



## Departments

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#### A Virtual Standoff

*By George Wiley*

Payors are taking a wait-and-see approach before reimbursing for virtual colonoscopy, but there is anticipation, even eagerness, to the waiting.

Reimbursement by insurance carriers for CT scans of the colon the so-called virtual colonoscopy (VC) is virtually nonexistent. According to a public relations officer at Medicare headquarters in Washington, DC, there is no Medicare application on file for the procedure, much less approval. Regional carriers for private and public insurance programs are not reimbursing either. The procedure to identify colon polyps is too experimental. Too much about reliability and accuracy is yet to be documented, payors say. Nonetheless, insurance carriers are carefully watching research reports. Everybody admires a technique that promises high accuracy at possibly lower cost and greater patient comfort.

Reports on the accuracy of virtual colonoscopy vary. But these early studies may be far from comparable. People involved in the research appear optimistic. Colon examinations themselves got a boost in July when the US Preventive Services Task Force issued its strongest call ever for routine colon cancer screening for high-risk patients with family histories of the disease and for all persons 50 and older. The Task Force bulletin said an estimated 143,000 patients would be diagnosed this year with colorectal cancer and that 57,000 would die from it, making colorectal cancer the second worst cancer killer, behind lung cancer.

#### THE PAYORS

At Blue Shield of California, Medical Director for Medical Policy Jonathan Freudman, MD, says, "We're not reimbursing for virtual colonoscopy yet. It seems like a promising procedure, but more study is needed to determine its value. We're going to be watching it closely in the future."

Freudman, an internist who also sits on the Blue Cross/Blue Shield national medical policy board, says accuracy and reliability are not the only questions to be answered about virtual colonoscopy. Even if VC proves useful, it may be duplicative in the sense that a positive reading would then lead to an endoscopic colonoscopy anyway, Freudman says. "There are also the things that most patients hate, such as the preparation stuff and the enema, and VC still has that," Freudman adds.

On the other hand, says Freudman, there may be a shortage of gastroenterologists needed to perform conventional colonoscopies, particularly if more societal emphasis is being put on

colon screening. "If you look at the number of gastroenterologists, it is my impression that in some locales they aren't there in sufficient number. If the VC procedure is just as accurate, that would help, but more study is needed," Freudman says.

Cornelia Taylor, MD, also an internist, is assistant vice president of medical affairs at Regence Blue Cross/Blue Shield of Oregon, which serves about 1.5 million subscribers. Taylor manages utilization management for her carrier, and as such she is in charge of the review process that approves new procedures. So far, Regence has not approved virtual colonoscopy. Taylor's concerns echo Freudman's. There is not enough information, and from an insurance carrier's point of view, a VC examination that found something would simply lead to what Taylor and the industry call "the gold standard," endoscopic examination.

Even though some studies have found VC effectiveness in the 90% range, says Taylor, conventional methods have found colonic polyps missed by VC. Taylor says VC may ultimately prove most promising for low-risk patients who might be screened more quickly and efficiently than with sigmoidoscopy or the gold standard endoscopy. "It's new and it's interesting," says Taylor, "but so far with virtual colonoscopy we're not really seeing that studies have been sufficiently good to show that it can be used and should be used in place of the gold standard." Taylor says her carrier's reimbursement for the gold standard varies by contract but is between \$500-600 for the professional fees and between \$800 and \$1800 for facility fees. "At the high end, it could be \$2400 for the technical and professional fees combined," she notes.

## **THE NATIONAL CANCER INSTITUTE**

At the National Cancer Institute (NCI), the jury is still out on VC as well. NCI is following the research closely, according to Edward V. Staab, MD, chief of the diagnostic imaging branch in the biomedical imaging program, Division of Cancer Treatment and Diagnosis, at NCI's Washington, DC, headquarters.

"The sensitivity and specificity [for VC] are very low in some of the research nowhere near the 80% and 90% we've been hearing about," says Staab. "The sensitivity is more in the 40% range, sensitivity being the ability to detect a 1-cm polyp."

He adds, "The problem is that if you get someone who really knows what they're doing, pays an awful lot of attention to cleaning out the bowels, is very, very adept at doing this study, and has the right equipment, then you get an 80% to 90% sensitivity. You can find quite a few things.

"But then," he says, "when you go out in the real world and say, OK, guys, start doing this,' suddenly it drops off. We talk about effectiveness. Effectiveness is just how good this study is in the hands of experts. Then we talk about efficacy and that's how good it is in the hands of everybody else that is doing studies, and efficacy frequently falls off rapidly from effectiveness. That is something that we really haven't paid too much attention to in the past with most of the studies that we do."

Staab says it is premature to start generalized VC screening. He praises researchers who are taking their time to develop the software to make VC routinely reliable, if the procedure ever gets to that point. "These researchers aren't running off and selling the procedure," he said. "They're trying to make it better before they figure out whether it's going to be useful or not."

## **THE RESEARCHERS**

Ronald M. Summers, MD, PhD, is chief radiological investigator in the Clinical Image Processing Service in the Department of Radiology at the National Institutes of Health

(NIH) in Bethesda, Md. Summers is working on computer-aided detection (CAD) software to highlight polyps on VC scans. Summers says he has spent several years developing the software, which "takes about 2 minutes to search along the wall of the colon looking for bumps and protrusions." He says the software seeks polyps 5 mm and above, but mainly searches at the 1-cm level.

"It seems to be successful in preliminary trials, and we are working now to show that it's robust, with new data and larger databases," he says. In the initial phase, the software operated with about 70% sensitivity to 1 cm and larger polyps, he adds. Summers says the software is needed because radiologists using VC must do reads that are "very tedious and time-consuming to interpret." He says a high error rate on readings was another factor spurring the software. "There are differences in the ability of radiologists to interpret these studies. Few have seen many cases, and not many of them have been trained in the best way possible."

Summers says a positive VC result must lead to follow-up investigation. "Certainly, CT can't biopsy," he notes. There is also the problem with bowel cleansing. To make VC really effective as a quick, painless colon cancer screening technique that patients will accept, it will probably be necessary to eliminate the need for overnight bowel cleansing. Summers says researchers are working on iodine and barium based compounds that will act as tagging agents to highlight residues in the colon. "But if CT colonoscopy can be made inexpensive enough, and if something can be done to eliminate the bowel cleansing, this may become a reasonable screen for colon cancer," he concludes.

Judy Yee, MD, is an associate professor of radiology at the University of California at San Francisco. She is also chief of CT and GI (gastrointestinal) radiology at the San Francisco Veterans Administration hospital, where she is researching virtual colonoscopy. "It is a moving target," she says, noting that improvements in CT scanners and related software mean continual testing and retesting. Yee says she has, for instance, switched from inflating bowels with air prior to examinations to now inflating with carbon dioxide, because she thinks it is more comfortable for patients. In her own research, Yee adds, she has achieved between 92% and 96% specificity rates for identifying 1 cm and larger polyps.

Because VC is quicker and more comfortable and has no appreciable recovery period, Yee says the technique is very promising. People who should have colon screens now avoid them because of the time consumed and the discomfort. "VC is very important because less than 40% of those who should be screened are getting screened," she asserts. She says an added benefit to a VC is that it can find other problems "because you can also see everything in the abdomen and pelvis." Yee says the cost for a VC for her VA patients varied from \$600 to \$1,500 for both the professional and technical fees.

## **IMAGING CENTERS**

While virtual colonoscopies are beyond the reach of patients who expect reimbursements from their health carriers, at least in most big cities anybody can walk into an imaging center and pay cash for the procedure. At CT Screening International, which operates 13 centers from its headquarters in Irvine, Calif, virtual colonoscopies are becoming increasingly popular, according to Patrick Githens, who is the company's Southern California regional manager and chief technician for the western United States.

"Some sites are scheduling up to four patients per day," Githens says. "We do them in the morning because of the prep. Some of our doctors have read down to 2 mm, although they generally guarantee anything above 1 cm."

Githens says the charge for a stand-alone VC is \$975, but if patients order a VC in combination with a full-body scan, the total charge is \$1,450. Patients are given a CD-ROM of the screening and referred to gastroenterologists if necessary, he adds. He says his

company is working on a databank of screening results but can report no data currently. "I think virtual colonoscopy in general is much more sensitive than traditional colonography," he said. "The GI doctor can only see where he's pointing that camera. With our rebuilding software, we can tell you anything about that polyp.

"Once insurance companies realize this is a much lower cost screening, they will jump all over it," Githens predicts.

They have not done so yet. But they are paying attention.

*George Wiley is a contributing writer for Decisions in Imaging Economics.*