Concierge Medicine-No Guarantee against Failure to Diagnose Lung Cancer

Abstract: A healthy, athletic woman elected to follow her primary care physician (PCP) into the PCP’s new concierge practice. The promise of accessibility to the PCP on weekends and nights, as well as the promise of obtaining “state of the art” diagnostic and screening studies, above and beyond the usual preventive testing being offered, appealed to her sense of remaining healthy and fit. A radiologist interpreted a CT scan, performed as part of this extra screening package, as “No abnormalities found in visualized lungs.” Four years later, an incidental finding on a CT virtual colonoscopy, revealed a mass in her left lower lung.

The Case

A healthy, athletic woman elected to follow her primary care physician (PCP) into the PCP’s new concierge practice. The promise of accessibility to her PCP on weekends and nights, as well as, being offered “state of the art” diagnostic and screening studies marketed by the practice, above and beyond the usual preventive testing, appealed to her desire to remain healthy and fit. All imaging studies ordered by the concierge physicians were read and interpreted by the radiologists next door at the Imaging Center, with the exception of the Coronary Calcium Scans (CCSs) ordered by this patient’s concierge PCP. In his deposition, this particular physician stated he was “trained” to read CCSs for the purpose of calcium scoring. Because this patient didn’t want to take prescription medication for high cholesterol, the PCP ordered and interpreted CCSs over a four year period to screen for coronary artery disease. He interpreted each of these studies as negative for coronary artery disease, and made notations, “visualized lung fields were clear”.

In his deposition, the PCP testified that he had been mentored in how to read CCSs for the purpose of calcium scoring.
only. He further stated he did not have to visualize the entire scan to rule out coronary artery disease which was his only purpose for ordering these scans. The slices of the CCS he reviewed depicted the coronary arteries, but he saw no abnormalities on those images. Because the patient had none of the risk factors for, or symptoms of, lung cancer, he wasn’t prompted to thoroughly examine the lung fields visible on the scan.

In her initial visit to the practice, the patient also had a non-contrast, full body CT scan as part of the screening package included in her concierge membership. According to the radiologist who read the scan, this type of study is done for screening---without any diagnostic criteria, and without contrast---which makes it more difficult to interpret.

The radiologist interpreted the patient's full body CT scan as “unremarkable with no findings of clinical significance.” In his deposition, the defendant radiologist stated that in hindsight, he could identify an abnormal area in the left lung. He further stated the abnormality was only visible on 3 out of more than 200 images from the full body scan. The areas of abnormality were adjacent to the left hilum and were visible in the soft tissue windows of the CT scan, not on the lung fields which enhance lung tissue.

Four years later, the patient underwent a CT virtual colonoscopy at the same Imaging Center, read and interpreted by a different radiologist. An incidental finding revealed a mass in her left lower lung. Subsequent studies and biopsies led to a diagnosis of lung cancer for which she underwent aggressive chemotherapy. The following year, the patient was diagnosed with metastatic brain cancer, and began radiation therapy. She was given a poor prognosis. The patient was a broker with a well-known real estate company. She and her husband had three small children.

Allegations

The plaintiff alleged the concierge PCP, who read her coronary artery calcium CT scans for four consecutive years, was negligent in failing to identify a lung mass suspicious for cancer. The plaintiff further alleged the first radiologist who read and interpreted the non-contrast, full body CT scan, failed to identify a lung mass suspicious for cancer. This was the only scan involving that particular radiologist.

In addition to the medical malpractice action, the plaintiff also filed a breach of contract and fraud claim, alleging the concierge clinic made fraudulent promises to her in their marketing materials and on their website.

Disposition After the defense attorneys weighed the elements of physician duty, damages the patient suffered, and the applicable standard of care issues, a decision was made to settle the case. A very large amount of money was paid out on behalf of the PCP, his concierge practice, and the radiologist who read the total body CT scan.

Risk Management Commentary

Lung cancer carries such a high morbidity/mortality rate that once the lung mass was detectable in this patient, treatment did not significantly change her outcome. According to the oncology expert, the patient’s stage T1b carried with it a 47% five year survival rate. The expert further opined that it was not likely the patient would be cured of this particular cancer, even if it had been diagnosed when she first joined the practice and was asymptomatic.

Standard of care violated by both the PCP and the Radiologist

Physicians may be held liable for his/her interpretation of labs and diagnostic studies. In general, whether or not a physician should seek to have a study over-read is certainly a judgment call, and associated with that physician’s competency.

In this case, experts were critical of the PCP for not reading the entire coronary artery CT scan. The American College of Radiology (ACR) proposed credentialing guidelines for CCSs provide that "in addition to an examination of the cardiac structures of interest, the interpreting physician is responsible for examining all the visualized non-cardiac structures, and must report any clinically relevant abnormalities of these adjacent structures.” Since the PCP mentioned in his report, “visualized lungs are normal”, the reviewers were uncomfortable with the PCP’s position that he was just looking at the heart. The mass was visualized as early as the first coronary artery CT scan the PCP ordered and read for the patient.
The reviewers further opined the standard of care required that the PCP read the entire coronary artery CT scan, and have that study over-read by a radiologist. Although the PCP correctly interpreted the CCS studies as negative, he was likely not competent to read the non-cardiac portions of the study. Thus, he was required to have those studies over-read.

Regarding the full body CT scan interpreted by the radiologist, the experts opined the radiologist violated the standard of care in failing to identify an abnormality in the left lung. Radiology reviewers believed the full body CT scan showed a left lower lobe mass in the area inferior to the left inferior pulmonary vein; that the mass was approximately 2 cm in size; and was spiculated on the full body scan. Further, the mass was “obvious”, meaning that a reasonable radiologist would have not only identified it, but would have also recommended a follow-up chest CT scan with contrast.

**Additional Risk Management considerations:**

- Ordering CCSs for screening purposes is not recommended in low risk, asymptomatic individuals, except for those with a family history of premature coronary artery disease. Net reclassification of risk by coronary calcium scanning, when added to clinical risk scoring, is least effective in low risk individuals.
- The new American College of Cardiology Foundation (ACCF) and the American College of Cardiology (ACC) guidelines for CCSs call for consideration of asymptomatic individuals with an intermediate (10% to 20%) 10-year risk of cardiac events based on the Framingham risk score or other global risk algorithm, and for diabetics older than age 40. Management of these patients depends upon the CCS findings. The Framingham scores for the particular patient in this case were apparently within normal range.
- This is a lack of formal guidelines and research on the use of serial CCSs for assessment of progression of coronary calcification, although further evidence is now emerging.
- Discourage patients who push for excessive and unnecessary studies, even if they can be done without additional cost to the patient, and under the concierge agreement. Defensive medicine may be counterproductive in some instances, possibly increasing malpractice risk. The principle of ordering tests only if needed (and, if ordered, that they be fully evaluated), applies equally to a “concierge practice”, just as it does in more traditional medical practice.
- In promoting and explaining your concierge practice—or any of your practice’s services—take care not to overstate what you can provide. Avoid representing or inferring that the quality of care you provide is higher than that offered by other physicians.
- Ensure all promotional materials are reviewed by an attorney to prepare an appropriate disclaimer, and to ensure compliance with federal and state laws, especially if advertising will be done via internet or across state lines.
- And finally, have legal reviews performed on an ongoing basis to reduce the risks of civil liability claims, and potential federal regulatory liability related to your advertising practices.

[i] Concierge Medicine definition: A form of medical care in which a patient pays a physician an annual retainer in exchange for improved physician access and additional services; also called “boutique care”. Concierge practices vary widely in structure, payment requirements, and form of operation. In particular, they differ in the level of service provided and the amount of fee charged and whether they are cash only or accept some insurance plans.

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