BMJ Open

Participatory governance over research in an academic research network. The case of Diabetes Action Canada

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026828.R1
Article Type:	Communication article
Date Submitted by the Author:	09-Oct-2018
Complete List of Authors:	Willison, Donald; University of Toronto, Institute of Health Policy, Management and Evaluation Trowbridge, Joslyn; University of Toronto Dalla Lana School of Public Health Greiver, Michelle; University of Toronto, Family and Community Medicine Keshavjee, Karim; Infoclin Mumford, Doug; Patent representative Sullivan, Frank; University of St. Andrews, ; North York General hospital,
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Ethics, Health policy, Health services research, Patient-centred medicine
Keywords:	Information governance, research governance, participatory governance

Participatory governance over research in an academic research network
The case of Diabetes Action Canada

Donald J. Willison
Joslyn Trowbridge
Michelle Greiver
Karim Keshavjee
Doug Mumford
Frank Sullivan

Manuscript word count: 4314

Abstract word count: 263

Author Contributions:

Willison and Trowbridge conducted the literature review and developed the initial and successive conceptual and operational governance models. Greiver, Keshavjee, and Sullivan reviewed and suggested revisions to the models. Willison developed the training workshop syllabus and content. Greiver and Mumford reviewed and suggested revisions to the workshop material. Willison wrote the initial draft of the manuscript and made subsequent revisions, in response to feedback from Trowbridge, Greiver, Keshavjee, Mumford and Sullivan.

Acknowledgements:

We wish to acknowledge the contribution and assistance of Conrad Pow, Senior Project Manager, and members of the Data Governance Working Group. Mr. Pow assisted with the development and refinement of the operational protocol for the application and review process for requests to access to the data. The members of the Data Governance Working Group were charged with setting the terms of reference for the governance process and reviewing successive drafts of the conceptual and operational models of the governance process.

Corresponding author:
Donald Willison, ScD
Associate Professor
Institute of Health Policy, Management and Evaluation
University of Toronto
155 College Street, Suite 425
Toronto, Ontario, Canada L9G 4V7
don.willison@utoronto.ca

Abstract

Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. Researchers need to develop governance policies that can assure the public that their information is being used responsibly.

Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

Methods

We developed our governance principles and processes through literature review and iterative consultation with key actors in the research network including: a data governance working group, the lead investigators, and patient advisors. We then recruited persons to participate in the governing and advisory bodies.

Results

Our governance process is informed by eight principles: (1) transparency; (2) accountability; (3) follow rule of law; (4) integrity; (5) participation and inclusiveness; (6) impartiality and independence; (7) effectiveness, efficiency and responsiveness; and (8) reflexivity and continuous quality improvement. We describe the rationale for these principles, as well as their connections to the subsequent policies and procedures we developed.

We describe the function of the Research Governing Committee (RGC), the majority of whom are either persons living with diabetes or physicians whose data are being used, and the patient and data provider advisory groups with whom they consult and communicate.

Conclusions

We developed a values-based information governance framework and process for Diabetes Action Canada that adds value over-and-above existing scientific and ethics review processes by adding a strong patient perspective and contextual integrity. This model is adaptable to other secure data repositories.

Key words:

Information governance; research governance; participatory governance;

Strengths and Limitations of this study

- The governance framework is built on values-based principles designed to gain the trust of patients and health care providers
- Half of the research governing committee members are people living with diabetes or their caregivers
- While this is a case study, we believe the governing principles are generalizable to other health research data repositories, and the operational model is adaptable to other settings.

1. Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. These include health research by both public and private sector researchers. Recent events involving questionable uses of these records have shaken the confidence of the public regarding potential misuse of their personal information.[1 2] As the number and size of health information platforms grow, and data linkages continue to become more extensive, researchers need to develop governance policies that can assure the public that their information is being used ethically, securely and with a clear public interest. In this paper, we present the conceptual and operational governance frameworks developed for Diabetes Action Canada – a pan-Canadian research consortium funded by the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research (SPOR) Program in Chronic Disease.[3]

Diabetes Action Canada's mandate is to improve the lives of Canadians living with diabetes and its related complications. It facilitates connections between patients, their primary healthcare providers, specialists, and health researchers with the goals of improving health care and reducing costs to the health care system. A key component of its mandate is to conduct patient-oriented research to help achieve these goals.[4]

To support its research activities, Diabetes Action Canada has developed a national diabetes repository – a secure analytical research environment situated at the Centre for Advanced Computing at Queen's University in Kingston, Ontario – where analyses can be conducted securely in a virtual environment.[5] The data in the repository originate from the electronic medical records (EMRs) from the practices of family physicians who contribute to the Canadian Primary Care Sentinel Surveillance Network (CPCSSN).[6] The data extracted from these records are de-identified at the source. Prior to de-identification, a pseudonymous variable is generated and a key-code file allowing re-identification is generated at the site of care and left there. This permits linkage with other records and re-identification of records at source. Only the subset of records of persons living with Type 1 or Type 2 diabetes is imported into the repository.

Early on, the need to develop a process to govern access to the data was recognized. While there was a considerable body of literature addressing information governance within the business literature, at the outset of this project, there was little literature in the context of health data repositories.[7 8]

In this paper we describe the conceptual and operational models that were developed for the Diabetes Action Canada research governance process, with the hope that it may

provide a model for other researchers who are also addressing similar issues over governance of the research in their research network.

2. Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

3. Methods

We reviewed the business and health literature on the topics of information governance and research governance, with a focus also on participatory governance and public trust. Based on this review, we developed a conceptual model for information governance that served as the foundation for the development of our operational model.

The conceptual and operational models were developed by the authors of this paper and vetted among the key actors in the research network including: a data governance working group, the lead investigators of the network, and patient advisors associated with the network. Once the models were endorsed by these groups, we recruited patients, health care professionals, researchers, and an individual with content knowledge in research ethics to participate in the governing and advisory bodies.

In the next section, we describe the relevant literature that informed our models, the models we developed, and the initial operation of the governance process.

4. Results

4.1 Conceptual model

4.1.1 Considerations

There are many definitions of information governance. We started with Smallwood's definition: *"…the overarching polices and processes to optimize and leverage information while keeping it secure and meeting legal and privacy obligations, in alignment with stated organizational business objectives*."[9] From this definition, we abstract three core goals of information governance:

1. To optimize data use to meet one's business objectives
2. To keep the data secure
3. To meet legal and privacy obligations

While this definition works well for private sector data holdings and uses, in the context of health research using data generated in the course of health care, additional considerations come into play. In the business model, the business entity usually owns the data and leverages the data to meet its business objectives. Hence, the individual firm is responsible for its information governance policies and practices.

In the context of a public sector health research network, data are often drawn from multiple parties where there is often no clear single owner of the data. Indeed, privacy legislation in Canada does not discuss ownership of data. It is framed in the language of custody and control over data, and to duties and obligations of those holding the data.

Similarly, in the United Kingdom, the revised Caldicott principles delineate six principles for the secure management of personal health information. The updated version added a seventh principle: the duty to share information can be as important as the duty to protect patient confidentiality.[10]

Consequently, we suggest that, for health research, it is more appropriate to refer to stewardship rather than ownership of data. In addition, contributors to the research enterprise should carry a collective responsibility for information governance and the business objective must also meet a public interest test.[11]

Further, for use of data in the public sector, it is now recognized that, to ensure social license for use of the data, the information governance objectives may need to go beyond mere compliance with formal regulations.[1] Laurie and Sethi argue that "*a good governance framework needs to include an overt statement of the values and standards according to which activity will be assessed. This must be accessible and sufficiently adaptable to be adopted and implemented across all levels of decision-making and by all actors involved in the process*."[12] Similarly, Barocas and Nissenbaum state that "*procedural approaches cannot replace policies based on substantive moral and political principles that serve specific contextual goals and values*."[13]

Based on these considerations, we added a fourth objective to Smallwood's three core goals of information governance:

4. Earn and maintain the trust of patients, partners, data providers, and the public for use of data for research in the public interest.

Trust is, in fact, a linchpin in the public acceptability of the research enterprise. Carter and colleagues argue that: *"… individuals' cooperation with specific research studies is usually secured through three principal mechanisms: their expectations about how research is conducted and regulated; their trust in the institutions and individuals who recruit them; and their beliefs in the wholesomeness and public value of the research endeavour.*"[1]

Elsewhere, they expand on the trust element: "*the public's support and tolerance for research, and its associated risks, often depends far more on an often fragile set of cues about the safety and social good of research participation, and on institutional and professional credentials, than it does on the formal architecture of research regulation, or on rational assessment of the detail of information sheets or other documents aimed at gaining 'informed consent*'." That does not negate the importance of attention to details around regulation and good communications. It does, however, point to the fragile dependence of the research enterprise on care taken by all researchers to ensure that their work is conducted with high integrity and that the public interest in the research be clearly articulated.

Trust assumes some level of uncertainty and, consequently, vulnerability.[14] We recognized that much of the information use being planned would take us into "*grey zones*" of research use: the indistinct interface between research and clinical practice, the health care system, and management of the health of populations of people living with diabetes. Consequently, we identified the need to incorporate reflexivity into our research governance process. That is, the governance process has to critically assess

common regulatory assumptions and practices in the context of new research circumstances and test alternative assumptions and practices.[17]

Particularly when the individual does not have an opportunity to exercise control over the use of their data, it is important to ensure that the public or patients, as appropriate, be involved at multiple stages in the governance process. The importance of stakeholder involvement in governance has been widely recognized.[18-22]

Finally, we needed to consider how the governance process we developed would complement the existing scientific and ethics review processes to which any research protocol would also be subjected. Given the focus on trust of both patients and the health care professionals whose data were being used, we chose to focus on how best to account for the patient's perspective throughout all stages of the research process.

4.1.2 Guiding Principles

Based on the considerations above, we identified eight principles that would guide our governance process:

1. Transparency
2. Accountability
3. Follow rule of law
4. Integrity
5. Participation and inclusiveness
6. Impartiality and independence
7. Effectiveness, efficiency and responsiveness
8. Reflexivity and continuous quality improvement

Below, we provide a brief description of how these broad principles would inform our governance process, and how these principles map to the four goals of information governance. A more detailed description is available upon request.

1. Transparency

All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in an easily understandable format. (maps to: earn and maintain trust; meet privacy obligations)

2. Accountability

A governing body is accountable to those who will be affected by its decisions or actions. This is enforced through transparency and the rule of law. (maps to: earn and maintain trust, meet legal obligations)

3. Following the rule of law

The governance framework should follow all appropriate legal frameworks and the governing body should ensure compliance with applicable laws, regulations, standards and organizational policies across jurisdictions and institutions. (meet legal obligations, earn and maintain public trust)

4. Integrity

The governing process should ensure that uses of the data: (a) have a clear patient/public interest that is consistent with the intended purpose of the repository; (b)

are of high scientific and ethical integrity; and c) are maintained in a secure and private manner. (Meet business objectives; meet legal and privacy obligations; earn and maintain trust; keep data secure)

5. Participation and Inclusiveness

Patients and their families, health care professionals, and researchers should participate in governance over data use – through the patient advisory councils and other stakeholder advisory groups.

The governing bodies responsible for access to data in the repository should account for differing interests to reach a broad consensus on what is in the best interest of those with diabetes and their families. Participation in governance should be inclusive, equitable, informed and organized. The full range of positions of the advisory groups should be considered. Ongoing, 2-way engagement between the governing body and advisory groups is best. (Earn and maintain trust)

6. Impartiality and independence

As described above, the goal in deliberations is to reach a broad consensus on what is in the best interest of those living with diabetes and their families. All members in the process must look beyond their personal interests as either patients, health care providers, or researchers.

In addition, the governance process must be able to operate in a zone of bounded independence[23] from management, to ensure that its decisions are free from institutional conflicts of interest. (Earn and maintain trust,)

7. Effectiveness, Efficiency and Responsiveness

Governance over the data repository should ensure the objectives of the organization are being met in an effective and efficient fashion. The governing processes should serve all within a reasonable timeframe. (Earn and maintain trust; meet business objectives)

8. Reflexivity and Continuous Quality Improvement

Information governance should include processes that: allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use. It should promote a culture of reflexivity, and responsiveness among researchers and those governing access to the data. [24] (Earn and maintain trust).

4.2 Operational model

4.2.1 Structure

Building on these governance principles, we then formulated an operational model for our governance process. In this section and the next, we make explicit links to these guiding principles.

Our operational model is summarized in Figure 1. Below, we focus on the roles of the Research Governing Committee and its internal and external advisory groups.

[Insert Figure 1 near here.]

Research Governing Committee

The Research Governing Committee is the overall authority for governance over any research – observational studies or clinical trials – that are conducted involving data or patients in the Network. It has decision-making authority regarding individual studies. The Committee is accountable to the Steering Council, the highest authority in Diabetes Action Canada. (Principle 2: Accountability; Principle 6: Impartiality and independence.)

In its early stages, the Committee is reviewing all applications. This will help it work through and document the important issues in approving applications and to develop standardized approval policies so that, in future when volumes increase and processes become routine, it will only have to review studies that have been flagged by the Repository Manager as requiring Committee input.

There are two ways in which the Research Governing Committee adds value over and above scientific and ethics review. First, it ensures contextual integrity of the research, through an intimate understanding of the data and the health care settings in the system being studied. Equally important, it ensures a patient-centered perspective of the research, by checking that the research:
(a) includes patient-relevant outcomes;
(b) has taken into adequate account benefits and burdens/risks among people living with diabetes; and
(c) is engaging in good communication practices with research participants, particularly around approaching and consenting to participate in research and in communicating about use of their health information for research. (Principle 4: Integrity of purpose)

Half of the Committee members (n=6) are people who are living with diabetes or their caregivers. Another two members are representatives from the Data Provider Advisory Group, described below. Currently these are physicians who are members of CPCSSN, a subset of whose de-identified electronic medical records reside in Diabetes Action Canada's secure data repository. Another two members are researchers, whose roles are to be technical advisors around scientific validity and merit of the research proposal. The other two members are individuals with expertise in research ethics or law. The Committee may draw in outside experts if required. One of the two co-chairs of the Committee is a patient representative. The other co-chair is drawn from the rest of the members of the Committee. (Principle 5: Participation and inclusiveness)

Data Provider Advisory Group

Currently, the main data source for research activities of the Network consists of the de-identified electronic medical records of physicians participating in CPCSSN. The Data Provider Advisory Group was developed to ensure that the perspectives of these data providers are represented at the Research Governing Committee, through two members that group participate on the Research Governing Committee. Three of the seven members of the Group are front-line family physicians (i.e. not academics). In future, as the sources of research data grow, other health care professionals and data providers will be added to this advisory group.

This group provides advice on research applications, considering: logistics of conducting the research in the practice setting (particularly if a clinical trial); design

considerations, as they relate to practice-level decisions; and interpretation of findings. They also serve as liaisons with the larger group of practices that are providing data to the repository. (Principle 5: Participation and inclusiveness)

Patient Circles

Patient Circles were developed at the outset of Diabetes Action Canada.[25] Patient Circle members either have diabetes themselves or are caregivers for a person living with diabetes. They are called upon individually and collectively for advice on multiple aspects of the network endeavours.

Currently, there are three Patient Circles:

1. The General Patient Circle (10-15 people)
2. The Francophone and Immigrant Patient Circle (6-8 people)
3. The Indigenous Patient Advisory Circle (8-15 people)

Members of the patient advisory circles have been drawn from multiple sources, including: an online survey, snowball sampling, and from community organizations. Members are selected to maximize diversity in age, gender, and geographic location. In addition, candidates are interviewed to identify those with good group skills and a desire to contribute to a goal that exceeds his/her own health situation. They are then offered training in patient-oriented research.

The six patient representatives on the Research Governing Committee have been identified from the General Patient Circle and from a list of potential candidates for the Circles maintained by Diabetes Action Canada. The patient co-Chair of the Research Governing Committee provides reports to the General Patient Circle, apprising them of the activity of the Research Governing Committee and soliciting their input, should there be any controversial issues with which they are grappling. The General Patient Circle is the liaison point because there is representation from the Francophone and Immigrant, and the Indigenous patient circles in the General patient circle. (Principle 5: Participation and inclusiveness)

External Ethics Advisory Group

This Committee will act as a 'critical friend' to advise on issues that cannot be resolved through deliberations among Research Governing Committee members and the internal advisory groups described above. This advisory group provides one more instance of the governing principle of reflexivity. It will be at arm's length to the Research Governing Committee. It carries no formal authority, but has the freedom to go public if it is concerned about some particular policy direction taken by Diabetes Action Canada. Members will be drawn from ethics and legal scholars outside Diabetes Action Canada, both nationally and internationally, with expertise in: governance over secondary use of data; privacy and access to data; registry-based clinical trials; and practice-based research. (Principle 8: Reflexivity and continuous quality improvement)

4.2.2 Process

Standard operating procedures, including application forms, have been developed. A summary of the application process for research use of the data is provided in Appendix 1.

In the application form, several questions focus on the patient-orientation of the research. For example, the researcher is asked to indicate:
(a) the patient outcomes being measured;
(b) how the research will benefit those living with diabetes or the public more generally;
(c) the potential research-related risks of the study to research participants/data subjects and potential adverse social implications of the research; and
(d) the ways in which people living with diabetes have been involved in the planning of the research. (Principle 4: Integrity of purpose, scientific integrity, ethical integrity)

The Repository Manager reviews the application for completeness. If the project has not received scientific review, the protocol is sent to a scientific advisory group for their approval prior to review by the Research Governing Committee. Researchers are encouraged to submit prior to Research Ethics Board approval to ensure the feasibility and appropriateness of the proposed protocol from the perspective of Diabetes Action Canada. In that way, re-work at the level of the REB is minimized. (Principle 4: Scientific and ethical integrity; Principle 7: Effectiveness, efficiency, and responsiveness)

Applications for research use of the data are circulated to Research Governing Committee members at least two weeks in advance, to provide an opportunity for patient and data provider members of the Committee to identify issues requiring deliberation with their respective advisory group, in advance of the Research Governing Committee meeting. (Principle 5: Participation and inclusiveness)

At the Committee meeting, when vetting a particular protocol, patient and data provider representatives are invited to comment first. Concerns raised by the researchers and ethics people follow thereafter. The Committee members aim for a consensus-based resolution to any concerns. When Committee members fail to come to consensus, even subsequent to consultation with the Patient Advisory Circles and the Data Provider Advisory Group, The Research Governing Committee may turn to the Ethics Advisory Group for guidance on how to proceed with an application or to seek general policy direction. (Principle 5: Participation and inclusiveness; Principle 6: Impartiality and Independence; Principle 8: Reflexivity and continuous quality improvement)

For applications in which concerns have been raised that there is insufficient patient or health care provider input into the research, the Committee may exercise the option to assign a patient or health care professional member of the Committee (or one of the Advisory Groups) to become a collaborator on the project to provide advice and the patient's or HCP's perspective on the research, throughout the project. They also retain the option to review a draft report prior to publication of findings. (Principle 4: Scientific integrity (to ensure adequate inputs) and Principle 5: Participation and inclusiveness)

The Repository Manager will monitor the time required for protocols to pass various checkpoints in the system, to identify any unnecessary bottlenecks in the system and make recommendations for process improvement. (Principle 7: Effectiveness, efficiency and responsiveness; Principle 8: Reflexivity and continuous quality improvement.)

Finally, Diabetes Action Canada is in the process of posting:

- its policies around data collection, access, use and retention of data; and

- its business processes and governance activities;

so they can be readily accessible to partners and the public. In future, it will also perform regular audits of its data use practices. (Principle 1: transparency; Principle 2: Accountability)

4.2.3 Implementation

In January of 2018, a day-long training workshop was convened for the Research Governing Committee. A training manual was produced for that purpose, and will be posted on the Diabetes Action Canada website. Topics covered in the workshop included:

- An explanation of the types of studies that they would be encountering (data studies; studies making direct contact with patients; and hybrid studies)
- The stages of the research process and how the Research Governing Committee fits into this
- What are research governance and information governance and how will they be applied in the context of Diabetes Action Canada's secure data repository?
- Diabetes Action Canada's governing principles, and how these may apply when reviewing protocols.
- What is the "added value" of the Research Governing Committee vis-à-vis scientific and ethic review
- The structure and function of the governing process and their specific contributions.

Participants were then led through two case studies to test out the application and review process.

4.3 Evaluation

At the time of writing, the Diabetes Action Canada secure data repository has been available for research for only a few months. We are in the early days of implementing the governance process and we are still refining those processes – both the internal functioning of the Research Governing Committee and the consultative processes. We are also continuing to address learning needs of Research Governing Committee members.

Similarly, our plans for the evaluation of the governance process are in the formative stages. Drawing from relevant SPOR[26] and PCORI[27] evaluation frameworks, key issues that we will address in the evaluation include:

- Periodic review of DAC's information governance processes and procedures on to ensure that they conform to and are congruent with the objectives and principles enunciated in this paper.
- Process measures, such as: patient representatives' sense of empowerment in the process; and the timeliness of the reviews – both objectively and from the perspective of researchers who submit applications
- Outcome measures, such as: the proportion of projects reviewed in which changes were recommended and the nature of the changes recommended, including: (a) addition of more patient-relevant outcomes, (b) improvements in

participant communications materials (e.g. consent forms and information materials); and (c) reductions in risks and burdens to patient participants.

5. Discussion

Diabetes Action Canada has developed and implemented an information governance process established on values-based principles designed to foster public trust in the responsible use of the data in a secure data repository. We believe the conceptual model is generalizable to other settings and the operational model is adaptable to a wide range of other research settings. While we have drawn our inspiration from a wide cross-section of literature, the model has been particularly influenced by the conceptual work of Laurie and Sethi.[12 24 28 29]

While all eight principles enunciated are important in fostering public trust, the integrity and participation principles are particularly relevant. The integrity principle establishes the criterion that the research must have a clear patient or public interest, while the participation principle ensures the substantive participation of patients and other relevant stakeholders, which helps to achieve the integrity principle.

Over the past decade, there have been many studies examining the public's or patients' attitudes toward the conditions under which data studies may be acceptable.[30] Much less common is the involvement of patients or the public in an ongoing fashion in the governance over *programs* of data-intensive research. The closest exemplar we were able to find in the area of data-intensive research is the consumer panel for data linkage research, associated with the SAIL databank.[31] Their panel is advisory in nature, addressing both access policy and individual projects and representatives of that panel sit on an independent Information Governance Review Panel. The governance process developed for Diabetes Action Canada goes one step further. It gives people living with diabetes and data providers majority representation in the key decision-making body in the governance process. We are unaware of any other research governance structures that have instilled as strong a role for patients and health care professionals in a research network. We are not suggesting that all research networks should choose as radical a path. However, we believe strong lay participation in policy making and governance is an increasingly important approach to securing the trust of the public.

As our research platforms grow in size and scope, the need for public trust in in the uses of these datasets also grows. We believe our model for governance over health information platforms adds substantively to the conceptual and methodologic foundations for information governance to help address this need.

Competing interests:

The Institute of Health Policy, Management and Evaluation received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Willison's time for the development of the governance process for the Diabetes data repository.

The Department of Family and Community Medicine, University of Toronto, received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Greiver's time for the development of the Diabetes data repository.

Dr. Keshavjee received personal fees from InfoClin Inc during the conduct of the study toward designing the architecture of the Diabetes data repository. In addition, Dr. Keshavjee has a patent “Prediction of Diabetes Mellitus Type 2 Using Biomarkers in Electronic Health Records and Differential Calculus”, pending.

Funding:

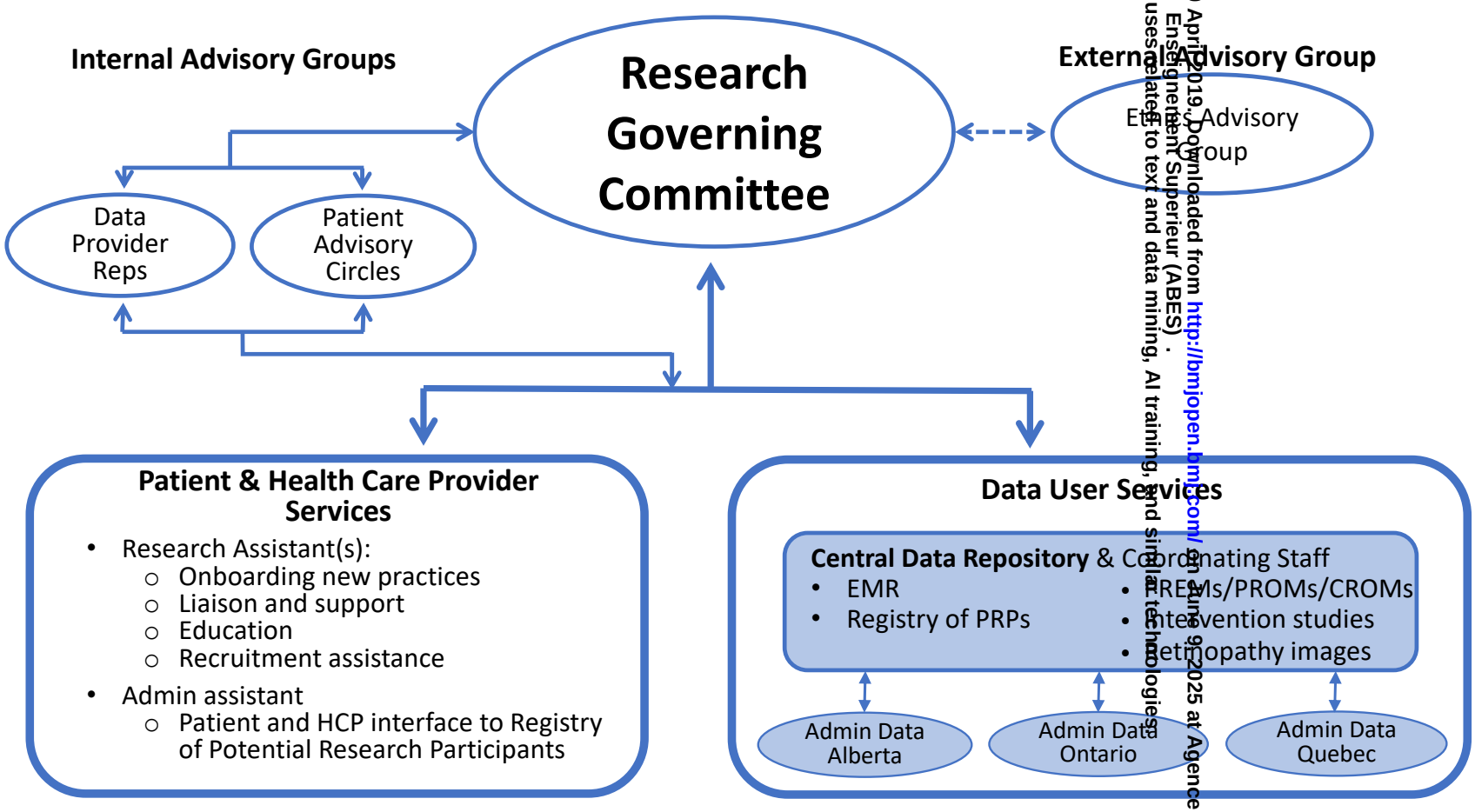
This work was supported by Diabetes Action Canada, which is funded, in part, through a Canadian Institutes of Health Research chronic disease network grant under the Strategy for Patient-Oriented Research (Funding Reference number: SCA 145101)

References

1. Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why care.data ran into trouble. Journal of medical ethics 2015;**41**(5):404-09.
2. Powles J, Hodson H. Google DeepMind and healthcare in an age of algorithms. Health and Technology 2017;**7**(4):351-67.
3. Anonymous. Strategy for Patient-Oriented Research 2018 [Available from: http://www.cihr-irsc.gc.ca/e/41204.html.
4. Anonymous. Strategy for patient-oriented research. Patient engagement framework. Ottawa, Ontario: Canadian Institutes of Health Researach, 2014.
5. Anonymous. Launch of the Diabetes Action Canada National Data Repository: Diabetes Action Canada; 2018 [Available from: https://diabetesaction.ca/launch-of-the-diabetes-action-canada-national-diabetes-repository/.
6. Garies S, Birtwhistle R, Drummond N, et al. Data Resource Profile: National electronic medical record data from the Canadian Primary Care Sentinel Surveillance Network (CPCSSN). Int J Epidemiol 2017;**46**(4):1091-92f.
7. Burton PR, Murtagh MJ, Boyd A, et al. Data Safe Havens in health research and healthcare. Bioinformatics (Oxford, England) 2015;**31**(20):3241.
8. Lea NC, Nicholls J, Dobbs C, et al. Data Safe Havens and Trust: Toward a Common Understanding of Trusted Research Platforms for Governing Secure and Ethical Health Research. JMIR medical informatics 2016;**4**(2):e22.
9. Smallwood R. *Information governance: Concepts, strategies, and best practices*. Hoboken, NJ: Wiley, 2014.
10. Department of Health. Information: To share or not to share? The Information Governance Review. 2013. https://www.gov.uk/government/publications/the-information-governance-review (accessed 2018-09-25).
11. Simm K. The Concepts of Common Good and Public Interest: From Plato to Biobanking. Cambridge Quarterly of Healthcare Ethics 2011;**20**(4):554-62.
12. Laurie G, Sethi N. Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework. Edinburgh: University of Edinburgh, 2012.
13. Barocas S, Nissenbaum H. Big Data's End Run around Anonymity and Consent. Privacy, Big Data, and the Public Good. New York, NY: Cambridge University Press, 2014.
14. Nissenbaum H. Securing trust online: Wisdom or oxymoron? Boston University Law Review 2001;**81**(3):635-64.
15. Magnus D, Wilfond BS. Research on medical practices and the ethics of disclosure. Pediatrics 2015;**135**(2):208-10.
16. Wilfond BS, Magnus DC. The Potential Harms and Benefits from Research on Medical Practices. Hastings Center Report 2015;**45**(3):5-6.
17. Laurie GT, Dove ES, Ganguli-Mitra A, et al. Charting Regulatory Stewardship in Health Research Making the Invisible Visible. CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 2018;**27**(2):333-47.
18. O'Doherty KC, Burgess MM, Edwards K, et al. From consent to institutions: Designing adaptive governance for genomic biobanks. Social Science and Medicine 2011;**73**(3):367-74.

19. Greenhalgh T, Morris L, Wyatt JC, et al. Introducing a nationally shared electronic patient record: Case study comparison of Scotland, England, Wales and Northern Ireland. International Journal of Medical Informatics 2013;**82**(5):e125-e38.
20. Geissbuhler A, Safran C, Buchan I, et al. Trustworthy reuse of health data: a transnational perspective. International journal of medical informatics 2013;**82**(1):1-9.
21. Allen C, Des Jardins TR, Heider A, et al. Data Governance and Data Sharing Agreements for Community-Wide Health Information Exchange: Lessons from the Beacon Communities. eGEMs (Generating Evidence & Methods to improve patient outcomes) 2014;**2**(1):1057.
22. Kaushal R, Hripcsak G, Ascheim DD, et al. Changing the research landscape: the New York City Clinical Data Research Network. JAMIA 2014;**21**(4):587-90.
23. Beecher JA. The prudent regulator: politics, independence, ethics, and the public interest. Energy Law Journal 2008;**29**(2):577.
24. Laurie G. Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law. Human genetics 2011;**130**(3):347-56.
25. Anonymous. How partient-parters are involved 2018 [Available from: https://diabetesaction.ca/patient-partners-involved/.
26. Anonymous. Evaluation of the Strategy for Patient-Oriented Research. Ottawa, Canada: KPMG, 2016.
27. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. Journal of comparative effectiveness research 2015;**4**(2):133.
28. Laurie G, Sethi N. Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data. European Journal of Risk Regulation : EJRR 2013;**4**(1):43.
29. Sethi N, Laurie GT. Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together. Medical Law International 2013;**13**(2-3):168-204.
30. Aitken M, De St Jorre J, Pagliari C, et al. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Medical Ethics 2016;**17**(1):1-24.
31. Jones KH, McNerney CL, Ford DV. Involving consumers in the work of a data linkage research unit. International journal of consumer studies 2014;**38**(1):45-51.

Figure 1. Governance Structure



Appendix 1. Application process for research use of the data in the research repository

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Submission and Approval Process	SOP#	Diabetes Action CanadaNDR-PSAP001.0
Document Number	001	Author	Conrad Pow
Version Number	1.0	Reviewer	
Superseded Version	Draft	Reviewer Date	
Effective Date	05/01/2018	Status	

1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to define all key aspects involved in the Submission and Approval of projects requesting to access to data held within the Diabetes Action Canada National Diabetes Repository.

2. SCOPE

This document is intended for all projects that have been submitted to the Diabetes Action Canada National Diabetes Repository. This applies to Diabetes Action Canada staff, Diabetes Action Canada Committee Members and Diabetes Action Canada researchers wishing to conduct a secondary data analysis project.

3. ROLES AND RESPONSIBILITIES

3.1 Diabetes Action Canada Repository Manager: Responsible for the overall operations (recruitment, developing policies and procedures, site relationship) and communication regarding the Diabetes Action Canada National Diabetes Repository.

3.2 Diabetes Action Canada Repository Data Manager: Responsible for data extraction, processing, quality check, destruction, reports, transfer, secondary data usage, and managing the data dictionary; responsible for updating the Diabetes Action Canada Repository Manager on changes or problems with the Diabetes Action Canada National Diabetes Repository.

3.3 Diabetes Action Canada Repository Research Administrator: Responsible for managing the participant database and facilitating meetings.

3.4 Diabetes Action Canada Researcher: Responsible for ensuring that all project team members, including self, are familiar with the Diabetes Action Canada Policies and Procedures pertaining to the National Diabetes Repository. Will be responsible for ensuring that all project team members have signed COI statement. Will be responsible for the management and oversight of the project.

3.5 Diabetes Action Canada Repository Scientific Advisory Committee (SAC): The SAC is made up of 3 members. The SAC is responsible for reviewing projects

proposing to access data in the Diabetes Action Canada National Diabetes Repository. The SAC will review the scientific merit and methodology of the project.

3.6 Diabetes Action Canada Repository Research Governing Committee (RCG): The RCG will ensure the focus of the proposed project is aimed at what is in the best interest of the patient and that aligns with Diabetes Action Canada's mission and values.

4. SECONDARY DATA USAGE

Data in the Diabetes Action Canada Repository will only be available to Diabetes Action Canada researchers wishing to conduct secondary data analysis. Once approved, they will be given remote access to a specified data cut in a secure zone at the Centre for Advanced Computing Canada (CAC).

5. SUBMISSION AND APPROVAL PROCESS

STEP 1: Diabetes Action Canada Researcher will electronically fill and submit an Access Request Form (Appendix 1) through the Researcher portal at https://repository.diabetesaction.ca The form outlines the purpose, methodology, requested data elements and timeframe. It also requires a copy of the full research proposal and whether there is any identified or perceived risks.

STEP 2: The Repository Manager and the Repository Data Manager will review the Access Request Form to assess the feasibility of the project based on the data elements requested. This may include a meeting with the Researcher to discuss the data elements requested, project objectives and overall budget.

STEP 3: If the project has been peer-reviewed (eg. CIHR has reviewed and reviewed the submitted protocol) then proceed to Step 4, if not, the Access Request Form and full research proposal will be reviewed by the National Diabetes Repository Scientific Advisory Committee (SAC) to assess the scientific merit and methodology of the project. The researcher will be updated on the scientific assessment by the SAC, if any concerns are raised, the Researcher will be requested address them prior to the project moving any further.

STEP 4: The Repository Manager will provide the RGC a copy of the Access Request Form to advise on, but not limited to: (1) The project is in the best interest of the patients; (2) The project goals align with institutional mission and values. Once approval has been received from the RGC, the Repository Manager will provide the Researcher written confirmation that the proposed project is feasible. The Confirmation of Feasibility (COF) letter will also identify the estimated costs for conducting the project.

STEP 5: If the project is not part of a larger REB approval, the Researcher will be required to apply for REB approval. The COF letter can be provided to the REB as supporting documentation assuring Diabetes Action Canada supports the project. In addition, the Researcher must submit confirmation of funding (Peer Reviewed Grant, Institutional Funds, Investigator Funds…)

STEP 6: Once REB approval has been obtained, the Researcher will upload the REB approval letter through the Researcher portal along with the REB submission.

STEP 7: The Repository Manager, along with the RGC, will review the Access Request Form to ensure it aligns with the REB submission and approval.

STEP 8: After confirmation of REB alignment, the Repository Manager will provide the Researcher Diabetes Action Canada Repository Researcher Agreement (Appendix B) and Confidentiality Agreement (CA) (Appendix C).

STEP 9: After both Agreements have been fully executed, the Repository Manager and the Repository Data Manager will work with the Researcher to finalize the required data elements to create a Dataset Creation Plan (DCP). The DCP will be used to create a project specific dataset.

STEP 10: The Repository Data Manager will upload the project specific dataset to the secure workspace for the researcher to conduct analysis.

STEP 11: Once all agreements are in place, the Repository Data Manager will provide the Researcher the login credentials to remotely access the secure environment.

BMJ Open

Participatory governance over research in an academic research network. The case of Diabetes Action Canada

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026828.R2
Article Type:	Communication article
Date Submitted by the Author:	19-Dec-2018
Complete List of Authors:	Willison, Donald; University of Toronto, Institute of Health Policy, Management and Evaluation Trowbridge, Joslyn; University of Toronto Dalla Lana School of Public Health Greiver, Michelle; University of Toronto, Family and Community Medicine Keshavjee, Karim; Infoclin Mumford, Doug; Patent representative Sullivan, Frank; University of St. Andrews, ; North York General hospital,
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Ethics, Health policy, Health services research, Patient-centred medicine
Keywords:	Information governance, research governance, participatory governance

Participatory governance over research in an academic research network
The case of Diabetes Action Canada

Donald J. Willison
Joslyn Trowbridge
Michelle Greiver
Karim Keshavjee
Doug Mumford
Frank Sullivan

Manuscript word count: 5420

Abstract word count: 263

Author Contributions:

Willison and Trowbridge conducted the literature review and developed the initial and successive conceptual and operational governance models. Greiver, Keshavjee, and Sullivan reviewed and suggested revisions to the models. Willison developed the training workshop syllabus and content. Greiver and Mumford reviewed and suggested revisions to the workshop material. Willison wrote the initial draft of the manuscript and made subsequent revisions, in response to feedback from Trowbridge, Greiver, Keshavjee, Mumford and Sullivan.

Acknowledgements:

We wish to acknowledge the contribution and assistance of Conrad Pow, Senior Project Manager, and members of the Data Governance Working Group. Mr. Pow assisted with the development and refinement of the operational protocol for the application and review process for requests to access to the data. The members of the Data Governance Working Group were charged with setting the terms of reference for the governance process and reviewing successive drafts of the conceptual and operational models of the governance process.

Corresponding author:
Donald Willison, ScD
Associate Professor
Institute of Health Policy, Management and Evaluation
University of Toronto
155 College Street, Suite 425
Toronto, Ontario, Canada L9G 4V7
don.willison@utoronto.ca

Abstract

Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. Researchers need to develop governance policies that can assure the public that their information is being used responsibly.

Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

Methods

We developed our governance principles and processes through literature review and iterative consultation with key actors in the research network including: a data governance working group, the lead investigators, and patient advisors. We then recruited persons to participate in the governing and advisory bodies.

Results

Our governance process is informed by eight principles: (1) transparency; (2) accountability; (3) follow rule of law; (4) integrity; (5) participation and inclusiveness; (6) impartiality and independence; (7) effectiveness, efficiency and responsiveness; and (8) reflexivity and continuous quality improvement. We describe the rationale for these principles, as well as their connections to the subsequent policies and procedures we developed.

We describe the function of the Research Governing Committee (RGC), the majority of whom are either persons living with diabetes or physicians whose data are being used, and the patient and data provider advisory groups with whom they consult and communicate.

Conclusions

We developed a values-based information governance framework and process for Diabetes Action Canada that adds value over-and-above existing scientific and ethics review processes by adding a strong patient perspective and contextual integrity. This model is adaptable to other secure data repositories.

Key words:

Information governance; research governance; participatory governance;

Strengths and Limitations of this study

- The governance framework is built on values-based principles designed to gain the trust of patients and health care providers
- Half of the research governing committee members are people living with diabetes or their caregivers
- While this is a case study, we believe the governing principles are generalizable to other health research data repositories, and the operational model is adaptable to other settings.

1. Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. These include health research by both public and private sector researchers. Recent events involving questionable uses of these records have shaken the confidence of the public regarding potential misuse of their personal information.[1 2] As the number and size of health information platforms grow, and data linkages continue to become more extensive, researchers need to develop governance policies that can assure the public that their information is being used ethically, securely and with a clear public interest. In this paper, we present the conceptual and operational governance frameworks developed for Diabetes Action Canada – a pan-Canadian research consortium funded by the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research (SPOR) Program in Chronic Disease.[3]

Diabetes Action Canada's mandate is to improve the lives of Canadians living with diabetes and its related complications. It facilitates connections between patients, their primary healthcare providers, specialists, and health researchers with the goals of improving health care and reducing costs to the health care system. A key component of its mandate is to conduct patient-oriented research to help achieve these goals.[4]

To support its research activities, Diabetes Action Canada has developed a national diabetes repository – a secure analytical research environment situated at the Centre for Advanced Computing at Queen's University in Kingston, Ontario – where analyses can be conducted securely in a virtual environment.[5] The data in the repository originate from the electronic medical records (EMRs) from the practices of family physicians who contribute to the Canadian Primary Care Sentinel Surveillance Network (CPCSSN).[6]

The CPCSSN extracts de-identified EMR records from the practices of consenting primary care providers. Structured data from the chart are included as well as selected free text terms. This includes data from the summary health profile such as health conditions, allergies and immunizations. CPCSSN also extracts selected laboratory data, vital signs, medications prescribed, dates of encounters, dates and types of referrals and risk factors (smoking status, alcohol use) and patient demographics.[6]

Patients are notified of the collection for research purposes through posted notices in the physicians' offices. Patients can opt out at any time by contacting a member of the practice-based research network in their region. Notices advising patients of this are posted in the offices of participating primary care providers.[7]

The data extracted from these patients' records are de-identified at the source. Prior to de-identification, a pseudonymous variable is generated and a key-code file allowing re-identification is generated at the site of care and left there. This permits linkage with other records and re-identification of records at source. Only the subset of records of persons living with Type 1 or Type 2 diabetes is imported into the repository.

Other systems internationally use similar methods to extract, transform and manage primary care EMR data for purposes of clinical research, epidemiology and the study of health systems. As an example, the UK's Clinical Practice Research Datalink (CPRD) has been in existence for over 30 years.[8] The CPRD extracts de-identified data that are similar to those in CPCSSN and manages a growing list of research services based on these data. It has been part of more than 2,000 peer reviewed publications on a range of topics including medication use and safety, health policy and chronic disease management. The CPCSSN has now been in existence for a decade; its pattern of growth and development as Canada's primary care EMR repository is following a path similar to the CPRD's.

During this developmental phase, access to the data in the repository is restricted to researchers within Diabetes Action Canada. In future, the intention is for this to be open to outside researchers.

Early on, the need to develop a process to govern access to the data was recognized. While there was a considerable body of literature addressing information governance within the business literature, at the outset of this project, we were aware of relatively little literature in the context of health data repositories.[9-13]

In this paper we describe the conceptual and operational models that were developed for the Diabetes Action Canada research governance process, with the hope that it may provide a model for other researchers who are also addressing similar issues over governance of the research in their research network.

2. Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

3. Methods

Our work was informed by three sources of literature:

1. basic business texts in data governance;[14 15]
2. a database of 32 articles gathered from the authors' existing library and recommendations from our Data Governance Working Group; and
3. a scoping review of the literature using Ovid Medline from 2000 to 2017, with the assistance of a health sciences research librarian.

The full scoping review process and resulting analysis are the subject of a forthcoming publication. Search terms for the scoping review combined the topics of biobank and electronic medical records, governance and regulation, and social licence and trust. This returned 1075 articles, which were combined with the earlier database of 32

articles. On screening of abstracts of the 1075 papers, 122 articles were identified for coding in NVivo by the two authors. The initial coding scheme was developed based on guidance from the business texts and input from the Data Governance Working Group. The coding scheme was amended following the initial pilot coding of the first five papers. The results of this analysis informed the development of the conceptual and operational models for information governance models described in this paper.

The draft conceptual model was developed first. This was vetted through face-to-face meetings, initially with the data governance working group members, which included a patient representative. Feedback largely consisted of requests for clarification or elaboration on the principles selected. After a couple of iterations, the draft was then presented to the Executive Director and lead investigators of the network for their feedback, and with the General Patient Advisory Circle, which has patient representatives from several of the more specialized patient advisory circles associated with the network. At the executive level and in the Patient Circle, there was strong endorsement, particularly for the participatory component being advocated.

The operational framework was developed in conjunction with both the data governance working group and the technical working group that was responsible for developing the operational model for the repository. The technical working group was fortunate to have a patient representative with a strong systems background. The operational framework was designed to address the oversight process for requests to access the data in the repository, as opposed to the technical and procedural security aspects. A similar process was used for vetting the operational model as was done for the conceptual model. As with the conceptual model, revisions consisted more of refining and clarification.

Once the models were endorsed by these groups, we recruited patients, health care professionals, researchers, and an individual with content knowledge in research ethics to participate in the governing and advisory bodies. Patients were recruited through the Network partners who were responsible for recruiting participants in the Patient Advisory Circles. Health care professionals were recruited through our partners in the Canadian Primary Care Sentinel Surveillance System. The two researchers were selected from within the network on the basis of their expertise in observational and clinical trials research.

In the next section, we describe the relevant literature that informed our models, the models we developed, and the initial operation of the governance process.

4. Results

4.1 Conceptual model

4.1.1 Considerations

There are many definitions of information governance. We started with Smallwood's definition: *"…the overarching polices and processes to optimize and leverage information while keeping it secure and meeting legal and privacy obligations, in alignment with stated organizational business objectives*."[14] From this definition, we abstract three core goals of information governance:

1. To optimize data use to meet one's business objectives
2. To keep the data secure
3. To meet legal and privacy obligations

While this definition works well for private sector data holdings and uses, in the context of research using data generated in the course of health care, additional considerations come into play. In the business model, the business entity usually owns the data and leverages the data to meet its business objectives. Hence, the individual firm is responsible for its information governance policies and practices.

In the context of a public sector health research network, data are often drawn from multiple parties where there is often no clear single owner of the data. Indeed, privacy legislation in Canada does not discuss ownership of data. It is framed in the language of custody and control over data, and to duties and obligations of those holding the data. Similarly, in the United Kingdom, the revised Caldicott principles delineate six principles for the secure management of personal health information. The updated version added a seventh principle: the duty to share information can be as important as the duty to protect patient confidentiality.[16]

Consequently, we suggest that, for health research, it is more appropriate to refer to stewardship rather than ownership of data. In addition, contributors to the research enterprise should carry a collective responsibility for information governance and the business objective must also meet a public interest test.[17]

Further, for use of data in the public sector, it is now recognized that, to ensure social license for use of the data, the information governance objectives may need to go beyond mere compliance with formal regulations.[1] Laurie and Sethi argue that "*a good governance framework needs to include an overt statement of the values and standards according to which activity will be assessed. This must be accessible and sufficiently adaptable to be adopted and implemented across all levels of decision-making and by all actors involved in the process*."[13] Similarly, Barocas and Nissenbaum state that "*procedural approaches cannot replace policies based on substantive moral and political principles that serve specific contextual goals and values*."[18]

Based on these considerations, we added a fourth objective to Smallwood's three core goals of information governance:

4. Earn and maintain the trust of patients, partners, data providers, and the public for use of data for research in the public interest.

Trust is, in fact, a linchpin in the public acceptability of the research enterprise. Carter and colleagues argue that: *"… individuals' cooperation with specific research studies is usually secured through three principal mechanisms: their expectations about how research is conducted and regulated; their trust in the institutions and individuals who recruit them; and their beliefs in the wholesomeness and public value of the research endeavour.*"[1]

Elsewhere, they expand on the trust element: "*the public's support and tolerance for research, and its associated risks, often depends far more on an often fragile set of cues about the safety and social good of research participation, and on institutional and professional credentials, than it does on the formal architecture of research regulation,*

or on rational assessment of the detail of information sheets or other documents aimed at gaining 'informed consent'." That does not negate the importance of attention to details around regulation and good communications. It does, however, point to the fragile dependence of the research enterprise on care taken by all researchers to ensure that their work is conducted with high integrity and that the public interest in the research be clearly articulated.

Trust assumes some level of uncertainty and, consequently, vulnerability.[19] We recognized that much of the information use being planned would take us into "*grey zones*" of research use: the indistinct interface between research and clinical practice, the health care system, and management of the health of populations of people living with diabetes. Consequently, we identified the need to incorporate reflexivity into our research governance process. That is, the governance process has to critically assess common regulatory assumptions and practices in the context of new research circumstances and test alternative assumptions and practices.[20]

Particularly when the individual does not have an opportunity to exercise control over the use of their data, it is important to ensure that the public or patients, as appropriate, be involved at multiple stages in the governance process. The importance of stakeholder involvement in governance has been widely recognized.[21-25]

Finally, we needed to consider how the governance process we developed would complement the existing scientific and ethics review processes to which any research protocol would also be subjected. Given the focus on trust of both patients and the health care professionals whose data were being used, we chose to focus on how best to account for the patient's perspective throughout all stages of the research process.

4.1.2 Guiding Principles

Based on the considerations above, we identified eight principles that would guide our governance process:

1. Transparency
2. Accountability
3. Follow rule of law
4. Integrity
5. Participation and inclusiveness
6. Impartiality and independence
7. Effectiveness, efficiency and responsiveness
8. Reflexivity and continuous quality improvement

While these principles have drawn from a wide cross-section of literature, the model has been particularly influenced by the conceptual work of Laurie and Sethi, who called for values-based – as opposed to technical – principles and the incorporation reflexivity to proceed in the face of uncertainty.[11-13 26] Smallwood's definition of information governance informed the first 3 principles[14] and Carter and colleagues, who highlighted the importance of public trust and social licence inspired the introduction of the integrity principle.[1]

Below, we provide a brief description of how these broad principles inform our operational governance process, and how these principles map to the four goals of

information governance described above. A more detailed explanation of the principles may be found in Appendix 1.

1. Transparency

All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in an easily understandable format. (maps to: earn and maintain trust; meet privacy obligations)

2. Accountability

A governing body is accountable to those who will be affected by its decisions or actions. This is enforced through transparency and the rule of law. (maps to: earn and maintain trust, meet legal obligations)

3. Following the rule of law

The governance framework should follow all appropriate legal frameworks and the governing body should ensure compliance with applicable laws, regulations, standards and organizational policies across jurisdictions and institutions. (meet legal obligations, earn and maintain public trust)

4. Integrity

The governing process should ensure that uses of the data:

a) have a clear patient/public interest that is consistent with the intended purpose of the repository;
b) are of high scientific and ethical integrity. Ethical integrity includes: respect for persons, beneficence/non-maleficence, and justice. Justice includes concern for equity; and
c) are maintained in a secure and private manner.

(Meet business objectives; meet legal and privacy obligations; earn and maintain trust; keep data secure)

5. Participation and Inclusiveness

Patients and their families, health care professionals, and researchers should participate in governance over data use – through ongoing communication between the Research Governing Committee and the three patient advisory circles (general, Francophone and immigrant, and Indigenous), and other stakeholder advisory groups.

The governing bodies responsible for access to data in the repository should account for differing interests to reach a broad consensus on what is in the best interest of those with diabetes and their families. Participation in governance should be inclusive, equitable, informed and organized. The full range of positions of the advisory groups should be considered. Ongoing, 2-way engagement between the governing body and advisory groups is best. (Earn and maintain trust)

6. Impartiality and independence

As described above, the goal in deliberations is to reach a broad consensus on what is in the best interest of those living with diabetes and their families. All members in the process must look beyond their personal interests as either patients, health care providers, or researchers.

In addition, the governance process must be able to operate in a zone of bounded independence[27] from management, to ensure that its decisions are free from institutional conflicts of interest. (Earn and maintain trust,)

7. Effectiveness, Efficiency and Responsiveness

Governance over the data repository should ensure the objectives of the organization are being met in an effective and efficient fashion. The governing processes should serve all within a reasonable timeframe. (Earn and maintain trust; meet business objectives)

8. Reflexivity and Continuous Quality Improvement

Information governance should include processes that: allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use. It should promote a culture of reflexivity, and responsiveness among researchers and those governing access to the data. [26] (Earn and maintain trust).

4.2 Operational model

4.2.1 Structure

Building on these governance principles, we then formulated an operational model for our governance process. In this section and the next, we make explicit links to these guiding principles.

Our operational model is summarized in Figure 1. Below, we focus on the roles of the Research Governing Committee and its internal and external advisory groups.

[Insert Figure 1 near here.]

Research Governing Committee

The Research Governing Committee is the overall authority for governance over any research – observational studies or clinical trials – that are conducted involving data or patients in the Network. It has decision-making authority regarding individual studies. The Committee is accountable to the Steering Council, the highest authority in Diabetes Action Canada. (Principle 2: Accountability; Principle 6: Impartiality and independence.)

In its early stages, the Committee is reviewing all applications. This will help it work through and document the important issues in approving applications and to develop standardized approval policies so that, in future when volumes increase and processes become routine, it will only have to review studies that have been flagged by the Repository Manager as requiring Committee input.

There are two ways in which the Research Governing Committee adds value over and above scientific and ethics review. First, it ensures contextual integrity of the research, through an intimate understanding of the data and the health care settings in the system being studied. Equally important, it ensures a patient-centered perspective of the research, by checking that the research:

1. includes patient-relevant outcomes;
2. has taken into adequate account benefits and burdens/risks among people living with diabetes; and

3. is engaging in good communication practices with research participants, particularly around approaching and consenting to participate in research and in communicating about use of their health information for research. (Principle 4: Integrity of purpose)

Half of the Committee members (n=6) are people who are living with diabetes or their caregivers. These people were identified chiefly through the Network partners who were responsible for creating the Patient Advisory Circles, from the same pool of patients used to recruit the Patient Advisory Circle members. Another two members are representatives from the Data Provider Advisory Group, described below. Currently these are physicians who are members of CPCSSN, a subset of whose de-identified electronic medical records reside in Diabetes Action Canada's secure data repository. Another two members are researchers, whose roles are to be technical advisors around scientific validity and merit of the research proposal. The other two members are individuals with expertise in research ethics or law. The Committee may draw in outside experts if required. One of the two co-chairs of the Committee is a patient representative. The other co-chair is drawn from the rest of the members of the Committee. (Principle 5: Participation and inclusiveness)

Data Provider Advisory Group

Currently, the main data source for research activities of the Network consists of the de-identified electronic medical records of physicians participating in CPCSSN. The Data Provider Advisory Group was developed to ensure that the perspectives of these data providers are represented at the Research Governing Committee, through two members that group participate on the Research Governing Committee. Three of the seven members of the Group are front-line family physicians (i.e. not academics). Current members were suggested by CPCSSN Executive. In future, as the sources of research data grow, other health care professionals and data providers will be added to this advisory group.

This group provides advice on research applications, considering: logistics of conducting the research in the practice setting (particularly if a clinical trial); design considerations, as they relate to practice-level decisions; and interpretation of findings. They also serve as liaisons with the larger group of practices that are providing data to the repository. (Principle 5: Participation and inclusiveness)

Patient Circles

Patient Circles were developed at the outset of Diabetes Action Canada.[28] Patient Circle members either have diabetes themselves or are caregivers for a person living with diabetes. They are called upon individually and collectively for advice on multiple aspects of the network endeavours.

Currently, there are three Patient Circles:

1. The General Patient Circle (10-15 people)
2. The Francophone and Immigrant Patient Circle (6-8 people)
3. The Indigenous Patient Advisory Circle (8-15 people)

Members of the patient advisory circles have been drawn from multiple sources, including: an online survey, snowball sampling, and from community organizations.

Members are selected to maximize diversity in age, gender, and geographic location. In addition, candidates are interviewed to identify those with good group skills and a desire to contribute to a goal that exceeds his/her own health situation. They are then offered training in patient-oriented research.

The six patient representatives on the Research Governing Committee have been identified from the General Patient Circle and from a list of potential candidates for the Circles maintained by Diabetes Action Canada. The patient co-Chair of the Research Governing Committee provides reports to the General Patient Circle, apprising them of the activity of the Research Governing Committee and soliciting their input, should there be any controversial issues with which they are grappling. The General Patient Circle is the liaison point because there is representation from the Francophone and Immigrant, and the Indigenous patient circles in the General patient circle. (Principle 5: Participation and inclusiveness). Further, there will be a separate governance process developed for research involving Indigenous people.

External Ethics Advisory Group

This Committee will act as a 'critical friend' to advise on issues that cannot be resolved through deliberations among Research Governing Committee members and the internal advisory groups described above. This advisory group provides one more instance of the governing principle of reflexivity. It will be at arm's length to the Research Governing Committee. It carries no formal authority, but has the freedom to go public if it is concerned about some particular policy direction taken by Diabetes Action Canada. Members will be drawn from ethics and legal scholars outside Diabetes Action Canada, both nationally and internationally, with expertise in: governance over secondary use of data; privacy and access to data; registry-based clinical trials; and practice-based research. (Principle 8: Reflexivity and continuous quality improvement)

4.2.2 Process

Standard operating procedures, including application forms, have been developed. A summary of the application process for research use of the data is provided in Appendix 2.

In the application form, several questions focus on the patient-orientation of the research. For example, the researcher is asked to indicate:
(a) the patient outcomes being measured;
(b) how the research will benefit those living with diabetes or the public more generally;
(c) the potential research-related risks of the study to research participants/data subjects and potential adverse social implications of the research; and
(d) the ways in which people living with diabetes have been involved in the planning of the research. (Principle 4: Integrity of purpose, scientific integrity, ethical integrity)

The Repository Manager reviews the application for completeness. If the project has not received scientific review, the protocol is sent to a scientific advisory group for their approval prior to review by the Research Governing Committee. Researchers are encouraged to submit prior to Research Ethics Board approval to ensure the feasibility and appropriateness of the proposed protocol from the perspective of Diabetes Action Canada. In that way, re-work at the level of the REB is minimized. (Principle 4:

Scientific and ethical integrity; Principle 7: Effectiveness, efficiency, and responsiveness)

Applications for research use of the data are circulated to Research Governing Committee members at least two weeks in advance, to provide an opportunity for patient and data provider members of the Committee to identify issues requiring deliberation with their respective advisory group, in advance of the Research Governing Committee meeting. (Principle 5: Participation and inclusiveness)

At the Committee meeting, when vetting a particular protocol, patient and data provider representatives are invited to comment first. Concerns raised by the researchers and ethics people follow thereafter. The Committee members aim for a consensus-based resolution to any concerns. When Committee members fail to come to consensus, even subsequent to consultation with the Patient Advisory Circles and the Data Provider Advisory Group, The Research Governing Committee may turn to the Ethics Advisory Group for guidance on how to proceed with an application or to seek general policy direction. (Principle 5: Participation and inclusiveness; Principle 6: Impartiality and Independence; Principle 8: Reflexivity and continuous quality improvement)

For applications in which concerns have been raised that there is insufficient patient or health care provider input into the research, the Committee may exercise the option to assign a patient or health care professional member of the Committee (or one of the Advisory Groups) to become a collaborator on the project to provide advice and the patient's or HCP's perspective on the research, throughout the project. They also retain the option to review a draft report prior to publication of findings. (Principle 4: Scientific integrity (to ensure adequate inputs) and Principle 5: Participation and inclusiveness)

The Repository Manager will monitor the time required for protocols to pass various checkpoints in the system, to identify any unnecessary bottlenecks in the system and make recommendations for process improvement. (Principle 7: Effectiveness, efficiency and responsiveness; Principle 8: Reflexivity and continuous quality improvement.)

Finally, Diabetes Action Canada is in the process of posting:

- its policies around data collection, access, use and retention of data; and
- its business processes and governance activities;

so they can be readily accessible to partners and the public. In future, it will also perform regular audits of its data use practices. (Principle 1: transparency; Principle 2: Accountability)

4.2.3 Implementation

In January of 2018, a day-long training workshop was convened for the Research Governing Committee. A training manual was produced for that purpose, and will be posted on the Diabetes Action Canada website. Topics covered in the workshop included:

- An explanation of the types of studies that they would be encountering (data studies; studies making direct contact with patients; and hybrid studies)
- The stages of the research process and how the Research Governing Committee fits into this

- What are research governance and information governance and how will they be applied in the context of Diabetes Action Canada's secure data repository?
- Diabetes Action Canada's governing principles, and how these may apply when reviewing protocols.
- What is the "added value" of the Research Governing Committee vis-à-vis scientific and ethic review
- The structure and function of the governing process and their specific contributions.

Participants were then led through two case studies to test out the application and review process.

4.3 Evaluation

At the time of writing, the Diabetes Action Canada secure data repository has been available for research for only a few months. We are in the early days of implementing the governance process and we are still refining those processes – both the internal functioning of the Research Governing Committee and the consultative processes. We are also continuing to address learning needs of Research Governing Committee members.

Similarly, our plans for the evaluation of the governance process are in the formative stages. Drawing from relevant SPOR[29] and PCORI[30] evaluation frameworks, key issues that we will address in the evaluation include:

- Periodic review of DAC's information governance processes and procedures on to ensure that they conform to and are congruent with the objectives and principles enunciated in this paper.
- Process measures, such as: patient representatives' sense of empowerment in the process; and the timeliness of the reviews – both objectively and from the perspective of researchers who submit applications
- Outcome measures, such as: the proportion of projects reviewed in which changes were recommended and the nature of the changes recommended, including: (a) addition of more patient-relevant outcomes, (b) improvements in participant communications materials (e.g. consent forms and information materials); and (c) reductions in risks and burdens to patient participants.

5. Discussion

In Canada, governance over research involving humans, their data, and their samples focuses on the scientific and ethical integrity of the research. Scientific integrity is largely addressed though peer review processes at the funding and publication stages of the research lifecycle, much like research in other jurisdictions. Ethical integrity is formally addressed through review of research protocols prior to study commencement by research ethics boards at the researchers' institution(s). Ethics guidance is provided by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, second edition (TCPS-2), which addresses research involving human participants, their tissue, or their data.[31] For database research, one still needs to consider relevant privacy laws, which are a provincial jurisdiction. These provincial privacy laws have provisions for secondary research use of data without consent. While they are

substantively similar, founded on the Canadian version of the OECD Privacy Principles,[32 33] there are notable inconsistencies across provinces. Some have health-specific privacy legislation, others legislation that covers all sectors; some have multiple legislation to consider. In some cases small differences in wording and interpretation of legislation present challenges to cross-national data studies.

Most legislation also requires the review and approval of the research protocol by the institution that is the legal data custodian or steward of the data. While Diabetes Action Canada does not currently manage personal – i.e. identifiable – health information, the data it holds are of sufficient granularity as to make it possible to indirectly re-identify individuals, should the data be linked or manipulated. Therefore, data in its custody are not released to researchers. Instead, the researcher must apply for permission to gain secure remote access to the data for analyses.

Within this research governance landscape, Diabetes Action Canada has developed and implemented an information governance process designed to foster public trust in the responsible use of the data in their custody. The operational model has been designed to complement the scientific and ethics review processes that research already receives, and is adaptable to other settings.

We believe the principles in the conceptual model we developed are generalizable to many other settings. That being said, we advise that any organization that considers adopting these principles critically analyse whether they are consonant with the values of the organization, as it is these core principles to which they will repeatedly return when making difficult or controversial decisions.

While all eight governing principles enunciated are important in fostering public trust, the integrity and participation principles are particularly relevant. The integrity principle establishes the criterion that the research must have a clear patient or public interest, and be of high scientific and ethical integrity. The participation principle ensures the substantive participation of patients and other relevant stakeholders, which helps to achieve the integrity principle.

Over the past decade, there have been many studies examining the public's or patients' attitudes toward the conditions under which data studies may be acceptable.[34] Much less common is the involvement of patients or the public in an *ongoing* fashion in the governance over *programs* of data-intensive research. The closest exemplar we were able to find in the area of data-intensive research is the consumer panel for data linkage research, associated with the SAIL databank.[35] Their panel is advisory in nature, addressing both access policy and individual projects and representatives of that panel sit on an independent Information Governance Review Panel.

The governance process developed for Diabetes Action Canada goes one step further. It gives people living with diabetes and data providers majority representation in the key decision-making body in the governance process. We are unaware of any other research governance structures that have instilled as strong a role for patients and health care professionals in a research network. We are not suggesting that all research networks should choose as radical a path. However, we believe strong lay participation in policy making and governance is an increasingly important approach to securing the trust of the public.

As our research platforms grow in size and scope, the need for public trust in the uses of these datasets also grows. We believe our model for governance over health information platforms adds substantively to the conceptual and methodologic foundations for information governance to help address this need.

Competing interests:

The Institute of Health Policy, Management and Evaluation received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Willison's time for the development of the governance process for the Diabetes data repository.

The Department of Family and Community Medicine, University of Toronto, received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Greiver's time for the development of the Diabetes data repository.

Dr. Keshavjee received personal fees from InfoClin Inc during the conduct of the study toward designing the architecture of the Diabetes data repository. In addition, Dr. Keshavjee has a patent "Prediction of Diabetes Mellitus Type 2 Using Biomarkers in Electronic Health Records and Differential Calculus", pending.

Funding:

This work was supported by Diabetes Action Canada, which is funded, in part, through a Canadian Institutes of Health Research chronic disease network grant under the Strategy for Patient-Oriented Research (Funding Reference number: SCA 145101)

References

1. Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why care.data ran into trouble. Journal of medical ethics 2015;**41**(5):404-09.
2. Powles J, Hodson H. Google DeepMind and healthcare in an age of algorithms. Health and Technology 2017;**7**(4):351-67.
3. Anonymous. Strategy for Patient-Oriented Research 2018 [Available from: http://www.cihr-irsc.gc.ca/e/41204.html.
4. Anonymous. Strategy for patient-oriented research. Patient engagement framework. Ottawa, Ontario: Canadian Institutes of Health Researach, 2014.
5. Anonymous. Launch of the Diabetes Action Canada National Data Repository: Diabetes Action Canada; 2018 [Available from: https://diabetesaction.ca/launch-of-the-diabetes-action-canada-national-diabetes-repository/.
6. Garies S, Birtwhistle R, Drummond N, et al. Data Resource Profile: National electronic medical record data from the Canadian Primary Care Sentinel Surveillance Network (CPCSSN). Int J Epidemiol 2017;**46**(4):1091-92f.
7. Birtwhistle R, Keshavjee K, Lambert-Lanning A, et al. Building a pan-Canadian primary care sentinel surveillance network: initial development and moving forward. J Am Board Fam Med 2009;**22**(4):412-22.
8. Clinical Practice Research Datalink: Medicines and Healthcare Products Regulatory Agency, UK; [Available from: https://www.cprd.com/.
9. Burton PR, Murtagh MJ, Boyd A, et al. Data Safe Havens in health research and healthcare. Bioinformatics (Oxford, England) 2015;**31**(20):3241.
10. Lea NC, Nicholls J, Dobbs C, et al. Data Safe Havens and Trust: Toward a Common Understanding of Trusted Research Platforms for Governing Secure and Ethical Health Research. JMIR medical informatics 2016;**4**(2):e22.
11. Laurie G, Sethi N. Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data. European Journal of Risk Regulation : EJRR 2013;**4**(1):43.
12. Sethi N, Laurie GT. Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together. Medical Law International 2013;**13**(2-3):168-204.
13. Laurie G, Sethi N. Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework. Edinburgh: University of Edinburgh, 2012.
14. Smallwood R. *Information governance: Concepts, strategies, and best practices*. Hoboken, NJ: Wiley, 2014.
15. Ladley J. *Data governance: How to design, deploy, and sustain an effective data governance program*. Waltham, MA: Morgan Kauffman, 2012.
16. Department of Health. Information: To share or not to share? The Information Governance Review. 2013. https://www.gov.uk/government/publications/the-information-governance-review (accessed 2018-09-25).
17. Simm K. The Concepts of Common Good and Public Interest: From Plato to Biobanking. Cambridge Quarterly of Healthcare Ethics 2011;**20**(4):554-62.
18. Barocas S, Nissenbaum H. Big Data's End Run around Anonymity and Consent. Privacy, Big Data, and the Public Good. New York, NY: Cambridge University Press, 2014.

19. Nissenbaum H. Securing trust online: Wisdom or oxymoron? Boston University Law Review 2001;**81**(3):635-64.
20. Laurie GT, Dove ES, Ganguli-Mitra A, et al. Charting Regulatory Stewardship in Health Research Making the Invisible Visible. CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 2018;**27**(2):333-47.
21. O'Doherty KC, Burgess MM, Edwards K, et al. From consent to institutions: Designing adaptive governance for genomic biobanks. Social Science and Medicine 2011;**73**(3):367-74.
22. Greenhalgh T, Morris L, Wyatt JC, et al. Introducing a nationally shared electronic patient record: Case study comparison of Scotland, England, Wales and Northern Ireland. International Journal of Medical Informatics 2013;**82**(5):e125-e38.
23. Geissbuhler A, Safran C, Buchan I, et al. Trustworthy reuse of health data: a transnational perspective. International journal of medical informatics 2013;**82**(1):1-9.
24. Allen C, Des Jardins TR, Heider A, et al. Data Governance and Data Sharing Agreements for Community-Wide Health Information Exchange: Lessons from the Beacon Communities. eGEMs (Generating Evidence & Methods to improve patient outcomes) 2014;**2**(1):1057.
25. Kaushal R, Hripcsak G, Ascheim DD, et al. Changing the research landscape: the New York City Clinical Data Research Network. JAMIA 2014;**21**(4):587-90.
26. Laurie G. Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law. Human genetics 2011;**130**(3):347-56.
27. Beecher JA. The prudent regulator: politics, independence, ethics, and the public interest. Energy Law Journal 2008;**29**(2):577.
28. Anonymous. How partient-parters are involved 2018 [Available from: https://diabetesaction.ca/patient-partners-involved/.
29. Anonymous. Evaluation of the Strategy for Patient-Oriented Research. Ottawa, Canada: KPMG, 2016.
30. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. Journal of comparative effectiveness research 2015;**4**(2):133.
31. 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*. Ottawa: Interagency Secretariat on Research Ethics, 2014.
32. Organisation for Economic Co-operation and Development. The OECD Privacy Framework. Paris, France, 2013.
33. Canadian Standards Association. Model code for the protection of personal information. A national standard of Canada. Ontario, 1996.
34. Aitken M, De St Jorre J, Pagliari C, et al. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Medical Ethics 2016;**17**(1):1-24.
35. Jones KH, McNerney CL, Ford DV. Involving consumers in the work of a data linkage research unit. International journal of consumer studies 2014;**38**(1):45-51.

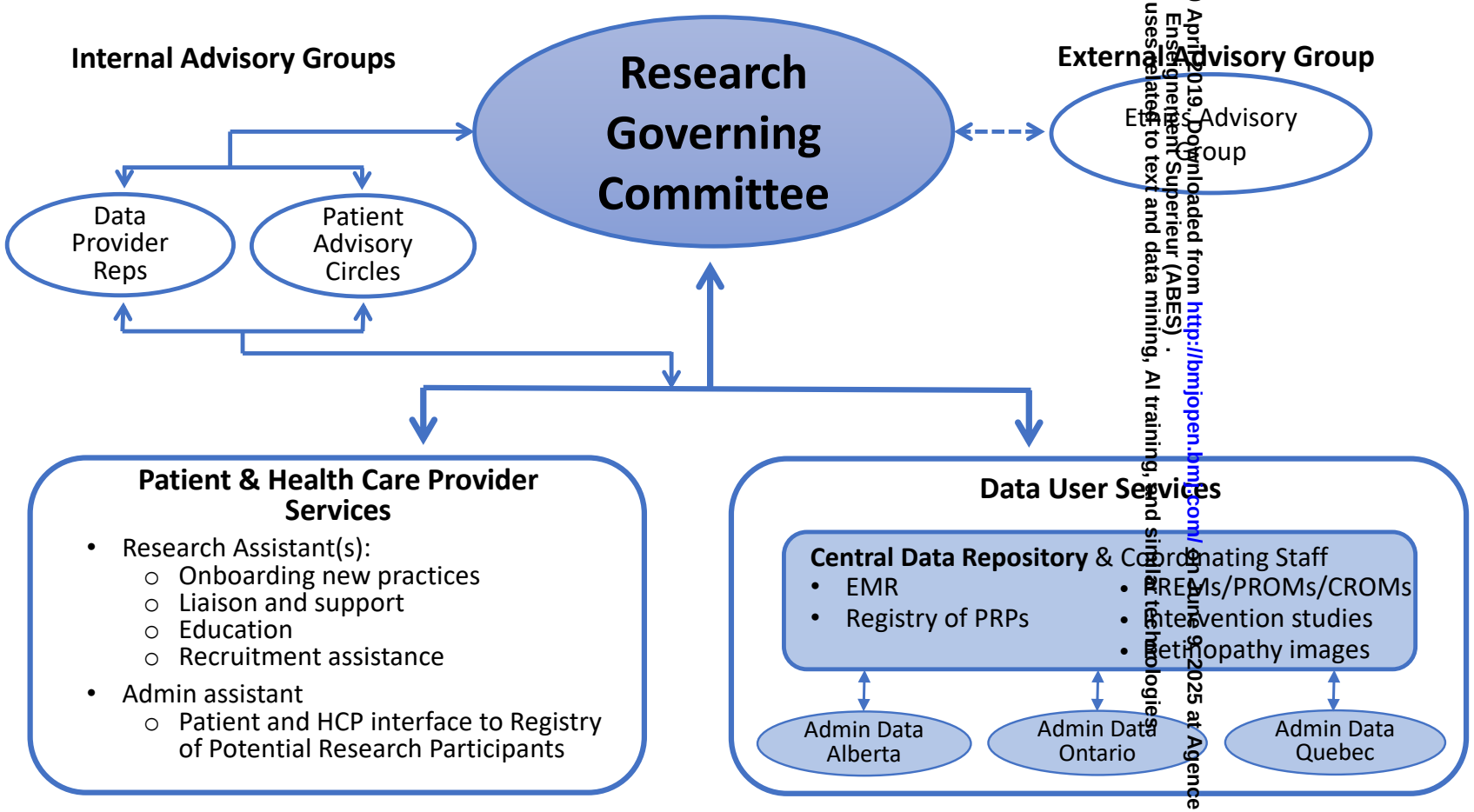
Additional Files:

Figure 1. Diabetes Action Canada Research Governance Structure

Appendix 1. Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

Appendix 2. Application process for research use of the data in the research repository

Figure 1. Diabetes Action Canada Research Governance Structure



Appendix 1

Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

1. Preamble

1.1 Information governance goals and principles

A clear governance framework for the collection, use and storage of health data is critical to establishing and maintaining trust that data are secure and being used responsibly. In this document, we propose governing principles and an operational framework adapted from the field of Information Governance (IG) to governing the data to be held in the custody of Diabetes Action Canada.

The field of IG encompasses a broad range of concepts and activities from records and content management to business intelligence. IG is focused on analyzing and optimizing how information is accessed, controlled, managed, shared, stored, preserved and audited. Smallwood defines IG as "The overarching polices and processes to optimize and leverage information while keeping it secure and meeting legal and privacy obligations, in alignment with stated organizational business objectives."(Smallwood 2014) He discusses key outputs of IG, such as mapping information creation and usage, ensuring data has integrity, validity, accuracy and quality, and harvesting and leveraging information.

1.2 Application to governing health data: values-based governance

The IG field is based on a business model, where data are owned and governed by an individual enterprise and used mainly for purposes that meet business requirements. Governing the use of health-related data for research purposes differs in at least two fundamental ways:

1. The holders of health-related data are not "owners" of the data. Rather, they are stewards entrusted with the responsibility for ensuring appropriate use of the data. (In Ontario, legislation uses the term "data custodian".)
2. Responsibility for appropriate use is shared among the many data stewards or custodians that contribute data to the research project.

As research is usually not specified as a primary use of the data collected, data stewards or custodians must be satisfied that the data they contribute meet legal and ethics requirements, are appropriately governed, such that any request for use of the data for research satisfies some public interest test.

In their working paper describing elements of 'good governance' of health-related research involving patient data, Laurie and Sethi note: "A good governance framework needs to include an overt statement of the values and standards according to which activity will be assessed. This must be accessible and sufficiently adaptable to be adopted and implemented across all levels of decision-making and by all actors involved in the process." (Laurie and Sethi 2012) Similarly, remarking about the shortcomings of anonymization and consent to adequately address privacy in an era of Big Data, Barocas and Nissenbaum conclude: Procedural approaches cannot replace policies based on substantive moral and political principles that serve specific contextual goals and values." (Barocas and Nissenbaum 2014)

2. Diabetes Action Canada repository goals and principles

Diabetes Action Canada is creating a research repository that will serve as a platform for observational studies. Within the research repository, it will be possible to link: (1) clinical data from primary care practices, laboratories and other clinical systems; (2) administrative data derived from health care transactions, sociodemographic data; (3) retinopathy images from ophthalmologists, optometrists, and special clinics and (4) patient reported outcomes and evaluations. The research repository will also contain a registry of potential research participants that will facilitate recruitment of patients into prospective clinical studies by identifying in advance patients with diabetes who agree to be approached to participate in varied research projects.

Contributing data sources and anticipated requests for access to data will be varied and geographically dispersed. An efficient response to this heterogeneity will require clear and definitive governance processes.

Our goals are to:

1. Optimize use of data to meet Diabetes Action Canada objectives
2. Keep data secure and maintain the integrity and quality of data
3. Meet legal, privacy and confidentiality obligations
4. Earn and maintain the trust of patients, partners, and public for use of data for research

For researchers to earn and maintain public trust, our governance framework must go beyond compliance with formal regulations to earn and maintain a 'social licence' for the use of the data.(Carter, Laurie et al. 2015) The Diabetes Action Canada data repository and patient registry will accomplish this through a focus on research that is scientifically sound, ethically robust and in the public interest. Strong data safeguards and responsiveness to the evolving societal context are also important to building public trust.

In anticipation of information use requests that may take us into "grey zones" of research governance, we have included the concept of 'reflexivity' in the proposed principles. Reflexivity is a way of governing that "encourages actors to scrutinize and reconsider their underlying assumptions, institutional arrangements, and practices" (Laurie 2011) in order to encourage learning and allow research to proceed in the face of uncertainty.

3. Principles for Governance of the Diabetes Action Canada Repository

1. Transparency

All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in easily understandable format.

Diabetes Action Canada will accomplish this in the following ways:

- Establish clear policies around data collection, access, use, and retention, and make these policies readily accessible to Diabetes Action Canada partners and to the public
- Document business processes and governance activities
- Establish and communicate consequences of breach
- Perform regular audits of data use practices
- Maintain a culture of openness

2. Accountability

A governing body is accountable to those who will be affected by its decisions or actions. This is enforced through transparency and the rule of law.

Within Diabetes Action Canada:

- The highest level of governance within Diabetes Action Canada rests with the Steering Council. Patients or their representatives constitute 50% of the Steering Council.
- The oversight and communication of policies and procedures related to information governance will be delegated to the Research Governance Committee (RGC), which will report to the Steering Council.
- The RGC will serve as a resource to the data steward, who will be responsible for the day-to-day implementation of these policies.
- The RGC will also ensure that the policies and procedures are kept up-to-date in response to emerging issues.

3. Following the rule of law

The governance framework should follow all appropriate legal frameworks and the governing body should ensure compliance with applicable laws, regulations, standards and organizational policies across jurisdictions and institutions.

Diabetes Action Canada will:

- Provide protection from data breach, corruption and loss
- Follow legal frameworks for data collection, retention, use and disposition
- Develop internal controls to monitor compliance

4. Integrity

The governing process should ensure that uses of the data: are consistent with the goals of Diabetes Action Canada and the intended purpose of the repository; and are of high scientific and ethical integrity.

Applications for use of data in the custody of Diabetes Action Canada must demonstrate:

A. Integrity of purpose:
   - There is a clear patient/public interest that the research will address. This should be consistent with the mission of Diabetes Action Canada.

B. Scientific integrity:
   - The applicant's research team has the capacity to analyse the data
     - For studies that are led by patients, if there is not already a researcher partner identified, Diabetes Action Canada willl endeavour to link the applicant with researchers who could provide the needed analytic support.
   - The research plan demonstrates the ability to answer the researcher's question with high validity.
     - For data studies the focus will be on the analytic plan and the capacity of the data – either alone or in combination with other data provided by the researcher – to answer the research question with high validity.

C. Ethical integrity:
   - Respect for persons. For example, as appropriate: addressing privacy, confidentiality, consent, ability to withdraw at any time;

- Beneficence/non-maleficence. For example:
  - minimizing harm – both to research participants/data subjects and in terms of the use of the findings;
  - maximizing benefit;
- Justice. For example:
  - The research will not exploit patients who participate in in the research or whose data are used in the research.
  - The research aims to either reduce inequity or, at the least, not exacerbate existing inequities.

5. Participation and Inclusiveness

Patients and their families, health care professionals, and researchers should participate in governance over data use – through the patient advisory councils and other stakeholder advisory groups.

The governing bodies responsible for access to data in the Diabetes Action Canada repositories should take into account differing interests to reach a broad consensus on what is in the best interest of those with diabetes and their families.

- Participation in governance should be inclusive, equitable, informed and organized;
- The full range of positions of the advisory groups should be considered in the development and implementation of governing mechanisms;
- Ongoing, 2-way engagement between the governing body and advisory groups is best.

In addition, applicants for use of data in Diabetes Action Canada's custody must demonstrate how patients – and, as appropriate, other stakeholders such as health care providers – contribute to the research throughout the lifecycle of the research, from development of the research question through KTE.

6. Impartiality and independence

As described above, the goal in RGC deliberations is to reach a broad consensus on what is in the best interest of those with diabetes and their families. All members of the RGC must look beyond their personal interests as either patients, health care providers, or researchers.

- In the event of personal conflict of interest – whether actual or perceived – individual members of the RGC will declare their conflict up front, and recuse themselves from deliberations on that project. The conflict may be, for example, financial, collegial, or intellectual.

In addition, the RGC must be able to operate in a zone of bounded independence* from Diabetes Action Canada management, to ensure that its decisions are free from institutional conflict of interest.

* Beecher argues that 'regulatory autonomy and discretion are not absolute but "bounded" and regulators are held responsible for their decisions and their behavior in a complex and diffuse system of interests, relationships, and processes.' Beecher, J. A. (2008). "The prudent regulator: politics, independence, ethics, and the public interest." Energy Law Journal **29**(2): 577.

- This will be accomplished, at least in part, through its line of accountability directly to the highest level of authority within Diabetes Action Canada – the Steering Council – and through its composition of 50% membership being patients or patient advocates.

7. Effectiveness, Efficiency and Responsiveness

Governance over the data repository should ensure the objectives of Diabetes Action Canada are being met in an effective and efficient fashion. The governing processes should serve all within a reasonable timeframe.

- Resources should be managed to ensure timely and secure access to the right data for the intended purpose. This includes:
  - Training and education of people on policies and procedures
  - Ensuring high quality metadata to aid efficient and valid data use

8. Reflexivity and Continuous Quality Improvement

Information governance should include processes that: allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use.

To accomplish this, Diabetes Action Canada will:

- Promote a culture of reflexivity[†], and responsiveness among researchers and those governing access to the data. For example: develop virtuous feedback loops that encourage researchers to openly discuss with the data custodian any data challenges and ways to address these challenges.
- Develop an external ethics advisory group that will serve as a "critical friend" to facilitate reflexive decision-making in the face of uncertainty

In addition, as stewards of the data repository, Diabetes Action Canada will endeavor to enrich the data in the repository over time by incorporating additional data gathered in the course of research studies that used Diabetes Action Canada data or that recruited patients in the Diabetes Action Canada registry of potential research participants.

4. References

Barocas, S. and H. Nissenbaum (2014). Big Data's End Run around Anonymity and Consent. Privacy, Big Data, and the Public Good. New York, NY, Cambridge University Press.

Beecher, J. A. (2008). "The prudent regulator: politics, independence, ethics, and the public interest." Energy Law Journal **29**(2): 577.

Carter, P., G. T. Laurie and M. Dixon-Woods (2015). "The social licence for research: why care.data ran into trouble." Journal of medical ethics **41**(5): 404-409.

[†] Reflexive governance is a mode of steering that encourages actors to scrutinize and reconsider their underlying assumptions, institutional arrangements, and practices. It requires that actors have the capacities and competencies to interact in relational and deliberative ways; that they engage in and learn from experimentation through collaborative forms of joint enquiry; and that their learning is informed by cognitive processes entailing the adjustment and redefinition of frames, representations and collective identities. Laurie, G. (2011). "Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law." Human genetics **130**(3): 347-356.

Laurie, G. (2011). "Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law." Human genetics **130**(3): 347-356.

Laurie, G. and N. Sethi (2012). Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework. Edinburgh, University of Edinburgh.

Smallwood, R. (2014). Information governance: Concepts, strategies, and best practices. Hoboken, NJ, Wiley.

Appendix 2. Application process for research use of the data in the research repository

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Submission and Approval Process	SOP#	Diabetes Action CanadaNDR-PSAP001.0
Document Number	001	Author	Conrad Pow
Version Number	1.0	Reviewer	
Superseded Version	Draft	Reviewer Date	
Effective Date	05/01/2018	Status	

1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to define all key aspects involved in the Submission and Approval of projects requesting to access to data held within the Diabetes Action Canada National Diabetes Repository.

2. SCOPE

This document is intended for all projects that have been submitted to the Diabetes Action Canada National Diabetes Repository. This applies to Diabetes Action Canada staff, Diabetes Action Canada Committee Members and Diabetes Action Canada researchers wishing to conduct a secondary data analysis project.

3. ROLES AND RESPONSIBILITIES

3.1 Diabetes Action Canada Repository Manager: Responsible for the overall operations (recruitment, developing policies and procedures, site relationship) and communication regarding the Diabetes Action Canada National Diabetes Repository.

3.2 Diabetes Action Canada Repository Data Manager: Responsible for data extraction, processing, quality check, destruction, reports, transfer, secondary data usage, and managing the data dictionary; responsible for updating the Diabetes Action Canada Repository Manager on changes or problems with the Diabetes Action Canada National Diabetes Repository.

3.3 Diabetes Action Canada Repository Research Administrator: Responsible for managing the participant database and facilitating meetings.

3.4 Diabetes Action Canada Researcher: Responsible for ensuring that all project team members, including self, are familiar with the Diabetes Action Canada Policies and Procedures pertaining to the National Diabetes Repository. Will be responsible for ensuring that all project team members have signed COI statement. Will be responsible for the management and oversight of the project.

3.5 Diabetes Action Canada Repository Scientific Advisory Committee (SAC): The SAC is made up of 3 members. The SAC is responsible for reviewing projects

proposing to access data in the Diabetes Action Canada National Diabetes Repository. The SAC will review the scientific merit and methodology of the project.

3.6 Diabetes Action Canada Repository Research Governing Committee (RCG): The RCG will ensure the focus of the proposed project is aimed at what is in the best interest of the patient and that aligns with Diabetes Action Canada's mission and values.

4. SECONDARY DATA USAGE

Data in the Diabetes Action Canada Repository will only be available to Diabetes Action Canada researchers wishing to conduct secondary data analysis. Once approved, they will be given remote access to a specified data cut in a secure zone at the Centre for Advanced Computing Canada (CAC).

5. SUBMISSION AND APPROVAL PROCESS

STEP 1: Diabetes Action Canada Researcher will electronically fill and submit an Access Request Form (Appendix 1) through the Researcher portal at https://repository.diabetesaction.ca The form outlines the purpose, methodology, requested data elements and timeframe. It also requires a copy of the full research proposal and whether there is any identified or perceived risks.

STEP 2: The Repository Manager and the Repository Data Manager will review the Access Request Form to assess the feasibility of the project based on the data elements requested. This may include a meeting with the Researcher to discuss the data elements requested, project objectives and overall budget.

STEP 3: If the project has been peer-reviewed (eg. CIHR has reviewed and reviewed the submitted protocol) then proceed to Step 4, if not, the Access Request Form and full research proposal will be reviewed by the National Diabetes Repository Scientific Advisory Committee (SAC) to assess the scientific merit and methodology of the project. The researcher will be updated on the scientific assessment by the SAC, if any concerns are raised, the Researcher will be requested address them prior to the project moving any further.

STEP 4: The Repository Manager will provide the RGC a copy of the Access Request Form to advise on, but not limited to: (1) The project is in the best interest of the patients; (2) The project goals align with institutional mission and values. Once approval has been received from the RGC, the Repository Manager will provide the Researcher written confirmation that the proposed project is feasible. The Confirmation of Feasibility (COF) letter will also identify the estimated costs for conducting the project.

STEP 5: If the project is not part of a larger REB approval, the Researcher will be required to apply for REB approval. The COF letter can be provided to the REB as supporting documentation assuring Diabetes Action Canada supports the project. In addition, the Researcher must submit confirmation of funding (Peer Reviewed Grant, Institutional Funds, Investigator Funds…)

STEP 6: Once REB approval has been obtained, the Researcher will upload the REB approval letter through the Researcher portal along with the REB submission.

STEP 7: The Repository Manager, along with the RGC, will review the Access Request Form to ensure it aligns with the REB submission and approval.

STEP 8: After confirmation of REB alignment, the Repository Manager will provide the Researcher Diabetes Action Canada Repository Researcher Agreement (Appendix B) and Confidentiality Agreement (CA) (Appendix C).

STEP 9: After both Agreements have been fully executed, the Repository Manager and the Repository Data Manager will work with the Researcher to finalize the required data elements to create a Dataset Creation Plan (DCP). The DCP will be used to create a project specific dataset.

STEP 10: The Repository Data Manager will upload the project specific dataset to the secure workspace for the researcher to conduct analysis.

STEP 11: Once all agreements are in place, the Repository Data Manager will provide the Researcher the login credentials to remotely access the secure environment.

ACCESS TO DATA FOR SECONDARY USE FOR RESEARCH

Researcher completes **access request form** that outlines the project, methodology and timeframe. This is sent to the Repository Manager for review. 1

Repository Manager reviews the request and confirms the feasibility of the project. Once confirmed, the **request is sent to the Scientific Advisory Committee**. 2

The Research Governing Committee (RGC) will review to advise if the project is in the best interest of patients and project goals are in line with organization mission and values. If concerns are raised, revisions to the request will be necessary, if not, w**ritten confirmation of acceptance** will be provided to the researcher. 3

The Researcher will be required to provide confirmation of **REB approval,** confirmation of **funding** and a signed **confidentiality agreement**. 4

Documents will be reviewed for alignment with REB submission. Researcher will enter into an **Agreement with Diabetes Action Canada**. This Agreement will outline the data access provisions, requirements and any controls. 5

Researcher will be able to access the repository in the **secure environment** to carry out their analytical work. **Data will not be disclosed Outside** of this of the physical or virtual environment 6

BMJ Open

Participatory governance over research in an academic research network: the case of Diabetes Action Canada

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026828.R3
Article Type:	Communication article
Date Submitted by the Author:	15-Feb-2019
Complete List of Authors:	Willison, Donald; University of Toronto, Institute of Health Policy, Management and Evaluation Trowbridge, Joslyn; University of Toronto Dalla Lana School of Public Health Greiver, Michelle; University of Toronto, Family and Community Medicine Keshavjee, Karim; Infoclin Mumford, Doug; Patent representative Sullivan, Frank; University of St. Andrews, ; North York General hospital,
Primary Subject Heading:	Health informatics
Secondary Subject Heading:	Ethics, Health policy, Health services research, Patient-centred medicine
Keywords:	Information governance, research governance, participatory governance

Participatory governance over research in an academic research network
The case of Diabetes Action Canada

Donald J. Willison
Joslyn Trowbridge
Michelle Greiver
Karim Keshavjee
Doug Mumford
Frank Sullivan

Manuscript word count: 5420

Abstract word count: 263

Author Contributions:

Willison and Trowbridge conducted the literature review and developed the initial and successive conceptual and operational governance models. Greiver, Keshavjee, and Sullivan reviewed and suggested revisions to the models. Willison developed the training workshop syllabus and content. Greiver and Mumford reviewed and suggested revisions to the workshop material. Willison wrote the initial draft of the manuscript and made subsequent revisions, in response to feedback from Trowbridge, Greiver, Keshavjee, Mumford and Sullivan.

Acknowledgements:

We wish to acknowledge the contribution and assistance of Conrad Pow, Senior Project Manager, and members of the Data Governance Working Group and the Technical Working Group. Mr. Pow assisted with the development and refinement of the operational protocol for the application and review process for requests to access to the data. The members of the Data Governance Working Group were charged with setting the terms of reference for the governance process and reviewing successive drafts of the conceptual and operational models of the governance process. The Technical Working Group reviewed the drafts of the operational model.

Corresponding author:
Donald Willison, ScD
Associate Professor
Institute of Health Policy, Management and Evaluation
University of Toronto
155 College Street, Suite 425
Toronto, Ontario, Canada L9G 4V7
don.willison@utoronto.ca

Abstract

Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. Researchers need to develop governance policies that can assure the public that their information is being used responsibly.

Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

Methods

We developed our governance principles and processes through literature review and iterative consultation with key actors in the research network including: a data governance working group, the lead investigators, and patient advisors. We then recruited persons to participate in the governing and advisory bodies.

Results

Our governance process is informed by eight principles: (1) transparency; (2) accountability; (3) follow rule of law; (4) integrity; (5) participation and inclusiveness; (6) impartiality and independence; (7) effectiveness, efficiency and responsiveness; and (8) reflexivity and continuous quality improvement. We describe the rationale for these principles, as well as their connections to the subsequent policies and procedures we developed.

We describe the function of the Research Governing Committee (RGC), the majority of whom are either persons living with diabetes or physicians whose data are being used, and the patient and data provider advisory groups with whom they consult and communicate.

Conclusions

We developed a values-based information governance framework and process for Diabetes Action Canada that adds value over-and-above existing scientific and ethics review processes by adding a strong patient perspective and contextual integrity. This model is adaptable to other secure data repositories.

Key words:

Information governance; research governance; participatory governance;

Strengths and Limitations of this study

- The governance framework is built on values-based principles designed to gain the trust of patients and health care providers
- Half of the research governing committee members are people living with diabetes or their caregivers
- While this is a case study, we believe the governing principles are generalizable to other health research data repositories, and the operational model is adaptable to other settings.

1. Background

Digital data generated in the course of clinical care is increasingly being leveraged for a wide range of secondary purposes. These include health research by both public and private sector researchers. Recent events involving questionable uses of these records have shaken the confidence of the public regarding potential misuse of their personal information.[1 2] As the number and size of health information platforms grow, and data linkages continue to become more extensive, researchers need to develop governance policies that can assure the public that their information is being used ethically, securely and with a clear public interest. In this paper, we present the conceptual and operational governance frameworks developed for Diabetes Action Canada – a pan-Canadian research consortium funded by the Canadian Institutes of Health Research's Strategy for Patient-Oriented Research (SPOR) Program in Chronic Disease.[3]

Diabetes Action Canada's mandate is to improve the lives of Canadians living with diabetes and its related complications. It facilitates connections between patients, their primary healthcare providers, specialists, and health researchers with the goals of improving health care and reducing costs to the health care system. A key component of its mandate is to conduct patient-oriented research to help achieve these goals.[4]

To support its research activities, Diabetes Action Canada has developed a national diabetes repository – a secure analytical research environment situated at the Centre for Advanced Computing at Queen's University in Kingston, Ontario – where analyses can be conducted securely in a virtual environment.[5] The data in the repository originate from the electronic medical records (EMRs) from the practices of family physicians who contribute to the Canadian Primary Care Sentinel Surveillance Network (CPCSSN).[6]

The CPCSSN extracts de-identified EMR records from the practices of consenting primary care providers. Structured data from the chart are included as well as selected free text terms. This includes data from the summary health profile such as health conditions, allergies and immunizations. CPCSSN also extracts selected laboratory data, vital signs, medications prescribed, dates of encounters, dates and types of referrals and risk factors (smoking status, alcohol use) and patient demographics.[6]

Patients are notified of the collection for research purposes through posted notices in the physicians' offices. Patients can opt out at any time by contacting a member of the practice-based research network in their region. Notices advising patients of this are posted in the offices of participating primary care providers.[7]

The data extracted from these patients' records are de-identified at the source. Prior to de-identification, a pseudonymous variable is generated and a key-code file allowing re-identification is generated at the site of care and left there. This permits linkage with other records and re-identification of records at source. Only the subset of records of persons living with Type 1 or Type 2 diabetes is imported into the repository.

Other systems internationally use similar methods to extract, transform and manage primary care EMR data for purposes of clinical research, epidemiology and the study of health systems. As an example, the UK's Clinical Practice Research Datalink (CPRD) has been in existence for over 30 years.[8] The CPRD extracts de-identified data that are similar to those in CPCSSN and manages a growing list of research services based on these data. It has been part of more than 2,000 peer reviewed publications on a range of topics including medication use and safety, health policy and chronic disease management. The CPCSSN has now been in existence for a decade; its pattern of growth and development as Canada's primary care EMR repository is following a path similar to the CPRD's.

During this developmental phase, access to the data in the repository is restricted to researchers within Diabetes Action Canada. In future, the intention is for this to be open to outside researchers.

Early on, the need to develop a process to govern access to the data was recognized. While there was a considerable body of literature addressing information governance within the business literature, at the outset of this project, we were aware of relatively little literature in the context of health data repositories.[9-13]

In this paper we describe the conceptual and operational models that were developed for the Diabetes Action Canada research governance process, with the hope that it may provide a model for other researchers who are also addressing similar issues over governance of the research in their research network.

2. Aim

To develop a generalizable model for governance of research emanating from health data repositories that will invoke the trust of the patients and the health care professionals whose data are being accessed for health research.

3. Methods

Our work was informed by three sources of literature:

1. basic business texts in data governance;[14 15]
2. a database of 32 articles gathered from the authors' existing library and recommendations from our Data Governance Working Group; and
3. a scoping review of the literature using Ovid Medline from 2000 to 2017, with the assistance of a health sciences research librarian.

The full scoping review process and resulting analysis are the subject of a forthcoming publication. Search terms for the scoping review combined the topics of biobank and electronic medical records, governance and regulation, and social licence and trust. This returned 1075 articles, which were combined with the earlier database of 32

articles. On screening of abstracts of the 1075 papers, 122 articles were identified for coding in NVivo by the two authors. The initial coding scheme was developed based on guidance from the business texts and input from the Data Governance Working Group. The coding scheme was amended following the initial pilot coding of the first five papers. The results of this analysis informed the development of the conceptual and operational models for information governance models described in this paper.

The draft conceptual model was developed first. This was vetted through face-to-face meetings, initially with the data governance working group members, which included a patient representative. Feedback largely consisted of requests for clarification or elaboration on the principles selected. After a couple of iterations, the draft was then presented to the Executive Director and lead investigators of the network for their feedback, and with the General Patient Advisory Circle, which has patient representatives from several of the more specialized patient advisory circles associated with the network. At the executive level and in the Patient Circle, there was strong endorsement, particularly for the participatory component being advocated.

The operational framework was developed in conjunction with both the data governance working group and the technical working group that was responsible for developing the operational model for the repository. The names and affiliations of the data governance and technical working group members may be found in Appendix 1. The technical working group was fortunate to have a patient representative with a strong systems background. The operational framework was designed to address the oversight process for requests to access the data in the repository, as opposed to the technical and procedural security aspects. A similar process was used for vetting the operational model as was done for the conceptual model. As with the conceptual model, revisions consisted more of refining and clarification.

Once the models were endorsed by these groups, we recruited patients, health care professionals, researchers, and an individual with content knowledge in research ethics to participate in the governing and advisory bodies. Patients were recruited through the Network partners who were responsible for recruiting participants in the Patient Advisory Circles. Health care professionals were recruited through our partners in the Canadian Primary Care Sentinel Surveillance System. The two researchers were selected from within the network on the basis of their expertise in observational and clinical trials research.

In the next section, we describe the relevant literature that informed our models, the models we developed, and the initial operation of the governance process.

4. Results

4.1 Conceptual model

4.1.1 Considerations

There are many definitions of information governance. We started with Smallwood's definition: *"…the overarching polices and processes to optimize and leverage information while keeping it secure and meeting legal and privacy obligations, in alignment with stated organizational business objectives*."[14] From this definition, we abstract three core goals of information governance:

1. To optimize data use to meet one's business objectives
2. To keep the data secure
3. To meet legal and privacy obligations

While this definition works well for private sector data holdings and uses, in the context of research using data generated in the course of health care, additional considerations come into play. In the business model, the business entity usually owns the data and leverages the data to meet its business objectives. Hence, the individual firm is responsible for its information governance policies and practices.

In the context of a public sector health research network, data are often drawn from multiple parties where there is often no clear single owner of the data. Indeed, privacy legislation in Canada does not discuss ownership of data. It is framed in the language of custody and control over data, and to duties and obligations of those holding the data. Similarly, in the United Kingdom, the revised Caldicott principles delineate six principles for the secure management of personal health information. The updated version added a seventh principle: the duty to share information can be as important as the duty to protect patient confidentiality.[16]

Consequently, we suggest that, for health research, it is more appropriate to refer to stewardship rather than ownership of data. In addition, contributors to the research enterprise should carry a collective responsibility for information governance and the business objective must also meet a public interest test.[17]

Further, for use of data in the public sector, it is now recognized that, to ensure social license for use of the data, the information governance objectives may need to go beyond mere compliance with formal regulations.[1] Laurie and Sethi argue that "*a good governance framework needs to include an overt statement of the values and standards according to which activity will be assessed. This must be accessible and sufficiently adaptable to be adopted and implemented across all levels of decision-making and by all actors involved in the process*."[13] Similarly, Barocas and Nissenbaum state that "*procedural approaches cannot replace policies based on substantive moral and political principles that serve specific contextual goals and values*."[18]

Based on these considerations, we added a fourth objective to Smallwood's three core goals of information governance:

4. Earn and maintain the trust of patients, partners, data providers, and the public for use of data for research in the public interest.

Trust is, in fact, a linchpin in the public acceptability of the research enterprise. Carter and colleagues argue that: *"… individuals' cooperation with specific research studies is usually secured through three principal mechanisms: their expectations about how research is conducted and regulated; their trust in the institutions and individuals who recruit them; and their beliefs in the wholesomeness and public value of the research endeavour.*"[1]

Elsewhere, they expand on the trust element: "*the public's support and tolerance for research, and its associated risks, often depends far more on an often fragile set of cues about the safety and social good of research participation, and on institutional and professional credentials, than it does on the formal architecture of research regulation,*

or on rational assessment of the detail of information sheets or other documents aimed at gaining 'informed consent'." That does not negate the importance of attention to details around regulation and good communications. It does, however, point to the fragile dependence of the research enterprise on care taken by all researchers to ensure that their work is conducted with high integrity and that the public interest in the research be clearly articulated.

Trust assumes some level of uncertainty and, consequently, vulnerability.[19] We recognized that much of the information use being planned would take us into "*grey zones*" of research use: the indistinct interface between research and clinical practice, the health care system, and management of the health of populations of people living with diabetes. Consequently, we identified the need to incorporate reflexivity into our research governance process. That is, the governance process has to critically assess common regulatory assumptions and practices in the context of new research circumstances and test alternative assumptions and practices.[20]

Particularly when the individual does not have an opportunity to exercise control over the use of their data, it is important to ensure that the public or patients, as appropriate, be involved at multiple stages in the governance process. The importance of stakeholder involvement in governance has been widely recognized.[21-25]

Finally, we needed to consider how the governance process we developed would complement the existing scientific and ethics review processes to which any research protocol would also be subjected. Given the focus on trust of both patients and the health care professionals whose data were being used, we chose to focus on how best to account for the patient's perspective throughout all stages of the research process.

4.1.2 Guiding Principles

Based on the considerations above, we identified eight principles that would guide our governance process:

1. Transparency
2. Accountability
3. Follow rule of law
4. Integrity
5. Participation and inclusiveness
6. Impartiality and independence
7. Effectiveness, efficiency and responsiveness
8. Reflexivity and continuous quality improvement

While these principles have drawn from a wide cross-section of literature, the model has been particularly influenced by the conceptual work of Laurie and Sethi, who called for values-based – as opposed to technical – principles and the incorporation reflexivity to proceed in the face of uncertainty.[11-13 26] Smallwood's definition of information governance informed the first 3 principles[14] and Carter and colleagues, who highlighted the importance of public trust and social licence inspired the introduction of the integrity principle.[1]

Below, we provide a brief description of how these broad principles inform our operational governance process, and how these principles map to the four goals of

information governance described above. A more detailed explanation of the principles may be found in Appendix 2.

1. Transparency

All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in an easily understandable format. (maps to: earn and maintain trust; meet privacy obligations)

2. Accountability

A governing body is accountable to those who will be affected by its decisions or actions. This is enforced through transparency and the rule of law. (maps to: earn and maintain trust, meet legal obligations)

3. Following the rule of law

The governance framework should follow all appropriate legal frameworks and the governing body should ensure compliance with applicable laws, regulations, standards and organizational policies across jurisdictions and institutions. (meet legal obligations, earn and maintain public trust)

4. Integrity

The governing process should ensure that uses of the data:

a) have a clear patient/public interest that is consistent with the intended purpose of the repository;
b) are of high scientific and ethical integrity. Ethical integrity includes: respect for persons, beneficence/non-maleficence, and justice. Justice includes concern for equity; and
c) are maintained in a secure and private manner.

(Meet business objectives; meet legal and privacy obligations; earn and maintain trust; keep data secure)

5. Participation and Inclusiveness

Patients and their families, health care professionals, and researchers should participate in governance over data use – through ongoing communication between the Research Governing Committee and the three patient advisory circles (general, Francophone and immigrant, and Indigenous), and other stakeholder advisory groups.

The governing bodies responsible for access to data in the repository should account for differing interests to reach a broad consensus on what is in the best interest of those with diabetes and their families. Participation in governance should be inclusive, equitable, informed and organized. The full range of positions of the advisory groups should be considered. Ongoing, 2-way engagement between the governing body and advisory groups is best. (Earn and maintain trust)

6. Impartiality and independence

As described above, the goal in deliberations is to reach a broad consensus on what is in the best interest of those living with diabetes and their families. All members in the process must look beyond their personal interests as either patients, health care providers, or researchers.

In addition, the governance process must be able to operate in a zone of bounded independence[27] from management, to ensure that its decisions are free from institutional conflicts of interest. (Earn and maintain trust,)

7. Effectiveness, Efficiency and Responsiveness

Governance over the data repository should ensure the objectives of the organization are being met in an effective and efficient fashion. The governing processes should serve all within a reasonable timeframe. (Earn and maintain trust; meet business objectives)

8. Reflexivity and Continuous Quality Improvement

Information governance should include processes that: allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use. It should promote a culture of reflexivity, and responsiveness among researchers and those governing access to the data. [26] (Earn and maintain trust).

4.2 Operational model

4.2.1 Structure

Building on these governance principles, we then formulated an operational model for our governance process. In this section and the next, we make explicit links to these guiding principles.

Our operational model is summarized in Figure 1. Below, we focus on the roles of the Research Governing Committee and its internal and external advisory groups.

[Insert Figure 1 near here.]

Research Governing Committee

The Research Governing Committee is the overall authority for governance over any research – observational studies or clinical trials – that are conducted involving data or patients in the Network. It has decision-making authority regarding individual studies. The Committee is accountable to the Steering Council, the highest authority in Diabetes Action Canada. (Principle 2: Accountability; Principle 6: Impartiality and independence.)

In its early stages, the Committee is reviewing all applications. This will help it work through and document the important issues in approving applications and to develop standardized approval policies so that, in future when volumes increase and processes become routine, it will only have to review studies that have been flagged by the Repository Manager as requiring Committee input.

There are two ways in which the Research Governing Committee adds value over and above scientific and ethics review. First, it ensures contextual integrity of the research, through an intimate understanding of the data and the health care settings in the system being studied. Equally important, it ensures a patient-centered perspective of the research, by checking that the research:

1. includes patient-relevant outcomes;
2. has taken into adequate account benefits and burdens/risks among people living with diabetes; and

3. is engaging in good communication practices with research participants, particularly around approaching and consenting to participate in research and in communicating about use of their health information for research. (Principle 4: Integrity of purpose)

Half of the Committee members (n=6) are people who are living with diabetes or their caregivers. These people were identified chiefly through the Network partners who were responsible for creating the Patient Advisory Circles, from the same pool of patients used to recruit the Patient Advisory Circle members. Another two members are representatives from the Data Provider Advisory Group, described below. Currently these are physicians who are members of CPCSSN, a subset of whose de-identified electronic medical records reside in Diabetes Action Canada's secure data repository. Another two members are researchers, whose roles are to be technical advisors around scientific validity and merit of the research proposal. The other two members are individuals with expertise in research ethics or law. The Committee may draw in outside experts if required. One of the two co-chairs of the Committee is a patient representative. The other co-chair is drawn from the rest of the members of the Committee. (Principle 5: Participation and inclusiveness)

Data Provider Advisory Group

Currently, the main data source for research activities of the Network consists of the de-identified electronic medical records of physicians participating in CPCSSN. The Data Provider Advisory Group was developed to ensure that the perspectives of these data providers are represented at the Research Governing Committee, through two members that group participate on the Research Governing Committee. Three of the seven members of the Group are front-line family physicians (i.e. not academics). Current members were suggested by CPCSSN Executive. In future, as the sources of research data grow, other health care professionals and data providers will be added to this advisory group.

This group provides advice on research applications, considering: logistics of conducting the research in the practice setting (particularly if a clinical trial); design considerations, as they relate to practice-level decisions; and interpretation of findings. They also serve as liaisons with the larger group of practices that are providing data to the repository. (Principle 5: Participation and inclusiveness)

Patient Circles

Patient Circles were developed at the outset of Diabetes Action Canada.[28] Patient Circle members either have diabetes themselves or are caregivers for a person living with diabetes. They are called upon individually and collectively for advice on multiple aspects of the network endeavours.

Currently, there are three Patient Circles:

1. The General Patient Circle (10-15 people)
2. The Francophone and Immigrant Patient Circle (6-8 people)
3. The Indigenous Patient Advisory Circle (8-15 people)

Members of the patient advisory circles have been drawn from multiple sources, including: an online survey, snowball sampling, and from community organizations.

Members are selected to maximize diversity in age, gender, and geographic location. In addition, candidates are interviewed to identify those with good group skills and a desire to contribute to a goal that exceeds his/her own health situation. They are then offered training in patient-oriented research.

The six patient representatives on the Research Governing Committee have been identified from the General Patient Circle and from a list of potential candidates for the Circles maintained by Diabetes Action Canada. The patient co-Chair of the Research Governing Committee provides reports to the General Patient Circle, apprising them of the activity of the Research Governing Committee and soliciting their input, should there be any controversial issues with which they are grappling. The General Patient Circle is the liaison point because there is representation from the Francophone and Immigrant, and the Indigenous patient circles in the General patient circle. (Principle 5: Participation and inclusiveness). Further, there will be a separate governance process developed for research involving Indigenous people.

External Ethics Advisory Group

This Committee will act as a 'critical friend' to advise on issues that cannot be resolved through deliberations among Research Governing Committee members and the internal advisory groups described above. This advisory group provides one more instance of the governing principle of reflexivity. It will be at arm's length to the Research Governing Committee. It carries no formal authority, but has the freedom to go public if it is concerned about some particular policy direction taken by Diabetes Action Canada. Members will be drawn from ethics and legal scholars outside Diabetes Action Canada, both nationally and internationally, with expertise in: governance over secondary use of data; privacy and access to data; registry-based clinical trials; and practice-based research. (Principle 8: Reflexivity and continuous quality improvement)

4.2.2 Process

Standard operating procedures, including application forms, have been developed. A summary of the application process for research use of the data is provided in Appendix 3.

In the application form, several questions focus on the patient-orientation of the research. For example, the researcher is asked to indicate:
(a) the patient outcomes being measured;
(b) how the research will benefit those living with diabetes or the public more generally;
(c) the potential research-related risks of the study to research participants/data subjects and potential adverse social implications of the research; and
(d) the ways in which people living with diabetes have been involved in the planning of the research. (Principle 4: Integrity of purpose, scientific integrity, ethical integrity)

The Repository Manager reviews the application for completeness. If the project has not received scientific review, the protocol is sent to a scientific advisory group for their approval prior to review by the Research Governing Committee. Researchers are encouraged to submit prior to Research Ethics Board approval to ensure the feasibility and appropriateness of the proposed protocol from the perspective of Diabetes Action Canada. In that way, re-work at the level of the REB is minimized. (Principle 4:

Scientific and ethical integrity; Principle 7: Effectiveness, efficiency, and responsiveness)

Applications for research use of the data are circulated to Research Governing Committee members at least two weeks in advance, to provide an opportunity for patient and data provider members of the Committee to identify issues requiring deliberation with their respective advisory group, in advance of the Research Governing Committee meeting. (Principle 5: Participation and inclusiveness)

At the Committee meeting, when vetting a particular protocol, patient and data provider representatives are invited to comment first. Concerns raised by the researchers and ethics people follow thereafter. The Committee members aim for a consensus-based resolution to any concerns. When Committee members fail to come to consensus, even subsequent to consultation with the Patient Advisory Circles and the Data Provider Advisory Group, The Research Governing Committee may turn to the Ethics Advisory Group for guidance on how to proceed with an application or to seek general policy direction. (Principle 5: Participation and inclusiveness; Principle 6: Impartiality and Independence; Principle 8: Reflexivity and continuous quality improvement)

For applications in which concerns have been raised that there is insufficient patient or health care provider input into the research, the Committee may exercise the option to assign a patient or health care professional member of the Committee (or one of the Advisory Groups) to become a collaborator on the project to provide advice and the patient's or HCP's perspective on the research, throughout the project. They also retain the option to review a draft report prior to publication of findings. (Principle 4: Scientific integrity (to ensure adequate inputs) and Principle 5: Participation and inclusiveness)

The Repository Manager will monitor the time required for protocols to pass various checkpoints in the system, to identify any unnecessary bottlenecks in the system and make recommendations for process improvement. (Principle 7: Effectiveness, efficiency and responsiveness; Principle 8: Reflexivity and continuous quality improvement.)

Finally, Diabetes Action Canada is in the process of posting:

- its policies around data collection, access, use and retention of data; and
- its business processes and governance activities;

so they can be readily accessible to partners and the public. In future, it will also perform regular audits of its data use practices. (Principle 1: transparency; Principle 2: Accountability)

4.2.3 Implementation

In January of 2018, a day-long training workshop was convened for the Research Governing Committee. A training manual was produced for that purpose, and will be posted on the Diabetes Action Canada website. Topics covered in the workshop included:

- An explanation of the types of studies that they would be encountering (data studies; studies making direct contact with patients; and hybrid studies)
- The stages of the research process and how the Research Governing Committee fits into this

- What are research governance and information governance and how will they be applied in the context of Diabetes Action Canada's secure data repository?
- Diabetes Action Canada's governing principles, and how these may apply when reviewing protocols.
- What is the "added value" of the Research Governing Committee vis-à-vis scientific and ethic review
- The structure and function of the governing process and their specific contributions.

Participants were then led through two case studies to test out the application and review process.

4.3 Evaluation

At the time of writing, the Diabetes Action Canada secure data repository has been available for research for only a few months. We are in the early days of implementing the governance process and we are still refining those processes – both the internal functioning of the Research Governing Committee and the consultative processes. We are also continuing to address learning needs of Research Governing Committee members.

Similarly, our plans for the evaluation of the governance process are in the formative stages. Drawing from relevant SPOR[29] and PCORI[30] evaluation frameworks, key issues that we will address in the evaluation include:

- Periodic review of DAC's information governance processes and procedures on to ensure that they conform to and are congruent with the objectives and principles enunciated in this paper.
- Process measures, such as: patient representatives' sense of empowerment in the process; and the timeliness of the reviews – both objectively and from the perspective of researchers who submit applications
- Outcome measures, such as: the proportion of projects reviewed in which changes were recommended and the nature of the changes recommended, including: (a) addition of more patient-relevant outcomes, (b) improvements in participant communications materials (e.g. consent forms and information materials); and (c) reductions in risks and burdens to patient participants.

5. Discussion

In Canada, governance over research involving humans, their data, and their samples focuses on the scientific and ethical integrity of the research. Scientific integrity is largely addressed though peer review processes at the funding and publication stages of the research lifecycle, much like research in other jurisdictions. Ethical integrity is formally addressed through review of research protocols prior to study commencement by research ethics boards at the researchers' institution(s). Ethics guidance is provided by the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, second edition (TCPS-2), which addresses research involving human participants, their tissue, or their data.[31] For database research, one still needs to consider relevant privacy laws, which are a provincial jurisdiction. These provincial privacy laws have provisions for secondary research use of data without consent. While they are

substantively similar, founded on the Canadian version of the OECD Privacy Principles,[32 33] there are notable inconsistencies across provinces. Some have health-specific privacy legislation, others legislation that covers all sectors; some have multiple legislation to consider. In some cases small differences in wording and interpretation of legislation present challenges to cross-national data studies.

Most legislation also requires the review and approval of the research protocol by the institution that is the legal data custodian or steward of the data. While Diabetes Action Canada does not currently manage personal – i.e. identifiable – health information, the data it holds are of sufficient granularity as to make it possible to indirectly re-identify individuals, should the data be linked or manipulated. Therefore, data in its custody are not released to researchers. Instead, the researcher must apply for permission to gain secure remote access to the data for analyses.

Within this research governance landscape, Diabetes Action Canada has developed and implemented an information governance process designed to foster public trust in the responsible use of the data in their custody. The operational model has been designed to complement the scientific and ethics review processes that research already receives, and is adaptable to other settings.

We believe the principles in the conceptual model we developed are generalizable to many other settings. That being said, we advise that any organization that considers adopting these principles critically analyse whether they are consonant with the values of the organization, as it is these core principles to which they will repeatedly return when making difficult or controversial decisions.

While all eight governing principles enunciated are important in fostering public trust, the integrity and participation principles are particularly relevant. The integrity principle establishes the criterion that the research must have a clear patient or public interest, and be of high scientific and ethical integrity. The participation principle ensures the substantive participation of patients and other relevant stakeholders, which helps to achieve the integrity principle.

Over the past decade, there have been many studies examining the public's or patients' attitudes toward the conditions under which data studies may be acceptable.[34] Much less common is the involvement of patients or the public in an *ongoing* fashion in the governance over *programs* of data-intensive research. The closest exemplar we were able to find in the area of data-intensive research is the consumer panel for data linkage research, associated with the SAIL databank.[35] Their panel is advisory in nature, addressing both access policy and individual projects and representatives of that panel sit on an independent Information Governance Review Panel.

The governance process developed for Diabetes Action Canada goes one step further. It gives people living with diabetes and data providers majority representation in the key decision-making body in the governance process. We are unaware of any other research governance structures that have instilled as strong a role for patients and health care professionals in a research network. We are not suggesting that all research networks should choose as radical a path. However, we believe strong lay participation in policy making and governance is an increasingly important approach to securing the trust of the public.

As our research platforms grow in size and scope, the need for public trust in the uses of these datasets also grows. We believe our model for governance over health information platforms adds substantively to the conceptual and methodologic foundations for information governance to help address this need.

Competing interests:

The Institute of Health Policy, Management and Evaluation received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Willison's time for the development of the governance process for the Diabetes data repository.

The Department of Family and Community Medicine, University of Toronto, received funds from Diabetes Action Canada SPOR Network towards a partial secondment of Dr. Greiver's time for the development of the Diabetes data repository.

Dr. Keshavjee received personal fees from InfoClin Inc during the conduct of the study toward designing the architecture of the Diabetes data repository. In addition, Dr. Keshavjee has a patent "Prediction of Diabetes Mellitus Type 2 Using Biomarkers in Electronic Health Records and Differential Calculus", pending.

Funding:

This work was supported by Diabetes Action Canada, which is funded, in part, through a Canadian Institutes of Health Research chronic disease network grant under the Strategy for Patient-Oriented Research (Funding Reference number: SCA 145101)

References

1. Carter P, Laurie GT, Dixon-Woods M. The social licence for research: why care.data ran into trouble. Journal of medical ethics 2015;**41**(5):404-09.
2. Powles J, Hodson H. Google DeepMind and healthcare in an age of algorithms. Health and Technology 2017;**7**(4):351-67.
3. Anonymous. Strategy for Patient-Oriented Research 2018 [Available from: http://www.cihr-irsc.gc.ca/e/41204.html.
4. Anonymous. Strategy for patient-oriented research. Patient engagement framework. Ottawa, Ontario: Canadian Institutes of Health Researach, 2014.
5. Anonymous. Launch of the Diabetes Action Canada National Data Repository: Diabetes Action Canada; 2018 [Available from: https://diabetesaction.ca/launch-of-the-diabetes-action-canada-national-diabetes-repository/.
6. Garies S, Birtwhistle R, Drummond N, et al. Data Resource Profile: National electronic medical record data from the Canadian Primary Care Sentinel Surveillance Network (CPCSSN). Int J Epidemiol 2017;**46**(4):1091-92f.
7. Birtwhistle R, Keshavjee K, Lambert-Lanning A, et al. Building a pan-Canadian primary care sentinel surveillance network: initial development and moving forward. J Am Board Fam Med 2009;**22**(4):412-22.
8. Clinical Practice Research Datalink: Medicines and Healthcare Products Regulatory Agency, UK; [Available from: https://www.cprd.com/.
9. Burton PR, Murtagh MJ, Boyd A, et al. Data Safe Havens in health research and healthcare. Bioinformatics (Oxford, England) 2015;**31**(20):3241.
10. Lea NC, Nicholls J, Dobbs C, et al. Data Safe Havens and Trust: Toward a Common Understanding of Trusted Research Platforms for Governing Secure and Ethical Health Research. JMIR medical informatics 2016;**4**(2):e22.
11. Laurie G, Sethi N. Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data. European Journal of Risk Regulation : EJRR 2013;**4**(1):43.
12. Sethi N, Laurie GT. Delivering proportionate governance in the era of eHealth: Making linkage and privacy work together. Medical Law International 2013;**13**(2-3):168-204.
13. Laurie G, Sethi N. Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework. Edinburgh: University of Edinburgh, 2012.
14. Smallwood R. *Information governance: Concepts, strategies, and best practices*. Hoboken, NJ: Wiley, 2014.
15. Ladley J. *Data governance: How to design, deploy, and sustain an effective data governance program*. Waltham, MA: Morgan Kauffman, 2012.
16. Department of Health. Information: To share or not to share? The Information Governance Review. 2013. https://www.gov.uk/government/publications/the-information-governance-review (accessed 2018-09-25).
17. Simm K. The Concepts of Common Good and Public Interest: From Plato to Biobanking. Cambridge Quarterly of Healthcare Ethics 2011;**20**(4):554-62.
18. Barocas S, Nissenbaum H. Big Data's End Run around Anonymity and Consent. Privacy, Big Data, and the Public Good. New York, NY: Cambridge University Press, 2014.

19. Nissenbaum H. Securing trust online: Wisdom or oxymoron? Boston University Law Review 2001;**81**(3):635-64.
20. Laurie GT, Dove ES, Ganguli-Mitra A, et al. Charting Regulatory Stewardship in Health Research Making the Invisible Visible. CAMBRIDGE QUARTERLY OF HEALTHCARE ETHICS 2018;**27**(2):333-47.
21. O'Doherty KC, Burgess MM, Edwards K, et al. From consent to institutions: Designing adaptive governance for genomic biobanks. Social Science and Medicine 2011;**73**(3):367-74.
22. Greenhalgh T, Morris L, Wyatt JC, et al. Introducing a nationally shared electronic patient record: Case study comparison of Scotland, England, Wales and Northern Ireland. International Journal of Medical Informatics 2013;**82**(5):e125-e38.
23. Geissbuhler A, Safran C, Buchan I, et al. Trustworthy reuse of health data: a transnational perspective. International journal of medical informatics 2013;**82**(1):1-9.
24. Allen C, Des Jardins TR, Heider A, et al. Data Governance and Data Sharing Agreements for Community-Wide Health Information Exchange: Lessons from the Beacon Communities. eGEMs (Generating Evidence & Methods to improve patient outcomes) 2014;**2**(1):1057.
25. Kaushal R, Hripcsak G, Ascheim DD, et al. Changing the research landscape: the New York City Clinical Data Research Network. JAMIA 2014;**21**(4):587-90.
26. Laurie G. Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law. Human genetics 2011;**130**(3):347-56.
27. Beecher JA. The prudent regulator: politics, independence, ethics, and the public interest. Energy Law Journal 2008;**29**(2):577.
28. Anonymous. How partient-parters are involved 2018 [Available from: https://diabetesaction.ca/patient-partners-involved/.
29. Anonymous. Evaluation of the Strategy for Patient-Oriented Research. Ottawa, Canada: KPMG, 2016.
30. Esmail L, Moore E, Rein A. Evaluating patient and stakeholder engagement in research: moving from theory to practice. Journal of comparative effectiveness research 2015;**4**(2):133.
31. 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*. Ottawa: Interagency Secretariat on Research Ethics, 2014.
32. Organisation for Economic Co-operation and Development. The OECD Privacy Framework. Paris, France, 2013.
33. Canadian Standards Association. Model code for the protection of personal information. A national standard of Canada. Ontario, 1996.
34. Aitken M, De St Jorre J, Pagliari C, et al. Public responses to the sharing and linkage of health data for research purposes: a systematic review and thematic synthesis of qualitative studies. BMC Medical Ethics 2016;**17**(1):1-24.
35. Jones KH, McNerney CL, Ford DV. Involving consumers in the work of a data linkage research unit. International journal of consumer studies 2014;**38**(1):45-51.

Additional Files:

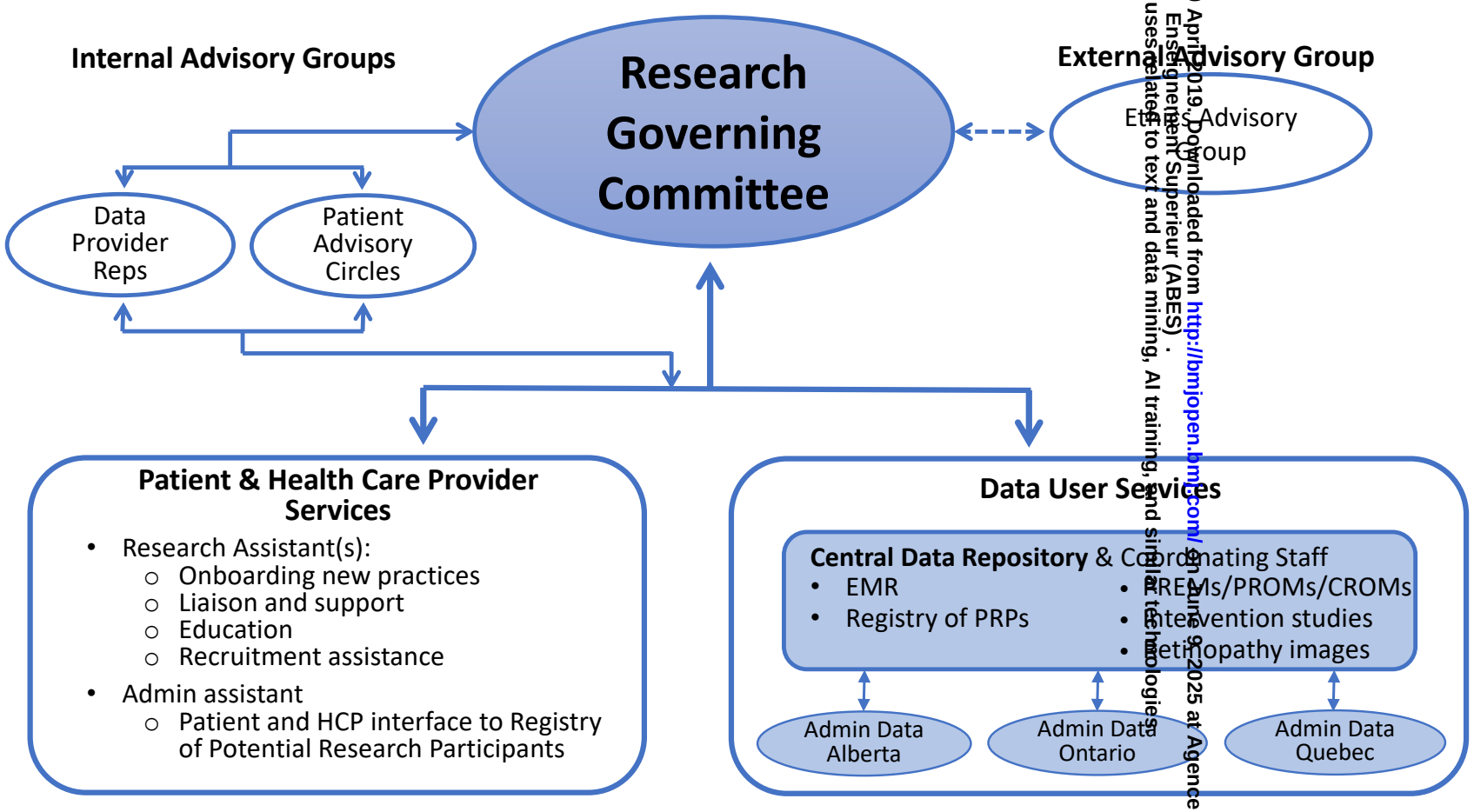
Figure 1. Diabetes Action Canada Research Governance Structure

Appendix 1. Diabetes Action Canada's Data Governance Working Group and Technical Group members

Appendix 2. Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

Appendix 3. Application process for research use of the data in the research repository

Figure 1. Diabetes Action Canada Research Governance Structure



Appendix 1

Diabetes Action Canada – Data Governance Working Group Members

Person	Affiliation / Role	Representation / Expertise
Donald Willison (Chair)	Associate Professor, Institute of Health Policy, Management and Evaluation, University of Toronto	Data governance, public involvement in research.
Richard Birtwhistle	Emeritus Professor of Family Medicine and Public Health Sciences, Queen's University	Founding Chair, Canadian Primary Care Sentinel Surveillance Network (CPCSSN)
Serge Dumont	Professor, School of Social Work, Faculty of Social Sciences, Laval University Scientific director, Laval University Community-Based Primary Health Care Research Centre	Leading the Best data governance practices: Systematic Review. CIUSSS de la Capitale-Nationale, Quebec-City, QC
Ross Gray	Patient Partner, Diabetes Action Canada, CIHR SPOR Network	Patient representative
Michelle Greiver	Associate Professor, Dept. of Family and Community Medicine, University of Toronto *Gordon F. Cheesbrough Research Chair in Family and Community Medicine,* North York General Hospital	Director, University of Toronto Practice-based Research Network, which is part of CPCSSN. Health Informatics expertise
Karim Keshavjee	CEO, InfoClin Inc. Adjunct Professor, Institute for Health Policy, Management and Evaluation, University of Toronto	Data governance, System architecture design, Health informatics
Donna Manca	Research Director and Professor, Department of Family Medicine, Faculty of Medicine & Dentistry, University of Alberta	Data governance
Frank Sullivan	Professor of Primary Care Medicine, University of St. Andrews. Director of Research, School of Medicine. Professor, Department of Family & Community Medicine and Dalla Lana School of Public Health, University of Toronto. Adjunct Scientist Institute for Clinical Evaluative Sciences (ICES)	Established the SHARE register and recruitment tool, NHS Scotland
Xiaolin Wei	Associate Professor, Clinical Public Health Division, and Institute of Health Policy, Management and	Established diabetes registry in China

Person	Affiliation / Role	Representation / Expertise
	Evaluation, Dalla Lana School of Public Health, University of Toronto.	

Diabetes Action Canada – Technical Committee Members

Person	Affiliation / Role	Representation / Expertise
Michelle Greiver (Chair)	Associate Professor, Dept. of Family and Community Medicine, University of Toronto *Gordon F. Cheesbrough Research Chair in Family and Community Medicine,* North York General Hospital	Director, University of Toronto Practice-based Research Network, which is part of CPCSSN. Health Informatics expertise
Babak Aliazardeh	UTOPIAN Data Analytics Manager, Department of Family and Community Medicine, University of Toronto	Development and maintenance of UTOPIAN primary care/ EMR data repository, data management and health informatics.
Aashka Bhatt	Research Officer, Diabetes Action Canada – CIHR SPOR Network. University of Toronto Practice-Based Research Network, Dept. of Family and Community Medicine, University of Toronto	Administrator and Practice Facilitator
Neil Drummond	Professor and Alberta Health Services Research Chair in Primary Care Department of Family Medicine, University of Alberta	Epidemiology, research methods, primary care EMR data.
Christopher Ducharme	Manager of Research Informatics at the Applied Health Research Centre at St. Michael's Hospital	Electronic data capture and clinical data management systems.
Jean-François Ethier	Clinician-scientist, and Associate Professor, Department of Medicine, Université de Sherbrooke and the Sherbrooke University Health Center.	Director of the data access group, Quebec SPOR Support Unit / Health informatics expertise
Shivani Goyal	Assistant Professor, Dalla Lana School of Public Health, Institute of Health Policy, Management and Evaluation, University of Toronto Lead - Strategy & Research, University Health Network.	Patient perspective, feasibility and applicability of architecture for patient-centered population health projects.
Karim Keshavjee	CEO, InfoClin Inc	Data governance, System architecture design, Health informatics

Person	Affiliation / Role	Representation / Expertise
	Adjunct Professor, Institute for Health Policy, Management and Evaluation, University of Toronto	
Ken Martin	Information & Technology Manager, Canadian Primary Care Sentinel Surveillance Network (CPCSSN)	Health informatics, Enterprise & system architecture, Data governance & processing, Primary care EMR data
Doug Mumford	Patient Partner, Diabetes Action Canada, CIHR SPOR Network	As volunteer at Leadership Sinai Centre for Diabetes, lead development of online patient portal for persons with diabetes.
Frank Sullivan	Professor of Primary Care Medicine, University of St. Andrews. Director of Research, School of Medicine. Professor, Department of Family & Community Medicine and Dalla Lana School of Public Health, University of Toronto. Adjunct Scientist Institute for Clinical Evaluative Sciences (ICES)	Established the SHARE register and recruitment tool, NHS Scotland
Charles Victor	Senior Director, Strategic Partnerships and External Services at ICES – Institute for Clinical Evaluative Sciences	Data repository management, data linkage and data access models for the purpose of research
Catharine Whiteside	Executive Director, SPOR Network in Diabetes, Emerita Professor and Former Dean of Medicine, University of Toronto	Dr. Whiteside is a MD and PhD graduate from the University of Toronto and is certified in Internal Medicine and Nephrology.
Donald Willison	Associate Professor, Institute of Health Policy, Management and Evaluation, University of Toronto	Data governance, public involvement in research.

Appendix 2

Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

Governing Principles for the Diabetes Action Canada Data Repository for Patient-oriented Research

1. Preamble

1.1 Information governance goals and principles

A clear governance framework for the collection, use and storage of health data is critical to establishing and maintaining trust that data are secure and being used responsibly. In this document, we propose governing principles and an operational framework adapted from the field of Information Governance (IG) to governing the data to be held in the custody of Diabetes Action Canada.

The field of IG encompasses a broad range of concepts and activities from records and content management to business intelligence. IG is focused on analyzing and optimizing how information is accessed, controlled, managed, shared, stored, preserved and audited. Smallwood defines IG as “The overarching polices and processes to optimize and leverage information while keeping it secure and meeting legal and privacy obligations, in alignment with stated organizational business objectives.”(Smallwood 2014) He discusses key outputs of IG, such as mapping information creation and usage, ensuring data has integrity, validity, accuracy and quality, and harvesting and leveraging information.

1.2 Application to governing health data: values-based governance

The IG field is based on a business model, where data are owned and governed by an individual enterprise and used mainly for purposes that meet business requirements. Governing the use of health-related data for research purposes differs in at least two fundamental ways:

1. The holders of health-related data are not “owners” of the data. Rather, they are stewards entrusted with the responsibility for ensuring appropriate use of the data. (In Ontario, legislation uses the term “data custodian”.)
2. Responsibility for appropriate use is shared among the many data stewards or custodians that contribute data to the research project.

As research is usually not specified as a primary use of the data collected, data stewards or custodians must be satisfied that the data they contribute meet legal and ethics requirements, are appropriately governed, such that any request for use of the data for research satisfies some public interest test.

In their working paper describing elements of ‘good governance’ of health-related research involving patient data, Laurie and Sethi note: “A good governance framework needs to include an overt statement of the values and standards according to which activity will be assessed. This must be accessible and sufficiently adaptable to be adopted and implemented across all levels of decision-making and by all actors involved in the process.” (Laurie and Sethi 2012) Similarly, remarking about the shortcomings of anonymization and consent to adequately address privacy in an era of Big Data, Barocas and Nissenbaum conclude: Procedural approaches cannot replace policies based on substantive moral and political principles that serve specific contextual goals and values.” (Barocas and Nissenbaum 2014)

2. Diabetes Action Canada repository goals and principles

Diabetes Action Canada is creating a research repository that will serve as a platform for observational studies. Within the research repository, it will be possible to link: (1) clinical data from primary care practices, laboratories and other clinical systems; (2) administrative data derived from health care transactions, sociodemographic data; (3) retinopathy images from ophthalmologists, optometrists, and special clinics and (4) patient reported outcomes and evaluations. The research repository will also contain a registry of potential research participants that will facilitate recruitment of patients into prospective clinical studies by identifying in advance patients with diabetes who agree to be approached to participate in varied research projects.

Contributing data sources and anticipated requests for access to data will be varied and geographically dispersed. An efficient response to this heterogeneity will require clear and definitive governance processes.

Our goals are to:

1. Optimize use of data to meet Diabetes Action Canada objectives
2. Keep data secure and maintain the integrity and quality of data
3. Meet legal, privacy and confidentiality obligations
4. Earn and maintain the trust of patients, partners, and public for use of data for research

For researchers to earn and maintain public trust, our governance framework must go beyond compliance with formal regulations to earn and maintain a 'social licence' for the use of the data.(Carter, Laurie et al. 2015) The Diabetes Action Canada data repository and patient registry will accomplish this through a focus on research that is scientifically sound, ethically robust and in the public interest. Strong data safeguards and responsiveness to the evolving societal context are also important to building public trust.

In anticipation of information use requests that may take us into "grey zones" of research governance, we have included the concept of 'reflexivity' in the proposed principles. Reflexivity is a way of governing that "encourages actors to scrutinize and reconsider their underlying assumptions, institutional arrangements, and practices" (Laurie 2011) in order to encourage learning and allow research to proceed in the face of uncertainty.

3. Principles for Governance of the Diabetes Action Canada Repository

1. Transparency

All decisions, policies, and practices regarding data use are freely accessible to those affected by the decisions and to the public. These shall be available in easily understandable format.

Diabetes Action Canada will accomplish this in the following ways:

- Establish clear policies around data collection, access, use, and retention, and make these policies readily accessible to Diabetes Action Canada partners and to the public
- Document business processes and governance activities
- Establish and communicate consequences of breach
- Perform regular audits of data use practices
- Maintain a culture of openness

2. Accountability

A governing body is accountable to those who will be affected by its decisions or actions. This is enforced through transparency and the rule of law.

Within Diabetes Action Canada:

- The highest level of governance within Diabetes Action Canada rests with the Steering Council. Patients or their representatives constitute 50% of the Steering Council.
- The oversight and communication of policies and procedures related to information governance will be delegated to the Research Governance Committee (RGC), which will report to the Steering Council.
- The RGC will serve as a resource to the data steward, who will be responsible for the day-to-day implementation of these policies.
- The RGC will also ensure that the policies and procedures are kept up-to-date in response to emerging issues.

3. Following the rule of law

The governance framework should follow all appropriate legal frameworks and the governing body should ensure compliance with applicable laws, regulations, standards and organizational policies across jurisdictions and institutions.

Diabetes Action Canada will:

- Provide protection from data breach, corruption and loss
- Follow legal frameworks for data collection, retention, use and disposition
- Develop internal controls to monitor compliance

4. Integrity

The governing process should ensure that uses of the data: are consistent with the goals of Diabetes Action Canada and the intended purpose of the repository; and are of high scientific and ethical integrity.

Applications for use of data in the custody of Diabetes Action Canada must demonstrate:

A. Integrity of purpose:
   - There is a clear patient/public interest that the research will address. This should be consistent with the mission of Diabetes Action Canada.

B. Scientific integrity:
   - The applicant's research team has the capacity to analyse the data
     - For studies that are led by patients, if there is not already a researcher partner identified, Diabetes Action Canada willl endeavour to link the applicant with researchers who could provide the needed analytic support.
   - The research plan demonstrates the ability to answer the researcher's question with high validity.
     - For data studies the focus will be on the analytic plan and the capacity of the data – either alone or in combination with other data provided by the researcher – to answer the research question with high validity.

C. Ethical integrity:
   - Respect for persons. For example, as appropriate: addressing privacy, confidentiality, consent, ability to withdraw at any time;

- Beneficence/non-maleficence. For example:
  - minimizing harm – both to research participants/data subjects and in terms of the use of the findings;
  - maximizing benefit;
- Justice. For example:
  - The research will not exploit patients who participate in in the research or whose data are used in the research.
  - The research aims to either reduce inequity or, at the least, not exacerbate existing inequities.

5. Participation and Inclusiveness

Patients and their families, health care professionals, and researchers should participate in governance over data use – through the patient advisory councils and other stakeholder advisory groups.

The governing bodies responsible for access to data in the Diabetes Action Canada repositories should take into account differing interests to reach a broad consensus on what is in the best interest of those with diabetes and their families.

- Participation in governance should be inclusive, equitable, informed and organized;
- The full range of positions of the advisory groups should be considered in the development and implementation of governing mechanisms;
- Ongoing, 2-way engagement between the governing body and advisory groups is best.

In addition, applicants for use of data in Diabetes Action Canada's custody must demonstrate how patients – and, as appropriate, other stakeholders such as health care providers – contribute to the research throughout the lifecycle of the research, from development of the research question through KTE.

6. Impartiality and independence

As described above, the goal in RGC deliberations is to reach a broad consensus on what is in the best interest of those with diabetes and their families. All members of the RGC must look beyond their personal interests as either patients, health care providers, or researchers.

- In the event of personal conflict of interest – whether actual or perceived – individual members of the RGC will declare their conflict up front, and recuse themselves from deliberations on that project. The conflict may be, for example, financial, collegial, or intellectual.

In addition, the RGC must be able to operate in a zone of bounded independence* from Diabetes Action Canada management, to ensure that its decisions are free from institutional conflict of interest.

* Beecher argues that 'regulatory autonomy and discretion are not absolute but "bounded" and regulators are held responsible for their decisions and their behavior in a complex and diffuse system of interests, relationships, and processes.' Beecher, J. A. (2008). "The prudent regulator: politics, independence, ethics, and the public interest." Energy Law Journal **29**(2): 577.

- This will be accomplished, at least in part, through its line of accountability directly to the highest level of authority within Diabetes Action Canada – the Steering Council – and through its composition of 50% membership being patients or patient advocates.

7. Effectiveness, Efficiency and Responsiveness

Governance over the data repository should ensure the objectives of Diabetes Action Canada are being met in an effective and efficient fashion. The governing processes should serve all within a reasonable timeframe.

- Resources should be managed to ensure timely and secure access to the right data for the intended purpose. This includes:
  - Training and education of people on policies and procedures
  - Ensuring high quality metadata to aid efficient and valid data use

8. Reflexivity and Continuous Quality Improvement

Information governance should include processes that: allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use.

To accomplish this, Diabetes Action Canada will:

- Promote a culture of reflexivity[†], and responsiveness among researchers and those governing access to the data. For example: develop virtuous feedback loops that encourage researchers to openly discuss with the data custodian any data challenges and ways to address these challenges.
- Develop an external ethics advisory group that will serve as a "critical friend" to facilitate reflexive decision-making in the face of uncertainty

In addition, as stewards of the data repository, Diabetes Action Canada will endeavor to enrich the data in the repository over time by incorporating additional data gathered in the course of research studies that used Diabetes Action Canada data or that recruited patients in the Diabetes Action Canada registry of potential research participants.

4. References

Barocas, S. and H. Nissenbaum (2014). Big Data's End Run around Anonymity and Consent. Privacy, Big Data, and the Public Good. New York, NY, Cambridge University Press.

Beecher, J. A. (2008). "The prudent regulator: politics, independence, ethics, and the public interest." Energy Law Journal **29**(2): 577.

Carter, P., G. T. Laurie and M. Dixon-Woods (2015). "The social licence for research: why care.data ran into trouble." Journal of medical ethics **41**(5): 404-409.

[†] Reflexive governance is a mode of steering that encourages actors to scrutinize and reconsider their underlying assumptions, institutional arrangements, and practices. It requires that actors have the capacities and competencies to interact in relational and deliberative ways; that they engage in and learn from experimentation through collaborative forms of joint enquiry; and that their learning is informed by cognitive processes entailing the adjustment and redefinition of frames, representations and collective identities. Laurie, G. (2011). "Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law." Human genetics **130**(3): 347-356.

Laurie, G. (2011). "Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law." Human genetics **130**(3): 347-356.

Laurie, G. and N. Sethi (2012). Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework. Edinburgh, University of Edinburgh.

Smallwood, R. (2014). Information governance: Concepts, strategies, and best practices. Hoboken, NJ, Wiley.

Appendix 3. Application process for research use of the data in the research repository

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Submission and Approval Process	SOP#	Diabetes Action CanadaNDR-PSAP001.0
Document Number	001	Author	Conrad Pow
Version Number	1.0	Reviewer	
Superseded Version	Draft	Reviewer Date	
Effective Date	05/01/2018	Status	

1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to define all key aspects involved in the Submission and Approval of projects requesting to access to data held within the Diabetes Action Canada National Diabetes Repository.

2. SCOPE

This document is intended for all projects that have been submitted to the Diabetes Action Canada National Diabetes Repository. This applies to Diabetes Action Canada staff, Diabetes Action Canada Committee Members and Diabetes Action Canada researchers wishing to conduct a secondary data analysis project.

3. ROLES AND RESPONSIBILITIES

3.1 Diabetes Action Canada Repository Manager: Responsible for the overall operations (recruitment, developing policies and procedures, site relationship) and communication regarding the Diabetes Action Canada National Diabetes Repository.

3.2 Diabetes Action Canada Repository Data Manager: Responsible for data extraction, processing, quality check, destruction, reports, transfer, secondary data usage, and managing the data dictionary; responsible for updating the Diabetes Action Canada Repository Manager on changes or problems with the Diabetes Action Canada National Diabetes Repository.

3.3 Diabetes Action Canada Repository Research Administrator: Responsible for managing the participant database and facilitating meetings.

3.4 Diabetes Action Canada Researcher: Responsible for ensuring that all project team members, including self, are familiar with the Diabetes Action Canada Policies and Procedures pertaining to the National Diabetes Repository. Will be responsible for ensuring that all project team members have signed COI statement. Will be responsible for the management and oversight of the project.

3.5 Diabetes Action Canada Repository Scientific Advisory Committee (SAC): The SAC is made up of 3 members. The SAC is responsible for reviewing projects

proposing to access data in the Diabetes Action Canada National Diabetes Repository. The SAC will review the scientific merit and methodology of the project.

3.6 Diabetes Action Canada Repository Research Governing Committee (RCG): The RCG will ensure the focus of the proposed project is aimed at what is in the best interest of the patient and that aligns with Diabetes Action Canada's mission and values.

4. SECONDARY DATA USAGE

Data in the Diabetes Action Canada Repository will only be available to Diabetes Action Canada researchers wishing to conduct secondary data analysis. Once approved, they will be given remote access to a specified data cut in a secure zone at the Centre for Advanced Computing Canada (CAC).

5. SUBMISSION AND APPROVAL PROCESS

STEP 1: Diabetes Action Canada Researcher will electronically fill and submit an Access Request Form (Appendix 1) through the Researcher portal at https://repository.diabetesaction.ca The form outlines the purpose, methodology, requested data elements and timeframe. It also requires a copy of the full research proposal and whether there is any identified or perceived risks.

STEP 2: The Repository Manager and the Repository Data Manager will review the Access Request Form to assess the feasibility of the project based on the data elements requested. This may include a meeting with the Researcher to discuss the data elements requested, project objectives and overall budget.

STEP 3: If the project has been peer-reviewed (eg. CIHR has reviewed and reviewed the submitted protocol) then proceed to Step 4, if not, the Access Request Form and full research proposal will be reviewed by the National Diabetes Repository Scientific Advisory Committee (SAC) to assess the scientific merit and methodology of the project. The researcher will be updated on the scientific assessment by the SAC, if any concerns are raised, the Researcher will be requested address them prior to the project moving any further.

STEP 4: The Repository Manager will provide the RGC a copy of the Access Request Form to advise on, but not limited to: (1) The project is in the best interest of the patients; (2) The project goals align with institutional mission and values. Once approval has been received from the RGC, the Repository Manager will provide the Researcher written confirmation that the proposed project is feasible. The Confirmation of Feasibility (COF) letter will also identify the estimated costs for conducting the project.

STEP 5: If the project is not part of a larger REB approval, the Researcher will be required to apply for REB approval. The COF letter can be provided to the REB as supporting documentation assuring Diabetes Action Canada supports the project. In addition, the Researcher must submit confirmation of funding (Peer Reviewed Grant, Institutional Funds, Investigator Funds…)

STEP 6: Once REB approval has been obtained, the Researcher will upload the REB approval letter through the Researcher portal along with the REB submission.

STEP 7: The Repository Manager, along with the RGC, will review the Access Request Form to ensure it aligns with the REB submission and approval.

STEP 8: After confirmation of REB alignment, the Repository Manager will provide the Researcher Diabetes Action Canada Repository Researcher Agreement (Appendix B) and Confidentiality Agreement (CA) (Appendix C).

STEP 9: After both Agreements have been fully executed, the Repository Manager and the Repository Data Manager will work with the Researcher to finalize the required data elements to create a Dataset Creation Plan (DCP). The DCP will be used to create a project specific dataset.

STEP 10: The Repository Data Manager will upload the project specific dataset to the secure workspace for the researcher to conduct analysis.

STEP 11: Once all agreements are in place, the Repository Data Manager will provide the Researcher the login credentials to remotely access the secure environment.

ACCESS TO DATA FOR SECONDARY USE FOR RESEARCH

Researcher completes **access request form** that outlines the project, methodology and timeframe. This is sent to the Repository Manager for review. 1

Repository Manager reviews the request and confirms the feasibility of the project. Once confirmed, the **request is sent to the Scientific Advisory Committee**. 2

The Research Governing Committee (RGC) will review to advise if the project is in the best interest of patients and project goals are in line with organization mission and values. If concerns are raised, revisions to the request will be necessary, if not, w**ritten confirmation of acceptance** will be provided to the researcher. 3

The Researcher will be required to provide confirmation of **REB approval,** confirmation of **funding** and a signed **confidentiality agreement**. 4

Documents will be reviewed for alignment with REB submission. Researcher will enter into an **Agreement with Diabetes Action Canada**. This Agreement will outline the data access provisions, requirements and any controls. 5

Researcher will be able to access the repository in the **secure environment** to carry out their analytical work. **Data will not be disclosed outside** of this of the physical or virtual environment 6