

## Briefly

**Value for money:** The United Kingdom's National Health Service (NHS) has primarily pumped the billions of pounds it has received over the past decade into staff salaries rather than measures to improve productivity, according to a study by the National Audit Office. While the annual NHS budget rose to £102 billion from £60 billion over the decade, productivity plummeted 14% since the year 2000, concludes the report, *Management of NHS Hospital Productivity*. "This increased funding has paid for more, better paid staff, and extra goods and services. Hospital activity — adjusted to reflect improvements in the quality of care — has not risen at the same rate as these additional resources, indicating that productivity has declined," adds the report ([www.nao.org.uk/publications/1011/nhs\\_hospital\\_productivity.aspx](http://www.nao.org.uk/publications/1011/nhs_hospital_productivity.aspx)). — Wayne Kondro, *CMAJ*

**Canada lags in preventing hospital infections:** Canada's burden of health care-associated infection outstrips that of other developed nations and even some developing countries, according to a systematic review conducted by the World Health Organization ([www.who.int/gpsc/country\\_work/summary\\_20100430\\_en.pdf](http://www.who.int/gpsc/country_work/summary_20100430_en.pdf)). From 1995 to 2008, Canadian health care facilities reported the highest prevalence of hospital infections of 12 developed nations, at 11.6%. The overall prevalence of hospital infections in developed countries varied between 5.1% and 11.6%, and approximately the same proportion of hospitalized patients acquired at least one such infection during that period. The European Centre for Disease Prevention and Control reported an average prevalence of 7.1% in European countries, while the estimated incidence rate in the United States was 4.5% in 2002. Hospital infection prevalence rates in developing nations were higher than those in developed countries, ranging between 5% and 19%, with most reporting values greater than 10%. Latvia

(5.7%), Lebanon (6.8%), Thailand (7.3%) and Lithuania (9.2%) all reported prevalence rates lower than Canada. — Lauren Vogel, *CMAJ*

**FDA and industry:** The United States Food and Drug Administration (FDA) has unveiled a website aimed at better informing industry about agency standards for regulated products and application processes. The website, FDA Basics for Industry ([www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm](http://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm)) is part of the agency's response to President Barack Obama's 2009 transparency initiative. "Clarity and consistency are pillars of an effective regulatory system that efficiently regulates products essential to health," said FDA Commissioner Dr Margaret Hamburg in a press release ([www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239086.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239086.htm)). "In order to succeed, the FDA must clearly communicate standards and expectations to the industries it regulates." The website is one of 19 "action items" that the FDA identified in a recent report as being integral to improving transparency for industry ([www.fda.gov/downloads/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/UCM239088.pdf](http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencytoRegulatedIndustry/PhaseIIITransparencyReport/UCM239088.pdf)). Dr. Joshua Scharfstein states in the report that the FDA is also "setting the expectation of responding to email questions about the regulatory process within 5 days, whenever practicable, or acknowledge receipt of the question and provide an estimated time for response. FDA is also making agency presentations at key meetings widely available and taking a range of other steps to improve transparency to manufacturers and the importing community. FDA is proposing for comment five additional steps, including publishing on FDATRACK a timeline for high priority guidances that includes dates for publication of the draft guidance, receipt of public comments, and publication of the final guidance." — Wayne Kondro, *CMAJ*

**Hasty retreat:** United States President Barack Obama's administration has quickly rescinded a new Medicare regulation that would have allowed physicians to bill for advice provided as part of "advanced end-of-life planning" conducted during annual physical examinations or wellness visits. Although the regulation, which took effect Jan. 1, had been lauded by many doctors and health professionals, it was lambasted by critics who believed it was tantamount to the creation of "death panels" which would determine whether Medicare beneficiaries should be allowed to live. "It has since become apparent that we did not have an opportunity to consider prior to the issuance of the final rule the wide range of views on this subject held by a broad range of stakeholders (including members of Congress and those who were involved with this provision during the debate on the Affordable Care Act)," the Centers for Medicare & Medicaid Services stated in announcing the retreat ([www.ofr.gov/OFRUpload/OFRData/2011-00164\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-00164_PI.pdf)). — Wayne Kondro, *CMAJ*

**Alcohol swab recall:** The Shandex Sales Group has issued an urgent recall for alcohol swabs on the Canadian market because of *Bacillus cereus* contamination. "The Shandex Sales Group is requesting that wholesalers, pharmacies and other retail locations immediately stop sale of these products," Health Canada said in announcing the recall ([www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/\\_2011/2011\\_02-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2011/2011_02-eng.php)). The swabs are primarily used to cleanse the skin prior to injections. All lot numbers of alcohol swabs sold under the brand names Remedy Rx, Uniprix, Life Brand, Equate, Personelle, Rexall and Exact are affected by the recall. — Wayne Kondro, *CMAJ*

**US cancer costs:** The United States National Cancer Institute projects that the cost of diagnosing and treating cancer in the US in the year 2020 will rise

at least 27% to US\$158 billion and could reach as high as US\$208 billion, from a 2010 level of US\$124.6 billion. The institute said its projections (<http://costprojections.cancer.gov/>) are based on the supposition that the number of American cancer survivors will increase by 31% to 18.1 million by 2020 from a current level of 13.8 million. “The rising costs of cancer care illustrate how important it is for us to advance the science of cancer prevention and treatment to ensure that we’re using the most effective approaches,” Robert Croyle, director of the institute’s division of cancer control and population sciences, stated in a press release ([www.cancer.gov/newscenter/pressreleases/CostCancer2020](http://www.cancer.gov/newscenter/pressreleases/CostCancer2020)). “This is especially important for elderly cancer patients with other complex health problems.” — Wayne Kondro, *CMAJ*

#### **Acetaminophen/opioid combinations:**

The United States Food and Drug Administration (FDA) has asked manufacturers of prescription combination products to limit the amount of acetaminophen contained in such products to no more than 325 mg per tablet or capsule. Frequent or excessive use of such combination products, in which acetaminophen is typically mixed with opioids such as codeine, oxycodone and hydrocodone, elevates the risk of liver failure, as does the use of such products in combination with alcohol, the FDA said. “Overdose from prescription combination products containing acetaminophen account for nearly half of all cases of acetaminophen-related liver failure in the United States; many of which result in liver transplant or death,” stated Dr. Sandra Kweder, deputy director of the Office of New Drugs in FDA’s Center for Drug Evaluation and Research in the announcement ([www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239894.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239894.htm)). “The risk of liver injury primarily occurs when patients take multiple products containing acetaminophen at one time and exceed the current maximum dose of 4,000 milligrams within a 24-hour period.” The FDA will also require that boxed warnings be added to all acetaminophen prescription labels. — Wayne Kondro, *CMAJ*

**Bureaucratic multiplication:** Arguing that excessive bureaucracy and red tape is “stifling” health research and driving clinical trials offshore, the United Kingdom’s Academy of Medical Sciences is recommending the creation of new bureaucracy, namely, a Health Research Agency with responsibility for the regulation and oversight of health research, including a single national system for achieving ethics approval of research protocols. In a report, *A new pathway for the regulation and governance of health research*, the academy also urges that the Medicines and Healthcare products Regulatory Agency should actively pursue revisions to the European Union’s Clinical Trial Directive so as to reduce the directive’s scope. It should also be made responsible for ensuring that British-based clinical trial “approval and monitoring requirements are proportionate to risk; (and) simplify the requirements for safety reporting to improve the quality of drug safety data and monitoring ([www.acmedsci.ac.uk/download.php?file=/images/project/129468115924.pdf](http://www.acmedsci.ac.uk/download.php?file=/images/project/129468115924.pdf)). — Wayne Kondro, *CMAJ*

**Canadians reach for the remote:** Just 15% of Canadian adults achieve the minimum internationally-recommended standard of undertaking at least 150 minutes of moderate-to-vigorous physical activity a week that is necessary to obtain substantial health benefits, according to a Statistics Canada survey. *The Canadian Health Measures Survey: Physical activity of youth and adults*, found that 17% of men and 14% reach the minimum target, while just 7% of young people aged 5 to 17 achieve the recommended minimum 60 minutes of moderate-to-vigorous physical activity daily ([www.statcan.gc.ca/daily-quotidien/110119/dq110119b-eng.htm](http://www.statcan.gc.ca/daily-quotidien/110119/dq110119b-eng.htm)). — Wayne Kondro, *CMAJ*

**Ante up for residents:** The United States Supreme Court has ruled that medical residents should not be considered full-time students for tax purposes, so teaching hospitals must cough up social security taxes for those residents to the US Internal Revenue

Service. With an estimated 100 000 medical residents working in the US annually, roughly US\$700 million was on the line for residents and teaching hospitals, who argued that residents should be exempted from the taxes because the work was part of their training. But US Supreme Court Chief Justice John Roberts rejected arguments that residents should not be considered as not having started their working lives because they were not yet fully trained. The Internal Revenue Service “did not act irrationally in concluding that residents who work long hours, serve as highly skilled professionals, and typically share some or all of the terms of employment of career employees” are exactly the kind of employees who should be making contributions to social security programs, Roberts said in his decision ([www.supremecourt.gov/opinions/10pdf/09-837.pdf](http://www.supremecourt.gov/opinions/10pdf/09-837.pdf)). Social security taxes in the US are set at 12.4% of salaries, with half paid by the employer (roughly US\$3100) and half by the employee. — Wayne Kondro, *CMAJ*

**Medical device approvals:** The United States Food and Drug Administration (FDA) has announced that it will streamline its review process for providing market approval for so-called lower-risk medical devices such as catheters, or diagnostic imaging devices. The 25-element plan to speed up approval for medical devices will also include the creation of a “Center Science Council of senior FDA experts to assure timely and consistent science-based decision making,” and new guidelines on when clinical data must be submitted as part of a pre-market submission for a new product. The plan will result “a smarter medical device program that supports innovation, keeps jobs here at home, and brings important, safe, and effective technologies to patients quickly,” Dr. Jeffrey Shuren, director of the FDA’s Center for Devices and Radiological Health, said in a news release ([www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm240418.htm)). — Wayne Kondro, *CMAJ*

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