

## FOR THE RECORD

**Untreatable gonorrhea rampant**

Arguing that the incidence of drug resistant gonorrhea is reaching “crisis” dimensions, the World Health Organization (WHO) has unveiled an action plan to contain antimicrobial resistance (AMR) in *Neisseria gonorrhoeae* before it becomes entirely untreatable.

With Australia, France, Japan, Norway, Sweden and the United Kingdom reporting cases of resistance to cephalosporin antibiotics in their use of the so-called treatment option for gonorrhea, and an estimated 106 million people infected annually with the sexually transmitted disease, the world stands at a precipice that could ultimately cause the death of millions, WHO states in its Global action plan to control the spread and impact of antimicrobial resistance in *Neisseria gonorrhoeae* ([http://whqlibdoc.who.int/publications/2012/9789241503501\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241503501_eng.pdf)).

“The emergence, in *N. gonorrhoeae*, of decreased susceptibility and resistance to the ‘last-line’ cephalosporins, together with the longstanding high prevalence of resistance to penicillins, sulfonamides, tetracyclines and, more recently, quinolones and macrolides (including azithromycin), is cause for concern. Gonorrhoea has the potential to become untreatable in the current reality of limited treatment options, particularly in settings that also have a high burden of gonococcal infections. The loss of effective and readily available treatment options will lead to significant increases in morbidity and mortality, as the future could resemble the pre-antibiotic era when there was a risk of death from common infections such as a streptococcal throat infection or from a child’s scratched knee,” the plan states.

“Gonorrhoea is becoming a major public health challenge, due to the high

incidence of infections accompanied by dwindling treatment options,” Dr. Manjula Lusti-Narasimhan, a scientist in the agency’s Department of Reproductive Health and Research, stated in a press release ([www.who.int/mediacentre/news/notes/2012/gonorrhoea\\_20120606/en/index.html](http://www.who.int/mediacentre/news/notes/2012/gonorrhoea_20120606/en/index.html)). “The available data only shows the tip of the iceberg. Without adequate surveillance we won’t know the extent of resistance to gonorrhoea and without research into new antimicrobial agents, there could soon be no effective treatment for patients.”

The plan urges that countries move rapidly with prevention programs to constrain the spread of gonorrhoea, while adopting more traditional approaches to diagnosing the disease, bolstering lab capacity and surveillance procedures to detect emerging, resistant strains of *N. gonorrhoeae*, and implementing “systematic monitoring of treatment failures by developing a standard case definition of treatment failure, and protocols for verification, reporting and management of treatment failure guidance.” It also urges research into “newer molecular models for monitoring and detecting AMR” and “alternative” treatments for gonococcal infections.

Treatment options *N. gonorrhoeae* are dwindling, the report states. “Decreasing susceptibility to the ‘last-line’ third generation cephalosporins is beginning to manifest as clinical treatment failures,” including increasing reports of failure to treat with oral cefixime, as well as a 2011 case which involved high-level resistance to injectable ceftriaxone.

“A critical issue with regard to AMR in *N. gonorrhoeae* is that it can occur within and across antibiotic classes, providing this bacterium with the remarkable ability to acquire and retain genetic and phenotypic resistance to several classes of antibiotics at the same time, even when their use has been discontinued. Three important features of the bacterium are at the ori-

gin of this resistance: the ability of the gonococcal genome to undergo continual mutation and internal recombination, resulting in rapidly evolving gonococcal populations; acquisition by gonococci of all or part of external resistance or virulence genes from other *Neisseria* species; the highly transformable nature of the bacterium, which can frequently release DNA and also efficiently incorporate exogenous DNA acquired from other *Neisseria* species and closely related bacteria.”

Compounding that problem is the fact that diagnosis of gonococcal infections is now primarily based on non-invasive specimens such as urine and vaginal swabs, which “cannot, at this stage, be used to determine AMR in *N. gonorrhoeae* which has created difficulties in identifying the magnitude of AMR in this organism in many parts of the world. Although these diagnostic advances have increased screening and treatment opportunities, they have also resulted in a reduction in routine clinical AMR testing, fewer available gonococcal isolates on which to perform antimicrobial susceptibility testing, and a loss of skills to perform culture by many laboratory technicians and other health-care providers who once had the skills. As isolation and antimicrobial susceptibility testing of *N. gonorrhoeae* is the only reliable method to detect AMR at present, it is necessary to revive the older techniques and skills of culturing the organism in order to rapidly identify AMR.”

While single-dose cephalosporin therapy remains the recommended treatment for most gonococcal infections, the plan urges that countries enhance their capacity to detect cephalosporin-resistant *N. gonorrhoeae* through such means as “building awareness” among clinicians and imposing a “mandatory requirement for laboratory technicians to report AMR testing results to the local and national health authorities.” The plan also urges expansion of early

detection procedures in patients with asymptomatic infections.

The plan also recommends broad efforts to contain AMR, including the development of comprehensive national strategies. “The promotion of national standard treatment guidelines requires proper training and supervision of health-care providers. The lack of appropriate legislation and poor enforcement of the proper use of antimicrobials, such as selling antibiotics over the counter or turning a blind eye to self-medication practices, have resulted in an irrational use of antimicrobial medicines and may have contributed significantly to AMR in *N. gonorrhoeae*. Promotion and enforcement of evidence-based treatment guidelines, and enforcement of prescription-only use of antimicrobials through established pharmacies and outlets, are important actions needed at national levels.”

In cases where a cephalosporin-resistant strain of *N. gonorrhoeae* has been diagnosed, the plan urges a patient- and public-health oriented approach, including the collection of additional clinical, epidemiological and personal information from the patient and their sexual partners. As well, “it is important to maintain reserves of high-efficacy treatment options for patients with probable Ceph-R *N. gonorrhoeae*. Clinicians treating patients with suspected or confirmed treatment failure or persons infected with a strain found to demonstrate in vitro resistance, should conduct culture and susceptibility testing of relevant clinical specimens, or refer to a specialist centre and reference laboratory and re-treat the patients with higher doses of ceftriaxone, in the first instance. Doses of 500 mg to 1 g ceftriaxone, given intramuscularly, should be considered.”

“Health departments should prioritize notification of the sexual partners of patients with *N. gonorrhoeae* infection thought to be associated with cephalosporin treatment failure or partners of patients whose isolates demonstrate decreased susceptibility to cephalosporin. It is important to rapidly identify, screen and treat the sexual partners of patients with Ceph-R *N. gonorrhoeae* or confirmed treatment failure, and, ideally, to test any identi-

fied isolates for antimicrobial susceptibility.” — Wayne Kondro, *CMAJ*

## Global patient safety agency urged

A global entity tasked with analyzing health care mishaps and issuing reports that include details on causal factors and recommendations for prevention would save money and lives, according to United States patient safety advocates.

As envisioned, such an entity would target “high-impact, high-volume, high-preventability health care accidents,” says Dr. Charles Denham, chairman of the Texas Medical Institute of Technology in Austin, Texas, and chairman of the Global Patient Safety Forum, “the convening organization of the world’s leading patient safety organizations,” based in Geneva, Switzerland.

Leaders of health care organizations worldwide have a “moral imperative” to share information that could prevent future accidents and “an intrinsic desire” for such information, Denham adds. “They don’t get up in the morning to come in and have accidents; they really want to prevent them and they don’t have enough information to go on. We think that just one of these reports will save a number of lives. It’s a very low-cost, high-return, life-saving approach that can be undertaken.”

Because the nature and rates of health care accidents are similar in many countries, creating a global patient safety body of the sort makes sense, Denham contends. Countries such as Canada, Australia and “progressive European countries” would most likely be interested in participating, he says. “I can almost imagine any country that is not currently undergoing terrific strife today is going to be interested.”

As the potential scope and parameters of the proposed global safety entity have not been developed or articulated, it is unclear how it might differ from the Global Patient Safety Forum, which has four initiatives: the creation of a fellowship program; the establishment of a “solutions engagement program for high-performance healthcare initia-

tives”; the creation of a “global patient safety framework” that will establish a “global Safe Practices Synchro-harmonization program”; and the broadcasting of “quality patient safety documentaries” (<http://www.globalpatientsafetyforum.org/>).

Proponents of the notion gathered in Washington, DC, at the “Patient Safety and High Performance Leadership Summit: Issues in Governance, National Collaboratives, and HIT [Healthcare Information Technologies]” in April for blue sky discussions on the need for such an agency ([www.safetyleaders.org/webinars/indexWebinar\\_April2012.jsp](http://www.safetyleaders.org/webinars/indexWebinar_April2012.jsp)). Several pointed to aviation as an example of how standardization can drive down accident rates and how a similar approach might work for health care.

“In the US, commercialization went five years without having a single crash; in health care in the US, we’re killing 100,000 people per year,” says Dr. David Bates, senior vice-president for quality and safety and chief quality officer at Brigham and Women’s Hospital in Boston, Massachusetts. “Aviation, by standardizing the way that they do things, by reducing some of the unnecessary variation in the way that commercial aviation is managed, has very dramatically improved safety.”

Although a pilot might prefer to take off steeply or more gradually, they are told the exact angle at which to take off — an example of how the reduction of “unnecessary variation” can reduce accident rates, Bates adds. “Because people have to follow those guidelines, planes are just much less likely to run into each other. In medicine we’ve let people do things pretty much completely the way that they want and that carries a good bit of risk.”

If done right, such a resource could be a valuable tool for “people at all levels of health care,” but it must be dynamic to have any prospect of success, stresses Philip Hassen, adjunct professor of public health at the University of Alberta in Edmonton, president of the Canadian Network for International Surgery and former CEO of the Canadian Patient Safety Institute.

Considerations such as chronic diseases and comorbidities might affect

how a clinician approaches a patient's problem, Hassen says. "In most of the work we've done in the past in these areas we give guidelines and then we permit people to make exceptions because there are typically some exceptions to be made in the way in which you apply a solution to a particular medical problem."

Another concern is that standardization could stifle innovation, he adds. "It's the matter of dynamically being able to change those best practices as new evidence occurs or new best practices are established. And you allow for variation when you want to study something, because you need to be able to study new inventions, and that means you're varying from the standard protocol. You have to give room for all of that when you're doing it so people can continue to mature and evolve good health care and safer health care."

While that's a valid concern, Bates says, there are "enormous amounts of variation in health care and there's good evidence that standardizing care for many domains has substantially improved both quality and safety and efficiency."

There's also the matter of getting health care organizations and physicians to sign on, Hassen notes. "One of the difficulties is of course there are other people who think they have the right answer, so you've really got to make sure there is good consensus and that people believe this is the new gold standard available to them." — Michael Monette, *CMAJ*

## The high cost of hospital readmissions

If you asked an acute care patient what place they would like to visit within a month of discharge, the hospital would likely be at the bottom of the list. Yet 1 in 12 Canadians do just that, and it's costing the health care system in the neighbourhood of \$2 billion a year. Many readmissions, however, could be avoided by better identifying those most likely to return to hospital within short periods and improving the care they receive before and after discharge.

About 8.5% of patients in acute care settings are readmitted to hospital within 30 days, according to All-Cause Readmission to Acute Care and Return to the Emergency Department, a study released June 14 by the Canadian Institute for Health Information ([https://secure.cihi.ca/free\\_products/Readmission\\_to\\_acutecare\\_en.pdf](https://secure.cihi.ca/free_products/Readmission_to_acutecare_en.pdf)). The cost of the 181 551 readmissions over the 11-month study period was around \$1.8 billion. That works out to 11% of all the money spent on inpatient care, not including physician fees for services.

Though a large portion of readmissions may be inevitable, it's possible that 9%–59% of them could be avoided, the paper notes. Even at the low end of the range, that would free up many millions of dollars to allocate to other areas of health care.

The study divided patients into four groups: medical, surgical, pediatric and obstetric. The first group, consisting of people admitted for acute care, had the highest readmission rate, at 13.3%. That was twice as high as in the surgical and pediatric groups. Meanwhile, only 2% of obstetrics patients made unplanned return trips to hospital within a month of leaving.

Reasons for readmission were grouped into three categories: patient effects, hospital effects and community effects. There is nothing that can be done about reducing certain personal risk factors, such as age or comorbidities. The largest contributor to readmissions in the medical group, for instance, was if the patient had chronic obstructive pulmonary disease.

The two primary hospital effects that influence readmission rates are hospital size and length of stay. Large community hospitals have the lowest readmission rate (7.6%), whereas small hospitals have the highest (12.4%), likely because more of their patients fall into the medical category, which accounts for 41.6% of all readmissions.

Shorter lengths of stay also contribute to higher readmission rates. If the time in hospital is one day shorter than the national average for the expected length of stay, the paper states, the risk of readmission soars by 40%. Still, merely increasing lengths of stays is hardly the solution, the paper

suggests, as this would only lead to other problems, including increased wait times, fewer beds for new cases and more hospital-acquired infections.

Community factors associated with readmission rates include access to post-acute care services and neighbourhood affluence. Readmission rates were higher in rural areas (9.5%) than in urban regions (8.3%), likely because there are more seniors in rural areas yet less access to home care and other post-acute services, the paper suggests. People living in the poorest areas were also readmitted at a higher rate (9.5%) than those in the most affluent communities (7.9%), reflecting the well-known ties of socio-economic status to health.

The study also found that 9% of people in Ontario, Alberta and Yukon made unplanned trips to emergency departments within a week of leaving an acute care setting, at a cost of \$30.6 million. Around 31% of these people were subsequently readmitted to hospital. Many of these patients, however, simply required follow-up care and were not readmitted, particularly in the surgical group. For example, about 20% of unilateral knee replacements and hysterectomies resulted in unplanned follow-up care in emergency departments.

To reduce readmission rates, the paper suggests, hospitals should attempt to identify those at highest risk and implement interventions before and after discharge. Possible pre-discharge interventions include patient education, discharge planning and scheduling follow-up appointments. Possible post-discharge interventions include follow-up phone calls, patient hotlines and timely clinical follow-up.

"Reducing readmission rates is not a simple task; rather, it is a multi-faceted issue that requires multiple actions from all levels of the health care system," the paper concludes. "This report provided information about patient-level, hospital-level and community-level factors that contribute to readmission rates in Canada. An improved understanding of these factors may contribute to increased collaboration among leaders of the different system components to improve readmission outcomes." — Roger Collier, *CMAJ*

## A nurse-led plan to transform health care

**N**urses must play a greater role, if not the lead role, in the transformation of Canada's health care system to meet the changing health needs of its aging and increasingly diverse population, the nation's nurses argue.

The science and practice of nursing should be core components of a transformed health care system that is less focused on providing acute care because they're capable of more inexpensively performing many of the tasks that doctors now perform and thus can reduce overall health costs, the Canadian Nurses Association's National Expert Commission argues in a 9-part plan to reform health care, *A Nursing Call to Action* ([www2.cna-aiic.ca/CNA/documents/pdf/publications/nec/NEC\\_Report\\_e.pdf](http://www2.cna-aiic.ca/CNA/documents/pdf/publications/nec/NEC_Report_e.pdf)). "In almost every study, the nursing interventions were as or more effective than usual care for the same or less cost," the report states. "If we change usual care, so it is funded and structured to be led by nurses, we could free up the time of other professionals, improve outcomes and rein in costs."

Patient safety would also be improved, the report adds, as research indicates that higher nursing staff levels save lives by reducing many risks to patients, including hospital-acquired pneumonia, unplanned extubations and bloodstream infections.

The 9-part action plan suggests nurses are capable of leading transformative change because they are well-educated, affordable, in possession of a vast reservoir of collective wisdom, and experienced in all health care settings and with patients of all ages. They are also strong in number, with 285 000 registered nurses plus 90 000 licensed practical nurses and registered psychiatric nurses.

"The success of our Plan of Action depends on nurses to lead transformative change and real innovation," states the report. "Where nurses lead to improve health, care and value in health care and where they collaborate to build a healthier Canada, we know the public, other

health professionals and governments will not fail to join in."

That is not to say, however, that nurses are already fully prepared to lead the transformation charge. But they can put themselves in that position by acting in four areas to "develop, implement and maintain a new model of care delivery": intensify their roles as leaders of health system transformation by expanding their scope of work to permit functions such as prescribing and admitting/discharging patients; address issues related to social, economic, environmental and Indigenous determinants of health; promote healthy lifestyles; and "advocate forcefully for health care transformation."

Nurses have already taken many innovative initiatives to expand their roles in health care, the report adds, citing such examples as nurse "navigators" for cancer patients in Quebec; a nurse practitioner-led surgical spine clinic in Toronto, Ontario; and primary care teams that use nurses to perform tasks that free physicians to spend time with patients with complex conditions.

The action plan also urges:

- Engaging other health professionals and policy-makers in selecting five key health goals and ensuring Canada ranks in the top five nations of the world in those outcomes by 2017;
- Partnering with governments, the public and other health professionals to move beyond institution-based health care to a community model that focuses on prevention, health promotion and the management of chronic conditions;
- Holding a national summit of stakeholders from the health professions, the community, governments and social-service agencies in late 2012 to begin working on a system that will ensure timely access to services to prevent illness and injury, promote health and manage and treat health problems;
- Investing more strategically to improve factors — such as poverty, inadequate housing, food insecurity and social exclusion — that influence health;
- Better identifying vulnerable and marginalized individuals, such as disabled people and those living in

poverty, and focusing resources in areas that will best address their health needs;

- Pressing governments to create processes that support healthier lifestyles;
- Developing a "comprehensive national commitment" to safety and quality in the health care system;
- Advocating for more people from Aboriginal populations and minorities to join the health professions;
- Escalating the use of technology — smart phones, e-mail, Skype, telehealth, etc. — to provide more services to Canadians, while accelerating the implementation of electronic medical records so they are "fully accessible, portable and interactive."

"Meeting the changed and changing health and wellness needs of Canadians in the 21st century means shifting our focus from hospitals to primary health care networks, run by teams of professionals that ensure continuity of care," the report states. "Public health policy and education that encourage healthy life choices need to be emphasized. As well, the providers and organizations offering these new types of care will need to embrace cultural awareness, be able to offer care in multiple languages, and be sensitive to the traumatic backgrounds of many Aboriginal people and those from areas of political and military unrest. Services will have to be designed to meet the needs of a growing proportion of older patients." — Roger Collier, *CMAJ*

## Lack of harm reduction programs "criminal"

**P**ublic health is being sacrificed at the altar of "repressive drug law enforcement practices," the Global Commission on Drug Policy says, while urging drug decriminalization and the expansion of harm reduction programs such as sterile syringe exchanges, safe injection facilities and prescription heroin initiatives.

"The global war on drugs is driving the HIV/AIDS pandemic among people who use drugs and their sexual partners," the commission states in a report, *The War on Drugs and HIV/AIDS: How the Criminalization of Drug Use*

Fuels the Global Pandemic ([www.drugpolicy.org/sites/default/files/GCDP\\_HIV-AIDS\\_2012\\_REFERENCE.pdf](http://www.drugpolicy.org/sites/default/files/GCDP_HIV-AIDS_2012_REFERENCE.pdf)). “Throughout the world, research has consistently shown that repressive drug law enforcement practices force drug users away from public health services and into hidden environments where HIV risk becomes markedly elevated. Mass incarceration of non-violent drug offenders also plays a major role in increasing HIV risk.”

The 21-member commission, which includes former UN High Commissioner for Human Rights Louise Arbour, prominent authors Mario Vargas Llosa and Carlos Fuentes, as well as six former presidents or prime ministers, argues that failure to implement such harm reduction measures to reduce HIV infection and protect drug users is nothing short of “criminal.”

Along with urging the adoption of such evidence-based strategies, the commission recommended that governments be pushed “to halt the practice of arresting and imprisoning people who use drugs but do no harm to others,” and that “the public and private sectors should invest in an easily accessible range of evidence-based options for the treatment and care for drug dependence, including substitution and heroin-assisted treatment. These strategies reduce disease and death, and also limit the size and harmful consequences of drug markets by reducing the overall demand for drugs.”

Drug policy success should be measured by “indicators that have real meaning in communities, such as reduced rates of transmission of HIV and other infectious diseases (e.g., hepatitis C), fewer overdose deaths, reduced drug market violence, fewer individuals incarcerated and lowered rates of problematic substance use,” the report also recommends.

There’s a “mistaken assumption that drug seizures, arrests, criminal convictions and other commonly reported indices of drug law enforcement ‘success’ have been effective overall in reducing illegal drug availability,” the report states. “However, data from the United Nations Office on Drugs and Crime demonstrate that the worldwide supply of illicit opiates, such as heroin, has increased by more than 380 percent

in recent decades, from 1000 metric tons in 1980 to more than 4800 metric tons in 2010. This increase coincided with a 79 percent decrease in the price of heroin in Europe between 1990 and 2009.”

As well, the “global prohibition of drugs now fuels drug market violence around the world,” the report states. “For instance, it is estimated that more than 50,000 individuals have been killed since a 2006 military escalation against drug cartels by Mexican government forces. While supporters of aggressive drug law enforcement strategies might assume that this degree of bloodshed would disrupt the drug market’s ability to produce and distribute illegal drugs, recent estimates suggest that Mexican heroin production has increased by more than 340 percent since 2004.”

The report adds that the drug war fuels the HIV pandemic in the following ways: “Fear of arrest drives persons who use drugs underground, away from HIV testing and HIV prevention services and into high risk environments; restrictions on provision of sterile syringes to drug users result in increased syringe sharing; prohibitions or restrictions on opioid substitution therapy and other evidence-based treatment result in untreated addiction and avoidable HIV risk behavior; conditions and lack of HIV prevention measures in prison lead to HIV outbreaks among incarcerated drug users; disruptions of HIV anti-retroviral therapy result in elevated HIV viral load and subsequent HIV transmission and increased antiretroviral resistance; [and] limited public funds are wasted on harmful and ineffective drug law enforcement efforts instead of being invested in proven HIV prevention strategies.” — Wayne Kondro, *CMAJ*

## New app for managing medications

**I**n a bid to reduce the incidence of medication misuse, seven Canadian health organizations have launched a free iPhone and iPad app, MyMedRec, aimed at promoting appropriate and safe use of prescription drugs.

The new app, along with the website [www.knowledgeisthebestmedicine.org](http://www.knowledgeisthebestmedicine.org),

was developed by the Institute for Safe Medication Practices Canada. It allows “patients and caregivers to have their medication and immunization record at their fingertips. It includes features such as refill and dose reminders, storing of medication histories and multiple patient profiles, email and picture capabilities, as well as contact information of prescribers and pharmacies,” according to a press release ([https://www.canada.pharma.org/en/documents/20120620\\_NewsRelease-KiBM\\_FINALLEN.pdf](https://www.canada.pharma.org/en/documents/20120620_NewsRelease-KiBM_FINALLEN.pdf)).

“The tool will help patients and caregivers compile a full list of their medications whether prescription, over the counter or natural health products and share the information with their health care team as they see fit. The app is also supported by the [www.knowledgeisthebestmedicine.org](http://www.knowledgeisthebestmedicine.org) website which contains health information, relevant links and safe medication use tips, as well as a variety of downloadable medication records for those who don’t have iPhones,” the press release added.

The app is very user-friendly, says Shannon MacDonald, vice president of public affairs and partnerships at Canada’s Research Based Pharmaceutical Companies (Rx&D). It allows users to take pictures of a particular medication bottle or pill, which can then be linked to a reminder alarm, she explains. “It actually will print the picture of that medication and what the pill looks like, right alongside the information.”

It also protects patient privacy, MacDonald adds. “We specifically designed the app so that no personal information lives on any server. The app is ‘sandboxed’, which means in the app world that no other app can access the information that lives in that app. The only place that confidential information exists is within the app on your personal device or on your personal computer if you have chosen to use the downloadable PDF files off the website.”

The new electronic tools are also part of the ongoing Knowledge is the Best Medicine consumer awareness program funded by Rx&D and supported through the collaboration of five other health organizations: The Canadian Nurses Association, the Canadian Pharmacists Association, the Canadian Medical Association, the Institute for Safe Medication

Practices Canada, the Victorian Order of Nurses and the Best Medicines Coalition. An estimated 50% of patients take medications incorrectly, according to the World Health Organization. Incorrect medication usage can be anything from not filling or refilling a prescription, taking the incorrect amount or administering it at the wrong time.

Although the app is currently limited to Apple products, MacDonald says developers hope to “transition pretty quickly to android and blackberry [platforms].” For those without a smartphone, the website provides the tools necessary to create a personalized medication book which can be stored on the computer or printed, as well as health information and medication safety tips. Brochures and medication record books will continue to be distributed to those who prefer the original printed product.

“We designed [MyMedRec as] a self-management tool, in particular for people managing multiple medications,” says MacDonald, “but we quickly realized that it is a tool that anybody can use at any age and stage of life to better manage their health information.” — Siobhan Deshauer, Ottawa, Ont.

## Drug industry research outlays plummet

**A**lthough brand-name drug industry revenues increased 4.7% to \$17.8 billion in 2011, their research and development (R&D) outlays plummeted 15.8% to a level not seen in over a decade, according to

the Patented Medicines Price Review Board (PMPRB) annual report.

The decline in R&D outlays, to roughly \$991 million from \$1.2 billion in 2010, marks the fourth consecutive year in which the brand-name drug industry has pared, according to the Patented Medicine Prices Review Board Annual Report 2011 ([www.pmprb-cep.mb.gc.ca/CMFiles/Publications/Annual%20Reports/2011/2011-Annual-Report\\_EN\\_Final-for-Posting.pdf](http://www.pmprb-cep.mb.gc.ca/CMFiles/Publications/Annual%20Reports/2011/2011-Annual-Report_EN_Final-for-Posting.pdf)).

When the Canadian government agreed in 1987 to extend patent protection for new drugs and to jettison a compulsory licensing regime that had allowed generic drug firms to readily produce knock-offs, the brand-name drug industry committed to increasing basic R&D spending to 10% of sales.

Within years, though the industry was actively lobbying to include all clinical trials in that calculation, as well as costs related to drug regulation submissions and bioavailability studies ([www.cmaj.ca/lookup/doi/10.1503/cmaj.060883](http://www.cmaj.ca/lookup/doi/10.1503/cmaj.060883)).

Midway through the last decade, outlays for basic research accounted for just 18.2% of the brand-name industry's R&D expenditures ([www.cmaj.ca/lookup/doi/10.1503/cmaj.080989](http://www.cmaj.ca/lookup/doi/10.1503/cmaj.080989)). That decline continues as the latest PMPRB report indicates that basic research accounts for just 17.3% of industry outlays, while clinical trials account for 55% and “other” expenditures 27.8%.

While “Canadians spend much more today on patented drug products than they did a decade ago,” that's not necessarily a function of rising prices, the report states. Other factors include “increases in total population; changes

in the demographic composition of the population (for example, shifts in the age distribution toward older persons with more health problems); increases in the incidence of health problems requiring drug therapy; changes in the prescribing practices of physicians (for example, shifts away from older, less expensive drug products to newer, more expensive medications, or a shift toward higher, more frequent dosages); increases in the use of drug therapy instead of other forms of treatment; [and] the use of new drug products to treat conditions for which no effective treatment existed previously.”

The report also indicates there were 109 new patented drug products for human use sold in Canada in 2011. When those were reviewed to determine if they were being sold at “excessive” prices, 86 passed the test, “10 were at levels that appeared to exceed the Guidelines by an amount which did not trigger the investigation criteria [and] 13 were priced at levels that appeared to exceed the Guidelines and investigations were commenced.”

Canadian drug expenditures as a percentage of gross domestic product continues to be at the high end of the scale in comparison with those of other developed Western nations, the report adds. At 1.94% in 2009, Canada's outlay trailed only the United States (2.09%). In comparisons, outlays were lower in France (1.9%), Germany (1.73%), Italy (1.73%), Sweden (1.25%), Switzerland (1.15%) and the United Kingdom (1.14%). — Wayne Kondro, *CMAJ*

*CMAJ* 2012. DOI:10.1503/cmaj.109-4248