One morning last spring, Thomas A. Conley, RRPT, CHP, got an early-morning surprise when reading the newspaper: “There was a huge color four-page ad for screening all over Kansas. That was the first I’d heard of it.” As the Director of the Radiation and Asbestos Control Section of the Kansas Department of Health and Environment, he is supposed to know about all the CT scanning operations in his state.

What made the ad especially surprising, he said, is that it promoted a mobile CT screening operation that does not employ on-site physicians.

“In Kansas, screening is illegal,” Mr. Conley explained. “The regulations basically say that any human exposure has to be specifically and individually ordered by a physician after an examination.” As elsewhere, mammography is exempted from the Kansas screening ban.

Mr. Conley ordered an inspection of the mobile screening operation. “People would call in and schedule it and then they’d have a doctor in Florida electronically sign an order that they faxed to the truck that the scanner was on.”

The scanning operation was run by technicians. “They electronically sent the images back to Florida to be read by their radiologist and then they would mail a report,” he said.

What’s more, the mobile scanner would not accept customers with symptoms or other indications suggesting disease, a position diametrically opposite to that of the Kansas rules that say individuals should be exposed to CT radiation only when there is reason to suspect something is awry.

Last August, Kansas regulators and CATScan 2000, the company running the mobile screening centers, signed a consent agreement. CATScan 2000 paid a $5,000 fine and rolled out of Kansas. The company still operates six mobile CT scanners in 14 states. Radiation control officials also sent notice to CT scanner operators around the state that (continued on page 13)

Whole-Body CT

have toured the site and they say, ‘I’ve looked at this and I don’t think this is of value.’

It’ll be better than if they just say ‘No,’ but they have very little knowledge. I think we still need to remember that at least from the point of view of the American College of Radiology, we don’t recommend these examinations.”

The impact of screening CT on patient-physician relationship bears some similarity to issues relating to alternative or complementary medicine. Whether or not whole-body CT screening is recommended or accepted by physicians, patients are aware of the test and some are undergoing it.

Increasingly the question for physicians is not whether CT screening is good or bad, but how to counsel curious patients, and then support and care for those patients who get screened… only to be given results that raise questions and fears.
Self-Referral
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screening is not an approved use in Kansas.

"It was a complete administrative misunderstanding," says CATScan 2000 CEO Gina Johnson. "Kansas has a requirement of a physical examination by a doctor before a preventive CT scan can be performed; and our protocol was not set up in such a way that we could make that happen in a cost-effective manner."

Despite the Kansas incident, and the skeptical view of leading medical groups, Ms. Johnson's faith is unshaken that her mobile CT screening improves the health and increases the longevity of customers.

"Absolutely and without question," she said in an interview. But she added that the CATScan 2000 screening trucks and promotional materials claiming "New Technology Could Save Your Life" won't roll into states that require on-site physicians or otherwise restrict self-referrals.

Each State Has Own Regulations

National statistics regarding self-referred CT screening are difficult to come by. Each state has its own regulations, ranging from those like Kansas that act to restrict CT scanning to diagnosis and treatment to a handful of states that have no rules prohibiting self-referred screening. (In general, the Food and Drug Administration regulates only the manufacturers of CT scanners.)

A draft statement from the Conference of Radiation Control Program Directors (CRCPD) urges, "Until large-scale clinical trials have been performed and analyzed thoroughly and effectively, insufficient scientific evidence exists for the efficacy and safety of the self-referral whole-body CT process. Unnecessary radiation exposure during medical procedures should be avoided at all costs."

Ron Fraess, Executive Director of CRCPD, which is an association of the 50 state directors of radiation use, says a resolution calling on members to actively discourage self-referral CT screening was one of the few such measures to pass unanimously.

For instance, a radiologist at a scanning center can write a prescription for a scan, as long as it doesn’t run afoul of the Medicare and Medicaid bans against physicians referring patients to scanning centers they have an interest in. Dr. Borgstedt predicts conclusive research into the pros and cons of CT screening will ultimately have more influence than regulations.

For now, he urges people to be skeptical about marketing claims for CT screening. "Have a 'buyer beware,' 'caveat emptor' type of approach and let people know what they are getting into for a fee. People can do what they want, but I think they should be aware of the potential consequences are of getting one of these," he says.

CT Screening Exams: Official Statements

ACR Statement on CT Screening Exams: www.acr.org

"The American College of Radiology recognizes that an increasing number of computed tomography screening examinations are being performed in the United States. Much CT screening is targeted at specific diseases, such as lung cancer for current and former smokers, coronary artery calcium scoring as a predictor of cardiac events, and CT colonography (virtual colonoscopy) for colon cancer.

"Early data suggest that these targeted examinations may be clinically valid. Large, prospective, multicenter trials are currently under way or in the planning phase to evaluate whether these screening exams reduce the rate of mortality."

"The ACR, at this time, does not believe there is sufficient evidence to justify recommending total-body CT screening for patients with no symptoms or a family history suggesting disease. To date, there is no evidence that total body CT screening is cost efficient or effective in prolonging life."

"In addition, the ACR is concerned that this procedure will lead to the discovery of numerous findings that will not ultimately affect patients' health but will result in unnecessary follow-up examinations and related costs and significant wasted expense."

"The ACR will continue to monitor scientific studies concerning these procedures."

American Association of Physicists in Medicine: www.aapm.org

"The use of computed tomography for total body screening of asymptomatic patients has not currently been found to be scientifically justifiable or clinically efficacious."

"The greatest concerns surrounding this procedure are: (1) that the procedure will lead to the discovery of minor anomalies that have no influence on patient health, but their identification will lead to added medical examinations with associated risks and unnecessary medical expenses, and (2) the wide-scale use of significant radiation exposures from total body screening." CT for a yet unproven screening procedure.

"Total body CT screening should not be confused with the scientific CT studies of screening for lung cancer in high-risk patients or cardiac scoring to identify calcification in coronary vessels. Scientists in the AAPM will continuously assess the scientific literature as to the efficacy of total body CT screening and make recommendations to this policy statement when appropriate."

Food and Drug Administration: www.fda.gov/cbdc/ct

"At this time the FDA knows of no data demonstrating that whole-body CT screening is effective in detecting any particular disease early enough for the disease to be managed, treated, or cured and advantageously spare a person at least some of the detriment associated with serious illness or premature death. Any such presumed benefit of whole-body CT screening is currently uncertain, and such benefit may not be great enough to offset the potential harms such screening could cause."

"Statements by CT imaging facilities that imply FDA ‘approval,’ ‘clearance,’ or ‘certification’ of CT for screening procedures misrepresent the actual situation. FDA has never approved or cleared or certified any CT system specifically for use in screening (i.e., of individuals without symptoms), because it has never demonstrated to the FDA that their CT scanner is effective for screening for any disease or condition."

Conference of Radiation Control Program Directors: www.crcpd.org

"No scientific studies have demonstrated that CT screening of individuals without symptoms provides a greater probability of benefit than harm."

"The main risks of CT screening scans for an individual are: (1) abnormal test results for a benign or incipient malignancy, leading to unnecessary and possibly invasive follow-up tests that may present additional risks; (2) normal findings that carry the possibility of inaccurate and false reassurance which may lead the patient to conclude that further routine screening tests such as for breast cancer, cervical cancer, colon cancer, hypertension, diabetes, etc. are unnecessary; and (3) the increased possibility of cancer induction from x-ray radiation exposure."