



AMERICAN COLLEGE OF SURGEONS

SURGERY NEWS

Personal Health Record Platforms Launched

BY ERIK GOLDMAN
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WASHINGTON — Search engine giant Google recently launched Google Health with an aim of establishing itself as the leading repository of personal health records. Google is also positioning itself as a primary clearinghouse for clinical information, self-care tools, and provider ratings to help patients make educated health care decisions.

Google Health emerged just as the smoke began to clear from Microsoft's launch of its own HealthVault platform for personal health records (PHRs) last fall.

Both companies see individual patients, not health care systems, as the primary locus of change for health care information technology, and both provide individuals with secure but user-friendly systems for aggregating all of their health care records, data, diagnostic images, laboratory results, and medical histories. They hope to put an end to the fragmentation, duplication, and lack of portability that characterize paper-based health record-keeping.

Executives at both HealthVault (www.healthvault.com) and Google Health (www.google.com/health) said that they believe digitally enabled patients will help push more doctors to implement electronic medical records systems.

"We now have more than 1 billion people worldwide using Google every day. Google is the No. 1 search engine for health information, and health topics are a top search category for Google," said Todd Wiseman, head of Google's Federal Enterprise Team, at the fifth annual World Health Care Congress.

Google Health will eventually enable people all over the country to store their PHRs and allow them to decide who may have access to those records. Users can also store medical contacts and other relevant information.

The system can automatically import physician reports, prescription history, and lab results. Eventually, it will enable people to schedule appointments, refill prescriptions, and employ personal health and wellness tools, along with clinical trial matching and other health management tools, Mr. Wiseman said.

Google Health will not charge people to store PHRs; likewise, doctors will be able to access their patients' PHRs—with patient permission, of course—at no cost.

A pilot field test of the Google Health system currently being run in partnership with the Cleveland Clinic is expected to ultimately accommodate PHRs of about 10,000 patients. "We're testing the process of data sharing in a live clinical-care delivery setting, with real patients and real

doctors. The goal is simply proof of concept," Mr. Wiseman explained.

Google offers several advantages compared to its competitors, according to Mr. Wiseman:

- ▶ It is wholly independent of any health care plan or provider system, and therefore it is completely portable.

- ▶ It is a neutral stakeholder as far as how someone uses their PHR, which is different from PHR systems tied to specific health plans.

- ▶ It has massive data storage capacity (Google already gives its Gmail users six gigabytes of e-mail storage capacity).

While Microsoft has been involved in health care IT solutions for hospitals and health plans for more than a decade, its PHR efforts are fairly new, said George Scriban, senior product manager for the company's HealthVault.

In an interview, Mr. Scriban said HealthVault, which is also free to consumers, tries to solve the fragmentation problem.

"Everybody's health care identity is spread around in little slices in different sectors. The employer has some information, various doctors have others, hospitals and payers and pharmacies have still others. The ideal is to have all one's information, presentable and portable and useful to any and all providers," Mr. Scriban said.

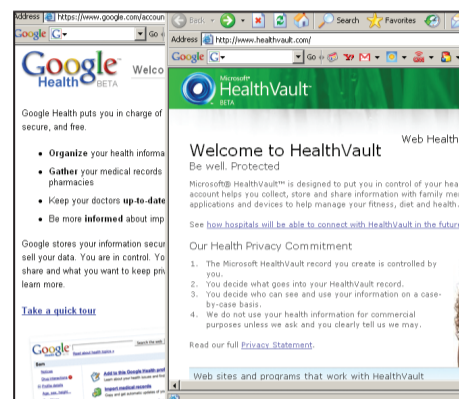
"When a patient gets a referral from one doctor to another, it is really that patient who acts as an information transporter, telling the new doctor his or her medical history, medication use, and in some cases actually transferring paper records," he said.

HealthVault tries to standardize, stabilize, and formalize that process, and Mr. Scriban contends that this will reduce errors, prevent loss of important information, eliminate redundancy, and give physicians a fuller picture of their patients' health. He added that HealthVault is being designed to interface with many different electronic medical records systems. He said that he hopes that as more patients create PHRs, more doctors will see the ultimate value in interconnectivity.

HealthVault and Google Health are similar in many respects.

"Both are backed by large companies with a lot of resources; [both companies] have looked at the same problem and arrived at similar conclusions. One conclusion is that you cannot revolutionize health care in one big step. The other is that the consumer is really the agent of change in all of this," Mr. Scriban said.

But Microsoft is primarily focused on enabling people to manage their health information, and less engaged in providing self-care tools, something that Google is pursuing.



Google and Microsoft aim to help patients make informed decisions.

Both Google and Microsoft are lining up partners across the health care landscape, including insurers and managed care plans, information service providers, medical organizations, and patient advocacy groups.

Microsoft recently partnered with Kaiser Permanente, an integrated health plan with more than 8 million members, to test the transfer of data from Kaiser's personal health record into HealthVault. The pilot project, launched in June, is open to Kaiser's 159,000 employees. The idea is to combine the clinical data entered by Kaiser physicians, which is available in the Kaiser personal health record, with patient-entered health information and clinical information from providers outside of the Kaiser system.

"Providing new ways to manage their health online is one more way we can engage consumers in their care," Anna-Lisa Silvestre, vice president of online services at Kaiser Permanente, said in a statement. "We believe that Microsoft HealthVault will be a valuable supplement to our expanding set of online features."

Kaiser officials plan to reevaluate the pilot later in the year before expanding it to Kaiser members.

Google's Mr. Wiseman said it is particularly important to create alliances with health plans. "A lot of people won't use Google Health unless their health plans support it." Google's other major focus is on consumer decision support tools.

Among Google Health's new partners is HealthGrades, the private company that has quietly emerged as the leader in online physician and hospital ratings. HealthGrades uses publicly available data on quality outcomes based on 32 standardized procedures and health conditions to grade physician and hospital performance. The ratings parameters are based on work done by the National Quality Forum.

Currently, Web users seeking HealthGrades ratings for a doctor or hospital must pay a fee. Under the partnership agreement, Google Health users would have free access to the ratings.

Though the specifics have not yet been worked out, the idea is that Google Health users searching for doctors or clinics would obtain a listing of the top 10 appropriate practitioners locally. Each listing would contain contact information, and access to the full HealthGrades profile for that physician or hospital.

At issue is how Google and HealthGrades will determine which practitioners and facilities show up on the top 10 list for a particular search. Dr. Samantha Collier, chief medical officer of HealthGrades, and Mr. Wiseman said that initially the order of rank will be based on Google's standard model, which lists the most trafficked sites highest. The rankings would not be based on the HealthGrades scores.

That seems somewhat contradictory to the company's stated mission of trying to steer patients to the doctors and hospitals with the best quality ratings, not simply the ones with the most Web hits. Mr. Wiseman said that at some point the model might change to one in which the listings were based on HealthGrades scores, but he would not comment further.

From a physician's perspective, it is difficult to say which mode of determining the listings would be preferable. On one hand, Web site traffic has little clinical relevance, and all but rules out doctors who do not have Web sites. On the other hand, rankings based on HealthGrades scores would only be as fair and reasonable as the scores themselves.

While HealthGrades does adjust for age and comorbidities, there are many who question the integrity and validity of the HealthGrades measures. Among the physicians concerned about provider ratings is Dr. Patricia L. Turner, an ACS Fellow and assistant professor of surgery at the University of Maryland, Baltimore, who commented on the systems. "These online grading systems are not vetted, are not validated, are not risk-adjusted, and are overall, in my opinion, not worth the bandwidth they take up," said Dr. Turner. "When Google or Microsoft get into the business, and they will, of ranking physicians, or providing lists of top physicians based on HealthGrades or any other such company, I will be very concerned about how those lists are constructed," she said.

Dr. Collier said that all the organizations involved take quality rating data very seriously, and while there's always room for improvement, cost is a factor. "Even getting the basic measures can cost \$60,000-\$100,000 per facility per year. To get to where we really need to be will cost a lot of money. Who's going to pay for that?"

Regardless of the answer, electronically empowered patients are likely to influence the future direction of health care. ■

PCI Sans On-Site Surgical Backup Deemed Safe

BY MITCHEL L. ZOLER
Elsevier Global Medical News

CHICAGO — Percutaneous coronary interventions done without on-site cardiac surgery backup were as safe as procedures done with on-site back-up in a registry of more than 300,000 total patients treated during 2004-2006.

Despite this positive showing for percutaneous coronary interventions (PCI) done without an on-site net, several experts voiced skepticism about how widespread the practice should become, including the advocates for this form of PCI who ran the study.

The results “confirm the safety of an off-site strategy at existing PCI centers where rigorous clinical, operator, and institutional criteria are in place and are monitored to ensure high-quality outcomes,” Dr. Michael A. Kutcher said at the Innovation in Intervention (i2) Summit. But, he added, “the findings of our study should not be extrapolated to encourage the widespread proliferation of off-site PCI programs. You need to look at what is best for patients,” said Dr. Kutcher, lead investigator in the study and professor and director of interventional cardiology at Wake Forest University in Winston-Salem, N.C.

“Yes, it is safe and efficacious, but should it be done? It must be looked at as a system-based approach to be sure that each patient gets proper care,” commented Dr. Rick A. Nishimura, professor of medicine at the Mayo Clinic in Rochester, Minn.

“Does anyone prefer to have PCI done at a low-volume center without surgical backup?” asked Dr. Timothy D. Henry in a separate talk at the meeting. “It is inappropriate to open new PCI centers that are not based on the health care needs of the community.” He noted that good coordination among regional centers and effective rapid transport programs can often speed patients who need emergency pri-

mary PCI for ST-elevation myocardial infarctions from rural locations to high-volume catheterization laboratories in less than 2 hours.

In many cases, what drives the opening of catheterization laboratories that perform PCI with off-site surgical backup are financial incentives to the hospital and to physicians, added Dr. Henry, an interventional cardiologist and director of research at the Minneapolis Heart Institute.

But some cardiologists passionately argued that there is a desperate need for PCI with off-site backup in remote, rural areas where transit to regional centers is unreliable and awkward.

“Until someone practices in an area where primary PCI is largely unavailable in a timely manner,” it’s hard to appreciate the need, commented Dr. Melissa Walton-Shirley, a cardiologist in Glasgow, Ky., and codirector of the Kentucky pilot project for primary PCI.



‘It must be looked at as a system-based approach to be sure that each patient gets the proper care.’

DR. NISHIMURA

Transporting patients to a referral center is dependent on many uncertainties: the weather (helicopters can’t fly when the air ceiling is low), availability of an ambulance, bed space in the tertiary center, and a patient’s willingness to be transported far from home. “Bringing patients to a tertiary center in a reasonable time frame is

still not as good as getting the infarcting patient onto a table” even faster. Two hours is not an optimal delay to angioplasty. “If we can do better, we should do better,” she said in an interview.

The data used in the current study were collected by the National Cardiovascular Data Registry (NCDR), a database funded and maintained by the American College of Cardiology. Dr. Kutcher and his associates stressed that the hospitals participating in the NCDR, a purely voluntary database, show their commitment to quality by subjecting their clinical experience to independent peer review. He estimated that about 100 U.S. centers today perform PCI with off-site backup and

Comparing PCI With and Without Surgical Backup

	PCI done with off-site backup	PCI done with on-site backup
PCI sites in a rural area	34%	17%
Average annual PCI volume	168 cases	746 cases
Average annual number of primary PCI cases	35	78
Sites performing fewer than 200 PCI cases/year	70%	6%
Sites performing fewer than 36 primary PCI cases/year	57%	20%

Note: Data from 61 U.S. sites performing PCI with off-site backup and 404 U.S. sites performing PCI with on-site backup.
Source: Dr. Kutcher

also participate in a data collection and review program, such as the NCDR and the Atlantic Cardiovascular Patient Outcomes Research Team (CPORT). But he also estimated that about 200 American PCI programs currently run using off-site surgical backup and have no systematic review of their performance. States have varying regulations that allow or prevent the practice (see map).

“No program should be allowed to implement primary PCI without being required to report their data to a registry,” said Dr. Walton-Shirley.

“The prestige of the [new NCDR paper presented at the i2 Summit] may inspire other PCI programs to become part, so I think enrollment [in the NCDR] will increase,” Dr. Thomas P. Wharton Jr. said in an interview. In addition, some states are developing regulations that will require PCI programs with off-site backup to participate in programs like the NCDR, said Dr. Wharton, a coinvestigator with Dr. Kutcher and an interventional cardiologist in Exeter, N.H.

Their study used data collected by the NCDR CathPCI registry on consecutive cases done during Jan. 1, 2004, through March 30, 2006, with 308,161 patients treated at 465 U.S. centers. This included 9,029 patients treated with off-site surgical backup at 61 centers, and 299,132 patients treated at 404 centers with on-site surgical backup.

Forty-nine of the centers with off-site backup completed a survey. Responses showed that the average distance to a surgical facility was 35 miles, with 12 centers (24%) located more than 40 miles from their surgical backup. The average transit time to the surgical backup facility was 25 minutes, with 13 centers (26%) located more than 30 minutes away.

The most common mode of transit available for transfer to the surgical site was a ground ambulance at 26 (53%), with another 11 (22%) sites relying primarily on helicopter, and 11 more sites (22%) using both helicopter and ground transport.

Of the 49 surveyed PCI sites, 45 (92%) provided 24/7 coverage. Primary PCI alone was offered at 9 sites (18%), with both primary and elective PCI offered at the other 40 sites (82%). The sites with off-site backup tended to be in more rural locations and had substantially lower annual PCI volumes, compared with PCI centers with on-site backup (see table). The median time to reperfusion in patients undergoing primary PCI was 1.4

hours at all 61 sites with off-site backup, compared with 1.5 hours at sites with on-site backup.

The procedure success and complication rates were virtually identical between sites with and without on-site backup. So was the rate of emergency coronary bypass surgery, which was needed by 0.3% of patients treated at centers with off-site backup, and by 0.4% of those treated with on-site backup. The mortality rate among patients who needed emergency coronary bypass surgery was 13.6% in patients treated with off-site backup, and 12.6% among patients treated with on-site backup, a difference that was not statistically significant, Dr. Kutcher said at the meeting, cosponsored by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions.

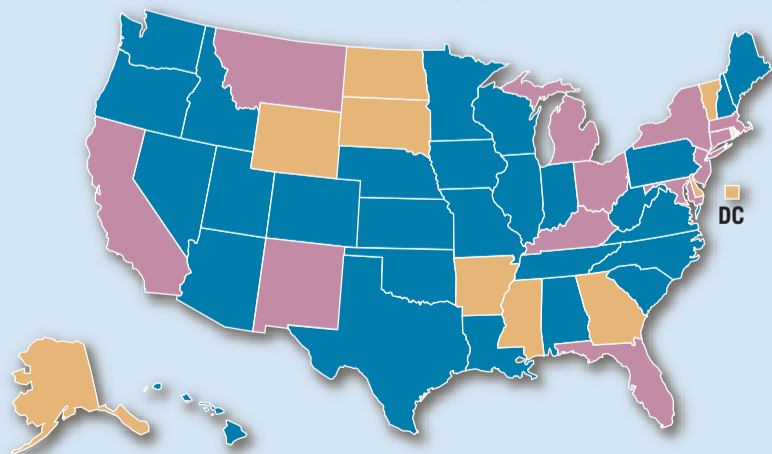
Overall mortality was significantly higher among patients treated with off-site backup, 1.8%, compared with those treated with on-site backup, 1.2%, but this did not account for baseline differences in severity of illness and other potential confounders.

In an analysis that adjusted for potential confounding variables, patients treated with and without on-site backup showed no significant differences in total mortality, mortality in patients undergoing primary PCI, mortality in patients with elective PCI, and mortality in patients who did not require emergency bypass surgery. Among patients who needed emergency bypass surgery, patients treated at centers with on-site backup had a 59% increased risk of death, compared with patients treated at sites with off-site backup, a difference that just reached statistical significance ($P = .049$), Dr. Kutcher said.

Current PCI guidelines from the American Heart Association, American College of Cardiology, and Society for Cardiovascular Angiography and Interventions, published in 2006, said that performing elective PCI at centers with off-site surgical backup is “not recommended” (a class III category), and that primary PCI at these locations “may be considered” (a class IIb category) (*J. Am. Coll. Cardiol.* 2006;47:216-35). The new findings reported by Dr. Kutcher warrant upgrading both of these recommendations and designating both uses of PCI at centers with off-site backup as class IIa recommendations, indicating that the weight of evidence is in favor of usefulness, commented Dr. Stephan Windecker, director of invasive cardiology at the Swiss Cardiovascular Center in Bern.

Surgical Backup Status for Sites Performing PCI

■ No PCI without on-site cardiac surgery
 ■ Primary PCI without on-site cardiac surgery
 ■ Primary and elective PCI without on-site cardiac surgery



Note: Based on July 2006 data from the Society for Cardiovascular Angiography and Interventions.
Source: *Catheter Cardiovasc. Interv.* 2007;69:471-8

Robotic Endometrial Staging Favored for Obese Patients

BY SHARON WORCESTER
Elsevier Global Medical News

TAMPA — Robotic surgery is preferable to laparoscopy for comprehensive surgical staging in obese and morbidly obese women with endometrial cancer, a study of 81 women suggests.

Between 2005 and 2007, 49 obese and morbidly obese women underwent robotic endometrial staging surgery with the da Vinci robotic system. Outcomes in these women were retrospectively compared with those from similar consecutive laparoscopic surgeries performed between 2000 and 2004 in 32 obese and morbidly obese women, Dr. Paola A. Gehrig reported at the annual meeting of the Society of Gynecologic Oncologists.

Robotic surgery was found to be associated with significantly shorter operative time, compared with laparoscopy (mean of 189 vs. 215 minutes, $P = .0004$), less blood loss (an estimated mean of 50 vs. 150 mL, P less than .0001), improved lymph node retrieval (total of 31 vs. 24 lymph nodes retrieved, $P = .0040$), and shorter hospital stay (mean 1.02 vs. 1.27 days, $P = .0119$).

The findings suggest that robotic surgery is the preferred minimally invasive surgical approach for comprehensive surgical staging of endometrial cancer in these populations, said Dr. Gehrig of the University of North Carolina at Chapel Hill. Weight is a particularly important consideration, she noted, given that about a third of all women in the United States are obese or morbidly obese, and that obese women have an increased risk of developing endometrial cancer.

In one recent prospective study, she noted, 68% of women presenting with endometrial cancer were obese; in another study, 25%

were morbidly obese. Other studies suggest that obese women have an increased relative risk of death from all causes—including postoperative complications, she said.

Patients in both groups in the current study were similar with regard to age (mean of 61 years), and body mass index: 37.5 kg/m² (range 20-53) in the robotic surgery group and 35 (range 30-55) in the laparoscopy patients. The groups were also similar with regard to cancer stage and tumor grade. Obesity was defined as BMI of 30 or greater, and morbid obesity as BMI of 40 or greater.



These procedures were performed by a single surgeon with extensive robotic surgery experience.

DR. LEISEROWITZ

“While you can question the clinical significance of a 26-minute operating room difference ... and you can question the clinical significance of a 100-mL blood loss over time, I think that robotics can provide us with a more generalizable procedure for those practitioners who want to proceed with minimally invasive surgery,” Dr. Gehrig said.

Given the increased risk of death from all causes—including postoperative complications—in these patients, every effort should be made to improve outcomes, she said. “Robotic surgery provides a useful platform by which this can be achieved,” she said, adding that additional prospective study with attention to cost and with longer follow-up is needed.

Dr. Gehrig reported that she had no financial conflicts to disclose.

In a formal comment on the findings, Dr. Gary Leiserowitz praised the study design as well as the effort to “push the boundaries of robotic surgery,” but added that it is important to keep surgeon skill level in mind. The procedures in this study were performed by a single surgeon with extensive robotic surgery experience, noted Dr. Leiserowitz, chief of gynecologic oncology at the University of California, Davis Cancer Center. ■

RFID-Based Interference Poses Safety Hazards

BY KATHRYN DEMOTT
Elsevier Global Medical News

Radio frequency identification devices for tracking blood products and medical supplies in hospitals demonstrated enough electromagnetic interference with intensive care unit equipment to be potentially hazardous to patients, according to a report in JAMA.

The findings are alarming because the application of such radio frequency identification devices (RFIDs) is increasingly being explored in health care settings, noted Dr. Donald Berwick in an accompanying editorial. The ubiquitous technology used in everything from security access cards to electronic toll-collection devices that hang on car windshields is currently under investigation for remotely monitoring medical equipment and for tracking inventory and the placement of specific items such as surgical sponges.

The findings suggest that on-site tests of electromagnetic interference are warranted before hospitals start using new RFIDs, said Dr. Erik Jan van Lieshout, one of the study's coauthors from the University of Amsterdam, and associates.

The investigators analyzed the effects of two RFIDs on 41 medical equipment systems in simulation studies that did not involve patients. Of the two RFIDs studied, one had an active tag, which means that the power source transmits continuously to the reader device, and the other had

a passive tag, meaning that it is powered by the electromagnetic field of the reader.

The RFIDs were selected because they were being studied for their usefulness in tracking blood products and expensive medical supplies in the ICU.

Each of the 41 medical equipment systems was subjected to three tests of electromagnetic interference in a one-bed ICU room.

Of the 123 tests, 34 induced an electromagnetic interference incident that was reproducible. Of those incidents, 22 were considered potentially hazardous and included the switching off of ventilator equipment, complete stoppage of syringe pumps, and incorrect inhibition of pacemakers (JAMA 2008;299:2884-90).

The passive RFID tag induced a greater number of both incidents and potentially hazardous incidents, compared with the active RFID tag. The median distance at which the incidents occurred was 30 cm.

In his editorial, Dr. Berwick took issue with the investigators' disclaimer that their findings apply only to the specific RFID systems they tested.

“Frankly the 2 tested systems are not unlike many others in current use, and attention must be paid to these disturbing findings,” wrote the president and chief executive officer of the Institute for Healthcare Improvement, based in Cambridge, Mass. (JAMA 2008;299:2898-99). ■



The findings are alarming because the application of such devices is increasingly being explored.

DR. BERWICK

Obstructive Sleep Apnea Tied to Need for Inpatient Acute Care

BY HEIDI SPLETE
Elsevier Global Medical News

BALTIMORE — Obstructive sleep apnea is associated with significant morbidity among hospital inpatients, based on a review of approximately 60,000 hospitalized patients at a single facility during a 2-year period.

“Our goal was to characterize the frequency with which OSA patients needed acute care,” said Dr. Lisa Wolfe of the division of pulmonary medicine at Northwestern University, Chicago. Dr. Wolfe presented the results of the study at the annual meeting of the Associated Professional Sleep Societies.

Increased morbidity has been associated with OSA in outpatients, but the impact of OSA on

inpatients has not been well studied, Dr. Wolfe said. The Joint Commission has invited the medical community to comment on how to reduce the risk of postoperative complications in patients with OSA, as it evaluates guidelines for patient care, she added.

Dr. Wolfe and her colleagues reviewed data from all hospitalized patients at Northwestern Memorial Hospital in Chicago between September 2005 and May 2007. Acute care management was defined as rapid response team calls, code calls, or unplanned transfers to the intensive care unit. OSA was identified based on medical records.

Overall, 56 of 1,377 patients

with OSA required action from a rapid response team, compared with 800 of 59,030 patients without OSA (4.1% vs. 1.4%). Similarly, significantly more patients

AMONG OSA PATIENTS, SIGNIFICANTLY MORE NONSURGICAL PATIENTS REQUIRED ACUTE CARE THAN DID SURGICAL PATIENTS.

with OSA required code calls, compared with patients without OSA (2.9% vs. 1.7%). On average, one patient with OSA underwent acute care management every 4.5 days.

Among patients with OSA, significantly more nonsurgical pa-

tients required acute care than did surgical patients (7.5% vs. 4.1%), but the reasons for this difference were unclear.

“We know that OSA is a predictor for other health problems,” Dr. Wolfe said.

The study was limited by its use of medical records and by a lack of data on continuous positive airway pressure (CPAP) therapy, but the findings support results from previous studies and emphasize the need for enhanced monitoring of hospitalized patients with OSA to reduce their use of acute care resources, she noted.

The topic of OSA as a marker of increased mortality in hospitalized patients attracted nation-

al attention in the wake of a study conducted at the Mayo Clinic in Rochester, Minn., in 2001, Dr. Wolfe said. In that study, which included patients who had undergone surgeries for hip or knee replacements, patients with OSA were significantly more likely to have complications, compared with control patients who didn't have OSA. The complications often were serious and contributed to longer hospital stays.

Further studies are needed to explore ways to ensure patient safety and to assess the implications of improved monitoring strategies for hospitalized patients with OSA, Dr. Wolfe added. Dr. Wolfe reported that she had no financial conflicts to disclose. ■