CPCSSN Framework for managing conflict of interest and bias regarding relationships with Funders (and Other) Partners

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Experts in policy and ethics nationally and internationally are calling for more explicit and preplanned ethics evaluation in policy related to health and health care. Ethical analysis should not to be considered an 'add-on' but an integral part of the process of engaging in any partnership to conduct research. This document is meant to describe how the Canadian Primary Care Sentinel Surveillance Network (CPCSSN) intends to match its overall mission and priorities to those of potential partners and mitigate any possible misalignment or risks.

A.   Objectives:
1. To describe the foundational ethical values and principles necessary for partnering with the CPCSSN;
2. To describe the decision-making framework that the CPCSSN will use in partnerships with entities such as governmental, non-governmental organizations and for-profit entities.
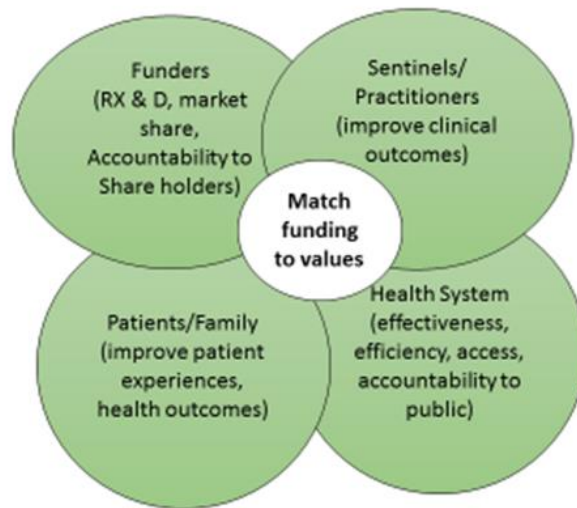
B.   Background
The Canadian Primary Care Sentinel Surveillance Network (CPCSSN) is the only pan-Canadian network that collects electronic medical record (EMR) data for research, surveillance and primary healthcare practice quality improvement. CPCSSN extracts, cleans, and maintains longitudinal de-identified patient data from more than 1,200,000 Canadians using the EMRs of more than 1,000 primary care practitioners. Examples of the extracted data includes health conditions, risk factors and behaviors, prescribed medications, laboratory tests, and referrals to other healthcare providers.

CPCSSN provides a well-established foundation with which to engage health researchers from a variety of backgrounds as well as information technology (IT) developers, and computer scientists. For the latter, CPCSSN's electronic medical record platform has great potential for use in the development and evaluation of patient-specific technology tools, including apps and patient access portals.

CPCSSN data are a significant opportunity to generate new knowledge about the organization and delivery of primary healthcare with the overall goal to spur change that will make a difference in the lives of patients and their families across Canada. This decision-making framework will address the CPCSSN's values and goals.

Figure 1 shows the complex relationship between this network and its partners, particularly potential funders.

Improving the care and quality of life of people with multiple chronic conditions-- multimorbidity

C. Definitions

Values are "concepts we use to explain how and why various realities matter. Where moral values are secure, we can cultivate a wide array of values. Where moral values are in danger, all values are at risk." [ref: EBE Vol. 5, 2515-2520].

Principles are generally understood as guides to decision and action embodying sets of values. Ethical frameworks are not a theoretical task; they are directed to guide *practical* decisions and actions. We ask questions such as: "What are our criteria for decisions and actions regarding partnership funding?"

Our values based decision-making framework should first and foremost guide the overall priorities and activities for the CPCSSN. The values ought to be reflected in any approved project and in the subsequent knowledge translation activities generated by each project.

Conflict of interest can be described as 'a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain)' (Thompson, 1993; Lemmens and Freedman, 2000; Krimsky, 2006). Conflict of interest has three components — a trust-based relationship, a conflicting interest and an exercise of judgment. The relationship between the parties in question is often trust based, such that one party (the trustor) is entitled to trust that the other (the trustee) will promote or protect their interests in relation to matters within that relationship. The second component is an influence that tends to make the trustee's judgment on a given decision less reliable for promoting or

protecting the trustor's interests than it would normally be (Davis, 1998). Third, the trustee must be in a position to make a decision that affects the trustor's interests.

D. CPCCSN Mission

CPCSSN's mission is to improve primary healthcare delivery, practice and policy through surveillance, research and quality improvement. CPCSSN's achieves its mission by creating a central data repository of EMR data elements from it different network nodes across Canada. This repository has three main purposes: (1) surveillance of chronic conditions; (2) quality improvement feedback to participating primary care practitioners and their clinics/organizations; and (3) development of new knowledge through research.

CPCSSN, through its partnerships with participating sentinels, is a data steward of de-identified pan-Canadian EMR data which can serve as a bridge between primary care, public health, and other health sectors. The EMR data that makes up the repository consists of "coded information", which is defined as information that has been stripped of identifiers and replaced with a CPCSSN ID number.

E. CPCSSN values

CPCSSN's values include the following core concepts:
- Providing excellent and robust data and analyses, where bias and conflict of interests are mitigated as much as possible;
- Improving patient care and health service delivery with a particular focus on primary care
- Inclusiveness and collaborative relationships with researchers, clinicians, and stakeholder groups whose mission, values, and practices are in alignment with CPCSSN;
- Transparency and accountability for the surveillance, quality improvement, and research produced;
- Effective stewardship of the data repository created by participating sentinels ensuring data quality, security, privacy and appropriate which meet or exceed local and national regulatory standards;
- No identifiable data regarding CPCSSN practitioners or patients is released to third parties.

CPCSSN recognizes that there may be times where it is mutually beneficial to work with for-profit partners. There are three additional principles that the CPCSSN will use to guide working with for-profit partners:
- Alignment with the CPCSSN mission and values – CPCSSN private sector work must provide a public benefit;
- Transparency – full results reports, the identities of for-profit entities that use the CPCSSN data, and dataset creation plans will all be publicly available
- For-profit entity work undertaken with the CPCSSN must be in addition to, and in no way detracting from, CPCSSN research or quality improvement work – this includes the requirement that work with for-profit entities is financially viable

In the event of work with for-profit partners: (a) the research is conducted at arm's length from the partner; (b) no partner's employees, contractors, or agents are part of the project team; (c) the partner has no influence on study direction or analysis; and (d) the sponsor has no access to data, other than a final report. Apriori primary and secondary outcomes must be registered with the CPCSSN and that the

CPCSSN will make the results of any for-profit analyses publicly available through such means as peer-reviewed publication, report or brief available on its website and upon request.

F. **Safeguarding CPCSSN Data for secondary use (includes Research, Surveillance or Quality Improvement)**

The CPCSSN platform adheres to a privacy and information system security framework (Williamson et al., 2013, p. 5) using:

► Privacy by Design Principles, the standard principles adopted by governments and privacy commissioner offices throughout the world

► Information Standards Organization (ISO) 27001/2, governing information system security

► Tri-Council Policy Statement, Ethical Conduct of Research Involving Humans (TCPS2) 2014, governing the use of health information in research

The CPCSSN has completed and will regularly review privacy impact assessments (PIA) and threat risk assessments (TRA). The scope of the PIAs include every stage of the information flow between the network nodes and the CPCSSN central repository. The PIAs are intended to pay close attention to CPCSSN's technological, organizational, and physical safeguards for health information. After the baseline PIAs were completed, each network node continues to use the CPCSSN Privacy Compliance Checklist to undertake their own compliance monitoring on an annual basis. A TRA was also conducted and included CPCSSN's management of personal information and personal health information, and all end user connection points (access by regional data managers, researchers, research associates, etc.). The CPCCSN data are housed at the Centre for Advance Computing (CAC) at Queen's University in Kingston, Ontario. The decision to use the CAC was made with security in mind. The regional server requires that all remote connections to it be encrypted (e.g. through a VPN or SSH connection). This ensures that even if someone gains unauthorized access to the regional server, patient data will remain secure. Other benefits of the central management with the CAC are: 1) Physical access to the CAC server room is controlled, logged, and monitored (e.g. with video cameras), 2) Access to the regional server can be revoked in the event that an employee is terminated or leaves the project, 3) A strong, consisted firewall policy can be applied for all CPCSSN servers by the CAC, and 4) Software security updates can be uniformly applied to all of the servers.

Another key ethical safeguard is the continuous renewals of approvals from Research Ethics Boards (REB) in Canada and yearly updates for investigators to declare any potential conflicts of interest. Each PCRN had to obtain REB approval before its collected health information could be used for research purposes. The CPCSSN executive committee ensures that annual renewal will be obtained from all local PCRN University affiliated.

Safeguards are taken to prevent identifiable patient data from being stored in the CPCSSN repository such as (e.g. data management tools to identify and remove names, health care numbers, credit card numbers, etc). Safeguards will be taken to prevent identifiable patient data from being released from the CPCSSN repository.

Standard Operating Procedures (SOP) in Privacy, Ethics and Information Security the CPCSSN have been developed. These address security incidents and reporting. CPCSSN has a protocol for reporting incidents and in the event of a real or perceived incident there is a step-by-step process of what to do in the event of an incident (Appendix A).

All research utilizing CPCSSN repository data must be approved by relevant Research Ethics Boards and the CPCSSN Standing Research Committee in accordance with CPCSSN's Standard Operating Procedures (SOP) in Privacy, Ethics and Information Security and the CPCSSN Information and Data Sharing Agreement. In the case of research, the researcher will be allowed limited use of the CPCSSN data according to what is agreed upon in the CPCSSN Information and Data Sharing agreement. The research will not be allowed to use the data obtained for other purposes outside that agreement.

No partner organizations or individuals will be given authority to limit sharing of findings with the public assuming the information falls within the previously stated privacy limitations and partnership agreements.

Consent of Participating Primary Care Practitioners
All participating CPCSSN sentinels are offered the opportunity to opt out of participating in research projects at two broad levels:
1) Full participation with all studies and partnerships with organizations and individuals deemed acceptable by the CPCSSN Steering Committee (this includes charities, governmental organizations and for-profit entities).
2) Participation restricted to studies and partnerships only with publicly funded agencies and granting agencies.

G. Guide to Decision Making and Approval of studies involving Partnerships *(eg. funders sentinels, patients, researchers, decision-makers):*
(Informed by Canadian Institutes of Health Research Ethics Framework for Partnerships with the Private Sector, 2013)

Who are the CPCSSN's Right Partner(s)? The CPCSSN should ideally partner only with organizations and individuals whose mission, values and practices are in alignment with CPCSSN. There will be situations where CPCSSN's mission, values and practices do not fully align with those of a partner. In these cases, CPCSSN and its partner would need to ensure we have sufficient alignment of mission, values and practices.

For-profit entities or charities whose mission, values or practices conflict with our values (e.g., companies that manufacture or sell products that are known to be harmful to human health, without counter-balancing benefits, or that knowingly engage in practices that violate human rights) should be excluded from partnerships CPCSSN.

If conflicts arise or are discovered, the CPCSSN reserves the right to terminate or reassess the project scope. In accordance with local and national REB standards all projects will be reviewed yearly to ensure compliance with all CPCSSN policies and the values stated in this document.

Are we better together? Partnerships should promote initiatives that each partner, on its own, could not address as comprehensively or as effectively.

The following outline examples of the types of research CPCSSN has an interest in pursuing with partner organizations (non-profit or for profit):

1. Funding that enhances our capacity to process and evaluate primary care EMR data that are usable by any researchers using the database in the future. This includes work such as developing new disease case detection capacity and enhancements in coding algorithms of clinical inputs and outcomes.
2. Projects with feasible timeframes.
3. Funding that leads to quality improvement or educational content for family physicians and their practices that is consistent with the goals and principles of the College of Family Physicians of Canada and other health profession colleges/associations (e.g. Canadian Nurses Association).

Do we have shared objectives? Partners should agree explicitly on the objectives of the partnership, even though they may have different motivations and values. To achieve success, partners should establish a common understanding regarding the objectives of the partnership, and should negotiate the management of the partnership in ways that can best achieve them by building trust and maintaining open-mindedness. In some instances, such as when the stakes in the outcome of a partnership are high, greater harmonization between partners, their visions or their operations may be necessary to ensure the success of a partnership. All partnership agreements will be ratified by the CPCSSN Steering committee upon entering in agreement and yearly in coordination with REB approvals

Are there any conflicting objectives? If partner objectives are not aligned with the CPCSSN mission and values, use of the CPCSSN data is likely not possible. Examples of the types of projects not acceptable to the CPCSSN are those whose primary goal is marketing, the data are skewed for purposes such as disease awareness, the answer to the question being asked has already been completed, or evidence can be found using other data or methods (e.g. meta analyses).

Do we have fair selection? The selection of partners should be transparent. To help select right partners among potential organizations, the CPCSSN Steering Committee should develop objective criteria and transparent procedures that are applied across the organization to ensure fairness. Entering into partnerships will be discussed and agreed upon with a majority vote by the advisory board.

Do we have an appropriate proportion of for-profit partners? The CPCSSN is at risk of obligation and conflict of interest where for-profit entities represent the majority proportion of infrastructure or project funding. The CPCSSN will have a diversified funding scheme made up of tri-council funding, governmental and non-governmental organizations and for-profit entities. The proportion will be regularly reviewed the CPCSSN advisory committee (made up of Network Directors, etc) and communicated sentinels on a yearly basis.

Appendix A –CPCSSN values expanded

Empowerment of practitioners and patients
CPCSSN recognizes that demonstrating integrity is essential for building trust among the organizations and people with whom it deals. It is critical for establishing and maintaining an excellent reputation with the Canadian public. We operate with professional integrity to maintain confidence in the organization itself, in its relationships, its data gathering, management and analysis services, its information and knowledge products.

Transparency
The CPCSSN practices being transparent about what it is doing, how and when it is doing it, with whom it is engaged, and what impact it believes the activity or product may or will have. Information is conveyed in timely and appropriate ways to relevant stakeholders and audiences in the spirit of intentional openness. Transparency is created by communicating regularly with participating sentinels, making information available on our website and reporting to our funders. Transparency is a pre-condition for any form of accountability.

Accountability
We appreciate the importance of establishing a highly accountable organizational culture. Attaining and maintaining organizational accountability necessitates our willingness to accept full personal accountability for the assigned roles and responsibilities related to governance, management practices, the implementation of the CPCSSN's strategic plan, and to the delivery of value to internal and external stakeholders. It also requires risk and liability management which CPCSSN mitigates by complying with all ethical, legal, privacy and regulatory requirements and procedures.

Collaboration
Success is supported by our commitment to be a trusted and respected partner and collaborator. When appropriate, we share our skills, talents, knowledge and resources with others who hold a shared purpose and direction. As a pan-Canadian 'network of networks' we nurture our unique capacity to contribute to the strengthening and advancement of primary healthcare (primary care and public health) research, practice and policy at regional, provincial and national levels through partnership and collaborative initiatives. In the spirit of collaboration, we may serve as a bridge or connector between information technology, healthcare and academia.

Stewardship
CPCSSN is a steward of a data repository containing clinical electronic medical record data from primary care. Referring to data and knowledge product accessibility, we support processes and agreements that enable timely access to accurate and quality data, data sharing, analysis, translation and interpretation, and the information exchange of such. We work to improve ease of use of the above.

CPCSSN remains flexible to enable positive, creative, organized and timely reaction to the needs of the organization, our partners, funders, investors, stakeholders, and the broader community. We endeavour to engage in regular knowledge exchanges at multiple levels to facilitate response to 'environmental' changes and emergent opportunities or concerns.