Overview

- Quick and Dirty overview of the CLSA?
- Ethical and legal issues: Balancing act
- Feasibility studies informing the methodological development of the CLSA
- Informed consent
The Canadian Longitudinal Study on Aging (CLSA)

A key component of the Canadian Lifelong Health Initiative, a strategic initiative of CIHR

- The Canadian National Birth Cohort
- The Canadian Longitudinal Study on Aging

More than 160 researchers - 26 institutions

Multidisciplinary - biology, genetics, medicine, psychology, sociology, demography, economics, epidemiology, nursing, nutrition, health services, biostatistics, population health
Innovation - Cell to Society

- Mid life to old age
- Quantitative traits
  - Physical
  - Social
  - Psychological
- Gene-environment interactions
- Disease, disability, psychosocial consequences
- Adaptation
### Focus of Measurement

<table>
<thead>
<tr>
<th>Biomedical</th>
<th>Psychosocial</th>
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<tbody>
<tr>
<td>- Activities of daily living/disability/injuries</td>
<td>- Lifestyle/behaviours</td>
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<td>- Frailty/co-morbidities</td>
<td>- Social networks and social support</td>
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<td>- Chronic diseases</td>
<td>- Values and meaning</td>
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<td>- Cognitive function</td>
<td>- Everyday competence, adaptive functioning, coping</td>
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<td>- Mental Health</td>
<td>- Personality, emotion, psychopathology</td>
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<td>- Oral health</td>
<td>- Work to retirement transitions</td>
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<td>- Vision, hearing</td>
<td>- Structural inequalities</td>
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<td>- Medications</td>
<td>- Built environments/physical environment</td>
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<td>- Health Care Use</td>
<td>- Economics (wealth)</td>
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<td>- Institutional care</td>
<td>- Healthy aging and well being</td>
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<td>- Genetics/Biomarkers</td>
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<td>- Nutrition</td>
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CLSA Architecture

- Inception Cohort: 50,000
- Follow-up over 20 years
- In-depth data collection on 30,000 (at 10 sites)
- Questionnaires, Database linkage
- Data collection every 3 years and maintaining contact between data collection waves

Every 3 years and maintaining contact between data collection waves.
Data collection: Basic

- Questionnaire data (50,000)
  - Telephone interviews
  - Common core of questions
    - Basic demographics, social, economic, nutrition, lifestyle

- Linkage to existing data bases (50,000)
  - Administrative: physician services, hospitalizations
  - Homecare, community services, mental health services
  - Mortality
  - Environmental, neighbourhood indicators
Data collection: Comprehensive

- Comprehensive assessment (30,000)
  - Additional questionnaire based information via in-person interviews
    - Social, behavioural, economic, nutrition, lifestyle
  - Clinical assessment
    - Medical, neuropsychological, physical measures
  - Blood and urine samples
    - Blood chemistry panel, biomarkers, genetics, genomics
Ethical, Legal and Societal Issues
Ethical and Legal Issues

- Informed consent
  - For 20 year duration
  - For storage of biological samples, clinical, questionnaire based information
  - Genetic and biochemical testing
  - Products from biological samples: cell lines
  - For unspecified research projects in the future
Ethical and Legal Issues

- Informed consent
  - Capacity to consent
    - Cognitive versus other factors that impact capacity to consent
    - Proxy consent
  - Full consent versus staged consent
    - Blanket consent versus issues related to re-consent
Ethical and legal issues

- Informing participants/family physicians
- Risks and benefits
- Linkage with existing healthcare and other data bases
  - Privacy and confidentiality
  - Data ownership issues
- Public access of CLSA data
Feasibility Studies
Phase 1 Studies and progress

1. Exploring the acceptability and feasibility of conducting a large longitudinal population-based study in Canada---Complete

2. Testing the CCHS as a potential participant recruitment vehicle for the CLSA—Complete

3. Feasibility of blood and urine specimen collection and OGTT in private and hospital based clinical laboratories ---Complete

4. Feasibility of accessing health care utilization databases--complete

5. Return of individualized test results to participants and/or nominated health care providers---complete
Phase 1 Studies and progress

- 6. Development and evaluation of disease ascertainment algorithms ---ongoing

- 7. Telephone cognitive tests as tools for the identification of eligible study subjects in population based research--ongoing

- 8. Assessment of the logistics of data collection methods and data transfer for text material---complete

- 9. Exploring attitudes about mental incapacity and long term participation in the CLSA Protocol ---ongoing

- 10. Improving the informed consent process for complex population based research: finding the optimal information strategy---ongoing
Views of Canadians

Objectives

- To explore Canadians’ beliefs and attitudes toward a multi-faceted, long term study on aging

Methods

- Focus groups conducted in six Canadian cities: Vancouver, Calgary, Winnipeg, Hamilton, Montreal, Halifax

Themes

Healthy aging
Benefits to participants
Collection of biological samples, DNA
Unforeseen uses of data
Commercialization

Importance of research
Impact on participant behaviour
Response burden
Data linkage
Privacy & confidentiality
Key Findings

- General willingness to provide blood and urine samples
  - Adds credibility to the study

- Few concerns with respect to privacy and confidentiality
  - Trust that confidentiality would be protected
  - “Only those with something to hide would be concerned about providing a DNA sample”

- Most concerns centered around the use of DNA
  - Information not be shared with insurance companies, third parties
  - Why do you need it
  - How would it be used
  - Who would have access to it

- Private companies should not profit from the study results
Data Linkage with Health Care Utilization Data Bases

Objectives

- Examine barriers and facilitators to accessing and linking with health care utilization databases
- Explore the feasibility of using health insurance registries as the sampling frame for a national study
- Develop best practice guidelines for use of and access to health care utilization data

Methods

- Telephone interviews conducted with P/T Data Stewards (n=20) and P/T Information Privacy Commissioners / Ombudsmen (n=13)
HCU Databases

- Health insurance registration
- Physician claims
- Hospitalization data
- Prescription drug plan databases
Key Findings

- Informed consent: study questions, data accessed, for how long, where stored, how used, who has access, periodic re-consent
- Data access agreement: Provincial/territorial MOH
- Privacy Impact Assessment
- Provincial privacy legislation AND health information legislation is constantly evolving
- Complex process, but possible
- Requires extensive “up front” work with data stewards, managers
Development and Testing of Informed Consent for CLSA
Defining Informed consent

- Legally fit to give consent (*competence*)

- Have the free power of choice (*voluntariness*)

- Have sufficient knowledge and comprehension of the elements of the proposed research (*adequate information*)
Components of the CLSA Informed Consent form

– Capacity to consent
– Questionnaire
– Physical examination
– Neuropsychological testing
– Biological sample
– Linkage to databases
– Storing blood for future analysis
– Voluntary participation
– Privacy and confidentiality
– Use of data
– Commercial issues (if any)
Consent Process

- Preferences for presentation of the form
  - One long consent or divide into several components
- Review of the consent form
  - In person at participant’s house
  - In person at clinical data collection site
  - Over the phone
Consent Process

- Detailed versus Basic
  - Basic points of the study and participant involvement
  - Basic points followed by a detailed information about each component
- Renewal of consent
- Withdraw from study and future use of data
- Linkage to HCU databases
Consent Study

- Objectives
  - To examine the impact on the level of comprehension and acceptability of different methods of obtaining informed consent
  - To determine the best way of presenting the content of the consent form
Optimal Consent study

Randomization

CLSA Brochure
- 1-step form
- Multi-step form

CLSA Brochure

Video
- 1-step form
- Multi-step form
Ethical, Legal, Societal Issues (ELSI)

- Lawyers
- Ethicists
- Philosophers
- Geneticists
- Epidemiologists
- Social scientists
- Privacy commissioner
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