



CLSA Canadian
Longitudinal
Study on Aging

ELCV Étude Longitudinale
Canadienne sur le
Vieillessement

Return of Individualized Test Results to Participants in a Longitudinal Population-Based Study

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Introduction

The proposed Canadian Longitudinal Study on Aging (CLSA) is a broad, multi-disciplinary study of adult development and the aging process. A total of 50,000 men and women aged 40 and older will be assembled and followed over two decades. The study takes a multi-disciplinary approach to examine the interplay of genes, nutrition, lifestyle, and environment factors and its consequences on the aging process, including the development of disease and disability. The identification of factors that determine the pathways to a range of outcomes, both positive and negative, will pave the way for the development of interventions that promotes the health of the population. Scheduled to be launched in 2008, the CLSA will require the long-term participation of volunteers drawn from the Canadian population.

As part of the CLSA, participants will be asked to participate in a physical assessment, including the provision of blood and urine samples. A key issue that arises is whether or not individualized clinical information collected as part of this assessment should be returned to study participants, and if so, a) what information should be returned, b) in what manner should the information be returned, and c) to whom should the information be returned.

The goal of this study is to ascertain views on the return of clinical information from investigators of other longitudinal studies, potential study participants, and experts. This poster presents the preliminary results of a web-based survey to determine the practices of other longitudinal studies concerning the return of individualized test results to study participants.

Methods

An invitation to participate in a web-based survey was sent to 68 principal investigators or identified contact persons of longitudinal studies on aging from around the world. The longitudinal studies were selected from CIHR and NIH publicly available database lists and supplemented by longitudinal studies that are disease specific in nature. The web survey assessed:

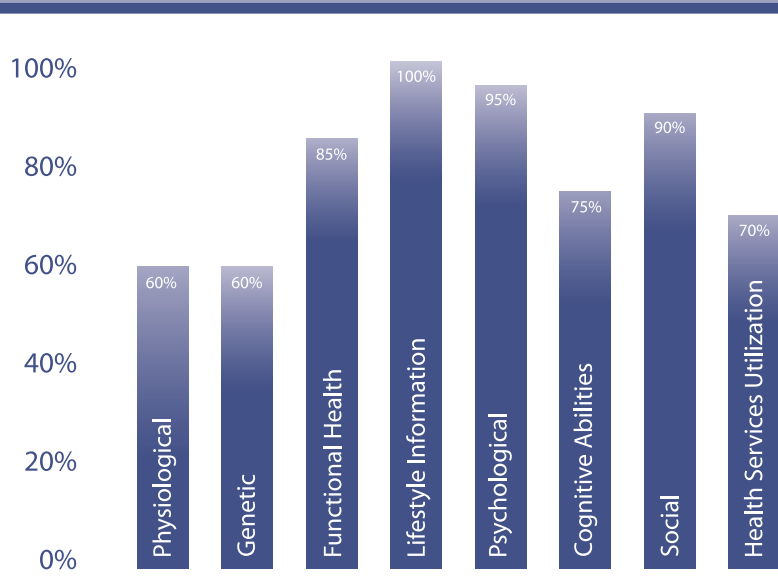
- a) characteristics of the study (number of participants, age of participants, year started/ended, interval between data collection waves)
- b) types of health measures collected and whether individualized information was returned to participants
- c) factors that impacted on the decision whether or not to return individualized information to participants

Results

Characteristics of Studies

- To date, responses received from 20 studies
- All but three studies had under 9,000 participants, with a range of 534 to 121,700 participants
- Thirteen studies started prior to 1990, the earliest study started in 1956 and the most recent in 2004; eighteen studies are still ongoing
- Eleven studies reported 36 months or less between the last two waves of data collection, with a range of 12 to 144 months
- Six studies included participants below the age of 40 and six studies included participants only 65 years and older

Table 1. Percentage of Studies That Reported Collecting the Following Types of Data



- The types of data collected in the studies are presented in **Table 1**

Types of Measures Collected and Returned as Individualized Results

- 70% of studies reported returning individualized test results to participants
- Almost two thirds of studies that returned results to participants returned them by mail and just over a quarter returned them in person
- All studies that returned results to physicians returned them through the mail
- Table 2 presents the types of measurements that were collected and returned to participants as indi-

Table 2. Percentage of Studies That Collected Each Type of Measure and Returned Individualized Results to Participants

Type of Measure	NOT COLLECTED (%)	COLLECTED BUT NO INDIVIDUALIZED RESULTS RETURNED (%)	COLLECTED & SOME OR ALL INDIVIDUALIZED RESULTS RETURNED (%)
Anthropometric measures	15	55	30
Functional ability	50	40	10
Neuropsychological exam	55	30	15
Blood pressure	35	25	40
EKG	78	6	17
Advanced clinical tests	69	5	27
Vision exam	58	16	27
Hearing exam	69	11	21
Oral exam	90	5	5
Blood biomarkers	30	15	55
Urine biomarkers	55	25	20
Biosample for genetic purposes	40	60	0

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Factors That Impacted Decision to Provide Participants with Individualized Results

Table 3. Degree to Which Each of the Following Factors Impacted the Decision to Provide Participants with Individualized Test Results

	Returned Results (n=11)			Did Not Return Results (n=5)		
	Not a Factor	Minor Factor	Major Factor	Not a Factor	Minor Factor	Major Factor
Ethical Considerations	0	9	91	0	20	80
Legal Considerations	36	46	18	40	60	0
Financial Considerations	82	18	0	20	60	20
Potential Liability	64	27	9	60	40	0
To Increase Participation	0	100	0	60	40	0

- Table 3 presents factors that impacted on the decision to provide participants with individualized test results

Responses to open-ended questions indicated that:

- Ethical considerations were considered important in making the decision to return clinical information. However,
 - Some respondents felt an ethical obligation to return information
 - Other respondents felt it was unethical to return information, particularly if the results were not interpreted by a qualified health professional
- Reasons provided for returning results included
 - Ethical considerations
 - Participant retention
 - Benefit to participants, particularly around their own health
- Reasons provided for not returning individualized results included
 - Ethical considerations

- Lack of interpretation by a qualified health professional
- Tests not done in clinical settings or test reliability too low
- Results not readily interpretable

Discussion

- Overall, a majority of studies returned some individualized information to study participants
- Results were most often returned through mail
- Ethical considerations was the most important factor in deciding whether or not to return individualized test results
- Approximately three-quarters of respondents recommended that a longitudinal study return individualized test results; one quarter did not recommend the return of individualized test results
- Reasons provided in favour of returning individualized results included ethical considerations, participant retention, benefits to participants
- Reasons provided against returning individualized results were ethical considerations, lack of interpretation, tests not done in clinical settings or reliability too low, and results not readily interpretable

Next Steps

- Additional reminder notice to be sent to web survey nonrespondents
- Final data analyses and interpretation of web survey results
- Focus groups of Canadians 40 years and older to be conducted across Canada in fall, 2005 to determine the types of results they would like to have returned and how they would like to receive them
- Hosting of one-day workshop of epidemiologists, clinical researchers, bioethicists, and family physicians in winter, 2006 to discuss issues related to returning individualized study results to participants

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