



NHLBI diabetes trial partially halted amid safety concerns

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See story #1

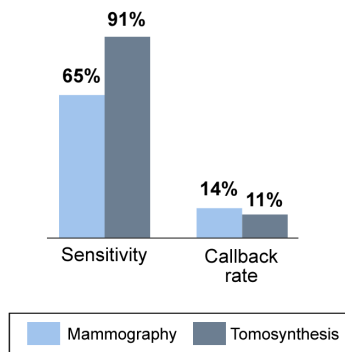
RESEARCH HIGHLIGHT

Tomosynthesis may replace mammography in next decade

Recent clinical trials indicate digital breast tomosynthesis yields higher sensitivity for detection of cancer with fewer false positives than conventional mammography by reducing the effects of tissue obstruction and overlap. If larger trials confirm these results, tomosynthesis could replace a majority of mammograms across the next decade, making the purchase of tomosynthesis-upgradeable full-field digital mammography equipment a wise consideration for hospitals upgrading to digital mammography today. To learn more, please see the Innovations Center’s *Future of Diagnostic Imaging* brief.

Early comparative results

Breast tomosynthesis efficacy versus mammography in 100 subjects



Source: Lo et al., *RSNA* 2006 abstract

THIS DAY IN BRIEF

Wal-Mart shifts retail clinic strategy with upgrades, provider partnerships

After one-fourth of Wal-Mart’s walk-in retail clinics unexpectedly shuttered last month, the world’s largest retailer today is expected to announce a revamped strategy that standardizes clinic operations and partners the company with hospitals and medical groups for several hundred new in-store clinics.

See story #2

Survival for elderly lung transplant patients largely positive, study says

Just as a growing number of surgeons are eschewing conventional practices that have historically excluded elderly patients from receiving transplanted organs, a new study in the February issue of the *Journal of Thoracic and Cardiovascular Surgery* finds that elderly lung transplant patients have “acceptable” survival rates, *USA Today* reports.

See story #3

FDA round-up: Generic biologics, generic Zyprexa, Fosamax

The *Daily Briefing* today summarizes recent FDA activity, including White House calls for the agency to have more authority over generic biologics, advisory panel approval of a longer-lasting version of Zyprexa (olanzapine), and approval of a generic version of the osteoporosis treatment Fosamax (alendronate sodium tablets).

See story #4

FROM THE ADVISORY BOARD

Regional Stroke Network Development teleconference announced

The Innovations Center is hosting a “Regional Stroke Network Development” teleconference to outline the major benefits, challenges, and recommendations surrounding stroke network implementation.

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St. Vincent Health System (Ark.) (#2) ■ UCLA Medical Center (#3)
University of Southern California (#7)



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Thursday, February 07, 2008

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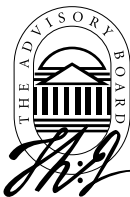
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► Today's Headlines

1 NHLBI diabetes trial partially halted amid safety concerns

The NIH's **National Heart, Lung, and Blood Institute** (NHLBI) has “abruptly” halted a portion of a large-scale clinical trial testing various treatment options for high-risk type 2 diabetes patients 18 months early amid evidence that more aggressive medical treatment regimens increased the risk of death compared with standard treatments. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) study enrolled 10,251 type 2 diabetics ages 40 to 82 from the United States and Canada who had a history of heart problems or at least two risk factors for cardiovascular disease. Citing substantial evidence that intensively lowering diabetes patients' blood glucose levels to near-normal levels decreases their risk of cardiovascular events, researchers randomized study participants to receive intensive treatment designed to lower their blood sugar to a target hemoglobin A1C of less than 6%—a typical level for adults without diabetes—or standard treatment aiming for a target A1C of 7% to 7.9%, the average achieved by most diabetics. The **American Diabetes Association** (ADA) has long recommended that type 2 diabetics aim for A1C levels below 7%, saying that every point-drop in A1C lowers the risk of serious complications such as blindness or kidney failure by as much as 40%. While the NHLBI researchers found that patients undergoing the more aggressive intervention—which included intensive insulin administration and blood sugar monitoring, frequent interactions with clinic staff, and other therapies—had a lower chance of developing cardiovascular problems, they also observed that adverse events within that group were associated with a far higher risk of death compared with the standard treatment group. At roughly four years follow-up, 257 patients in the intensive treatment group had died compared with 203 in the standard treatment group; the researchers note, however, that death rates in both treatment groups were still lower than those seen in similar populations in other studies. In stopping that portion of the trial, researchers said they will assign all patients in the intensive treatment group to begin receiving standard treatment and will continue tracking their outcomes. Noting that the underlying causes of the mortality disparity remain unclear, the researchers add that their analyses have not linked the increased mortality risks to any particular drug or combination of drugs.

The *New York Times* states that the “surprising results” are likely to “call in to question how [type 2 diabetes]...should be managed,” adding that the findings will present a challenge for the ADA as it seeks to update A1C recommendations. The NHLBI, meanwhile, says the results reinforce current practice, adding that diabetics with heart disease should aim to stop at an A1C level of 7% rather than dipping below that threshold. Noting that “we've got half a century of literature that is put on the back burner right now by one study,” the president of the **American College of Cardiology** cautions that the new NHLBI recommendations “may not be the final decision” (NHLBI [release](#), 2/7; Kolata, [Times](#), 2/7 [registration required]; Neergaard/Schmid, [Associated Press](#), 2/6; Cooley, [CQ HealthBeat](#), 2/6 [subscription required]).

SEPARATE *NEJM* STUDY TOUTS BENEFITS OF MULTIFACTORIAL DIABETES THERAPY

Meanwhile, a separate study published in today's *NEJM* finds that a combination of low-dose aspirin, cholesterol- and blood pressure-lowering medications, and intensive therapy designed to lower blood sugar significantly lowered the risks of all-cause mortality and cardiovascular death in type 2 diabetes patients already showing signs of kidney damage. For the study, Dutch researchers randomized 160 patients with type 2 diabetes and persistent microalbuminuria—the presence of a type of protein in the urine that indicates kidney damage has already occurred—to receive intensive, multifactorial treatment with angiotensin inhibitors, daily low-dose aspirin, and lipid-lowering agents or conventional therapy for a mean treatment period of 7.8 years. At 13.3 years follow-up, the researchers found that the intensive therapy group had experienced a 20% absolute risk reduction in all-cause mortality and

12.5% absolute risk reduction in death from cardiovascular causes compared with the standard treatment group. Additionally, 40 patients in the conventional therapy group died across the study period compared with 24 in the intensive therapy group, “underscor[ing] the poor prognosis in the absence of intense treatment,” according to the authors. Commenting on the findings, the study’s lead author notes that physicians treating type 2 diabetes patients with microalbuminuria should “use a comprehensive approach to reduce as many risk factors as possible” (Gaede et al., [NEJM](#), 2/7 [subscription required]; Gordon, [HealthDay](#), 2/6).

2 Wal-Mart shifts retail clinic strategy with upgrades, provider partnerships

After one-fourth of Wal-Mart’s walk-in retail clinics unexpectedly shuttered last month, the world’s largest retailer today is expected to announce a revamped strategy that standardizes clinic operations and partners the company with hospitals and medical groups for several hundred new in-store clinics, the *New York Times* reports. Previously, Wal-Mart leased space to a handful of independent firms that managed clinics across a total of 77 stores; as a result, clinic operations often varied from store to store, and Wal-Mart reportedly received only a day’s notice when financial problems forced New York-based CheckUps to shut down 23 of its store-based clinics in January. Moving forward, Wal-Mart will co-brand each clinic under its own logo and require the clinics to have consistent looks, prices, and record keeping systems. The company also will directly partner with health care providers to deliver treatment, beginning with the first “Clinic at Wal-Mart” in Little Rock, Ark., which will be run by **St. Vincent Health System** nurse practitioners when the clinic opens in April. Wal-Mart also plans to open 200 new clinics with RediClinics, which already operates 13 clinics in Wal-Mart stores and works by contracting with local health care providers.

As Wal-Mart aims to open 400 in-store clinics by 2010—and with fellow retailers CVS, Target, and Walgreen planning to open more store-based clinics of their own—the industry trade group **Convenient Care Association** (CCA) estimates that there will be more than 1,500 store-based clinics across all retailers by year-end, up from 800 in November 2007. However, industry analysts note that most clinics have yet to turn a profit, as in-store clinics need up to three years to recoup start-up costs. In addition, the clinics have drawn criticism from groups including the **American Academy of Pediatrics**, who contend the clinics “add to fragmentation in the health care system.” The CCA notes that about 7% of Americans have tried a store-based clinic at least once (Freudenheim, [Times](#), 2/7 [registration required]; [Times](#), 1/28 [registration required]; Kabel, [AP/Baltimore Sun](#), 2/7 [registration required]; Goldstein, [Wall Street Journal](#), 1/29 [subscription required]).

3 Survival for elderly lung transplant patients largely positive, study says

Just as a growing number of surgeons are eschewing conventional practices that have historically excluded elderly patients from receiving transplanted organs, a study slated for publication in the February issue of the *Journal of Thoracic and Cardiovascular Surgery* finds that elderly lung transplant patients have “acceptable” survival rates, *USA Today* reports. Although limited donor supply and survival concerns have prevented many elderly patients from receiving organ transplants, recent data suggests that the number of people ages 65 and older who received an organ transplant nearly tripled from 1,145 to 3,154 between 1996 and 2005. For the study, researchers from the **UCLA Medical Center** reviewed the medical records of 100 patients who received lung transplants at the facility between March 2000 and September 2006 and found that 50 of the lung transplants reviewed were performed on patients between ages 65 and 72; the remaining 50 transplants were performed on patients younger than 65. While acknowledging that the older cohort was more likely to receive single-lung transplants and nonstandard lungs—those deemed “less than perfect” by transplant

teams—the researchers say the two groups had comparable early survival rates of 95.7% for older patients and 95.9% for younger patients. However, they report that the disparity widened after one year, with older and younger patients posting 79.7% and 91.2% survival rates, respectively. Three-year survival rates were 73.6% for the older cohort compared with 74.2% for the younger cohort.

Noting that the one-year survival gap likely stemmed from older patients' susceptibility to infection, the researchers say the findings "warrant[t] adjustments in the immunosuppression protocols for older patients." The study's lead author adds that future research should examine "the effects of lung transplantation in older recipients on the donor pool and on other, younger patients on the waiting list." Noting that several decades ago, the idea of transplants for elderly patients would have seemed farfetched, the vice chairman of the ethics committee for the **United Network for Organ Sharing** says the industry has "broadened [its] horizons," adding that "if [those] were organs that were going to go into the trash, then it seems like a win-win" (UCLA [release](#), 2/4; Davis, [USA Today](#), 2/4).

4 FDA round-up: Generic biologics, generic Zyprexa, Fosamax

The *Daily Briefing* today summarizes recent FDA activity, including White House calls for the agency to have more authority over generic biologics, advisory panel approval of a longer-lasting version of Zyprexa (olanzapine), and approval of a generic version of the osteoporosis treatment Fosamax (alendronate sodium tablets).

WHITE HOUSE CALLS FOR FDA AUTHORITY OVER GENERIC BIOLOGICS IN BUDGET PLAN

In releasing its \$3.1 trillion budget proposal for fiscal year (FY) 2009 this Monday, the White House said it would seek to give the FDA the authority to regulate generic biologic drugs, in addition to recommending a \$130 million budget increase for the agency. According to FDA COO John Dyer, the agency has begun drafting a proposal to establish this authority; Sen. Charles Schumer (D-N.Y.) also reports that FDA Commissioner Andrew von Eschenbach has approached him with hopes of speeding generic biotech drugs to the market. *CQ HealthBeat* notes that lawmakers have previously—but unsuccessfully—pursued similar legislation to give the FDA authority over follow-on biologics (see related story in the Feb. 15, 2007, [Daily Briefing](#)). Meanwhile, the Bush administration also said it is seeking \$2.4 billion for the FDA in FY 2009, marking a 5.7% increase over the current year's budget; Congress would provide \$1.77 billion, with the remaining \$628 million coming from drug and device maker user fees. Under the plan, the FDA would see increases of \$42.2 million for food safety and \$17.4 million for medical product safety and development (Agnes Carey, [CQ HealthBeat](#), 2/4 [subscription required]; Corbett Dooren, [Wall Street Journal](#), 2/4 [subscription required]; [CongressDaily](#), 2/6 [subscription required]; Dixon, [Reuters](#), 2/6).

FDA PANEL VOTES TO RECOMMEND LONG-ACTING ZYPREXA FOR SOME PATIENTS

A committee of FDA advisors yesterday unanimously recommended the approval of a long-acting, injectable form of **Eli Lilly's** schizophrenia drug Zyprexa. While FDA scientists said Zyprexa Adhera—which is injected into muscle and designed to last two to four weeks—appears effective in treating schizophrenia, they voiced concern about the "profound sedation" observed in 24 of 1,915 patients exposed to long-acting Zyprexa in clinical trials. In making its recommendation, the panel said use of the injectable version should be limited to patients with a history of poor medication adherence. Currently, Zyprexa is sold as a once-daily pill to treat schizophrenia and bipolar disorder (Goldstein, [Wall Street Journal](#), 2/6 [subscription required]; Corbett Dooren, [Wall Street Journal](#), 2/5 [subscription required]; [AP/Boston Globe](#), 2/6 [registration required]).

TEVA, BARR RECEIVE APPROVAL FOR GENERIC FOSAMAX

Generic drug makers **Teva Pharmaceutical Industries** and **Barr Pharmaceuticals** yesterday received final marketing approval for a generic version of **Merck**'s osteoporosis treatment Fosamax—one of the most frequently dispensed drugs in the nation. The FDA approved Teva to manufacture three once-daily dosing strengths of 5, 10, and 40 milligrams and two once-weekly dosing strengths of 35 and 70 milligrams; Barr was cleared to manufacture a 70 milligram once-weekly dose. Both companies will begin shipping the drugs immediately under 180 days of market exclusivity (AP/CNNMoney.com, 2/6; FDA [release](#), 2/6).

► From the Advisory Board

5 Regional Stroke Network Development teleconference announced

More and more hospitals are delivering superior stroke and cerebrovascular care to wider service areas by engaging in mutually beneficial hub-and-spoke referral networks. Driven in part by legislative and credentialing trends, stroke network development requires dedicated coordination among hospital departments, first responder services, and collaborating institutions. In addition, telemedicine can enable specialist consultation for stroke diagnoses and facilitate referrals when interventional care is necessary.

The Innovations Center is hosting a “Regional Stroke Network Development” teleconference featuring a panel discussion of leading stroke care experts on Feb. 13 at 1 p.m. EST to outline the major benefits, challenges, and recommendations surrounding stroke network implementation. Panelists will include Dr. Marilyn Rymer from the **Mid America Brain and Stroke Institute**, Bill Hamilton from **REACH Call™** and **MCG Rural Telestroke Network**, and Robert Fisher from the **Michigan Stroke Network**.

For more information

Health Care Advisory Board members may register for this upcoming teleconference on the Advisory.com [website](#). For more information on the Health Care Advisory Board, please contact Neha Shah at shahn@advisory.com.

6 H*Works provides hospital leaders with permanent results

H*Works recently announced four new additions to its robust portfolio of engagements: **The 100 Day Volume Campaign**, **The High-Performing Hospital Diagnostic**, **The Employee Engagement Initiative**, and **The Physician Practice Improvement Engagement**.

H*Works, the consulting division of the Advisory Board Company, actively partners with hospitals to help them achieve lasting results by implementing those best practices that address their greatest operational, financial, and strategic issues. By addressing only those problems for which the Advisory Board has already amassed a substantial body of best practices, tools, and case study experience, H*Works offers an answers-first advantage installing known, proven practices and processes quickly and with sustained results.

For more information

To learn more about the full range of offerings in the H*Works portfolio and how they can be applied to your hospital's top priorities, please contact Liz Colacicco at colacice@advisory.com or 202-266-5478.

► Regional Round-up

7 Around the nation: Bite-sized hospital and health industry news



- **California:** Uninsured Californians pay more on average for hospital services than government payers such as Medicare despite statewide efforts to curb aggressive collection practices, according to a study released this week by the RAND Corp. and the **University of Southern California**. According to the findings—based on 2001–2005 data submitted by hospitals to a state agency—hospitals collected payments that were 18% higher on average from uninsured patients than from Medicare patients between 2001 and 2002 and roughly 20% higher between 2004 and 2005. Noting that the uninsured paid the same or higher rates than Medicare from 2001 to 2005—a period when Medicare payments to California hospitals increased by about 13%—the researchers conclude that actual net prices paid by the uninsured increased across the study period. Hospital officials, meanwhile, say the findings do not take into account steps the industry has taken recently to reduce the burden on the uninsured, with a spokesperson for the **California Hospital Association** calling the report “completely irrelevant to what’s happening in hospitals today” (Colliver, [San Francisco Chronicle](#), 2/5).
- **Illinois:** A new partnership announced this week involving **HHS**, the **American Medical Association**, the Chicago Department of Public Health, and dozens of other health advocacy groups aims to help Chicago residents achieve healthy lifestyles. The new initiative will focus on managing chronic conditions, reducing obesity, and controlling high blood pressure. Organizers will meet across the next 18 months to examine current programs and design new ones. HHS officials note that they hope to implement similar partnerships in other major cities ([Arlington Heights Daily Herald](#), 2/5; [Cityofchicago.org release](#), 2/4).
- **Iowa:** State legislators have introduced a measure that would extend health coverage to all Iowa children within the next three years. In addition to expanding existing programs to include 25,000 more children, the proposal would provide subsidies to parents of an additional 19,000 children to enroll in private health care plans; the subsidy would likely be offered to families with incomes ranging from 200% to 300% of the federal poverty level. The measure also would create a Health Care Insurance Exchange, a semi-public agency that would oversee standards for assistance, among other issues (Glover, [AP/Chicago Tribune](#), 2/5 [registration required]).
- **Tennessee:** Under new rules approved by the state’s Board of Medical Examiners on Jan. 22, plastic and oral surgeons and other physicians who perform office-based procedures requiring anesthesia would have to register with the state and undergo inspections to satisfy stricter safety regulations. The new rules—which would bring physician office-based procedures requiring general anesthesia under the same guidelines as those performed in hospitals and outpatient surgery centers—also would limit to four hours the expected length of procedures performed in surgical suites and would allow for only three patients to be incapacitated at one time. In addition, physicians would be required to have admitting privileges at a hospital within 30 miles. The rules must receive approval from the state attorney general before becoming law (Ward, Nashville [Tennessean](#), 2/6).
- **Washington:** Nursing union leaders and the **Washington State Hospital Association** have agreed to a measure that would require each hospital in the state to devise a staffing plan designed to facilitate safe patient care. Under the agreement, which hinges on legislative

approval, hospitals would designate nurse staffing committees to create “unit-by-unit, shift-by-shift” nurse staffing plan. Additionally, hospitals would be obligated to post the amount of budgeted staff in their facilities and report actual staffing levels (Ostrom, [Seattle Times](#), 2/5; Ammons, [AP/Tacoma News Tribune](#), 2/5).

► Endnotes

8 Et cetera

Sleepless Sunday: Most adults say Sunday is worst night of sleep

A survey of 3,500 adults conducted by the hotel chain Travelodge finds that nearly 60% of respondents reported having their worst night’s sleep on Sunday, while 80% said they sleep the soundest on Friday night, BBC News reports. Additionally, when questioned about the consequences of sleep deficits, nearly half of adults said they suffered from a lack of concentration at work, one-third reported becoming irritable, and one-fifth said they had nodded off at their desks. More than one-quarter of respondents, meanwhile, said they had called in sick on Mondays after having a bad night of sleep—which they attributed to factors including having a difficult boss, having to give a presentation, and missing a work deadline. A sleep expert from the Norfolk and Norwich University Hospital in England says that while work stress is one cause of restless nights, sleeping patterns also become “messed up by having lie ins and late nights; people don’t tend to do much physical or mental activity on Sunday.” Noting that “what your body really wants is to go to bed and get up at the same time each day,” he recommends that people alleviate insomnia by staying active during the day and maintaining a routine sleep cycle.

—[BBC News](#), 1/21