

Principles and operational model for governing Diabetes Action Canada's data repository for patient-oriented research

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Introduction

Diabetes Action Canada is developing a data repository and registry of potential research participants to support research, QI, and service to improve diabetes care. Central to the repository are pseudonymised linkable electronic medical records (EMRs) from family practices that are participating in the Canadian Primary Care Sentinel Surveillance Network (CPCSSN).

Objectives and Approach

We sought to develop an information governance process that would engender the trust of patients and the health care professionals (HCPs) that their EMR data were being managed responsibly in the best interests of patients living with diabetes. Following an extensive literature review, we developed a principles-based governance framework and operational model, with a strong focus on patient participation in the governance process. We recruited patients through our pre-existing patient advisory circles and physicians through our partners in CPCSSN. In January 2018, we held a training workshop for Research Governing Committee (RGC) members.

Results

We identified eight values-based principles to guide our governance process: transparency; accountability; following the rule of law; integrity of purpose, science and ethics; participation and inclusiveness; impartiality and independence; effectiveness; efficiency and responsiveness; and reflexivity and continuous quality improvement of process. Patients represent 50% of RGC members and HCPs 20%. Patient members provide their perspectives on: goals and outcomes of the research; the benefits and burdens among people living with diabetes; and the communication preferences of patients around recruitment. HCPs provide a deep understanding of the settings and systems in which care is provided to ensure contextual integrity of the research. Two researchers and one person with bioethics

expertise provide technical and ethics perspectives on data requests.

Conclusion/Implications

Governance must go beyond legal compliance to ensure a 'social licence' for the use of the data. In part, we address this through our guiding principles, our emphasis on patient and healthcare provider perspectives, and focus on research that is scientifically sound, ethically robust and in the public interest.

