New network created to assess drug safety

Think of it as a sort of rapid response team to determine the safety and efficacy of drugs once they are being used in general patient populations.

Part of a bid to improve the measurement of the adverse effects of drugs long after they've been assessed in clinical trials, the new mechanism, the Canadian Network for Observational Drug Effect Studies (cNODES), was launched Oct. 31. It will tap provincial, territorial and United Kingdom hospitalization and pharmaceutical databases for the information needed to conduct rapid studies of emerging adverse effects of specific drugs.

The network consists of 60 researchers at universities across Canada who will collaborate on projects to review postmarket data drawn from existing databases representing about 27 million people. Its first study will assess whether high-dose prescriptions of statins, which are used to lower cholesterol, can cause acute kidney injuries, says Samy Suissa, director of the Centre for Clinical Epidemiology at the Lady Davis Research Institute/Jewish General Hospital in Montréal, Quebec.

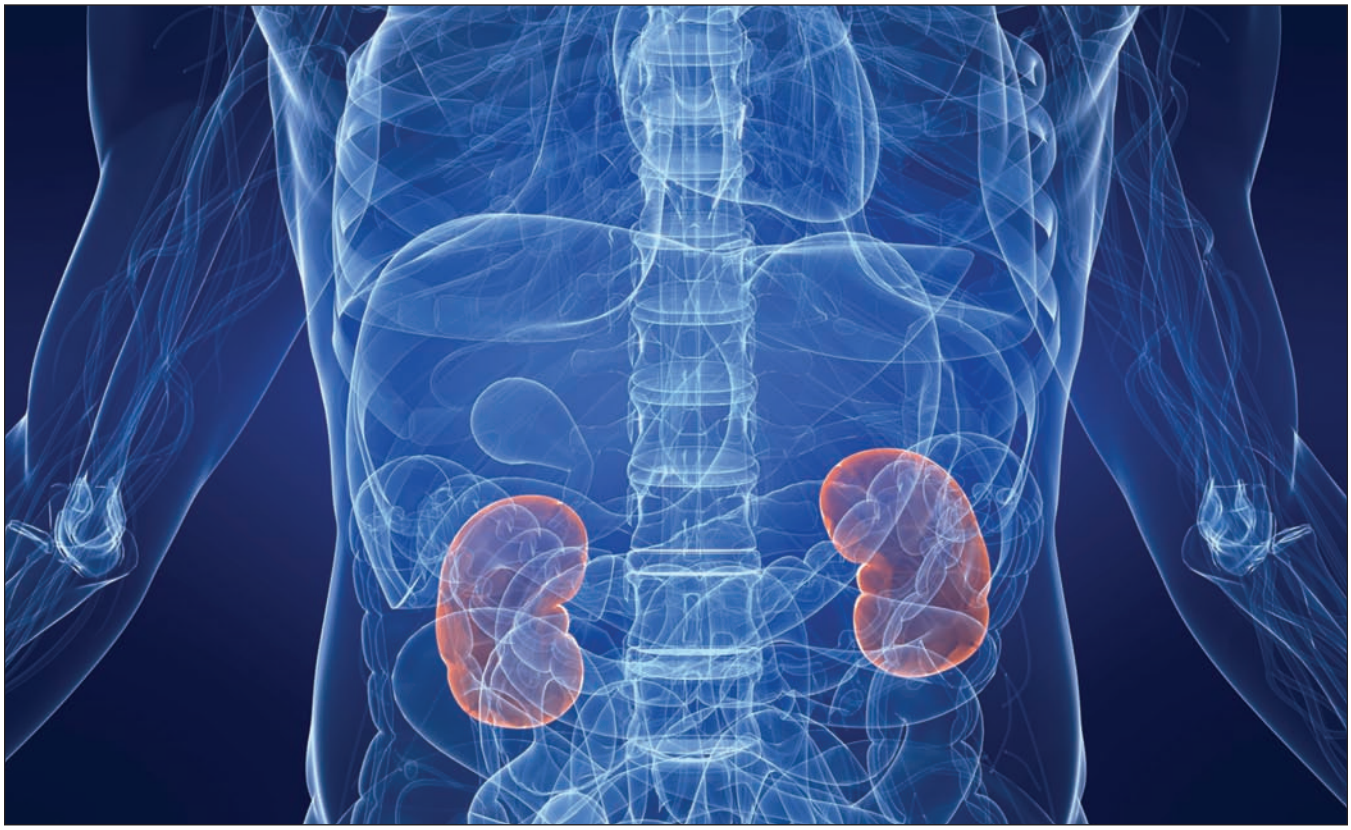
"We are going to do studies according to identical protocols across all of the databases, and then pool all of this information together to get the answer to the question about the safety and benefit of a drug," says Suissa, the network's principal investigator.

The researchers will seek associations among hospital visits, pharmacy prescription databases and vital statistics information, such as deaths. Groups of investigators will conduct studies of the same drugs independently and simultaneously, following the same protocol and using multiple databases, says Suissa.

The initiative is the first to be funded under the Canadian Institutes of Health Research's (CIHR) Drug Safety and Effectiveness Network, which was created to support postmarket studies of drugs and is contributing $17.5 million over five years toward cNODES.

"The idea behind this network is rapid response," says Suissa, who predicts that cNODES will be able to address four questions about drug safety annually, producing one study about every three months.

Currently, patients and health care professionals have to rely on infrequent and often contradictory studies about adverse drug effects, Suissa adds. "We wait, and the accumulation of evidence takes a few years before we say 'Well, now we are convinced, with all of the



The first study to be conducted by the Canadian Network for Observational Drug Effect Studies is one on whether high-dose prescriptions of statins can cause acute kidney injuries.

data, that there is an effect, or there is no effect'."

The new network was designed to produce definitive epidemiological studies more rapidly, he says.

In addition to the statin study, which is to be released by the end of the year, cNODES researchers are also looking at whether proton pump inhibitors that many Canadians take to treat indigestion may cause pneumonia.

The studies are to be published in peer-reviewed journals, and reports sent to all provincial and federal health authorities. They'll also be posted online at either the CIHR or the Drug Safety and Effectiveness Network website.

The network's mandate "aligns really nicely" with the work of the Canadian Patient Safety Institute, says Marie Owen, medication reconciliation lead for the nonprofit corporation. "This year we've made improving communication about medications a priority," she says.

Using the health databases to mine data will be particularly informative, agrees Marg Colquhoun, project lead for the Institute for Safe Medication Practices Canada. "Getting information to the public about the safety of medication sooner — who would not think that was a great idea?"

Suissa says all completed network studies will include recommendations about dosing, when and when not to prescribe drugs, and what alternatives exist.

Researchers will focus their efforts on serious adverse events that result in hospital visits, rather than adverse event reporting by patients or doctors, because they need a large number of verifiable reports to draw solid conclusions about the drugs, Suissa says. "If a query cannot be addressed by the data that we have, then we don't go ahead with the study. We'd rather have a solid study where we can believe the results, than an iffy study where we have no idea what the results mean."

The drugs or classes of drugs to be investigated must also be ones that affect large numbers of Canadians, Suissa adds. The network estimates that 10 000 Canadians die and about 150 000 are hospitalized each year because of adverse drug reactions. — Laura Eggertson, Ottawa, Ont.

CMAJ 2011. DOI:10.1503/cmaj.109-4045