

FEASIBILITY STUDY FOR THE CANADIAN LONGITUDINAL STUDY ON AGING (CLSA)

EXPLORING ATTITUDES ABOUT MENTAL INCAPACITY AND LONG TERM PARTICIPATION

Linda Furlini^{1,2}, Jennifer Uniat¹, Christina Wolfson^{1,2,3}, Parminder Raina⁴, Susan Kirkland⁵, Camille Bullock⁵, Tim Chipman⁵, Homa Keshavarz⁴, Judy Keys⁴, Geoff Strople⁵, Karen Szala-Meneok⁵

¹ Centre for Clinical Epidemiology and Community Studies, Sir Mortimer B. Davis - Jewish General Hospital

² Department of Epidemiology and Biostatistics, McGill University

³ Division of Geriatric Medicine, McGill University

⁴ McMaster University

⁵ Dalhousie University



Canadian Longitudinal Study on Aging
Étude Longitudinale Canadienne sur le Vieillessement



OVERVIEW OF THE CLSA

- Broad, multidisciplinary study of adult development and the aging process
- Recruitment of 50,000 Canadian women and men aged 40 to 84 living in the community
- Observational study where a variety of data collection methods will be used (telephone and face to face interviews, physical and psychological assessments and biological samples).
- REQUIRES THE LONG TERM PARTICIPATION OF PARTICIPANTS:
 - followed for a period of 20 years
 - not cognitively impaired at baseline

INTRODUCTION

CLSA researchers will face particular challenges ensuring participants provide ongoing informed consent for a period of some twenty years.

In the event that a participant develops mental incapacity:

- Will researchers be permitted to use data that have already been collected?
- Can they use data for purposes that were not foreseen at the time participants provided informed consent?
- Can researchers continue to take samples and collect other data from mentally incapacitated participants?

BACKGROUND

Challenges to providing Informed Consent

- Aging significantly increases likelihood of suffering from diseases that affect mental capacity to provide informed consent, particularly dementia (e.g. Alzheimer's disease, vascular dementia)
 - Current incidence considerably underestimated (Canadian Study on Health and Aging Working Group)
 - Prevalence will be magnified by aging baby boomers
- Some conditions, such as stroke, may be transient.
- Professionals have difficulty ascertaining mental capacity.

Substitute Decision-Makers (proxies who will answer for the participant in the event of mental incapacity)

- Reduce attrition
- May contribute to the reliability of participant information

Means to appoint Substitute Decision-Maker

- Advance Directives** (e.g. *Mandat en cas d'incapacité, Mandate in the Anticipation of Incapacity, Procurator*)
Legal document allowing participant to appoint a substitute decision-maker for health purposes, including research
- Research Advance Directives** (specifically for CLSA)
Informed consent form allowing participant to appoint a substitute decision-maker at inception of the study for purposes of the research only

- Research Study Advocates**
Informed consent form allowing participant to appoint professionals with some expertise in substitute decision-making

Risks of Participation

- A tendency to focus on risks in studies, such as the CLSA, where participants receive little or no personal benefit
- Potential risk: Threat to personal privacy (data collection, data linkage, data storage, future uses of DNA samples)

Canadians lack information about:

- computerized medical records
- developments in technology
- substitute decision-making

Notably, researchers lack information about:

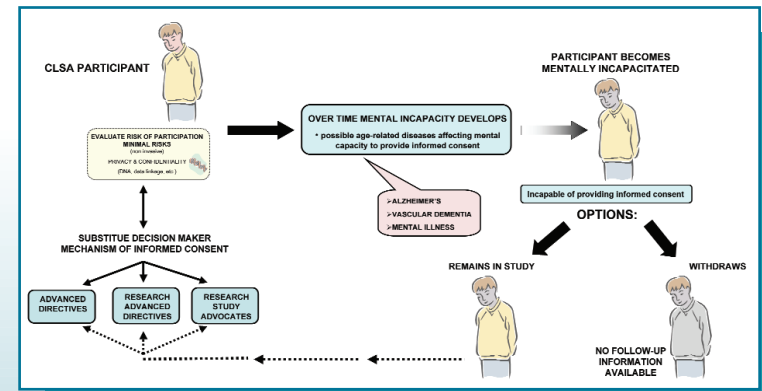
- developments of new technology
- substitute decision-making

Public Engagement

- The perspectives of potential participants and substitute decision-makers are needed:
 - to help identify problems
 - to reduce confusion about the CLSA
 - to ensure public trust.

THE NEXT STEP - NEED FOR A STUDY

Little is known about how Canadians' view providing informed consent if mental incapacity develops during the course of a longitudinal observational study



THE MAIN OBJECTIVE OF THIS FEASIBILITY STUDY IS TO DETERMINE HOW POTENTIAL CLSA PARTICIPANTS PERCEIVE ONGOING INFORMED CONSENT IF MENTAL INCAPACITY DEVELOPS.

Questions under study will include:

- Would Canadians enrolled in the study be willing to participate if they became mentally incapacitated during the course of the study?
- Who will make decisions about this study on their behalf?
- If substitute decision-makers are used, how will they be appointed? What will be their roles and responsibilities?
- What are the risks of participation (e.g., due to developments in technology, data and/or stored biological samples that may be used for purposes that were unforeseen when the study began)?
- What types of information do participants or their substitute decision-makers need to encourage ongoing participation?

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