

FOR THE RECORD

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United States experiencing a “diagnosis epidemic”

The likelihood of a person being diagnosed with a disease is much higher in some regions of the United States than in others, which could lead to a distortion in health insurance markets and the “dumping” of high-risk patients, according to a new study (<http://content.nejm.org/cgi/content/full/NEJMsa0910881?resourcetype=HWCI>).

The study used Medicare claims of people who were at least 65 years old to track diagnostic trends, and grouped regions into five quintiles according to intensity of hospital and physician services. The researchers focused on 255 264 people who, in the three-year period from 2001–2003, moved from one region to another. They discovered that people who moved from a “quintile 1” region, where practice intensity was lowest, to another area in the same quintile had a 61.7% increase in diagnoses, attributed to aging. But those who moved from a quintile-1 region to a quintile-5 region experienced a 100.8% increase.

Led by researchers from the Dartmouth Institute for Health Policy and Clinical Practice, the study found that doctors in some US cities — such as Miami, Florida and McAllen, Texas — ordered more diagnostic tests and referred more patients to subspecialists than doctors in other areas, such as Atlanta, Georgia and Jackson, Mississippi. Furthermore, the researchers suggest that patients in “high-intensity” areas (based on number of diagnoses, laboratory tests and imaging tests) fared no better than those in lower intensity areas. The high number of medical tests in some areas has caused what some researchers refer to as an “epidemic of diagnosis.”

These findings should be of concern, the researchers suggest, because a geographical bias will distort risk-adjustment data, which in turn will distort comparative-effectiveness studies, measurements of health care performance and payment reform policies. The US government’s move to reform health care makes this problem all the more pressing, the study suggests, due to new incentives that will make bundled payment systems more attractive to Medicare and Medicaid.

“As payers move toward more bundled and value-based payment systems, incentives to avoid providing care for patients who are difficult to treat or patients for whom the cost of treatment is high will only increase,” states the study. “Inadequate risk adjustment could thus lead to flawed inferences, the ‘dumping’ of high-risk patients, and distortions in insurance markets.” — Roger Collier, *CMAJ*

Quebec Auditor General again slags public–private partnerships

The auditor general of Quebec has issued another report panning the use of public–private partnerships (PPPs) to build and maintain the province’s hospitals.

There are “major inaccuracies” in the cost analyses used to justify building Montréal, Quebec’s new McGill University teaching hospital and Université de Montréal research centre as PPPs, including erroneous claims that PPPs are more cost-effective than conventional public procurement methods, Auditor General Renaud Lachance said in a special report to the Quebec assembly.

It was misleading for proponents to argue that the PPP delivery model would save the province \$33.8 million in the construction and operation of the two hospital projects, Lachance stated in his *Special report dealing with the*

watch over the projects to modernize Montréal’s University Health Centers. “The conventional method is more economical by at least \$10.4 million.”

In the report, Lachance blamed Infrastructures Québec, the province’s PPP agency, for exaggerating the maintenance costs of conventional projects in their calculations (English highlights at www.vgq.gouv.qc.ca/en/en_publications/en_rapport-annuel/en_fichiers/en_Highlights2010-2011-CHU.pdf and complete report in French at: www.vgq.qc.ca/fr/fr_publications/fr_rapport-annuel/fr_2010-2011-Rapport-CHU/fr_Rapport2010-2011-CHU.pdf).

“Indeed ... the new value-added analyses for these projects are based on several of the same assumptions that we had deemed inappropriate or unfounded in the past,” Lachance added.

It constituted Lachance’s second warning against the PPP approach. In November 2009, he was skeptical of Infrastructures Québec claim that PPPs were preferable to conventional public projects, and worried the approach would cost taxpayers more in the long run (www.cmaj.ca/cgi/doi/10.1503/cmaj.109-3159).

Following the last report, bidders on the projects were called upon to come up with a better price.

But Lachance’s latest report takes issue with the notion that the revised bidding process saved the province money. He claimed negotiations actually added \$108.4 million to the cost of the projects and reduced potential revenues by outsourcing the McGill hospital’s parking garage to an outside operator.

Under a PPP, the government chooses a consortium to design, build, finance and operate a hospital, typically for 30 years. For the duration of the contract, the consortium is owner of the hospital and the government pays an annual rent. Under a conventional project, the government remains owner of the hospital, is directly involved in the hiring of contractors, and finances con-

struction and maintenance through long-term public debt.

While Canada's three most populous provinces — Ontario, Quebec, and British Columbia — have been quick to jump on the PPP bandwagon in recent years, there's been little examination of the risks associated with the change (www.cmaj.ca/cgi/doi/10.1503/cmaj.081540).

According to Lachance, PPP deals don't promote accountability. He concluded the signing of the two Montréal contracts was done "without having a vision of the projects as a whole in terms of their global costs and the operating budgets that will be necessary for these new institutions."

The McGill hospital is expected to cost \$1.343 billion, while the research centre is expected to cost \$470 million.

Negotiations with two bidding consortiums to define plans for a proposed \$2.6-billion Université de Montréal teaching hospital are ongoing, with the signing of a deal expected in January 2011. — Lauren Vogel, *CMAJ*

Been down that path

Consider it a case of wait time déjà vu. For the second consecutive year, the Wait Time Alliance has issued a national report card that says that spotty progress and inadequate information are the primary features of Canada's \$6 billion effort to decrease wait times in five designated areas of clinical priority.

The 2010 report card, *No Time for Complacency*, states that "despite some improvement in wait time grades, long waits for care continue to be an issue and much of the wait time picture remains clouded in mystery."

In a section entitled "the illusion of progress — grading the original 5 'priority areas,'" the report singles out Newfoundland and Labrador as being particularly remiss in reducing wait times in the five areas: joint replacement (hip and knee), cataract surgery, coronary artery bypass grafts; radiation therapy; and diagnostic imaging (magnetic resonance imaging and computed tomography). The alliance of 14 national organizations indicated there's been very little improvement since its 2009 report card

(www.cmaj.ca/earlyreleases/4theRecordAugJuly09.dtl).

"In a worrisome trend, the wait-time data for Newfoundland and Labrador and Alberta are both more than 6 months old. The situation in Alberta is particularly concerning because the province is no longer reporting in a timely manner and has failed to implement a wait-time guarantee as promised," the report states (www.waittimealliance.ca/media/2010reportcard/WTA2010-reportcard_e.pdf).

It also sounds an alarm that some provinces are not looking at wait time benchmarks as minimum standards. "It should be noted that these benchmarks set by governments represent maximum acceptable wait-time targets and should not be viewed as desired wait-time targets."

In an effort to broaden the wait time picture, the alliance also sought to report on the extent of delays for non-priority clinical areas and for the first time, provided data on wait times for pediatric surgeries.

But in seeking to report on wait times in areas which have not been deemed priorities, the alliance said it discovered a veritable, virtual "black hole" in which information is "scarce or non-existent."

"The most striking finding is the lack of public reporting on wait times for the important services/procedures selected by the WTA outside the original 5 priority areas. This is not to say that governments are not reporting any other wait times, just not the important procedures selected by the WTA. For instance, no province is currently reporting wait times for any services/procedures in anesthesiology (chronic pain), gastroenterology and psychiatry."

With respect to pediatric surgeries, the alliance found that more than 17 000 Canadian children waited longer for their surgeries in 2009 than medical experts recommend. The alliance's analysis of data from 15 pediatric academic health sciences centres indicates that "overall 73% of children received their surgeries within the benchmark for an overall score of 'B'. ... Dentistry (driven by patients having procedures for dental caries), ophthalmology (driven by patients receiving

surgery for 'wandering eye') and plastic surgery (driven by patients receiving cleft lip and/or cleft palate surgery) proved to be the areas of greatest need, with the lowest percentage of cases completed within their benchmark."

The alliance also graded provincial wait time websites for the first time and found that only Ontario warranted an A-grade. B-grades issued to Saskatchewan, New Brunswick, British Columbia and Nova Scotia, while C-grades went to Manitoba, Prince Edward Island and Quebec. Alberta and Newfoundland and Labrador got an F, or failing, grade. — Wayne Kondro, *CMAJ*

Twelve great achievements in public health

Asserting that advances in public health have added 25 years to the average lifespan, the Canadian Public Health Organization has released a list of 12 great public health achievements of the past century. Ten of the 12 had been identified previously by the United States Centers for Disease Control and Prevention. But the Canadian Public Health Organization, which is celebrating its 100th year, modified one of those, the fluoridation of drinking water, to more broadly include healthy environmental policies. It also added two achievements identified as "particularly Canadian," i.e., "Acting on the social determinants of health" and "Universal policies" (<http://cpha100.ca/12-great-achievements>). The 12 great achievements:

Safer and healthier foods: Contaminated food and water was a major health concern in Canada a century ago, leading to illnesses such as typhoid fever, tuberculosis and botulism. "Understanding the links between nutrition and health has increased dramatically over the past 100 years."

Control of infectious diseases: Controlling the spread of infectious diseases has long been a primary goal of public health experts in Canada.

Healthier environments: Environmental policies have helped reduce toxic emissions and improve air and water quality.

Vaccination: Fewer than 5% of deaths in Canada are attributed to infectious diseases, down substantially from a century ago. “Immunization has probably saved more lives in Canada in the last 50 years than any other health intervention.”

Recognition of tobacco use as a health hazard: Tobacco consumption in Canada has declined dramatically because of tobacco control efforts made in recent years.

Motor-vehicle safety: Many injuries have been prevented and many lives saved thanks to laws against drinking and driving and increased use of seat belts.

Decline in deaths from coronary heart disease and stroke: For more than 40 years, rates of death from cardiovascular disease have been declining. “The 1997 death rates were almost half those of 1969.”

Healthier mothers and babies: Maternal and infant health in Canada is now among the best in the world.

Acting on the social determinants of health: There is increased recognition that factors such as income, education, social connections and physical well-being have strengthened the health of the public in Canada.

Universal policies: Universal access to health care means Canadians aren’t denied medical treatment because of their socio-economic status.

Safer workplaces: From 1988 to 2006, the number of injuries per 1000 workers dropped from 40 to 20.

Family planning: All forms of contraception became legal in Canada in 1969. Two years later, the federal government began funding birth-control services across the country. — Roger Collier, *CMAJ*

Brand-name drug companies continue to break research and development spending promise

Spending on pharmaceutical research and development (R&D) in Canada by brand-name drug companies dropped to a 20-year low in 2009, according to the latest annual

report by the Patented Medicine Prices Review Board.

The board found that brand-name drug companies spent \$1.2 billion, or 7.5% of their sales revenue, on R&D in Canada last year. That’s a 2.9% decrease from 2008, and the lowest percentage of revenues spent on R&D since 1988. It also represents the ninth consecutive year that brand-name drug companies have broken a public promise to spend a minimum 10% of their Canadian sales revenues on R&D.

Canada’s Research-Based Pharmaceutical Companies (Rx&D), an association of 50 firms, made that commitment in 1987 when the federal government extended patent protection on new drugs to a minimum of 20 years from the date on which a patent application is filed. The industry met the 10% target by 1993, in large measure because they successfully lobbied for the inclusion of monies spent on clinical trials as part of the R&D calculation. But in recent years, the ratio of R&D spending-to-sales has been steadily declining.

In 2009, the brand-name drug industry spent \$237.1 million on basic research. That’s only 1.8% of the industry’s total Canadian sale revenues of \$13.334 billion, and 19.4% of R&D expenditures. The majority, 56.2%, went to applied research (work intended to improve manufacturing processes, preclinical trials and clinical trials), while 24.3% went to “other qualifying research” (drug regulation submissions, bioavailability studies and Phase IV clinical trials).

In a press release, Rx&D President Russell Williams cited the economic recession, global industry restructuring, and patient access gaps for new medicines as reasons for the decline in R&D spending. “The commitment made in 1987 was based on a favourable environment of access and reimbursement. That environment has significantly deteriorated and the commitment may no longer be sustainable unless Canada becomes more internationally competitive.”

According to the release, the ratio doesn’t accurately capture the brand-name drug industry’s true investment in Canada. Williams estimated that “almost 20% of the sector’s committed

investments are not used and thus not reported” by the Patented Medicine Prices Review Board. “Governments, research institutions and industry need to work cooperatively to reduce duplication and coordinate efforts to make our country a global destination for clinical trials research.”

Canada’s R&D-to-sales ratio ranked second lowest out of seven comparator countries in the board’s report, just ahead of Italy at 7.1%. Ratios in all other countries were significantly higher. France, ranking third lowest, had a ratio double that of Canada, at 16.3%. Germany, the United States, and Sweden had ratios between 17% and 29%, while the United Kingdom and Switzerland topped out at 45.0% and 112.7%, respectively.

The report also notes that despite low domestic investment in R&D, Canadians are still paying among the highest prices internationally for brand-name drugs. Canadian prices ranked third highest of the seven comparator countries.

Several comparator countries achieved R&D-to-sales ratios well above those in Canada despite patented drug prices that are not substantially higher, and are sometimes lower, than prices in this country. While France boasted a R&D-to-sales ratio twice that of Canada, on average, the nation’s brand name drugs cost at least 10% less than in Canada.

Although Canadian sales of patented drugs rose 2.8% to \$13.3 billion in 2009, the growth rate has declined over the past decade. Throughout the latter part of the 1990s, the growth rate soared as a result of a succession of new “blockbuster” drugs. In 1999, for example, sales rose 27.0%. But the share of brand-name drug products as a percentage of overall drug sales has declined since 2003. In 2009, older products introduced in the late 1990s still accounted for nearly 35.9% of all sales. — Lauren Vogel, *CMAJ*

No generic bargain

Canadians pay too much for generic drugs as a result of a lack of transparency within the system and other trends such as the failure to extend drug-plan policies to

the private insurance market, the shift in the “balance of power” within the generic drug market to pharmacies and the failure to pass on the benefits of increased competition to consumers instead of allowing pharmacies to profit primarily, according to the Health Council of Canada.

“Pharmacies reaped the benefits of reduced drug-acquisition costs and these became an integral part of their retail business model, allowing the number of pharmacies to grow,” states a discussion paper commissioned by the Health Council of Canada from SECOR Consulting. “Over time, the agglomeration of retail pharmacies into franchises, chains, and banner groups shifted the balance of power — these pharmacies could now drive their drug-acquisition costs further down by demanding ever-deeper rebates from the manufacturers. These rebates — also referred to as professional allowances and off-invoice discounts — became the primary lever through which generic firms competed for pharmacy shelf space.”

“The market dynamics that governments themselves had a hand in creating ultimately became a source of frustration for them. Realizing they were allocating too much profit to the supply chain they began to reduce reimbursement rates. At the same time, governments noted the lack of transparency as to how profits in the supply chain are distributed. They are faced with the challenge of not knowing how much profit can be squeezed from the supply chain through reductions in reimbursement levels before the chain is damaged” (http://healthcouncilcanada.ca/docs/rpts/2010/generics/generics_June182010_rpt.pdf).

“This discussion paper highlights the complex reasons as to why generic drug prices are so high and the longstanding lack of transparency about how prices are set,” John G. Abbott, CEO of the Health Council of Canada, said in a news release (www.healthcouncilcanada.ca/docs/rpts/2010/generics/Generics_June182010_PressRelease.pdf).

Among measures proposed in the paper to “improve affordability, sustainability and transparency” are:

- Drug insurance plans could revisit maximum reimbursement prices,

using “industry information and pricing data from other countries for guidance. This approach mirrors the actions that many provinces are already taking and is basically an extension of the status quo. If governments are to continue to intervene in the market, they need to ensure that public plans do not achieve lower prices at the expense of private plans. They need to ensure that private plans do not pay more than public plans either by making pricing well-known or through regulation.”

- Set reimbursement prices at the pharmacy level, including “the actual cost of the drug, wholesaler fees, and pharmacy fees for dispensing and counselling.”
- Use alternative and competing distribution channels such as mail-order pharmacies and automated dispensaries.
- Compel drug plans, including employer-sponsored plans, to use tiered formularies “to encourage their beneficiaries to use low-cost drugs. Tiered formularies and their associated patient co-payments effectively sensitize the consumer to the cost of medications. However, care must be taken to ensure that patients continue to take appropriate drugs — both for their own benefit and because inferior health outcomes would cost the health system more than any monies saved.”
- List newly approved drugs on provincial and territorial formularies “in a timely manner.” The current delay in listing results in “public drug plans paying additional money for a brand name drug, even though a lower-cost generic version is available.”
- Expand the role of pharmacists in providing “additional paid services” such as blood tests and vaccinations. — Emily Panetta, Ottawa, Ont.

Ontario coroner’s jury calls for drug safety measures

An Ontario teen’s suicide has prompted recommendations for the creation of a province-wide drug information system and a

national arm’s-length drug safety board to regulate prescription medications.

The recommendations to improve drug safety in Canada are among 16 emerging from the coroner’s jury into the death of 18-year-old Sara Carlin of Oakville, Ontario, whose family believes she became depressed after taking the drug Paroxetine (Paxil) for anxiety.

The jury called upon Ontario’s Ministry of Health and Long-Term Care to develop a drug information system to track and monitor all drugs dispensed in the province. The system would promote patient safety by collecting data on the prescribing and dispensing of all drugs in the province in a single repository. Data collected by the system would also be available on request to scientists to further research in drug and patient safety.

At the national level, the jury recommended the creation of an arm’s-length body independent of Health Canada and drug industry funding to research drug safety, investigate adverse reactions, and issue warnings to the public, health care professionals and hospitals. The drug safety board would receive funding from the federal government and be required to report to Parliament.

Other recommendations from the jury included the creation of an Ontario-wide suicide prevention strategy similar to those adopted in other provinces, such as Alberta; mandatory reporting to Health Canada of all serious drug-related adverse events by both pharmaceutical companies and healthcare professionals; and new guidelines and training for family physicians on prescribing selective serotonin reuptake inhibitors [SSRI antidepressants].

The jury concluded the teen’s cause of death was “hanging by ligature while affected by depression, cocaine and ethanol.” While it stopped short of saying that paroxetine had a role in her death, the teen’s family say the fact that assigning blame is beyond the purview of such inquests and the fact that the jurors recommended such an array of regulatory measures are indicators that they believed the drug played a major role in the teen’s death.

Health Canada has stated that it will ensure the recommendations of the five-member coroner's jury are given careful consideration within the current regulatory framework. Groups mentioned in the jury's report have a year to respond to the recommendations. — Lauren Vogel, *CMAJ*

International food safety meeting sets melamine limits

The first global limits on melamine contamination of food and baby formula are among a spate of new standards set by the World Health Organization (WHO) and the United Nations' Food and Agriculture Organization's joint food safety commission.

Over 180 countries at the annual meeting of the Codex Alimentarius Commission agreed to curb melamine content to an upper limit of 1 mg per kg in infant milk formula, and 2.5 mg per kg in all other foods.

Stopping short of an outright ban on the industrial chemical, the limits still allow for the "unintentional and unavoidable" occurrence of very low levels of melamine in some foods that

stem from contact with plastics and the insecticide cyromazine.

"These are definitely not of health concern," said WHO expert Angelika Tritscher during a press briefing. "The body is very capable of dealing with low levels of melamine."

Only high levels of melamine can cause adverse health effects, she said. "If you have high levels, then you have an indication of adulteration, an illegal act that cannot be accepted under any circumstances."

In 2008, the intentional addition of melamine to Chinese milk killed at least six children and made some 30 000 ill. The speed with which the international community acted to impose limits on melamine in the wake of the scandal established an "excellent example" for future cooperation on food safety, said Tritscher.

Other guidelines released by the commission this week called for changes to international production and harvesting practices for bagged produce and seafood. Significantly, the commission decided that manure and contaminated water should no longer be used to fertilize and irrigate "ready to eat" salads and vegetables.

While there is no yearly estimate of

the number of people who fall sick from eating bagged salads, WHO director of food safety and zoonoses Jørgen Schlundt linked the use of manure and water contaminated with animal and human feces to recurring outbreaks of disease in both developed and developing nations.

Standards set by the commission aren't legally binding, and the group doesn't track implementation rates among participating nations as the cost of systematic, global tracking is prohibitive. But Tritscher said evidence that nations are lowering levels of contamination in the food supply suggests they are implementing the commission's guidelines.

Scientists aren't even sure of the exact burden of disease posed by microbiological and chemical contaminants in food, said Schlundt. "We're estimating that at least a third of the total global population gets sick from food every year, probably more in the poorest countries."

The WHO hopes to produce an atlas of the global food borne disease burden by 2012 or 2013. — Lauren Vogel, *CMAJ*

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