

CHP/PCOR Quarterly Update

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CHP/PCOR study influences HIV screening guidelines

In late September, the federal Centers for Disease Control and Prevention announced new guidelines recommending that all Americans ages 13 to 64 be voluntarily screened for HIV. That's a big change from the prior guidelines, which recommended testing only for high-risk individuals, such as those with multiple sex partners.

The guidelines were influenced by a study published last year in the *New England Journal of Medicine*, led by **Douglas Owens**, a CHP/PCOR core faculty member and an investigator at the VA Palo Alto. Owens and his colleagues, including CHP/PCOR researchers and affiliates **Gillian Sanders**, **Vandana Sundaram**, **Kristof Neukermans** and **Laura Lazzeroni**, found that expanding HIV screening would be a cost-effective way

to increase life expectancy and decrease the transmission of HIV. Below, Owens discusses the study and the new screening guidelines.

Q. Why does this new policy matter, and whom will it help?



Douglas K. Owens

Owens: The policy is a profound change because it advises that all individuals ages 13 to 64 be screened for HIV. It matters because it will identify people who have HIV but don't know it. These people will benefit because they'll have access to life-prolonging drugs that they otherwise might not have received until very late in the course of HIV disease. The rest of

the community will benefit, through reduced transmission of HIV.

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Study aims to measure, improve hospitals' safety culture

Executives at Northwest Hospital Center in Baltimore, Md., thought they were doing a good job of promoting patient safety and quality care. The 200-bed community hospital participates in a statewide patient safety consortium; it closely monitors data on key safety measures, such as patient falls and infections; and it has implemented initiatives aimed at meeting a national accrediting body's annual patient safety goals.

Northwest's leadership was interested in knowing how their 295 physicians and 1,500 staff members felt about patient safety issues: Did they have the resources they needed to provide the safest possible care? If they saw a

co-worker make a mistake, would they report it, or keep quiet for fear of being punished? Did they believe management understood the problems at their facility that could lead to medical errors?

Like most hospitals, Northwest had few resources to gain such insight. So when the hospital's leadership was approached in 2004 by CHP/PCOR researchers about participating in a national study of patient safety culture, they gladly signed up.

The study, led by CHP/PCOR fellow **Laurence Baker**, is the largest effort to date to measure

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Anthrax in children difficult to detect and treat, report finds

Difficulties in diagnosing anthrax may lead to dangerous delays in caring for children infected with the deadly disease, finds a report by CHP/PCOR researchers with the Stanford-UCSF Evidence-based Practice Center. Treating pediatric anthrax is a special challenge because currently recommended therapies (including antibiotics such as ciprofloxacin) have not been widely used to treat children with the disease.

The report, titled “Pediatric Anthrax: Implications for Bioterrorism Preparedness,” was prepared for the federal Agency for Healthcare Research and Quality (AHRQ) and was publicly released in mid-August.

Since anthrax exposure occurs rarely in the United States and most of the recent cases have been naturally occurring, clinicians may not have firsthand knowledge about the disease and might have difficulty diagnosing it. In addition, symptoms of pediatric anthrax can be easily confused with those of more common respiratory infections; inhalational anthrax has symptoms similar to influenza, for example. Also, there is little evidence about the effectiveness in children of interventions currently recommended for adults.

“This report provides important information for dealing with exposure of children to anthrax,” said AHRQ director Carolyn M. Clancy. “It analyzes what is currently known about how this terrible disease affects children and identifies research needed to make us more effective in protecting our children from anthrax.”

The researchers — led by CHP/PCOR senior scholar **Dena Bravata**, with **Jon-Erik Holty**, **Robyn Lewis**, **Paul Wise**, **Smita Nayak**, **Hau Liu**, **Kathryn McDonald** and **Douglas Owens** — found very little published evidence about the efficacy of treating children who have anthrax with newer antibiotics such as ciprofloxacin. They also

found no reports of using anthrax vaccine for children. The report calls for more research on the effectiveness in children of non-antibiotic therapies that have been used with considerable success in the past, such as anthrax antiserum and pleural fluid drainage.

Anthrax typically is contracted by direct contact with the bacterium *Bacillus anthrax*, an organism that grows in the soil. It commonly causes illness in farm animals, and is not transmissible from one person to another. The three principal types of anthrax are cutaneous, gastrointestinal, and inhalational. The most widely reported recent cases of anthrax in the United States followed the introduction of bacterial spores into the U.S. mail system in 2001, which resulted in five deaths among 22 cases.

For the report, investigators analyzed 62 pediatric cases obtained through an extensive review of the scientific literature. Because case reports of pediatric anthrax are rare, investigators examined cases from as early as 1900, to maximize the available evidence. More than half the cases involved children between ages 14 and 18; data on younger children, especially those under age 2, were more limited. There were only two cases of inhalational anthrax, the most deadly form of the disease.

Bravata noted that the recent *E. coli* outbreak from contaminated spinach — which resulted in severe morbidity and mortality principally among children — reminds us of children’s vulnerability to infectious agents, and highlights the importance of public health planning specifically for children. ❖

This article was based on an AHRQ press release. The pediatric anthrax report, and an interview with Bravata, were featured in AHRQ’s “Healthcare 411” weekly podcast series in September.

Collaborative project studies intersection of health, governance

Modern medicine has produced interventions that seem almost miraculous in their ability to prevent and treat deadly diseases. The use of chemically treated mosquito nets can drastically reduce malaria infections, for example, while powerful antiretroviral drugs can give HIV/AIDS patients added years of life.

While these advances are cause for great optimism, they’re not necessarily enough to bring about promised health improvements, particularly in developing countries. Experience has shown that good governance — stable, accountable political systems that can manage resources responsibly and take care of their citizens’ needs — may be crucial to the success of disease-fighting

efforts. Health programs run by incompetent, corrupt or illegitimate governments will likely falter, no matter how well-equipped or well-intended. In 2002, for example, the World Health Organization launched its “3x5 campaign” to get 3 million HIV/AIDS patients in developing countries on antiretroviral treatments by 2005. While the initiative made significant headway, it fell far short of its goal, likely due in part to some nations’ ineffective management and weak healthcare infrastructure.

To explore this issue in depth and to improve developing nations’ responses to infectious diseases and other healthcare challenges, CHP/PCOR is collaborating with

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HEALTH & GOVERNANCE, FROM PAGE 2

the Center on Democracy, Development and the Rule of Law (CDDRL) on a seed project involving physicians, economists, political scientists, engineers and nongovernmental organizations. The researchers, supported by a generous private donation, are examining these key questions: What are the limitations of providing technical healthcare solutions in developing countries? How do governments help or hinder the implementation of these solutions? When governments fail to help, how and when should nongovernmental organizations step in? When are NGOs effective, when are they ineffective, and what lessons can be learned from their experiences?

The project — believed to be the first multidisciplinary scholarly examination of the relationship between governance and health — is important because “medical discoveries can produce wonderful interventions, but if you can’t get them to the people who need them, it’s not worth much,” said CHP/PCOR faculty member **Paul Wise**, a lead investigator for the project.

Wise explained that while some simple interventions — such as giving a one-dose vaccination — can succeed without much government help, other interventions — such as administering complex multi-drug regimens over several months — seem to depend much more on elements of good governance, including well-trained health workers, government financial support, and a network of clinics that serve people even in remote areas.

In an extreme example of what happens when supportive governance is lacking, government officials in South Africa have at times undermined NGOs’ efforts to administer anti-retroviral therapies to AIDS patients there, by failing to provide financial support and by spreading dangerous rumors that the drugs actually cause AIDS.

In cases like these, Wise said, “lack of adequate governance is no excuse for inaction. You can’t sit around and wait for good governance while people are dying; you’ve got to struggle through it and demand appropriate government action.”

For the Health and Governance Project, researchers will gather and analyze data from case studies focused on various diseases and interventions in different parts of the world. Potential case studies include malaria and HIV/

AIDS in Africa, air pollution in China, and tuberculosis and HIV/AIDS in Russia. Further details will be worked out at a planning workshop at Stanford later this year, which will bring together faculty from several Stanford departments, including medicine, political science, economics and engineering. Additional conferences will be held this spring and summer, featuring outside experts and NGO leaders as well as the Stanford investigators.

From their analyses, the researchers aim to uncover general lessons and develop policy recommendations on how best to combat disease in the developing world. They will present their findings in workshops and white papers, and by next fall they plan to pursue a major grant from the Bill and Melinda Gates Foundation.



Red Cross volunteers administer measles vaccines to children in Kenya in June 2002.

Photo by Daniel Cima, American Red Cross

The Health and Governance project grew out of discussions between faculty at CHP/PCOR and CDDRL over the last year and a half. Kathryn Stoner-Weiss — CDDRL’s associate director of research, senior research scholar and a lead investigator on the project — became interested in a possible collaboration when she attended CHP/PCOR’s 2004 annual retreat and heard Wise speak about his work on health disparities among different socioeconomic and

racial groups, and the question of whether new medical technologies narrow or widen those gaps.

“A lot of the problems Paul was talking about had to do with politics and government, not just health care,” Stoner-Weiss said. “I realized that fit in very well with much of what we do at CDDRL,” studying how and why states fail and what the consequences are for their citizens.

After further contact between Stoner-Weiss, Wise, CHP/PCOR executive director and senior scholar **Kathryn McDonald**, and Jeremy Weinstein — an assistant professor of political science, who has studied insurgent violence in Africa and Latin America — the four began discussing the idea of a research proposal focused on governance and health. The project became a reality late last spring when Howard and Karin Evans — Stanford alumni interested in improving health in developing countries — had a similar interest and offered to support the effort with a seed grant.

“Who better to do a project like this?” Wise said. “We have world-class health policy experts working with world-class experts on governance. It’s a no-brainer.” ❖

Many without insurance can afford coverage, study finds

When policymakers discuss the problem of the uninsured, they often say the reason so many Americans don't have health insurance (currently estimated at 46 million) is that the coverage is "unaffordable." But a study by CHP/PCOR fellow **Kate Bundorf** and adjunct associate **Mark Pauly**, published in the July issue of the *Journal of Health Economics*, reaches a somewhat different conclusion.

The study finds that depending on the definition of "affordability" that is used, health insurance can be said to be "affordable" to between one-quarter and three-quarters of the uninsured — a group the researchers call "uninsured afforders." The study also finds that there are many people who have obtained health insurance without being able to afford it — a group the researchers call "insured non-afforders."

The paper, believed to be the first scholarly attempt to define "affordability" in the context of health insurance, doesn't make specific policy recommendations on how best to reduce the number of uninsured. But Bundorf and Pauly conclude that "making insurance affordable for everyone who cannot afford it will not come close to achieving universal coverage" and that "dramatic reductions in the number of uninsured will require policies targeted to both those who can and cannot afford coverage."

If society prefers to give health insurance subsidies only to those who can't afford coverage, for example, then imposing an individual mandate may be appropriate for those who can afford coverage, the authors say.

Bundorf said that "when policymakers talk about the uninsured, the issue of affordability comes up all the time, but no one had really defined what affordability means" in terms of health insurance. So she and Pauly set out to examine the question in a methodical, quantifiable way.

In their study, they proposed two key approaches, which they called normative and behavioral, to defining health insurance affordability, and they examined how using various definitions changes the estimates of the proportion of U.S. uninsured who can't afford coverage. According to a normative definition, health insurance is considered affordable for an individual if, based on that person's income and the cost of the insurance plan, the individual can purchase health coverage and still have enough money left over for necessary goods including housing, food and clothing.

The behavioral definition of affordability is based not on particular income or price thresholds, but on how most people actually behave with respect to purchasing health insurance. Imagine, for example, that a group of 100 people with the same income are considering purchasing a specific health insurance plan at a given cost. If most of those individuals ("most" could mean 55, 75 or 90 percent, depending on the precise definition) purchase the health plan, the plan is considered "affordable" at that price. But if most people in the group do not purchase the health plan, it would be considered "unaffordable" at that price.

Bundorf and Pauly do not advocate using a particular definition of affordability; instead, they examine how the number of "uninsured afforders" and "insured non-afforders" changes when various definitions are used. For their study, they analyzed year 2000 data from the federal government's Medical Expenditure Panel Survey, which provides detailed information on individuals' insurance status as well as their demographic, socioeconomic and health information.

'The uninsured are pretty diverse, so if you want to reduce the number of uninsured, you need to develop policies targeting both groups.'
-Kate Bundorf

To apply the normative definition of affordability, the researchers examined rates of insurance coverage by poverty-level indicators. To apply the behavioral definition, they used regression models to examine the relationship between insurance coverage and individual characteristics related to the affordability of insurance, such as employment, income, and family structure.

The authors found that no matter which definition of affordability they used, a sizable portion of the uninsured — ranging from 25 percent to 75 percent — could afford to buy coverage but chose not to. They also found that a small portion of those who couldn't afford to buy health insurance purchased it anyway, apparently placing a high value on health coverage.

The findings, Bundorf said, show that "the uninsured are pretty diverse, so if you want to reduce the number of uninsured, you need to develop policies targeting both groups" [those who can and cannot afford insurance]. She noted that "if you're only going to give subsidies to those who can't afford health insurance, you're going to miss a significant portion of the uninsured," and other types of policies, such as an individual mandate, may be necessary to reach them.

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CHP/PCOR Profile: Katherine Herz

Research interests: children's health, economic development and public policy, in the United States and abroad

Where she's from: born and raised in the Washington, D.C. area

Education: BA in economics from Princeton, and an MD from UC-San Francisco, where she also completed a pediatrics residency. For her senior thesis at Princeton, she studied the impact of Medicaid-provided prenatal care on the incidence of low birthweight, and found that regular prenatal care translated into fewer low-birthweight babies, suggesting that spending on the care was worthwhile.



Work at CHP/PCOR: As a trainee in the AHRQ's Fellowship in Health Care Research and Policy, Herz is conducting a cost-effectiveness analysis of combination drug therapies for malaria in Uganda, in collaboration with infectious disease specialists at UC-San Francisco. Herz will be analyzing data the UCSF researchers have obtained from several randomized clinical trials they've conducted in Uganda, evaluating the use of one artemisinin-based drug and two other, non-artemisinin-based therapies.

Career interests: Herz wanted to be a pediatrician since age 6, and her interest in human biology dates back even further. According to a much-told family story, when she was 3 years old she needed to have blood drawn, and when the nurse told her to look away, she cried because she wanted to see the blood! She was drawn to pediatrics because "that's where you can get a big return on a person's health. If you treat a child [for a disease], it can have a huge impact on the rest of their life."

Herz is also interested in health policy, specifically in promoting policies that will improve public health in disadvantaged communities and developing countries. "I'm drawn to global health, but I also realize there are more than enough health problems and disparities to go around in the U.S."

Work in policy/politics: As the daughter of a World Bank economist (her mother) and a National Science Foundation lawyer (her father), Herz grew up around policy discussions and absorbed an interest in politics. In college, she did two Capitol Hill summer internships — at the Department of Health and Human Services' Public Health Policy Division, and the Congressional Caucus for Women's Issues. She spent two other summers volunteering for the Clinton-Gore campaign (1992) and the Kerry-Edwards campaign (2004), doing event planning and audience building. She recalls the work as exhausting and all-consuming, yet rewarding. "You really felt like you were part of something."

Hobbies: skiing, reading, cooking, hiking, remodeling her Mountain View condo

Little-known fact: Herz has served as a certified Wilderness First Responder, and has done treks in Peru, Mt. Shasta and Nepal (Mt. Everest base camp).

INSURANCE AFFORDABILITY, FROM PAGE 4

Policymakers in Massachusetts are grappling with these issues as they craft policies to implement the state's new health insurance law, which requires all state residents to purchase health insurance by July 1, 2007, and requires employers in the state with 11 or more employees to provide coverage for workers or pay an annual fee of \$295 per worker. The law also will establish a low-cost,

state-subsidized health insurance program for residents with annual incomes less than 300 percent of the federal poverty level, and will expand Medicaid coverage for state residents.

In the combination of approaches the Massachusetts policymakers are using to achieve near-universal health coverage in their state, "you can see the tension we point to in this paper," Bundorf said. ❖

Harkness Fellow presents findings on technology coverage decisions

After spending the last academic year surveying and interviewing decision makers at major U.S. health systems, **Stirling Bryan** has become something of an outside expert on how medical technology coverage decisions are made in the United States.

At a CHP/PCOR special seminar on Aug. 2, Bryan — a professor of health economics at the University of Birmingham (U.K.) and a 2005-06 Harkness Fellow in Health Care Policy — presented the results of his fellowship research project, which he conducted while based at CHP/PCOR during the 2005-06 academic year. The project was aimed at understanding how medical-technology coverage decisions are made in the United States; how cost-effectiveness information is used (or not) and why; and how coverage policy could be improved in the U.S. and the U.K.

Bryan undertook case studies of four large U.S. healthcare systems: Kaiser Permanente, Aetna, Blue Cross Blue Shield, and the Veterans Health Administration. He conducted written surveys and audiotaped interviews of 16 key decision-makers at the organizations; convened roundtable discussions among them; attended meetings of their technology coverage review committees; and reviewed documents from those committees.

At all four systems, Bryan found that technology coverage decisions are made based on systematic information-gathering and analyses of published clinical evidence — a process he found thorough and objective. Coverage decisions, he noted, are made by formal committees, using evidence-based criteria. And when the organizations revise their policies or forge new ones, he said, “there is an impressive, organization-wide process to gather views and input from across the organization,” thus increasing the chance that clinicians and other stakeholders will follow the new policies.

On the other hand, Bryan’s research confirmed that U.S. healthcare systems generally do not incorporate cost-effectiveness information into their decision-making, with a few notable exceptions (such as the VA’s drug formulary). In fact, they make a conscious effort to avoid cost considerations, even when stakeholders try to raise the issue. This is in contrast to the U.K.’s National Health Service, which commissions independent cost-effectiveness analyses of medical therapies and technologies through the National Institute for Health and Clinical Excellence (NICE), and uses

these analyses to help decide which health services will be covered for all U.K. citizens.

While several of the U.S. decision-makers Bryan interviewed said they personally support using cost-effectiveness information, they said their organization tends not to do so because of a feared backlash from enrollees and the media. “I found widespread frustration with the lack of use of cost-effectiveness information,” Bryan told attendees at the Aug. 2 seminar. “People told me, ‘What we don’t want to be doing is publicly saying we’re considering cost, because that would get us in trouble.’”

Bryan identified the following major barriers to the use of cost-effectiveness information in the United States:

- **Litigation/regulation.** Health plans fear that if they exclude a service from coverage based on cost-effectiveness, they’ll be sued by disgruntled enrollees, or a state oversight board (such as California’s Department of Managed Health Care) could overrule their decision on appeal.
- **Free-market preference.** Americans prefer relying on market-based approaches to limit healthcare spending, such as “consumer-driven health plans” that make patients pay a greater share of their healthcare expenses.
- **Cultural resistance.** Americans resist any notion of rationing medical services, believing they can (or should) “have it all.”

Given the large number of uninsured Americans, the high and rising cost of U.S. health care, and the fact that medical technology use is a major contributor to rising costs, Bryan said the U.S. healthcare system must ultimately incorporate cost-effectiveness information into its decision-making. He proposed that health insurers be “bolder” and test the market with a new class of so-called “prudent health plans,” which would cover a comprehensive package of health services but would exclude high-cost therapies that provide only marginal benefit.

Seminar attendees noted that the Massachusetts law passed in April, requiring all of the state’s uninsured residents to obtain health coverage, will for the first time create a viable market for such a “prudent health plan.”



Stirling Bryan

HIV SCREENING, FROM PAGE 1

Q. How did your findings contribute to the CDC adopting the new guidelines?

Owens: First, we found that widespread screening provides a substantial health benefit to HIV-positive people who are identified through screening and receive treatment earlier than they would have otherwise. Early treatment added about a year and a half of life expectancy for these people. Second, we found a substantial potential benefit to the community because of reduced transmission of HIV. Transmission is reduced because many people cut down on risky behaviors (like unprotected sex) when they're identified as having HIV, and because anti-retroviral treatment makes a person less infectious. Our key finding was that routine screening is cost-effective even if only 1 in 2,000 people who are screened have HIV. This means HIV screening is cost-effective in a much broader group than was recognized previously.

Q. How and why did the CDC revise its guidelines? What role did you play in the decision-making?

Owens: CDC officials made this change because they saw mounting evidence that the prior approach to screening — focusing on those with identifiable risk factors — simply wasn't working. If you test people based on risk behavior, you miss many people who have HIV. Even among people who had easily identified risk behaviors, many of them weren't being tested. We also know that most people who have HIV are diagnosed very late in the disease, when they can't get the full benefit from anti-retroviral therapy.

Our involvement in the decision-making was to help assess the prevalence of HIV at which routine screening would be recommended. Through several conference calls with CDC officials, we presented our work and explained the issues related to cost-effectiveness and prevalence. Based on those results and the results of a similar study from Yale, the agency went in the direction of lowering the threshold for screening quite substantially — to 1 in 1,000 from a prior threshold of 1 percent.

Q. Will most physicians follow the new guidelines? What can be done to make sure they do?

Owens: That's the big question. The CDC's previous screening guidelines were not widely adopted. The new recommendations are much easier to adopt, because they don't depend on clinicians determining the prevalence of HIV in their patient population. Still, it will take a lot of follow-up to make sure physicians implement the guidelines. One key obstacle will be getting payers to reimburse for HIV testing. That's a critical issue, which the CDC is well aware of.

Q. Some HIV/AIDS advocates object to the new guidelines because they recommend removing two requirements that some states now have: mandatory signed consent forms and counseling before testing. Does removing these requirements pose a big problem?

Owens: It's important to note that the new guidelines say people should always be informed before testing and should be able to decline. Informed consent and pretest counseling had become significant barriers that were preventing people from being tested. Everyone agrees that no one should be tested without their knowledge, but that doesn't mean you need a separate consent form. Of course, the confidentiality of the test results should continue to be carefully protected. I would point out that some states have laws requiring informed consent, but whether they will now change those laws isn't clear. ❖

Announcements from summer '06

CHP/PCOR core faculty member **Jay Bhattacharya** has been appointed as a research fellow at the Hoover Institution, for a two-year period beginning September 2006. The fellowship supports Bhattacharya's health policy research — particularly on the economics and public policy of obesity — and it gives him access to the Hoover Institution's archives and other resources. Jay will have an office at Hoover, though he will still be based at CHP/PCOR.

A paper co-authored by CHP/PCOR core faculty member **Grant Miller**, on "The Role of Public Health Improvements in Health Advances: The 20th Century United States," was selected as the winner of a new award given by the American Sociological Association's Section on the Sociology of Population. The biennial award recognizes distinguished contribution to literature in population, and was announced at the annual meeting of the American Sociological Association. The paper was published in February 2005 in *Demography*.

CHP/PCOR senior research scholar **Sara Singer** was awarded, for a second year, a Doctoral Research Award and an appointment as a Pre-doctoral Fellow from the Center for Public Leadership at the Kennedy School of Government for the 2006-07 academic year.

On Sept. 7, CHP/PCOR's Center on Advancing Decision Making in Aging (**CADMA**) held the first in a series of Interdisciplinary Dialogues, on the topic of "Obesity, Physical Activity and Aging." The discussion brought together 12 junior and senior investigators from a variety

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CHP/PCOR in the news, summer 2006

- Indiana's state health department in July ended a free osteoporosis screening program, citing a CHP/PCOR study which questioned the accuracy and value of heel ultrasound, the technology used in the testing program.

The study, led by recently graduated trainee **Smita Nayak** and published in June in the *Annals of Internal Medicine*, evaluated all the available research on the accuracy of heel ultrasound to identify patients with osteoporosis according to WHO guidelines. According to the study, there is not enough evidence that the use of heel ultrasound can definitively rule in or rule out a diagnosis of osteoporosis based on the WHO criteria.

- *Science News* magazine reported on a study that CHP/PCOR trainee **Hau Liu** presented at the Endocrine Society's annual meeting (June 24-27 in Boston), on the use of human growth hormone in healthy elderly people for its supposed anti-aging benefits. Based on their meta-analysis of 19 clinical trials, Liu and colleagues found that human growth hormone has substantial risks and no functional benefits for healthy elderly people. In the clinical trials, those who took human growth hormone experienced more joint pain and swelling than those who took a placebo.

- A study led by CHP/PCOR associate **Alex Macario**, professor of anesthesia, found that the use of radio frequency ID tags (RFID) can help surgeons eliminate the problem of instruments being left inside a patient's body after surgery. In eight surgeries at Stanford, a surgeon inserted one or two RFID-tagged surgical sponges inside the patient's incision while it was still open. Another surgeon then used a 12-inch wand designed to detect the sponge.

In all cases, the surgeon accurately located the inserted sponges in less than three seconds. The wand never failed to detect a sponge and never indicated a sponge when none was present. The study appeared in July in the *Archives of Surgery*. Its findings were covered by several news outlets, including the *New York Times*, Reuters, the *Charlotte Observer*, *New York Newsday*, the *Washington Post*, Nature.com, RedHerring.com, ABCNews.com, and the Wall Street Journal's Web site.

- CHP/PCOR executive director **Kathryn McDonald** commented for a *Saint Louis Post-Dispatch* article that discussed how physicians nationwide are turning to evidence-based medicine to improve their patient care.

- An article in the *Dallas Morning News*, on new therapies to treat osteoporosis, quoted CHP/PCOR trainee **Hau Liu** and discussed his study evaluating the cost-effectiveness of the drug teriparatide (Forteo) versus the standard treatment alendronate (Fosamax).

- CHP/PCOR director **Alan Garber** provided comment for an Associated Press article on the debate surrounding the value of expensive high-tech treatments given to patients in their final months of life.

- Garber also commented in a *Washington Post* article about the FDA's recent approval of the first completely implantable artificial heart. Given its high cost and limited benefit for patients, Garber questioned the device's value, saying the money might be better spent on cheaper treatments that could help more people.

- Health care is consuming an increasing portion of the U.S. gross domestic product, but is the increased spending worth it? In a *New York Times* article on the debate, CHP/PCOR core faculty member **Victor Fuchs** said the answer is likely no. He noted that buying health care is fundamentally different from other consumer goods. A key consideration, he said, should be whether healthcare spending brings the most value for the dollar.

- With a different take on the issue, CHP/PCOR core faculty member **Jay Bhattacharya** was quoted in another *New York Times* column discussing a view held by some health economists (including Bhattacharya) that the United States' hefty healthcare spending *is* worth it, since the spending translates into longer life and a better quality of life for many patients.

- CHP/PCOR core faculty member **Alain Enthoven** commented for a *Christian Science Monitor* article on a new twist on overseas medical tourism: some U.S. companies are providing a health benefit that allows employees to go overseas for medical care, and some are considering plans that would require employees to go overseas. Enthoven said it's a sign that the U.S. healthcare system may be pricing itself out of reach.

- CHP/PCOR fellow **Laurence Baker** commented in a *San Francisco Chronicle* article on recent U.S. census figures which found that a record 46.6 million Americans had no health insurance in 2005 and that fewer people received coverage through their employer. Baker said the number of legislative efforts to reduce the number of uninsured shows rising concern over the issue. ❖

SAFETY CULTURE, FROM PAGE 1

and seek to improve hospitals' "safety culture," defined as a set of attitudes and beliefs about patient safety which pervade an organization, from the president to the housekeeping staff. The project builds on a decade of patient safety research conducted by **David Gaba** (a CHP/PCOR fellow and professor of anesthesia) and **Sara Singer** (a CHP/PCOR senior research scholar also studying at Harvard).

The concept of safety culture, now increasingly applied to health care, originated in high-risk fields such as naval aviation and nuclear power, where researchers found that an organizational culture of safety seemed to play a key role in fostering an excellent safety record. "It's hard to put your finger on it, because it's not something concrete," Baker explained. "It's basically an attitude that says safety takes precedence over everything else."

The patient safety project is aimed at producing a detailed picture of patient safety culture in the nation's hospitals; examining whether certain kinds of hospitals have a stronger safety culture than others; determining whether safety culture is associated with patient outcomes; and testing whether it can be improved through an intervention that gets hospital executives out of their offices and brings them into closer contact with staff on the front lines.

The 92 participating hospitals include those large and small, for-profit and nonprofit, rural and urban, academic and community-based. In the project's first phase, completed in spring 2005, the hospitals sent a two-page "safety climate survey" to all their senior managers and active hospital-based physicians, and to a sample of all other staff. The questionnaire was developed by the Stanford researchers to measure workers' perceptions of various aspects of safety culture, including fear of blame and shame; units' level of support for safety efforts, and senior managers' involvement with safety issues.

When Northwest's leadership received a summary of the hospital's survey results, they were surprised to see that on several questions, managers responded more positively than front-line staff, indicating that managers perceived a stronger safety climate than those providing the care.

"We'd been talking a lot about patient safety, but things hadn't filtered down to the staff as much as we expected. They didn't feel like we knew what was going on," said Candy Hamner, the hospital's vice president of care management. The results "showed us we needed to focus on closing that communication gap and making sure our people knew how much we cared about patient safety."

Northwest's experience wasn't unique. In a key finding, the CHP/PCOR researchers have documented a significant

difference in the way managers and front-line staff perceive their hospital's safety culture, with managers taking a much rosier view. In the first round of national hospital surveys, senior managers gave a "problematic" response on 12 percent of the questions, while staff gave a problematic response on 17 percent.

This difference isn't surprising, Baker said, given that "managers aren't out there on the floor with patients, so they're not as aware of the day-to-day problems." The discrepancy also reflects the different priorities of managers and staff, he noted. "CEOs and CFOs have to worry about market positioning, insurance contracts, profitability. They tend to hear about patient safety only when there's a major problem."

The researchers hypothesized that if hospital managers had greater contact and communication with front-line staff, it would narrow the difference in perception, which would strengthen hospitals' safety practices and culture. Building on business theories of "management by walking around," the researchers — with **Anita Tucker**, assistant professor at the Wharton School — developed a simple yet potentially powerful intervention program.

The intervention requires a handful of executives at each hospital to participate in a sequence of three activities on several high-risk units, including the emergency department, ICU, surgery and pharmacy. Twenty-four of the participating hospitals were randomly selected to implement the 18-month program beginning in early 2005, and Northwest Hospital Center was among them. Four of its senior leaders participated in the intervention: the president; Hamner; and two other vice presidents.

For the first activity of the intervention, dubbed "work-site visits," the participating executives spend 45-60 minutes observing the day-to-day operations of a particular unit, by shadowing front-line staff on the unit. During these visits, the executives are instructed not to make judgments but to observe and ask questions, to learn what obstacles may be preventing staff from providing safe care.

"It's amazing how few senior managers visit the front lines regularly," Singer said, adding that the intervention program "isn't rocket science. We designed it to be practical — something hospitals would want to keep doing long after our study ended."

For Hamner and her colleagues, the floor visits were an eye-opener, letting them see firsthand the complexities and challenges of providing patient care. When Hamner visited the hospital's pharmacy, she noticed that the pharmacists were inputting medication orders in a noisy area with frequent interruptions. They told Hamner the

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distracting environment sometimes made it difficult for them to focus on their work — a situation that could lead to medication errors.

“If we’d thought about the best way to organize the work in that unit, we wouldn’t have set it up that way,” Hamner said, adding that a redesign and reorganization of the pharmacy and its workflow is now being planned. “While we want to promote patient safety, we don’t always make it easy for staff to do their jobs safely.”

On another unit visit, Hamner was shadowing a triage nurse in the emergency department. While the nurse was busy evaluating a patient, two urgent cases came in, requiring the charge nurse to scramble for extra staff, and making Hamner realize that better policies were needed on how to handle sudden surges in ER caseloads.

Also in the emergency department, staff members pointed out a supply problem: during the night shift, certain medical instruments were kept locked up in a separate room. This caused some procedures to be delayed, as physicians had to wait for the equipment to be retrieved.

The project intervention specifies that after conducting the work-site visits on a given unit, the executives then host a “town-hall meeting” on the unit, to discuss employees’ concerns about and ideas for improving patient safety. At Northwest Hospital Center, the meetings prompted both positive and negative feedback. Employees on one unit talked about how much they appreciated the teamwork and trust among their co-workers. Others at the meetings raised concerns and suggested changes to prevent errors.

“When we asked for their ideas, we got lists and lists of issues. It was like opening up Pandora’s Box,” said Barb Oliver, the hospital’s director of patient safety. “We had to make sure we listened and responded, because if they raised issues and it fell on deaf ears, it would be worse than not asking them in the first place.”

Alyson Falwell, project manager for the study, said prompt follow-up is crucial to building a strong safety culture. “If you ask 100 hospital CEOs whether they think patient safety is important, they’ll all say yes, but they need to back it up with action. There’s a big difference between talking the talk and walking the walk.”

To make sure the hospitals “walk the walk,” the third part of the intervention requires that soon after the town-hall meeting on each unit, a multidisciplinary team including

staff members, an area manager and a senior executive meets to prioritize the problems identified and develop plans to address them. Management also sends out periodic communications to update staff on their progress.

Questions from the Patient Safety Climate Survey

(respondents indicate “strongly agree,” “agree,” “neither agree nor disagree,” “disagree,” or “strongly disagree”)

- I am provided with adequate resources (personnel, budget and equipment) to provide safe patient care.
- Senior management has a clear picture of the risks associated with patient care.
- Asking for help is a sign of incompetence.
- Staff speak up freely if they see something that may negatively affect patient care.
- My performance is evaluated against defined safety standards.
- In the last year, I have done something that was not safe for the patient.
- When I take time to communicate about patient safety problems, there is appropriate follow-up.
- Clinicians who make serious mistakes are usually punished.
- Good communication flow exists up and down the chain of command regarding patient safety issues.

Northwest’s management created several working groups to tackle various issues. To address the problem of medical equipment being locked up during the night shift in the ER, policies were revised and most of the equipment was moved to a more accessible, unlocked area. To better respond to sudden surges in ER caseloads, the department created a triage workgroup, which gathered several weeks of data on the volume and severity of ER patients by hour of the day. The group pilot-tested some staffing changes, to include adding a second triage nurse and technician during high-volume hours. Some permanent changes will include additional staffing and reconfiguration of the triage space.

This fall, the hospitals in the study are repeating the safety culture surveys, enabling them, and the researchers, to track changes in their safety culture over time. The researchers expect that, compared with the control group, the intervention hospitals will show a greater improvement in safety culture scores, and a smaller difference between managers’ and front-line workers’ perceptions of safety culture.

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Many implementation details have yet to be worked out, however. CHP/PCOR director **Alan Garber** said that while the Massachusetts law is a good concept, developing a truly low-cost health plan that would provide adequate health coverage would be a big challenge, because “to get the costs down to the levels that would allow the successful implementation of purchase mandates and public funding, you’d have to make Draconian cuts” in the services covered or in reimbursements to providers.

Garber also noted that policymakers’ ability to reduce the nation’s drug and medical device costs is constrained by federal law, which bars Medicare from negotiating volume price discounts with manufacturers. “Medicare pays as much as \$200,000 a year for some patients receiving [the cancer drug] Avastin. Who sets the price? Typically, it’s the manufacturer.” Bryan commented about his impression that the drug industry influences U.S. healthcare coverage policy.

Regarding the implementation of coverage policies, Bryan said he was impressed with the monitoring that takes place within U.S. healthcare systems, to make sure clinicians adhere to these policies. Adherence seems to be quite high in well-integrated systems such as Kaiser Permanente and the VA, he noted.

Several attendees commented that while this may well be true for drug formularies and similar guidelines, U.S. clinicians are notoriously poor at following clinical practice guidelines for primary care and prevention. Most healthcare organizations, they said, give physicians few concrete incentives to follow such guidelines.

Noting the increasing interest in cost-effectiveness analysis and the limited availability of good cost-effectiveness information, Bryan advocated greater international collaboration in this area. “I’m not suggesting we take a cost-effectiveness analysis from NICE and apply it to Blue Cross Blue Shield,” he said, “but there are models in use already that would be a good starting point.”

Bryan concluded by discussing positive features he had identified in U.S. healthcare systems, which he believes the U.K. could learn from. These include using structured, organization-wide processes to seek input for new policies; using information systems to monitor clinical practice patterns and utilization; and building a culture of “resource stewardship” which emphasizes that physicians should weigh the costs and benefits of medical interventions to make the best use of limited resources. He noted that economics typically isn’t a significant component of the curriculum in U.K. medical schools. ❖

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The researchers are also seeking to show for the first time that there is a meaningful relationship between safety culture and patient outcomes — that hospitals with a stronger safety culture have lower rates of patient deaths or complications than those with a weak safety culture.

By comparing a subset of the hospitals’ first round of survey scores with their data from the national Patient Safety Indicators (measures developed by the Stanford-UCSF Evidence-based Practice Center that track errors, complications and other adverse events) the researchers have found a statistically significant relationship between the safety indicators and some aspects of safety culture. They believe they’ll see an even stronger correlation after analyzing the results of the second round of surveys.

“Making that link between safety culture and outcomes is important because we need to be able to say, ‘Culture matters,’” Baker said. “We hope our data will help people see the urgency of this.”

Baker acknowledges that bringing about lasting improvements in patient safety is a difficult task: “Culture is a very hard thing to change, and healthcare in

particular is a slow-moving entity.” Even so, the Stanford research has identified two key factors that seem to be crucial determinants of safety culture: fear of blame and punishment, and a willingness to seek help. The findings suggest that hospitals must create an environment where staff members feel comfortable asking questions, and where errors are dealt with not through blame and punishment but by examining and correcting the processes that allow errors to happen.

The final aim of the safety culture project is that the participating hospitals will incorporate the key elements of the intervention — periodically observing and meeting with front-line staff — into their ongoing operations. Hamner said the leadership at Northwest Hospital Center has resolved to do just that.

“What this project did for us was open up a dialog with our staff. We want to keep that momentum going,” she said. “As far as I’m concerned, there’s never too much focus on patient safety. You have to keep at it — keep communicating, communicating, communicating.” ❖

CHP/PCOR Research staff members working on the patient safety project include Toby Rathgeb, Jennifer Hayes, and Shoutzu Lin.

ANNOUNCEMENTS, FROM PAGE 7

of disciplines — including economics, psychology, geriatric medicine and health policy — sharing their perspectives on obesity and physical activity among older adults. The Interdisciplinary Dialogues aim to generate ideas that could develop into seed proposals or foster new interdisciplinary partnerships. Judging by the lively discussion, those goals were met, and we look forward to future Interdisciplinary Dialogues on other topics.

News from **BK Yoo**, a former CHP/PCOR research associate who is now an assistant professor of Community & Preventive Medicine at the University of Rochester (and also a CHP/PCOR adjunct associate): In July, Yoo published his first book, *Health Economics for “Reform”* (published in Japanese, as “*Kai-kaku no Tame no Iryou-Keizai-Gaku*”). In September, the Japanese newspaper *Nikkei* (known as “the *Wall Street Journal* of Japan”) published a positive review of his book. As a result, its sales ranking on Amazon.com-Japan jumped from 15,000th to 53rd.

Hellos and goodbyes:

During the summer quarter, CHP/PCOR welcomed the following new trainees and research staff members:

Eran Bendavid, a trainee with the AHRQ’s Fellowship in Health Care Research and Policy, is also pursuing a fellowship in infectious diseases at Stanford. He is interested in using multidisciplinary methods to study the prevention and treatment of infectious diseases in developing countries. He has conducted research on topics including the safety and efficacy of tuberculosis rechallenge therapy in South Africa. He received a BA in chemistry and philosophy from Dartmouth College, an MD from Harvard, and completed an internal medicine residency at Stanford.

Kristen Chan, a research assistant working on projects with Paul Wise, received a master’s degree in chemical engineering from Ryerson University (Toronto). Her research has focused on food science and engineering, and she has worked with professors on product development in materials science and low-fat food products.

Lynn Davis, a trainee with the AHRQ fellowship, is also a clinical fellow in Reproductive Endocrinology and Infertility at Stanford. She is interested in improving health policy and decision-making in areas of women’s health and reproductive biology, including pre-

implantation genetic diagnosis, recurrent pregnancy loss, and complications of infertility therapy. She received a BA in biology from the University of Virginia, an MD from the University of Colorado, and completed an OB/GYN residency at Brigham and Women’s Hospital.

Amar Desai, a trainee with the AHRQ fellowship, is also pursuing a fellowship in nephrology at UCSF, where he completed his residency in internal medicine. He is interested in quality improvement, chronic disease management, and the experiences of underserved communities. He has conducted research on topics including quality of care in the treatment of Barrett’s esophagus, and computer-based systems to improve clinicians’ compliance with clinical practice guidelines. He received a BA in public policy from Brown University, an MPH from Harvard, and an MD from Brown University.

Jonas Schreyögg, a 2006-07 Commonwealth Fund Harkness Fellow in Health Care Policy, is conducting research based at CHP/PCOR for the coming academic year. He is a senior lecturer in the Department of Health Care Management at the Berlin University of Technology, and a research officer for the European Observatory on Health Systems and Policies. He has published research on subjects including pharmaceutical regulation in Germany and the effects of drug budgets on physicians’ prescribing behavior. At CHP/PCOR, he is comparing the cost of healthcare services, at the micro level, between the U.S. and Europe. He received an MA and PhD in economics from the Berlin University of Technology.

CHP/PCOR said a fond farewell last quarter to Harkness Fellow **Stirling Bryan**; VA fellowship trainee **Smita Nayak**; project manager **Tamara Sims**; research staff member **Sarah Songer**, and information editor and outreach coordinator **Sara Selis**.

Bryan returned to the U.K. to resume his post as professor of health economics at the University of Birmingham. Nayak began a new position at the University of Pittsburgh as a clinician-investigator in the Division of General Internal Medicine. Sims is pursuing a PhD in psychology at Stanford. Sarah Songer is studying book arts in San Francisco.

Sara Selis is pursuing an opportunity as online associate editor for the healthcare division of CMP Media in San Francisco. Sara has enjoyed being part of the CHP/PCOR community and working on this newsletter. She leaves with fond memories and best wishes. ❖

Publications from the summer quarter

Bravata DM, Wang E, **Holty JE**, Lewis R, **Wise PH**, **Nayak S**, **Liu H**, **McDonald KM**, **Owens DK**. *Pediatric Anthrax: Implications for Bioterrorism Preparedness*. AHRQ Evidence Report, under contract #290-02-0017. Prepared by the Stanford-UCSF Evidence-based Practice Center, August 2006. Agency for Healthcare Research and Quality, Rockville, Md.

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Schünemann H, Jaeschke R, Cook D, Bria WF, Fahy BF, El Solh AA, Ernst A, **Gould MK** et al, on behalf of the ATS Documents Development and Implementation Committee. "An official ATS statement: Grading the quality of evidence and strength of recommendations in guidelines." *American Journal of Respiratory and Critical Care Medicine* 174 (2006): 605-14.

Shojania KG, Ranji SR, **McDonald KM**, Grimshaw JM, **Vandana S**, Rushakoff RJ, **Owens DK**. "Effects of Quality Improvement Strategies for Type 2 Diabetes on Glycemic Control: A Meta-Regression Analysis." *Journal of the American Medical Association* 296, no. 4 (July 26, 2006): 427-440.

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Presentations from the summer quarter

Kate Bundorf

“The Effects of Public Reporting of Health Plan Quality on Quality of Care in the Medicare Program.” AcademyHealth 2006 Annual Research Meeting, invited session on Health Care Quality Reporting. June 25-27, 2006 in Seattle.

Susan Frayne

“Managing Medical Conditions in Women with Mental Illness.” National VHA Women’s Mental Health Committee Meeting, Aug. 9, 2006 in Washington, D.C.

“Making the system work for patients with PTSD.” Invited oral presentation for VHA National Primary Care Preventive Medicine Conference, July 18, 2006 in Arlington, Va.

Alan Garber

“Will the Costs of Health Care Kill Innovation?” Oregon Health Forum, 2006 Health Policy Conference, Sept. 12, 2006 in Portland, Ore.

Mary Goldstein

“History of Geriatrics.” Seminar at Geriatrics Research Education and Clinical Center (GRECC), Aug. 8, 2006 at VA Palo Alto Health Care System.

“Quality Improvement through Automated Clinical Decision Support with Clinical Practice Guidelines.” Research seminar at Geriatrics Research Education and Clinical Center (GRECC), Aug. 8, 2006 at VA Palo Alto.

Hau Liu

“The Safety and Efficacy of Growth Hormone in the Healthy Elderly: A Systematic Review.” The Endocrine Society Annual Meeting 2006, June 2006 in Boston.

“Rates of Bone Turnover By Ethnicity, Gender, and Age: Urine N-Telopeptide and Serum Bone Specific Alkaline Phosphatase Levels in a Nationally-Representative Cohort.” American Society for Bone and Mineral Research, 28th Annual Meeting, Sept. 17, 2006 in Philadelphia.

About CHP/PCOR

The **Center for Health Policy (CHP)** and the **Center for Primary Care and Outcomes Research (PCOR)** are sister centers at Stanford University that conduct innovative, multi-disciplinary research on critical issues of health policy and healthcare delivery. Operating under the Freeman Spogli Institute for International Studies and the Stanford School of Medicine, respectively, the centers are dedicated to providing public- and private-sector decision-makers with reliable information to guide health policy and clinical practice.

CHP and PCOR sponsor seminars, lectures and conferences to provide a forum for scholars, government officials, industry leaders and clinicians to explore solutions to complex healthcare problems. The centers build on a legacy of achievements in health services research, health economics and health policy at Stanford University. For more information, visit our Web site at <http://healthpolicy.stanford.edu>