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Secondary Use of Personal Information in Health Research: Case Studies

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About CIHR

The Canadian Institutes of Health Research (CIHR) is Canada's premier federal agency for health research. CIHR was created by Parliament on June 7, 2000. Its objective is "*to excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system.*" (*CIHR Act*, S.C. 2000, c. 6).

The CIHR concept involves a multi-disciplinary approach, organized through a framework of 13 'virtual' institutes, each one dedicated to a specific area of focus to address important health issues such as:

- Aboriginal people's health
- cancer
- circulatory and respiratory health
- gender and health
- genetics
- health services and policy research
- healthy aging
- human development and child and youth health
- infection and immunity
- neurosciences, mental health and addiction
- musculoskeletal health and arthritis
- nutrition, metabolism and diabetes
- population and public health

These 'virtual' institutes support and link researchers located in universities, hospitals and other research centres across Canada, in partnership and collaboration with governments, voluntary health organizations, private sector and others, both nationally and internationally. The institutes embrace four pillars of research:

1) biomedical;
2) clinical science;
3) health systems and services; and
4) the social, cultural and other factors that affect the health of populations.

CIHR's vision is a truly integrative one, encouraging health research across institutes, across pillars, across sectors and across jurisdictions.

As a critical part of its mandate, CIHR must also:

- promote, assist and undertake health research that meets the highest international standards of ethics;
- foster the discussion of ethical issues[1] and the application of ethical principles to health research;
- monitor, analyze and evaluate ethical issues pertaining to health or health research; and
- encourage inter-disciplinary, innovative and integrative research on ethical issues pertaining to health.

For more information about CIHR, visit **http://www.cihr-irsc.gc.ca**.

[1] 'Ethical issues' include ethical, legal and socio-cultural issues.

[Executive Summary]

The challenge facing Canada today is to reach a workable and practical balance between the value Canadians place on the improvement of their health, the effectiveness of their health care services and the sustainability of their health care system, and the equally compelling value they place on their right to privacy and confidentiality with respect to their personal information.

Health research, particularly in the areas of health services and policy, population and public health, critically depends on the ready availability of existing data about people. Such data include health surveys; hospital, physician and laboratory records; provincial and federal billing and registration data; birth and death records; socio-demographic data; cancer registry data; and employment records. Large volumes of such data are generally needed in order to assemble unbiased samples from which health researchers can draw meaningful conclusions that are representative of populations.

The data are analyzed for the purposes of:

- monitoring the health of the population;
- identifying populations at high risk of disease;
- determining the effectiveness of treatment;
- quantifying prognosis and survival;
- assessing the usefulness of preventive strategies, diagnostic tests and screening programs;
- informing health policy through studies on cost-effectiveness;
- supporting administrative functions; and
- monitoring the adequacy of care.

Health research based on the secondary use of data contributes to our present level of understanding of the causes, patterns of expression and natural history of diseases. It also helps us to assess the impact of strategies for improving prevention, diagnosis and treatment and to evaluate policies for increasing the effectiveness and economic efficiency of health services. Indeed, in the present climate of major public concern about the quality and sustainability of our health care system, health research is urgently needed to help inform and guide health care reform.

While health research is of great social importance, Canadians also highly value their rights to privacy and confidentiality. These rights are intimately connected with the right to respect for one's dignity, integrity and autonomy in a free and democratic society and are constitutionally enshrined in the *Canadian Charter of Rights and Freedoms* (Part I of the Constitution Act, 1982, being enacted as Schedule B to the *Canada Act* 1982, c. 11) and Quebec's *Charter*

of Human Rights and Freedoms (R.S.Q. c. C-12). Privacy and confidentiality lie at the root of international and national ethics guidelines, as well as professional codes of conduct.

Data protection legislation is rapidly emerging across the country with different requirements applying either at the provincial, territorial or federal level, to personal information generally or personal health information, in the private or public sector. Yet, health services and population health research often crosses provincial or even national borders, and require access to general personal information (e.g. income level, education, work history, etc.), as well as personal health information (e.g. physician, laboratory, hospital records, registration and billing data, etc.), that may be derived from either public or private sources. By their very nature, therefore, these types of studies can potentially invoke multiple laws with varying, and often, inconsistent requirements.

Despite the patchwork of existing legislation, most data protection laws are generally modeled after the internationally accepted *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* developed by the Organization for Economic Cooperation and Development (OECD) in 1980. These guidelines have since been adapted by Canadian businesses, consumer groups and governments, under the auspices of the Canadian Standards Association, reformulated into the *Model Code for the Protection of Personal Information* CAN/CSA-Q830-96 (the 'CSA' Code) and more recently incorporated as Schedule 1 of the federal *Personal Information Protection and Electronic Documents Act* (S.C. 2000, c.5). (for the complete text of the Act, see **http://www.parl.gc.ca/36/2/parlbus/chambus/house/bills/government/C-6/C-6_4/C-6_cover-E.html**).

The CSA Code is based on ten fair information principles:

- Accountability
- Identifying purposes
- Consent
- Limiting collection
- Limiting use, disclosure and retention
- Accuracy
- Safeguards
- Openness
- Individual access
- Challenging compliance

It is in this context that CIHR created an ad hoc working group composed of health researchers in order to provide real-life examples of research involving the secondary use of data in Canada (see Appendix A for a list of members and Appendix B for a description of the method followed). The objective of this initiative is to foster dialogue:

- with those who draft policies and laws and those responsible for interpreting them, by providing tangible illustrations of their practical application in the health research context;
- among researchers about how to comply with the spirit of the fair information principles and how to improve current information practices; and
- with privacy advocates and the broader public on the benefits and concrete realities of health research.

Nineteen (19) case studies were developed to describe real-life examples of actual research involving secondary use of data in Canada[2]. They attempt to outline why each study is socially valuable and the benefits that have resulted, or may result. They detail the kind of information health services and population health researchers need and why. They explain how these researchers collect, use and disclose data, what retention practices are followed, what security safeguards are used and what review and oversight mechanisms are in place. When considered in light of existing laws and ethics guidelines, these case studies highlight the practical challenges that arise when applying various legal and ethical norms in the specific context of population health and health services research. Accordingly, the case studies identify a number of ethical and legal issues that warrant further consideration and discussion.

An in-depth analysis of these cases studies focused on a number of important questions specific to health services and population health research, including:

i. Why do health researchers need to make secondary use of data?
ii. Why is it sometimes impracticable to obtain consent?
iii. Why do research databases need to be retained over a long period of time?
iv. Why do current access policies and linkage practices among data custodians vary so?
v. What security safeguards do health researchers currently use?
vi. What review and oversight mechanisms are currently in place?

[2] Note, although case studies 5 and 6 involve secondary use of tissue originally collected for another purpose, the present document does not purport in any way to cover the complex issues specifically related to the collection and storage of human tissue for research purposes. These warrant further development and analysis that are beyond the scope of this project.

Secondary Use of Data

The case studies demonstrate that the ability to conduct health research, particularly research on health services and population health, depends heavily on large volumes of readily-accessible, existing data. Such data may include information derived from: personal interviews; analyses of tissue samples; results of scientific tests; physician, hospital and laboratory records; birth and death records; billing claims and employee records. The case studies focus on examples of research using data that were originally collected for another purpose (secondary use of data). Such existing data are often found to be extremely useful for identifying and understanding problems, as well as for providing potential solutions.

Researchers who study health services or the health of populations rarely have any direct interest in knowing the specific identities of the people they study. Their focus is on aggregate trends. So, while personal information about identifiable individuals may be the source of data, this type of research is conducted with information that has either been made completely anonymous or has had as many identifiers as possible removed and replaced with encrypted codes. Indeed, many investigators conducting studies would not need any personal identifiers at all were it not for the need to consider the effect of important individual characteristics or to link data about individuals so as to construct histories over time. In some cases, therefore, the possibility of linking de-identified data to other potentially identifying information remains crucial. This is necessary in order to:

- study the relationship between certain health determinants and health status;
- group together individuals on the basis of common characteristics such as age or geographic location; or
- track individuals over time in order to study the evolution of certain diseases after long latent periods or to assess their progress through the continuum of health care.

Researchers should implement deliberate strategies that make it impossible (or at least extremely difficult) to determine the identity of an individual from the data they use. Current practices for anonymizing, de-identifying and linking personal information (whether carried out by the original data-holder before releasing the data for research purposes or by the researchers themselves once in possession of the data) tend to vary significantly according to what is considered 'identifiable'. The ongoing challenge will be to reach agreement on what constitutes an appropriate degree of identifiability, recognizing that this concept will continue to evolve. Approaches for de-identifying and linking data need to achieve greater consistency to streamline efforts for meeting and continually improving best practices.

Consent

In clinical research studies, researchers directly interact with potential participants in well-defined protocols and provide them with the detailed information required for obtaining their informed consent. However, strict application of traditional consent

procedures in health services and population health research raises problematic issues, particularly for retrospective studies that rely on already-existing, historical or archival data, including sample survey data. Among the factors that often make seeking consent impracticable, impossible or self-defeating in these particular types of studies are:

- the sheer size of the populations studied;
- the proportion of individuals who may have since relocated or died;
- the risk of introducing potential bias through the consent procedure itself thereby affecting the generalizability and validity of research results;
- the creation of even greater privacy risks by having to link otherwise de-identified data with nominal identifiers in order to communicate with individuals so as to seek their consent;
- the risk of inflicting psychological, social or other harm by contacting individuals and/or their families in delicate circumstances;
- the difficulty of contacting individuals directly when there are no ongoing relations with them;
- the difficulty of contacting individuals even indirectly through public means such as advertisements and notices; and
- the undue hardship that would be caused by the additional financial, material, human, organizational or other resources required to obtain individual consent.

As regards prospective data collection (for inclusion in a registry, for example), obtaining express consent for future research purposes also poses a challenge. On the one hand, obtaining specific consent for all possible secondary uses of the information which often cannot be predicted at the time of collection, is not feasible. On the other hand, obtaining unqualified, blanket consent for undefined future health research purposes is empty and meaningless and may sometimes reduce, rather than increase, privacy protection on false assurances that informed consent has been obtained.

The case studies demonstrate the need for constructive, creative and innovative ways of respecting peoples' right to know and to control how their information is used without necessarily requiring that express consent be obtained from every individual in every instance. The case studies demonstrate the need to develop appropriate alternatives to the traditional consent model, specifically for population health and health services research, taking into account the overall balance of risks and benefits both to individuals and society as a whole. These alternatives do not in any way abrogate the obligations to ensure, among other things, that:

- an open, transparent and accountable process is implemented for managing privacy;
- the appropriate confidentiality agreements are in place binding users of the information; and
- effective safeguards are taken to protect the data against unauthorized disclosure.

Retention and Destruction of Data

The existence of data archives and registries, and the retention of data by researchers more generally, make it possible to reconstitute the data if and when needed, since researchers are often required to retain data for possible verification and auditing purposes (though these requirements tend to vary among sponsors and/or publishers). They also enable the expansion of the research question to eventually incorporate additional dimensions or examine related hypotheses in the future. Finally, in unique cases, they allow the identification of potentially affected patients in order to notify them about possible long-term risks of contracting fatal diseases or experiencing adverse effects that were unknown at the time of certain interventions (e.g. risks of contracting Creutzfeldt-Jakob disease in human growth hormone trials, contracting HIV in hepatitis B trials or experiencing adverse effects from certain vaccines).

The automatic destruction of data and/or all possible identifiers immediately upon the fulfillment of each discrete research purpose would prevent these and other important subsequent uses. Furthermore, the destruction of large databases would result in a huge waste of valuable public funds. Having to re-create new data archives for each new research project would be completely impossible and/or entirely cost-prohibitive. Creative means need to be further explored to assess under what conditions databases should be retained in the long-term and if so, how they should be secured (for instance kept in the hands of trusted guardians, subject to formal periodic audits and proper oversight).

Data Access Policies and Capacity for Data Linkage

Access to existing data for purposes of carrying out health services or population health research often involves many different data stewards or custodians. These may include hospitals, public health clinics and laboratories, physicians' offices, research centres, pharmacies, employers, registries, health information producers, and federal/provincial/ territorial/ municipal government departments and agencies.

The case studies reveal a significant degree of variation in the access policies of these different custodians. Data access policies may involve research agreements that custodians require researchers to sign before releasing any data to them. Whether such agreements are more or less sophisticated and/or detailed in content and conditions is often dictated by different legislative requirements that vary across institutional settings, sectors and jurisdictions. Data access policies may also require, as a condition for releasing data, review and oversight by designated bodies. Some custodians may require approval by their own internal oversight body, in addition to any other review and oversight mechanism(s) that may be required by law. The criteria by which these multiple oversight bodies will consider data access requests will depend, once again, on any internal criteria specific to the custodian and whatever other criteria are imposed by legislation across institutional settings, sectors and jurisdictions.

Moreover, the ability of custodians to perform data linkage in-house for researchers will largely depend on their capacity and resources, which also tend to vary quite significantly. Custodians that can perform data linkage completely in-house rarely need to release any identifying information to researchers. However, custodians that do not have the capacity to perform this service on behalf of researchers are often requested to release identifying information in order for researchers to be able to carry out the linkage themselves. Clearly there is a need to harmonize legislative requirements and data access policies, accommodating for different capacity levels across institutions, in order to better streamline requests for access to information for research purposes.

Security Safeguards

The case studies reveal a wide range of security safeguards that are commonly used in the context of research, including:

- organizational safeguards, such as limited personnel access, security clearance and employee confidentiality agreements;
- physical safeguards, such as locked rooms, filing cabinets and facilities; and
- technological safeguards, such as data encryption, special algorithms, passwords, access codes, tracking features, firewalls, etc.

Further options for protecting personal information are multiplying rapidly with advances in computing technology and a spectrum of new solutions is emerging. More sophisticated techniques are increasingly available for authenticating individual users and limiting access to only the minimal data needed in the most general form possible, thereby ensuring confidentiality of the data while also retaining their usefulness for research purposes. The challenges now lie in: better disseminating information about existing security systems and processes; developing a set of minimum standards; ensuring greater consistency in the application of minimum standards; and, continually reviewing, updating and adapting those standards as technology advances. There is clearly a need to identify best practices that are pragmatic, cost-effective and sufficiently flexible to evolve over time and accommodate different research methods.

Review and Oversight Mechanisms

Health services and population health studies conducted in universities and affiliated institutions are typically reviewed by research ethics boards (REBs). REBs are composed of specialized experts in research, ethics and law, as well as lay members of the community. REBs are close to the ground and sensitive to local needs and values. They play a critical role in ensuring the protection of individual privacy, within a larger ethical framework, in accordance with fundamental principles of:

- respect for human dignity;
- respect for free and informed consent;
- respect for vulnerable persons;
- respect for privacy and confidentiality;
- respect for justice and inclusiveness;
- balancing of harms and benefits;
- minimizing harm; and
- maximizing benefit.

In Canada, only those research studies approved by REBs are eligible for funding by the three federal granting agencies and/or regulatory approval under the *Food and Drugs Act* (R.S.C. c. F-27). In particular cases involving secondary use of data or proposed data linkages, academic REBs consider, among other factors: the sensitivity of the information involved; the possibility of identifying particular individuals; the magnitude and probability of harm or stigma resulting from identification; the context in which the information was originally collected; the possibility of obtaining consent; the appropriateness of using alternative strategies for informing participants and/or consulting with representative members of the study group; as well as any legal provisions that may apply in the situation. In their review, REBs apply a proportionate approach in balancing risks and benefits and modulate their requirements accordingly. (Canadian Institutes of Health Research, Social Sciences and Humanities Research Council, Natural Sciences and Engineering Research Council, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, August 1998).

Areas for further improvement include: strengthening privacy expertise and education of REB members particularly in light of rapidly evolving technology and emerging legislation; ensuring adequate resources for REBs to meet their mandate for continuing review, monitoring and periodic audits; increasing public accountability and transparency of REBs; and, further exploring the relationship between REBs, privacy commissioners and other oversight bodies. Indeed, in some provinces, legislation requires that privacy commissioners or special privacy committees designated by law also approve (or at least be notified of) the proposed research or data linkage. As discussed above, various data custodians may, in addition, require review and approval by their own internal data access committees. The challenge, therefore, will be to align these various review and oversight bodies to ensure complimentary forms of meaningful protection rather than imposing unnecessary and duplicative hurdles.

Conclusion

In summary, the case studies provide examples of how researchers, who use secondary data, attempt, through various ways, to comply with the spirit of the fair information principles contained in the CSA Model Code. They suggest that there is a need to further develop creative, effective and innovative mechanisms for protecting privacy and confidentiality of data, as well as the need for ongoing discussion and continual improvement of best practices. The CIHR case studies further provide concrete illustrations of the importance for interpreting and applying privacy laws and policies in a flexible, feasible and workable manner in order to permit the valuable social benefits of health research to continue. The case studies suggest that the health research community should work actively with privacy advocates, consumers and the general public to identify and implement strategies for balancing the right of individuals to have their personal information protected and their desire for improved health, more effective health services and a strengthened and sustainable health system.

[Introduction]

The processing and linking of a broad array of personal data for many purposes, including research, is generating considerable public concern. The privacy and confidentiality of personal health information raises particularly complex issues since personal health information is often regarded as highly sensitive. Consumers, providers and professional groups have expressed the need for controls on the collection, use and disclosure of personal information and want assurances that such information will not be used inappropriately. Governments in Canada are moving to strengthen privacy protection through laws and regulations in step with the international community.

This said, the use of personal information is crucial in order for health researchers to assist policy-makers in improving the health of Canadians and strengthening their health care system. Health research involves an integrated and multi-disciplinary approach. Health research embraces the study of disease at the biomedical level and the study of treatment and preventive applications in well-controlled clinical contexts. At the more macroscopic level, health research also involves evaluating health services and studying the health of populations. More specifically, health services and population health research includes:

- developing and evaluating health strategies, services, programmes or policies;
- studying geographic and temporal patterns of disease in the general population or certain sub-groups of the population; and
- identifying and quantifying the risk of disease that may be attributed to a particular exposure.

Contrary to biomedical and clinical research that depends heavily on individual level data collected directly from research participants through personal contact, a substantial proportion of health services and population health research is conducted using large databases usually collected for other purposes. This is referred to as 'secondary use' of existing data. Examples of data used for secondary purposes include data that were originally collected to:

- administer programs and services (e.g. physician and drug claims databases);
- manage employees, health professionals and hospitals (e.g. employee records and job descriptions);
- deliver clinical care (e.g. medical records); or
- diagnose or identify a disease (e.g. blood, urine and tissue samples).

The secondary use of personal data for health research purposes can have broad social benefits. However, strict compliance with laws aimed at protecting the privacy and confidentiality of individuals presents special challenges in the context of health services and population health research.

For instance, it is often not practical to obtain consent at the time the secondary use of the data is made, which could be several years after the original collection. Nor is it feasible to obtain, at the point of original collection, meaningful informed consent for all potential secondary uses that may eventually be made of the data since future purposes are often unknown and impossible to specify.

The requirement to destroy or completely anonymize all personal data once the specified purpose has been achieved also poses particular challenges for health researchers who are often obliged to retain data, sometimes for up to twenty (20) years for auditing and verification of research results. Moreover, the necessary destruction of large and extremely valuable research databases each time a specific research project is completed entails a huge waste of scarce public resources and corresponding lost opportunities to improve health and health services.

There is significant variability in legal conditions for accessing data for research purposes across jurisdictions (e.g. different provinces), sectors (e.g. private or public sectors) and institutional settings (e.g. governments, hospitals, universities), depending on whether the information is general (e.g. income level, education, work history, etc.) or health-related (e.g. physician, laboratory, hospital records, registration and billing data, etc.). This makes the application of laws in large epidemiological studies highly complex and in some cases simply unworkable.

There is a clear need to address public concerns regarding the secondary use of personal data for health research. Many questions need to be considered, for instance:

1) Why do health researchers need to make secondary use of personal information? For what purposes?
2) Why is it sometimes impracticable to obtain express consent before making secondary use of data for research purposes? What are some other options?
3) Why do research databases need to be retained over a long period of time? Under what conditions should the data be kept?
4) Why do current access policies and linkage practices vary so significantly among data custodians? Can these be better harmonized?
5) What security safeguards do health researchers currently use? What are some future challenges and opportunities?
6) What current review and oversight mechanisms exist? Can these be more effectively aligned?

Findings from an analysis of the case studies are outlined below, followed by a summary table of relevant issues emerging from the case studies, and the nineteen case studies themselves. The subsequent appendices describe the members of the working group and the method followed in developing the case studies. Useful links and a selected bibliography are also included for information and interest.

[Analysis of Case Studies]

I. Why do health researchers need to make secondary use of data?

The attached case studies illustrate that researchers need to make secondary use of existing personal information to:

1) study patterns of diseases in the population;
2) identify causes of disease and their impact;
3) develop and evaluate preventive and therapeutic strategies, health services, programs, and policies;
4) assess data quality; and
5) assemble potential research participants.

1. To study patterns of diseases in the population

Population health or health services researchers generally need to look at whole populations, or a representative sample of individuals to address questions about geographic or temporal patterns of disease, and to develop strategies to help control and manage disease. Sometimes, all of the information needed to answer the research question is contained in databases created for other uses and the researcher does not need to individually contact the thousands of people involved to obtain any further information. The researcher does not need to know who the actual individuals are. It is information on the whole study population that is important to the researcher. However, an individual identifier is sometimes necessary to link information about the same individual across databases (e.g. data on prescriptions with data on hospital admissions) or to link information on the same individual within a given database (e.g. to identify prescriptions written to the same patient in a prescription claims database). Usually, the identifier can be non-nominal, and once linkage is complete, the set of information about an individual can often be de-identified or completely anonymized such that re-identification is rendered extremely difficult, if not impossible.

- **Case Study # 4 – *National diabetes surveillance system:*** The national diabetes database is being developed for surveillance and research purposes by assembling and linking information from existing databases routinely maintained by provinces, such as: hospital files, physician billing records and drug claims data. These databases contain information on diagnoses of diabetes, complications, age, sex, residence, treatment, costs, follow-up and outcomes. A better understanding of the incidence of diabetes and related complications over time, across geographic space and among populations, as well as an evaluation of existing prevention and treatment programs, are extremely valuable for tracking the pattern of the disease and developing new strategies to help manage it.

- **Case Study # 5 –** ***Use of RFLP molecular epidemiology to find out how tuberculosis is spread among people infected with HIV:*** Researchers in Quebec used the test results of sputum samples stored in the Public Health Laboratory, linked with non-identifying demographic information (age, sex and residence) at the Department of Health to assess how tuberculosis (TB) actually spreads: either as a re-activation of a previous infection or as a new infection following a recent external exposure to the disease. The weakening of the immune system due to HIV infection facilitates the spreading of new infections, including tuberculosis. Understanding the role of HIV in the spread of the disease is important to help control tuberculosis infections.

2. To identify causes of disease and their impact

The secondary use of existing data is often required to conduct studies examining the causes of disease, or to determine whether persons who are exposed to a substance are at increased risk of adverse health effects. Many epidemiological studies investigate the health effects of exposures or events that occurred in the past (e.g. exposure to asbestos among shipyard workers, or exposure of Gulf War veterans to depleted uranium). For both ethical and logistical reasons, researchers must often rely on retrospective studies that draw upon existing data designed for other purposes. Researchers cannot expose persons to a suspected environmental toxin to study its health effects. Instead, researchers need to study people who have already been exposed, and compare their overall health to that of control participants who have not been exposed.

- **Case Study # 16 –** ***Rapid surveillance of cancer in neighbourhoods near point sources of pollution:*** The Ontario Property Assessment File (which identifies where people pay their taxes) can be used to link information about where Ontario residents live with information from Ontario's cancer registry and with Ontario's death records. These linked data can then be used to learn if there are significantly higher risks of cancer or death for persons who live in certain areas. Because these data are already collected on an ongoing basis, assessment of risks can be done relatively quickly and easily to identify and divert potential adverse effects.

- **Case Study # 13 –** ***Cancer and other problems associated with breast implants:*** Surgical records were used to identify 25,000 women in Ontario and Quebec who had received implants for cosmetic reasons. Information about the women and their surgical procedures taken from physician and hospital records was linked by Statistics Canada with information on deaths or diagnosis of cancer to determine whether women who had had breast implants were at greater risk of particular cancers or death than women in the general public.

- **Case Study # 14 –** ***Second cancers following treatment for non-Hodgkin lymphoma*****:** Data from the Ontario Cancer Registry were used to study whether the type of chemotherapy and radiation therapy used to treat non-Hodgkin lymphoma (NHL) was

associated with increased risk for subsequent cancers. The study was able to demonstrate that patients with NHL continued to be at significantly elevated risk of second cancers for up to two decades following the diagnosis. This persistently elevated risk has important implications for the medical surveillance of these patients.

3. To develop and evaluate health strategies, treatments, services, programs and policies

Pre-existing databases are primary sources of information for monitoring and evaluating the performance of the healthcare system and the effectiveness of new health programs and policies. Comprehensive databases for documenting physician visits, hospitalizations and prescription drug use are available in many provinces. Studies using this information are critical for improving the delivery of health care and ensuring that new health programs and policies are indeed effective.

- **Case Study # 2 –** ***Seasonal patterns of Winnipeg hospital use:*** There are repeated crises in emergency rooms and waits for hospital beds during flu season. This study examined patterns of hospital use, focusing on January to April over several years, to estimate the extent of this problem and suggest ways to avoid crises in the future. This was a descriptive study, and its validity and value depended on complete and accurate data on hospital use. De-identified data on hospital discharges, collected routinely for administrative purposes, were used for the study. The study found that crises had resulted from flu outbreaks, that the increased need for hospital beds resulting from these outbreaks could be predicted, and that there were ways to avoid the crises.

- **Case Study # 8 –** ***Barriers to accessing health care in Canada: is the system fair?*** This study sought to determine whether lower-income Canadians are using the health care system as much as wealthier Canadians, and if not, why they do not. If lower-income Canadians were not using the health care system as much as their wealthier counterparts, the study also sought to determine whether there were systemic reasons for this trend. Researchers used existing data obtained from a national survey conducted by Statistics Canada and linked it to other provincial databases containing information on peoples' use of health services and physician billing data.

- **Case Study # 11 –** ***The impact of having elderly and welfare patients in Quebec pay a greater share in the costs of their prescription drugs:*** This study examined the impact of a recent policy requiring patients to pay a greater share of their prescription drug costs under the provincial drug plan. The study showed that this cost sharing arrangement resulted in a significant reduction of drug use to control illness among some patients most in need, leading to an increase in serious adverse effects. The study findings resulted in an immediate change to the provincial drug insurance policy allowing free access to drugs for elderly patients and those welfare participants unable to work due to illness. The change in policy came into force as law within six (6) months of the final report of the study.

4. To assess data quality

Data quality is an important issue in research on populations. Research based on poor quality data is wasteful of resources and misleads policy-makers and the general public. Researchers use existing data in order to determine whether and how to refine their research method and analysis so as to draw clearer and more accurate inferences from their research results.

- **Case Study # 3 –** ***Assessing the accuracy of the Nova Scotia Health Survey:*** Canada-wide or province-wide health surveys provide important information based on representative samples of the population. People who refuse to take part in such a survey or who cannot be reached for one reason or another often account for 25% or more of those selected to be in the sample. It is important to know whether non-respondents differ in any systematic way from those who do take part. Hence, in this study, data about physician visits, hospitalizations and drug prescriptions were linked with the sample of persons who were selected to take part in the Nova Scotia survey. This permitted researchers to compare the health characteristics of persons who had taken part in the survey with those of persons who had not taken part. Based on this comparison, researchers were able to develop 'correction' factors that now allow more accurate inferences to be drawn from the survey.

5. To assemble potential research participants

Existing data are also used to identify or assemble potential research participants. In these cases, individuals identified as eligible participants are then contacted and asked whether they would agree to participate in a research study or to provide further information needed to answer a research question. Researchers may also use databases to identify potential controls or comparison populations.

- **Case Study # 17 –** ***Patient outreach via PharmaNet:*** In British Columbia, a province-wide network of pharmacy computers was used to 'flag' the records of persons taking five or more prescription drugs. Once this study population was selected, a one-line message was sent to the pharmacist to offer patients an educational service that could assist them in better managing their medications. The research aimed to see whether study patients who agreed to this additional instruction would better refill their prescriptions at the right times, than those control patients who did not receive similar instruction.

- **Case Study # 15 –** ***Ontario familial colon cancer registry:*** To learn more about the genetic causes of cancer, cancer patients identified through their provincial cancer registry are contacted to ask whether they, and their family members, would consent to provide more information through questionnaires and tissue samples for possible inclusion into the family registry. If they are eligible and agree to be included in the registry, they may subsequently be contacted by researchers to invite them to participate in a specific research project, conditional upon their informed consent for that project.

- **Case Study # 10 – *A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests:*** This study set out to determine whether reminder letters sent to hard-to-reach women could increase their likelihood to have regular Pap tests. In order to develop and refine the list of potentially eligible women for inclusion in this study, researchers needed to consult physician records, the provincial cancer registry and the provincial cytology registry. The study results indicated that these hard-to-reach women were no more likely to come in for their Pap test after receiving a reminder letter. Hence, the development of population-based programs and policies will likely require multiple approaches to successfully recruit these women for screening.

II. Why is it Sometimes Impracticable to Obtain Consent?

Health services researchers and population health researchers who depend heavily on access to large, pre-existing databases face special challenges when having to seek informed consent from individual data subjects. This situation differs significantly from the usual work of clinical researchers that depends on the prospective collection of new data from individuals where the opportunity to seek informed consent is much more feasible in practice. There are several reasons for this difference.

1. Unforeseen opportunities at the time of collection / Unfeasible conditions at the time of research

A. Administrative databases collected for other purposes

It is often realized, much later, that large administrative health databases routinely collected for another purpose provide a unique opportunity to answer new and important research questions about patterns of disease, risks of disease or the effectiveness of certain health services, treatments or policies. Physician claims data, routinely collected under provincial health plans for the purpose of paying physicians, include information such as patient and physician identifiers, the date of service, the type of service performed, the primary diagnosis and the amount paid for the service. Prescription drug claims data, collected under provincial drug programs, typically include physician, pharmacy and patient identifiers, the type of drug prescribed, the quantity dispensed and the cost. Other related databases include: hospital discharge abstracts, patient files, health provider files, laboratory files and vital statistics data.

Collectively, these databases describe nearly all of the publicly-funded healthcare services provided in each province. Such information would be virtually impossible for researchers to reconstruct for both logistical and financial reasons. These databases have thus become indispensable sources of data for health services research in Canada. All the valuable research uses that can be made of these data simply could not be anticipated at the time the data were collected and therefore, consent to use these data for research was never

obtained. To attempt to contact the thousands of individuals whose data are included in these large administrative databases years later in order to seek their informed consent to use their de-identified data for research purposes is unfeasible. Many people have relocated or died since the time of the original data collection. Moreover, the time and costs required to try to reach the thousands of individuals involved would be, in many instances, completely prohibitive.

- **Case Study # 7 – *Use of anti-arrhythmia drugs in Saskatchewan:*** Some drugs used to correct irregular pumping of the heart can, in some people, cause dangerous changes in rhythm. Professional practice guidelines recommend what types of drugs should be prescribed to avoid this problem. In Saskatchewan, prescription drug data were linked with hospital records to determine the degree to which physicians in the province were following these practice guidelines and whether non-compliance with the practice guidelines was contributing to the incidence of rhythm problems. Many of the individuals whose data were included in these administrative databases had likely relocated or died making it impossible for the researcher to trace their whereabouts.

- **Case Study # 20 – *Studying the health of health care workers:*** Health care workers represent a significant portion of the workforce in Canada and it is essential for the delivery of health care services that these workers be healthy. The purpose of this study is to create a research database to study the health status and health determinants among health care workers. Data from employee files will be linked with data on medical services, hospitalization, pharmacare, mental health, cancer incidence, mortality and workers' compensation. Because the study will span a ten-year period and involve records of more than 50,000 workers, many of whom have relocated several times since their data were originally collected, contacting each person individually will simply not be feasible.

B. Patient registries developed for statistical and research purposes

Other examples of systematic and ongoing collection of large amounts of data that are extremely useful for research purposes are patient registries. Such registries collect personal information on patients afflicted with a particular disease (e.g. cancer) or patients who received specific health interventions (e.g. cardiovascular surgery or immunizations). These databases are often collected specifically for public health and/or research purposes. In some cases, use of the personal information for research purposes is expressly permitted by the enabling statute that creates the registry (e.g. Ontario's *Cancer Act*, R.S.O. 1990, c. C.1, section 7(1)). In other cases, consent to use personal information for research purposes is obtained from the patients themselves.

Obtaining consent for use of personal information for research purposes presents special challenges in the case of registries. Registries are not created for a single research study. Rather, they provide critical infrastructure to support a broad array of studies that meet important information needs about our health and our healthcare system. Among other

things, they are used to assess patterns of disease, determine risks of disease, assess the safety and effectiveness of therapies, measure the quality of care being provided, evaluate the impact of health policies and develop strategies to improve health and health care. Consent could be sought either at the time data are collected for inclusion into the registry or when data are used for specific research studies. However as described below, special challenges arise at either stage.

At the time the data are collected prospectively for general inclusion in a registry, it may be difficult to provide specific information on the potential uses of the data. In other words, while an individual may consent to future use of their data for research on a certain disease, their consent may not necessarily be meaningful if they cannot be informed in sufficient detail of what those specific research projects will involve.

- **Case Study # 18 – *The registry of the Canadian Stroke Network:*** The Canadian Stroke Network Registry involves the ongoing collection of treatment and care data from patients during the acute phase of stroke and the follow-up period afterwards. Its overall purpose is to provide readily available information for research in the area of stroke treatment and prevention. However, at the time at which express consent from the participant is obtained, the specific research purposes for which their information will be used cannot be specified. At the time of collection therefore, participants are given the choice to consent to some general uses of their information, but not others (*i.e.* access to their current hospitalization records for entry into the registry but not the linkage of their data with administrative files from provincial health ministries).

At the time a specific research study is conducted based on retrospective collection of data, the study can be described in more detail and consent obtained at that point might arguably be much more informed and meaningful. However, having to make contact with potential research subjects whose data are included in a registry may prove to be costly, time-consuming and difficult for some of the reasons elaborated above. That is, many subjects may be hard to trace years after collection due to relocation or even death. This being said, a few registries have implemented a regular follow-up program precisely to maintain a complete and accurate record of changes over time. It may be that individuals are regularly contacted to check blood pressure and serum lipids or to answer questions about quality of life and adverse health events. In the case of these registries, establishing contact for research purposes may be significantly less problematic.

- **Case Study # 14 – *Second cancers following treatment for non-Hodgkin lymphoma*:** Data from the Ontario Cancer Registry were used to study whether the type of chemotherapy and radiation therapy used to treat non-Hodgkin lymphoma (NHL) was associated with increased risk for subsequent cancers. At the time the study was undertaken, approximately 75% of the 2,100 NHL patients in the study cohort had died, mostly as a result of the progression of the disease. In this case, obtaining consent from the patients involved would simply not have been possible.

2. Inability to study important health research questions

The value of many types of population health or health services studies depends primarily on their ability to accurately describe or compare the characteristics of populations or groups. Examples include studies that aim to measure the distribution and frequency of risk factors and health problems in a population, to measure the health care needs of a population and to evaluate the actual effects of treatments in a population. Data suitable for such studies must either cover the entire population of interest or else constitute a representative sample of the population.

Data collected in the context of clinical trials, for instance, are of limited validity for describing the effects of a treatment in a population and are inappropriate for describing the characteristics of a population*. Clinical trials are typically designed to assess cause-and-effect relationships in a select group of patients. These study patients must meet strict criteria for inclusion in the research and therefore are usually not representative of the general population. Clinical trials assess the effectiveness of a treatment or intervention in certain well-defined circumstances. However, there is growing recognition of the need to understand how well treatments actually work in real-world settings. Data collected from surveys, and large amounts of data collected systematically and routinely for administrative uses (e.g. claims databases, registries, and employment records) are usually much better suited to address the real-world effectiveness of treatments, since they provide a more representative sample of the general population.

The potential benefits of descriptive studies and studies designed to assess real-world effectiveness of preventative and therapeutic strategies can sometimes be significantly undermined by efforts to obtain consent for secondary uses of data. In many cases, the likelihood of being able to contact and obtain consent from the thousands – sometimes millions — of individuals in many large databases is extremely small. Even if it were feasible in terms of economic costs and logistics, a requirement for individual consent

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* It is important here to discuss the notion of 'validity': Validity refers to the degree to which the inference drawn from a study, especially generalizations extending beyond the study sample, are warranted when account is taken of the study methods, the representativeness of the study sample, and the nature of the population from which it is drawn. Two varieties of study validity are distinguished:

1. Internal validity: The two groups being compared are selected in such a manner that the observed differences between them on the dependent variable under study [i.e. the outcome of interest] may, apart from sampling error, be attributed only to the hypothesized effect under investigation.
2. External validity (generalizability): A study is externally valid or generalizable if it can produce unbiased inferences regarding a target population beyond the subjects in the study. This aspect of validity is only meaningful with regard to a specified external target population. For example, the results of a study conducted using only white male subjects might or might not be generalizable to all human males (the target population consisting of all human males). It is not generalizable to females (the target population consisting of all people). The evaluation of generalizability usually involves much more subject-matter judgment than internal validity.

The above is adapted from John M. Last, *A Dictionary of Epidemiology*, 4th ed. New York: Oxford University Press, 2001.

could result in a systematic exclusion of persons who could not be reached or who declined to participate. It is known that persons who can be located and who have the time and inclination to participate in studies are often systematically different with respect to their age, sex, health and other characteristics than the general population. As a result, the requirement of obtaining consent to use secondary data can result in biased findings and undermine the potential benefits of the research.

Exorbitant costs, practical difficulties and biased findings that may result from a consent requirement do not, in and of themselves, constitute adequate justification for using data without consent. However, these factors do emphasize that the impact of requiring consent for secondary use of data can be substantial for some types of studies, even to the degree of defeating the potential benefits of a study. It would seem only reasonable then, that the loss of potential benefits resulting from the consent requirement must be weighed against the risk of harm resulting from possible infringement on privacy and confidentiality.

- **Case Study # 1 –** ***The computerization of medical practices for the enhancement of therapeutic effectiveness:*** The purpose of this research is to evaluate the usefulness of electronic medical records (EMRs) of 42,000 patients in primary care offices in the Hamilton-Niagara area and to study the benefits, risks and costs of these EMRs for physicians and their patients. A rigorous, comprehensive analysis of the use of EMRs is necessary to allow researchers to draw generalizable conclusions about whether this health care technology could help improve patient care and physician practices in a real-world setting.

- ***Case Study # 20 – Studying the health of health care workers:*** This study examines, over a fifteen-year period, the impact of workplace characteristics on specific causes of morbidity (musculoskeletal and mental health disorders) among health care workers in B.C.'s acute health care sector. As health care workers represent a significant portion of the workforce in Canada, healthy workers are considered essential to the delivery of care in our health system. A comprehensive study of occupational risks facing this large population over a long period of time is essential to help researchers draw generalizable conclusions about the health status of health care workers. This will allow policy-makers to develop methods of early detection and intervention to prevent or minimize the functional limitations and disabilities that force employees to leave the workforce.

Moreover, some studies are aimed specifically at examining the characteristics of certain sub-groups of the population who are non-responsive, hard-to-reach or generally non-compliant with recommended treatment. For instance, researchers need to understand whether those who do respond to requests to participate in research studies differ, in any systematic way, from those who do not respond to attempted contact by researchers. Being able to characterize non-respondents allows researchers to gauge the possible bias in their study results and draw more accurate inferences. Also, researchers sometimes set out to examine the specific characteristics of hard-to-reach populations who do not comply with recommended treatment. Better insight into the common characteristics of this particular sub-group of

the population is necessary in order to help improve health services and policies targeted specifically to them.

Requiring researchers to obtain consent from non-respondent, hard-to-reach or generally non-compliant individuals is often highly impracticable given the very nature of the group itself, or may be self-defeating given the purpose of the study. Two specific examples follow:

- **Case Study # 3 – *Assessing the accuracy of the Nova Scotia Health Survey:*** In this study, researchers set out to determine whether the health characteristics of non-respondents to the Nova Scotia Health Survey differed in any systematic way from the health characteristics of persons who did respond. Based on this comparison, researchers were able to develop 'correction' factors that now allow more accurate information to be drawn from the survey results. Requiring researchers to individually contact all non-respondents to obtain their consent before undertaking this comparison would have been practically impossible since many of the non-respondents were non-respondents precisely because they could not be reached in the first place.

- **Case Study # 10 – *A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests:*** This study set out to determine whether the strategy of sending reminder letters to 'hard-to-reach' women would increase their likelihood to undergo regular Pap tests. Hard-to-reach women who had never been screened or were seldom screened were sent a first letter and a subsequent follow-up letter by the research team reminding them to go to their physician for a regular Pap test. Had the physicians contacted these women in advance to request their consent to be contacted by the researchers, this would have made it impossible to determine whether any increase in the frequency of Pap tests among these women was due to the specific strategy under investigation (i.e. the reminder and follow-up letters) or the preliminary contact by physicians to obtain consent. Hence, in this case, preliminary contact by physicians to obtain consent would have confounded the results and completely defeated the purpose of the study.

3. Additional risks to privacy and confidentiality

There are situations where privacy protections, when applied in the research context, can actually result in unintended adverse consequences. For instance, in some cases, the very process of having to contact individuals to obtain their consent to use their de-identified data for research purposes could actually increase privacy and confidentiality risks for the individuals, sometimes outweighing the potential benefits of the study. When only de-identified data are released by the original data holder to the researcher, the researcher has no direct way of knowing – nor any desire to know – who the individual data subjects are. While it may still be possible to re-identify persons indirectly using other information about them (e.g. age, sex and a prescription refill history), it is very difficult to do in a database of hundreds of thousands of persons and completely unnecessary to do for the research purposes.

Requiring researchers to obtain individual consent before making secondary use of de-identified data places researchers in a particularly difficult situation for two reasons. Researchers must either rely on the original data holder to obtain prior authorization from the individual data subjects or researchers must seek access to identifying information in order to themselves contact individuals directly. As regards the first option, many data holders do not have the time, interest or resources to obtain this prior authorization on behalf of researchers; their engagement in the consent process may be virtually impossible to obtain in practice or less than optimal given their priorities. As regards the second option, researchers are placed in the odd situation of having to request access to identifying information from the original data holder that would otherwise not be needed to conduct the study. The release of direct identifiers in situations where they are not necessary to fulfill the research purpose defies the fair information principle of limiting collection and actually places the privacy and confidentiality of the data in greater jeopardy than would otherwise be the case.

- **Case Study #9 – *Needlestick injuries in nursing and laboratory staff:*** The purpose of this study was to determine the type and frequency of needlestick injuries in full-time nurses and laboratory technicians at three hospitals using staff health records and self-completed questionnaires. The researcher had the budget necessary to pay a staff member in personnel offices of each participating hospital to identify eligible participants from their employee files based on select criteria, and to establish contact with them in order to request authorization before releasing their contact information to the researcher. However, the staff did not have the necessary resources nor the relevant competencies available to do this.

- **Case Study # 5 – *Use of RFLP molecular epidemiology to find out how tuberculosis is spread among people infected with HIV:*** In this study, the Department of Health linked results of a genetic analysis of tuberculosis (TB) bacteria (grown from sputum samples stored at the Public Health Laboratory) with basic demographic data such as age, sex and residence. The linked, but de-identified information was provided to researchers who then proceeded to study patterns in the spread of TB and identify contributing factors. If researchers were to seek prior consent for conducting this study, they would have required names and addresses in order to contact the individuals concerned. Releasing identifying information to researchers, that they would not otherwise require but for the consent requirement, would have, in effect, posed greater risks to individual privacy and confidentiality.

Another unintended consequence of privacy protection arises in some cases where researchers are in direct contact with individual data subjects to request their participation in an anonymous questionnaire or their donation of an anonymous tissue sample for research purposes. The stringent requirement for written consent may, rather than afford greater protection, actually pose greater risk to the privacy and confidentiality of personal information. That is, individuals who would otherwise be willing to consent verbally to anonymous participation in research may be much more hesitant to sign a written consent form where their name becomes associated with the study. The inclusion of their name in circumstances

where, but for the consent requirement, it would be completely unnecessary to fulfill the research purpose, naturally contributes to risk of unauthorized disclosure to third parties.

- **Case Study # 6 – *HIV seroprevalence among women undergoing abortion in Montreal:*** Better understanding of the incidence of HIV infection and risk factors can help guide educational programs and policies aimed at preventing infection. In this study, women undergoing therapeutic abortions who had to have a blood test as part of their standard treatment were asked to donate part of the blood sample for anonymous HIV testing and to fill out an anonymous questionnaire about certain risk factors. A computer-generated scrambled code was used simply to link the results of the participants' blood test with their answers to the questionnaire. There was no possibility of identifying the individual women and once the links were made, even the scrambled code numbers were destroyed. In most legal jurisdictions where this international study was conducted, verbal consent sufficed for the purposes of recruiting participants. Under Quebec law, however, consent has to be given in writing. As a result, Quebec women who otherwise would have been willing to participate in the study on a completely anonymous basis refused to do so because they did not want to sign their name on a written consent form which would document their participation in an HIV study. Ironically, therefore, a legal requirement intended to provide greater protection to data subjects in this case, actually increased the perceived and actual risks to individual privacy.

4. Need for rapid response to a potentially urgent public health threat

Often, use of existing datasets can meet a critical need for rapid or timely access to information. Yet, obtaining individual consent for the use of the dataset or the prospective collection and analysis of new data could take years or even decades. Examples of relatively urgent health threats include concerns about the safety of a drug (e.g. cisapride), the potential risks posed by an exposure (e.g. blood transfusions potentially infected with HIV or Hepatitis C; E-coli infections caused by contaminated drinking water), and the adequacy and sufficiency of health services at times of crises (e.g. hospital emergency services, delays for cardiac surgery). Secondary use of existing data can, in such circumstances, provide pertinent information for rapid and effective risk assessment, where prospective collection of new data could not.

- **Case Study # 2 – *Seasonal patterns of Winnipeg hospital use:*** This study was undertaken in response to concerns about bed shortages and emergency room overloads in Winnipeg hospitals during certain periods of the year. Similar problems were occurring in other provinces. By using existing hospital data routinely collected for administrative purposes, researchers provided timely findings illustrating certain patterns and services of use, specifically, an increase in the need for hospital beds each year due to flu. The findings allowed policy-makers to predict and avoid annual crises the following year by adopting new policies for strengthening the influenza immunization program in Manitoba and better managing the use of hospital beds. These successful policies and programs have since been introduced in other provinces as well.

- **Case Study # 16 – *Rapid surveillance of cancer in neighbourhoods near point sources of pollution:*** A rapid computerized surveillance system capable of assessing the relationship between residential proximity to a potential source of pollution and the incidence of cancer can provide timely and reliable evidence to communities, alerting them if significant hazards exist, or reassuring them if no association is found. Notable examples of community concerns include residential proximity to nuclear reactors, metal smelters and foundries, chemical contamination of drinking water and industrial pollution.

5. Alternatives to Express Consent

For reasons elaborated above, obtaining express consent in the context of large studies on population health and/or health services can sometimes be impracticable to obtain. However, this does not prevent researchers from seeking alternative means for providing individuals with the opportunity to become engaged and/or opt-out of the research. Researchers could also find creative ways of consulting relevant communities and studying representative focus groups with a view to better understanding what might be concerns of the larger study population that need to be addressed in the research design. Below are two examples of alternative means of consultation employed by researchers when individual consent was impracticable to obtain.

- **Case Study # 13 – *Cancer and other problems associated with breast implants:*** The purpose of this study was to identify harmful health effects on women who received breast implants for cosmetic reasons between 1975 and 1989. Following the recommendations of the REB that reviewed the research proposal, the researchers in this case initiated a general information program that publicized the study aims and methods at professional meetings, through women's interest groups and in lay and scientific periodicals and newspapers. Informational pamphlets were also distributed to 35,000 physician offices across Canada for display in patient reception areas. A toll-free, bilingual hotline was set up in order to provide more detailed information and to allow women to opt out of the research.

- **Case Study # 16 – *Rapid surveillance of cancer in neighbourhoods near point sources of pollution:*** In this particular case study, it will be nearly impossible to obtain informed consent given the sample size of 100,000 people, as well as the long latency period for potentially adverse health effects and the likelihood of relocation or death. Nevertheless, the researchers will undertake a priori qualitative studies and interview focus groups representative of individuals, interest groups, government agencies, other stakeholders and cancer patients in order to better identify community concerns and interests prior to commencing the study.

III. Why do research databases need to be retained over a long period of time?

Many of the case studies were made possible by the existence of secure data archives containing historical records. These secure sites enable the linking of individual-level data in order to study important research questions as they emerge. Just as research laboratories allow basic scientists to advance knowledge about disease, so do these data archives provide the necessary tools for population health and health services researchers to conduct important studies about human health and the health care system, (e.g. studies on genetically modified foods, certain environmental exposures and hospital waiting lists.)

Other case studies involved the creation of registries or were based on data included in already-existing registries. As discussed above, registries are not created for a single research study. Rather, they provide critical infrastructure to support a broad array of studies that meet important information needs about our health and our healthcare system. They are used to, among other things, assess patterns of disease, determine risks of disease, assess the safety and effectiveness of therapies, measure quality of health care delivery, evaluate the impact of health policies and develop strategies for the improvement of health and health care.

The existence of data archives and registries, and the retention of data by researchers more generally, make it possible to reconstitute the data if and when needed, since researchers are often required to retain data for possible verification and auditing purposes (though these requirements tend to vary among sponsors and/or publishers). They also enable the expansion of the research question to eventually incorporate additional dimensions or examine related hypotheses in the future. Finally, in unique cases, they allow the identification of potentially affected patients in order to notify them about possible long-term risks of contracting fatal diseases or experiencing adverse effects that were unknown at the time of certain interventions (e.g. risks of contracting Creutzfeldt-Jakob disease in human growth hormone trials, contracting HIV in hepatitis B trials or experiencing adverse effects from certain vaccines).

The automatic destruction of data and/or all possible identifiers immediately upon the fulfillment of each discrete research purpose would prevent these and other important subsequent uses. Furthermore, the destruction of large databases would result in a huge waste of valuable public funds. Having to re-create new data archives for each new research project would be completely impossible and/or entirely cost-prohibitive. Creative means need to be further explored to assess under what conditions databases should be retained in the long-term and if so, how they should be secured (for instance kept in the hands of trusted guardians, subject to formal periodic audits and proper oversight).

- **Case Study #2 – *Seasonal patterns of Winnipeg hospital Use:*** The purpose of this study was to examine patterns of hospital use in Winnipeg during high flu seasons. The study required linkage of hospital discharge records and property registry information that

had originally been collected for other routine administrative purposes, and were now contained in de-identified form, in a secure research database maintained by the University of Manitoba. The specially linked set of data that had been created for this research project alone were destroyed upon the completion of the study. However, the computer program that did the linkages could not be destroyed because of the need to subsequently verify research results. Nor was the research database itself destroyed because of its enormous potential in helping to answer many other important health research questions.

- **Case Study #4 – *National diabetes surveillance system:*** The purpose of this registry is to serve as a resource that can be used to track the incidence of diabetes and related complications over time, across geographic regions and among populations. It will also provide an ongoing basis for comparing and evaluating prevention and treatment strategies. All of the research uses that will eventually be made of the data cannot be fully specified at the outset, nor can it be specified how long the data should be kept. To destroy this database after each specific research project is completed would defeat its very purpose and result in enormous waste of public resources.

- **Case Study #10 – *A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests:*** Upon the completion of this study, the data were not immediately destroyed. Rather, the researchers kept the research data in secure storage and restricted access for a number of years. This was because both the host institution and the sponsor of the study required the researchers to keep the raw data for at least 5 years after the end of the study in order to ensure that the data continue to be available in order to answer any questions about the quality of the study and to possibly verify the results obtained.

IV. Why do current access policies and linkage practices of data custodians vary so?

The case studies reveal a significant degree of variation in the conditions required for accessing existing data and the practices for carrying out data linkage. The case studies illustrate how access to existing data for research purposes can involve many different stewards or custodians. These include hospitals, public health clinics and laboratories, physicians' offices, research centres, pharmacies, employers, specially-created organizations with statutory responsibility for data (e.g. cancer registries, Canadian Institute for Health Information), and federal/provincial/municipal government departments and agencies (e.g. federal and provincial departments of health, Statistics Canada and provincial registrars of vital statistics). The different data access requirements across custodians can be due to differences in the practices currently adopted and/or requirements legally imposed in specific institutional settings, sectors and/or jurisdictions.

Health research frequently requires linking different data maintained by several different custodians. This can result in considerable complexity. For example, in Case Study #13 '***Cancer and other health problems related with breast implants***', researchers needed

access to patient files, including surgical records. In Quebec, researchers could seek access to this personal information from public hospitals subject to prior approval by the Director of Professional Services of each institution in accordance with sections 59 and 125 of the *Act respecting Access to Documents held by Public Bodies and the Protection of Personal Information* (R.S.Q. c. A- 2.1) and section 19.1 of the *Act respecting Health Services and Social Services* (R.S.Q. c. S-4.2). Whereas, in Ontario, researchers could only request access to this personal information from physicians' offices in accordance with the criteria specified in a regulation (O.Reg.856/93, as am. O.Reg 53/95) adopted under the Ontario *Medicine Act* (O.Reg. 856/93). Patient identifiers obtained from these records were then sent to Statistics Canada that, in turn, linked the data with information on the incidence of cancer and mortality. In order to do so, Statistics Canada had to obtain prior authorization from each provincial cancer registry and each provincial registrar of vital statistics. These provincial agencies regularly maintain these cancer and death records and routinely transmit them to Statistics Canada in compliance with the federal *Statistics Act* (R.S.C. c. S-19).

In some cases, the same data might be maintained by one or several custodians. For instance, in some provinces (e.g. Saskatchewan, Alberta and Quebec), access to administrative data (e.g. physician and drug claims data) can only be sought from provincial governments directly. However, in other provinces, such data are also maintained by research centres with a specific mandate to manage the data for research purposes. Examples include the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia, the Manitoba Centre for Health Policy and Evaluation (MCHPE) at the University of Manitoba, the Institute for Clinical and Evaluative Sciences (ICES) in Ontario, and the Population Health Research Unit (PHRU) at Dalhousie University in Nova Scotia. An advantage of these centres is that they can streamline the access and linkage of data from different custodians in a way that enhances security. For example, all four centres manage data provided by several different custodians (e.g. hospitals and different government departments), house the data in secure environments and have the internal capacity to link this data and remove all identifiers before releasing the data to researchers.

Before allowing researchers to gain access to personal information, some data custodians may either choose (or be required) to enter into detailed research agreements with the researcher. The essential purpose of the research agreement is to obtain a legal commitment on the part of the researcher to maintain the privacy and confidentiality of the data released. The specific terms of such agreements can vary significantly, as can sanctions for non-compliance, depending on the custodian's own internal policy and whatever other conditions are required or imposed by relevant legislation.

The case studies demonstrate an urgent need to harmonize data access policies and general practices among data custodians. At the same time, the case studies highlight an equally important need to open dialogue, build public trust and explore flexible and creative approaches for dealing with the unique ethical challenges specific to particular research studies.

- **Case Study #6 – *HIV seroprevalence among women undergoing abortion in Montreal:*** The purpose of this cross-national study was to survey and test women undergoing therapeutic abortion in order to assess the frequency of HIV infection in this particular group. Almost all women (99.6%) involved in the national study verbally agreed to answer an anonymous questionnaire about certain risk factors and to allow researchers to test, on a completely anonymous basis, left-over blood from blood samples they had to provide for therapeutic purposes anyway. As for the Quebec arm of the study, however, Quebec law required written consent be given for any use of tissue for research purposes. Women who would have been willing to provide verbal consent, were hesitant to sign their name on a written document that could potentially associate them with an HIV test and the participation rate in Quebec dropped as a consequence. This case study exemplified how lack of harmonious standards across the country can potentially impact the generalizability of research which is designed to be national in scope.

- **Case Study #18 – *The registry of the Canadian Stroke Network:*** The purpose of this ongoing national registry is to collect information on the treatment and care of stroke of patients during the acute phase of stroke and the follow-up period afterwards with the overall purpose of improving stroke treatment and prevention. Despite the fact that participants were required to provide express consent before their data could be included in the registry, researchers still faced substantial variation in the requirements imposed by different participating sites before participants could even be contacted. This case study highlights the need for a harmonized approach across jurisdictions and the importance of identifying best practices in the context of cross-national research projects involving the secondary use of data.

V. What security safeguards do health researchers currently use?

The case studies also illustrate the variety of safeguards and strategies used by the research community to secure the privacy and confidentiality of personal information in current practice. Approaches vary as to which technological, physical and organizational safeguards are used.

1. Technological Safeguards

In many of the case studies, technological safeguards were used to limit or control researcher access to identifiable data. Researchers used denominalized or non-nominal data where direct identifiers, such as names and addresses, were removed and replaced with scrambled code numbers or encrypted identifiers. In virtually all these cases, the data were denominalized by the original data custodian or independent third party so that researchers did not have access to any names and addresses – nor did they have any reason or desire to access these. In denominalized or non-nominal data, each individual can still be indirectly identified by creating a unique profile or record, based on other information in that record. Variables at high risk of indirectly identifying a unique record when used in combination,

include: date of birth, sex, ethnic origin, or presence of a relatively rare health condition. Other variables that carry the potential for indirectly identifying an individual on their own include health insurance number and social insurance number. Re-identification may occur when this information is then combined with another data source that contains this information in addition to directly identifying information.

However, the ease with which re-identification is possible can vary with the number of variables in the record and the capacity of each of those variables to uniquely identify an individual. For example, date of birth carries a relatively high risk of identifying an individual, year of birth a lesser risk, age somewhat less, and age category even less. Thus any record, apart from aggregated data, carries some risk of indirect identification, which must be estimated at the time of release of that information. This underlines the importance of the principle of collecting only as much information as is necessary to answer the study question, of user agreements limiting the additional uses of the information obtained, and the use of safeguards applied to information, even if direct identifiers have been removed.

Some of the cases illustrate unique and innovative technological approaches for masking the identity of research subjects from the researchers:

- **Case # 12 – *A randomized drug policy trial with camouflaged contacting of patients:*** In this study, researchers used a camouflage technique to blind themselves to the health status of eligible research subjects. More specifically, the study involved sending a questionnaire to all patients potentially affected by the new policy. In order to produce a mailing list without violating privacy and confidentiality, researchers obtained from the provincial drug plan, names and addresses of patients potentially affected by the policy (80%), mixed in with names and addresses of patients not affected by the policy (20%). The questionnaire was mailed out to all of the people on the list, and only those who were affected by the policy and who agreed to respond returned the questionnaire to the research team. This camouflage technique allowed the research team to target the relevant study population without knowing who they were until they had consented to participate in the policy trial.

- **Case Study # 17 – *Patient outreach via PharmaNet:*** A one-line message was created by PharmaNet's central computer (PharmaNet is a province-wide network of pharmacy computers) and systematically flagged in the record of potentially eligible patients. This was made possible through the use of a special algorithm that was added to the computer system to automatically identify and flag relevant patient records in the electronic database without any human intervention required. The flag was visible only to pharmacists in participating pharmacies who normally have access to this data when dispensing care. This allowed the pharmacist to approach eligible patients and ask them whether they would agree to participate in the study and allow their personal information to be analyzed by the research team. At no time did the researchers gain access to identifying information of any patient who did not agree to participate in the study.

In some cases, however, researchers require nominal information for the purpose of identifying eligible research subjects who could then be contacted in order to seek their consent to be enrolled in the study. In other cases, researchers require nominal information to link data about individuals in cases where the linkage could not be conducted by the data custodians themselves nor any suitable third party. In such situations, various technological means can be used to protect identifiable data while in the possession of researchers, including:

- individual authentication of users through unique log-on I.D.s;
- regular review of audit logs to detect any inappropriate access to sensitive information;
- special protection for remote electronic access and external communications;
- virus-checking programs and disaster recovery safeguards such as regular back-ups; and
- removal of all direct identifiers at the earliest possible opportunity in the study.

2. Physical Safeguards

The case studies also demonstrate a range of physical security measures that can be used to protect data holdings. These include housing servers and computers that contain protected data in secure settings that are physically inaccessible to all but legitimate staff for legitimate purposes. Architectural designs have been used to preclude public access to areas of research space where sensitive data are housed. Automatically locking doors and other security measures such as routine monitoring by a surveillance system have also been used to provide physical security to protect sensitive data. Special physical security measures can also protect data from hazards such as floods and fires.

3. Organizational Safeguards

Many of the research centres have implemented specific processes to make their organizations 'privacy sensitive'. Approaches to achieve this are variable, but may include:

- commitment to privacy and continued emphasis of its importance by management;
- development of privacy programs and implementation of security policies and procedures;
- regular staff training and education programs for newcomers and continuing employees;
- appointment of privacy officers and creation of security and confidentiality committees; and
- development of regular self-audits and external privacy reviews.

While such measures could be achieved in nearly any research setting, small research teams may lack sufficient financial and staff resources to implement them. Therefore, an important and essential safeguard is that most organizations require their research staff to sign oaths of confidentiality as an essential condition for employment and use violation of privacy as possible grounds for dismissal.

VI. What review and oversight mechanisms are currently in place?

All of the case studies were subject to prior review and approval. The oversight mechanisms range from: research ethics boards, peer review panels, internal privacy committees of data custodians, special privacy committees created by statute and privacy commissioners. These oversight mechanisms vary in terms of ethical expertise, scientific expertise and privacy expertise. They also vary in their degree of openness, transparency and public accountability and their ability to monitor compliance and audit practices over time. Some case studies were reviewed and approved by several oversight bodies depending on where the research was conducted. The sheer multiplicity of reviews, the associated time delays, the resources required to prepare several applications according to varying criteria, the unpredictability of outcomes and the potential for contradictory outcomes pose particular challenges for researchers.

In all but a few of the cases, studies were reviewed by institutional research ethics boards (REBs) in accordance with the ethical guidelines set out in the *Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans*. These are multi-disciplinary boards, composed of at least two members with expertise in the area of research under review; at least one member knowledgeable in ethics; at least one member knowledgeable in law; and at least one community member. REB review is mandatory for research funded by the federal granting agencies and generally required for all research conducted under the auspices of universities, affiliated teaching hospitals and research centres. REBs review research protocols according to a coherent ethical framework, which includes the principle of respect for privacy and confidentiality.

Peer review for scientific merit was also required for many of the case studies. The potential benefits of research depend on the attainment of high scientific and scholarly standards. Poorly designed or executed studies do not yield reliable information, are wasteful of public resources and, to the extent they involve human participants, undermine human dignity and worth. Evaluation of scientific merit and the qualification of investigators are rigorously carried out by expert peer review panels of federal and provincial research granting agencies as a fundamental condition for funding.

A number of data custodians also required some form of internal privacy or confidentiality review before releasing data to researchers. For example, the British Columbia Ministry of Health and B.C.'s PharmaNet require prior review and approval by their internal Data Access Committees before releasing personal information to researchers. Saskatchewan Health

requires review and approval by its Cross-Agency Study Committee for research involving linkage of databases. The Nova Scotia Department of Health and the Nova Scotia Population Health Research Unit similarly requires internal privacy review and approval before releasing data.

In some jurisdictions, specialized bodies created by statute are charged with overseeing the collection, use and disclosure of personal health information by data trustees. For example, the Manitoba Health Information Privacy Committee established under section 59 of Manitoba's *Personal Health Information Act* (S.M. 1997, c. P-33.5) is responsible for reviewing requests for access to personal health information for research (and other) purposes according to specific criteria set out in the Act.

Finally, in other jurisdictions, such as Quebec, requests for access to personal information for research or statistical purposes must be first reviewed and approved by the 'Commission d'accès à l'information' in accordance with the same specific criteria set out in both the *Act respecting Access to Documents Held by Public Bodies and the Protection of Personal information* (R.S.Q. c. A-2.1, s. 125), as well as the *Act respecting the Protection of Personal information in the Private Sector* (R.S.Q. c. P-39.1, s. 21). Where such requests are made by professionals for study, teaching or research purposes in the context of hospitals or other health care institutions, the statutory discretion of review and approval is delegated to the Director of Professional Services or the Executive Director of the institution (*Act respecting Health Services and Social Services*, R.S.Q. c. S-4.2, s. 19.1).

- **Case Study #8 – *Barriers to accessing health care in Canada: is the system fair?***
  This study sought to determine whether lower-income Canadians use the health care system as much as wealthier Canadians, and if not, why they do not. Before the study could begin, researchers needed to obtain approval in each of the five participating provinces, as well as Statistics Canada's own internal research review board. In each province, the study was reviewed and approved by a university research ethics board, and in most of the provinces, it also underwent some form of privacy/confidentiality review and required approval by provincial health departments. In addition, the project was reviewed by Statistics Canada to ensure that it met their confidentiality and security requirements. Each of these oversight bodies imposed different conditions and used different criteria for approval. Obtaining the required approvals from each of these collaborating provinces and Statistics Canada took over two years and the process had still not been completed at the time of publication of the present document. The difficulty experienced by the researchers in this study to obtain all the necessary approvals, by all the different bodies, according to all the different criteria required, speaks clearly to the need to resolve jurisdictional differences in approach to protecting personal health information across Canada.

VII. Conclusion

This analysis has addressed a number of issues that arise from the attached case studies. It has attempted to highlight a variety of strategies that researchers use to protect the confidentiality of research subjects and ensure ethical use of secondary data. However, it is only a start. The objective of the Working Group on Case Studies has been to provide concrete examples that will enhance the ability of researchers, policy makers, consumers and privacy advocates to engage in meaningful and constructive dialogue on the appropriate use of secondary data. The purpose of this analysis is to stimulate more informed discussion about the underlying values at stake.

Number	Title of Case Study	Collection / Use / Linkage of Data	Issues Raised
1	The computerization of medical practices for the enhancement of therapeutic effectiveness	Collection and use of de-identified data from patient medical records contained in doctors' offices; no direct patient contact involved; implied consent with possibility of opting out.	• Prior contact by original data custodian • Form of consent required
2	Seasonal patterns of Winnipeg hospital use	Linkage and analyses of de-identified data contained in provincial databases routinely collected for other purposes (i.e. hospital discharge data and population registry file); no direct contact involved; no consent obtained.	• Impracticability of obtaining consent • Long-term retention of data for future research purposes
3	Assessing the accuracy of the Nova Scotia health survey	Linkage and analyses of de-identified data contained in provincial databases routinely collected for other purposes (i.e. hospital discharge data and physician claims database); no direct contact involved; no consent obtained.	• Impracticability of obtaining consent
4	National diabetes surveillance system	Creation of a national diabetes database by linking and assembling de-identified data contained in provincial databases routinely collected for other purposes (i.e. hospital files, physician billing records and drug claims data); no direct contact involved; no consent obtained.	• Impracticability of obtaining consent • Need for harmonization of laws and policies across jurisdictions • Long-term retention of data for future research purposes
5	Use of RFLP molecular epidemiology to find out how tuberculosis is spread among people infected with HIV	Linkage and analyses of TB bacteria grown from individual sputum samples in a public health laboratory, with non-identifying demographic data held by the province's health ministry; no direct contact involved; no consent obtained.	• What constitutes personal information • Form of consent required
6	HIV seroprevalence among women undergoing abortion	Linkage of anonymous questionnaires with anonymous test results of blood samples obtained for therapeutic abortion purposes; direct patient contact; written consent obtained.	• Form of consent required • Need for harmonization of laws and policies across jurisdictions
7	New use of anti-arrhythmia drugs in Saskatchewan	Linkage and analyses of de-identified data contained in provincial databases routinely collected for other purposes (i.e. drug claims database, hospital discharge data and physician billing records); no direct contact involved; no consent obtained.	• Impracticability of obtaining consent

Number	Title of Case Study	Collection / Use / Linkage of Data	Issues Raised
8	Barriers to accessing health care in Canada: is the system fair?	Linkage and analyses of personal information contained in Statistics Canada's National Population Health Survey, with provincial databases routinely collected for other purposes (i.e. hospital discharge data and physician billing data); direct contact involved; express consent obtained.	• Validity of informed consent • Need for harmonization of laws and policies across jurisdictions
9	Needle stick injuries in nursing and laboratory staff	Collection and use of anonymous questionnaires, combined with general statistics at each participating hospital; direct contact involved; express consent obtained.	• Prior contact by original data custodian • Mandatory reporting and the researchers' duty of confidentiality
10	A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests	Linkage of personal information from electronic medical records, with provincial cancer and cytology registries for purpose of assembling study population; direct contact involved; no individual consent obtained but physician authorization granted.	• Prior contact by original data custodian • Impracticability of obtaining consent • Long-term retention of data for research purposes
11	The impact of having elderly and welfare patients in Quebec pay a greater share in the costs of their prescription drugs	Linkage and analyses of de-identified data routinely collected in provincial databases for other purposes (i.e. prescriptions claims data, hospital discharge data, physician billing data and mortality data); no direct contact involved; no consent obtained.	• Distinction between policy evaluation and research • Impracticability of obtaining consent
12	A randomized drug policy trial with camouflaged contacting of patients	Linkage of de-identified data routinely collected in provincial databases for other purposes (*i.e.* prescriptions claims data, hospital discharge data, physician billing data and mortality data) for the purpose of assembling a study population; quality of life questionnaires then sent to potentially eligible research subjects through camouflaged contacting method; consent obtained for linking questionnaires with administrative data.	• Distinction between policy evaluation and research • Prior contact by original data custodian
13	Cancer and other health problems associated with breast implants	Linkage and analysis of personal information obtained from hospital records and clinical records, with data obtained from provincial cancer registries and registrars of vital statistics; no direct contact involved; no individual consent obtained, but nation-wide publicity program conducted.	• Unique legal status of cancer registries • Prior contact by original data custodian • Impracticability of obtaining consent

Number	Title of Case Study	Collection / Use / Linkage of Data	Issues Raised
14	Second cancers following treatment for non-Hodgkin lymphoma	Linkage and analysis of personal information obtained from a provincial cancer registry with personal information contained in hospital and radiotherapy center records; no direct contact involved; no individual consent obtained as 75% of the study cohort had died.	• Unique legal status of cancer registries • Prior contact by original data custodian • Impracticability of obtaining consent
15	Ontario familial colon cancer registry	Reviewing tumor pathology report forwarded to a provincial cancer registry, as validated by attending surgeons, in order to first identify and invite eligible patients and families for inclusion in the registry; survey data and tissue samples then collected; direct contact involved; consent obtained.	• Unique legal status of cancer registries • Prior contact by original data custodian • Implications of assembling genetic information as a particularly sensitive category of personal information
16	Rapid surveillance of cancer in neighborhoods near point sources of pollution	Linkage and analysis of personal information contained in a provincial cancer registry with a provincial property assessment file and mortality database; no direct contact involved; no consent obtained; community-wide publicity and consultation process are planned.	• Unique legal status of cancer registries • Impracticability of obtaining consent • Community interests
17	Patient outreach via PharmaNet	Automatic flagging of eligible research subjects in the province's drug claims database through the use of a computerized algorithm in order to assemble a study population without any human intervention; direct patient contact involved; consent obtained.	• Prior contact by original data custodian
18	The registry of the Canadian Stroke Network	Creation of a national stroke registry by collecting, linking and assembling patients' survey data, health care utilization data and mortality data; direct patient contact involved; consent obtained.	• Prior contact by original data custodian • Validity of informed consent • Long-term retention of data for future research purposes • Need for harmonization of laws and policies across jurisdictions
19	Studying the health of health care workers	Linkage and analyses of de-identified health data contained in provincial databases routinely collected for other purposes (i.e. hospital records, physician billing data, drug claims data); no direct contact involved; no consent obtained.	• Impracticability of obtaining consent • Long-term retention of data for future research purposes

[Case Study # 1]

TITLE

The computerization of medical practices for the enhancement of therapeutic effectiveness

BACKGROUND

This research study, the first of its kind in Canada, was carried out by academic health researchers from McMaster University in Hamilton, Ontario. The study was sponsored by CIHR, the Ontario Ministry of Health and Searle Canada, an international pharmaceutical company. It was conducted from January 1998 to June 2001 in doctors' offices in the Hamilton-Niagara area.

RATIONALE

The implementation and analysis of electronic medical records (EMRs) over the next few years could potentially revolutionize the health care system in Canada. There is a critical need to examine the impact of EMRs particularly in the primary care context. This includes aspects such as: efficiency of clinical practice; satisfaction of health care professionals and patients; appropriateness of prescriptions; and privacy concerns of patients.

PURPOSE

The purpose of this research was to implement EMRs in primary care offices and to study the benefits, risks and costs for physicians and patients. Two sub-studies were also conducted to evaluate concerns physicians and patients have about the use of personal health data contained in EMRs for research purposes and to evaluate methods of consent for such use.

POTENTIAL BENEFITS

Computerized decision support delivered via the EMR has the potential to greatly improve the quality, safety and cost-effectiveness of health care. Previous research has shown that short, real-time messages tailored to the individual patient and delivered to the clinician at the point of care, can significantly improve health care practices. Moreover, high quality decision support usually requires extensive knowledge of each individual patient's history and medications. This background, combined with the increasing desire to reach out to specific groups of patients for disease management and health promotion purposes, make EMRs ideal delivery vehicles. Family physicians' practices were targeted for this study since they provide the majority of medical care to the population, coordinate the broadest range of medical services for patients and have limited time available for each patient.

METHOD

For the purposes of the study, physicians' names, patients' names and health card identification numbers were replaced by unique codes. The full medical record, in its encoded version, was electronically transferred to the research centre after hours via dedicated phone lines. No Internet connection was allowed and no individual-level data were transmitted outside of the research team. The research team did not include representatives of funding sources.

The research database contained information on more than 200,000 patient visits for 42,000 patients of 33 family physicians. The coded data were analysed to measure health care utilization patterns, ability to transition to computerized practice, facilitators and barriers to computerization, as well as the impact of EMRs on work flow, efficiency of practice and appropriateness of prescriptions. To support this work, an evaluation questionnaire was developed and validated, as were paper and electronic chart review processes.

Patients were informed of the study through a poster that was displayed in their physician's waiting room. The poster stated that:

a) the physician was now using an electronic medical record system to take care of all of their patients;
b) the physician was participating in a research study on EMRs; and
c) de-identified patient information might be used as part of the study.

The poster indicated that if patients had any concerns, they could address these with their physician at any time throughout the study.

Throughout the research, patients were allowed to opt-out and refuse to have their data sent to the research centre. Physicians were taught how to use the software to prevent transmission of data on patients who actively stated a preference not to have their personal information included in the research. No patient opted out therefore all patients whose data were entered into the EMR by participating physicians were included as part of the study.

Direct contact with patients by the research team was required only for the two sub-studies that examined patient concerns about the use of their personal health information for research purposes and their individual consent preferences. For these studies, patients were recruited by notices posted in their physician's office. Those who wished to participate gave specific approval to be contacted by the research staff. One study involved one-on-one interviews regarding health data privacy concerns and electronic systems; the other was an individual self-completed questionnaire on consent preferences related to electronic health data research.

PRIVACY RISKS AND INTENDED SAFEGUARDS

Although direct identifiers were removed from the EMRs before they were transmitted to the research centre, there was still a small risk of indirect patient or physician identification through the presence of relatively rare medical conditions or unique combinations of variables in the record. To safeguard against this risk, researchers adopted measures to ensure proper security and confidentiality of the data. A Code of Conduct was developed and adherence pledged in writing by all research staff and investigators. The Code of Conduct was modelled after the Canadian Standards Association Model Code for the Protection of Personal Information, with necessary adaptation to the specific working environment of EMRs. For example, it specified responsibilities for data security, purpose of collection, and specific security measures such as limited access, encryption, physical barriers to server, etc.

A security audit was carried out by an expert consultant. Specific recommendations were made to participating physicians wherever office security measures required improvement. These often involved physical security, location of back-up tapes or disks, or sharing of passwords.

Since direct identifiers were to be stripped off the electronic records before entry into the research database, the study's scientific advisory panel felt that express patient consent was not required. The university research ethics board that reviewed the study agreed with the scientific advisory panel, although this generated considerable discussion.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

At the time this study was conducted in Ontario, there was no legislation directly applicable to the collection, use and disclosure of personal information in physicians' offices. Ethics guidelines consider the consent requirement within a broader ethical framework that assesses risk of harm resulting from possible disclosure of personal information (both in terms of probability and gravity), as well as the potential benefits resulting from the study. In this case, because patient records were de-identified prior to being transmitted into the research database, and given the security safeguards that were implemented and the importance of research on the impact of EMRs on the future of health services, the research ethics board likely determined that the study could ethically proceed without the express consent of individual patients, as long as patients were informed of the study and did not object to the inclusion of their personal information.

Had express consent been required, the time and costs involved in individually contacting 42,000 patients would be considerable, and most likely impossible to carry out in the context of the current, overloaded primary care environment. Researchers were concerned that a requirement for express consent would potentially destroy the generalizability of data needed to draw conclusions about the impact of EMRs on clinical practice. If certain subpopulations of patients were systematically difficult to contact and/or refused to consent, this could bias the research results.

Interestingly, the sub-study that examined concerns regarding the use of personal information for research purposes and consent preferences revealed that patients and providers generally wanted to know what data were being collected, for what purpose and where the data were going. When given a choice between positive and negative consent options, three-quarters of the patients surveyed preferred a positive consent model, either written or verbal. However, based on the preliminary one-on-one interviews, patients expressed a concern that they did not want the consent process to take time away from the care provided by their physician. For their part, physicians were supportive in principle of patients' right to express consent but stated concern over their ability to obtain such consent through their office given limited time and resources.

As an alternative to express consent, researchers attempted to inform patients of the study through posters displayed in physicians' offices and, if there was no objection voiced on the part of the patients, it was assumed that patients implicitly consented to inclusion of their de-identified information in the research study. Informing patients through the use of posters in physician waiting rooms depends on the active intervention of physicians and their staff to post and maintain these posters regularly on their walls. Even then, there is no guarantee that patients will read the information or see the posters. Therefore, consideration should be given to augmenting posters with leaflets given out to patients as they check in with the receptionist.

Moreover, it is only the most assertive of patients who might, at their own instigation, choose to actively opt-out of such an implied consent model. For the rest, patients might be less likely to opt out if they are not given the real time and opportunity to do so, in the presence of a person who is specially designated to the task of explicitly explaining this option to them, answering their questions and listening to their concerns.

All of these factors are relevant and need to be carefully considered and weighed when selecting the appropriate form of consent to be obtained in the context of a particular study. In some provinces, legislative requirements might dictate the form required, leaving little choice for the research design.

FOR MORE INFORMATION

Keshavjee K, Troyan S, Holbrook AM, VanderMolen D, Measuring the Success of Electronic Medical Record Implementation Using Electronic and Survey Data. Proceedings of American Medical Informatics Association Symp 2001:309-12.

[Case Study # 2]

TITLE

Seasonal patterns of Winnipeg hospital use

BACKGROUND

This study was conducted under contract with Manitoba Health and completed in 1999 by the Manitoba Centre for Health Policy and Evaluation, University of Manitoba.

RATIONALE

During flu season there are repeated crisis periods in emergency rooms and lengthy waits for hospital beds. Researchers wanted to estimate the extent of the problem and suggest ways to avoid these crises in the future.

PURPOSE

The purpose of the study was to examine patterns of hospital use in Winnipeg, focusing on January to April, over a several year span.

POTENTIAL BENEFITS

The results of this study ultimately led to a stronger influenza immunization program in Manitoba, and identified strategies to better manage the use of hospital beds. In the first year after the program was introduced, the annual crisis in Manitoba was avoided. Since then, largely as a result of the study findings and the subsequent reduction of pressures on emergency rooms in Manitoba, other provinces that also experience these flu-related problems, including British Columbia and Ontario, followed suit by introducing similar programs.

Overall, the ability to understand the effects of flu on the health care delivery system led to an improved system of management to cope during outbreaks. This study yielded the following observations: researchers found that each year there is a small increase in the need for hospital beds because of flu; that these needs can be predicted; and that there are ways to avoid the annual crises.

METHOD

The University of Manitoba has created and maintains a secure database containing de-identified data for the purpose of research. These data were originally collected by Manitoba Health for routine administrative purposes. Manitoba Health, as the collectors of the data, removes or alters all names and health insurance numbers prior to releasing the data to the University research database such that individual persons cannot be identified.

Included in the research database at the University of Manitoba are de-identified hospital discharge records for the Province of Manitoba, as well as a de-identified population registry file. For the purpose of this particular study, the hospital discharge data were linked to the population registry file using scrambled. This de-identified, linked data made it possible to study the number and type of cases in Winnipeg hospitals over time and to determine what proportion of these cases were in fact related to flu.

The dataset that was created for this research project existed only during the time the study was conducted. However, the computer code that was used to create the dataset and the analyses were not to be destroyed because of the need to subsequently verify research results. The data code represents an enormous investment that can be used to support other research projects. It contains no individual level data.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The study posed a very low informational risk to Manitobans because the focus was on large groups (i.e. Winnipeg residents). The researchers did not look at any individual person's health information. Rather, the focus was to look at groups of individuals in order to study overall patterns of hospital bed use. All information which could identify an individual person was removed or altered by the original trustee (Manitoba Health) in such a way that researchers could use de-identified information to track people's hospitalizations during flu season, but they could not actually identify any of the individuals.

Several further precautions are taken to protect the security and confidentiality of the research database while it is being used. The research database is maintained in a secure data laboratory at the University of Manitoba. All of the information contained in this secure database is kept in an unlinked format. Information is linked using scrambled numbers only for specific projects that have received ethical approval for the linkage. The database is maintained over the long term as an important resource for research.

The scientists who maintain this database use a number of safeguards to protect the information. All access to data is carefully monitored. All employees must sign an oath of confidentiality and could lose their jobs in the event of breach (note, in the 15 years since the creation of this database, there has never been a breach of security). Researchers also take care not to publish results in any manner that might permit certain individuals to be recognized. The University of Manitoba also conducts regular security and privacy audits.

The study was reviewed and approved by the Research Ethics Board of the Faculty of Medicine of the University of Manitoba. The Health Information Privacy Committee was informed about the study and its methods. This Privacy Committee was set up by Manitoba Health to make sure that researchers, like other health data users, follow the principles of Manitoba's *Personal Health Information Act* (S.M. 1997. c. P-33.5). This Privacy Committee considers the informational risks of any research in relation to the benefits that might result from the research. (For more information, see **http://www.gov.mb.ca/health/hipc/index.html**)

DISCUSSION OF LEGAL AND ETHICAL ISSUES

While the study used potentially sensitive data for the entire population of Manitoba, individual consent was not sought from each individual given the sheer size of the study population, the practical difficulty in contacting this number of people to obtain consent, the fact that the informational risks associated were very low,and the social value and benefits of the research were very high.

If strict interpretations of the privacy law prevented health researchers from making secondary use of this existing administrative data without consent, they could not have carried out this study and would not have been able to describe how flu affects hospitals in Manitoba. New policies could not have been developed to prevent these yearly crises. This research project provided results that served the public interest, while posing minimal risks to the persons whose data were studied.

Likewise, if strict interpretation of the law required destruction, erasure or anonymization of a research database each time a specific research project was completed, it would result in enormous waste of public funds and resources preventing the possibility of future research to answer equally important and pressing health questions through the maintenance of this valuable database.

FOR MORE INFORMATION

The full study was published by the Manitoba Centre for Health Policy and Evaluation under the same title:
http://www.umanitoba.ca/academic/centres/mchp/reports/pdfs/seasonal.pdf

[Case Study # 3]

TITLE

Assessing the accuracy of the Nova Scotia Health Survey

BACKGROUND

This study was conducted in 1999 by researchers at Dalhousie University; it was funded by the Faculty of Graduate Studies and the Population Health Research Unit at Dalhousie University, Nova Scotia. The Nova Scotia Health Survey, on which this study was based, was conducted in 1995 by the Nova Scotia Health Department and researchers at Dalhousie University; it was funded by the National Health Research and Development Program and the Nova Scotia Department of Health.

RATIONALE

Health surveys are increasingly being used to measure health status, guide the allocation of health resources, measure how well the health system performs and, in general, help us better understand what determines health. These health surveys are used to describe the characteristics of populations (e.g. the proportion of persons who have a disease). For practical reasons, not every individual in a population can be surveyed; instead, researchers use a sample of the population that is large enough to represent the whole population. Normally, these are random samples (i.e. anyone in a given population can potentially be selected to be in the sample). The accuracy of a survey depends on how well the sample represents the population. In a good sample, the percentage of persons in different age groups, the ratio of men and women and the proportion of people living in different areas should be the same in the sample and in the whole population.

While good methods are used to pick random samples of potential participants in health surveys, many of the people selected may not want to participate. Others cannot be located, either because they have moved to another location, or because the researchers are simply unable to make contact with them. Non-respondents and persons unable to be located often amount to more than 25% of the people selected to be in a sample. If non-respondents are different than those who respond, it can bias the overall results of the health survey. For example, if non-respondents as a group were less healthy than those who did respond, researchers would underestimate the extent of health problems in the population. This bias is called 'non-response bias', and is among the most important threats to the accuracy of the information obtained from health surveys. Little is known about how non-response bias affects the accuracy of health surveys, as very few studies have examined this question, in Canada or internationally.

PURPOSE

The purpose of this research study was to understand how non-response bias affects the accuracy of health surveys. Specifically, the purpose was to measure the direction and amount of non-response bias in the Nova Scotia Health Survey (NSHS), and develop adjustment factors to correct for the bias.

POTENTIAL BENEFITS

Based on the results of this study, adjustment factors can be developed and used to abstract from the NSHS more accurate information about the general health status of Nova Scotians and the health services they use.

METHOD

A sample of those to be contacted and asked to participate in the NSHS was selected at random from a database of all Nova Scotians who were registered with the provincial medicare program (the 'registration file'). The registration file contained peoples' names, addresses, age, sex and health insurance numbers. Those sampled were sent a letter from the Nova Scotia Department of Health explaining the survey, and telling them that a public health nurse would contact them. The public health nurses were unable to contact 15% of the sample; 23% of the sample were contacted by a nurse but declined to participate; and only 61% participated in the survey.

For the purpose of assessing the accuracy of the NSHS, the health insurance number for each person in the sample (respondents and non-respondents) was used to link to other provincial health databases and obtain summary data on their use of health services and their health characteristics. More specifically, this study linked to the hospital discharge abstract database (which contains data on all hospital stays) and the physician claims database (which contains data on almost all visits to a physician). The summary information obtained from the linked files summarized each subject's use of health services (e.g. number of doctor visits, number of hospital visits and the total number of days in hospital) and general health characteristics (e.g. evidence of heart disease or high blood pressure based on diagnostic codes on physician claims or hospital discharge abstracts).

For the analysis, the researchers described how respondents differed from non-respondents in terms of age, sex, region of residence, use of hospital and physician services, and evidence of a selected group of health conditions. After this comparison, the researchers measured the degree of non-response bias and developed "correction factors" that can be used to reduce the non-response bias and obtain more accurate information from the NSHS.

PRIVACY RISKS AND INTENDED SAFEGUARDS

A potential privacy risk associated with linking data is that individuals who did not want to participate in the survey might be identified, along with information about their use of health services and their health characteristics. There is also a general concern that information on non-respondents might be retained and continue to pose risk of unauthorized disclosure in the future.

However, because of the design of the study protocol and the review process, it was highly unlikely that non-respondents could be identified, that the data could find its way into the hands of unauthorized third parties, or that data on non-respondents would be retained once the study was completed.

To conduct this study, the researchers designed a protocol that included a variety of security measures. The study was able to link health information without the researchers having any access to names, addresses or actual health numbers that could be used to directly identify individuals.

The protocol worked as follows:

1. The custodian for the NSHS (i.e. the researcher who originally conducted the NSHS) was asked to prepare a data file containing the NSHS study identifier, and the respondent/non-respondent status of each person in the sample. The custodian obtained this information from an electronic file that did not contain names or addresses. The custodian maintains names and addresses for NSHS respondents, but they are stored in locked filing cabinets in a secure area separate from the electronic data files.

2. The custodian sent the file containing the NSHS study identifier and the respondent/non-respondent status to the Nova Scotia Department of Health. Using their copy of the NSHS sample list, the Department of Health added and encrypted the health card number, and sent the file to the Population Health Research Unit (PHRU) at Dalhousie University. The PHRU manages provincial health care data for research purposes, and all the databases they manage contain health card numbers that are encrypted using the same procedure. PHRU does not have access to actual health card numbers, names or addresses. Since the Department of Health holds the encryption algorithm, their approval and assistance is required for all linkages of data to the PHRU databases.

3. PHRU linked the summary health care data to the NPHS file, removed the encrypted identifier, and made the file available to the researcher for analysis. The file did not contain either NSHS identifiers or encrypted health card numbers, and included only the variables from the NSHS which were needed for the study, and the summary variables on health services use and health characteristics.

4. Before obtaining access to the data, the researchers were required to sign a confidentiality agreement, and an agreement specifying that sensitive data would not be retained following the study.

5. Once the study was completed, detailed information on non-respondents was no longer needed. The file made available to the researcher was returned to PHRU, and all individual level study data in possession of the researcher was destroyed. Only aggregate results summarizing the differences between respondents and non-respondents were retained. However, all computer programs used to create the files and conduct the analysis were retained in the event that they be needed in the future for verification purposes.

A research proposal, which included a detailed description of the above-mentioned study protocol, was reviewed and approved by the Dalhousie Faculty of Medicine Ethics Review Committee, the Nova Scotia Department of Health, and the population Health Research Unit.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Based on the study design, it was not possible to contact subjects, especially non-respondents, to obtain consent. Many of the non-respondents were people who could not be contacted after repeated attempts, or for whom current contact information was not available. Moreover, contacting study subjects to ask for consent would have required researchers, or at least a third party, to access identifiable information. The study protocol was specifically designed to prevent researchers from accessing any identifiable information, so as to maintain anonymity throughout the study.

Evidence suggests that if consent for this study had been sought, most of the non-respondents would have agreed to participate, even though they had declined to participate in the survey. In many surveys, persons who are contacted but decline to participate in the survey, are asked if they would answer a few basic questions anyway (e.g. whether they smoke and their education level) so that the researchers can learn something about the health characteristics of non-respondents. A clear majority of non-respondents agree to do so.

However, the fact remains that there may have been some non-respondents who, if contacted and asked, might have declined to divulge any personal information about their health at all, even for the purpose of analyzing the general characteristics of non-respondent groups. Clearly, this study had to account for this possibility in its design so as to balance the potential loss of privacy for some non-respondents with the public benefit of greater knowledge about non-response bias of surveys.

For this reason, the study protocol was specifically designed to ensure strong protection of personal information. The informational risks to the non-respondents in this case were virtually non-existent. No identifying information was used in the study and once the

correction factors were developed, all non-respondent information was completely removed from the research database. In this specific case, the harms and benefits were weighed and considered by the Dalhousie Faculty of Medicine Research Ethics Review Committee, the Nova Scotia Department of Health and the Population Health Research Unit. It was reasonably felt by these multiple reviewers that the benefits of proceeding with the study outweighed any inconvenience or harm that might result to non-respondents.

[Case Study # 4]

TITLE

National diabetes surveillance system

BACKGROUND

The National Diabetes Surveillance System (NDSS) is currently under development by Health Canada and the provincial health ministries.

RATIONALE

Diabetes is a common health problem, particularly for older ages, and is a major cause of heart disease, blindness, kidney failure and a variety of other health problems. In order to more effectively manage this disease, information is needed to help allocate resources where they are needed, track progress in managing the disease, and evaluate new treatments and programs. Currently, such information is not readily available.

PURPOSE

The purpose of the NDSS is to develop a national database of diagnosed cases of diabetes in order to facilitate the long-term surveillance of diabetes and related complications throughout the country, and to provide a basis for comparing prevention and treatment strategies.

POTENTIAL BENEFITS

Information about the incidence of diabetes and related complications in certain areas or among groups of persons, as well as information about the effectiveness of prevention and treatment programs, is extremely valuable for developing new strategies to help manage the disease.

Although evidence on diabetes is available from carefully designed clinical studies using a selected number of patients in a controlled environment, these studies do not tell us how widespread the disease is, among which sub-groups of the population, where and why, nor do they tell us how prevention and treatment strategies are working in actual practice and how cost-effective they are. More macro-level data (i.e. data that can more accurately describe the whole population) are needed by governments, public health agencies, non-governmental organizations, Aboriginal communities and private sector, in order to monitor the disease and assess the quality of diabetes care across populations.

Establishing a national database for surveillance and research purposes ensures that data are available when needed and can extend longitudinally in order to track a disease and

assess the effectiveness of prevention or treatment strategies over time. Having to assemble such enormous amounts of data for each discrete research study, only to have to destroy them upon completion and re-assemble them for the next research study, would be completely time and cost-prohibitive.

METHOD

The national diabetes database is being developed by assembling information from existing databases routinely maintained by provinces, such as, hospital files, physician billing records and drug claims data. These databases contain information on diagnoses of diabetes, complications, age, sex, residence, treatment, costs, follow-up and outcomes. Other relevant sources of data are databases maintained by clinics and programs that specialize in diabetes care.

Using standardized procedures, currently under development, each province will link data about diabetes patients from its existing databases and incorporate these into a provincial database. As these data are highly confidential and sensitive, nominal information will not be included. Instead, a unique code number will be assigned to each patient. The coded data for each province will be assembled, maintained and controlled by its respective Ministry of Health.

Each year, the various provinces will summarize their data into standard tables and send these to Health Canada for creation of the national diabetes database. The national database will not have individual-level data. Instead, it will include only aggregate information, such as, the percentage of persons who have diabetes in different parts of the country, by sex and age group, the cost and frequency of different treatments, outcomes, etc. Health Canada will release general reports documenting trends and patterns of diabetes in Canada.

Because standardized procedures will be used by the various jurisdictions to assemble data in each of their respective databases, research studies comparing their data will be possible, albeit subject to very different access laws and policies.

PRIVACY RISKS AND INTENDED SAFEGUARDS

A risk inherent in the creation of any database is that of unauthorized access that might reveal information about an identifiable individual. Several safeguards have been put in place in the development of the national diabetes database in order to minimize this risk. The national diabetes database will contain only aggregate information that cannot possibly be linked to any specific individual. The various databases maintained by the provinces that feed into the national diabetes database will not contain any nominal information, but only coded information carefully controlled by each province according to its policies and laws. All employees involved in assembling data for inclusion into these databases will be subject to confidentiality agreements and security procedures established by each individual health department.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

As a general principle of law and ethics, consent should be obtained before collecting personal health information for inclusion into a database. While this general principle might not apply to the creation of a national diabetes database that will contain only aggregate information, it may (depending on the jurisdiction) apply to the various provincial databases that will feed into the national database, since these will contain coded, but still potentially identifiable, information. However, because the creation of each provincial database involves retrospective collection of enormous amounts of data, obtaining individual consent would simply not be practical for many reasons. Many diabetes patients may die or relocate making it almost impossible to track them down. The non-response rate among various sub-groups could adversely impact the value of this database by excluding large or significant portions of the affected population, rendering it virtually useless as a basis on which to draw generalizable conclusions. Moreover, the sheer cost of attempting to contact tens of thousands of individuals would simply be prohibitive.

Secondly, this case raises the issue of how much jurisdictions vary in their approach and the conditions under which they will permit non-consensual access to personal information for research purposes. Research agreements mandated by law or policy often include very different terms and conditions for protecting personal information. Likewise, approval required by various oversight bodies will be subject to different criteria and approaches. This case highlights the current patchwork of legal and ethical norms across the country that makes intra and inter-jurisdictional flow of data extremely complex in an important national undertaking of this kind.

A third issue raised by this case study is one of retention of data. Generally, legal and ethical principles require that personal information be retained only as long as necessary to fulfill the purpose for which it was collected, after which it should be destroyed, erased or made anonymous. The purpose of a database of this kind, however, is to provide a resource that can be used to monitor and evaluate the quality of diabetes care on an ongoing basis. The specific uses of the data cannot be fully specified at the outset, nor can it be specified how long the data will be kept. To destroy a database after each specific research project is completed would defeat its very purpose and result in enormous waste of public resources. This being said, however, regular reviews and audits should be undertaken to ensure the continuing relevance of the database and the effectiveness of its security safeguards.

FOR MORE INFORMATION

http://www.hc-sc.gc.ca/hppb/ahi/diabetes/english/strategy/ndss.html

[Case Study # 5]

TITLE

Use of RFLP* molecular epidemiology to find out how tuberculosis is spread among people infected with HIV

BACKGROUND

This study was sponsored by the National Health Research and Development Program of Health Canada and conducted by academic researchers affiliated with a Montreal University and its teaching hospitals from 1996 to 1999. The laboratory aspect of the study was conducted in the Public Health Laboratory of Quebec; the data linkage was performed by the Department of Public Health; and the investigators performed the data analysis at one of the teaching hospitals.

RATIONALE

Tuberculosis (TB) has again become a problem in certain parts of Canada. This is particularly of concern to people who are HIV positive as they are more likely to get infections, including TB. It would seem, therefore, that the presence of HIV in the population might contribute to the spread of TB. If researchers could determine whether in fact HIV infection contributes to the spread of TB, this information may be able to assist policy-makers in designing strategies to decrease the spread of TB in the general population.

PURPOSE

To learn how various factors like HIV infection, affect the spread of TB in the general population.

POTENTIAL BENEFITS

A better understanding of how TB spreads could help develop better ways of controlling TB infection in the general population.

* RFLP refers to Restriction Fragment Length Polymorphism. This describes a technique in which DNA is isolated and cut with a restriction enzyme. The DNA so cut is then separated onto a gel. If a given trait or gene fragment appears as different bands in a given population, it is said to be polymorphic (having more than one form). This technique thus enables researchers to map genes or to follow their passage from one generation to the next.

METHOD

The Public Health Laboratory in Quebec conducted the analysis for this study using RLFP molecular epidemiology to examine TB bacteria. The Public Health Laboratory in Quebec is a reference laboratory for the testing of blood and tissue samples. Doctors who want to find out whether their patients have a certain infection send the patients' samples to this lab. The samples of TB bacteria to be studied were already stored at the Public Health Laboratory and identifiable (i.e. linked with identifying information). Reporting of TB is mandatory in Quebec; the cases used here had already been reported.

RFLP molecular epidemiology is a method that uses parts of chromosomes to identify similar sets of genes. Using this technique, it is possible to look at the TB bacteria in or grown from different samples of sputum (coughed-up material from the lungs) and to determine whether the bacteria which caused one case of TB was likely related to that which caused another case. Usually, TB in adults is caused by reactivation of an old infection. In those cases, the TB bacteria of various cases are generally unrelated. However, individuals with a compromised immune system (e.g. persons who are HIV positive), more likely become ill from a recent external exposure to the TB bacteria. In those cases, the TB bacteria may be genetically related. Hence, the genetic analysis of the bacteria can provide information on how the disease spreads.

The analysis of each sputum sample by the Public Health Laboratory was provided to the Quebec Department of Health. Using the personal identifiers (i.e. names, date of birth) provided with the results of the RFLP analysis, the Department of Health linked these lab results to non-identifying demographic information stored within the Department, such as age, sex and residence. Once the Department completed this linkage, all names were removed from the linked information. The linked, but de-identified information, was then provided to researchers so that they could study how the TB disease actually spreads.

The researchers did not seek consent to conduct this study. Many of the sputum samples were sent to the lab years ago. Since then, many of the patients had relocated and could not be easily contacted. Even if they could be contacted, the researchers would need to know the names of the patients in order to trace them and seek their consent. Yet, the study was precisely designed in such a way as to avoid releasing identifying information to the researchers. It was the Department of Health that was responsible for linking the lab results and the individual demographic data and then removing the identifiers before releasing the linked information to the researchers. In this way, the researchers would not be able to identify individuals with the information that was provided to them.

PRIVACY RISKS AND INTENDED SAFEGUARDS

In the course of this research project, only the staff of the Public Health Laboratory and Department of Health had access to information identifying the research subjects. The personnel of these organisations had access to this information in the course of their usual work, with the professional obligation to protect its confidentiality. The Public Health

Laboratory and Department of Health provided information without names to the researchers. Furthermore, the demographic information linked to the samples was not sufficient to identify research subjects. Therefore, researchers could not identify any particular person and the privacy and confidentiality of research subjects was well protected.

Researchers had this study reviewed and approved by the Research Ethics Board (REB) of the teaching hospital. The REB considered that the privacy and confidentiality of the research subjects would be well protected and that the potential benefits far outweighed any possible risk of harm. However, the REB did have concerns about the Quebec laws that might apply.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

The *Quebec Civil Code* requires written consent for the use of part of the body for research:

> **Art. 22.** *A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research.* [Emphasis added.]
>
> **Art. 24.** *Consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to an experiment shall be given in writing. It may be withdrawn at any time, even verbally.* [Emphasis added.]

One important issue for the researchers and for the REB was whether bacteria grown from sputum samples of TB patients were "*part of their body"* as defined in Article 22, so that using the samples would require written consent from the subjects.

The REB consulted various experts on the issue of whether bacteria grown from sputum samples could be considered part of the body and thus required consent for its use under the *Quebec Civil Code*. Some experts felt that bacteria grown from the sputum samples should not be considered part of the body, because the samples were something grown, developed after the TB patients gave their sputum sample. This research material was thus considered as not being part of the body of the patients. Thus, it was determined that Article 22 was not applicable to this project, and thus, written consent from the patients was not required. The Quebec Ministry of Health was told of the expert opinion but Ministry officials did not officially reply to the researchers.

The REB's interpretation of the law was sufficiently flexible in this case to allow the research to be carried out. However, this is an example of how legislation intended to protect research subjects might inadvertently interfere with important and legitimate research projects that have already integrated as part of their design, adequate ways of protecting research subjects by removing any possible way of identifying them.

[Case Study # 6]

TITLE

HIV seroprevalence among women undergoing abortion in Montreal

BACKGROUND

This study was conducted from 1993 to 2000 by academic researchers affiliated with a Montreal University and its teaching hospitals. The study was sponsored by the Laboratory Centre for Disease Control of Health Canada.

RATIONALE

There is a continuing need to carefully monitor the frequency of HIV infection in the population. In part, this can be done by examining the frequency of infection in smaller groups that can be more easily accessed and tested than the general population.

PURPOSE

The purpose of this study was to survey and test women undergoing therapeutic abortions in order to assess the frequency of HIV infection in this particular group.

POTENTIAL BENEFITS

Current information about the incidence of HIV infection and certain practices can help inform and better guide educational programs and policies aimed at preventing infection. Moreover, such information may help indicate how certain risk factors for infection may have changed. If public educational programs or policies are not working or if the importance of certain risk factors for infection have changed over time, strategies can be adapted to help better prevent HIV infection.

METHOD

Before undergoing therapeutic abortions, women must necessarily have a blood test. Researchers approached these women in the clinic of a large teaching hospital and sought their consent to participate in the study. Those who agreed to participate were asked to fill out anonymous questionnaires about certain risk factors for HIV infection.

Also, with their permission, leftover blood from the blood tests was used to test for HIV infection. For each participant, a computer generated a specific scrambled code linking the blood sample for the HIV test and the answers to the questionnaire. Once the results of the HIV tests were linked to the corresponding questionnaire, the computer-generated code was removed. In this way, it was not possible to identify the research subjects, even

if one had used the same computer program to try to retrace the scrambled codes. The linked information for each person was thus completely anonymized so that the researchers could look at risk factors and determine the incidence of HIV infection but could not possibly identify any of the research subjects.

PRIVACY RISKS AND INTENDED SAFEGUARDS

This study began before reforms to the *Quebec Civil Code* in 1994. The Research Ethics Board (REB) of the teaching hospital that reviewed this research proposal, worried that the results of the HIV test might be traced back to individual women in the study. However, they agreed that replacing names with code numbers for linkage purposes would effectively prevent this risk.

There was also the risk that, sometime in the future, the women might have to declare in an insurance contract or job application that they had once been tested for HIV and that this might cause them prejudice even though the test was conducted for research purposes and even though the women could never know the results of the test. The REB required that this risk be disclosed to the women at the beginning of the study.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Before 1994, women were informed about the study both verbally and through posters in the clinic waiting area. Every woman was given a clear choice to accept or decline to be part of the study. Those who did agree to participate, did so through verbal consent. Almost all of the women approached (99.6%) agreed to participate in the study.

Since 1994 revisions to the *Quebec Civil Code*, consent to donate blood or tissue for research purposes are required to be given in writing.

> **Art. 22.** *A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research.* [Emphasis added.]
>
> **Art. 24.** *Consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to an experiment shall be given in writing. It may be withdrawn at any time, even verbally.* [Emphasis added.]

Due to this change in the law, the REB required that written consent be obtained before women could participate in the research study. With this new requirement for written consent, the participation rate dropped from 99.6% to only 90%. Women who would have been willing to participate under conditions of complete anonymity, now hesitated to sign their name on a written document that would associate them with an HIV study, and might later be discovered by insurers or potential employers. Ironically, a legal rule that was

designed to better protect research subjects (i.e. the requirement for written consent), in this case afforded research subjects with less protection (of anonymity) and actually put them at greater risk of being personally identified. In the specific circumstances of this case, verbal consent might have been more desirable for all concerned, but after 1994 this was not permitted under Quebec law.

The frequency of HIV was very low in the study population (about 0.2%). However, the investigators and sponsor of the study expressed concern that women more likely to test positive for HIV might have been even less willing to sign a written consent form and therefore might have declined to participate in the study altogether. If this was indeed the case, the requirement for written consent jeopardized the scientific validity of the study because the researchers may not have had a completely accurate picture of the frequency of HIV in this population of women, let alone the general population.

Moreover, this study was but one arm of a broader national initiative. It exemplifies how lack of harmonious standards across the country can potentially impact the generalizability of research which is designed to be national in scope.

[Case Study # 7]

TITLE

New use of anti-arrhythmia drugs in Saskatchewan

BACKGROUND

This study was inspired by the results of the Cardiac Arrhythmia Suppression Trial and was funded by a grant from the Health Services Utilization and Research Commission of Saskatchewan and conducted by researchers at the University of Saskatchewan from 1998 to 1999.

RATIONALE

Changes in the normal rhythm of the heart's pumping (cardiac dysrhythmias) are serious conditions that often result in disability and, sometimes death. Some forms of dysrhythmia require immediate action to prevent sudden death, while most are somewhat less serious but may require treatment with drugs. Since the Cardiac Arrhythmia Suppression Trial, an important study on dysrhythmias, all of the drugs used to treat this condition have come under scrutiny by researchers. While drug treatments reduce the severity of dysrhythmia, they all, to some degree, cause potentially dangerous changes to the heart's rhythm. At the time of this study, there was no accurate information on what drugs were being used by physicians to treat this condition.

PURPOSE

The purpose of the study was to look at how physicians in Saskatchewan are treating dysrhythmia. More specifically, the purposes of the study were to document the types of treatments prescribed to prevent serious changes in the heart's rhythm among new users of two types of drugs. The researchers wanted to evaluate, where possible, why the drugs were being prescribed and to determine whether the treatment recommended in consensus guidelines was actually being followed.

POTENTIAL BENEFITS

The results of this study would indicate whether or not physicians were prescribing the recommended treatment to patients with dysrhythmia. This information could assist governments and professional organizations in developing strategies for educating physicians and for monitoring whether, over time, these strategies prove effective in improving treatment of dysrhythmia.

METHODS

In order to conduct this study, the researcher required information in the database of the Saskatchewan outpatient prescription drug plan. The drug plan database contains every prescription for drugs in the provincial 'formulary', a list of drugs that the government will pay for under the provincial drug plan. Drugs for arrhythmias are put in to classes. Class I drugs[1] and Class III drugs[2] are used to treat dysrhythmias only and Classes II and IV are used to treat a wide range of cardiovascular disease. The Class I drug propafenone and Class III drugs are the drugs preferred by specialist physicians for treating dysrhythmia. While the Class I drugs were all listed in the provincial formulary, Class III drugs, which are newer and more expensive, were on a special list at the time of the study and the province would only pay for them in special situations. Physicians wanting to prescribe these drugs had to request permission to have them paid for from Saskatchewan Health on an exceptional basis.

The prescription drug database served to identify groups of patients who were prescribed Class I and/or Class III drugs for the first time in 1993 or 1994 and to provide further necessary data about the specific name of the drug prescribed, the date of the prescription, the number of pills prescribed and their dose. Also required for the purpose of this study was a record of all the other drugs these patients had been prescribed and which had been paid for in the two years before the anti-arrhythmia drug was prescribed. This provided information about other drugs that might influence the prescribing of Class I and III drugs. Prescription information for the two years after this first prescription was also required to find out if the patient had stayed on the drug or had been switched to another drug.

Using the provincial health services number issued to every Saskatchewan resident, the Research Services Office of the Population Health Branch in the provincial health department linked the prescription information described above with information about patient age, sex, residence, hospital use and physician visits for the two years before and the two years after the anti-arrhythmia drug was prescribed. Residence was stated only as urban or rural. The hospital information included the date on which patients were discharged, the length of time they were in hospital, the diagnoses and any procedures like surgery or x-ray, which had been done. In most cases, the physician information included information about the doctor's specialty (e.g. family practice or cardiology), and when they graduated from medical school. This linked information allowed the researcher to characterize the group of patients using Class I and III drugs and examine their utilization of health services such as hospitals or physician visits. The linked information also provided insight into which physicians were prescribing the new drugs and whether they were younger or older.

[1] Class I drugs include: disopyramide, flecainide, mexiletine, procainamide, propafenone, quinidine and tocainide.

[2] Class III drugs include: amiodarone and sotalol.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The major concern in this study was that personal information might be released to unauthorized third parties. However, this was extremely unlikely due to the security systems set up in Saskatchewan. Any linkage of government databases on drugs or hospitalizations or physician visits must be done within and under the control of Saskatchewan Health. Saskatchewan Health contracts a private information management firm to act as their agent for the purpose of maintaining the databases and performing linkages. Staff members within the health department, as well as the staff in the information management firm, are bound by pledges of confidentiality and they could lose their positions if they breach confidentiality. Staff members are trained in the security measures used in both areas, which include password-protected computer files, locked storage in locked rooms with a limited number of persons permitted access to any one file.

In this case, staff members used health services numbers to conduct the necessary linkage across databases and then replaced these health numbers with a study code number assigned to each person in the study. The age of residents over 80 years old was aggregated in order to mask small numbers. Saskatchewan Health provided the requested information to the researcher, but with no names or health insurance numbers, only the study code numbers. The likelihood of researchers being able to identify a specific individual based on the kind of drugs they took, the kind of hospital services they used, their age, and whether they lived in an urban or rural area, when included with similar information about a thousand other patients, would be extremely small. Besides, what was of interest to the researcher in this study was information about the groups of patients using Class I or Class III, not information about specific individuals. Were it not for the need to link information in the prescription database with information in the provincial health care plan by staff members at Saskatchewan Health, no readily identifiable information would have been required for this study at all.

The study proposal was reviewed and approved by the University of Saskatchewan Advisory Committee on Ethics in Human Experimentation. The researcher also received approval from the CrossAgency Study Committee of Saskatchewan Health. A formal written agreement between the researcher and the government of Saskatchewan was entered into which specified the variables to be identified and supplied, the linkage to be done, the confidentiality and data security measures required, and the costs. The agreement also required that all copies of the data be returned or destroyed at the end of the study. Furthermore, the researcher had to justify to the CrossAgency why each piece of information was required for the purposes of the research; for example, why information was needed on all cardiac drugs and not just the drugs of particular interest.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Had express consent been required in order for the researcher to assemble the study population and then to enlist participation from each individual to participate in the study, the study would not have been possible. Were it not for the drug prescription and health

care utilization databases maintained in the province of Saskatchewan, and for the capacity at Saskatchewan Health to conduct data linkage, the researcher would have had no other choice but to contact every single physician in the province to find out whether they had patients with dysrhythmia and whether or not they were prescribed Class I and/or Class III drugs. The researcher would then have had to enlist the physicians' collaboration in contacting all of these patients beforehand to request permission to release identifying information about them to the researcher, so that the researcher could then follow up by individually contacting all those patients who agreed in order to explain the research and invite them to participate in the study so that the researcher could examine their drug and hospital files. The researcher would have also had to set up a parallel consent process for the physicians since they, too, are part of the study.

This complex consent process would have been impracticable for several reasons. First, many of the individuals that would have had to be contacted to provide consent in this study would have likely changed address, or telephone number, relocated or died, making it impossible for the researcher to trace their whereabouts.

Excluding significant numbers of physicians or patients from the study due to the inability of contacting them would have biased the results of the study that critically depended on a large amount of data in order to be sufficiently representative from which to draw valid conclusions.

Moreover, requiring informed consent in this case would have ironically increased threats to individual privacy since the researcher would have had to gain access to identifying information just so that he could track specific individuals down and attempt to establish contact with them through various means in order to get their consent. Without the consent requirement, the researcher did not require access to any identifying information for the purpose of carrying out the study. Only Saskatchewan Health and its agents needed it to perform in-house data linkage. Identifiers were removed before releasing any data to the researcher.

Finally, requiring the researcher to establish contact and obtain consent from such a large population would have been simply too costly to implement. The researcher could not have obtained the additional public funding needed to carry out such a vast undertaking. For all of these reasons, the study would have likely been abandoned if individual consent had been required.

FOR MORE INFORMATION

Rawson NSB, Cox JL, Stang MR, Rawson MJ. New use of antiarrhythmia drugs in Saskatchewan. Canadian Journal of Cardiology 2002; 18(1): 43-50.

[Case Study # 8]

TITLE

Barriers to accessing health care in Canada: is the system fair?

BACKGROUND

This study was funded by the Health Transition Fund and the Canadian Population Health Initiative, and was conducted between 2000 and 2002. The research team was composed of investigators in participating universities of five provinces – British Columbia, Saskatchewan, Manitoba, Ontario and Nova Scotia.

RATIONALE

According to the *Canada Health Act*, all Canadians should have access to the health services that they need regardless of their level of income or where they live in Canada. While all Canadians have free access to doctors and hospitals for most health problems, there are socio-economic barriers that inhibit some Canadians from full use and participation in the health care system. Some of the barriers that make it difficult for some Canadians to visit a doctor, regularly or at all, include: not being able to find a doctor in the first place; daycare for children during their visit.

Numerous studies have shown that lower-income Canadians have poorer health status than wealthier Canadians. However, despite poorer health status, other Canadian studies have found that lower-income Canadians are using the same, or less, of some types of physician and hospital services compared to higher income Canadians.

PURPOSE

The purpose of this study was to determine whether lower-income Canadians use the health care system as much as wealthier Canadians, and if not, why they do not.

POTENTIAL BENEFITS

This study could shed light on an area that has been largely under-studied. It could help to determine how widespread the problem is, if and where it is concentrated, and what the systemic reasons may be for why lower income people are not getting the health care services they need.

This research could also serve to develop indicators for a 'report card' on access to health care, and to identify factors that make it difficult for Canadians to access health care services. Results from the study could be used to make the health care system more responsive and inclusive, thus offering Canadians better access to health care when they need it.

METHOD

To measure whether people are getting the care they need the following data was required:

1) factors that predict a person's need for health care services such as their age, sex and overall measures of how healthy they are, including people's self-assessment of their health status;
2) data on peoples' use of health services, overall, as well as particular types of services such as Pap smears, for example; and,
3) factors that may affect a person's ability to access the health services they need, such as, their income and education level, where they live, the kind of job they have, their means of transportation and childcare arrangements.

Because the types of data needed are not available in one single source, it was necessary to link different sources of information. Information about peoples' health status and possible barriers to accessing health services was obtained from Statistics Canada's National Population Health Survey (NPHS), a general purpose health survey. In addition, information on peoples' use of health services was obtained from provincial databases that routinely collect data on hospital services and physician billing data in order to manage the province's health care plan.

For the purpose of conducting the NPHS, Statistics Canada selected people on a random basis. Statistics Canada interviewers first contacted them by phone or in person. The reasons for the survey were explained, and people were asked to participate. Their participation was voluntary. Respondents who initially declined were subsequently contacted by letter and then by senior staff to encourage them to participate. Respondents who agreed to participate in the NPHS interview were asked, at the end of the survey, if they would allow Statistics Canada to link their survey data to provincial administrative health databases and to share their personal information with their provincial government for research purposes. More than 90% of NPHS respondents agreed to have their data linked by Statistics Canada and shared with provincial governments for research purposes, and provided their health card number for this purpose.

For the purpose of this specific study, Statistics Canada first provided the researchers with a data file containing participant names, health card numbers and NPHS numeric identifiers, but not the actual survey responses. The researchers used these identifiers to assemble together data about the participants' use of physician services and hospital services through access requests made to each of their respective provinces. The assembled health services data and correlating identifiers were then sent back to Statistics Canada. Statistics Canada then linked this assembled health services data with the survey responses of each research participant. Analyses and linkage were conducted at the Halifax regional office of Statistics Canada by the researchers conducting the study.

Once respondents had consented to participate in the NPHS, there was no ongoing possibility for them to withdraw their consent, except for a subset of respondents who were re-interviewed in later rounds of the survey and had the opportunity then to withdraw their consent for linkage and data sharing (the NPHS is re-administered to a subset of respondents every two years).

The study only included those respondents who expressly agreed to have their data linked and shared; no sharing or linking of data was performed for those NPHS respondents who did not provide consent to use of their personal information for research purposes.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The risks to privacy and confidentiality in this study were minimal. Express consent was obtained from NPHS respondents for participation in studies such as this one, and Statistics Canada's security and confidentiality procedures are among the most stringent of any national statistical agency.

Statistics Canada conducted the data linkage and analysis in accordance with very stringent rules and security safeguards required under the federal *Statistics Act* (R.S.C. c. S-19). The researchers who had access to identifiable data in the course of this project had to receive clearance and be sworn in as 'deemed employees' of Statistics Canada. Accordingly, they had to undergo the same security checks, follow the same security policies and take the same oath of secrecy as Statistics Canada employees. The *Statistics Act* mandates this oath of secrecy and breach of the oath constitutes a criminal offence that could result in fine or imprisonment.

The researchers were screened upon entering the Halifax regional office, and were issued a card lock pass that limited and monitored all entries into the office. The Halifax office had a high level of security, and in fact was remodeled to increase the level of security in order to accommodate this project. All access to the building was restricted and monitored, unauthorized access through doors or windows was virtually impossible, and the area was protected by sophisticated alarm systems during non-working hours.

Computers used by the researchers were in a designated and locked room, located in a physically secure area accessed through a monitored card lock system. These computers were not linked to the internet and had locked floppy drives that could only be opened by Statistics Canada staff for the researchers to use. A Statistics Canada employee not associated with the project was in the room supervising the researchers at all times. Before any information, including study results, could be removed from the room by the researchers, they had to be approved for release by specially-trained Statistics Canada staff who carefully reviewed the results of the analysis to ensure that there was no risk of persons being identified. To be released, the information had to be completely anonymized, posing no risk of identifiability.

Before the study could begin, researchers needed to obtain approval in each of the five provinces, as well as by Statistics Canada's own internal research review board. In each province, the study was reviewed and approved by a university REB, and in most of the provinces, it also underwent some form of privacy/confidentiality review and required approval by provincial health departments (see attached summary). In addition, the project was reviewed by Statistics Canada to ensure that it met their confidentiality and security requirements. Each of these oversight bodies imposed different conditions and used different criteria for approval. Obtaining the required approvals from each of these collaborating provinces and Statistics Canada took more than 2 years, and Ontario has still not yet approved.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

In this case, NPHS respondents provided their express consent to allow Statistics Canada to link their personal information with provincial databases and to share their personal information with their provincial government for research purposes. However, the consent they provided was for general research purposes, which included this study and many others that were also based on the NPHS results. Respondents did not specifically consent to this particular research study. This issue raises the question of how specific consent must be in order to be considered sufficiently informed from a legal and ethical point of view.

National studies of this nature illustrate the critical need for inter-provincial flow of personal health information. Sharing data between provinces and linking them across various sources within each province, calls into play several laws and policies, each with their own criteria and conditions, and involving various oversight bodies with different mandates and approaches.

In this case study, obtaining all the required approvals took over two years and the process had still not been completed at the time of publication of the present document. The difficulty experienced by the researchers in this case to obtain all the necessary approvals, by all the different bodies, according to all the different criteria required, speaks clearly to the need to harmonize jurisdictional approaches to protecting personal health information across Canada.

FOR MORE INFORMATION

George Kephart, Rob Reid, Nazeem Muhajarine, Les Roos, Michael Wolfson, Jack Williams, Doug Manuel. Socioeconomic differences in the use of health care: why are there non-financial barriers to "medically necessary" services? Report #NA369, Health Transition Fund, Health Canada, May 1, 2001. Available at: **http://www.hc-sc.gc.ca/htf-fass/**

Summary of Required Approvals and Associated Barriers

Data Holder	University Ethics	Privacy and Confidentiality	Ministerial Approval	Other
BC	Yes	1. Data for the project were derived from the BC Linked Health Database. The database contains a variety of health related data, is only used for research purposes, and resides at the University of British Columbia. 2. Approval to access the data was required from the Data Access Committee (DAC), composed of 'data stewards' for each component of the database. The main purpose of the DAC is to ensure that research conducted is consistent with B.C.'s *Freedom of Information and Protection of Privacy Act*. 3. The DAC required a detailed specification of the data to be linked*. 4. The committee would not allow the release of potentially identifying information including 6-digit postal code.	Ministry of Health officials are key members of the DAC, including members from the Ministry's Information and Privacy Branch and the Research and Evaluation Branch.	The BC team required clarification from Statistics Canada on policy for future use of the data.
Saskatchewan	Yes	1. Reviewed by Data Access Review Committee internal to the department of health. The Committee, which has delegated authority, reviews all data requests for compliance with the Department's data access and confidentiality policies. The Committee does not include academic representation. 2. Saskatchewan Health's data release policies and practices can be quite restrictive about data sent outside the Department. 3. Saskatchewan Health required very detailed specifications on the data to be sent, and imposed a number of restrictions. For example, they would not provide detailed ICD codes required for CMG™ groupings from the hospital data. Extensive grouping of fields was required. 4. Saskatchewan Health only agreed to allow linkage and release of data for those persons who had given consent in both waves of the NPHS (i.e. the longitudinal file). Accordingly, we were unable to use data for NPHS respondents who were lost to follow-up between waves of the survey (in this case less than 50 subjects).		Cost to access data was initially prohibitive. However, in the end they extracted a limited set of administrative data at low cost. Data was released to the provincial investigator who signed a contract with Saskatchewan Health.

Summary of Required Approvals and Associated Barriers *(continued)*

Data Holder	University Ethics	Privacy and Confidentiality	Ministerial Approval	Other
Manitoba	Yes	1. Reviewed by an independent privacy and confidentiality committee. 2. The committee required a specific, detailed list of the fields to be sent to Statistics Canada*. 3. It also equired that confidentiality contracts be signed by all project investigators. 4. The final approval was inflexible to any change in protocol. For example, the original approval would not permit hospital data to go to CIHI for coding/grouping.	Essentially – linkage could not be conducted at the Manitoba Centre for Health Policy Research (MCHPE), so Ministry support was required.	1. Required clarification from Statistics Canada on future use of the data. 2. Linkage had to be conducted at Manitoba Health rather than MCHPE. Thus, the speed of getting the project done was to Manitoba Health's priorities rather than that of the research team. This has created problems for refinements to the 1994 link.
Ontario	Yes	Review was conducted within ICES by a privacy officer and the CEO. In addition the legal branch reviewed the project for compliance with the provincial *Freedom of Information and Protection of Privacy Act*. ICES has considerable latitude on access to and use of the NPHS data internally. For example, at the point of project initiation, they were already active in linking the NPHS to administrative data.	1. ICES is not authorized to send data to other organizations without ministerial approval. 2. Obtaining ministerial approval was very difficult largely because the project is not a priority. It has only just been granted. 3. Now that ministerial approval has been obtained, approval from the legal branch is required. This is still pending.	The privacy commissioner requires that the data must have a specified destruction date.

Summary of Required Approvals and Associated Barriers *(continued)*

Data Holder	University Ethics	Privacy and Confidentiality	Ministerial Approval	Other
Nova Scotia	Yes	Review was conducted within the Population Health Research Unit (PHRU) according to pre-approved criteria.	PHRUs contract with the Nova Scotia Dept of Health does not authorize it to send data out of the province. Thus, ministerial approval was required and obtained from the Deputy Minister.	PHRU works only with encrypted identifiers, and is dependent on Maritime Medical Care to implement encryption for linkage.
Statistics Canada	No	Approval from the Statistics Canada Policy Committee was required.	No	Access to data is subject to the federal *Statistics Act*, as well as to the provisions of the Deemed Employee contract. The deemed employee contract included problematic requirements on (a) publication and (b) submission of reports to other funders. This project required substantial changes to the deemed employee contract.

*Note: Initially, the researchers decided to link all useful, non-identifying information in the administrative data. One goal of the project was to create an ongoing resource for research using the NPHS data, based on respondents consent for linkage. Moreover, because obtaining provincial reviews can be time consuming, the research team wanted to avoid decisions on data requirements at the outset that might be limiting later on. However, many review bodies are geared to providing data on a project-by-project basis, and thus require detailed specifics on the data requirements for the project, along with the rationale for requested data elements. In some cases, grouping of variables (e.g. age) was required.

[Case Study # 9]

TITLE

Needle stick injuries in nursing and laboratory staff

BACKGROUND

This study was conducted by a graduate student in epidemiology from 1989 to 1990, and sponsored by the Division of Community Medicine at Memorial University of Newfoundland. Four teaching hospitals in St. John's, Newfoundland participated; one hospital was used to pilot the study and three hospitals were part of the final study.

RATIONALE

The study was conducted at a time when strategies and devices were being developed to protect health care workers from needle stick injuries that could potentially transmit HIV.

PURPOSE

The purpose of the study was to determine the type and frequency of needle stick injuries in full-time nurses and laboratory technologists at three hospitals using staff health records and self-completed questionnaires.

POTENTIAL BENEFITS

Knowledge of the type and frequency of needle stick injuries, where they occur in the hospital and who is at greater risk of injury can assist in developing hospital policies to protect workers from transmission of HIV and to provide the basis for educating nursing and laboratory staff in preventive strategies.

METHODS

Before undertaking the study, a pilot study was conducted to test the proposed method of mailing personally addressed letters and questionnaires to potential study participants and asking them to complete and return the enclosed questionnaires on an anonymous basis. As is customary in pilot studies, a small sample of persons were asked to provide feedback to the researcher on the acceptability and appropriateness of the covering letter and on the clarity of the questions and format of the questionnaire. These comments were checked against the responses given to see if the questions had produced the sort of information being sought by the researcher.

Potential research participants included nursing and laboratory staff in each of the four collaborating hospitals. The researcher first met with hospital administrators to explain

the study to them and ask for their support. The researcher then asked for time at regular staff meetings to explain the purpose of the study to the nurses and laboratory technologists, and describe generally how the study would be conducted.

The researcher asked the hospital administrators to provide her with the names of nurses and laboratory personnel at each hospital, their work location and full or part-time status. The researcher signed undertakings of confidentiality for both the hospital and for the supervisory committee. The requested information was provided to the researcher in the form of a computer file which the researcher then went through to exclude staff who were part-time, were designated as managers or who worked in areas where they would not handle needles. After these exclusions, the researcher used the computer file to select random samples of eligible staff from each hospital.

It is well known in the scientific community that people are more likely to answer letters addressed by name rather than 'occupant'or 'householder'. Consequently, the researcher sent everyone in the random sample a personally addressed letter explaining the study in greater detail, an anonymous questionnaire and a response card. The questionnaire included questions about the respondent's use of needles in a variety of procedures and perceived barriers to safe handling of needles in these situations. Such information was necessary in order to better inform those developing and implementing policies for needle-handling. Questions were also asked about needle stick injuries incurred and what action had been taken, in order to assess the need for more education about the importance of reporting and for more efficient follow-up of injury.

The questionnaire had no name or code number on it and participants were asked not to write their name on it. The cover letter from the researcher asked participants to fill out the questionnaire, put it in the provided envelope and return it through internal mail. The letter also asked participants to then sign the response card that had their name on it, put it in a separate envelope that was also provided and deposit it into the slotted drop boxes located in each work area. The researcher did not need to know the names of persons who had responded; it was the content of the responses that was of interest. The only identifying information required was on the response card in order to allow the researcher to send targeted reminder letters to those persons who had still not responded. In addition, general reminders to return the questionnaires were also posted in designated work areas in an effort to increase response rates.[1]

The researcher also needed general statistics on needle stick injuries for the period corresponding to the injuries reported in the questionnaire in order to compare the frequency of injuries in staff health reports with self-reported injuries by study respondents. Such information is kept by the staff health offices at each hospital who are responsible for tracking such injuries and implementing preventative programs to protect staff. These

[1] It is established methodology that multiple reminders for mailed questionnaires are required to achieve an acceptable response rate.

offices provided the researcher with these general statistics without any names or other identifiers.

After the collection and analysis of the data, a general report containing no identifiable information was prepared for each of the staff health offices and for the heads of nursing and laboratory staff in each of the hospitals including the hospital used in the pilot study.

All of the data collected during the study were destroyed when the student researcher completed her degree, (i.e. the university has no set policy on retention of data from independent graduate student theses). Questionnaires and response cards were shredded and computer files were deleted.

PRIVACY RISKS AND INTENDED SAFEGUARDS

To minimize the risk of linking questionnaire responses with the names provided on the response cards, the researcher picked up the cards regularly throughout the week and the questionnaires only once every week or two. Furthermore, no data were entered until the end of data collection to reduce the possibility of identifying late respondents. With this method, the researcher could not identify who had filled out each questionnaire, but she would know from the response cards who on the list had or had not returned a questionnaire.

Another risk posed by the study was that information would be revealed about those staff who had suffered an injury at work but who had not reported it, contrary to mandatory hospital reporting policies. Some respondents may not have reported the injuries because they did not want to appear careless; others may have wished to avoid the fairly lengthy follow-up procedures required of persons with a needle stick injury. The researcher had anticipated that this might be the case and understood that this information would be considered quite sensitive. It was for this reason that the survey was conducted completely anonymously with no ability to identify an individual who might report an injury to the researcher but not to staff health.

The paper copies of staff listings provided to the researcher by the personnel departments of each hospital were kept in locked storage in a locked office. All returned questionnaires, although anonymous, were also kept in locked storage. The tracking record (letter out, response back, follow-up out, etc.) was kept on a personal computer. Although password protection of computer files would be standard procedure today, this was not the case in 1989-1990. Only the researcher had access to the computer file and the locked storage.

The study was first reviewed by the research ethics committee of the Faculty of Medicine, Memorial University. The study was then reviewed and approved by the heads of nursing and of laboratories and the ethics committees of the four hospitals involved in the study.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Consent to participate in the survey was implied by the return of a completed questionnaire. Those who did not wish to take part did not respond. To ensure that participants had all the information necessary on which to make an informed choice about whether or not to participate, all of the relevant aspects of the study were explained in the covering letter accompanying the questionnaire, including the purpose of the study, the rationale behind the study, the voluntariness and anonymity of the study, what was expected of the participant, how long it would take, how to reach someone to ask questions about the study and how they could get the results of the study.

Ideally, the initial contact with eligible research participants is made by someone who would be expected to have relevant information about them. In this case, personnel offices of hospitals would be expected to have information about the employment status of nursing and laboratory staff. Therefore, the initial contact normally would have been made by the personnel offices asking eligible staff members for permission to release their names and contact information to the researcher. The personnel office would then provide to the researcher identifying information about only those eligible participants who agreed to the release of identifying information about them in order for the researcher to send them letters and questionnaires inviting them to take part in the study. However, in this case, the personnel offices did not have the resources necessary to search through their personnel files in order to identify potentially eligible research participants according to selection criteria specified in the research protocol, make a random selection among those potentially eligible and establish prior contact on behalf of the researcher. Even though funds were available in the researcher's budget to cover this expense and essentially pay an employee in each personnel office to carry out these tasks, there were no staff with the relevant competencies available to do this.

It is unlikely that this situation has changed much in recent years. Most hospital records departments are far too busy and under-resourced to take on added work on behalf of researchers. Consequently, there are situations where important research simply cannot proceed unless researchers gain direct access to identifying information in order to determine the list of eligible research participants based on specific selection criteria and approach participants directly, with or without prior contact by the original data custodian.

Moreover, researchers often need access to identifying information about not only those eligible participants who agree to be contacted and agree to participate in the study, but also require some information about those who did not (in this case, this would have included age group, sex, nursing area or laboratory area and years of employment). This information is critical in order to allow the researcher to address any possible bias in the results should those who had responded be found to be significantly different from those who had not, e.g. in age, years of experience or job category.

In this case, the first contact with potential research participants was handled in the way that was recommended by the ethics committee. The researcher first wrote to, and then spoke with, senior nursing and laboratory administrators, who in turn explained the study in general terms to their staff members. Staff members were informed that the researcher would be writing in the near future to individuals eligible to be included in the study. Accordingly, several weeks after each of these presentations, the letters were sent to only those eligible staff members.

Another issue raised by this case study, is that of the hospital's mandatory policy for reporting needle stick injuries. In this case, the researcher designed the study in such a way that the questionnaires were completely anonymized, so that she could have no possible way of knowing who had suffered a needle stick injury without reporting it. Had the study design been different, and had the researcher collected this information in a way that could have been traced back to specific individuals, she would have had to inform participants that she could protect their confidentiality, but she might not be able to fully guarantee it from legally-compelled disclosure. For instance, in the unlikely event of a law-suit against the hospital and/or its staff for damages resulting to a patient, the researcher could conceivably be subpoenaed by law and ordered by a court to produce information about any staff member who had not reported a needle stick injury. In such a case, she would have little choice not to do so without herself suffering legal sanctions. This is because, currently under Canadian law, there is no legally recognized privilege of the researcher-participant relationship that would protect the information from disclosure as relevant evidence in judicial or administrative proceedings. This is different than the situation in the U.S., for example, where certificates of confidentiality can be issued to researchers by the U.S. Secretary of Health protecting them from having to disclose relevant information in any legal proceeding.[2]

[2] Section 301(5)(d) of the U.S. Public Health Service Act reads as follows: "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use an defect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

[Case Study # 10]

TITLE

A randomized controlled trial of call/recall of 'hard-to-reach' women for Pap tests.

BACKGROUND

The study was conducted by an epidemiologist and a clinician at Memorial University of Newfoundland, and sponsored by the (then) National Health Research Development Program (NHRDP). The study was completed in 1994.

RATIONALE

Population studies have shown that the death rate from cervical cancer decreases with timely and effective screening, i.e. a Pap test. Current public health guidelines recommend that women between 18 and 69 years of age be screened regularly – every one to three years. However, there are many women who are 'hard-to-reach'. 'Hard-to-reach' women are women who are inaccessible due to economic, language or other socio-economic barriers, and/or who are reluctant to undergo screening. These women end up not being screened at all, or are screened so seldom that physicians are not likely to detect a cancer early enough to treat it before it becomes invasive.

PURPOSE

The purpose of this study was to determine whether personalized invitation and reminder letters could increase the rate of screening in women who had never undergone a Pap test or who had not had one in the past three years.

POTENTIAL BENEFITS

Sending a personalized invitation letter for a Pap test with one reminder letter is a fairly inexpensive and simple strategy that could lead to increases in the rate of screening in women who have never been screened or are seldom screened for cervical cancer. Population-based, cervical screening programs are usually funded by provincial governments. These programs need a simple, cost-effective approach for getting women to come in for screening, particularly those women who are hard-to-reach.

METHOD

The study participants were women patients of two family practices, one in St. John's, Newfoundland, and the other in a rural community an hour outside the city. The researchers met with physicians and staff at each of the two participating sites to explain the study

and how it would be implemented. The physicians in each practice gave the researchers permission to access patient records summarized in electronic files to select current patients potentially eligible to participate in the study, i.e. women, of appropriate age, who had had a physician visit during the last year. In order to make this first selection, the researchers worked with the computer manager responsible for the electronic files of the two practices. It is important to note that this preliminary selection process would not have been possible in other paper-based practices. At the time of the study, these two practices, both under the auspices of the Faculty of Medicine, were the only practices totally computerized in the province. Even today, very few practices in Newfoundland have electronic patient databases.

The researchers also met with staff of the Newfoundland Cancer Treatment and Research Foundation (NCTRF) to explain the purposes of the study. NCTRF is responsible for the maintenance of the provincial cancer and cytology registries. The cancer registry contains pathology reports from all of the pathology laboratories in the province and reports of death due to cancer from the Newfoundland Centre for Health Information. The cytology registry contains cytology records of Pap tests from all laboratories in the province.

NCTRF agreed to work with the researchers in order to further refine the preliminary list of potentially eligible patients. The formal application for access to registry data was approved by NCTRF on condition that the co-principal investigators and the research assistant sign confidentiality agreements. The preliminary list of names and health insurance numbers that had been extracted from the physicians' offices was provided in electronic file format to the registry staff of the NCTRF. As the registry staff was not equipped to do formal record linkage, they instead 'matched' the preliminary list against the computer files of the cancer registry to identify women who had already developed cervical cancer. The preliminary list was also 'matched' against the computer files of the cytology registry in order to identify those women who had had a Pap test in the last three years. All of the women on the preliminary list who had developed cervical cancer and/or had had a Pap test in the last three years were excluded from the study.

In addition, current screening guidelines recommend that women who have had a hysterectomy should be followed by their physicians and not be included in a general screening program. Therefore, researchers needed access to clinical records in order to determine which women on the list had had hysterectomies and therefore, should be excluded from the study. Permission to access these records was given by the physicians of the two practices for this specific purpose.

Using the final list, the researchers randomly chose which women would be sent an invitation letter to get a Pap test. Half of the women on the list were sent invitation letters and half were not. Four weeks after an initial letter, the women in the intervention arm of the study were sent reminder letters. These were personalized letters, since it is well established that sending personalized letters, as opposed to general notices, increases the likelihood of response. The letters were on Faculty of Medicine letterhead with the signatures

of both researchers. At the time of this study, physicians were not permitted by their licensing board to 'solicit' patients to come in to their practice for services, which meant they could not send out, or even be associated with, individual letters to their patients inviting them or reminding them to come in for their regular Pap tests. Therefore, the letters did not mention any physician name; rather, the researchers simply asked the women to make an appointment with their doctor to have a Pap test.

Some months later, the research assistant provided the staff at the cytology registry with the names and health insurance numbers of those women who had been selected as part the study sample in order to confirm which of these women, among those who had received a letter and those who had not, had in fact come in for a Pap test following the invitation and reminder letters. The research assistant also asked the computer manager of the two family practices to confirm which women in the study came in to see their physician since the letters were sent. This allowed the research team to determine whether women in the study had visited the practice but not been screened.

PRIVACY RISKS AND INTENDED SAFEGUARDS

In this study, identifiable data were essential for the purpose of matching records in the family practices with information in the registries. As well, names and addresses were needed to send personalized letters out to women selected to receive the intervention. In order to minimize the risk of disclosure to unauthorized third parties, the research team implemented the following safeguards.

Once the final study sample was selected, each woman in the study sample was assigned a study number. The code list (i.e. the list that contained both the names of the women with their correlative study numbers) was stored on a personal computer in a computer file protected by a password. Only two members of the research team knew the password and could access the code list: the research assistant on the project (who was responsible for sending out the personalized letters and verifying information with the registries and the two family practices) and the information system specialist in the department (who provided help with the information system). Both signed undertakings of confidentiality. Breach of confidentiality would have resulted in immediate dismissal of the research assistant from the project and possible dismissal of the systems specialist from the institution. Study numbers were used on all of the paper forms used to abstract information from the charts and in all of the computer files where the sequence of events in the study were tracked – confirmation of eligibility, letter out, reminder letter out, review for subsequent Pap test, etc. Paper files were stored in locked filing cabinets and kept in a locked room, along with the computer used in the study. The room was shared with one other research assistant on another study; each study was assigned its own locked filing cabinet.

After the study was over, all of the files were stored in boxes in a separate storage area maintained by the university. Files can be retrieved only by the investigator in the presence of the person responsible for this storage area. Both the host institution

(Memorial University) and the sponsor of the study (NHRDP) required storage of the raw data for at least five (5) years after the end of the study. This is also a general policy followed by most researchers to ensure the data are available in order to address any questions about the quality of the study and the results obtained. [Note: currently, drug trials require storage for 20 years.]

The study was reviewed and approved by the research ethics committee of the Faculty of Medicine, members of both practices and the research committee of the NCTRF.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Ideally, when researchers set out to assemble a study population from a patient group, prior contact with each patient should be made by the health care provider in order to obtain authorization before releasing nominal information to the researchers. If authorization is granted by the patient, the health care provider can then release nominal information to the researchers in order to allow the researcher to communicate directly with the patient, explain the research study and seek the patient's informed consent to participate in the study.

This case illustrates an exceptional situation where it was not possible for physicians to establish prior contact with their patients or for the researchers to obtain informed consent to participate in the study. As described above, the physicians' involvement in this case was limited by a policy that existed at the time, preventing them from soliciting patients to come in for services. Moreover, since the aim of this study was to determine whether an invitation and reminder letter could serve as an effective strategy for encouraging women patients to come into their doctor's office for a Pap test, contacting and seeking consent from these women beforehand would have defeated the whole purpose. The prior contact and the informed consent process could have confounded the research results, such that researchers could have never known whether it was the prior contact by the physician or the detailed explanation of the study by the researcher or the actual invitation and reminder letters or a combination of any of these factors that effectively prompted women to come in for a Pap test. Hence, they would not have been able to draw any valid conclusions from the study.

Finally, this case illustrates why personal information must be retained for a period of time following the completion of the study in order to allow for auditing of research results. If researchers were obliged to destroy or anonymize data immediately upon the fulfilment of the research purpose, strictly speaking, there would be no means for sponsors or publishers or other researchers to verify and ensure the quality of the data.

FOR MORE INFORMATION

Buehler SK, Parsons, WL. Effectiveness of a call/recall system in improving compliance with cervical cancer screening: A randomised controlled trial. Can Med Assoc J 1997; 157:251-6

[Case Study # 11]

TITLE

The impact of having elderly and welfare patients in Quebec pay a greater share in the costs of their prescription drugs

BACKGROUND

Researchers from McGill University and the University of Montreal were commissioned by the Quebec Ministry of Health to conduct this study. Additional funding was received from two federal funding agencies (the former Medical Research Council, and the National Health Research and Development Fund) to study the outcomes of possible changes in prescription drug use.

RATIONALE

In 1996, the Quebec Ministry of Health (MSSS) put in place a new cost-sharing policy for payment of prescription drugs. The new drug cost-sharing policy could have beneficial, as well as unintended effects. The express concern of the MSSS and consumer groups was that the elderly and welfare recipients who had previously obtained prescription drugs either free or at nominal cost, may be adversely affected by greater demands for out-of-pocket payments. More specifically, elderly who were paying up to $100 for their prescription drugs and people on welfare who received free medication would now have to pay $200 to $750 per year in user fees. The MSSS initiated this study to fulfill the legislated requirement that the impact of this new drug cost-sharing policy be properly evaluated.

PURPOSE

The purpose of this study was to evaluate the impact of this new drug cost-sharing policy on:

a) use of all prescription drugs;
b) use of essential, compared to less essential, drugs; and
c) changes in the frequency of hospitalizations, emergency room visits and deaths, associated with possible decrease in use of essential and less essential drugs.

POTENTIAL BENEFITS

The results of this research showed that the new drug cost-sharing policy in fact did have a substantial impact on the use of essential drugs by both the elderly and welfare recipients. In particular, welfare recipients, especially those with mental illness, reduced their use of drugs necessary to control their illness, resulting in a dramatic increase in the rate of emergency room visits, hospitalizations, long-term care admissions and deaths. The results of

the study quickly led to a change in the new drug cost-sharing policy. Legislation was put in place within six months of the final report of this study providing for free drugs to people who were unable to work because of their health problems.

METHOD

To conduct this study, the researchers needed to have access to several key pieces of information. First, the researchers had to know who might be affected by the new drug cost-sharing policy, who was covered by the Quebec drug insurance plan prior to the institution of the new policy and who was using prescription drugs.

Second, to assess the impact of the new drug cost-sharing policy on those persons who might be affected by it, researchers had to create a longitudinal history on the health status of each of these persons. The researchers required this information to determine:

1) whether there was a change in the use of prescription drugs after the new drug cost-sharing policy was implemented; and
2) whether any change in prescription drug use, brought about by the new drug cost-sharing policy, had unintended consequences of increasing the use of medical services, frequency of emergency room visits, hospitalizations or deaths due to deterioration in health status.

While, in this case, almost two million people were affected by the new drug cost-sharing policy, representative samples of 120,000 elderly and 120,000 welfare recipients were sufficient to adequately answer the question of impact. A pre-policy control period was used to assess impact for the same subpopulation of persons. Data needed for this longitudinal study were retrieved from historical information that is routinely collected by Quebec's health insurance agency (RAMQ) and the MSSS as part of their normal responsibility to administer the medical and drug insurance programs, and monitor hospital utilization in the province. More specifically, the research team retrieved information from the prescriptions claims database for each person in the sample. This database contains all records of payments to pharmacists for drugs dispensed to people who are insured through the Quebec government plan. This database was used to estimate the trend in prescription drug use in the three years before the new drug cost-sharing policy was implemented and in the 18 months thereafter. The use of prescription drugs was measured for each person so that the researchers could determine whether or not the new drug cost-sharing policy had greater impact on sick and poor people, relative to those who were in better health and had higher incomes.

In addition to the prescription drug database, the researchers retrieved information from other databases managed by RAMQ and MSSS about the payment of medical services, emergency room visits, hospitalizations and deaths. The researchers linked this information for each of the persons in the study for a three-year period before the new drug cost-sharing policy was implemented and for an 18-month period thereafter. The linkage was done using

an encrypted health insurance number. The encrypted health insurance number is created by the RAMQ in compliance with regulations from the Commission d'accès à l'information (CAI), the Quebec freedom of information office. Each research project has a different encryption code so that data retrieved for one project can never be linked to data from another project, even if the same patients happen, by chance, to be sampled. Each person in each different study is assigned a unique study code. This study code provides a means of removing identifying information, while still allowing information on prescription drug use to be linked with information in medical and hospital care files for the same individual, without knowing who they are.

PRIVACY RISKS AND INTENDED SAFEGUARDS

There is always concern that health information, such as mental illness, could be potentially linked to an identifiable person. The research team collaborated with community-based advocates for the elderly and welfare recipients so that the specific privacy concerns of these groups could be addressed in the research plan.

Researchers protected the personal information they required for this study using study codes to link all of the records for each of the research subjects in the study, without identifying any individual person. The study was described in a detailed submission that was presented to, and approved by, the CAI. The CAI monitors the use of de-identified data by researchers through regular random audits that involve on-site inspection of data security, access and analysis procedures. In this particular case, the CAI conducted an on-site audit to assess data security procedures and practices.

In addition, the study proposal was reviewed and approved by the Research Ethics Board of McGill University. The peer review committees of the then Medical Research Council, the National Health Research Development Program of Health Canada and Ministry of Health of Quebec reviewed the proposal for scientific validity.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Policy evaluation studies are a particular area of research where ethical and legal issues have not been well articulated. Health and drug insurance policies are 'interventions' that are often implemented without prior knowledge of the actual impact they will have on certain segments of the population. Most of these policies are not evaluated and proceed as un-tested 'experiments' in one jurisdiction, only to be subsequently adopted in other jurisdictions. When studied, some of these policies may ultimately be found to provide improvements in the health of the population, but others may eventually show adverse effects. To this day, the impact of many health and drug insurance policies that are implemented is still not known.

There are many reasons for this profound lack of knowledge. One of these is the difficulty researchers have accessing data needed for valid assessment of new policies. This problem

is accentuated by the lack of systematic collection of relevant data for the evaluation of policies generally. In this case, data needed to conduct the evaluation of the new cost-sharing plan was routinely collected as part of RAMQ and MSSS's responsibilities in administering the province's medical and drug insurance plans. These data were made available to researchers in this specific case in part due to the legislated requirement for evaluation, as well as the existence of an established set of policies and procedures for access and linkage of these data through the CAI. As it happened, data for this policy impact could be accessed in Quebec. However, this may not be the case elsewhere, or for different policies that are not required, by law, to be evaluated.

Furthermore, this research would not have been possible if written consent had been required for each of the 240,000 persons in the study. The sample had to be taken from lists of persons in the database at least three years before the new drug cost-sharing policy was implemented. In addition, the MSSS requisitioned the study some time after the new policy was put in place. Therefore, researchers would not have been able to locate a significant portion of the elderly or welfare recipients in the study population who had since died or were institutionalized, possibly as a result of the policy change itself. The exclusion of persons who were most severely affected would lead to biased conclusions by underestimating the negative impact of the policy change. In addition, researchers could not even have gained access to the last contact information of persons as this would violate existing regulations preventing MSSS and RAMQ from releasing nominal data. Therefore, to conduct policy evaluation studies on a large representative sample of individuals, researchers and policy-makers are totally dependent on non-consensual access to de-identified, but linkable databases.

A subportion part of this study involved a survey of a locally available sample of elderly persons and welfare recipients in order to determine how the change in payments for drugs had affected them. A collaborating research team, who had initially recruited elderly persons as part of a community-based control population for the evaluation of stroke outcome, sought consent from the persons recruited in that study group to also participate in the assessment of the drug policy. Of the 300 elderly persons who were sent questionnaires by the collaborating research team, only 20% returned them. For welfare populations, a Montreal-based welfare advocacy agency partnered with the research team to mail out questionnaires to their members. Of the 2,000 persons on welfare who were sent questionnaires by the welfare advocacy agency, only 19% returned them. Thus, the new drug cost-sharing policy evaluation team were never provided with any contact information but, rather, worked through these intermediaries.

When researchers compared the results of this local survey with the results of the database study they had performed, the results were very different. The people who were surveyed and who returned the survey indicated that the change in policy had not had very much impact on their use of prescription drugs or their health status. This reflected a common bias in surveys. That is, people who are willing to fill out a questionnaire and send it back are likely to be in better health than those who do not. If the researchers had used only

the results of surveys to evaluate the impact of the new drug cost-sharing policy, they would have falsely concluded that the drug plan had a very minor impact on these groups of individuals, when in fact, as this study clearly demonstrated, such was not the case.

FOR MORE INFORMATION

Tamblyn RM, Laprise R, Hanley J, Abrahamowicz M, Scott S, Mayo N, and Collaborators. (2001) "Adverse Outcomes of Prescription Drug Cost-Sharing Among the Poor and the Elderly." The Journal of the American Medical Association Vol. 285 (4) 421-429.

[Case Study # 12]

TITLE

A randomized drug policy trial with camouflaged contacting of patients

BACKGROUND

This study was sponsored by the Canadian Health Services Research Foundation, Health Transition Fund and British Columbia Pharmacare, with further analyses funded by the U.S. National Institute on Aging through Harvard University. The study occurred between 1999 and 2001, and was conducted at the University of British Columbia's (UBC) Faculty of Pharmaceutical Sciences and later at Harvard.

RATIONALE

In 1999, British Columbia Pharmacare, the publicly funded drug insurance program within the provincial Ministry of Health, introduced the Nebulizer-to-Inhaler Conversion policy. Under this policy, Pharmacare stopped covering the costs of respiratory medications that used nebulizers to deliver drugs to the lungs and encouraged doctors to switch patients with respiratory illnesses to medications delivered using metered-dose inhaler devices. However, upon request from a doctor, patients with special clinical needs were granted exemptions to this policy.

PURPOSE

To measure the intended and unintended impacts of Pharmacare's Nebulizer-to-Inhaler Conversion policy on health care utilization and quality of life.

POTENTIAL BENEFITS

Findings of this research could enable better versions of the policy to be designed and implemented, ultimately with a view to improving treatment of patients with respiratory illnesses. Other provinces that are considering implementing a similar policy may benefit if unintended impacts of the policy are found and can be avoided.

METHOD

In order to evaluate the intended effects and possible unintended impacts of its new conversion policy, Pharmacare agreed to grant an optional six-month exemption from the policy to 10% of physicians in the province. Although the policy itself was not considered experimental, the optional exemption created a randomized control group much like that which would be used in a scientific experiment. The purpose of the optional six-month delay was simply to establish a basis for comparison in order to evaluate the impact of the policy.

The principal investigator at UBC and co-investigator at Harvard were given de-identified data on health care utilization (i.e. prescription drugs, medical services, hospitalizations, long term care), and mortality (from 1997 through mid 2000) of all Pharmacare clients affected or potentially affected by the policy. The data had already been linked by personal health numbers (PHNs) at the Ministry of Health and then replaced by unique study numbers before the data were released to the researchers for study and comparison.

Furthermore, to measure any change in quality of life of patients immediately affected by the policy compared with those in the control group, questionnaires were sent to all patients potentially affected by the policy. To assemble a mailing list for this purpose without violating the privacy of patients' Pharmacare data, the Ministry of Health produced a 'camouflaged' list of patient names for the researchers. The camouflage method proceeded as follows: The Ministry combined scrambled PHNs of Pharmacare patients potentially affected by the policy with scrambled PHNs of a random sample of Pharmacare clients who were not affected by the policy. When the combined list of scrambled PHNs was unscrambled and converted to names, addresses and telephone numbers by the Ministry of Health's Client Registry, the health status of each patient remained unknown to Pharmacare or the researchers.

To complete the camouflaging, a general survey applicable to any Pharmacare client was also included in the mailing. Covering letters from both Pharmacare and the principal investigator explained that the Pharmacare computer had selected the patient from either a random list or a special list of patients, and therefore their health status was unknown to Pharmacare and the researchers. Any patient who did not wish to complete the questionnaire could merely decline to respond. The only way that researchers would learn anything about the health status of patients on the mailing list was if those patients voluntarily completed and returned the questionnaire.

The questionnaires were returned to one of the researchers. A majority of patients agreed to have their quality of life linked with health care utilization data and supplied their PHNs for this purpose. When analyses showed no significant difference in quality of life of treatment and control groups, the researchers decided linkage with health care utilization data was not needed after all. However, if linkage had been done, it would have been done using the PHN of only those participants who agreed to supply it.

The initial grants ended in March 2001. However, additional funds to compare alternative control groups were obtained by colleagues at Harvard University from the US National Institute on Aging. This justified extending the duration of data retention and providing the Harvard investigators with de-identified data in which the scrambled PHNs were replaced by study identification numbers.

PRIVACY RISKS AND INTENDED SAFEGUARDS

Given the design of the study, there was no risk that researchers could gain access to identifying information about patients' health status without patient permission. Nonetheless, there was a possibility that some patients might feel that their privacy had been violated.

In this case, researchers did not need access to any identifying information in order to assemble the study population or perform data linkage. The Ministry did the linkage entirely in-house and assigned unique study numbers before releasing data to the researchers. Due to variations in resources and internal capacity of data repositories across the country, this is not always possible.

In addition, the camouflage method allowed researchers to come into contact with potential research participants without ever knowing who they were or knowing anything about their health status before they consented to participate. In order to be most effective, camouflaging should aim to protect the privacy of targeted patients, while limiting the number of patients who need to be contacted overall in order to mask the identity of the target population. For instance, if the targeted patients constituted only 1% of the total population, then contacting a random sample of the population (which would naturally be camouflaged by 99% untargeted people) would be very inefficient. In this study, the sample was 80% targeted and 20% camouflaged. This proportion successfully preserved the privacy of the targeted patients' data, yet greatly reduced the number of people who needed to be contacted overall in order for the camouflage to be effective.

The study was approved by the UBC Ethics Committee, which has approved camouflaged contacting for several other studies. The privacy branch of the Ministry of Health also approved of camouflaged contacting. The Data Access Committee of the B.C. Ministry of Health approved the use of anonymous data on health care utilization and mortality of all Pharmacare clients included in the study.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Participation in the delayed control group was optional for physicians. They could withdraw from the control group by complying with the policy six months sooner than they were required to. They could also contact Pharmacare or UBC and ask to have their patients withdrawn from the analysis. (Only 1 out of approximately 600 control physicians asked for their patients to be excluded.) In this way, the physicians did give their consent, according to a negative consent model; that is to say, they were informed of the study and given the opportunity to withdraw from the group at any time.

Although physicians were invited to inform their patients about the study, the consent of patients was not required before including them in the delayed control group. Governments do not generally seek consent from a population before implementing a new policy. The only novelty about Pharmacare's policy change was that it involved designed delays that

allowed for a more rigorous evaluation and comparison of those patients to whom the policy applied immediately and those patients to whom the policy applied six months later.

Moreover, the health care utilization and mortality data was linked entirely within the confines of the Ministry and released to researchers in de-identified form only. At no time did the researchers require access to identifiable data to perform their analyses. In this case, the oversight bodies considered that it was justifiable to perform the research without having to obtain individual consent.

As for the quality of life portion of the study that required distribution of an individualized questionnaire, the camouflage method facilitated communication between the researcher and research participants without ever having to release any patient health information to the researchers. What constitutes an adequate degree of camouflage and a reasonable level of efficiency, however, is an important question. Does 20% camouflage provide sufficient protection of privacy? Should it be 50% or even 80% in more sensitive circumstances?

[Case Study # 13]

TITLE

Cancer and other health problems associated with breast implants

BACKGROUND

This study was conducted by Cancer Care Ontario and Laval University, Quebec, from 1995 to present in both Ontario and Quebec. The study was sponsored by Health Canada.

RATIONALE

Due to reports of health problems, most notably cancers, auto-immune disorders and local complications, the use of silicone gel-filled breast implants for cosmetic surgery was stopped in 1992 by Health Canada. Many Canadian women who received these implants, remain concerned about the long-term health effects of these medical devices.

PURPOSE

The purpose of this long-term follow-up study is to identify harmful health effects on a large number of women who received breast implants for cosmetic reasons from 1975 to 1989, compared with a group of women who had other types of cosmetic surgery within that same time frame.

POTENTIAL BENEFITS

This study may or may not find that there are certain health problems associated with breast implants. Either finding will be important knowledge for women and their doctors, influencing future management practices relating to these devices.

METHOD

To date, most breast implantation in Canada has been done in Ontario and Quebec. The investigators reviewed surgical records in these two provinces to identify approximately 25,000 women who received breast implants for cosmetic reasons. In Quebec, these records were reviewed in public hospitals where the surgery was performed, and in private clinics, with prior authorization from the Quebec Access to Information Commission and the Directors of Professional/Medical Services in each institution. In Ontario, the records of plastic surgeons were reviewed in their private practices, following written authorization from each surgeon. Women patients eligible for entry into this study had to be identified by going from hospital to hospital, and clinic to clinic. This method was necessary because there is no central registry containing this information.

Trained health record technicians were employed by the investigators to abstract personal information from patient records. This information included patient names, birth dates, and health numbers, as well as relevant surgical and medical details. These pieces of information were entered directly into a database file using laptop computers. The file was protected by a password known only to the individual abstractor. On a daily basis, these records were transmitted by modem from the laptop being used at the sites where the records were abstracted to central database files in the two study centres in Quebec City and Toronto. All of the records were password-protected and encrypted before they were sent so that unauthorized access could not identify specific persons. After successful completion of transmission, these patient records were deleted from the laptops. At the study centres, all patient records were separated into two files, one holding only patient identifiers, and the other only surgical and medical details, with a study number serving as the common key.

Only the patient identifiers needed for record linkage (e.g. names, addresses, birth dates) were sent to Statistics Canada. This allowed Statistics Canada to link these patient identifiers with information it had about newly diagnosed cancers and/or deaths that may have occurred after the surgery. Upon completion of the linkage, the cancer and death records would be sent back to the investigators with the permission of each provincial cancer registry and each provincial registrar of vital statistics.

Only two people had access to personal information contained in the central databases of each of the two research centres: the study coordinator and the person who provides the technical help for the database. Both of these staff are directly supervised by the principal Investigators and are employed by CCO and a Laval University-affiliated hospital research centre. The first analysis of the data is scheduled for late 2002 based on de-identified data pooled from both study centres. The pooled file would have study numbers for each patient and coded numbers for their surgeon so that neither could be identified. The de-identified (i.e. no names, complete dates, addresses, including postal codes, phone numbers) patient-specific files reside at Health Canada, in accordance with the Research Contracts entered into with Health Canada. The principal investigators oversee the analyses, which initially consist of basic tabulations and person-years statistical analysis, and will progress to multivariate analysis, including statistical regression modelling.

The identifiers will remain in a secure location until approximately 20 years of follow-up can be completed for most of the subjects.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The primary hazard to women participating in this study relates to harmful disclosure of sensitive, personal information without their prior consent. Information relating to breast implants is sensitive. Some women may even choose not to inform spouses, other family members, or their health professionals.

Safeguards were undertaken to minimize the risk of harmful disclosure, including measures related to personnel practices, technological security and physical security. All staff employed to abstract surgical records were trained health record technicians who swore an oath of confidentiality in relation to this study. This oath provides that any unauthorized use or disclosure of sensitive information is grounds for immediate dismissal. Also, in both provinces, the research team pledged that there would be no direct contact with the research participants and that all sensitive information would be kept confidential.

In terms of technological measures, personal identifiers were separated from surgical or medical information, and passwords used to gain access to the identifying information were known only to two staff in each the Toronto and Quebec City research centres.

The physical measures involved transporting laptop computers and other materials in locked cases. The central study office was located in secure quarters behind locked doors, with limited access.

Prior to commencement of this study, external peer review was undertaken by three experienced scientists from Canadian and American research institutes. Ethics review was undertaken at a university-based health sciences Research Ethics Board (REB) in each province. The REBs accepted the impracticality of collecting informed consent from the participants but recommended that a general educational program publicizing the study be developed, along with a toll-free telephone hotline for further information. The REBs also recommended that all women who do not wish their records to be included in the study should be given the opportunity to opt-out of the research by telephoning the hotline.

Furthermore, as the primary data custodians, provincial cancer registries retain the right to review and approve this proposal, even though they routinely transmit these cancer and death records to Statistics Canada, in compliance with the Federal *Statistics Act* (R.S.C., c. S-19).

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Access to hospital records in Quebec required formal application to the *Commission d'Accès a l'Information* under the province's public sector privacy legislation. This is because the complete listing of relevant surgeries exists in the central Med-Echo database held by the Government of Quebec. This database was used to identify all potentially eligible participants and the location of their surgical records. Subsequently, permission to review and abstract from the original surgical records was obtained from the Director of Professional/ Medical Services at each public hospital.

In Ontario, the required information was not indexed in a central government database, or even individual hospitals. The only feasible means of identifying eligible participants was through review of the surgical records held in each plastic surgeon's office. At the time this study began, no legislation existed in Ontario regulating access to records held by private

practitioners. However, a regulation (O.Reg. 856/93, am. O.Reg. 53/95) since adopted under the Ontario *Medicine Act* (S.O. 1991, c.30), states that physicians have discretion to grant researchers access to personal information concerning their patients, if they believe that the researcher will take reasonable steps to protect the identity of their patients.

For individual plastic surgeons in private practice who had eligible patients, the letter requesting access to records included a summary protocol and a list of the relevant data elements to be abstracted. The investigators pledged no further disclosure of patient information than what was described in the protocol. Any future research projects would require a new data access request by the researchers, as well as REB approval.

In this case, it would not have been practical for either the investigators or the surgeons to establish contact with 25,000 eligible women participants to obtain express consent directly from each of these women. Early pilot work indicated that three-quarters of the participants were no longer residing at the address recorded in the surgical records.

In order to receive the cooperation of women, surgeons and hospitals, a general informational program was initiated, publicizing the study aims and methodology at professional meetings, through women's interest groups and through lay and scientific periodicals and newspapers. Informational pamphlets were distributed to approximately 35,000 licensed physicians across Canada for display in the patient reception areas of their offices. A bilingual hot-line was established with a dedicated toll-free phone number in order to provide more specific information to interested women. For women who asked at that time or subsequently, that their records not be included, their records were removed from the database. Of approximately 25,000 women included in this study, there were approximately 20 who asked that their records be removed (less than 1 in 1000).

[Case Study # 14]

TITLE

Second cancers following treatment for non-Hodgkin lymphoma

BACKGROUND

This study was carried out in Ontario, Sweden, the Netherlands and Iowa, U.S.A., from 1993 to 1998 by Cancer Care Ontario (CCO), in collaboration with Cancer Research Centres in Sweden, The Netherlands and Iowa, U.S.A. The study was funded by the U.S. National Cancer Institute (U.S. NCI).

RATIONALE

Prior to this study, the risk of developing second cancers following non-Hodgkin lymphoma (NHL) had not been adequately assessed. With over 6,000 new cases of NHL diagnosed each year in Canada and with the dramatic improvements in survival as a result of chemotherapy in the mid-1970s, it is of increasing importance to patients and their doctors that the risk of developing second cancers following NHL be better defined in order to identify the potential benefits of increased medical surveillance/screening for these patients.

PURPOSE

The purpose of this research was to assess the risk of developing second cancers following NHL, particularly in long-term survivors, and to describe any relationship between dose of chemotherapy or radiotherapy required to treat NHL, and the subsequent risk of bladder cancer, kidney cancer and acute leukemias.

POTENTIAL BENEFITS

This study was able to demonstrate that patients with NHL continued to be at a significantly higher risk of developing second cancers for up to two decades following the first diagnosis of NHL. This persistently elevated risk may have important implications in terms of allocating additional resources for increased medical surveillance of these patients in order to help prevent the onset or spread of second cancers.

As shown in the subsequent analysis, the strong dose-response relationship between cyclophosphamide (a common chemotherapy drug) and subsequent bladder cancer underscores the importance of limiting the cumulative dose to only that which is minimally required to achieve therapeutic end-points. On the other hand, cyclophosphamide was associated with only a small increase in risk of leukemia, which was somewhat reassuring as this drug is frequently used in the treatment of NHL.

METHOD

As a first step in selecting participants for inclusion in this study, research staff at Cancer Care Ontario (CCO) reviewed the data contained in the Ontario Cancer Registry (OCR). CCO operates and maintains the OCR for compiling statistics and carrying out epidemiological or medical research as part of its statutory mandate under the *Cancer Act* (R.S.O. 1990 c. C.1). Through this first step, CCO research staff were able to identify approximately 2,100 cancer patients who were diagnosed with NHL between 1965 and 1980, who were between the ages of 18 and 70 when diagnosed, and all resided in Ontario at that time.

As a further step in refining the list of research participants, CCO research staff had to select only patients who had received initial treatment at one of CCO's Regional Cancer Centres (RCC) or the Princess Margaret Hospital (PMH). These specialized cancer treatment centres (all public institutions) are the only sources of radiotherapy in the province and provide the large majority of chemotherapy services across Ontario. They have excellent standardized treatment records that they retain in perpetuity, unlike the situation in many public hospitals. Over 80% of all NHL cases diagnosed in Ontario are referred to RCCs and PMH for treatment.

Furthermore, to be included in the study group, NHL patients had to have been free of a second cancer for at least two or more years. Second cancers occurring in previously registered cancer patients are routinely identified through the OCR. Incoming computerized records of hospitalization, biopsy, registration at RCCs or PMH, and death are linked using computerized algorithms in order to identify subsequent cancers. Four CCO staff were authorized to conduct these linkages. The accuracy of these linkages is critically dependent on completeness and accuracy of names, birth dates and health numbers in the files to be linked. A computerized set of algorithms is used to summarize information on the linked records.

As a result of pooling risk estimates across the participating cancer institutes, significant elevations in risk for acute leukemias, bladder cancer and kidney cancer were observed among NHL patients in the study group.

These findings served as the impetus for subsequent case-control studies in which more detailed treatment information about chemotherapy and radiotherapy dosages were collected and compared between NHL patients who developed the second cancer of interest, and other NHL patients of the same cohort who did not develop the second cancer. Two trained health record technicians employed by CCO were granted permission by the Medical Records Committees at the various RCCs and PMH to access and review the relevant medical records for these patients. The two health record technicians recorded relevant data about diagnosis and treatment on a standardized abstract form. Patient name, exact birth date, address and phone number were not recorded, although a study number unique to this project was assigned. There was no patient contact whatsoever.

The health record technicians brought these standardized abstract forms back to CCO's office; the Study Manager (part of the CCO research team) verified these forms in order to confirm the absence of patient identifiers. The de-identified forms were then transmitted to the Study Coordinating Centre at the U.S. NCI in order to be key-entered into a computerized database and pooled with similar data from the other participating institutes. The statistical analyses and syntheses of the findings were done collaboratively between the U.S. NCI and the participating research institutes.

The electronic file correlating the unique study number with patient identifiers is being retained by a Data Manager employed by CCO and kept separate from any personal health information that may identify individual patients. Because of the importance of long-term follow-up of these cases diagnosed in the 1980s and 1990s, the electronic file and the de-identified standardized abstract forms for this NHL cohort will be kept indefinitely in secure storage at CCO.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The primary hazard to patients participating in this research related to unauthorized disclosure of sensitive, personal information that may be distressing or embarrassing to them and their families. CCO research staff undertook to minimize the risk of such disclosure by implementing certain by personnel practices, technological safeguards and physical security measures.

CCO research staff, as well as the two experienced health record technicians employed by CCO to abstract medical records in the RCCs and PMH, took an oath of confidentiality in relation to this study, with the understanding that any breach in confidentiality was grounds for immediate dismissal. The handling of sensitive medical information and patient identifiers was restricted to only three people (the Study Manager and two health record technicians), all employed by CCO.

Computerized files and processes for selecting and linking data at CCO require far less human intervention than would otherwise be required in paper-based systems. All records, except pathology reports, are received electronically and subsequent editing, record linkage and summarization of these records are undertaken electronically, which minimizes the human viewing of sensitive details. Only pathology reports are currently received in hard copy. Sensitive details on positive biopsy reports must be coded and key-entered into an electronic file, which is subsequently linked to the OCR. This work is done by trained health record technicians in a secure environment at the OCR.

Further physical measures were taken to protect sensitive personal information from unauthorized disclosure. Abstraction and recording of personal health information performed by the health information technicians at RCCs and PMH were done on standardized abstract forms in de-identified form only, with unique study numbers. Sensitive information was transported from the relevant treatment centers to the CCO provincial office in locked

cases and stored in locked filing cabinets kept in a locked study office at CCO. Only de-identified records were transmitted to the coordinating centre at U.S. NCI for further editing and statistical analysis.

The use of patient identifiers was kept to an absolute minimum, essentially to facilitate identification of relevant medical records to obtain treatment information needed for the study and to verify accuracy and completeness of research findings.

All subsequent manuscripts were carefully reviewed to ensure that no personal information was disclosed in any publication.

The Research Ethics Board at the University of Toronto reviewed and approved this study, as well as subsequent nested case control studies. This approval had to conform to the U.S. Federal regulations governing federally funded research involving human subjects. These regulations require that any collaborating country in an international study involving the U.S. provide protection equivalent to their own. In addition, permission to review medical records at the RCCs and PMH was subject to review and approval of each agency.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Under the Ontario *Cancer Act*, CCO is mandated to collect information about diagnosed cases of cancer for inclusion into the OCR for statistical purposes and for epidemiological and medical research. Specifically, the Act stipulates that information about cancer patients "shall be kept confidential and shall not be used or disclosed by CCO to any person or any purpose other than for compiling statistics or carrying out medical or epidemiological research." Hospitals and laboratories that report personal health information about cancer patients to CCO for inclusion in the OCR are protected against liability under this legislation.*

Given its express statutory mandate, CCO is not required to obtain consent for statistical analysis or research on data contained in the OCR, since this is precisely the public policy reason for which CCO and the registry were created, ultimately with a view to improving diagnosis and treatment of cancer.

If consent had been required in this case, the research study could not possibly have been carried out. At the time the study was undertaken, approximately 75% of the 2,100 NHL patients in the study cohort had died, mostly as a result of the progression of the disease. Obtaining consent from these patients would simply not have been practical.

* In 1997, by an Order in Council of the Ontario Government, the Ontario Cancer Treatment and Research Foundation was re-named to become Cancer Care Ontario (CCO). The old mandate remained; however, the mandate of the new CCO was expanded to include province-wide planning and evaluation of cancer control services, according to a Memorandum of Understanding.

FOR MORE INFORMATION

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[Case Study # 15]

TITLE

Ontario familial colon cancer registry

BACKGROUND

This study was funded by the U.S. National Institutes of Health, Cancer Care Ontario and the National Cancer Institute of Canada. Six research sites across Canada, USA and Australia participated in this large multi-year research program conducted between 1997 and 2002.

RATIONALE

With the growing realization that cancer is fundamentally a disease of the human genome, and with technological advances that permit more careful and rapid identification of critical genetic changes/mutations that predispose to cancer, it is now particularly important to study families at high risk of developing certain cancers. This information will assist in better understanding whether genetic screening would be useful, whether preventive interventions could reduce the high risk of developing cancer, and whether different treatment regimens might be more effective in reducing the risk of recurrence or second cancers. The answers to these questions are also relevant to those who are not hereditarily predisposed, as they often develop the same genetic changes later in life, which may then manifest as sporadic cases of cancer.

PURPOSE

The goal of this project is to establish a computer-based registry of individuals who may have a genetic predisposition to colorectal cancer (CRC) for the purpose of carrying out research in this area. A large sample of low-risk cases, and unaffected population controls, will also be included in the registry. In particular, this registry will facilitate studies to help researchers understand how inherited and external risk factors affect, and possibly modify, the risk of CRC.

POTENTIAL BENEFITS

The presence of inherited mutations that predispose individuals to CRC and the development of new laboratory techniques to identify these high-risk genes, make it possible to identify individuals in the general population who are at much higher risk of developing cancer. With accurate identification, these individuals may benefit from interventions that prevent the occurrence of cancer or, if cancer does occur, prevent it from causing death.

With the increasing commercial availability of genetics tests, much uncertainty remains about the benefits and harms associated with screening. Well-designed scientific studies are a high priority as they can provide the most valid information relating to etiology, clinical management and psychosocial impact of this testing.

Although there may not be direct benefits to each family involved in this registry, genetic counselling is offered to all interested participants and their family members to ensure the availability of the best information possible about the disease.

METHOD

From 1997 to 2000, a preliminary list of approximately 1,800 to 2,000 eligible Ontario families was generated from the Ontario Cancer Registry (OCR). OCR contains data on all diagnosed cases of cancer, including CRC. It is operated and maintained by Cancer Care Ontario (CCO) for statistical purposes and epidemiological or medical research related to cancer. CCO receives notice of newly diagnosed cases of cancer via biopsy reports that are sent for inclusion into OCR by all licensed pathology laboratories in Ontario.

In order to develop the CRC research registry, CCO staff have to first approach the surgeon named on the biopsy reports and request the surgeon's permission to contact patients in order to send them and their families information about the CRC registry, along with a preliminary questionnaire. The surgeon is asked to complete a brief form validating and/or completing the necessary information to assess patient eligibility for inclusion into the CRC registry and provide the patient's current mailing address.

Once permission by the surgeon is received, and after approximately four to six months of the initial diagnosis, CCO staff send letters of invitation to eligible patients outlining the purpose of the CRC registry, what their participation would involve, the risks and benefits of participating and safeguards taken to protect sensitive information. Patients are told that those people who are included in the registry may be subsequently invited to take part in studies related to diagnosis and treatment of CRC. If patients agree to have their personal information included in the CRC registry, they are asked to provide written consent. Participants understand that inclusion into the registry is voluntary and that they may withdraw at any point without jeopardizing their medical care.

The first phase of participation requires patients to fill out a brief questionnaire asking about members of their family, particularly those who have also been diagnosed with cancer. This family questionnaire is used to identify those patients and their families who may qualify for subsequent research studies looking at family histories. They are asked for the names of the relative(s) and whether they are on the mother's or father's side of the family. Participants are advised that a genetics counsellor from CCO's CRC registry may telephone them to review details of their family history, as well as enlist their participation in the next phase. It is at the discretion of the individual patient to decide at that point whether they would rather first contact family members themselves to tell them about the development

of the CRC registry, or whether CCO staff may write to family members directly to invite them to participate as well.

For those eligible patients and family members who agree to participate, the second stage of the development of the CRC registry involves the donation of blood or an existing tumour sample for future laboratory studies. This request is processed through the CRC registry and the collected sample is sent directly to the Mount Sinai Hospital repository until it is processed and then returned to its host institute. The genetics counsellor will also discuss the implications of providing blood or tumour samples and will identify other relatives who may be invited to participate.

The third stage involves completion of a more detailed questionnaire that is mailed to participating patients and selected family members. Essentially, information is collected about other known or suspected risk factors for CRC, including diet, physical activity, other bowel disease, other cancers and general lifestyle characteristics. Also at this third stage, patients are asked whether they agree to continue participation. If so, they are asked to consent in writing to be contacted on an annual basis in order to update registry information.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The most significant adverse effect of the creation of this research registry will be that participants may discover that they are at increased risk of developing CRC because of a hereditary predisposition. For some people, this could lead to heightened anxiety and worry about developing cancer. To minimize this distress, a genetic counselor will be the only one allowed to discuss this matter with them. This counseling may be provided either face-to face at any one of the eight regional cancer centres across Ontario or by telephone. The counseling will include a discussion of individual cancer risks, an explanation of the causes of cancer, and a discussion of the availability of screening and preventive strategies.

Because of the sensitivity of the information collected, strict privacy and confidentiality safeguards must be maintained throughout the project. Identifiable family history, medical and other sensitive information gathered through the mailed questionnaires will be key-entered by CCO staff into a password-protected computer database residing on a dedicated computer at CCO's provincial office. This sensitive information will be part of the registry only and will not be released to any other parties unless the participants specifically request otherwise.

A detailed version of the proposal to create this research registry, including questionnaires, letters of invitation and proposed procedures to collect, store and test human tissue, was submitted to the Research Ethics Body (REB) at the University of Toronto, as well as REBs associated with each of CCO's eight regional cancer centres located across Ontario. Review and approval was subject not only to the conditions set out in Canadian laws and ethics guidelines on research involving humans, but in addition, because of the international

scope of the registry, the U.S. federal regulations also had to be adhered to. Progress reports have to be submitted to these REBs on an annual basis.

Before any specific research study using information in the CRC registry and/or collected tissues can proceed, detailed research protocols must be prepared, reviewed internally and approved by the principal investigators at all six research sites, as well as the coordinating centre at the U.S. National Cancer Institute. External ethics approval is also required for each of these emergent protocols. Participants are informed at least annually about progress in the development of the registry, as well as emerging research uses and eventual findings. Patient contact by investigators other than CCO staff is avoided.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

Cancer Care Ontario has a statutory responsibility under the *Cancer Act* (R.S.O. 1990, c. C.1) to protect the confidentiality of the personal information it collects and use it only for statistical purposes and epidemiological or medical research related to cancer. Individual consent to collect information about each newly diagnosed case of cancer for inclusion into the OCR is not required since the law expressly recognizes the public-health need to do so. Also, as per the *Cancer Act*, physicians, laboratories and other health care facilities may send relevant information about cancer patients to CCO for inclusion into the OCR without risk of liability. The law thereby recognizes that initial registration in the OCR of all patients newly diagnosed with cancer is crucial for the registry to be sufficiently representative so as to be useful and provide a solid basis for epidemiological research from which valid conclusions could be drawn.

As regards the development of the CRC familial registry, CCO staff had to obtain individual consent, since unlike the case of ORC, there is no specific law expressly allowing for the non-consensual creation of this registry on grounds of public policy. In this case, surgeons provided CCO staff with the mailing coordinates of their patients and permitted CCO staff to contact patients directly to seek consent to participate in the development of the CRC registry. Ideally, surgeons would have first contacted their patients to obtain authorization before releasing their coordinates. However, for the reasons explained above, this added step would have surely resulted in attrition rates so high as to make the registry virtually useless. Moreover, CCO staff are clearly equipped to handle personal information about cancer and mandated by law to safeguard its confidentiality. In addition, a regulation (O. Reg. 856/93 as am. O. Reg. 53/95) made under Ontario's *Medicine Act* (S.O. 1991, c. 30) supports the discretion of a physician to provide personal health information about his or her patient to a researcher for the purpose of research if the physician reasonably believes that the researcher will take reasonable steps to protect the identity of the patient.

A more significant ethical issue in this project is informing patients and their family members that they may be at a higher risk of CRC because of a hereditary predisposition. While researchers may not have identified optimal strategies for prevention and treatment of these high-risk families, it is apparent that the commercial availability of tests to detect

these high-risk genes encourages the uncontrolled dissemination of this screening activity, in the absence of clear management guidelines. Thus, good research is an immediate priority in order to uncover quickly, and validly, information about the etiology and management of these high-risk conditions. Given the uncertainty that exists, discussions with patients and their families about the implications will only be undertaken by trained genetics counsellors, preferably face-to-face in a clinical setting. This counselling service is provided free of charge to all participants.

For specific research projects requiring the use of some of the information in the familial registry, detailed scientific protocols must first be prepared and submitted for ethics review to both the REB associated with the familial registry and the REB of the research institution that the researcher is associated with. The REBs will review the study proposal to ensure that the research will be conducted fairly, that any benefit will clearly outweigh any harm, and that the privacy of all participants will be protected. Wherever possible, proposed research will be conducted using de-identified data (i.e. all identifying information will be removed from data and/or samples such that they cannot be traced or linked back to participants or family members). If the research can only proceed with identifiable data (e.g. additional questionnaires, record linkages), then each participant will be contacted again in order to solicit a new and distinct consent for the specific study.

All participants have the right to view all information that has been collected about them, or created from their tissue samples at any time. Again, given the sensitive nature of this information, it will only be disclosed to the requestor by a genetics counsellor in a face-to-face session. If at any time the participant wishes to withdraw from the study, he/she has the right to remove all existing data from the registry.

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[Case Study # 16]

TITLE

Rapid surveillance of cancer in neighbourhoods near point sources of pollution

BACKGROUND

This study was conducted from 2001 to 2002 by Cancer Care Ontario, in collaboration with the Durham Regional Health Department. Funding for this study was provided by Health Canada and the Canadian Nuclear Safety Commission.

RATIONALE

Community concerns about potential health hazards associated with residential proximity to point sources of pollution have been well documented. Notable examples include concerns about proximity to nuclear reactors, to metal smelters and foundries, chemical contamination of drinking water, and industrial pollution in general. Existing health outcome reports based on cross-sectional mortality or morbidity statistics that monitor these relationships have a number of flaws, most notably inability to control for residential mobility, inaccurate residence information, inability to control for known risk factors, and inability to take into account the long latency from initial exposure to associated health outcomes, at least for chronic diseases such as cancer. As such, communities are distrustful of existing statistical reports and desire better surveillance systems to alert them to significant health hazards, or reassure them if existing health outcomes are unlikely to be associated with certain exposures.

PURPOSE

The purpose of this research is to design, develop and test a computerized surveillance system to rapidly assess the relationship between residential proximity to real or perceived point sources of pollution, and the subsequent risk of cancer. This new system will be pilot-tested in the Durham Region of Ontario, where the question about the relation between neighbourhood proximity to the Pickering Nuclear Reactor and subsequent risk of cancer will be addressed.

POTENTIAL BENEFITS

The pilot testing may or may not find that there are certain cancers associated with living close to a perceived point source of pollution, specifically in this case, a nuclear-generating plant. Either finding will be important knowledge for residents and stakeholder groups, particularly if the knowledge can be generated quickly.

METHOD

A longitudinal cohort design is most appropriate for periodically estimating the risk of chronic diseases, such as cancer, among humans who are exposed to real or perceived external exposures. The choice of an historical, rather than prospective, cohort (i.e. a group of persons with something in common) shortens the start-up time of the surveillance program. This is a major concern given the long lag time that usually exists between exposure and outcome for most chronic diseases, including cancer (i.e. 10-30 years).

In order to overcome the problems of incompleteness, inaccuracy and imprecision of residential information on existing health records (e.g. CIHI hospitalization abstracts; death records), the Provincial Property Assessment File will be utilized to identify, with a higher level of accuracy and completeness, physical location of the usual place of residence of each inhabitant of Ontario. This file is prepared on an annual basis within each municipality, and eventually forwarded to the Ontario Ministry of Revenue where it is amalgamated to form a province-wide file. Completeness of this file is almost as high as the Canadian census, and it has sufficient identifiers to permit fast, accurate and cost-effective linkage to Ontario-wide health files, including the Ontario Cancer Registry (OCR) and the Ontario Mortality Database. As well, this file exists back as far as the early 1980s. This permits identification of the place of residence of Ontarians 15 to 20 years ago. This ensures that sufficient latency will have occurred in order for researchers to conduct a sensible assessment of the relationship between residential exposure to pollution and subsequent risk of chronic disease. In accordance with the Ontario *Freedom of Information and Protection of Privacy Act* (FIPPA) (R.S.O. 1990, c.F.31), a research application for access to these files, including personal identifiers necessary for record linkage (e.g. names, complete birth dates), will be sent to the Ministry of Revenue.

For the first phase of this project, a feasibility study will be undertaken in the Durham Region of Ontario, which has a population of approximately 0.5 million inhabitants, and includes the Pickering Nuclear Reactor, a notable site of concern to many of the residents of the Region.

In order for such a surveillance system to be effective, it must be both rapid and accurate. Given the need for speed, and cost efficiency, the use of existing computerized files and record linkage techniques would seem the most viable option for developing a surveillance system that represents a significant enhancement over traditional cross-sectional studies.

It is proposed that the feasibility study be undertaken at Cancer Care Ontario's (CCO) Provincial Office, which is the home of the OCR. An electronic copy of the Ontario Mortality Database also resides at CCO, to facilitate its cancer research. Additionally, expertise in linking computerized files in a secure fashion exists at CCO. CCO has considerable experience working with the Ontario Property Assessment File in relation to specific cancer research projects.

Because a unique personal identifier does not exist for all persons on these files, it will be necessary to use whatever discriminating personal information is available, including surnames, given names, birth dates, ages, sex, and residence. Probabilistic techniques are used in order to determine whether pairs of records likely describe the same person, or different people. Probabilistic techniques are necessary because of incompleteness, errors and truncations in many of these variables. Additionally, computerized techniques of record linkage minimize drastically the amount of human viewing that otherwise would be required to accurately link records across several files.

An additional scientific enhancement in this project will be to take into account the possible confounding effects of known risk factors (e.g. smoking) and socio-demographic factors (e.g. poverty) as they may also affect the risk of various cancers. This information will be available at the neighbourhood level, from community surveys and the national census. This neighbourhood level information is publicly available and may either be purchased from Statistics Canada, or accessed via the University of Toronto Data Liberation Initiative.

Ultimately, if the feasibility study proves successful, then a proposal will be prepared to design, develop and maintain an on-going surveillance system that will permit the linkage and rapid assessment of cancer risk for all residents in the province, back to the early 1980s. As is currently done with the OCR, these files will be maintained, linked and summarized on a dedicated computer, with password protection and other security measures consistent with CCO's UNIX environment and ORACLE relational databases. Only four named permanent staff at CCO will have access to the linked records of named individuals in this surveillance system.

PRIVACY RISKS AND INTENDED SAFEGUARDS

The most notable risk to individuals' right to privacy is the potential for sensitive medical information to be disclosed without their consent. This information may be embarrassing, distressing or possibly even discriminatory. Additionally, there is some risk that publicity about the surveillance system and ensuing findings may be harmful or discriminatory to the group of residents living in the area of concern. Worries may exist about falling or stagnant property values or low community morale.

While it is likely that better information about the possible association between health and point sources of pollution will be reassuring to communities, or at least lead to better remedial action, the risk of harming communities should not be discounted. While individual informed consent will be virtually impossible to solicit given the large sample size necessary (e.g. approximately 100,000 individuals) and the long latency of historical residential information that is required, it will be beneficial to do *a priori* qualitative studies, utilizing focus groups representing individual citizens, interest groups, government agencies, other stakeholders and cancer patients, to better elucidate community concerns and interests. These focus groups will be interviewed prior to initiating the pilot study, and they will be facilitated by an independent behavioural scientist who will be identified through a competitive RFA process. The results of these consultations will be made public, also.

The protocol for the feasibility study, which is still under development, will be submitted to the Office of Research Studies at the University of Toronto for ethics review. Further, this protocol will also be reviewed for scientific merit by three external reviewers with known expertise in this area of geographic surveillance.

Finally, all results emanating from the system will be carefully reviewed prior to publication or wider dissemination in order to be assured of no residual risk of disclosure. Eventually, dissemination will be undertaken through multiple vehicles at the national, provincial and local levels.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

In this case, obtaining consent from approximately 100,000 individuals in order to obtain information dating back 15-20 years would have been virtually impossible. In such circumstances, the laws of Ontario currently authorize non-consensual access to personal information for research purpose under specific and limited conditions. Access to the required information is authorized under several provincial statutes in Ontario, most notably the *Cancer Act* (R.S.O. 1990, c.C.1), which regulates access to the OCR, and FIPPA, which regulates access to all files held in the custody of the provincial government, including the Provincial Property Assessment File and the Ontario Mortality Database.

Under the *Cancer Act*, CCO has an express statutory mandate to create the OCR and to maintain it for research purposes. The Act states clearly that sensitive information about cancer patients must be kept confidential and can only be used for statistical purposes or for epidemiological and medical research. Applications for access to the OCR for the purpose of record linkage for research purposes require a detailed protocol and review and approval by an appropriately constituted research ethics body. The actual work of linking research files to the OCR is conducted at CCO, by only two employees. Generally, files that are released back to researchers, whether internal or external to CCO, have been de-identified in order to protect confidentiality, but still permit researchers to complete their analysis.

Under Ontario's FIPPA, disclosure of sensitive information without individual consent is permitted for research purposes so long as there is evidence that the research cannot be undertaken without this disclosure and that adequate safeguards are taken by the researchers to protect the confidentiality of this information. A formal application for access to these files is necessary and must be reviewed and approved within the appropriate Ministry of the Ontario government. For example, access to the Provincial Property Assessment File falls under the Ministry of Revenue, whereas access to the Ontario Mortality Database falls under the Ministry of Community and Commercial Relations. In the event that the pilot study is successful, then a full-fledged on-going surveillance system will require formal agreements between CCO and the Government of Ontario to facilitate the regular transfer of necessary files and on-going surveillance activities.

An additional issue raised by this case study is the issue of community interests. While the right to privacy is essentially recognized in law as an individual human right, collecting, using and linking personal information about many individuals, then analysing that information and drawing generalizable conclusions from it may sometimes result in potential discriminatory or other harm to communities of individuals in certain circumstances. This case study demonstrates the need to account for this risk and take active steps to manage and alleviate it.

[Case Study # 17]

TITLE

Patient outreach via PharmaNet

BACKGROUND

This study was sponsored by the British Columbia (BC) Health Transition Fund and BC Pharmacare. It was conducted throughout the province of BC from 1999 to 2001.

RATIONALE

Patients treated with multiple medications are at greater risk of experiencing an undesirable therapeutic outcome resulting from the complexity of their drug regimen. Adverse therapeutic outcomes such as drug interactions, allergic reactions, and accidental falls in the elderly, to name only a few, result in substantive physical and economic repercussions for the patient, his or her community, and the health care system.

In 1995, BC Pharmacare, the BC College of Pharmacists, the BC Pharmacy Association and pharmacies throughout BC, introduced PharmaNet, a province-wide network of pharmacy computers enabling online access to an individual patient's electronic record of filled prescriptions over 14 months. PharmaNet permits real-time adjudication of Pharmacare benefits and automated warnings of drug interactions. Patients are provided with the option of obtaining an individual password to control access to their records by any user.

PURPOSE

The purpose of this study was to measure the effect of 'flagging' a patient's unique electronic record in PharmaNet, indicating to the dispensing pharmacist that the patient is a candidate for educational intervention designed to improve medication compliance.

POTENTIAL BENEFITS

Overall patient health may improve if individualized instructions on managing complex medication regimens could be targeted to patients in need of such service in order to avoid adverse drug combinations and potentially dangerous reactions.

METHOD

This study tested a form of automatic notification to pharmacists at the time of filling a prescription. A one-line message was created by PharmaNet's central computer and systematically flagged in the record of any patient receiving five or more concurrent medications. This was possible through the use of a special algorithm that was added to the

system to automatically identify and flag relevant patient records in the electronic database without any human intervention required. The flag was visible only to pharmacists in pharmacies participating in the study.

A geographically stratified sample of pharmacies (n=110) was randomly assigned to experimental and control groups. When participating pharmacists saw the flag, they informed patients that, based on the number of medications they were currently receiving, they were eligible for an educational service that could assist them in managing their medications. Patients were invited to participate and asked to sign a consent form. Participants recruited at experimental sites received an individualized educational session. Participants recruited at control pharmacies received only the customary care provided by their pharmacist. Participants were informed that they could withdraw from the study at any time.

Statistical analyses of changes in patients' drug use were performed on data extracted from PharmaNet for only those patients who agreed to participate in the study and who provided written consent. The project involved no linkage with other data sets. The variable being compared in the experimental and control groups was the refill compliance of prescribed medications. It was expected that refill compliance would be improved in patients in the experimental pharmacies, more so than in the control pharmacies. Final analyses were not yet complete at the time of writing this case study.

The drug dispensing data from PharmaNet is being retained for approximately one year past the end of the funding for the project to enable additional analyses for publication in a scientific journal.

PRIVACY RISKS AND INTENDED SAFEGUARDS

There was virtually no risk of unauthorized access to patients' health information as a result of this study. This study simply introduced a flagging process that was specially designed so that no human handling of data was required between the activation of the algorithm and the automatic flagging of relevant patient records destined only for the pharmacists to see. Pharmacists already have access to individual patient records on BC's PharmaNet, subject to optional patient-password protection.

Once the relevant study population was identified, pharmacists obtained informed consent directly from patients for inclusion into the study. At no time were any data released to researchers until patients gave written consent to participate in the study and to allow access to their personal health information in order to perform statistical analyses of changes in subsequent drug use.

No other information from any other sources was required and therefore, no data linkage was performed.

The PharmaNet Data Access Committee, UBC's Research Ethics Committee, and the privacy branch of the Ministry of Health approved the study.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

As in Case number 12 involving camouflaged contacting, this case introduced an innovative technological solution for assembling the study population without requiring any patient contact information to be released to researchers. The special algorithm that was added to PharmaNet's system to allow for automatic flagging did not require any human intervention. Therefore, at no time before patients consented to participate in the study, did the research team know, or need to know, which patients were receiving five or more concurrent medications and how to contact them.

In this case, it was the pharmacists who recruited patients to participate in the study. It is generally preferable, from a legal and ethical perspective, to avoid situations where the health care provider is directly involved in the recruitment process of his or her patients as research participants. The rationale for this principle is that patients who are dependent on their health care provider for care, might feel coerced into participating in the research in order not to disappoint their health care provider and jeopardize the quality of their care. This raises in issue the voluntariness, and therefore, the validity of the consent they might give under such circumstances. The risk of this happening here was minimal. The pharmacists were not part of the research team and therefore, unlikely to place any undue pressure on patients. Moreover, participation in the study did not entail any possible adverse risks; on the contrary, participation could only result in more information being provided to patients about their drug regimen so as to avoid potentially adverse combinations.

[Case Study # 18]

TITLE

The registry of the Canadian Stroke Network

BACKGROUND

The Canadian Stroke Network (CSN) is a consortium of health researchers from 23 universities across Canada. Its mission is to improve stroke treatment, rehabilitation and prevention. CSN members work closely with the Heart and Stroke Foundation of Canada, stroke survivors and scientists around the world. CSN is funded by the Networks of Centres of Excellence and grants from non-profit organizations, provincial health ministries and private industry.

RATIONALE

Stroke is the leading cause of long-term disability among adults. As Canada's population ages, the incidence of stroke is expected to increase. There is a strong need to expand research in this area in order to enhance prevention and treatment strategies.

PURPOSE

Registries are databases that collect health information about the care and treatment of a representative sample of patients over a period of time in a "real world" care environment. The purpose of the CSN Registry in particular is to collect information about the care and treatment patients receive during the acute phase of stroke and the follow-up period afterwards.

POTENTIAL BENEFITS

Through ongoing analysis of information contained in the CSN Registry, researchers and health care providers will be better informed about the multiple treatments available for stroke and the outcomes associated with these treatments. This information can lead to overall improved care of stroke patients and more effective prevention strategies.

METHOD

Patients with stroke or transient ischemic attack are identified prospectively at the time of admission to a participating hospital. The invitation to participate in the Registry is made by a dedicated nurse coordinator employed by, and accountable to, the participating hospital. Each site has 0.5 or 1.0 FTE (full-time equivalent) staff for this purpose. During this initial contact, patients are provided with a brochure explaining the CSN and its Registry.

The nurse coordinator arranges, at an appropriate time for the patient (and his/her family), to explain the Registry and seek the patient's consent to participate in the Registry. Patients can refuse or can agree to any or all of the following:

- access to their current hospitalization records by the nurse coordinator to collect information relevant to their stroke for entry into the CSN Registry for future research uses;
- a follow-up telephone call by the nurse coordinator 6 months after the onset of their stroke to determine longer-term changes in their functional ability – this survey information is also intended for inclusion in the registry for future research purposes;
- linkage of their data in the registry, with administrative files from the provincial Ministry of Health, the Canadian Institute for Health Information and other sources, in order to collect information about physician services, laboratory services, subsequent hospitalizations, and deaths for research on resource utilization and health outcomes in stroke patients; and
- use of their records in future analyses performed at the Institute for Clinical Evaluative Sciences (ICES), an independent not-for-profit research organization based in Toronto, Ontario. The results of these analyses are released in aggregate form to third-party private companies seeking to improve services and products related to stroke.

Patients are advised at the outset that they may withdraw at any point in time. Should a patient choose to withdraw, they are asked to specify whether this means discontinuation of any further data collection or removal of their data from the database altogether, so that no future analyses will incorporate their information. Patients are advised at this point, however, that data cannot be removed from analyses that has already been conducted.

If a patient expressly consents to participate, the nurse coordinator enters their personal information into the registry computer housed at each participating hospital. Transfer of information from participating hospitals to the central data repository is carried out through secure telephone lines, using an automated protocol that removes all direct identifiers (i.e. the name, address, telephone number and family contacts) before transmission. All of the Registry information collected across Canada is stored at ICES headquarters and linkage with survey data and administrative records is also conducted at ICES headquarters, unless the custodian of these administrative records in a particular province requires linkage to be conducted at their site.

For the subset of patients who agree to be contacted 6 months after the onset of their stroke, the nurse coordinator keeps their names, addresses and telephone numbers in a secure fashion. Specifically, these identifiers are encrypted, password-protected and kept on a separate computer from the hospital's clinical information system. Only the local site investigator (MD), the nurse coordinator, and the central programmer at ICES may access this information.

Data are intended to be kept in the registry for up to 20 years, after which they will be deleted in a fashion consistent with the applicable legal requirements at the time of disposal.

PRIVACY RISKS AND INTENDED SAFEGUARDS

Access to data contained in the registry (i.e. information with direct identifies removed) is restricted to two individuals from ICES: the Director, Programming and Biostatistics and the Health Information Officer. All ICES employees are required to take an oath of confidentiality and face dismissal upon breach. Multiple physical, procedural, and technical means are employed to limit the possibility of disclosure. Details of these techniques are described on the ICES web site (**www.ices.on.ca**) for any patients interested in knowing further details. These include:

- physical methods (locked doors with tracked key access, locked filing cabinets, restricted access to certain office areas; video camera monitoring of the Institute);
- organizational policies and procedures (mandatory staff training and pledges of confidentiality, with immediate dismissal as a sanction; limited access to individual-level records on a 'need-to-know' basis); and
- technological methods (use of firewalls, 'moating' of data, password protection of files, and encryption of data).

The collection of data for the registry was approved by the local REB at each participating site. Some customization of data collection procedures was necessary to meet the requirements of specific data protection laws, notably in Alberta and Manitoba.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

While the brochure and consent form explain the types of research questions that may eventually be answered through future research using the registry data, they do not contain the specificity that is normally expected for consenting to a discrete research study. Even though patients are told this, the question remains: is the information provided to patients sufficient to constitute truly informed consent?

The timing of approaching patients to obtain consent also involves ethical considerations. Stroke patients and their families experience a great deal of distress and anxiety when first admitted into hospital. This distress and anxiety would only be compounded if the nurse coordinator were to approach them too early after admission to discuss their participation in the CSN Registry. The nurse coordinator must assess the medical circumstance and consider an appropriate time to speak to the patient and his or her family. However, approximately 31% of stroke patients at registry sites are discharged within 2 days of admission, leaving a very narrow time window for the nurse coordinator to find an appropriate time to approach and recruit these individuals.

Participation in the pilot phase was high (90-95%). However, upon expanding the registry to 21 data collection sites, the initial observation has been a high variation in both approach rate and participation rate across participating sites. Average approach rate was 50% of potential patients (range 18% to 77%) and participation rate among those patients who were approached was 83% (range 48% to 100%). This raises concerns about selection biases and generalizability, and the practicality of obtaining consent. Before the issue of practicality can truly be addressed, there is need for ongoing efforts to standardize the process and improve the consistency of data collection.

The interview to obtain consent is itself time consuming, often taking an hour. Much of this hour is spent answering general questions that patients have regarding their stroke since, in many cases, these coordinators are the first individuals to spend any considerable length of time talking with them.

There is substantial variation across sites as to what research ethics boards or hospital administrators require before nurse coordinators can approach a patient to invite them to participate in the registry. For example:

- Two participating sites will not allow the nurse coordinator to directly approach admitted patients. These sites require a two-stage consent procedure whereby a direct care provider first requests permission to release the name of a potentially eligible patient to the nurse coordinator. Then, the nurse coordinator approaches only those patients who gave permission to have their name released in the first place, in order to invite them to participate in the CSN Registry.
- At one site, if a patient refuses to consent to participation in the CSN Registry, the nurse coordinator is not permitted to collect even the minimal data set about them (basic demographic information). This information is necessary for determining the differences between those who choose to participate and those who do not; this is extremely important for the purpose of identifying potential selection bias in order to draw valid conclusions about any study findings. Yet, at this same site, the identical minimal data set that cannot be obtained from patients who refuse to participate, may be abstracted from the hospital chart post-discharge for those patients who could not be contacted during their hospitalization.
- Two sites will not allow the registry to collect the minimal dataset needed to allow researchers to assess the comparability of participants with those refusing to participate.
- A large proportion of patients presenting at the emergency department are not admitted to hospital, as they are deemed to have only a transient ischemic attack, as opposed to a stroke. While these patients are of interest to stroke researchers and eligible for participation in the registry:
  - 7 of 21 participating sites will not allow contacting of patients who have not been admitted to the institution; and
  - 12 of 21 sites will not allow consent to be obtained by telephone.

As this case study demonstrates, there are many varying interpretations among institutions in the same and/or different provinces as to what laws and ethics guidelines require before personal information can be collected and used for research. This study highlights the need for a harmonized approach across jurisdictions and the importance of identifying best practices in the context of cross-national research projects involving the secondary use of data.

[Case Study # 19]

TITLE

Studying the health of health care workers

BACKGROUND

This study was sponsored by the Canadian Institutes of Health Research, the University of British Columbia's Department of Health Care & Epidemiology and the Institute for Work & Health, an independent not-for-profit research organization, receiving support from the Ontario Workplace Safety and Insurance Board. The site of the databases, data linkages, principal investigator and co-investigators is Vancouver, British Columbia, and co-investigators and programmer/analysts are situated in Toronto, Ontario. The study population consists of the workforce of all acute care hospitals in British Columbia. The research study will be conducted between July 2001 and December 2004.

RATIONALE

Health care workers represent a significant portion of the workforce in Canada and it is considered essential to the delivery of care in our health system that these workers are healthy.

PURPOSE

The overall purpose of the study is to create a research database to study the health and factors affecting health status among health care workers. The database will be used to:

a) describe differences in health measures across demographic, occupational, workplace and geographical groups among British Columbia's health care workforce, and describe how these differences change or remain the same across a 10-year follow-up period;

b) investigate predictors of long-term disability claims for musculoskeletal and mental health disorders; and

c) investigate the relationship between workplace factors and the risk of musculoskeletal and mental health disorders, independent of individual and occupational factors.

POTENTIAL BENEFITS

Finding associations between occupation and workplace characteristics and specific causes of morbidity in health care workers can advance our understanding of the factors and influences affecting the health of employees, and help us to identify priorities for future

research and preventative action. Early detection and intervention may prevent or minimize the functional limitations and disabilities that force skilled health care employees to leave the workforce.

METHODS

A master list of employees working in acute care hospitals in the B.C. health care sector will be obtained from administrative data routinely collected by a large provincial benefits provider. The benefits provider is a not-for-profit health and welfare trust that administers employee benefits on behalf of participating employers in the B.C. health care sector. This 'employee file' will include personal identifying information (i.e. first name, last name, social insurance number, date of birth, gender) solely for the purposes of linking with other research data files.

Specifically, personal identifiers are needed to link the employee file with Ministry of Health data available through the B.C. Linked Health Database (BCLHD). The BCLHD was developed by the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia, under contract with the B.C. Ministry of Health. The BCLHD contains data on medical services, hospitalization, pharmacare, mental health, cancer incidence, mortality and workers' compensation. Access to these key health care files for research purposes is governed by an *Access Policy,* which was written specifically to conform with the *BC Freedom of Information and Protection of Privacy Act* (FIPPA). (For more information, see **http://www.chspr.ubc.ca/data.htm**)

Data analysts from CHSPR will conduct probabilistic linkage procedures, which uses combinations of identifiers, such as first name, last name and date of birth, to get the best possible match between an external research file, in this case the employee file, and the files in the BCLHD. Once the linkage with the BCLHD files is complete, all personal information, such as name and date of birth, are removed and a unique study identifier, used internally by CHSPR for the linkage procedures, is encrypted in the data file that is released to the research team. The coordinating file that can decode the encrypted identifiers is maintained by CHSPR and not disclosed to the researchers.

The research team will use the linked, but de-identified, data provided by CHSPR to describe differences in health outcomes across demographic, occupational, workplace and geographic characteristics among BC's health care workforce and to study how these differences change or remain the same over the follow-up period. The researchers will also use the data to investigate predictors, including workplace characteristics, of long-term disability claims for musculoskeletal and mental disorders, the predominant and fastest rising sources of disability respectively in this sector. The analysis of the data will be completed at the Institute for Work & Health (IWH) in Toronto and at the Department of Health Care & Epidemiology (HCEP), University of British Columbia, in Vancouver.

PRIVACY RISKS AND INTENDED SAFEGUARDS

A potential risk to individuals in this study is the disclosure of their personal health information. For this project, the personal identifying fields are removed after linkage procedures and personal identifiers are encrypted in the linked data released to researchers. This allows the researcher to have the information about individual persons needed to answer the research question but without being able to identify who those persons are. Indeed, the benefits to be derived from these linked data are not at the individual level of each health care worker, but rather, at the aggregate workforce level in order to better understand the determinants of health among the study population. No identification of individuals is either desired or intended. Nor will any individual contact with health workers occur at any point.

Access to the IWH work area is limited by security card entry, and the HCEP work area is patrolled and locked between 5 p.m. to 8 a.m. Research offices at both sites will be securely locked, except when the principal investigator or the data analyst is present. All data and notes will be kept in a physically secure, locked cabinet. The computer networks at both sites have a firewall server (a computerized barrier) that prevents unauthorized users from accessing the server where the computer data files will be stored. Access to the data files is further limited to the principal investigator and the statistical analyst by computerized security password. In addition, the security password will be changed every 90 days. The linked data will be removed from the computer system and returned to CHSPR to be destroyed after the completion of this research project, which is projected to be three years in length.

The principal investigator can renew the application to the Ministry of Health and to the benefits provider if additional time for analysis or additional years of data are subsequently required. The principal investigator and the data analyst will sign a confidentiality agreement with the Ministry of Health and the benefits provider agreeing to the aforementioned conditions for use of the data. According to that agreement the following applies:

> "In the event of a breach or a threatened breach of the Agreement, the Researcher agrees that the harm suffered by the Ministry and/or other agencies would not be compensable by monetary damages alone and, accordingly, the Ministry and/or other agencies shall, in addition to other available legal or equitable remedies, be entitled to an injunction against such breach or threatened breach"; and
>
> "In addition to other remedies available, the Ministry and/or other agencies will not provide any further personal information in individually identifiable form to the Researcher if any of the conditions set out in this agreement have been breached. Where applicable, referral to the appropriate regulatory body, the Ministry and/or other agencies, or other authority for investigation and possible disciplinary action may be undertaken".

Ethical approval has been received for the project from the University of British Columbia's Research Ethics Committee. Applications have also been submitted and approved to access

data for research and statistical purposes from Freedom of Information and Protection of Privacy Officer at the benefits provider and the Ministry of Health's Data Access Subcommittee. The Subcommittee has representatives from the Ministry's Information and Privacy Program and the Research and Evaluation Branch. The data access approvals cover the duration of the project and ethical approval must be re-submitted to UBC for each year of the project.

Data analysts at CHSPR complete probabilistic linkage according to the *Access Policy for Research Uses of Linked Health Data.* The research protocol is consistent with data linkage routinely undertaken by CHSPR and in accordance with Ministry of Health policies to ensure confidentiality and compliance with FIPPA.

Once completed, the findings of this study will be documented in aggregate form in order to ensure that individuals cannot possibly be identified from the information reported.

DISCUSSION OF LEGAL AND ETHICAL ISSUES

An important ethical issue arising from this study is the lack of individual consent to access health care utilization records.

This study will involve records for 50,000 workers over a 10-year period, from 1990 to 2001. The benefits provider does not have individual mailing addresses for the employee population to enable the research team to contact employees for permission to link their health care and related records. While other personal information is available, mailing addresses are not part of the standard employee record submitted to the benefits provider from the workplace. It is also not feasible to obtain an accurate mailing list for all 50,000 employees employed in the sector over the retrospective study period, as some individuals may have relocated, the main reason mailing lists are inaccurate over a long period of time.

Record linkage by a data custodian, without obtaining consent from each and every single individual was, in this case, the only feasible method to construct a database that is sufficiently comprehensive and longitudinal in nature to look at a variety of factors in many different worksites over time. Only a very large database is sufficient to conduct multi-level analysis at the worksite level. The integration of a large population-based administrative health database has been realized in British Columbia by constructing a historical file of all persons registered with the health care system and by probabilistically linking various external study files (e.g. employee file) to this file. The success of CHSPR's rigorously controlled and protected BCLHD has allowed research projects of this kind to be developed which would otherwise not have been feasible.

FOR MORE INFORMATION

Koehoorn M, Mozel M, Cole DC, Hertzman C, Ibrahim S, Ostry A (2002). The health of health care workers: profiles of extended health benefits utilization (abstract). La Medicina del Laboro: Italian Journal of Occupational Health and Industrial Hygiene, 93 (5), 445-446.

Glossary of Terms

Aggregate Data: These types of data may take two forms: aggregate or micro aggregate.

Aggregate data is data where, within each data sub-element the data have been averaged or grouped into ranges, and only the averages or ranges reported, not revealing the identity of the data subjects.

Micro-aggregate data are data with small randomly assembled clusters of cases averaged, in effect generating a set of pseudo-cases that represent the real population.[3]

Anonymous: This type of data has been permanently stripped of all identifiers such that the information has no reasonable potential for any organization or person to identify a specific individual.[4]

Best Practices: A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of research that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.[5]

Camouflaged: This refers to a technique which 'scrambles' the identifiers of a given target research group with a control group so that when researchers or third parties are examining the data, the health status of the specific individuals remains unknown. That is, whether a specific person belongs to the targeted group or to the control group, is not ascertainable by the researchers or the third party involved in the camouflaging.

Coded Data: Data for which personal identifiers are removed and secreted but which are still potentially traceable via a matching code.[6]

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[3] Alexander M. Walker, 'Generic Data' *Pharmacoepidemiology and Drug Safety* 4, 265-267 (1995).

[4] Canadian Institutes of Health Research (CIHR), *Recommendations for the Interpretation and Application of the* Personal Information Protection and Electronic Documents Act(S.C. 2000, c.5) *in the Health Research Context*. Ottawa, Public Works and Government Services Canada, 3 (2001)

[5] Adapted from Health Canada, Therapeutic Products Directorate Guidelines, *Good Clinical Practice: Consolidated Guideline*. Ottawa, Public Works and Government Services Canada, 5 (1997)

[6] William W. Lowrance, *Privacy and Health Research* A Report to the U.S. Secretary of Health and Human Services. Washington: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. Vii. (1997)

Confidentiality: Exists when information is communicated in the context of a special relationship (such as doctor-patient, lawyer-client, etc.) where the information is intended to be held in confidence or kept secret.[7]

Collection: The act of gathering, acquiring, or obtaining personal information from any source, including third parties, by any means.[8]

De-identified: This refers to personal information from which identifiers have been removed, such that it is difficult or nearly impossible to identify the specific individual whom it is about.

De-nominalized: This refers to personal information from which direct identifiers have been removed (i.e. names, addresses, telephone numbers).[9]

Disclosure: This refers to making *personal information* available to others outside the organization.[10]

Identifiable: This refers to information which may identify either directly or indirectly, a specific individual; or which may be manipulated by a reasonably foreseeable method to identify a specific individual, or which may be *linked* by a reasonably foreseeable method with other accessible information to identify a specific individual.[11]

Identifier: This refers to a piece of information which may, by itself or when *linked* with others lead to the identification of a specific individual. Examples of direct *identifiers* are names, addresses and telephone numbers. Examples of other *identifiers* include: postal code, date of birth, provincial health insurance number, social insurance number, other dates (i.e. death, diagnosis), sex, local *identifier* (i.e. hospital or physician billing number), ethnic group, occupation, age, etc.[12]

Informed consent: Consent is informed when it is given by a person who understands the purpose and nature of the study, what participation in the study requires the person to do and to risk, and what benefits are intended to result from the study.[13]

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[7] Adapted from *Black's Law Dictionary* 5th edition, 269-70 (1979)

[8] Canadian Standards Association (CSA), *CSA Model Code for the Protection of Personal information*

[9] Adapted from *Ibid.*

[10] *CSA Code.*

[11] CIHR *Recommendations*, (2001) 3

[12] Adapted from NHS Executive, *The Caldicott Committee: Report on the Review of patient-identifiable information – December 1997.* Appendix 7 — Patient-*identifiable* information.

[13] Council for International Organizations of Medical Sciences (CIOMS), *International Guidelines for Ethical Review of Epidemiological Studies*, 11-2 (1991)

It also refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in *research* involving themselves.[14]

Linkage: The bringing together of two or more separately recorded pieces of information concerning a particular individual or family.[15]

Micro-aggregate data: See **Aggregate data**.

Nominal/ Nominative: This refers to personal information which includes direct identifiers (i.e. name, address, telephone number).[16]

Non-nominal: See **De-nominalized**.

Personal Health Information: This refers to information concerning a living or deceased individual, and includes:

- physical or mental health;
- health services provided; the donation by the individual of any bodily part or any bodily substance or information derived from the testing or examination of a body part or bodily substance;
- information that is collected in the course of providing health services to the individual; or,
- information that is collected incidentally to the provision of health care.[17]

Personal Information: This refers to information about an identifiable individual, and is broader than personal health information.

Privacy: This refers to the claim of individuals, groups or institutions to determine for themselves when, how and to what extent information about them is communicated to others.[18]

[14] Tri-Council Policy Statement (TCPS), *Ethical Conduct for Research Involving Humans*, Public Works and Government Services Canada, 2.1 (1998)

[15] Howard B Newcombe, et al., 'Automatic linkage of vital records.' *Science,* 130:954-9, (1959) 87:420

[16] Adapted from *CIOMS,* 17 (1991)

[17] *Personal information Protection and Electronic Documents Act*, (S.C. 2000 c.5)

[18] Alan F. Westin, *Privacy and Freedom*, 7 (1967)

Research: This refers to a class of activities designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.[19]

Security: This consists of a number of measures that organizations implement to protect information and systems. It includes efforts not only to maintain the confidentiality of information, but also to ensure the integrity and availability of that information and the information systems used to access it.[20]

Use: This refers to the treatment and handling of personal information within an organization.[21]

[19] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, 11 (1993).
[20] National *Research* Council (USA), *National Research Council, Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure, Computer Science and Telecommunications Board, For the Record: Protecting Electronic Health Information*. 1-1 (1997).
[21] *CSA Code*.

Appendix A: Members of the Working Group on Case Studies

Dr. Sharon Buehler (Chair) is Honorary Research Professor of Epidemiology in the Division of Community Health, Faculty of Medicine at Memorial University of Newfoundland. She holds B.A. and M.A. degrees in biology and zoology. Her work on lymphoma in small communities on the northern peninsula of Newfoundland brought her to doctoral work in epidemiology at Memorial. Currently, with collaborators in oncology, she is assessing variation in the management of breast cancer and, with colleagues in family practice and business, looking at practice-based strategies to maintain continuity of primary care; she is part of the CIHR-funded Interdisciplinary Health Research Team on colorectal cancer based in Toronto and Newfoundland. She was director and is currently on the advisory committee of the Provincial Cancer Registry. She has served on the boards of the Canadian Society for Epidemiology and Biostatistics and the Canadian Cancer Society and was a member of the original Management Committee of the Canadian Breast Cancer Research Initiative. She currently sits on the CIHR Institute Advisory Board for Cancer. Her work in these groups and on her local ethics review board have fostered a keen interest in how research, and the involvement and protection of research participants, can be effectively communicated to the public and to policy makers.

Dr. Charlyn Black, Co-Director of the Manitoba Centre for Health Policy and Evaluation (MCHPE), is a CIHR Scientist and a nationally recognized health policy researcher. She plays a key role in working at the interface between research and policy and in ensuring that the Manitoba Centre's work is relevant to the policy process. Her research interests focus on applications of population-based information systems, uses of administrative data to assess and monitor quality, effectiveness and outcomes of medical care, and the development of data-driven information tools to inform and improve health care delivery. She serves on a number of influential committees, including the Federal/Provincial/Territorial Advisory Committee on Health Services (reporting to the Conference of Deputy Ministers of Health), the Canadian Population Health Initiative Council and the Steering Committee of the Western Canadian Waiting List Study. Since September 2000, she has taken a role as Senior Advisor to the President of CIHR and to the President and CEO of the Canadian Institute for Health Information (CIHI). Dr. Black received her medical degree from the University of Manitoba (1979) and her doctorate in health services research from the Johns Hopkins University (1990). As Associate Professor and Associate Head of the Department of Community Health Sciences, she is active in teaching at undergraduate, residency and graduate levels in the Faculty of Medicine at the University of Manitoba. She has practised medicine in a variety of primary care settings, including a core area clinic, a suburban private practice, and the far north.

Dr. Denis Cournoyer is an hematologist at the McGill University Health Center and an Associate Professor of Medicine, Oncology and Human Genetics at McGill University. He received his MD from the Université de Sherbrooke and trained in hematology at McGill. He then received training in molecular biology and molecular genetics in the Department of Biochemistry at McGill and in the Department of Molecular Genetics at Baylor College of Medicine in Houston. His research work relates to somatic gene therapy. He is Chair of the Research Ethics Office of the Montreal General Hospital and Director of the Research Ethics Office of the McGill University Health Centre. He is also a member of the Board of Directors of Héma-Québec, and of the Advisory Committee in Ethics of the Fonds de la Recherche en Santé du Québec.

Dr. Eric Holowaty is a cancer epidemiologist at Cancer Care Ontario, where he is also Director of the Cancer Surveillance Unit, which includes the Ontario Cancer Registry, the largest patient-specific population-based cancer registry in Canada. He is also an Associate Professor in the Department of Public Health Sciences at the University of Toronto, where his responsibilities include teaching as well as thesis supervision. His research interests include historical record linkage control studies, second primary cancers, health services research, cancer registration and quality control. He holds a number of research grants and contracts with Health Canada, the National Cancer Institute of Canada and the U.S. National Cancer Institute.

Dr. George Kephart is an Associate Professor and Clinical Research Scholar in the Department of Community Health and Epidemiology, Faculty of Medicine at Dalhousie University. He is also co-founder and Director of the Population Health Research Unit (PHRU), which maintains administrative health databases, and a variety of other databases, for health services and population health research. His research interests include health policy evaluation, access to health care services, and methodological issues in the use of administrative and longitudinal health data (including methods to protect privacy and confidentiality). Dr. Kephart's current research includes a study on the effect of user fees on prescription drug use in the Nova Scotia Senior's Pharmacare Program, a study on non-financial barriers to accessing health care services, and an evaluation of the validity of administrative health data for the study of diabetes. His research has been funded by the National Institutes of Health in the United States, the Medical Research Council of Canada (now CIHR), the Canadian Health Services Research Foundation, and the Canadian Population Health Initiative. Dr. Kephart holds an MS and a PhD from the University of Wisconsin-Madison in Sociology (Demography).

Dr. Malcolm Maclure is Senior Healthcare Epidemiologist in the Strategic Planning, Reports and Nursing Directorate of the British Columbia Ministry of Health. From 1991-2000, he was Manager of Statistical Analysis and Evaluation within BC Pharmacare. He is also Adjunct Associate Professor of Epidemiology at Harvard School of Public Health and Visiting Professor at the Department of Clinical Pharmacology and the Research Unit on

General Practice at the University of Southern Denmark. He splits his time between Pharmacare-sponsored studies in British Columbia and, working by telecommunication, several projects at Harvard and in Denmark that use the case-crossover study design, a method he invented. Five years ago, he began studying evidence-based policy-making, reference pricing policies, how to build bridges between researchers and government decision-makers, and methods for using health databases for contacting of patients without violating privacy. This work culminated in a randomized drug policy trial in 1999. He has helped initiate other ongoing trials in BC with randomized delayed controls that are evaluating impacts of the Therapeutics Initiative's *Therapeutics Letter,* the Medical Services Commission's Guidelines and Protocols, physician-office access to PharmaNet, the Foundation for Medical Practice Education's Practice-Based Small-Group Learning Program, and several strategies for educating asthma patients in self-care.

Dr. Colin Soskolne is Professor of epidemiology in, and former Director of Graduate Training for, the Department of Public Health Sciences at the University of Alberta. Colin received his PhD from the University of Pennsylvania in 1982. He has taught courses in Epidemiology, community medicine and occupational cancer Epidemiology at the University of Toronto (1982-1985) and, since 1985, at the University of Alberta. His areas of research expertise are the human health consequences of global change (including climate change), occupational cancer case-control studies, environmental cancer epidemiology, infectious diseases and applied ethics. He established the Epidemiology Program at the U of A, and then developed the Department-wide Graduate Training Program. He has published more than 250 peer-reviewed papers, book chapters, books, editorials, letters, book reviews and an interactive video disk. He has held grants from international, federal and provincial agencies. Dr. Soskolne consults for the World Health Organization, the National Cancer Institute (Naples, Italy), and for the University of Pretoria, South Africa. His research on sulfuric acid led, in 1991, to the I ARC designation of occupational exposures to strong-inorganic-acid mists containing sulfuric acid as a definitive human carcinogen. He has chaired and continues to serve on a number of professional committees, locally, nationally and internationally. Based on his work on a SSHRC-funded grant (1996-1999), Colin spent part of his sabbatical year (1998/99) with the WHO's European Centre for Environmentally & Health in Rome as Visiting Scientist. There, he produced a Discussion Document calling on WHO to address concerns about the consequences of environmental degradation for public health. His current research focus is in exploring the role of epidemiology in linking indicators of health and well-being to ecological declines.

Dr. Robyn Tamblyn is an Associate Professor in the Departments of Medicine and Epidemiology and Biostatistics at McGill University, Faculty of Medicine. She also holds a position as Medical Scientist at the McGill University Health Center Research Institute, is a CIHR scientist and a McGill University William-Dawson scholar. She heads an FRSQ-funded team to study the relationships between medical training, practice and health out-come. She spearheaded a series of initiatives aimed at enhancing the early uptake of evidence into primary care practice, the medical office of the 21st Century projects B

Phases I and II (MOXXI). More recently, she and her colleagues have obtained funding from the Canadian Foundation for Innovation to establish a novel provincial infrastructure for health care and research. The Quebec Integrated Health Care and Research Network will integrate data from the four academic university healthcentres and their extended primary care networks with the provincial health care database warehouse.

Dr. Ross Upshur received BA (Hons.) and MA degrees in philosophy before receiving his MD from McMaster University in 1986. After 7 years of rural primary care practice he returned to complete his MSc in epidemiology and fellowship training in Community Medicine at the University of Toronto. He is currently the director of the Primary Care Research Unit at the Sunnybrook Campus of the Sunnybrook and Women's College Health Sciences Centre. Dr. Upshur is a Research Scholar and Assistant Professor, Departments of Family and Community Medicine and Public Health Sciences at the University of Toronto. He holds a New Investigator Award from the Canadian Institutes of Health Research. He is a member of The Royal College of Physicians and Surgeons of Canada, The Joint Centre for Bioethics, University of Toronto and is an Associate Member of the Institute of Environment and Health at McMaster University and Adjunct Assistant Professor of Geography and Geology at McMaster University. His research interests include the concept of evidence in health care, medical epistemology, clinical reasoning, public health ethics, time series applications in health services research, empirical approaches in bioethics and environmental epidemiology.

Dr. Don Willison is Assistant Professor, Department of Clinical Epidemiology and Biostatistics, at McMaster University. He holds a Career Scholar award with the CIHR, and works out of the Centre for the Evaluation of Medicine at St. Joseph's Hospital in Hamilton, Ontario. Dr. Willison's training combines an undergraduate degree in pharmacy from the University of Toronto, a Master's degree in Design, Measurement, and Evaluation from McMaster University, and a Doctorate in Program Evaluation from the Department of Health Policy and Management, Harvard School of Public Health. On the data privacy front, Dr. Willison has recently completed a survey of patients' views on use of information from their electronic health record for research purpose and is currently organizing a Delphi panel examining research and policy priorities on the use of personal health information for research. Dr. Willison is working with the Canadian Stroke Network to develop a cross-Canada consent-based patient registry combining clinical information from in-hospital encounters, self-reported health outcomes through follow-up telephone surveys, and provincial administrative records. He has been working with both the new Canadian Institutes for Health Research (CIHR) and Canadian Institute for Health Information (CIHI) on policies related to the secondary use of personal health information for research purposes to create an environment that will continue to allow the use of personal health information for research purposes while addressing the privacy and confidentiality concerns expressed by the public and advocacy groups.

Other Contributors

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Ms. Elaine Gibson, Health Law Institute, University of Dalhousie, Halifax, Nova Scotia
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Appendix B: Method Followed

Drawing upon its strength as Canada's leading health research agency, CIHR gathered together a group of health researchers working in the areas of health services and population health research, from across the country, to develop case studies involving secondary use of data. No hypothetical cases have been used in this exercise; all of the cases retained in this document are real.

CIHR established its Working Group in the Fall of 2000. Meetings, electronic discussions and telephone conferences ensued over the next year to determine the range of case studies that would be canvassed and to develop a process to help identify and articulate privacy issues underlying each case study. A template was designed as a model for developing the case studies. Members of the Working Group then prepared case studies based either on their own experience or that of their colleagues who agreed to participate in the process.

Each case study demonstrates, in concrete terms: its purpose; the rationale; the potential health benefits it may lead to, or has led to; what information is required, at what level of identifiability and for what purpose; how the information is collected, used and disclosed; how consent is obtained and in what form; where consent is not obtained, an explanation of why not; what security measures are implemented to protect the data; how long data is retained, for what purposes and under what conditions; what review processes and approvals are required.

The draft case studies were reviewed from a multi-disciplinary perspective. Volunteers with expertise in the areas of law, ethics and/or public policy, were recruited from across the country to participate in this exercise, including academics, federal and provincial government lawyers, and individuals in private practice. Each individual case author was teamed up with a volunteer reviewer in their jurisdiction to allow for a more fulsome one-on-one discussion of the relevant privacy issues raised in each case study. Through this exercise, the pairs were able to discuss questions from different perspectives, which brought out more factual detail needed to enrich the description of the case study and improve its utility as an analytical and discussion tool. This preliminary review allowed the researchers to tell a fuller story so that privacy advocates, policy makers, legislators and other interested stake-holders may better understand the kind of work they do. The preliminary review also proved to be insightful for the researchers themselves as they re-considered and re-evaluated the facts and issues in each case and reflected on some possible best practices.

The working group then analyzed the collection of these case studies in light of fair information principles. The analysis discusses many practical issues that arise when applying these general principles to health research studies that critically depend on the secondary use of large volumes of data. The analysis identifies the many challenges that lie ahead

and have yet to be more fully debated among health researchers, policy-makers, consumers and privacy advocates in an effort to elucidate and refine the application of information principles in the context of health research.

Rather than wait for the completion of all of the case studies, the working group decided that it would put together a representative, though incomplete, package that could be publicly released on an interim basis. A preliminary draft of the document was released in December 2001. This allowed time for the working group to engage in a broader dialogue and obtain feedback on how the document could be improved for the final publication.

In June 2002, a consultation session was held in Ottawa with representatives from across the country, including experts in ethics, law and public policy. Based on the invaluable feedback received during that consultation, the working group refined its objectives and was able to better align the document with the identified needs of various communities. From that point onward, editorial work ensued to finalize the case studies publication and ensure its completion in time for a Workshop to be held in Ottawa on November 14-15, 2002 entitled "Privacy in Health Research: Sharing Perspectives and Paving the Way Forward".

Appendix C: Useful Links

American Health Information Management Association (AHIMA)
http://www.ahima.org/

British Columbia Centre for Health Services and Policy Research Data Access Guidelines
http://www.chspr.ubc.ca/data.htm

Caldicott Committee Report on Patient *Identifiable* Health Information in the National Health Service in Great Britain **http://www.doh.gov.uk/confiden/crep.htm**

Canadian Coalition on Cancer Surveillance, Use of Cancer Patient Information for Surveillance Purposes: A Systematic Review of Legislation, regulations, Policies and Guidelines (2000) **http://www.hc-sc.gc.ca/hpb/lcdc/bc/ccocs/cpisp-usrpac/pdf/ucpisp_e.pdf**

Canadian Institutes of Health Research (CIHR) Background Legal Research and Analysis in Support of CIHR's Recommendations with Respect to the Personal Information Protection and Electronic Documents Act (PIPEDA) (S.C. 2000, c.5) (November 2001)
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/legal_analysis_e.pdf

Canadian Institutes of Health Research (CIHR) Recommendations for the Interpretation and Application of the Personal Information and Electronic Documents Act (S.C.2000, c.5) in the Health Research Context (November 2001)
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/recommendations_e.pdf

Canadian Institutes of Health Research (CIHR) *Selected International Legal Norms in the Protection of Personal Health Information in Health Research*, 2001
http://www.cihr-irsc.gc.ca/publications/ethics/protection_pi_e.pdf

Canadian Institutes of Health Research (CIHR) *Personal information Protection and Electronic Documents Act: Questions and Answers for Health* Research*ers*, 2001
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/protection_qa_e.pdf

Canadian Institutes of Health Research (CIHR), *A Compendium of Canadian Legislation Respecting the Protection of Personal information in Health Research, 2000*
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/compendium_e.pdf

Note: These links were verified as accurate up to September 17, 2002. In addition, they are included for interest only, and are by no means exhaustive.

Canadian Institutes of Health Research (CIHR) *Personal health information: Balancing Access and Privacy in Health Research*, Summary, Recommendations & Follow Up, 2000
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/personal_health_information_e.pdf

Canadian Institutes of Health Research, Natural Sciences and Engineering *Research* Council of Canada, Social Sciences and Humanities *Research* Council of Canada, *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, 1998*
http://www.nserc.ca/programs/ethics/english/ethics-e.pdf

Canadian Institutes of Health Information (CIHI), *Privacy and Confidentiality of Health Information at CIHI: Principles and Policies for the Protection of Personal Health Information and Policies for Institution-Identifiable Information (3rd Edition)*
http://secure.cihi.ca/cihiweb/en/downloads/privacy_policy_priv2002_e.pdf

CMA Health Information *Privacy* Code
http://www.cma.ca/cma/common/displayPage.do?pageId=/staticContent/HTML/N0/l2/where_we_stand/1998/09-16.htm

Council of International Organizations of Medical Sciences (CIOMS) guidelines (both for epidemiology and for *research* involving humans)
http://www.cioms.ch/frame_menu_texts_of_guidelines.htm

Department of Health and Human Services (HHS) (USA), bibliography concerning Confidentiality of Electronic Health Data
http://aspe.os.dhhs.gov/datacncl/privbibl.htm

Department of Health and Human Services (HHS) (USA) Privacy and Health Research A Report to the US Secretary of Health and Human Services
http://aspe.hhs.gov/datacncl/PHR.htm

Health Privacy Project
http://www.healthprivacy.org/

Epidemiology for the Uninitiated
http://www.bmj.com/collections/epidem/epid.shtml

Institute for Clinical Evaluative Sciences, Privacy Code
http://www.ices.on.ca/

Institute of Medicine, Protecting Data Privacy in Health Services Research
http://www.nap.edu/books/0309071879/html/

Manitoba Centre for Health Policy Data Access Guidelines
http://www.umanitoba.ca/academic/centres/mchp/protocol/approval.shtml

Manitoba Health Information Privacy Committee Guidelines
http://www.gov.mb.ca/health/hipc/index.html

MRC UK *Personal information* in Health *Research*
http://www.mrc.ac.uk/pdf-pimr.pdf
executive summary
http://www.mrc.ac.uk/pdf-pimr_summary.pdf

National Academy Press, Improving Access to and Confidentiality of Research Data Report of a Workshop (2000) **http://www.nap.edu/books/0309071801/html/**

Nuremberg Code **http://ohsr.od.nih.gov/nuremberg.php3**

OECD List of *Privacy* and Data Protection Authorities in member states
http://cs3-hq.oecd.org/scripts/pwv3/privcontacts.htm

Privacy Commissioner of Canada, Annual Report to Parliament 2000-2001
http://www.privcom.gc.ca/information/ar/02_04_09_e.pdf

Privacy Commissioner of Ontario's Submission to the Ministry of Consumer and Business Services: Consultation Draft of the *Privacy of Personal Information Act, 2002*
http://www.ipc.on.ca/english/pubpres/reports/cbs-0202.htm

Privacy Laws & Business: Data Protection & Privacy Information Worldwide
http://www.privacylaws.com/

Saskatchewan consultation on protection of personal health information
http://www.health.gov.sk.ca/ph_br_health_leg_phiq/response/toc.htm

Senate Standing Committee on Social Affairs, Science and Technology, *Fourteenth Report*
http://www.parl.gc.ca/37/1/parlbus/commbus/senate/com-e/soci-e/rep-e/rep14dec01-e.htm

Senate Standing Committee on Social Affairs, Science and Technology, *The Health of Canadians – The Federal Role Interim Report Volume Five: Principles and Recommendations for Reform: Part I*
http://www.parl.gc.ca/37/1/parlbus/commbus/senate/com-e/soci-e/rep-e/repapr02vol5-e.htm

World Medical Association (WMA), Declaration of Helsinki
http://www.wma.net/e/policy/17-c_e.html

Appendix D: Selected Bibliography

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Note: This bibliography is not intended to be complete. Inclusion of articles should not be considered as indicative of support for the opinions expressed either by CIHR or the Government of Canada. Every effort has been made to include positions on privacy and research from across the spectrum.

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