

Ethical, Legal and Societal consideration in the design of Canadian Longitudinal Study on Aging (CLSA)

Parminder Raina, Susan Kirkland and Christina Wolfson

McMaster University

BCNAR Vancouver

February 1st, 2007





Hamilton



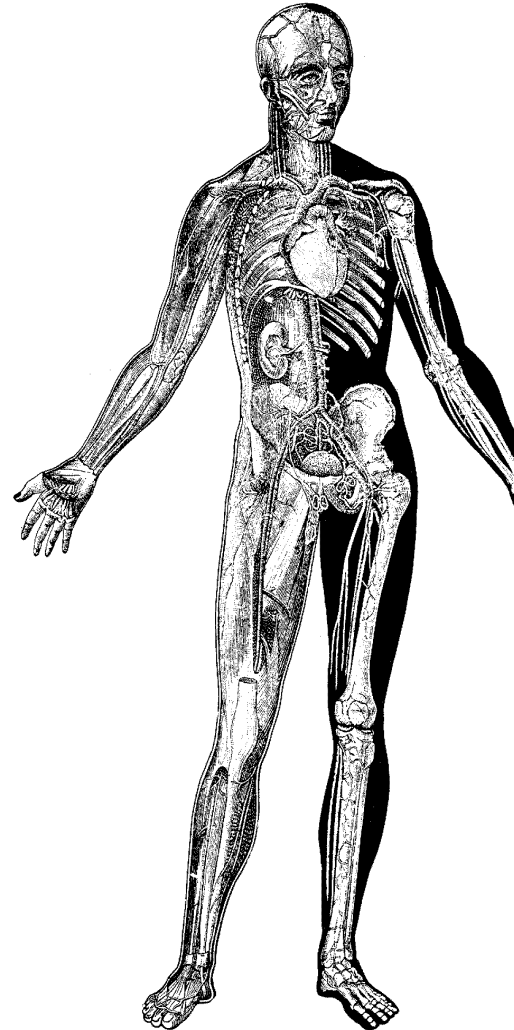
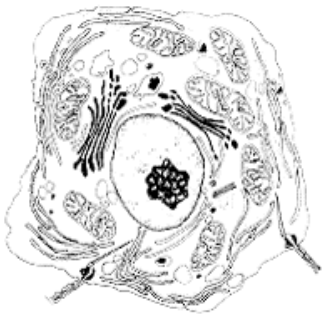
Overview

- 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

Biomedical

- Activities of daily living/disability/injuries
- Frailty/co-morbidities
- Chronic diseases
- Cognitive function
- Mental Health
- Oral health
- Vision, hearing
- Medications
- Health Care Use
- Institutional care
- Genetics/Biomarkers
- Nutrition

Psychosocial

- Lifestyle/behaviours
- Social networks and social support
- Values and meaning
- Everyday competence, adaptive functioning, coping
- Personality, emotion, psychopathology
- Work to retirement transitions
- Structural inequalities
- Built environments/physical environment
- Economics (wealth)
- Healthy aging and well being

CLSA Architecture

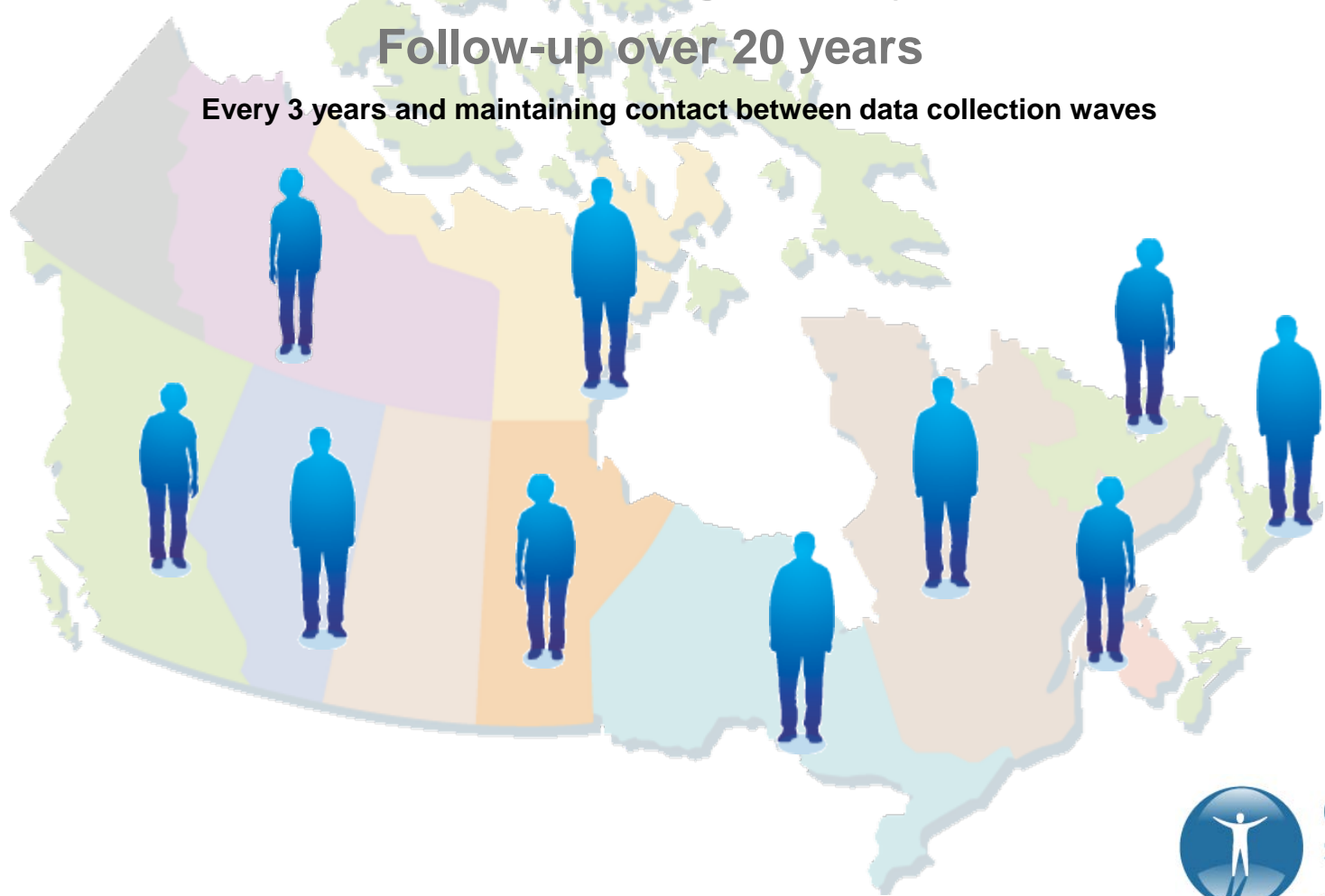


Data to be collected: 50,000 (at 10 sites)

Questionnaires, Biological, and Physical

Follow-up over 20 years

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

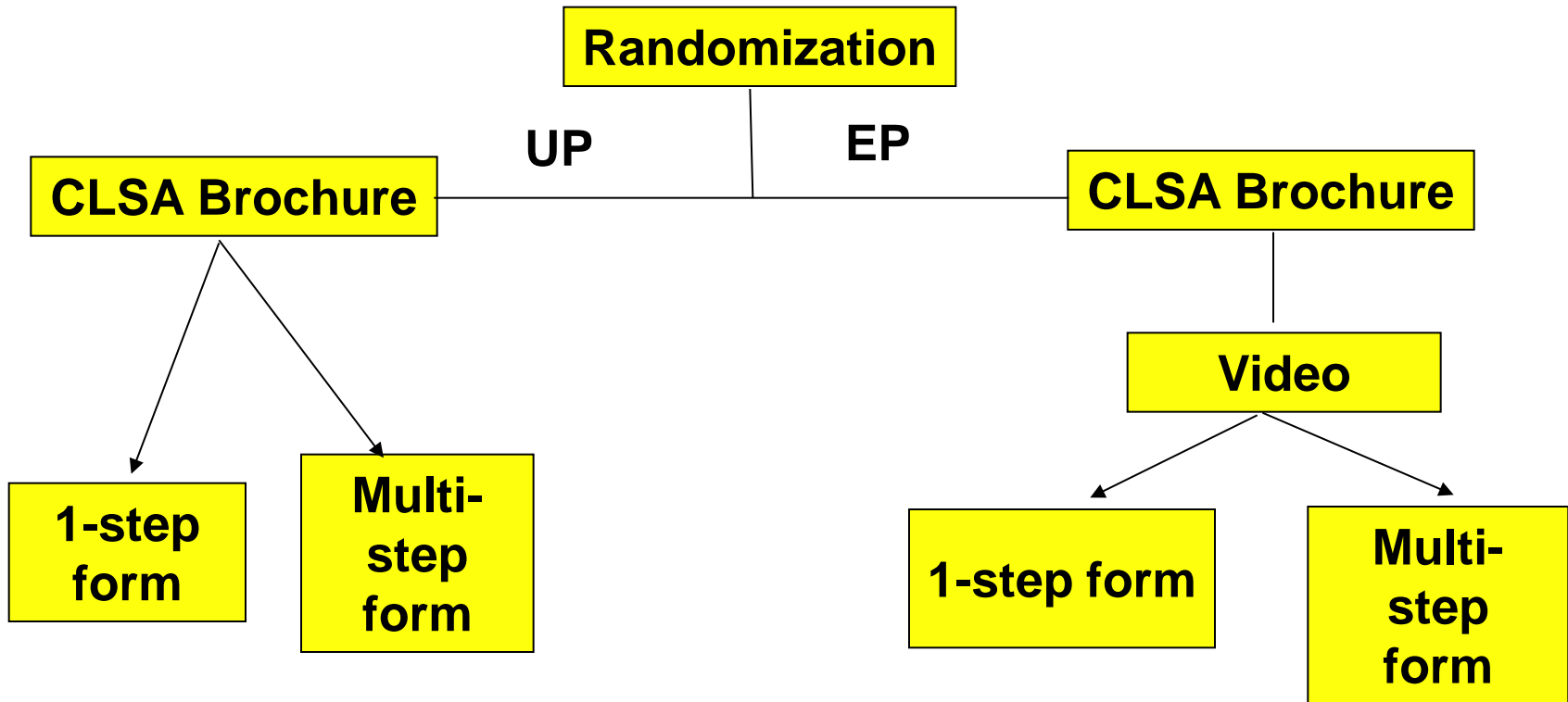
Consent Process

- 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

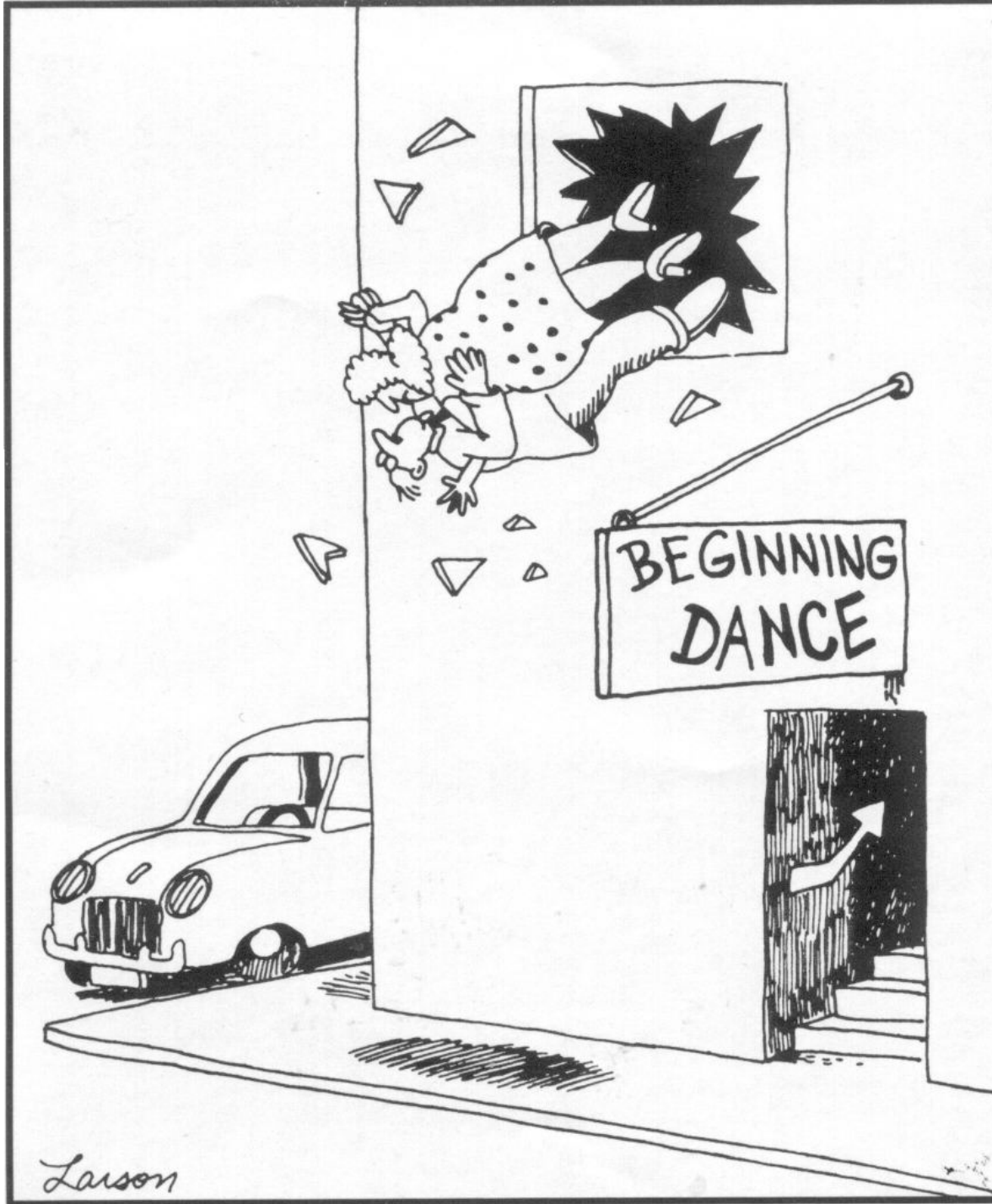
- Objectives
 - To examine the impact on the level of comprehension and acceptability of different methods of obtaining informed consent
 - To determine the best way of presenting the content of the consent form

Optimal Consent study



Ethical, Legal, Societal Issues (ELSI)

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





CLSA

ELCV

Email: CLSA@epid.jgh.mcgill.ca

Website: www.CLSA-ELCV.ca

