NEUROLOGICAL REGISTRIES BEST PRACTICE GUIDELINES AND IMPLEMENTATION TOOLKIT

National Population Health Study of Neurological Conditions

LAWRENCE KORNGUT
NEUROLOGIST
DEPT CLINICAL NEUROSCIENCES
UNIVERSITY OF CALGARY

FACULTY OF MEDICINE | UNIVERSITY OF CALGARY
CLINICAL NEURO SCIENCES CALGARY CANADA
HOTCHKISS BRAIN INSTITUTE
CNDR.ORG Canadian Neuromuscular Disease Registry

ACKNOWLEDGEMENTS

Co-PIs: Nathalie Jetté, Tamara Pringsheim

Kristin Atwood	Karen Barlow	Craig Campbell	Steve Casha	Lisa Casselman
Lynn Dagenais	Lundy Day	Paula de Robles	Elizabeth Donner	Guillermo Fiebelkorn
Claire Marie Fortin	Clare Gallagher	Angela Genge	Glenys Godlovitch	Ruth Hall
Mark Hamilton	Rachel Hayward	David B. Hogan	Nathalie Jette	Megan Johnston
Moira K. Kapral	Lawrence Korngut	Darren Lam	Diane Lorenzetti	Mark Lowerison
Gail MacKean	Jean K. Mah	Ruth Ann Marrie	James Marriott	Colleen Maxwell
Essie Mehina	Theo Mobach	Vanessa K. Noonan	Scott Patten	Ted Pfister
Tamara Pringsheim	Michael Shevell	Eric Smith	Thomas Steeves	Janet Warner
Cindy Watson	Samuel Wiebe	Christina Wolfson	Julie Wysocki	

The project team also wants to thank the following additional grant team members and collaborators for their guidance and advice along the way: Caitlin Smith; David Zygun; Frank Silver; Jack Puymirat; Jane Evans; Karen Turpin; Larry Svenson; Lewis Holmes; Lorne Zinman; Marcel Dvorak; Maryam Oskoui; Nancy White; Roger Freeman; Sandra Black; the members of the Scientific Advisory Committee; and the patients, caregivers, and families who contributed to our focus group discussions.

This study is part of the National Population Health Study of Neurological Conditions. We wish to acknowledge the membership of Neurological Health Charities Canada and the Public Health Agency of Canada for their contribution to the success of this initiative.

Funding for the study was provided by the Public Health Agency of Canada. The opinions expressed in this publication are those of the authors/researchers, and do not necessarily reflect the official views of the Public Health Agency of Canada.

NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND IMPLEMENTATION TOOLKIT

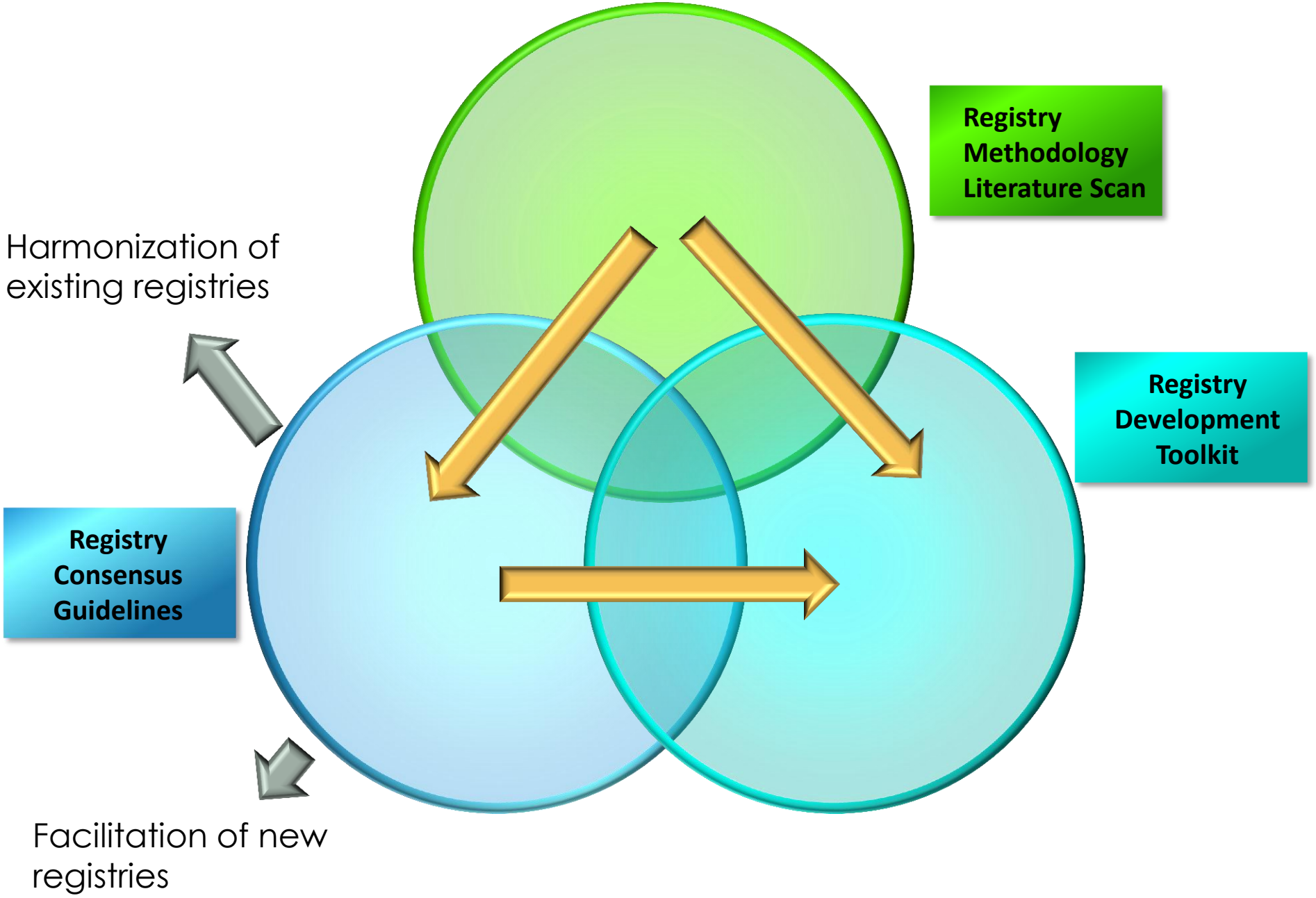
- Neurological conditions are will become an increasing healthcare burden for Canadians
- Information on many of the conditions is limited or unavailable
- Patient registries are a key source of data to assess the burden of neurological conditions
  - The WHO's World Health Report identified 5 core competencies for long term patient care. One of these 5 core competencies was the development of information and communication technologies including registries to ensure continuity of care.

BACKGROUND

- Objective
  - Create comprehensive registry guidelines and a toolkit for development and implementation of neurological disease registries in Canada
- Phase 1: Registry Development Literature Review
  - Identify existing registry methodology and published guidelines documents
  - Lead: Nathalie Jetté

BACKGROUND

- Phase 2: Consensus Guideline Development
  - Engage Stakeholders across neurological conditions and utilize information gained in Phase 1 to develop comprehensive registry guidelines
  - Patient focus groups to inform the process
  - Lead: Tamara Pringsheim
- Phase 3: Registry Toolkit Development
  - In consultation with stakeholders, and in compliance with guidelines, develop template documents and accessible tools for registry development and implementation
  - Lead: Lawrence Korngut

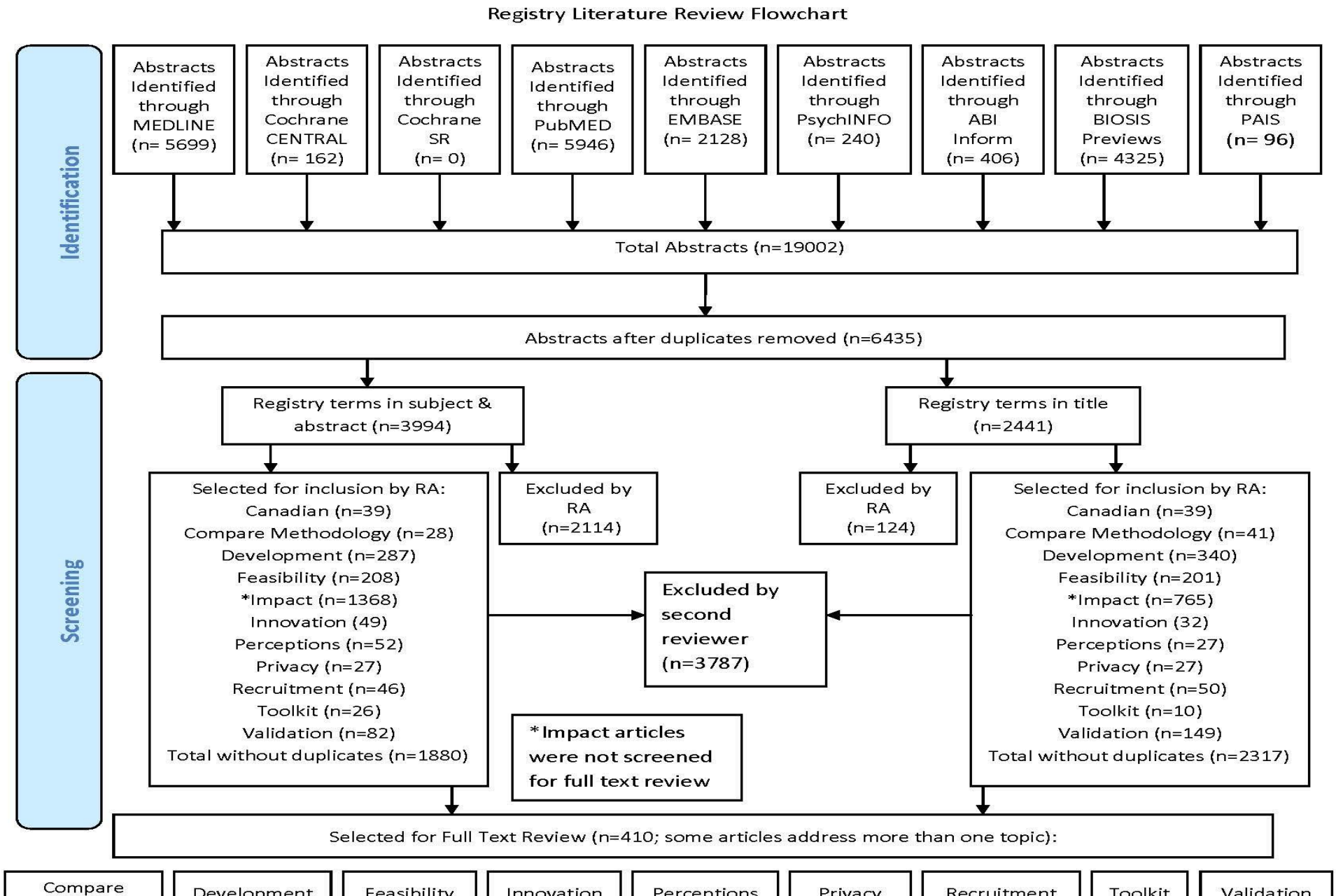

Registry
Methodology
Literature Scan
Harmonization of
existing registries
Registry
Development
Toolkit
Registry
Consensus
Guidelines
Facilitation of new
registries

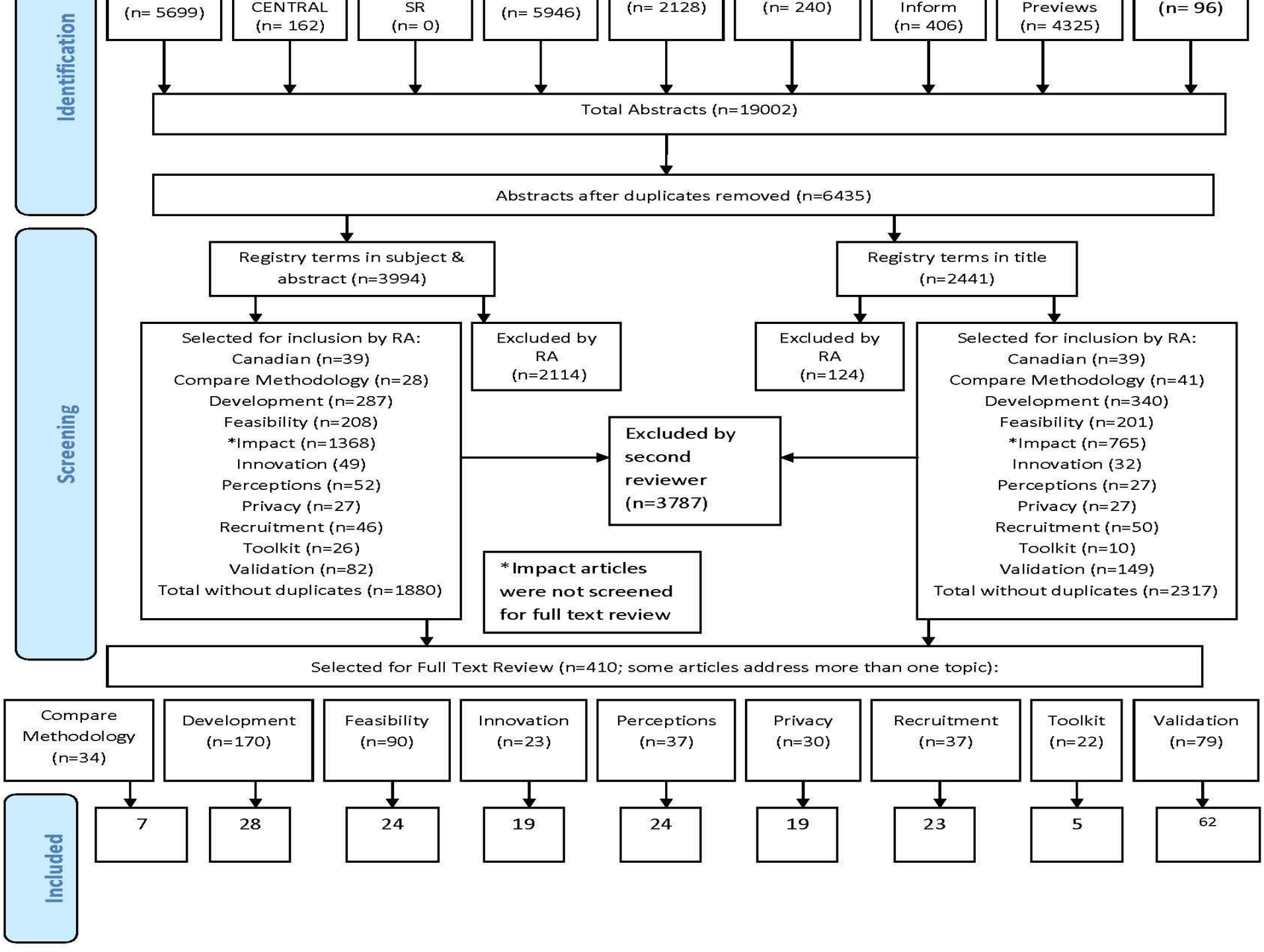
LITERATURE REVIEW

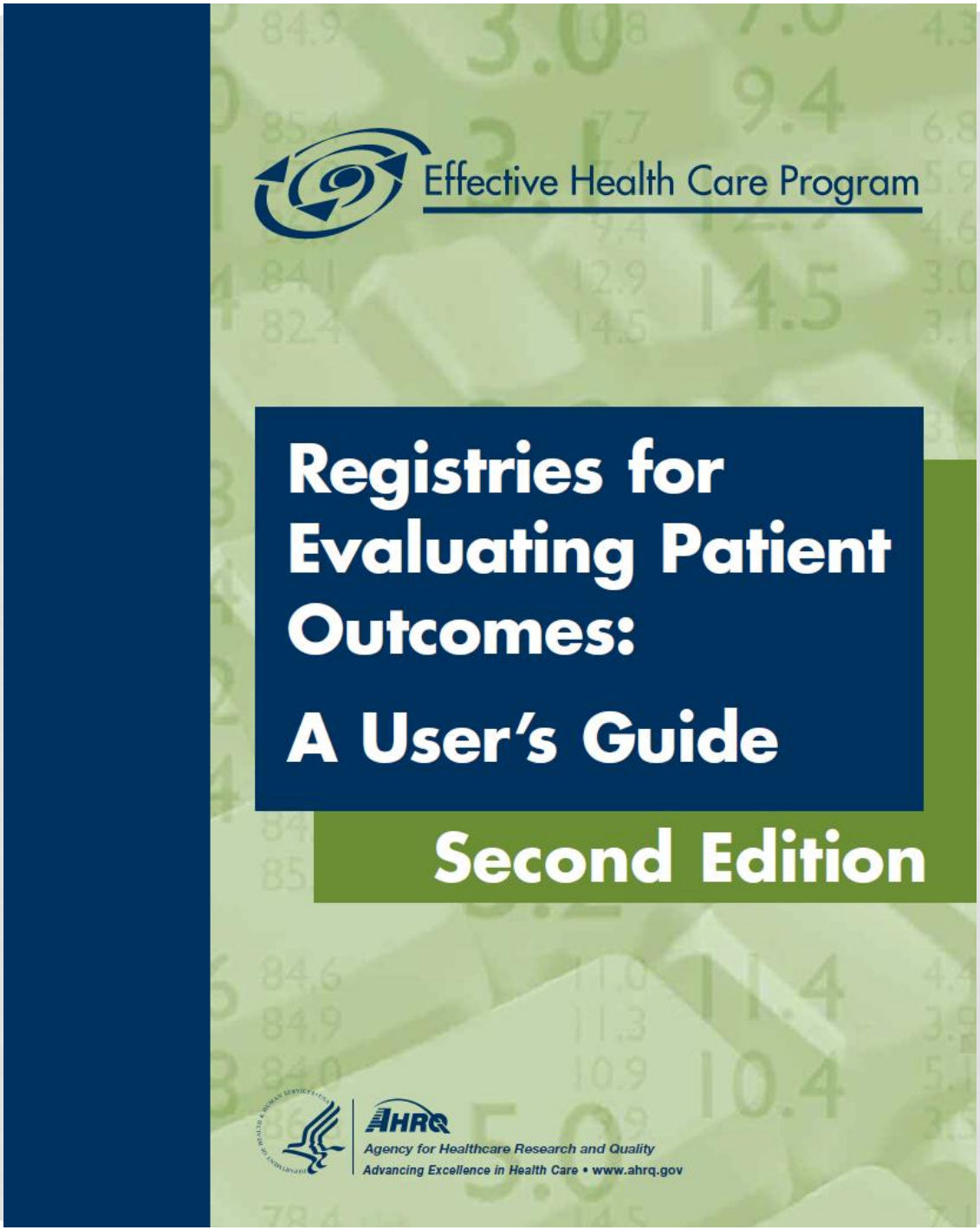
LEAD: DR. NATHALIE JETTÉ

INTRODUCTION AND RATIONALE

- Purpose: To identify existing registry best practices and other relevant resources
- Determine what and how much information is presently available
- Gather information about established standards, common practices, and best practices
  - Determine whether practices are consistent across registries
- Identify potential toolkit items


Registry Literature Review Flowchart
Identification
Abstracts Identified through MEDLINE (n= 5699)
Abstracts Identified through Cochrane CENTRAL (n= 162)
Abstracts Identified through Cochrane SR (n= 0)
Abstracts Identified through PubMED (n= 5946)
Abstracts Identified through EMBASE (n= 2128)
Abstracts Identified through PsychINFO (n= 240)
Abstracts Identified through ABI Inform (n= 406)
Abstracts Identified through BIOSIS Previews (n= 4325)
Abstracts Identified through PAIS (n= 96)
Total Abstracts (n=19002)
Abstracts after duplicates removed (n=6435)
Screening
Registry terms in subject & abstract (n=3994)
Registry terms in title (n=2441)
Selected for inclusion by RA:
Canadian (n=39)
Compare Methodology (n=28)
Development (n=287)
Feasibility (n=208)
*Impact (n=1368)
Innovation (49)
Perceptions (n=52)
Privacy (n=27)
Recruitment (n=46)
Toolkit (n=26)
Validation (n=82)
Total without duplicates (n=1880)
Excluded by RA (n=2114)
Excluded by RA (n=124)
Selected for inclusion by RA:
Canadian (n=39)
Compare Methodology (n=41)
Development (n=340)
Feasibility (n=201)
*Impact (n=765)
Innovation (32)
Perceptions (n=27)
Privacy (n=27)
Recruitment (n=50)
Toolkit (n=10)
Validation (n=149)
Total without duplicates (n=2317)
Excluded by second reviewer (n=3787)
*Impact articles were not screened for full text review
Selected for Full Text Review (n=410; some articles address more than one topic):
Compare
Development
Feasibility
Innovation
Perceptions
Privacy
Recruitment
Toolkit
Validation


Identification
(n= 5699)
CENTRAL
(n= 162)
SR
(n= 0)
(n= 5946)
(n= 2128)
(n= 240)
Inform
(n= 406)
Previews
(n= 4325)
(n= 96)
Total Abstracts (n=19002)
Abstracts after duplicates removed (n=6435)
Screening
Registry terms in subject & abstract (n=3994)
Registry terms in title (n=2441)
Selected for inclusion by RA:
Canadian (n=39)
Compare Methodology (n=28)
Development (n=287)
Feasibility (n=208)
*Impact (n=1368)
Innovation (49)
Perceptions (n=52)
Privacy (n=27)
Recruitment (n=46)
Toolkit (n=26)
Validation (n=82)
Total without duplicates (n=1880)
Excluded by RA (n=2114)
Excluded by RA (n=124)
Selected for inclusion by RA:
Canadian (n=39)
Compare Methodology (n=41)
Development (n=340)
Feasibility (n=201)
*Impact (n=765)
Innovation (32)
Perceptions (n=27)
Privacy (n=27)
Recruitment (n=50)
Toolkit (n=10)
Validation (n=149)
Total without duplicates (n=2317)
Excluded by second reviewer (n=3787)
* Impact articles were not screened for full text review
Selected for Full Text Review (n=410; some articles address more than one topic):
Included
Compare Methodology (n=34)
Development (n=170)
Feasibility (n=90)
Innovation (n=23)
Perceptions (n=37)
Privacy (n=30)
Recruitment (n=37)
Toolkit (n=22)
Validation (n=79)
7
28
24
19
24
19
23
5
62



Gliklich RE, Dreyer NA, eds. Registries for Evaluating Patient Outcomes: A User's Guide. 2nd ed. September 2010.

FEASIBILITY

- 90 full text → 24 included
- Factors that negatively affect feasibility
  - Confidentiality and privacy issues
  - Participation Issues
  - Issues related to multiple centers and locations
  - Data quality
  - Financial and funding constraints
  - Lack of time, effort, resources
  - Potential bias

HOW TO INCREASE LIKELIHOOD OF FEASIBILITY?

- Predefined purpose for registry
  - Is a registry the right methodology?
- Need adequate support
  - Plan ahead, and with great detail
- Funding
  - Adequate and sustainable
- Consider whether population based data collection is indicated

HOW TO INCREASE LIKELIHOOD OF FEASIBILITY?

- Minimal data set (complete enough to fulfill purpose of registry but limited enough to ensure feasibility)
- User friendly data entry (standardized, easy to access, focused data collection strategy, etc)
- Integrated data systems
- Collaboration between registries (if applicable)

METHODOLOGICAL COMPARISONS

- 34 full text → 7 included
- Physician versus patient driven registries
- Physicians driven registries:
  - Physicians have potential to gather large amounts of clinical and demographic information
  - Recruitment of patient by a physician = most successful recruitment strategies**
- Patient driven registries:
  - Provide access to potentially large patient populations in a cost-effective manner
  - But tends to produce lower quality data and higher potential for errors

PERCEPTIONS - PARTICIPANTS

- Predictors of participation
  - Satisfaction with care
  - Age (under 65 years)
  - Male gender
  - Education
  - Recruiting site
  - Ethnicity (white; US data)
- Predictors of non-participation
  - Concerns about privacy
  - Concerns about additional face to face visits
  - Ethnicity (non white)

Participants have a strong desire for information beyond the specific study when registering

PERCEPTIONS - PROVIDERS

- Motivated to participate if:
  - Effort minimal
  - Data entry efficient and simple
  - Operation cost is low
  - Results and outcomes relevant to clinical practice or research interests
  - Their input is sought early on and throughout the process
- Inhibitors to participation:
  - Mandatory participation

RECOMMENDATIONS CONSIDERING PERCEPTIONS TO ENSURE SUCCESS

- Key to address participant concerns about data access and type of data stored
- Key to address concerns about data security and privacy (not a single individual but a committee)
- Consider effective software platform with clear procedures supporting registry infrastructure

FOCUS GROUP OVERVIEW

LEAD: DR. TAMARA PRINGSHEIM

PURPOSE

- Examine patient perspectives about registries in order to:
- Augment literature regarding patient perceptions
- Increase likelihood that future registry development will be informed by opinions, priorities and concerns of patients and caregivers
  - Guidelines and Toolkit recommendation to coincide with patient perceptions

FOCUS GROUP PARTICIPANTS

Focus Group Participants	Neurological Condition	Role	
		Parent or Caregiver	Person Living with Neurological Condition
Group A (n=9)	Epilepsy Hydrocephalus Muscular Dystrophy Tourette Syndrome	9	0
Group B (n=8)	Dystonia Epilepsy MS	0	8
Group C (n=10)	ALS Huntington's Parkinson's	3	7
Total	**27**	**12**	**15**

REASONS FOR/INTEREST IN PARTICIPATING IN A REGISTRY

- To help others living with neurological conditions
- To develop "big picture" about a particular conditions
- To develop best practices about treatment
- To have access to credible, useful information

FACTORS THAT WOULD INFLUENCE PARTICIPATION

- Have a clear purpose that is clearly communicated
- Give opportunities to participate in ethical, meaningful research
- Be well managed and sustainable
- Ensure participation is not too onerous
- Allow participants to withdraw at any time

TYPES OF INFORMATION COLLECTED

- Participants were generally more comfortable:
  - Sharing medical information than with sharing personal information
  - Sharing information if they understand why it is necessary
- No one was willing to share SIN
- Some were concerned about Stigma/discrimination associated with sharing genetic information
- Group discussed opt out option for information items vs full participation

MOTIVATING FACTORS CONSISTENT WITH LITERATURE

1. Altruistic attitude - The perception of benefit to the greater good even beyond immediate individual benefit or the potential for individual benefit.

2. Data will be used by responsible people for legitimate purposes

3. Advances in research and the possibility of elucidation of treatment or cure and subsequently improved quality of life.

Concerns about privacy also coincided with literature

CONCLUSION

- People support and will participate in registries if:
- They are convinced of the registry's value
- The registry generates knowledge that will
  - Help health professionals better treat conditions
  - Lead to improvements in prognosis and quality of life
- Focus Group manuscript prepared and submitted to research journal for publication

IMPLEMENTATION TOOLKIT

LEAD: DR. LAWRENCE KORNGUT

REGISTRY TOOLKIT – INITIAL SEARCH

- Template documents for ethics submissions
- Report on REB/IRB requirements variance between provinces.
- Template policies and procedures to ensure consistent registry implementation across Canada so that data collection is secure, valid, high quality, and will produce comparable results.

CONSENSUS MEETING 2 FEEDBACK

Category	Number of Resources Found	Number of Resources Retained Following Meeting #2
Data Collection, Storage and Curation	53	2
Patient Recruitment and Registry Sustainability	9	15
Ethical and Legal Considerations	40	29
Quality Assurance and Registry Evaluation	10	10
Validation, Interpretation and Linkage of Registry Data	9	9
Online Registries	2	0
Total	138	65

WHERE DO WE GO FROM HERE?

Canadian Registry Network
Réseau canadien de registres

1. Guideline oversight
2. Toolkit maintenance
3. Case report/data set metaregistry
4. Seek funding for common infrastructure/technology
5. Collaborate
6. Data linkages
7. Reduce cost

Connecting researchers *everywhere*
Rapprocher les chercheurs *partout*

Canadian Registry Network
Réseau canadien de registres

The Canadian Cerebral Palsy Registry

The Canadian Neuromuscular Disease Registry (CNDR)

The North American Research Committee on Multiple Sclerosis (NARCOMS) Registry

The Ontario Stroke Registry

The Quebec Myotonic Dystrophy Registry

The Rick Hansen Spinal Cord Injury Registry (RHSCIR)

Canadian Hydrocephalus Clinical Research Network (under develop
The Southern Alberta Dementia Registry (under development)
The Sudden Unexplained Death in Epilepsy (SUDEP) Registry (under development)

Connecting researchers *everywhere*
Rapprocher les chercheurs *partout*

Canadian Registry Network
Réseau canadien de registres

Join us!

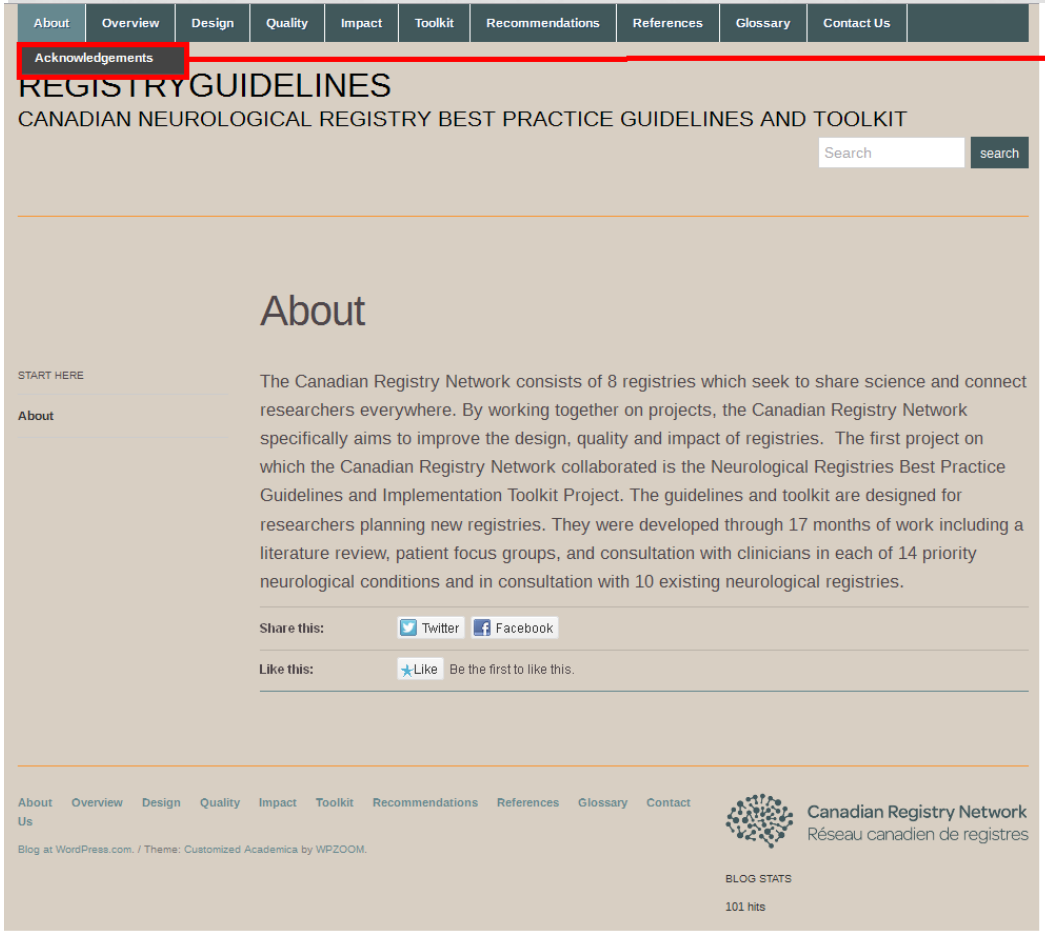
Sharing Science
Le Partage de la Science

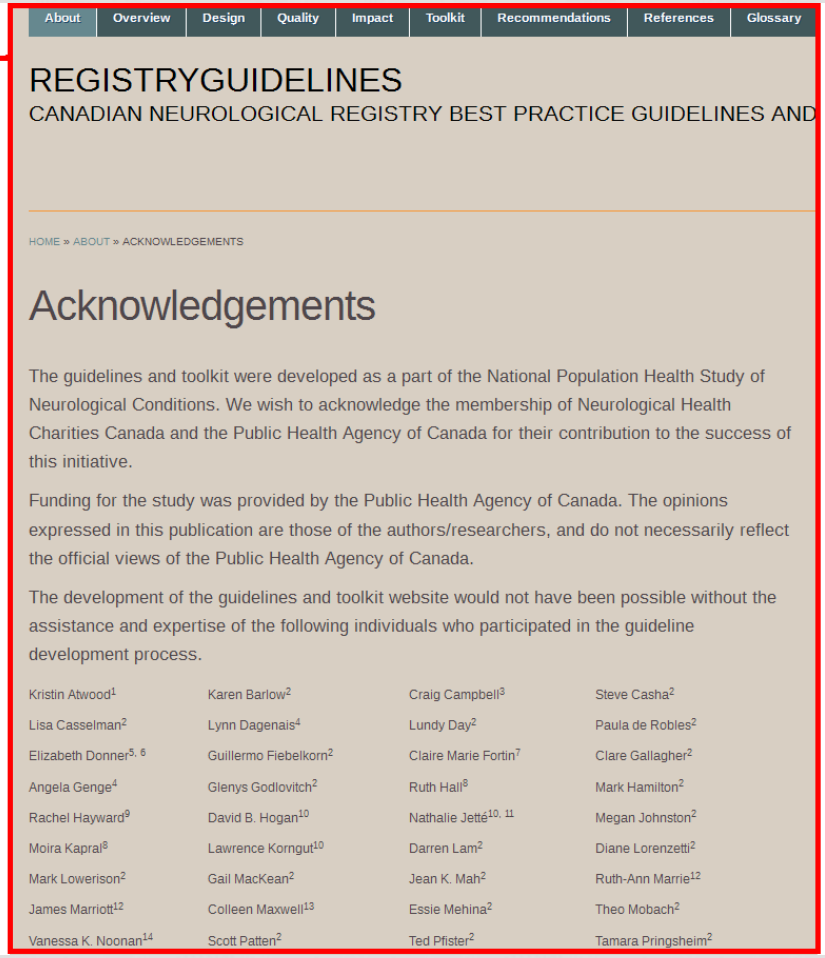
Connecting
researchers *everywhere*
Rapprocher
les chercheurs *partout*

YOU CAN ACCESS THE TOOLKIT WEBSITE AT

canadianregistrynetwork.org

HOME PAGE


About
Overview
Design
Quality
Impact
Toolkit
Recommendations
References
Glossary
Contact Us
Acknowledgements
REGISTRYGUIDELINES
CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT
Search
search
About
START HERE
About
The Canadian Registry Network consists of 8 registries which seek to share science and connect researchers everywhere. By working together on projects, the Canadian Registry Network specifically aims to improve the design, quality and impact of registries. The first project on which the Canadian Registry Network collaborated is the Neurological Registries Best Practice Guidelines and Implementation Toolkit Project. The guidelines and toolkit are designed for researchers planning new registries. They were developed through 17 months of work including a literature review, patient focus groups, and consultation with clinicians in each of 14 priority neurological conditions and in consultation with 10 existing neurological registries.
Share this:
Twitter
Facebook
Like this:
Like
Be the first to like this.
About Overview Design Quality Impact Toolkit Recommendations References Glossary Contact Us
Blog at WordPress.com. / Theme: Customized Academica by WPZOOM.
Canadian Registry Network
Réseau canadien de registres
BLOG STATS
101 hits


About
Overview
Design
Quality
Impact
Toolkit
Recommendations
References
Glossary
REGISTRYGUIDELINES
CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND
HOME » ABOUT » ACKNOWLEDGEMENTS
Acknowledgements
The guidelines and toolkit were developed as a part of the National Population Health Study of Neurological Conditions. We wish to acknowledge the membership of Neurological Health Charities Canada and the Public Health Agency of Canada for their contribution to the success of this initiative.
Funding for the study was provided by the Public Health Agency of Canada. The opinions expressed in this publication are those of the authors/researchers, and do not necessarily reflect the official views of the Public Health Agency of Canada.
The development of the guidelines and toolkit website would not have been possible without the assistance and expertise of the following individuals who participated in the guideline development process.
Kristin Atwood[1]
Karen Barlow[2]
Craig Campbell[3]
Steve Casha[2]
Lisa Casselman[2]
Lynn Dagenais[4]
Lundy Day[2]
Paula de Robles[2]
Elizabeth Donner[5, 6]
Guillermo Fiebelkorn[2]
Claire Marie Fortin[7]
Clare Gallagher[2]
Angela Genge[4]
Glenys Godlovitch[2]
Ruth Hall[8]
Mark Hamilton[2]
Rachel Hayward[9]
David B. Hogan[10]
Nathalie Jetté[10, 11]
Megan Johnston[2]
Moira Kapral[8]
Lawrence Korngut[10]
Darren Lam[2]
Diane Lorenzetti[2]
Mark Lowerison[2]
Gail MacKean[2]
Jean K. Mah[2]
Ruth-Ann Marrie[12]
James Marriott[12]
Colleen Maxwell[13]
Essie Mehina[2]
Theo Mobach[2]
Vanessa K. Noonan[14]
Scott Patten[2]
Ted Pfister[2]
Tamara Pringsheim[2]

REGISTRYGUIDELINES

CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

The Case for Neurological Registry Best Practice Guidelines in Canada

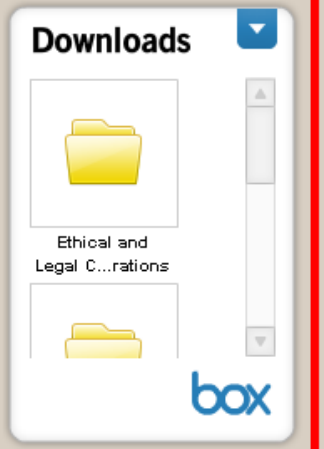
Contributors: Nathalie Jette[1,2], Megan Johnston[3], Tamara Pringsheim[3], Lawrence Korngut[2]

[1] Institute of Public Health, University of Calgary, [2] Hotchkiss Brain Institute, University of Calgary, [3]University of Calgary

Rationale

Why are neurological conditions so important to Canadians?

In 2005, The World Health Organization (WHO) reported that neurological conditions account for over 6% of the global burden of disease.(World Health Organization 2006) The relative contribution of neurological conditions is greater in high income countries such as Canada.(World Health Organization 2006) The burden of neurological conditions is substantial because many: (1) are chronic and lack curative therapies; (2) occur or manifest throughout the lifespan (e.g. epilepsy, traumatic brain injury); (3) follow a progressive course; (4) lead to functional limitations; and (5) require significant healthcare resources and caregiver investment. The WHO predicts that the healthcare burden from neurological conditions will increase over the next 20 years. Estimated total deaths attributed to neurological conditions are predicted to rise by approximately 0.6% by 2030 while estimated total disability is predicted to rise by about 0.5%.(World Health Organization 2006)



ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members

REGISTRYGUIDELINES

CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

Overview

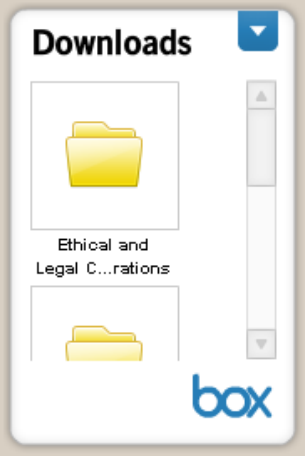
The guidelines are organized into three parts consecutively addressing registry design, quality and impact. Each part begins with an executive summary that summarizes key points. More in-depth and supporting information is presented thereafter.

It is our hope that the guidelines and accompanying toolkit will be useful to registry leaders, staff, investigators, patient organizations, governmental agencies, the pharmaceutical and biotechnology industries, and other institutions, groups and individuals with respect to the following:

1. Determining whether a registry is appropriate to address a specific question or series of questions.
2. Providing resources to assist in developing the case for a registry
3. Providing a comprehensive framework for registry design (i.e. protocol development, ethics board submission, data collection infrastructure development).
4. Understanding and addressing the importance of quality control and assurance
5. Techniques in validation and interpretation of registry data
6. The importance of the impact of a registry and it's measurement.

The guidelines and accompanying toolkit can also be used to:

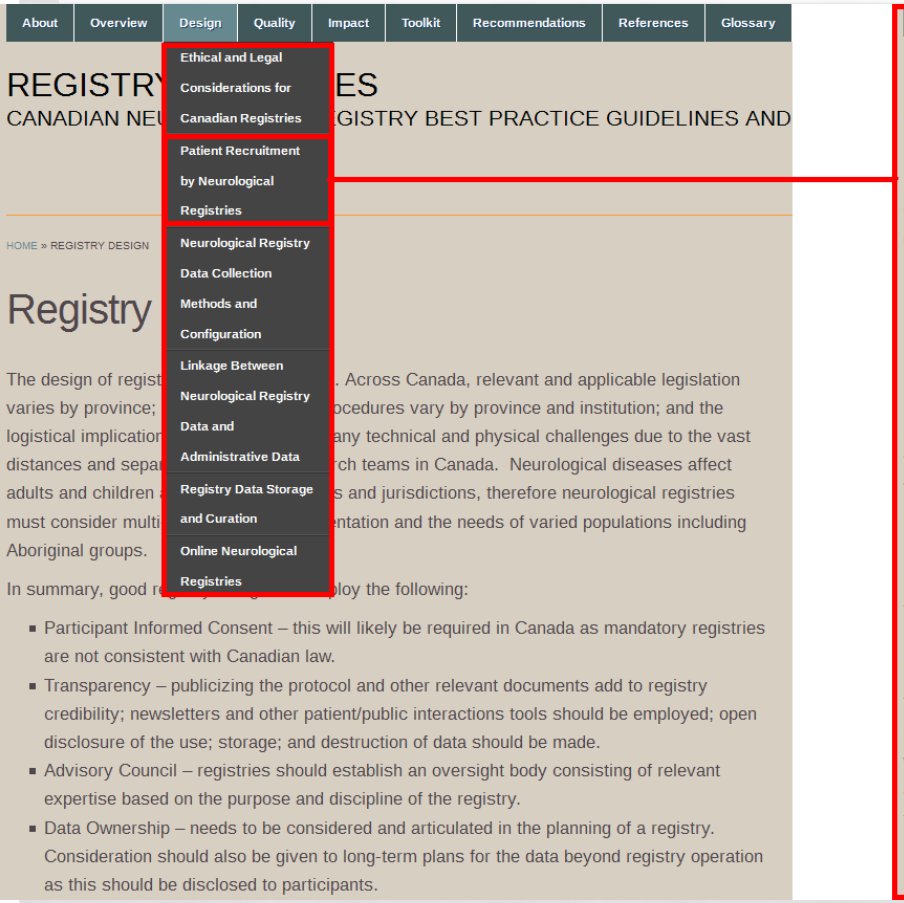
1. Identify appropriate references from the literature to support funding application and manuscript preparation
2. Support registry standards and best practices in Canada in funding applications and ethics board submissions.
3. Provide published benchmarks for data quality
4. Provide examples of registry impact

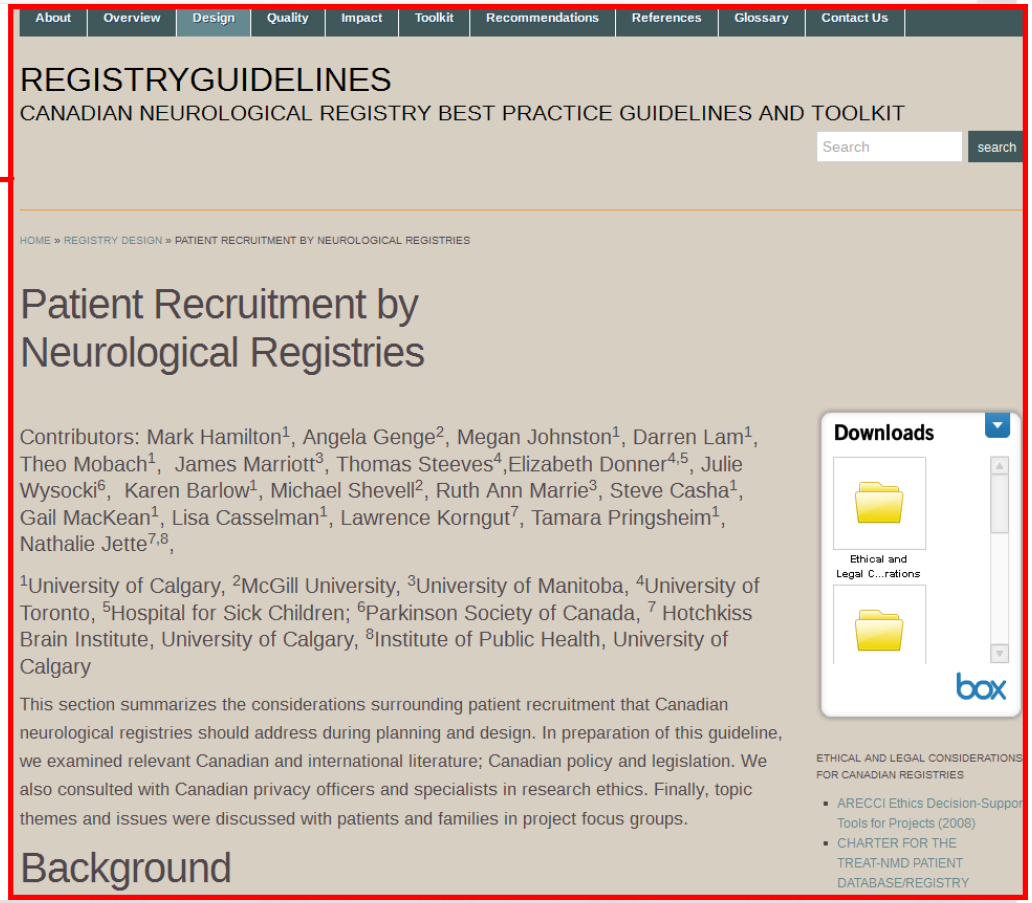


ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

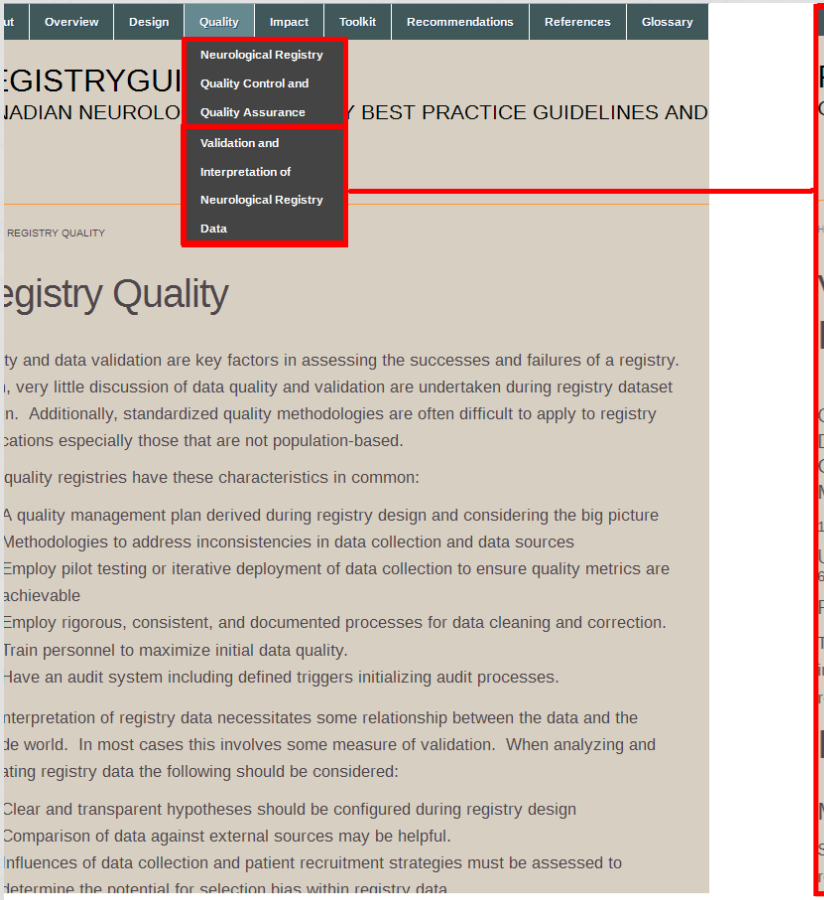
- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members
- Consent Templates (UBC BCCA Research Ethics Board)

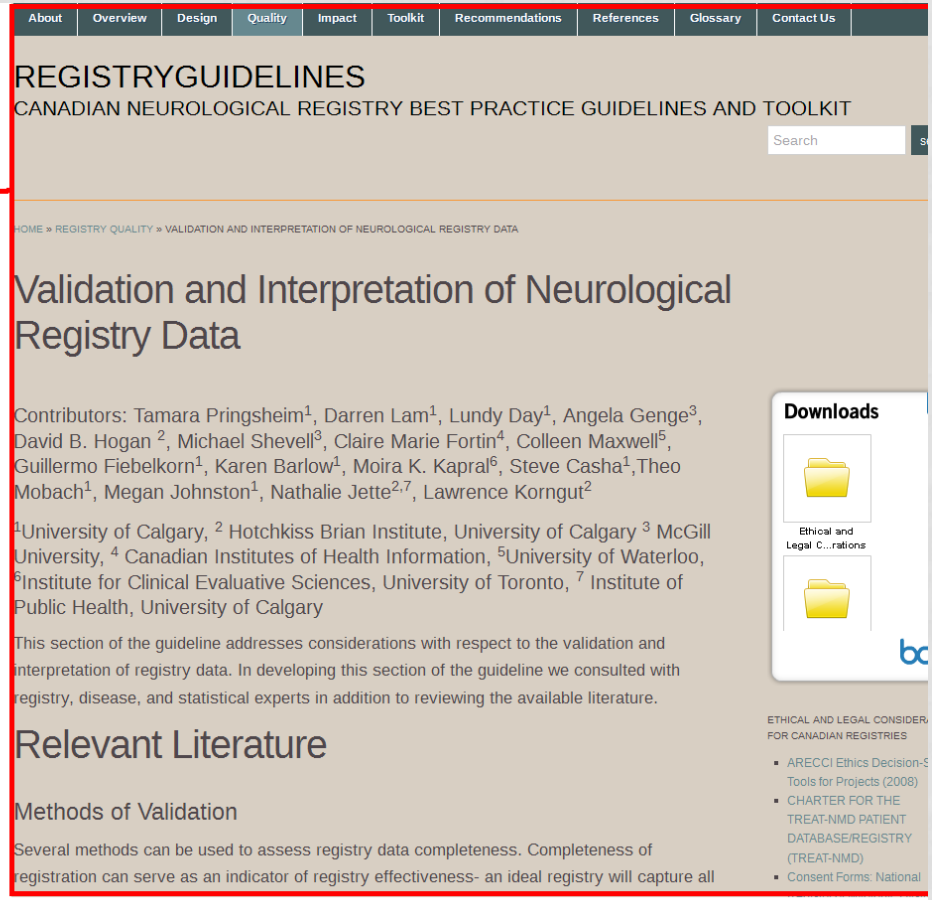
REGISTRY DESIGN



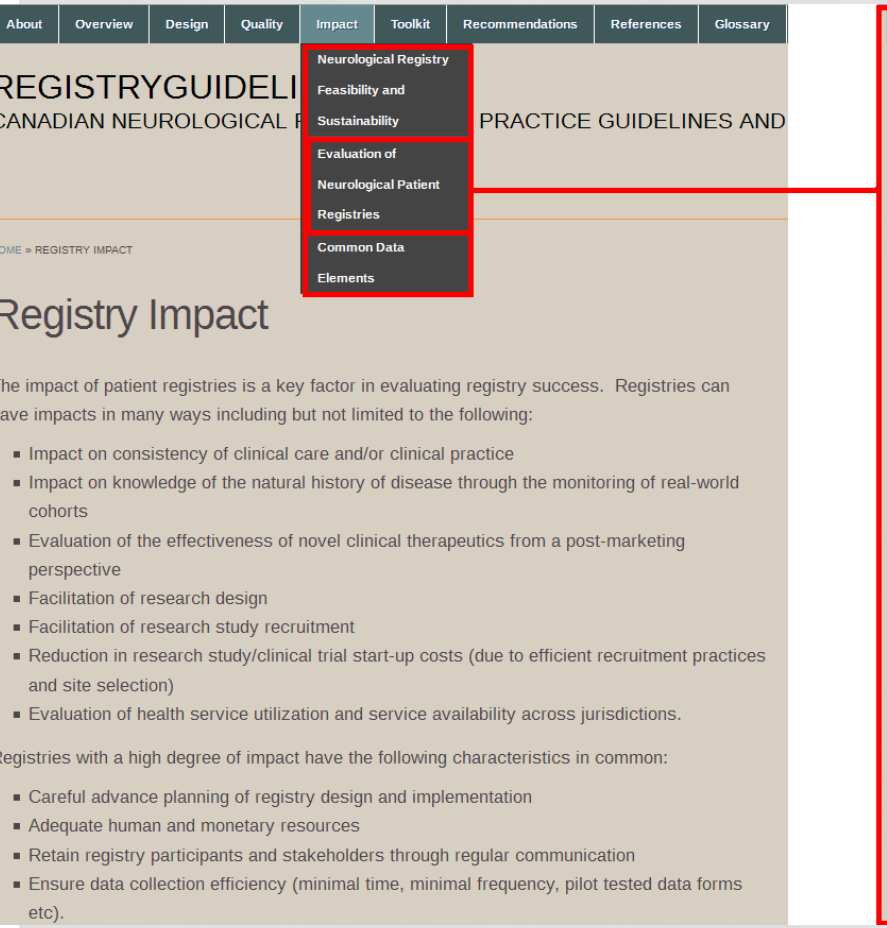


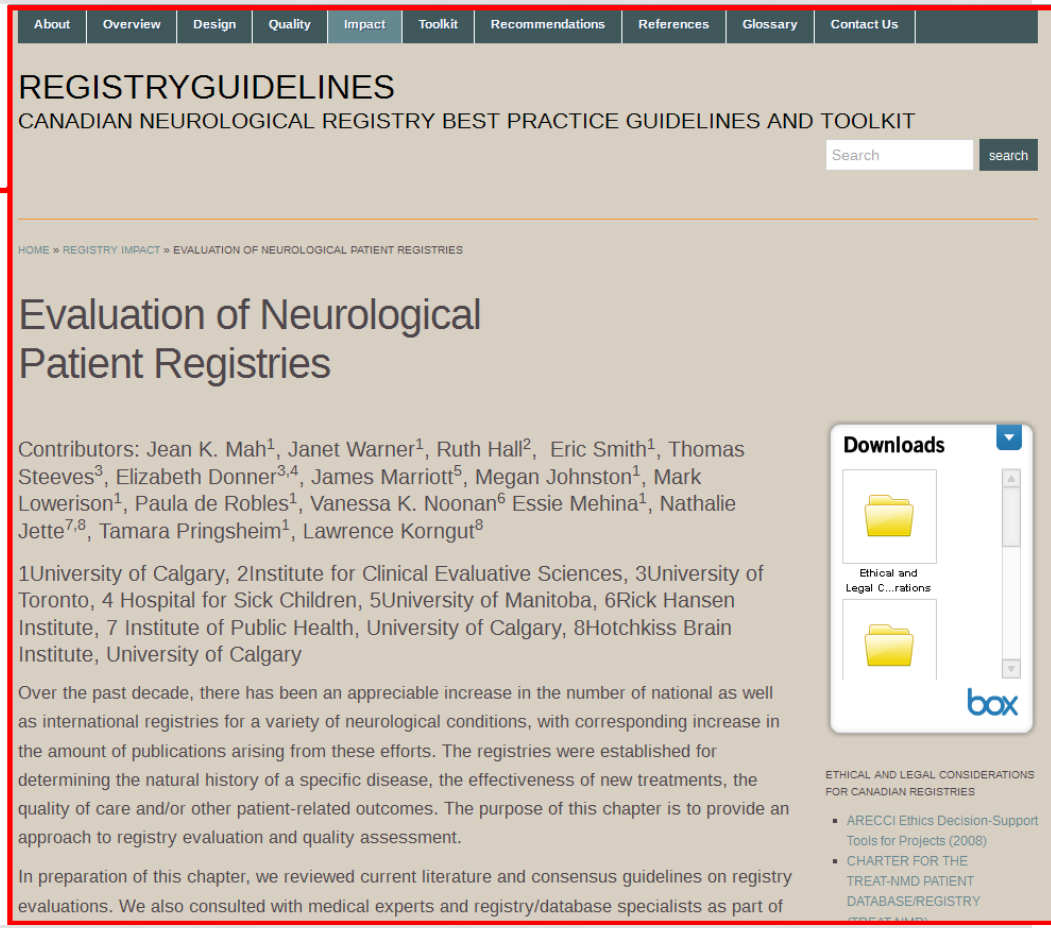
REGISTRY QUALITY





REGISTRY IMPACT





REGISTRYGUIDELINES

CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

Glossary

Aboriginal – a term used to refer collectively to all First Nations, Métis, and Inuit peoples in Canada.

Biobank/biobanking – the collection of biological samples including but not limited to blood, tissue, skin, nails, and hair in a centralized repository. This may or may not include information about the individuals who provided the samples.

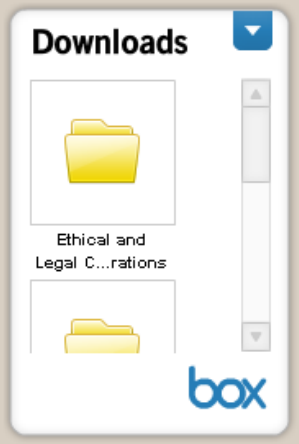
Capacity – with respect to the provision of informed consent, capacity is the individual capability to understand information presented and to understand the potential consequences of any decision made based on such information. .

Clinical Trial Registry – a clinical trial registry is typically a registry created during a clinical trial. Clinical trial registries may include device or treatment registries and may be run by investigators or by for-profit entities.

Informed Consent – in Canada this is consent provided by an individual participating in research in a manner that is voluntary and given after the individual has been made fully aware of the nature of the research and the possible risks and benefits of participation. Informed consent must also be ongoing and able to be withdrawn at any time.

Intellectual property (IP) – the basic legal right conferred by patents, trademarks, copyright and other similar concepts which allows the owner of such property to exclude others from using that property without permission. Typically the property is derived from some form of creative pursuit and thus is referred to as intellectual.

Research ethics board (REB) – an appointed institutional body consisting of researchers, community members and other experts (e.g. legal, ethics, medical) which reviews the ethical acceptability of all research activities conducted at the institution or under its jurisdiction.



ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members
- Consent Templates (UBC BCCA Research Ethics Board)
- Evans' Registry Protocol

REGISTRYGUIDELINES

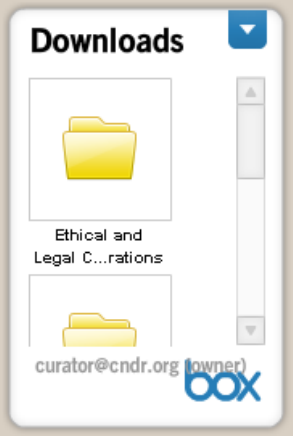
CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

Recommendations

REGISTRY DESIGN

Ethical and Legal Consideration

- All registries operating in Canada (domestic or foreign) should adhere to Canadian ethical, legal and privacy standards.
- Registries should pro-actively consider legal and ethical issues within their operating jurisdictions. Careful consideration of issues such as capacity to consent and data confidentiality must be undertaken.
- Registries should be transparent in their operation. Transparency includes at a minimum clear articulation of the registry purpose; data ownership; data security measures; data usage; and operating term. If a limited operating term is expected, information on how data will be destroyed at the end of the term should be disclosed. It is also recommended that registries make protocols, policies and procedures; and other appropriate documentation available publicly to increase credibility.
- Registry operation should include an Advisory Council with broad expertise and perspectives.
- Participant consent should be considered ongoing and the informed consent process must include adequate time for reflection. Consent may also consist of three components: 1) consent to collection of data; 2) consent to the initial registry research purpose; 3) consent to subsequent research uses of the data (i.e. additional research projects). Additionally participants must always have the right to withdraw.
- Registries including a biobank component must be reviewed by an REB and the purpose of the biobank must be clear and fully disclosed.
- Registries with plans to sell data to a third party, especially a private entity, must disclose this.



ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members
- Consent Templates (UBC BCCA Research Ethics Board)
- Evans' Registry Protocol
- Indiana University Informed

REGISTRYGUIDELINES

CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

References

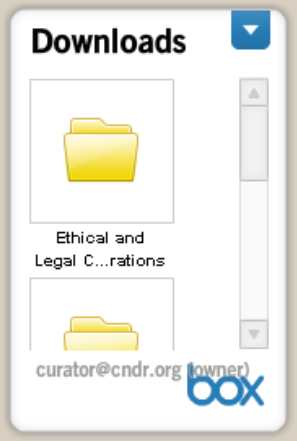
The Case for Neurological Registry Best Practice Guidelines in Canada

1. World Health Organization. Neurological Disorders: Public Health Challenges. Geneva: WHO Press; 2006.
2. Canadian Institute for Health Information. The Burden of Neurological Diseases, Disorders and Injuries in Canada; 2007.
3. Caesar-Chavannes CM, S. . National Population Health Study of Neurological Conditions in Canada. Chronic Diseases and Injuries in Canada. 2013;33(3) (in press).
4. Dreyer NA, Garner S. Registries for robust evidence. JAMA. 2009;302(7):790-1.
5. Gliklich RE, Dreyer NA, (eds). Registries for evaluating patient outcomes: A user's guide. 2nd ed. Rockville, MD: Agency for Healthcare Research and Quality 2010.

Registry Design

Ethical and Legal Considerations for Canadian Registries

1. The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Washington, DC: Department of Health, Education, and Welfare: OPRR Reports; 1979.
2. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2). Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada; 2010.
3. Gliklich RE, Dreyer NA, (eds). Registries for evaluating patient outcomes: A user's guide. 2nd ed. Rockville, MD: Agency for Healthcare Research and Quality 2010.



ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members
- Consent Templates (UBC BCCA Research Ethics Board)
- Evans' Registry Protocol
- Indiana University Informed

REGISTRYGUIDELINES

CANADIAN NEUROLOGICAL REGISTRY BEST PRACTICE GUIDELINES AND TOOLKIT

Toolkit

Information, templates and resource documents for the toolkit website were collected from existing registries (regardless of disease group) and government/research organizations and academic institutions. The toolkit links to such resources as template documents for ethics submission, template data forms and template policies and procedures. The objective of the toolkit is to ensure consistent registry implementation across Canada so that data collection is secure, valid, high quality, and will produce comparable results.

To Use the Toolkit

The Toolkit is located on the right hand side of this page and all other pages.

Downloads

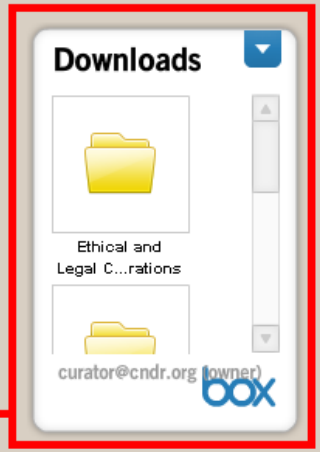
The white box contains downloadable content such as consent form templates, policy and procedure documentation, recruitment materials and terms of reference documents for working groups and committees. The downloadable content is organized into the following categories:

1. Ethical and Legal Considerations for Canadian Registries
2. Patient Recruitment by Neurological Registries
3. Neurological Registry Feasibility and Sustainability

Links

Below the white box are links to useful resources which are organized in the following categories:

1. Ethical and Legal Considerations for Canadian Registries
2. Linkage Between Neurological Registry Data and Administrative Data
3. Neurological Registry Feasibility and Sustainability



ETHICAL AND LEGAL CONSIDERATIONS FOR CANADIAN REGISTRIES

- ARECCI Ethics Decision-Support Tools for Projects (2008)
- CHARTER FOR THE TREAT-NMD PATIENT DATABASE/REGISTRY (TREAT-NMD)
- Consent Forms: National Registry of Myotonic Dystrophy & FSHD Patients and Family Members
- Consent Templates (UBC BCCA Research Ethics Board)
- Evans' Registry Protocol
- Indiana University Informed

ACKNOWLEDGEMENTS

Co-PIs: Nathalie Jetté, Tamara Pringsheim

Kristin Atwood	Karen Barlow	Craig Campbell	Steve Casha	Lisa Casselman
Lynn Dagenais	Lundy Day	Paula de Robles	Elizabeth Donner	Guillermo Fiebelkorn
Claire Marie Fortin	Clare Gallagher	Angela Genge	Glenys Godlovitch	Ruth Hall
Mark Hamilton	Rachel Hayward	David B. Hogan	Nathalie Jette	Megan Johnston
Moira K. Kapral	Lawrence Korngut	Darren Lam	Diane Lorenzetti	Mark Lowerison
Gail MacKean	Jean K. Mah	Ruth Ann Marrie	James Marriott	Colleen Maxwell
Essie Mehina	Theo Mobach	Vanessa K. Noonan	Scott Patten	Ted Pfister
Tamara Pringsheim	Michael Shevell	Eric Smith	Thomas Steeves	Janet Warner
Cindy Watson	Samuel Wiebe	Christina Wolfson	Julie Wysocki	

The project team also wants to thank the following additional grant team members and collaborators for their guidance and advice along the way: Caitlin Smith; David Zygun; Frank Silver; Jack Puymirat; Jane Evans; Karen Turpin; Larry Svenson; Lewis Holmes; Lorne Zinman; Marcel Dvorak; Maryam Oskoui; Nancy White; Roger Freeman; Sandra Black; the members of the Scientific Advisory Committee; and the patients, caregivers, and families who contributed to our focus group discussions.

This study is part of the National Population Health Study of Neurological Conditions. We wish to acknowledge the membership of Neurological Health Charities Canada and the Public Health Agency of Canada for their contribution to the success of this initiative.

Funding for the study was provided by the Public Health Agency of Canada. The opinions expressed in this publication are those of the authors/researchers, and do not necessarily reflect the official views of the Public Health Agency of Canada.

Canadian Registry Network
Réseau canadien de registres

THANK YOU

Contact information:
Dept Clinical Neurosciences
University of Calgary
480060, 4th Floor Administration
Clinical Neurosciences
South Health Campus
4448 Front Street SE
Calgary, AB, T3M 1M4
Phone: (403) 956-2462
Lawrence.korngut@albertahealthservices.ca

Faculty of Medicine | University of Calgary
Clinical Neuro Sciences Calgary Canada
Hotchkiss Brain Institute
CNDR.org Canadian Neuromuscular Disease Registry