have little incentive to address the issue of the cost of inappropriate imaging. One exception may be Highmark Blue Shield, which recently initiated aggressive efforts to control self-referral in outpatient imaging centers. Another may be those insurers that also act as managed care organizations. Kaiser Permanente, the oldest health maintenance organization, might serve as a potential model for the creation of quality health care at less cost.

To be successful, the radiology community will need to address these issues on many levels, from the education of health care consumers, payers, and health care system administrators to increased regulation by the government and the insurance industry. To use our own limited resources effectively, we may need to focus on the most important areas of inappropriate use that affect quality of care and inefficiency of health care resource use. After cardiology imaging tests, the fastest growing imaging studies are CT, MRI, and PET. Not coincidentally, these three modalities yield the greatest profit from technical fee reimbursements. The ACR is committed to the long-term educational efforts needed to succeed in building consensus on the issues both within the radiology profession and beyond.

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