FOR THE RECORD

Published at www.cmaj.ca between Sept. 28 and Oct. 7

HIV treatment goal unlikely to be achieved

While there have been advances in worldwide access to HIV testing, prevention, treatment and care in low- and middle-income countries, there is little chance of achieving the global goal of universal access to antiretroviral therapy and interventions to prevent mother-to-child transmission of HIV by the end of 2010, the World Health Organization reports.

The universal access goal — agreed to by United Nations member states in 2006 and defined as coverage of 80% of the population in need — is “unlikely” to be achieved given that only 5.2 million, or 36%, of low- and middle-income country residents living with a CD4 cell count of < 350 cells/mm³ received antiretroviral therapy in 2009, according to the report, *Towards Universal Access: scaling up priority HIV/AIDS interventions in the health sector 2010 Progress Report*. An estimated 14.6 million people are in need of antiretroviral therapy. About 28% (356 000) of children younger than 15 years of age who need antiretroviral therapy were receiving it, while the percentage of pregnant women living with HIV in low- and middle-income countries who receive antiretroviral therapy to prevent mother-to-child transmission was 53% (www.who.int/hiv/accessformedia/report_en.pdf).

“Overall antiretroviral therapy coverage among children in low- and middle-income countries was lower than that among adults (37% [35–41%]). Moreover, in 54 reporting countries, only 15% [10–28%] of children born to HIV-positive mothers received an HIV test within the two first months of life,” the report says, urging greater efforts to

“scale up early testing of HIV-exposed infants, reduce the rate of loss to follow up among them in the postnatal period, and further integrate HIV interventions with services for maternal, newborn and child health.”

The report notes that among 144 low- and middle-income countries reporting data in 2009, eight (Botswana, Cambodia, Croatia, Cuba, Guyana, Oman, Romania and Rwanda) had already achieved universal access to antiretroviral therapy, while 15 had achieved the 80% target for antiretroviral prophylaxis to prevent pregnant women from transmitting HIV to their children. Another 22 countries are within reach of the 80% goal.

But the report warns that political and economic considerations threaten the global effort to constrain HIV/AIDS. “At the same time [as progress is being made], the global HIV response has been buffeted by both the global financial crisis and changing public health and development priorities at national and international levels.”

“After years of considerable increases in international assistance from high-income countries for the global HIV response, funding remained essentially flat over the 2008–2009 period. According to recent estimates, commitments from donor governments totalled US\$8.7 billion, the same as in 2008. In comparison, it has been estimated that US\$26.7 billion would be necessary — from all sources, including domestic and international — for the global HIV response in low- and middle-income countries in 2010,” the report states.

“The global economic crisis of 2008–2009 has put the sustainability of many HIV programmes at risk. It is clear that without continued and strengthened financial and programmatic commitments, there is considerable danger that these achievements could be undone,” the report concludes. “Addressing the challenges posed by

the MDGs [Millennium Development Goals] pertaining to HIV requires action along four main strategic directions: (i) expanding and optimizing the global HIV response, (ii) catalysing the impact of HIV programmes on other health outcomes, (iii) strengthening health systems for a sustainable and comprehensive response, and (iv) tackling the structural determinants of the response, including human rights violations.” — Wayne Kondro, *CMAJ*

CMA urges overhaul of electronic health records strategy

Roughly 20 500 Canadian physicians who have not yet received government support to adopt health information technologies should receive \$35 000 apiece to migrate onto electronic platforms, the Canadian Medical Association says. That should include \$20 000 apiece primarily for equipment and an additional \$15 000 each for “transition support and change management.”

The \$720 million outlay is part of \$923 million that the CMA says should be shelled out over the next five years to shift Canada’s health information technology strategy away from large-scale systems and architecture toward frontline points of care at the “grass-roots” level.

“The goal now needs to be (to) speed up information liquidity,” CMA says in a strategy paper, *Toward Patient-Centred Care: Digitizing Health Care Delivery — The CMA 5-year strategy for health information technology (HIT) investment in Canada*, (www.cma.ca/multimedia/CMA/Content/Images/Inside_cma/HIT/CMA-5year-HIT-strategy_en.pdf). “By automating and connecting ambulatory points of care (e.g., physician offices, labs, pharmacies and hospitals), we will more quickly deliver IT solutions that support clinicians, produce timely clinical value for patients and providers, and

achieve savings in the shorter term (12–18 months) for the health care system.”

CMA President Dr. Jeff Turnbull argued that a “reboot” of Canada’s strategy is vital. “We want investments that translate into tangible benefits, namely improved patient care and better outcomes,” he said in a press release (www.cma.ca/advocacy/hit-strategy).

CMA says in its strategy document that failure to meet targeted implementation dates, budget overruns and inadequate accountability measures have characterized Canada’s “top-down” HIT strategy to date. “But health care is fundamentally a locally-delivered service. More than 85% of care occurs at the community level and very few individuals go outside their local catchment area to receive care. To accelerate adoption of information technology in health care, we must focus on the patients and where they interact with the health care delivery system.”

To that end, CMA says investments should be focused on several “clinical and system priorities,” specifically, “chronic disease management, prevention and health promotion, medication management, continuity of care (information flow, access and wait times), patient involvement and public health reporting.”

In turn, that will necessitate a focus on three “interim” goals: “significant adoption of EMRs [electronic medical records] by primary care and specialist physicians in ambulatory settings; accelerating the exchange of health information to support the majority of health care transactions; and increasing the effective use of EMRs and related solutions to meet pressing health and system issues.”

CMA also urges the adoption of two internationally-established performance measures to determine whether new Canadian investments are fruitful, to wit: “physician use of EMRs/HIT in their practices on a routine basis for ‘core tasks’ and computerized capacity to generate patient information.”

Along with the \$720 million recommended to bring all Canadian physicians up to electronic speed, CMA urged \$10 million be spent on “functional requirements for specialist that can be built into EMR products, the e-referral process,

hospital interfaces, unique device integration and documentation requirements,” and that \$5 million be spent on “data migration to offset the burden for physicians of having to switch EMR systems as the marketplace matures.”

CMA said \$37 million should be spent on research and the development of electronic tools that better integrate HIT into clinical practice, while \$151 million should be spent on accelerating health information exchange, including \$100 million on the development of “regional interoperability solutions” that allow doctors to share data with medical administrators, patients and each other. — Wayne Kondro, *CMAJ*

Gaps remain in women’s health research

Two decades of effort to boost women’s health research have reduced the toll of several serious disorders among American women, but there’s been limited or no progress on several other conditions that still profoundly affect their quality of life, according to a report from the United States Institute of Medicine (IOM).

The report, *Women’s Health Research: Progress, Pitfalls, and Promise*, found improvements in women’s health research have lessened the burden of disease and reduced deaths among American women because of cardiovascular disease, breast cancer and cervical cancer (www.nap.edu/openbook.php?record_id=12908&page=1). Less, but still significant, progress was made in reducing the effects of depression, HIV/AIDS and osteoporosis.

However, fewer gains have been made on chronic and debilitating conditions that cause suffering among women but have lower death rates. Unintended pregnancy, alcohol and drug addiction, autoimmune disease, lung cancer and dementia saw little progress over the last two decades.

“These issues require similar attention and resources if we are to see better prevention and treatment in more areas,” Nancy Adler, chair of the IOM’s committee on women’s health

research, said in a news release. “And across all areas, researchers need to take into account the effects of both biologically determined sex differences and socially determined gender differences as a routine part of conducting research” (www.iom.edu/Reports/2010/Womens-Health-Research-Progress-Pitfalls-and-Promise/Press-Release.aspx).

What gains have been made have been driven by new requirements for researchers to include women in studies, research approaches that tackled conditions from several fronts and better funding from public and private stakeholders.

But the full benefit of the improvements has yet to be realized, according to the report, as researchers still don’t routinely analyze and report results separately for women and men. To that end, the report recommended that journal editors require all papers reporting the outcomes of clinical trials to present data on men and women separately, unless a paper’s focus is sex-specific.

It also called for the US Food and Drug Administration to enforce companies’ compliance with requirements to provide sex-specific data on new drugs and devices.

The report, sponsored by the US Department of Health and Human Services, also found that some groups of American women have not equally benefited from what progress has occurred in research as women who are socially disadvantaged because of their race, income level or educational background were underrepresented in many studies. To redress that, it recommended that National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Disease Control and Prevention develop targeted initiatives to increase research on these underrepresented groups. — Lauren Vogel, *CMAJ*

United States clinical trial safety data reporting requirements revised

The United States Food and Drug Administration (FDA) has unveiled its final revisions

to regulations that tighten safety reporting requirements for clinical trials of new drugs and biologics, as well as bioavailability and bioequivalence studies.

The FDA's "final rule" will oblige companies to report to the agency within 7 to 15 days "all findings from clinical or epidemiological studies that suggest a significant risk to study participants; serious suspected adverse reactions that occur at a rate higher than expected; (and) serious adverse events from bioavailability studies which determine what percentage and at what rate drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug."

"The revisions will improve the utility of IND [investigational new drug] safety reports, reduce the number of reports that do not contribute in a meaningful way to the developing safety profile of the drug, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, subject bioavailability and bioequivalence studies to safety reporting requirements, promote a consistent

approach to safety reporting internationally, and enable the agency to better protect and promote public health," the FDA states in its posting on the Federal Register (http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2010_register&docid=fr29se10-3.pdf).

The regulations, which take effect Mar. 28, 2011, will require sponsors to notify the FDA, and all participating investigators in a trial, of any suspected or life-threatening adverse drug events or reactions that are "both serious and unexpected, based on the opinion of either the investigator or sponsor (as opposed to only the sponsor)."

The agency also indicated that it was retreating from a proposed definition that would have required reporting of any "noxious or unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response." Concerns had been raised that such a definition would stifle clinical trials.

Instead, the FDA adopted the terms "adverse event" and "suspected adverse reactions" to cover reportable incidents.

An adverse event "means any untoward medical occurrence associated with the use of a drug in humans, whether or

not considered drug related. ... 'Suspected adverse reaction' means any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, 'reasonable possibility' means there is evidence to suggest a causal relationship between the drug and the adverse event."

In its nonbinding guidance to industry on the effect of the new rule, the FDA states that an adverse event can be "any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. An adverse event can arise from any use of the drug (e.g., off-label use, use in combination with another drug) and from any route of administration, formulation, or dose, including an overdose" (www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf).

Separate rules for postmarket safety reporting are still under development, the agency said. — Wayne Kondro, *CMAJ*

DOI:10.1503/cmaj.109-3690