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Appendix 2

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

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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.

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[*] 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.

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