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**Abbreviation:**

URL = uniform resource locator

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# Self-referred Whole-Body CT Imaging: Current Implications for Health Care Consumers<sup>1</sup>

**PURPOSE:** To conduct an empirical analysis of self-referred whole-body computed tomography (CT) and develop a profile of the geographic and demographic distribution of centers, types of services and modalities, costs, and procedures for reporting results.

**MATERIALS AND METHODS:** An analysis was conducted of Web sites for imaging centers accepting self-referred patients identified by two widely used Internet search engines with large indexes. These Web sites were analyzed for geographic location, type of screening center, services, costs, and procedures for managing imaging results. Demographic data were extrapolated for analysis on the basis of center location. Descriptive statistics, such as frequencies, means, SDs, ranges, and CIs, were generated to describe the characteristics of the samples. Data were compared with national norms by using a distribution-free method for calculating a 95% CI ( $P < .05$ ) for the median.

**RESULTS:** Eighty-eight centers identified with the search methods were widely distributed across the United States, with a concentration on both coasts. Demographic analysis further situated them in areas of the country characterized by a population that consisted largely of European Americans ( $P < .05$ ) and individuals of higher education ( $P < .05$ ) and socioeconomic status ( $P < .05$ ). Forty-seven centers offered whole-body screening; heart and lung examinations were most frequently offered. Procedures for reporting results were highly variable.

**CONCLUSION:** The geographic distribution of the centers suggests target populations of educated health-conscious consumers who can assume high out-of-pocket costs. Guidelines developed from within the profession and further research are needed to ensure that benefits of these services outweigh risks to individuals and the health care system.

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The past decade of direct-to-consumer marketing of health products, prescription pharmaceuticals, and surgical procedures has opened the door to personalized and virtually customized disease management. As part of this emerging era of self-directed medical care, since the late 1990s consumers have been able to refer themselves for imaging examinations—primarily computed tomography (CT)—without physician input or referral. A whole-body CT examination typically includes a noninvasive evaluation of the coronary arteries for calcification and an evaluation of the lungs, abdomen, and pelvis for cancer. It commonly delivers 0.2–2.0 rad (2–20 mGy) of radiation, depending on the procedure and patient's body (1).

Proponents of early screening and self-referral (1,2) view the risks as relatively unimportant compared with the potential benefits of early detection, individual empowerment to pursue health care choices, convenience, and direct radiologist-patient contact. Parallel concerns, however, exist over issues such as radiation exposure, risks associated with any medical procedure that has not been empirically evaluated for effectiveness in prolonging life or reducing morbidity, hidden medical and psychologic consequences of false-positive results, and risks associated with results that are abnormal but not clinically meaningful ([www.fda.gov/cdrh/ct/screening.html](http://www.fda.gov/cdrh/ct/screening.html); 3–13). In October 2001, for example, the Pennsylvania

State Department of Environmental Protection ordered a CT screening center to cease providing services to patients without physician referral because it violated a registration provision that limits radiation exposure to patients in screening centers (14). The registration provision requires Department of Environmental Protection review of safeguards taken by the facility and alternatives to screening.

The distinguishing feature of American medicine in the 20th century has been technologic innovation. In our society, which equates better technology with better care (11) and believes that more information is necessarily beneficial, the potential profitability for independent screening has piqued the interest of entrepreneurial physicians—an interest that is expected to yield a 25% annual increase in revenues over the next several years (15). These projections are in sharp contrast, however, with the ongoing debate about the value and legitimacy of self-referred imaging that has clearly divided the medical community. Thus, the purpose of our study was to conduct an empirical analysis of self-referred whole-body CT imaging and develop an initial profile of the geographic and demographic distribution of centers, types of services and modalities, costs, and procedures for reporting results.

## MATERIALS AND METHODS

### Internet Search

Internet Web sites for radiologic screening centers accepting self-referred patients were identified by using Yahoo and Google search engines. These search engines were selected for their wide use and large indexes (16,17). The searches used five keywords—"full body scan," "total body scan," "whole body scan," "preventive imaging," and "radiological screening"—all entered without Boolean operators or quotation marks.

### Site and Demographic Variables

Geographic location, type of screening site, services provided, imaging modalities used, costs, and procedures for handling imaging results were characterized on the basis of the information directly available from the Web sites. Each center with a distinct location was separately analyzed, taking into consideration that companies with a single Web site may own or serve multiple centers. Content analysis (18) was performed by one of the authors (E.F.) and reviewed by two addi-

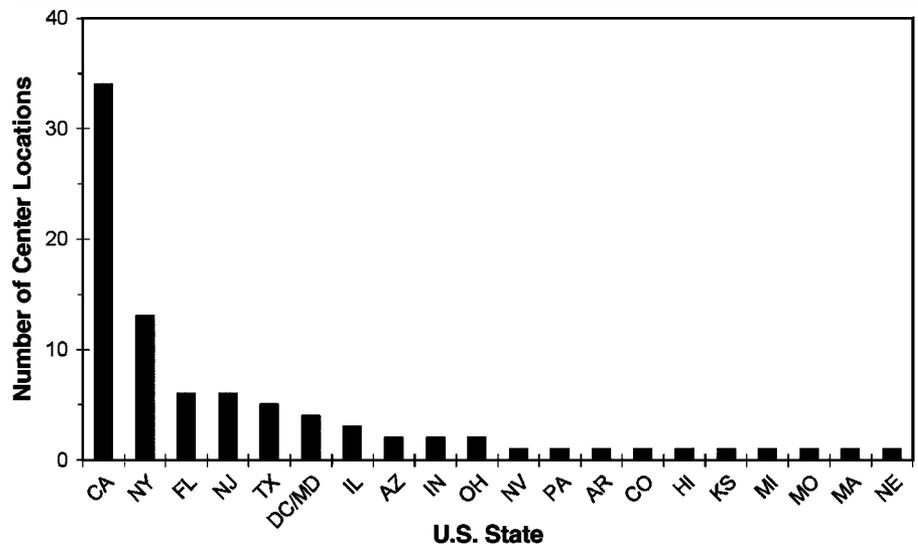


Figure 1. Geographic distribution of radiologic screening centers in the United States.

tional authors (J.I., S.W.A.). Any issues were resolved by consensus.

Demographic characteristics of the centers were extrapolated from geographic location with reference to 1990 U.S. Census data available at the time of analysis. Census Tract Street Locator and the Topologically Integrated Geographic Encoding and Referencing system were used to obtain the census tract number for each center location. Census Tract Street Locator and 1990 Decennial Census Lookup were then used to find population size and composition, educational attainment (for persons 18 years and older), median household income, per capita income, and percent below poverty level for each location.

### Statistical Analysis

Descriptive statistics (ie, frequencies, means, SDs, ranges) were generated to describe the characteristics of the samples (19). Data were compared with national norms by using a distribution-free method for finding a 95% CI for the median (19). If the CIs did not include the national norm, we concluded that our sample was significantly different ( $P < .05$ ) from the national population.

## RESULTS

### Internet Search

The keywords returned uniform resource locators (URLs) numbering from several hundred to several thousand. Of the first 200 URLs for each search category, all U.S. companies (88 individual centers in distinct locations) with home

TABLE 1  
Types of Radiologic Screening Centers

Type of Radiologic Screening Center	No. of Centers
Diagnostic radiology centers	43 (49)
Comprehensive screening centers	12 (14)
Exclusively radiologic screening	33 (37)
Total	88 (100)

Note.—Numbers in parentheses are percentages.

pages and internal links that specifically advertised whole-body imaging for the purpose of health screening of self-referred patients were retained for analysis. URLs of centers located outside the United States, companies that produced imaging software or scanner equipment, and centers that offered mammograms but not other radiologic screening tests were excluded. No known relevant or retainable results appeared above the 200-URL level in any of the searches.

### Geographic and Demographic Characteristics

Centers were found in 21 states or districts across the United States (Fig 1), with the largest concentrations in California ( $n = 30$ , 34%) (especially in the southern regions of the state) and New York ( $n = 13$ , 15%). As shown in Table 1, 43 (49%) of the 88 centers studied were diagnostic radiology screening centers that concurrently offered conventional physician-ordered diagnostic services.

**TABLE 2**  
Distribution of Radiologic Screening Centers in the United States

Demographic	Radiologic Screening Centers (95% CI)		National Average	P Value
	Lower Range	Upper Range		
<b>Population composition</b>				
European American	78.10	86.84	73.60	<.05
African American	1.51	2.81	11.06	<.05
American Indian	0	0.23	0.72	<.05
Asian American	2.58	5.11	2.68	
Hispanic	4.36	6.80	8.25	<.05
Other	0.85	2.11	3.62	<.05
<b>Education</b>				
<9th grade	2.58	5.13	10.39	<.05
9th–12th grade	6.26	10.45	14.38	<.05
High school graduate	17.52	24.20	29.99	<.05
Some college	21.45	25.18	18.74	<.05
Associate degree	5.41	6.51	6.16	
Bachelor degree	18.21	26.09	13.11	<.05
Professional or graduate degree	7.71	15.47	7.22	<.05
<b>Income level</b>				
Below poverty line	5.7	7.9	13.1	<.05
Per capita income (\$)	17,708	25,836	14,420	<.05
Median household income (\$)	36,827	43,785	30,056	<.05

Note.—Data are percentages, unless otherwise indicated.

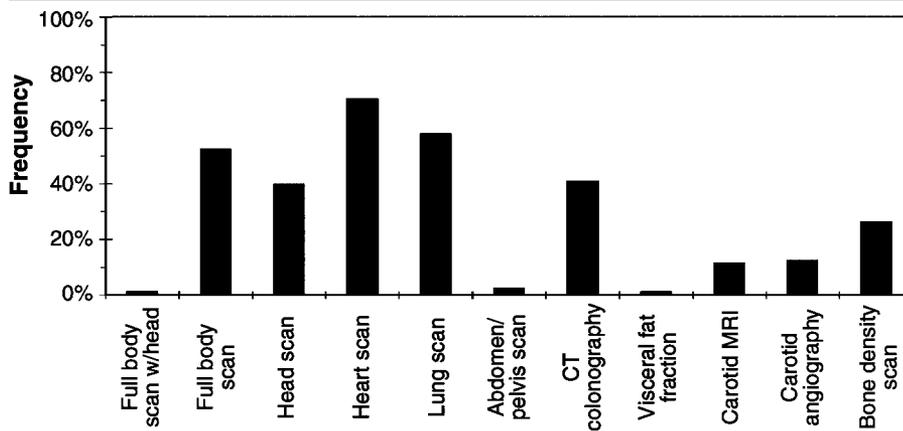


Figure 2. Services offered by radiologic screening centers.

Another 12 (14%) offered a vast array of screening tests, including nonradiologic tests. The other 33 (37%) were exclusive to the radiologic screening market.

Table 2 shows the demographic data of the radiologic screening centers corresponding to their geographic locations. Because the distributions of data from the screening centers were highly skewed, traditional hypothesis tests could not be used. We calculated CIs for each comparison (19) with a distribution-free method appropriate for such data and compared these with national averages. We found that the centers were located in areas with a significantly higher percentage of European Americans and a lower percentage of African Americans and other minorities (except Asian Americans) than the na-

tional average ( $P < .05$ ). Areas housing screening centers also included a significantly higher percentage of people with advanced degrees than the national average ( $P < .05$ ) and a lower percentage of people with less than a ninth grade level of education ( $P < .05$ ).

In the census tracts where screening centers were located, the percentage of the population below the federally defined poverty level was significantly lower than the national average ( $P < .05$ ), and per capita median income and average median household income were significantly greater ( $P < .05$ ). During the revision of this report, we reproduced the search methods of the original work and examined the state of the industry exactly 1 year later. We discovered 48 new

centers and similar characteristics, reflecting a growth of 55% to our database alone during a 12-month period.

### Screening Services

Figure 2 shows the varied radiologic screening services offered at the centers. Most offered multiple service options. Although 47 (53%) of the 88 centers offered whole-body examinations, only one center routinely offered whole-body examinations that include the head. Heart and lung examinations were the most numerous, with 62 (70%) of the centers providing heart examinations and 51 (58%) providing lung examinations. Head examinations were offered in 35 (40%) of the centers, and CT colonography was offered in 36 (41%).

When looking solely at centers that offered the neck-to-pelvis whole-body examination, 45 (51%) were exclusive to the self-referred screening market. Only 26 (30%) of the centers that offered whole-body examinations were standard radiology offices or departments.

A relatively large number of centers offered brain examinations with both CT and magnetic resonance imaging, although virtually all of these centers provided this service as an additional procedure at a discounted price after and in conjunction with the purchase of another type of screening. These services were focused on imaging for strokes and brain tumors.

### Screening Costs and Modalities

Costs for the whole-body examination in our database ranged from \$795 to \$995. A whole-body examination that included the head averaged \$850. A whole-body examination that included a bone-density test averaged \$1,215. Forty-two (47%) of the centers that offered whole-body examinations used electron-beam CT, while another 25 (28%) used helical CT (Fig 3). The remaining centers used multisection CT, fast CT, or an unspecified type of CT.

### Reporting

Of the 88 centers studied, 57 (65%) described their procedures for handling patient results. These procedures varied greatly. As shown in Figure 4, direct hard-copy mailing was the sole method of reporting results to the patient in 25 (44%) of the 57 radiologic screening centers that explained their patient notification procedures; 10 of these 25 centers offered the heart examination, which generates a

calcium score from electron-beam CT that approximates the extent of coronary atherosclerosis. Nineteen (33%) of the 57 centers provided results during a consultation between a radiologist and the patient, and a report was mailed to the patient afterward. After the initial consultation, one center sent a report directly to a physician of the patient's choice. Nine centers (16%) offered physician consultation, a written report of the examination results, and a CD-ROM of the images generated. One center offered a postexamination phone consultation, followed by a mailed report.

## DISCUSSION

The results of this work offer a profile of whole-body imaging centers accepting self-referred patients through an analysis of the information made available to the consumer on the Internet. Taking into consideration that our results are valid only for the 88 centers with searchable Web sites that matched the query terms we used, we found that these centers are distributed widely across the United States with a concentration on the coasts. Further demographic analysis of the location of these centers places them in areas of the country characterized by a population that is highly educated and of relatively high socioeconomic status. In the 2001 analysis time frame of the study, a majority of centers used electron-beam CT or helical CT; we note that sales of helical CT scanners are rising faster than sales of electron-beam CT scanners today. Whole-body, heart, and lung examinations are the most common services offered.

Communication about scope, effectiveness, and convenience is key to the success of any health care product marketed directly to consumers, and an important limitation of this research is its exclusive focus on information available on the Internet. While Internet-based information may be readily available to many prospective consumers of self-referred imaging, analysis of the full range of information sources and advertising is clearly needed for continued understanding of the industry's reach and effect on individuals and society. This includes, for example, examination of the content of and expenditures on newspaper and radio advertising, the factors that motivate consumers to respond to the product marketed, and the opportunity for screening self-referral overall.

Results of other studies of health care

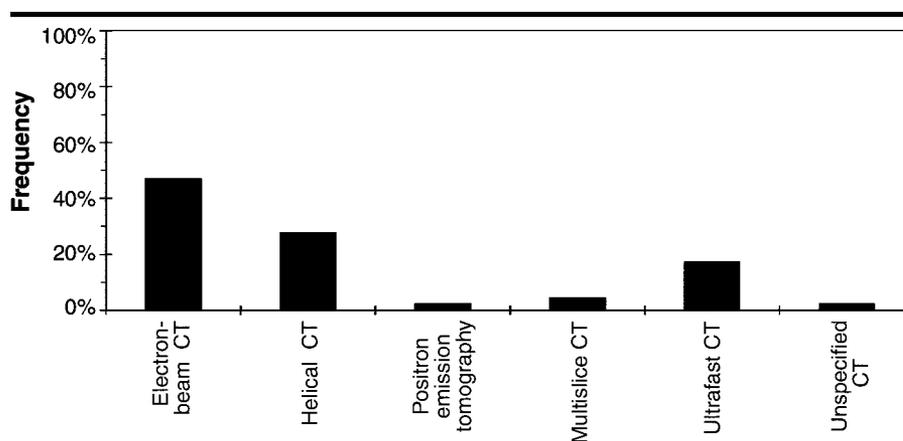


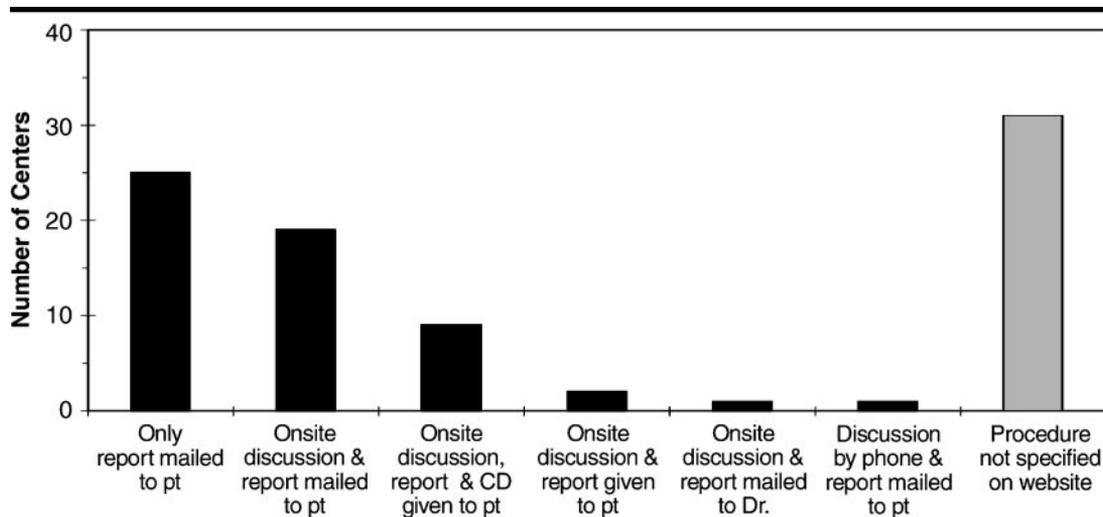
Figure 3. Imaging modalities used for whole-body CT examination.

products have shown that direct-to-consumer advertising for medical services often emphasizes fears that individuals harbor about certain diseases. These advertisements have also been shown to be limited in both completeness and quality and, by urging dialogue with a physician, imply that patients may be able to negotiate treatments or procedures they are not currently receiving (20–24). In fact, the United States is the only industrialized country in which direct-to-consumer marketing of prescription pharmaceuticals is legally practiced (21). (The U.S. Food and Drug Administration first issued a voluntary moratorium on direct-to-consumer marketing in 1983 and lifted the moratorium in 1985, making ads subject to existing rules for all drug labeling. In 1999, the U.S. Food and Drug Administration issued the current guidelines for direct-to-consumer broadcast advertising, including requirements for the communication of risk information and referral to other sources for information in print, on the Internet, or by telephone [21,25–27].) Most recently, the National Health Council (29) published a report in which it was concluded that the benefits of direct-to-consumer advertising of drugs outweigh the risks, as long as the advertising is in compliance with U.S. Food and Drug Administration guidelines and regulations. The report endorses direct-to-consumer advertising as a way of raising consumer awareness, enabling informed patient-physician dialogue (30), and improving compliance with treatment regimens. Results of other studies, however, have highlighted the need for careful balance when advertising is used simultaneously as an educational tool designed to benefit the consumer and as a marketing tool that is

designed to create a favorable attitude toward a company and its products (31).

Our analysis of industry Web sites provides a portrait of the development of for-profit radiologic imaging centers, an industry that is characterized by rapid growth. The phenomenon of self-referral for imaging is part of a broader trend in health care and can be understood only against this background. Specifically, the emergence of independent imaging centers is consistent with increasing demand for medical information and greater control over individual health. The imaging industry describes the benefits of screening with a similar framework, highlighting a shift in the locus of decision making from the physician to the patient, expanded patient autonomy and individual freedom to determine care, the possibility of a life-saving finding, and scheduling and payment convenience.

Ideally, population-based screening and screening of asymptomatic individuals should be tested in a controlled setting prior to broad adaptation. While there are practical difficulties in conducting rigorous randomized clinical trials, foregoing this step may jeopardize future research, place the patient at risk for unexpected health consequences due to invasive follow-up, and lead to unwarranted health care expenditures well beyond the out-of-pocket expense initially incurred. To date, professional organizations such as the American College of Radiology and the American Heart Association have not endorsed this screening technology, and third-party payment is not available. Additional risks are created by the marketing techniques, including discount pricing, with little discussion of the inherent limitations of the screening modalities and the expected



**Figure 4.** Procedures for reporting screening results. Gray bar shows the number of centers not identifying procedures for reporting results on their Web sites.

occurrence of false-positive results (3,5,6,30,32). Of equal and continued concern is the diagnosis of clinically uncertain or unimportant findings that may require elaborate follow-up or the diagnosis of disease for which therapy is not known to be effective. Similar issues have rekindled the debate about the medical benefit and cost effectiveness of mammography screening (33), although selective mammography and cardiac scoring in at-risk patients must clearly be distinguished from screening of the general population. Finally, a substantial social concern is the conflict of interest experienced by physicians who serve simultaneously as company stockholder and health care provider (7,8,12,13,34–39).

This is a critical juncture in the development of a new form of preventive health care. We are witnessing the development of for-profit imaging centers using powerful radiologic techniques, with potential patients purchasing services after receiving information from advertisements, Web sites, or word of mouth. The history of new medical technologies in the United States is distinguished by an intense technologic imperative (40–42); once new services become routine, it is exceptionally difficult to interrupt established practice to conduct a comprehensive evaluation. Given the broad geographic distribution and rapid growth of screening centers and the high penetration of print and broadcast media advertisements, this technology may become well established in the public mind in advance of careful research.

We believe that the time is ripe for intensive investigation that will culmi-

nate in clinical guidelines. In particular, protocols that will establish criteria for practitioners to use when accepting self-referred patients (43)—especially for repeat examinations—and more stringent guidelines for direct-to-consumer advertising (44) are urgently needed. In addition, well-designed, longitudinal, population-based research addressing the safety and efficacy of this approach to diagnostic screening and studies addressing the factors that fuel consumer motivation to self-refer must be conducted. Finally, although enhanced consumer choice may be the primary justification for self-referral, careful outcomes analysis of the downstream costs to the health care system must be initiated. Does this practice reduce the burden of disease for those screened? If so, could we justify withholding self-referred imaging from the population as a whole?

Diagnostic screening technologies offer the promise of early detection and improved survival. Experience shows, however, that achieving this promise may create daunting health policy challenges, at least until reliable information about the safety and efficacy of self-referral imaging centers is gathered. Professional associations must create clinical protocols to guide practice under conditions of uncertainty. Appropriate governmental oversight will ultimately improve the quality of information and education provided to consumers and patients, allowing the goals of empowerment and informed choice to be truly met.

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