



**M**ichael Gould, MD, MS, recalls his early career, reviewing dozens of chest CT scans with his colleagues—fellow pulmonologists—during monthly tumor board meetings.

Many of the images contained a shadowy spot in the lungs. Those spots often revealed a lung nodule—a potentially cancerous growth.

If caught at its earliest stage, lung cancer can be cured surgically. But many of the nodules Dr. Gould saw had progressed beyond that point.

“It seemed wrong to me that we were seeing so many nodules at that stage,” said Dr. Gould, who is now the director of Health Services Research & Implementation Science at Kaiser Permanente Southern California. “I thought there had to be a smarter way.”

The quest to find a better way to identify potentially cancerous nodules prompted Dr. Gould to shift from a clinical career to a research path. Ultimately, it led him to Kaiser Permanente.

## **Inquiry draws allies to the quest**

Soon after joining Kaiser Permanente, Dr. Gould met George Yuen, MD, now chief of pulmonology for the Southern California Region and Orange County.

Dr. Gould was pursuing a study about shared decision making, which encourages patients and clinicians to make health decisions together.

“First, we make sure you as a patient understand the issues,” said Dr. Yuen. “Then we work together to make a decision that aligns with your values.”

Decisions about lung nodules are complex. About 3 to 5 lung nodules out of 100 prove to be cancerous. Biopsies can definitively identify lung cancer. But they are invasive and introduce different risks.

“When I talk to a patient, I tell them we see a lot of lung nodules, and the vast majority are innocent,” said Dr. Yuen. “People often worry about cancer. We talk about their individual risk factors and their values, and together make a decision about what to do.”

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Above: Dr. George Yuen, Leslie Barcelon (from behind)

Opposite page, clockwise from top left: Fernando Barreda, Dr. Michael Gould, Cynthia Bishop, Danielle Altman



Decisions about lung nodules are complex. About 3 to 5 lung nodules out of 100 prove to be cancerous. Biopsies can definitively identify lung cancer. But they are invasive and introduce different risks. A new pragmatic trial will evaluate different strategies for monitoring lung nodules.

Many patients and physicians opt to monitor lung nodules using CT scans. Radiologists examine the size, shape, and density of the nodules. They also consider individual health risks, such as a history of smoking.

"We have pretty good criteria to sift out which spots are benign," said Anne Kosco, MD, chief of radiology at the Kaiser Permanente Los Angeles Medical Center. "If we can't call a spot benign, we have to monitor it."

### The question: how much is enough?

How often nodules should be monitored remains an open question.

Scanning patients too frequently may cause them to worry. It increases the likelihood of unnecessary biopsies or other procedures. More-frequent scans also expose patients to more radiation. On the other hand, if a patient doesn't come in often enough, a nodule could grow and become a major problem.

Existing guidelines provide recommendations on how often patients should be scanned. But the guidelines rely on expert consensus rather than empirical evidence.

"There are different systems out there for follow-up, but none have evidence behind them," said Dr. Kosco.

### Funding opportunity provides path forward

In 2014, the Patient-Centered Outcomes Research Institute (PCORI) named 14 research priorities. One of them was how to evaluate patients with nodules that might be cancer.

"When the PCORI opportunity came up, I was working on another grant. I put it aside," said Dr. Gould. "This is the study I've prepared for my entire life without knowing it."

Dr. Gould worked with colleagues to develop a proposal for a pragmatic trial to evaluate different approaches to monitoring lung nodules. PCORI funded the study in 2015.

"A pragmatic trial seeks to answer questions in real practice settings, rather than the controlled environment of a classic randomized trial," said Dr. Gould. "By embedding this in clinical practice, we can make the study more efficient without compromising validity."



### A pragmatic approach to gathering evidence

The 5-year study will compare outcomes from 2 different strategies for monitoring lung nodules. One uses more-frequent scans to follow patients. The other uses less. The study will begin enrollment in the fall of 2016.

Across the country, 14 health care organizations are participating, including Kaiser Permanente's Colorado and Northwest regions. Researchers will compare a range of outcomes for the 2 strategies, including:

- Percentage of lung cancers that have grown to more than 2 centimeters.
- Time to diagnosis and treatment.
- Cancer survival rates.
- Patient perceptions and experiences.
- Adherence to 1 of the 2 recommended strategies.

Findings from the study will provide much-needed guidance for pulmonologists, radiologists, and patients.

"If a less-frequent schedule has similar outcomes, I would change my recommendations to decrease the number of scans," said Dr. Yuen. "If, on the other hand, we see an increase in higher-stage cancers with less-frequent scanning, I would stay with more-frequent scanning."

"This study will help us find the sweet spot for the right frequency of scans," said Dr. Kosco. "Knowing what is optimal will help us practice smarter medicine."