Health Policy Research Program
Summary of Research Results

Title:	**Evaluation of Data Sources to Support Pharmacosurveillance**
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Research Category:	**Research**
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Summary

Background and Objectives: Regular monitoring of medications in real clinical practice for benefits, harms and costs (pharmacosurveillance) has been widely advocated as necessary and feasible to optimize care at both the individual patient level (patient safety) and the public policy (post-marketing surveillance and cost-effectiveness) level. Our study determined the information needs, information availability and methodologic and information privacy challenges for pharmacosurveillance in Canada.

Target Audience: Primarily drug regulators, drug benefit plans, formulary managers and advisors, pharmacoepidemiology researchers.

Methods: Using nominal group consensus technique with experts in 11 domains from across the country, we determined the information required to provide optimum routine pharmacosurveillance (gold standard dataset).

Three main data sources – large, linked administrative databases (LADs), electronic health records (EHRs) and patient registries (PRs), were then analyzed to determine how much of the gold standard dataset requested by the expert panel, was actually available. This was measured in terms of a) data field present and b) completeness (data in the field).

One of the data resources, LAD, was used to explore methods to adjust for channelling bias (patient allocation bias) by comparing results before and after application of 3 main adjustment methods with those of landmark randomized trials (RCTs) – using hormone replacement therapy and cardiovascular disease as the clinical scenario. As well, techniques for data mining large health databases for early signals of unexpected benefit and harm, were reviewed and applied.

Finally emerging regulations and guidelines regarding the use of health information, both identified and de-identified, and their impact on pharmacosurveillance research and policy development, were examined.

Results: The "gold standard" dataset contained 138 information items, ranging from 0 items of family history to 64 items related to current and past medication use. None of the data resources contained all of this information, nor the information subset that the consensus panel universally supported. LADs tend to have very high rates of completeness (data in the field) but have less than half of the required fields. EHRs hold many more of the data fields (potentially all but costing information) but are more variable in their field content and data completeness. PRs tend to be disease or drug-focused and are not catalogued anywhere, making them difficult to access or to use other than for selected questions.

None of the 3 channeling bias adjustment methods examined were able to fully reproduce the RCT results. Data mining techniques within large electronic health record systems or administrative databases, are worth exploring for early signals of drug effectiveness or harm. Data mining methods used in commercially available software require further validation.

Regarding health information privacy, both patient and physician remain concerned about who has access to the patient's information, even when it is anonymized. Both groups are the least concerned about access by university or hospital-based research groups. The lack of consistency and oversight of privacy regulations and interpretation of regulations between the provinces, has led to unacceptable delays in accessing health data for research or policy development purposes.

Implications:

- A data resource suitable for routine, rapid investigation of pharmacosurveillance issues would likely require linkage across LADs and EHRs.
- A registry of health data resources in Canada would be helpful to understand what data resides where and to ensure that the data are properly managed, supported and protected.
- The technical feasibility of pharmacosurveillance is a major problem, given the lack of data standards or data integration standards in Canada.
- Coordination and support for Canada's many data resources, particularly research-quality electronic health records and linked provincial databases, will be required to develop their full value for research and policy purposes.
- Further work is required to adjust for the effect of biases inherent in observational data. Without this, interpretations of cause and effect are flawed and may be fatal, and the databases will only be useful for retrospective evaluation of practices or for generating hypotheses for further rigorous, randomized controlled trial (RCT) testing.
- For the foreseeable future, RCTs will remain the "gold standard" for understanding benefit and harm.
- Information privacy guidelines stipulate very strong data security, data confidentiality and research competence be in place.

- Health information privacy legislation and guidelines are evolving swiftly. Analyses performed in academic settings with high quality privacy rules and practices, are the least problematic.

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- The print version of the full report can be obtained in the language of submission from the Health Canada Library through inter-library loan.
- An electronic version of the report in the language of submission is available upon request from Health Canada by e-mailing rmddinfo@hc-sc.gc.ca.

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