

The Return of Individualized Test Results to Study Participants and/or General Practitioners

Technical Report of the Focus Group Findings

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Executive Summary

Introduction

Although longitudinal studies which incorporate a health component often return overall results to participants, returning individual test results presents much greater challenges. Not only does it impose costs and add considerable complexity to the administration of the study, but it has been theorized that study validity could be compromised if participants seek treatment or initiate lifestyle changes as a consequence of clinical information received through study participation. It has also been argued that it is unethical and potentially harmful to inform participants of a serious health condition, especially one with limited treatment options, without also offering interpretation and counseling. Not returning individual test results also raises ethical issues about the responsibility of health studies to research participants. Some researchers feel that there is a moral imperative to share significant findings and argue that not to do so could potentially be deleterious to the health of participants. Not returning results could also compromise recruitment and hurt retention, especially in a multi-year study, if participants perceive the return of results as a benefit or the non-return of results as unreasonable.

The issue of returning individual test results is evolving, along with views of research participants. The shift in terminology from 'subject' to 'participant' underlies this change and reflects a more balanced relationship; one in which participants may derive benefits from their involvement while also contributing to the overall goals of the research. Research ethics boards have played a role in this shift by helping to ensure that the interests of research participants are protected. The argument can also be made that informed consent implies the disclosure of any research finding that could impact on ongoing participation, such as a serious illness. Increasingly, studies with a health component are seen to have an ethical obligation to return information which could benefit participants, or in legal terms, a 'duty of care' to mitigate harm. Depending on the jurisdiction, participants may also have legal rights to their own data under 'freedom of information and protection of privacy' legislation. Aside from moral and legal arguments there may be advantages to returning individualized results to participants in the form of a tangible sign of appreciation and concern which participants may perceive as a benefit of initial and ongoing participation. However, there are also significant costs associated with returning results to participants. Results may be ambiguous or lack the context that can be provided by a personal physician. Results may also cause psychological stress by disclosing a condition that is not treatable. In addition to the logistical challenge of screening results and communicating them to participants, the study could also be liable if false or misleading results are released.

Funding bodies and regulators are beginning to address some of these issues. The Tri-Council Policy Statement on *Ethical Conduct for Research Involving Humans* states under the *Free and Informed Consent* clause that studies *may* be required to provide: "An assurance that new information will be provided to the subjects in a timely manner whenever such information is relevant to a subject's decision to continue or withdraw

from participation¹.” The US Code of Federal Regulations says essentially the same thing but lists it as a general requirement under informed consent: “A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.”² The Council for International Organizations of Medical Sciences provides the clearest statement on this issue: “that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status; that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility.”³

It is clear that in such an evolving climate the decision to return or not return test results, as well as the conditions and the mechanisms for doing so, must be part of the planning process for longitudinal studies which incorporate health measures. A series of focus groups were conducted across Canada in 2005 to explore issues around the return of individual test results with participants matching the criteria for recruitment to the Canadian Longitudinal Study on Aging.

Sources of Health Information

Participants exhibited a strong interest in their personal health and their specific risk factors for various diseases, particularly those associated with aging. They were also interested in accessing diagnostic tests like MRI and CT but well aware of the difficulty of doing so in the absence of specific risk factors. Underlying these concerns, but largely unspoken, was the desire to age well but also the fear of aging and its consequences.

The number of different sources of health information mentioned by participants spoke not only to their interest in their own health but also to the diversity of sources available to them. For these participants, at least, physicians appeared to have lost their monopoly on health care information and the Internet had become the key source of information: “I think people... are becoming more knowledgeable about some of the medical terms: cholesterol, high-low, blood pressure, different things like that, and they want that information. At one time when you went to the doctor and he said you were fine, that was fine; it was good enough. But it isn't anymore because people have access to the Internet for one thing.” However it was not clear whether the volume, variety and veracity of information available to health care consumers was unequivocally helpful in managing their individual health care.

¹ Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Free and informed consent Article 2.4 Table 1(1)

² US Code of Federal Regulations Protection of Human Subjects: General requirements for informed consent 45 Code of Federal Regulations 46.116 (b)(5)

³ Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) Guideline 5: Obtaining informed consent Guideline 5 (7)(8)

It was apparent from many of the comments that most participants wanted to be active partners in their own health care and rejected the traditional view of “doctor knows best”. They were not only willing to verify information and even question their physicians but also wanted more specific information from health care providers including easier access to, and even copies of, their medical records. A number of participants monitored their own health in various ways and seemed to be seeking the tools that would help them become more effective managers of their own health. Some participants felt that they needed to advocate on their own behalf: “I’ve learned since the age of 55... that you have to advocate for yourself because there’s no one else to advocate for you.” For some participants, at least, their limited knowledge combined with concern for their own health and health outcomes trumped the superior knowledge but limited time and perhaps concern of health care providers.

Many participants also questioned the state of health care, particularly doctor shortages and increased wait times: “I believe that there’s got to be a better means of regulating it and also controlling the costs that are involved for the doctors’ visits. We talk about nationally how much our health care is costing us and you just look at that alone...” Underlying this and other comments was an implicit price value equation for health care in Canada in which the value seemed to lag behind the cost. Participants also were critical of the role of the media in reporting conflicting health care studies and promoting advertising that contributed to unhealthy lifestyle choices: “What is good for you last week, three weeks later after research or some study or magazine article: gee, don’t touch that, don’t even look at it, it will kill you, you know. Vioxx is the perfect example of that.”

Views on the Return of Health Results to Participants

Participants overwhelmingly felt that, in general, those involved in health studies should receive their own results or at least have the option of receiving them. While acknowledging that there were difficulties associated with delivering and receiving results, participants generally felt that those involved in such studies had a right to receive personal test results and the study had a duty to provide them. “If these tests actually identify a significant issue, don’t you have a legal, if not an ethical, duty to disclose this to the people?”

This view was reinforced when participants were polled about whether they would want their results back if they were involved in the CLSA. A large majority indicated that they would like to receive them personally and/or have them sent to their health care provider. While results that were within the normal range were viewed as ‘nice to have’, those outside the normal range, especially if they indicated a potentially serious problem were viewed as essential. The study was clearly seen as having an obligation to participants to provide these “red-flagged” results. “...if there’s anything extreme, then I would expect to be advised...”

Participants identified a number of reasons why the study might not return individual results to participants including: alarming participants, cost and logistics, skewing the results and the need to have results interpreted. None of these reasons, however, was

compelling enough to make participants question their desire to receive results, especially “red-flagged” results. In fact participants were quick to point out ways in which the task of returning results could be effectively managed: “So can I think of a reason why I wouldn’t want to send it out and why I would want to be selective on what I send out, then that would be it, it would probably just be cost and logistics.”

Speaker A: “...once you put up the red flag and now they go and get treatment, you’re skewing the results of your 20 year study probably, if you’re trying to have a totally objective study.”

Moderator: “And is that problematic, do you think?”

Speaker A: “I don’t think it’s as problematic as not letting somebody know that they have a possibly terminal illness that they need treated.”

Participants clearly saw the benefits to their own health of being part of a study which involved various health measures. Many saw it as a way of monitoring their own health, and being able to make comparisons over time and with the entire study group. Perhaps, most importantly, participants saw study participation as possibly allowing for the early detection of a serious condition or disease that they would otherwise be unaware of: “...they do all these wonderful tests and now, you know, they’re picking up on anything that my doctor may not have sent me for because there was no suspicion ahead of time.”

Responsibility for Health

Focus group participants generally accepted responsibility for their health: “It’s not the researcher’s responsibility. We’re supposed to be taking care of ourselves. We’re supposed to be checking up on ourselves. If we decide to take part in a study, it’s to help, like you said, with research. It’s not to then give the responsibility of our health to somebody else.” However, participants felt that they had a right to information the study might uncover about their health status. This responsibility was greatest in the case of results falling outside the normal range and/or indicating a potentially adverse disease or condition: “I think they have an ethical and moral obligation to give the results to the person... If they find a growth in a person’s abdomen the size of a grapefruit, to suggest that they’re going to go: ‘well that’s interesting’ and shuffle it off into the research bin, I think defies a lot of common sense.” Most participants did not view participation in the study as a substitute for health care but did view it as a supplement to their health care with the potential to reveal something of which they and their physician were unaware. There was also an acknowledgement that for some participants the study tests might constitute the only health care they receive.

Generally, participants felt that those selected to take part in the study should be offered the choice of whether or not to receive results, to whom they should be sent and whether to receive all results or only those indicating a potentially serious problem. Most also felt that those wishes should be respected regardless of outcomes: “So I’d like to get a form saying: ‘who would you like these results sent to – yourself, your doctor? Would you like to be informed if there’s...’ we’d break them up with five or six conditions...”

Most participants did not expect the study to provide them with interpretation of test results or counseling, preferring to deal with their own physicians: “I don’t think the researchers’ job is to interpret for us.” Most participants did not expect the study to provide written materials such as pamphlets on various diseases but some considered these as nice to have and reasoned that it would be relatively simple for the study to provide such information as a courtesy: “On your way out we have the wall of pamphlets here... heart disease, cholesterol, blood pressure... But I don’t think you’d have to have: ‘here’s your information package’ because, again, that’s not your focus. You’re not there as a diagnostic tool.”

Although there was recognition by a number of participants that this is a research study, there was still a clear expectation that potentially adverse results be communicated to participants or their physicians. While other aspects of the study’s relationship with participants were seen as beneficial, desirable or “nice to have”, this element of disclosure of adverse results appeared to be non-negotiable for most participants.

Receipt of Test Results

The variance in views on whether participants, their physicians or both should receive test results underlines the wisdom of leaving this choice up to participants. In several groups participants came to this conclusion independently after debating the merits of the other choices. While this view was not universal, it does represent an evolution of thought that occurred in some groups in which a dichotomous view (individual or physician), was superseded by an inclusionary view (both), and finally resolved by leaving the decision up to the participant: “Well I would have mine sent to the doctor. I wouldn’t want them myself because there might be things in there I wouldn’t understand...” “Participants, because it is your health, your body, and you can do whatever you want with them afterwards...” “...why not give people the choice? You know, send it to the person; send it their doctor or both. And they can choose...”

Many participants viewed results that were in the normal range as “nice to have” but not a necessity and some even felt that their physicians should not have to deal with results they did not request. However, results indicating a potentially serious disease or condition were seen as essential information that had to be reported to the individual or their physician as quickly as possible. While some participants had expectations that the study should inform them of any serious results in a sensitive humane manner, most participants limited the study’s responsibility to communication. A majority of participants felt that potentially “serious” results should be returned more quickly than results falling within the normal range but this view is somewhat at odds with a research study in which tests would likely be analyzed much more slowly than those ordered by a physician for diagnostic purposes: “But if they are mailing out results, it makes sense that the ones that have a red flag should go out first.” It is unclear whether participants clearly understood this constraint and it would be critical to have this clearly explained to potential participants to prevent any over-reliance on health measures conducted by the study for diagnostic purposes.

Participants were divided on the role of physicians in the study. While most saw them as recipients and interpreters of study results, a minority reserved their right to receive results and consult their physicians at their own discretion. Most participants felt that anyone selected for the study should have a personal physician or should get one so that they could serve as a conduit for any potentially serious results: "...we're saying a report should go to your doctor. If you don't have a doctor where does it go then?"

Receipt of DNA Results

Although most participants found the prospect of not receiving the results of an initial DNA test acceptable, the whole topic of DNA testing was controversial and sparked considerable discussion. While participants generally would not refuse to participate based on DNA sampling, they raised many questions and concerns. For a significant number, their willingness to participate hinged on the study successfully addressing these questions and concerns. A minority of participants appeared to be quite well informed about the potential value of DNA analysis for population health while some others seemed to have learned about DNA from television crime dramas.

Participants, while generally accepting that results would not be returned, were, nonetheless, eager to receive them when offered: "Then I would want to know, just like my blood tests and stuff." Several even anticipated the question about future receipt of DNA results by pointing out that medical advances would, no doubt, improve the diagnostic value of DNA analyses. However, this desire for results was somewhat tempered by the realization that knowing about an untreatable disease or condition might not be desirable: "Yeah, I'm not sure I want to know about something that might happen that I can't do anything about, really..."

Concern was expressed about storage and destruction of DNA, security and who might be able to access DNA data: "It would have to be very, very confidential... They would have to guarantee that this is in a safe and that it will stay in the safe." Some participants did not feel that it was possible to offer strict guarantees of security either because of the possibility of computer systems being breached or because DNA profiles could be subpoenaed in a court proceeding.

It is clear that most participants would be willing to take part in a study that involved the collection and analysis of DNA but only if they knew the purpose and were assured of the confidentiality of their genetic information: "I want to know what this is going to be used for... It has to be specific: what is it going to be used for, before I sign the agreement..." They also expected to receive relevant information from their DNA analysis if and when it became diagnostically useful.

Return of Results as a Benefit of Participation

A number of participants indicated that they saw value in receiving some of their results even before they were asked if receiving them would make them more likely to participate. Among other reasons, participants viewed 'a second opinion' as desirable, wanted to be able to track their own health status over time and felt that the tests they underwent as part of the study could potentially reveal a serious condition of which they

were unaware. When asked if the receipt of results would make them more likely to participate, most agreed: “It is additional motivation; you learn about yourself, your health...” However, there were some for whom the offer of results would not influence their decision to participate: “I would participate regardless if I was asked.” A few participants cited altruistic reasons for participating in the study: “I think some people would participate just totally altruistically...” Only one participant indicated that their participation would hinge on receiving their individual results. A number of participants felt that, generally, the offer to return results would be an incentive for participants to both enroll and continue to participate in the study. Some participants felt that the offer of desirable diagnostic tests, such as MRI, would encourage even greater participation.

Behavioural Change

Many participants felt that they were able to change their behaviour as a result of health information that they became aware of. Many spoke of lifestyle changes they had made and often described the transition as a gradual process bounded by the level of their concern and the difficulty of changing old habits. While most felt they would not change their behaviour prior to having a physical assessment as part of the study, this was not universal: “Well, maybe I would watch myself.” For most, behaviour change subsequent to a physical assessment was predicated on the seriousness of the results. “Yes, if they tell me I have to improve this or that, that my cholesterol is high, of course I will take the necessary steps to improve it...” Participants were well aware of the difficulty of initiating and maintaining lifestyle changes, with a number citing examples of changing their habits with the best intentions only to later revert to previous behaviours: “When I would go to my doctor and he’d say lose weight, I’d probably behave myself for a couple of weeks, and then eventually the old habits would creep back in.” Several felt that the ability to change old habits was related to the consequences of not doing so. While most participants would not alter a physician appointment because of having a physical assessment as part of the study, a few saw no point in duplicating the process if the study was returning their results. Others saw the availability of study results as a benefit and would delay an appointment in order to have these results available to their physician: “Yeah, if I was getting the results, then I would postpone my doctor’s appointment so that I could add those results to my review.” The description of behaviour change as ‘an inside job’ accurately sums up many of the views expressed by participants.

Consent to Receive or not Receive Results

For many participants choice was a key aspect of the consent process. They wanted to be able to decide not only who should receive their test results but also whether to receive them at all. While almost all participants wanted their own results, with few exceptions they felt that this choice should not be forced on anyone: “...there will be those who don’t want to know. It can be left up to each person to decide...” While participants clearly understood the concept of informed consent and wanted to fully comprehend their rights, responsibilities, and their options before agreeing to participate in the study, they did not want these choices to be cast in stone, preferring regular opportunities to revisit their decisions: “You don’t want these results or you only want them if there is a ‘red flag’ and it’s a form we fill out every 3 years.”

Participants struggled with the question of not returning potentially serious results to someone who had elected not to receive any results. Some participants advocated respect for the decision while others argued that the study had an ethical responsibility to inform the participant regardless of their decision: "...you should respect my wish, whatever my wish is, you should respect it. You shouldn't override it." "But isn't there an ethical issue here, and the ethical issue is that... this person has a major medical issue and... you're not taking a positive step to help them." While this debate was not resolved by any means, there appeared to be movement in most groups towards the principle of respecting a participant's informed decision not to receive any results. This view was certainly not shared by everyone and there was also considerable concern expressed that the consent be formulated in such a way as to protect the study from any liability arising from the non-return of adverse results. Participants felt that the potential consequences of choosing not to receive any results had to be made very clear and that anyone choosing this option should sign a waiver to indemnify the study from any potential liability: "I think the study should have the participants sign a waiver... I agree not to know."

Although there was a suggestion that accepting results be a condition of participation, most participants did not agree with this view. Some even felt it would affect study validity by restricting participation to those willing to receive their results.

Conduct of the Study

Participants were very curious about virtually all aspects of the study and asked many questions both during the discussions and after the focus group during question and answer sessions. This indicates a strong level of interest in the study among most focus group participants. However, not all questions were informational and it was clear that for some, at least, they were seriously considering their own participation in the study. Participants seemed to appreciate the logistical challenges of mounting such a large study and were interested in how these challenges would be met. All the questions were not innocuous, however, with some participants questioning the purpose of the study and what it would achieve. Some even wondered if the benefits would justify the expense. There were also questions about who would benefit from the study possibly indicating some level of suspicion about the motives for carrying out the study and who might profit from it. While commercialization was not mentioned in this context, this concern may have prompted this line of questioning: "And why are they doing this? I mean the obvious, but it's horrifically expensive. How is it being paid for and ultimately who is going to benefit?"

There was a significant amount of discussion about the types of tests the study would incorporate and who would be carrying them out. While not explicitly stated, some participants seemed to be weighing the level of effort and inconvenience against the personal benefits, such as return of results, which might accrue to them. The questions about who would be doing the testing also seemed to underlie fear of someone other than a doctor or health professional performing a physical assessment and other tests.

Concerns about privacy and confidentiality were largely centred on who would have access to the data. Participants asked about insurance companies and commercialization, but also issues such as data ownership and data destruction: “Would something like this be... sold to insurance companies?” “OK, but for instance, if there is a private company who wants to create an anti-aging enzyme, will they have access to this research?” Some were clearly looking for very precise and legally binding guarantees to protect their confidentiality.

Participants made a number of suggestions that they felt would make the study more attractive, such as offering particular diagnostic tests, which they felt would increase recruitment and retention. In the Montreal group, participants pointed out the importance of having francophones involved in all aspects of testing and communication with participants. The importance of having a comprehensive consent process to ensure participants knew exactly what they were agreeing to was also mentioned.

The policy implications of the research were not lost on participants who recognized the potential value, not only in the area of health, but also related fields: “And is the purpose of the study... to direct money in specific directions to improve health? Is that the long term purpose?” Participants showed a good understanding of several issues affecting study validity, including the importance of a representative sample and the effects of behavioural change on study results. There was also discussion of factors which would impact study participation with recognition that participants may need incentives to begin and continue to participate in a 20 year study. In line with other feasibility study results, altruism was an important motivating factor for some participants.

1. Purpose of the Research Project

1.1. 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 as they enter into and comprise the senior population. The study takes a lifespan perspective and adopts a variation of the determinants of health framework to conceptualize the ways in which social and physical environments, genetic, biological and clinical factors, lifestyle and behavioural factors, social and societal factors, economic prosperity, and the health care system are inter-related to influence disease, function and well-being as individuals age. 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 intervention strategies. Scheduled to be launched in 2008, the CLSA will require the long-term participation of volunteers drawn from the Canadian population and will entail a variety of data collection methods including telephone and face to face interviews, physical assessments, and the provision of biological samples such as blood and urine. This study is one of a series of feasibility studies funded as part of the CLSA development phase.

Given the magnitude, depth, length and complexity of the CLSA, an important element requiring careful consideration is the return of individualized results to research participants. This consideration requires balancing the rights of participants to have information about themselves against the possibility that providing such information may in fact be more harmful than beneficial to individuals. In addition, in a study in which participants are repeatedly asked to provide a large amount of personal information over a long period of time, the provision of such information could be viewed as a benefit of participation, and enhance participation and retention. Unfortunately, there is little information in the literature to guide decisions about what individual information to return and how to return it in longitudinal observational studies. Exploring these complex issues allows the CLSA to better design a study that reconciles epidemiologic principles, legal and ethical obligations, and logistical and resource realities.

1.2. Obligations and Responsibilities of Researchers to Study Participants

Researchers must abide by a set of regulatory and ethical rules. Generally, health researchers refer to the Helsinki Declaration (World Medical Association Declaration of Helsinki 2004), the Canadian Tri-Council Policy Statement on the Ethical Conduct for Research on Humans (Medical Research Council of Canada, National Science and Engineering Research Council of Canada et al. 1998), the International Guidelines for Ethical Review of Epidemiological Studies (Council for International Organizations of Medical Sciences 1991), and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences 2002). These guidelines outline general obligations and responsibilities that researchers have towards research participants and include the four basic ethical

principles, namely respect for persons, beneficence, non-maleficence, and justice. Only one of the above mentioned guidelines, the Council for International Organizations of Medical Sciences (CIOMS), specifically addresses the return of individual results to participants:

Communication of study results

13. Part of the benefit that communities, groups and individuals may reasonably expect from participating in studies is that they will be told of findings that pertain to their health. Where findings could be applied in public health measures to improve community health, they should be communicated to the health authorities. In informing individuals of the findings and their pertinence to health, their level of literacy and comprehension must be considered. Research protocols should include provision for communicating such information to communities and individuals (Council for International Organizations of Medical Sciences 1991).

Impossibility of communicating study results

14. Subjects of epidemiological studies should be advised that it may not be possible to inform them about findings that pertain to their health, but that they should not take this to mean that they are free of the disease or condition under study. Often it may not be possible to extract from pooled findings information pertaining to individuals and their families, but when findings indicate a need of health care, those concerned should be advised of means of obtaining personal diagnosis and advice (Council for International Organizations of Medical Sciences 1991).

Most recently, the CIOMS draft guidelines (Council for International Organizations of Medical Sciences 2005) state the following:

7) that, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;

8) that subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given the reasons for such non disclosure).

Whereas some relevant literature has addressed the importance of returning *study results* to research participants in the context of clinical trials (Fernandez, Kodish et al. 2003a) (Schulte and Singal 1996; Partridge, Burstein et al. 2003; Partridge, Wong et al. 2005; Zlotnik Shaul, Reid et al. 2005), similar discussions regarding the return of individual results are not evident, and little useful literature exists on how epidemiological studies have addressed the return of individual results. Moreover, the issues are somewhat different for clinical trials, which involve an intervention, and observational studies, which do not.

It may, however, be fruitful to consider the rationale behind returning *study results* to participants, as the same rationale may apply to *individual results*. The act of returning information to research participants acknowledges the central role of the research

participant to the process of health research and reduces the chance of participants feeling exploited (Fernandez, Kodish et al. 2003a). The research community can also gain by providing results to research participants in that it may enhance trust in the researchers and the research process and it could raise public awareness of the importance of research on knowledge (Fernandez, Kodish et al. 2003a; Fernandez, Kodish et al. 2003b). In an age of increased demands for accountability and transparency, some argue that that researchers should be accountable not only to funders but also to research subjects who provide the material means for research, including blood, urine, DNA and other specimens (Zlotnik Shaul, Reid et al. 2005). Recent clinical trial literature found that as high as 96% of participants have a strong desire to know the results of the research in which they have taken part (Partridge, Burstein et al. 2003; Partridge, Wong et al. 2005).

The same considerations (respect for persons, beneficence, non-maleficence, and justice) also apply to returning *individual results* to participants. The research participant, if he or she chooses to receive individual test results, could positively act upon the information provided to her/him and perhaps enhance his/her quality of life. However, negative consequences may also occur if information is provided outside of the clinical context or if clinical results are interpreted without taking into account the full medical history of the individual, particularly with respect to medications or treatments. Conversely, physicians may not be prepared to deal with test results that they did not order. For example, it can be argued that it is unethical to return information to participants for which they and/or their physician can do nothing about, such as genetic information. There are also issues with respect to returning information for which established clinical guidelines do not currently exist.

Observational studies are markedly different from clinical trials, and longitudinal studies, with repeat measurements, raise additional issues. Thus, the potential issues in returning individual results to research participants in a longitudinal observational study are complex and require in depth examination.

1.3. Purpose

Before the CLSA begins in 2008, a policy will need to be developed concerning the issue of returning individual test results to research participants. Potential research participants will need to know and understand before signing a consent form whether or not the CLSA will provide any individual results. If the CLSA decides not to return personal information, a carefully written rationale must be provided. It is reasonable to assume that for some research participants the provision of individual data may influence the decision to participate in a 20 year long study. If the CLSA does decide to return individual information, a carefully designed plan needs to be instituted that will address a multiplicity of questions. For example:

- Should all test results from the physical assessment be returned? Why or why not?
- Are there other results that should be returned?

- When should individual results be returned?
- How should test results be returned?
- To whom should test results be returned?

The 3-part study described here will begin to address some of the above questions and the findings will assist the CLSA to develop a policy around the return of individual test results to research participants.

1.4. Study Goal and Objectives

The main goal of this study is to explore the issue of returning individualized test results to research participants. The information gathered in this study will enable the CLSA to develop policies and procedures around the return of individualized test results to research participants. The information is applicable to any longitudinal study of adults in Canada.

The study is designed to meet the following objectives:

1. Gain baseline information on the practices of other longitudinal studies regarding the return of individualized information to participants.
2. Gain an understanding of the beliefs, attitudes, and preferences of potential participants regarding the return of individualized test results.

The three major activities carried out for this study include:

1.4.1. Part 1: Web-based Survey

- Conducting a web based inventory survey of other longitudinal studies to ascertain which longitudinal studies do/do not return individualized test results to participants and/or general practitioners.
- Exploring which functional health measures each longitudinal study returned to its research participants and/or general practitioners.
- Exploring the reasons why longitudinal studies decide either to return or not return individualized test results to research participants and/or general practitioners.

1.4.2. Part 2: In-depth Telephone Interviews

- Conducting follow-up telephone interviews with selected studies identified in the web survey to obtain more detailed information.

1.4.3. Part 3: Focus Groups

- Exploring the attitudes of Canadian adults over 40 years of age toward the return of individualized test results in the context of a 20-year longitudinal study.
- Exploring the attitudes of Canadian adults over 40 years of age on the types of individualized test results they would like to receive and how they wish to receive them.

This technical report will address the findings from the focus group research only.

2. Study Design and Research Methodology

Focus groups were determined to be the most effective methodology to elicit attitudes and beliefs about the return of test results, allowing rich detail to emerge through the exchange of multiple views. It is important to note that focus group discussions were intended to allow a wide range of opinions to emerge in a forum in which there was no right or wrong answers. Our purpose was not to educate or inform participants but, rather to observe and record their views on the subjects presented to them. No attempt was made to correct erroneous perceptions of what the CLSA might or might not actually do, although clarification was provided as to the intent of the questions when necessary. Participants were provided with the opportunity to ask questions at the conclusion of the group discussions during which factual responses were provided to the extent that such information was available. The methodology for data collection and analysis is described in detail below. Six focus groups were held in six different regions across Canada, corresponding to the proposed regions for data collection for the CLSA. The six sites were: Halifax, Montreal, Hamilton, Winnipeg, Calgary and Vancouver.

2.1. Recruitment

Recruitment for all six focus groups was conducted by telephone. This was accomplished in a two-stage process. First, a commercial sampling firm was used to generate random telephone numbers. Second, market research firms in the cities where focus groups were held recruited participants. Details of this process are outlined below.

The sample of telephone numbers was obtained from ASDE Inc., a firm that specializes in providing telephone samples for research studies. The sample was drawn by generating random telephone numbers based on the working residential telephone exchanges within the six study areas identified in the CLSA Protocol. For these focus groups a fifty kilometre radius of each city centre was chosen as the study area from which participants would be selected. The randomly drawn telephone numbers then were checked against published telephone listings in order to produce a Directory Listed (DL) sample. If this sample had been designed to be representative of the population living in these areas a Directory Not Listed (DNL) sample would also have been drawn in an attempt to include unpublished and not yet listed telephone numbers. However, since focus groups are, by definition, not representative, a directory listed sample was judged to be adequate for recruiting purposes.

Using this sample, market research firms in Halifax, Montreal, Winnipeg, Calgary and Vancouver undertook recruitment⁴. These firms have extensive experience recruiting for focus groups in their own areas and are able to provide precise information on location and other particulars as well as make reminder telephone calls. Using our own sample helped to guard against recruiting individuals who are in a database of those who may be more likely to attend focus groups. These firms all belong to market research organizations that adhere to ethical principles typically required by university research ethics boards.

These market research firms recruited participants one to two weeks before the focus groups were scheduled to take place, using an established recruiting screener provided by the CLSA. Twelve participants were recruited for each focus group. However, due to attrition, this resulted in groups of between 5 and 11 participants. Since the CLSA will use participants 40 years and older, only those in this age group were eligible for recruitment. When someone under the age of 40 answered the phone, s/he was asked if there was anyone in the household over the age of 40. In this study a gender balance within each focus group was desirable in order to obtain the views of both men and women. In order to ensure participants of all ages were included, recruits were also balanced by age group. This was achieved by observing quotas. For example, once 6 females had been recruited for a 12 person focus group, only males were then eligible for inclusion. If a female answered the phone, she was asked if there were any males in the household over the age of 40. If there were none, the contact was thanked and the call terminated. Similarly, once 6 participants from the 40 to 59 age group were recruited only those 60 and over were eligible for inclusion, ensuring that there was also a balance between these age groups.

When a call resulted in contact with an individual eligible for the study, the person was provided with a brief description of the study and asked if s/he would be willing to participate. Those who indicated that they would be willing to participate in this study were given specific information about the date, time and location of the focus group. They were also asked to provide their mailing address so that a letter of confirmation could be sent.

CLSA staff then mailed participants a brochure describing the CLSA study, a copy of the consent form and written confirmation of the date, time and location of the focus group. A reminder call the day before the focus group was also made to each participant.

2.2. Informed Consent Process

As indicated above, the consent form was mailed to participants along with the brochure and focus group information. An accompanying letter requested that potential participants review the consent form prior to attending the focus group and indicated

⁴ Because the Hamilton focus group was held at McMaster University, recruiting was done from Halifax. In all other cities with the exception of Halifax and Hamilton recruiting was done by the same firm whose facilities were used for the focus groups.

that it was not necessary to sign it beforehand. A toll free telephone number and e-mail address were provided to allow potential participants to contact a CLSA staff member to obtain additional information on the consent process or any other aspect of the focus group. Several participants availed themselves of this opportunity for clarification or to indicate that they were unable to attend the focus group. Providing the consent form in advance gave participants time to review and absorb the information contained in the consent form and facilitated the actual consent process. Participants were also given the opportunity to ask questions about the consent form and consent process immediately prior to the beginning of the focus group discussions.

In addition to the moderator, who was a CLSA staff member, one additional CLSA staff member was present at each group to help expedite the signing of consent forms and other documents as well as take notes. The importance of confidentiality, including the fact that participants should keep information shared in the focus group confidential, was addressed by the moderator prior to the start of each group discussion. One other individual, typically a focus group facility host, was present to help process participants and to be available in case a participant was unable to continue to participate and needed to leave the room.

2.3. Subject Participation

All focus groups were conducted in English, with the exception of the Montreal group, which was conducted in French by a French speaking moderator.

The focus groups took place in dedicated focus group facilities in all cities except Halifax and Hamilton where centrally located university boardrooms were used for convenience and cost savings. Participants were seated around a table with the moderator and the note taker. The focus groups took approximately two hours.

Focus group participants were asked to provide demographic information (i.e., age, sex, education, ethnicity, employment) through a brief questionnaire which was completed prior to the beginning of the focus group but after signing the consent form. Identifying information such as name and address was not included on the questionnaire. Participants received a \$40 honorarium intended to offset the costs associated with attending the group. The option to fill out a form requesting a summary of the research findings was also provided to participants. Focus group participants were then asked to participate in a guided discussion concerning their views on the return of individualized test results to study participants or their physicians in the context of a longitudinal study on health and aging. Topics for discussion included receipt of test results, DNA testing, consent to receive or not receive results and responsibility for health. The moderator guide, consent form and participant questionnaire are included as Appendices A, B and C, respectively.

All focus groups were audio-taped and field notes taken. All audio-tapes were transcribed. Access to the audio-tapes was limited to the transcriber and CLSA staff involved in the data analysis.

The type of information sought from participants was unlikely to cause significant emotional or mental anguish and, indeed this was the case. No participants left the discussion prematurely and most commented that they enjoyed participating in the discussion.

2.4. Data Analysis

The audio tapes from the focus groups were transcribed verbatim. The transcript from the French Language focus group was translated into English and transcribed in one operation. This transcript was also reviewed for accuracy by a third party. Additionally, CLSA staff took notes of key points in the discussion. After each focus group, the moderator and CLSA staff held a debriefing session to share impressions, compare notes, interpret participants' comments and/or behaviour and make summary and reflection notes. Meetings were held with the French language moderator both prior to and following the focus group to help familiarize her with the subject matter and also to gain insight into her impressions of the discussion.

The primary purpose of these focus groups was to discuss attitudes and beliefs about the return of individualized test results to study participants or their physicians in a population-based, longitudinal study such as the CLSA. To that end, the focus group topics were designed to elicit information around themes and concepts that are likely to be important considerations in this regard. Themes believed to be important included general beliefs and attitudes toward the return of clinical results, ethical responsibility, ownership of data and consent. Using a thematic analysis^{5,6} approach, specifically framework analysis, data generated from the focus groups was coded and organized around these a priori identified themes. In addition to the identified themes, several emergent themes were identified.

After a thorough familiarization with the transcripts through both listening and reading, members of the research team identified 10 major themes. Two members of the research team then independently coded all the transcripts to these themes using NVivo qualitative software. The coding was then compared and any differences resolved through discussion. Next, sub-themes for most of the themes were developed through review and discussion. Each theme was then sub-coded by the identified sub-themes. Based on this organizational structure study findings were written emphasizing factors that emerged as important considerations in the discussion of returning individualized test results in a long term study such as the CLSA. The study findings are enriched by direct quotes from focus group participants illustrating key points under each of the themes.

⁵ Taylor SJ, Bogdan R, Introduction to Qualitative Methods: A Guidebook and Resource. John Wiley and Sons Inc. 1998.

⁶ Strauss AL, Qualitative Analysis for Social Scientists. Cambridge University Press. 1987.

The final document will be used to help guide the development of the CLSA and in particular, policy and practice around the return of individual test results. It is also intended that excerpts from this document will be disseminated to a research audience via publication in a scholarly journal. Additionally, an abbreviated summary will be available on the CLSA website for the lay public.

3. Study Findings

3.1. Profile of Focus Group Participants

Focus groups ranged in size from 5 to 11 participants with a total of 48 across the six groups. However, one participant did not fill out a participant questionnaire so this profile is based on 47 responses. Individually, and in total, the groups were well balanced by gender with responses from 22 males and 25 females. Participant age ranged from 40 to 84 with a mean of 58. Sixty percent of participants were in the 40 to 59 age group with 40% in the 60 and older group. The majority of participants (76%) were born in Canada. In terms of ethnicity, over half of the responses (52%) indicated British Isles origins⁷. Seventeen percent of responses indicated French origins and a further 24% other European origins. Only 1 participant indicated aboriginal origins. The remainder indicated African, Arab or other, origins. Sixty percent of participants were married with 28% being widowed, separated or divorced; only 12% were never married. Only 37% reported having children still at home. Participants varied in terms of education with 45% reporting one or more university degrees. Sixty-one percent of participants were employed either full or part-time and a further 28% were retired. The remaining 11% were homemakers or students. Household income varied considerably with 20% of participants reporting less than \$25,000 and 28% reporting \$75,000 or more with the remaining 52% between these levels. While no claims can be made for representativeness, it is evident from this profile that focus group participants were diverse in terms of their age, education, employment status and income. This also confirms the informal finding that there was significant variation in socio-economic status among participants.

3.2. Sources of Health Information

Participants were asked a very general question about the types of personal health information they were most interested in as a way of introducing the topic of returning individualized test results and providing some background for both the discussion and the analysis. Specific probes to this question dealt with sources of information, specificity of information, alternate sources of information and self-monitoring of health indicators. Additional probes focused on behavioural change as a result of receiving health information and any information that participants would like to receive that they

⁷ Participants were permitted to indicate a number of ethnic origins. The percentages are based on total responses, not individuals.

could not currently access. Seven sub-themes were identified under the general heading of health information.

Participants initially had some difficulty with this question and hesitated before answering. Some sought clarification. Although it was designed as an “icebreaker”, it did not function particularly well in this regard. These difficulties were partially resolved by combining the first probe concerning sources of health information with the question. Participants may have perceived this question as overly personal at this point in the discussion and their replies seemed to confirm this. However, once the discussion began, participants were forthcoming with their views, providing a wealth of information on diverse topics.

3.2.1. Health Interests

Initial reactions to this question in a number of groups focused on the possibility of contracting a particular disease. Most of those mentioned were associated with aging such as diabetes, cancer, heart disease, osteoarthritis and Alzheimer’s. Diabetes was mentioned quite frequently with one participant referring to the “diabetes time bomb.” When asked to explain he offered the following:

“...a high percentage of the population, based on their lifestyle and their weight, their obesity... is going to have diabetes in the near future and it’s going to reach epidemic proportions... over the next 15 years.”

Participants were interested in both risk factors for particular diseases and anything they should be doing to lessen the risk. One participant simply stated: “I’d like to know what the possibilities are of contracting Alzheimer’s.” while another speculated: “...am I a candidate for a heart attack in two years time...?” In the opinion of one participant: “...most people die of either cancer or heart disease sooner or later... so I’m trying to prolong that as long as possible.” Other diseases/conditions mentioned were strokes and TIA’s, specific cancers and depression.

A number of participants were interested in having specific diagnostic tests, some of which they felt were not readily available: “I would like to have an MRI or CAT scan. Saying that, knowing that it’s almost impossible unless you do have an urgency about it.” Other tests which participants cited as desirable diagnostic tools were ECG’s and stress tests, x-rays, blood pressure, cholesterol, PSA, and other specific blood tests. “...an ECG is a pretty simple thing. And it shows if you have something really wrong with your heart...”

A few participants were interested specifically in knowing more about the aging process. “I’d like to know more about the aging process as I went along.” One participant wanted to know if there was a connection between aging and depression while others felt that mental health was as important, if not more important than physical health. “...physical and mental, both are important to me. If I had to pick between the two I would say that if my head works, the rest will follow.” Another participant expressed fear of the aging

process. “I’m scared [to be] 70 years old, what’s going to happen? I’m really scared to be 70.”

A number of participants wanted more information on lifestyle and nutrition, essentially what they needed to do to be more proactive about their health.

“I think it’s really important to get preventative information...instead of fixing something, it’s about being proactive and keeping healthy and proper nutrition... to facilitate better health in the aging process...”

In several groups participants commented on the difficulty of obtaining access to their personal medical files and advocated policy or legislative changes to make access easier. “I mean in the health care system... it should be the law, if the person asks for his medical file, he has to say yes and be legally obligated to do it.” There were also comments on the need to advocate on your own behalf in order to receive diagnostic services. “...they will order the standard tests but they won’t give you any extras unless you ask, and then maybe sometimes even demand.”

There were also a few comments about receiving health information but wishing you had not asked.

“There’s test for genetic markers... that I don’t necessarily want to know because if they find it, there’s nothing they can do about it... Sometimes that’s too much information because how are you going to live your life from now until then?”

3.2.2. Sources of Information

Participants were asked to identify their sources for health information. In most groups the initial reaction was to identify their family physicians but this response was often followed very quickly by “the Internet”. A number of participants used these two sources in conjunction with one another, using the Internet to research a diagnosis or condition and then questioning their physician further based on their research.

“I would talk to my doctor first and then based on what he says, review it on the Internet, and based on that research, query him again if there are inconsistencies or I don’t understand things.”

Many participants reported using the Internet to research their health or what their physicians had told them but several felt that caution was needed because not all information was reliable.

Speaker A: “I would use the Internet, but I’d make sure that it’s an .edu or an .nih or .gov site so it’s reliable.

Moderator: “And what does that mean?”

Speaker A: “National Institutes of Health, a government site or an educational site just so it is reputable.”

Moderator: “So do you think there is some information on the Internet that is unreliable?”

Speaker A: “My elementary kids can put up any information on the Internet. I wouldn’t want people believing it.”

This skepticism about health information also extended to personal physicians with some participants openly expressing a lack of faith in their physicians. This was not evident among all participants, especially not older ones, many of whom expressed a high level of confidence in their physicians, or in all groups, but it was mentioned a number of times.

“I actually trust my doctor very little. I mean I trust him to do testing and things like that, but in terms of his ability to keep up on current medical information, he is bombarded and is not going to spend three or four hours a day reading...”

Some participants used the group as a forum for their complaints about the medical profession, specifically their attitudes toward patients. This was particularly evident in the Montreal group. “...the doctors did not speak to us at all, not one word... as if they are gods!”

Some participants expressed more faith in medical specialists and saw their personal physicians more as “gatekeepers” to these health care providers. I’m not even that confident with my doctor... I will get him to refer me to a specialist. I have more confidence in them.”

Participants reported using a wide variety of individuals as sources of health care information. Friends and relatives, especially those with a health care background such as nurses, nutritionists and paramedics were mentioned. Other health care providers such as nurses, chiropractors, pharmacists, physiotherapists and dieticians/nutritionists were also seen as sources of information. Somewhat surprisingly, a number of participants reported using health food store employees and fitness centre employees such as personal trainers as sources of health information. This is surprising only because they are obviously in the business of selling products and services and may be seen as having a vested interest in promoting these products and services.

Alternative medicine was also mentioned regularly, usually in the context of consulting naturopaths, herbalists or other practitioners of holistic medicine but some participants were cautious about this: “So alternative sources, I think are worth looking at but you do have to exercise caution.” while others were more doubtful: “I’m somewhat skeptical when it comes to some of the alternative whims just because I worry about the fad thing, you know, what’s “in”...”

Some participants pointed out the many choices available to health care consumers and emphasized that it was up to each individual to decide what sources to use or whether to use any at all. These comments were interesting because they seemed to imply that all sources were of equal value. “You handle it the way you’re comfortable... whoever

you decide... the advice could be consult your care giver or whatever you want to term them. Doctor, pharmacist..."

Other sources of health information mentioned were books, journals and media including radio, television and magazines. Some participants mentioned specific magazines such as the *Berkeley Health Letter*, specific television programs such as *The Fifth Estate* and specific local radio programs: "[Radio station] on Saturday morning, I listen to him like the bible. Yeah, I would not trust doctors."

One participant felt that the media, along with disease associations were not doing a good job of emphasizing prevention.

"I feel that very little information that comes my way through the media, through doctors or associations... I find a lot of it's not helping me to be proactive... I'd like to see more emphasis put on prevention of a lot of these things like arthritis, osteoporosis..."

Some participants mentioned educational material, services, and seminars etc., provided through their provincial health department or local health care authority as sources of health information. Also mentioned were seminars sponsored by associations such as the Canadian Diabetes Association.

One participant felt that information on mental and emotional health was difficult to obtain: "I think the area that's hard to get information for is more the psychological/emotional aspects of aging."

3.2.3. Informed Consumer

Focus group participants generally presented as well informed health care consumers. Whether this is generally true or whether these focus groups tended to attract participants who were more concerned and better informed about their health is impossible to determine but it seems likely that a health related focus group would be likely to appeal to the more health conscious among the population.

When prompted as to whether they asked for specific readings and results of tests from their physicians or were satisfied simply to know they were in the "normal range", many participants wanted to have specific information but with some interpretation by their physician of what that reading indicated.

"So I like the numbers because then I can compare; so I like to know the exact facts. Don't give me the general statement; give me the specifics, yeah. I don't think you could be too specific unless it got to the point that it was jargon that I wasn't understanding..."

"I do trust their interpretation of the numbers and some of the things I've asked them, whether it's cholesterol and it's a number that I know in my mind what it means. So I like to know the number. But some of the areas I've been tested

for in the past, the numbers that they have arrived at don't really mean anything to me so I have to depend upon my doctor's interpretation to understand what's going on."

However, many participants felt that the specific number was not meaningful to them, or they would not remember it, and were satisfied to know they were in the normal range, or not, and if not, were more interested in knowing what they should be doing to bring those readings into the normal range, or at least improve them.

"I actually had a medical quite recently and the doctor told me what the blood pressure reading was and it meant nothing to me, so I said just tell me whether it's okay or not, and he said it's fine, so that's good enough for me."

"...when he says, well, you're in an OK range but you really should improve your bad cholesterol, okay then, that makes sense, right? But if you give me a number it wouldn't have meant anything."

Several participants commented that the public was becoming more sophisticated in their understanding of health related matters and more involved in managing their own health care and this was an underlying factor in wanting more specific information.

"I think people... are becoming more knowledgeable about some of the medical terms: cholesterol, high-low, blood pressure, different things like that, and they want that information. At one time when you went to the doctor and he said you were fine, that was fine; it was good enough. But it isn't anymore because people have access to the Internet for one thing. They can raise a lot of questions and they like to know."

A few participants indicated that they only wanted specific readings if they were outside the normal range.

"If he says it's good, I usually take his word. Sometimes he tells me, sometimes he doesn't. But it's not a big thing as long as it's in the normal range. If it gets where it's not normal, then I would want to know more detail about it."

A number of participants felt that it was important to actually get a copy of test results, such as those from a blood test, both as a matter of right but also as a way of remembering the readings and keeping track of them for later comparison: "I'd like to get copies of the stuff instead of it all going to the doctor." "It should be available if you want it, I guess is what I'm saying." For some participants knowing the normal range and being able to compare your results was a key factor as well: "And what is normal and what ours are, so that you have the range, and you get a printout of it."

“It’s nice if they give you the range of what is normal and then you know where you fit in within that, but if you don’t have a context in which to put it in, it sometimes doesn’t mean anything.”

Several participants also commented on the fact that guidelines for what is considered normal change over time and this makes it difficult for the lay public to understand and compare their readings over time: “But the numbers change over time. It used to be there were different numbers for your cholesterol and now there are new levels. I’m happy if they say it’s good.” “Because maybe it wasn’t abnormal 20 years ago, maybe they’ve changed the normalcy...”

Some participants were dissatisfied with the fact that their results were not communicated to them in a timely fashion and/or that they had to make a further appointment with their physicians in order to receive their results: “But twelve months later I find out my cholesterol was up... a little bit. I would like to have known that sooner than... at my next annual check-up...”

“...he won’t give it to me over the phone and it’s like it’s privileged information. It’s a state secret. Well, it’s my blood, it’s my PSA, and yet the only way to get a follow-up answer is to make an appointment... but that means... he’s getting a visitation that he can bill OHIP for.”

A number of participants reported that they monitored their own health care through various means. Blood pressure and blood sugar were cited most often with some participants indicating that they used the blood pressure devices often found in pharmacies. Others had invested in their own sphygmomanometers and glucometers. “I’ve used a blood pressure machine at Lawton’s.” “Yeah, I take my own blood pressure... it’s just one of those little digital ones...” For a few monitoring took the form of simply paying attention to their health.

“And I think it’s probably a good idea to monitor yourself a little bit because otherwise you can let something get so bad that it’s a huge thing to work on when you find out what it is and what you can do about it.”

In one group, participants had a lively discussion about the accuracy of home blood pressure monitors: “I think they can be very misleading. There are all different kinds on the market and I’m not convinced that there’s a lot of accuracy there.”

A few participants discussed the importance of advocating on your own behalf with the health professions and staying informed and up to date through various sources: “I’ve learned... that you have to advocate for yourself because there’s no one else to advocate for you.” “The doctor’s not the one who’s taking the medicine, so you want to get as much corroboration that this is an appropriate thing to do.” “I guess it depends on how much you want to know and take control of your own life and your own body and all that...” “Like in any profession; it is also up to us to ask questions.”

Some participants talked about their relationship with their health care provider, specifically getting back the results of tests and the protocol around returning normal and adverse results: “So I would like the phone call either way just saying, you know what, that was clear, that was good... because otherwise you just wait and you worry...” There were also comments made about the difficulty in accessing certain diagnostic procedures and some cynicism about physicians and clinics creating rules and systems that maximized their profit at the expense of patient convenience.

Participants also made a number of suggestions which they felt would improve the doctor patient relationship including being able to get test results over the phone, scheduling blood and other diagnostic tests in advance of appointments and computerizing patient records to allow easier access.

“The doctor I go to is in a clinic and about 2 years ago they went and put everything on computer and I’ll say what was my blood pressure last time, and he says well here it is, and do you want to keep a record of it?”

3.2.4. State of Health Care

Participants made a number of comments on the state of the health care system in Canada. One focus was the difficulty in getting a family physician, and the resulting increased reliance on clinics: “You can’t get a family doctor. You cannot just pick up the phone, call the medical society and say which doctor is accepting new patients?” “I’ve had three doctors and all three of my doctors have moved.” “I don’t have a regular doctor. I can’t get one.”

“Then again we’re also assuming that everyone has a family doctor and consistently goes to a family doctor. And not all Canadians do. I know a family that just goes to a neighbourhood clinic and they have for close to 20 years. They just get whoever happens to be on duty to handle whatever particular ailment they have at the time.”

Some participants also felt that the shortage of doctors had increased wait times for physician visits: “...it is very hard getting a physical with your doctor. You almost have to wait three or six months.”

The cost of health care was also mentioned by some participants, particularly in relation to physician billings: “I believe that there’s got to be a better means of regulating it and also controlling the costs that are involved for the doctors’ visits. We talk about nationally how much our health care is costing us and you just look at that alone...” “I think that is almost abuse of taxpayers’ money...forcing somebody to come in for an appointment to get a prescription...” One participant felt that regulations made the system inefficient: ““But that’s so they both get paid. The ultrasound technician is going to tell the doctor what this means and now the doctor gets to tell you and they both get paid.”

Some participants expressed concern over the perceived lack of access to their medical files: “Why can’t I have a copy of them? It’s my medical records. They know more about me than I do. It’s kind of ridiculous.” “May I remind you that the Quebec law on health care says clearly that your medical file belongs to you...”

There were also concerns expressed in one group about the confidentiality of medical records and the ease of accessing personal records contained in large health care utilization databases: “...my Dad was in the hospital last week...they found out all his pills just by going onto some kind of giant database.”

Physicians were the object of both praise and criticism in the focus group discussions but more of the latter than the former. There was considerable discussion about unnecessary appointments and the need to see a physician to get a prescription renewed. Several participants classed this as revenue generation but others felt that physicians were tied to a regulatory system: ...”the doctor is being tied into regulations...”

Some participants made suggestions for improving the health care system such as family health practices: “...where contact with a whole group of medical professionals was easy at the same place. I think that would be very effective for the health of seniors.”

3.2.5. Media reports

Participants made a number of comments about the unreliability of some of the health information that they received through the media, mostly concerning the fact that studies often contradicted earlier findings and it was difficult to ascertain what, if anything, to believe: “And this is the trustworthiness of the information that we get. Love to have all the information, but what can I believe?” “...the Journal of Medicine came up with something last week and today the British Journal of Medicine totally contradicted it, you know...”

Rather than attributing this to the nature of scientific investigation, some participants seemed to be more cynical, ascribing ulterior motives to companies seeking to promote their products: “...I find that when you look at who’s funding so much of this research, there’s some ulterior motive behind all the research... Somebody is looking into making a buck off of it...”

However, a few participants exhibited a more sophisticated understanding of why studies might yield contradictory results and, indeed, the value of a large population-based study like the CLSA.

“Well, I think the data from this could be very useful... I think a lot of these numbers you see bandied about on the Internet, and the doctors give you, I’m not sure how good they are. These studies are often small studies and somewhat skewed by different things. The other studies give different results.”

A number of participants commented on the role of the media in reporting the latest study or the latest “fad” and felt that some reporting bordered on the irresponsible: “I think we’re inundated an awful lot with the media and... I hate that they can get people very disturbed and very worried about themselves...”

Speaker A: “...it’s a bit confusing when you’ve been taking some medication and all of a sudden they come on TV and say: Oh this is bad. You shouldn’t be taking that. You have to use your common sense, I think, like if it’s a low dosage, then there’s not as much danger.”

Speaker B: “There always seems to be a flavour of the day...”

Speaker A: “You got it.”

Speaker B: “What is good for you last week, three weeks later after research or some study or magazine article, gee, don’t touch that, don’t even look at it, it will kill you, you know. Vioxx is the perfect example of that”

Speaker A: “Yeah, Vioxx, right. Well I take Celebrex, but if I didn’t take it, I couldn’t walk, so I take it.”

Some participants felt that the media was not doing a good job publicizing the preventive aspects of a healthier lifestyle: “I think the focus has to be on the prevention issue. It has to start with the young children.” “...the baby boomers are coming at us with coronary heart disease in massive numbers...but what information had been given to us in the previous years about this cardiovascular problem?” A few participants felt that media advertising promoted unhealthy habits: “So if we can get the cigarette ads off the TV, why can’t we get the junk [food] ads off the TV?”

3.2.6. Lifestyle

A number of participants commented on the benefits of pursuing a healthier lifestyle specifically nutrition and physical activity: “... people mentioned getting nutritional information... Once you start to look into that, you realize how much it affects you... For a lot of people it changes behaviour.” “...when I...exercise, I’m always more healthy. And at present I’m exercising again, so I’m really healthy... so exercise to me is one of the things...”

In speaking about healthy aging, one participant related the lifestyle advice given by a commentator: “And his advice wasn’t what to do, what to eat, it wasn’t a pill, it wasn’t a vegetable, it wasn’t a fruit. He says, stay active, keep yourself busy and keep your friends and socialize. Don’t stop socializing.”

3.2.7. Comparison of Individual with Overall Results

In several groups participants were interested in being able to compare their individual health and/or fitness over time, or with others in their age group: “I’d like to see some kind of indication on changes in life; in my personal health.” “I’d like to know where my fitness level stacked up against other people of my age group...” “Another thing I need

to know is what is, not just my scores, but what is a normal score because they seem to change a lot and the range of what normal is.”

“And so that when you were asking about last year’s results, for example, are they up from the year before or the year before that, are you tracking higher and are you within what he would consider to be normal for you or normal for the adult range?”

In one group, participants advocated a reporting system for test results which would show individual results with a comparison to established norms: “It would be very easy to set up a chart so that when those results came out, you’d have two sides, one with the norms and one what you are.”

Participants exhibited a strong interest in their personal health and their specific risk factors for various diseases, particularly many of those associated with aging. They were also interested in accessing diagnostic tests like MRI and CT but well aware of the difficulty of doing so in the absence of specific risk factors. Underlying these concerns, but largely unspoken, was the desire to age well but also the fear of aging and its consequences.

The number of different sources of health information mentioned by participants spoke not only to their interest in their own health but also to the diversity of sources available to them. For these participants, at least, physicians appeared to have lost their monopoly on health care information and the Internet had become a key source of information. However it was not clear whether the volume, variety and veracity of information available to health care consumers was unequivocally helpful in managing their individual health care.

It was apparent from many of the comments that most participants wanted to be active partners in their own health care and rejected the traditional view of “doctor knows best”. They were not only willing to verify information and even question their physicians but also wanted more specific information from health care providers including easier access to, and even copies of, their medical records. A number of participants monitored their own health in various ways and seemed to be seeking the tools that would help them become more effective managers of their own health. Some participants felt that they needed to advocate on their own behalf because no one else would do it for them. For some participants, at least, their limited knowledge combined with concern for their own health and health outcomes trumped the superior knowledge but limited time, and perhaps concern, of health care providers.

Many participants also questioned the state of health care, particularly the shortage of doctors and wait times. Underlying this and other comments was an implicit price/value equation for health care in Canada in which the value seemed to lag behind the cost. Participants also were critical of the role of the media in reporting conflicting health care studies and promoting advertising that contributed to unhealthy lifestyle choices.

3.3. Views on the Return of Health Results to Participants

A brief paragraph was read to participants indicating that those selected to take part in the CLSA would undergo a physical assessment involving routine procedures, such as blood tests and having their blood pressure taken, and explaining that these tests were being conducted for research purposes, in order to better understand the aging process. Participants were then told that some people felt that the results of these tests should be returned to participants and other people felt that they should not be. They were then asked for their views on this topic. Specific probes dealt with the need to interpret these results, the responsibility of health studies to participants, reasons for not returning results to participants and whether participants would want their own personal results back if they were part of a study like the CLSA. A further question stated that results from this type of study would typically not be as useful as results received from a physician with medical knowledge and knowledge of the patient. Participants were then asked if knowing this changed how they felt about receiving their own results.

3.3.1. General Views

Participants generally felt that those who take part in the CLSA should receive the results of tests conducted for research purposes and that health studies generally had an obligation to provide this information. For a number of participants this was a moral or ethical imperative for the study and for some others a question of an individual's right to information about themselves: "...there's an obligation to divulge that information to people who would like it." "Don't you have a legal, if not an ethical, duty to disclose this to the people?" "I would want them because it is just information about your body, which I think can make a difference."

Participants had difficulty answering this question in the abstract, however, with most framing their responses in terms of their own personal feelings and others basing their responses on the potential for serious adverse findings: "So if you find something seriously wrong... I think it is your responsibility to let someone know..." "There's an ethical side of this... a humane side of this too. It's not just a technical black and white study, it's the humane side of it; you don't just let someone..."

A number of participants made a clear distinction between results that fell within the normal range or indicated a minor problem and those falling outside the normal range and/or potentially indicating a serious health problem: "So if you find something seriously wrong... I think it's your responsibility to let someone know..."

"I guess the issue is what have you identified? If it's an issue with the cholesterol being off a little bit or something, that's not a big deal. But what if the tests identify something very serious? How is that to be handled?"

For many participants receiving test results was a matter of choice. Although there was debate in some groups about the logistics of offering and receiving results, the consensus in all groups was that the study had an obligation to offer results whether or not all participants chose to receive them and regardless of what they chose to do with

them upon receipt. “I should be given the choice.” “...maybe you ask them going in, if we find something important do we tell you? Maybe people don’t want to know.” “...you can do whatever you want with them afterwards; if they don’t want to go to the doctor they don’t have to.”

One of the choices that participants felt was important was to have their physicians or other health care providers involved in receiving and interpreting the results: “I think that one of the choices should be to have the results sent to your physician.” However, some participants pointed out that not everyone would want their test results going to their doctor directly because they might not be comfortable with certain information being passed on.

“...would you have an opt-out clause that [said]: ‘no, I don’t want these results being passed on to my physician.’ You get into ethical kinds of issues with some of the tests depending on what you propose.”

Most participants recognized that many test results would require interpretation but felt that it was up to participants to seek counseling from their physician or other health care provider and did not expect that the study would provide this: “You could take the numbers to your doctor and then they could interpret it...” “...you could choose who or what professional you want interpreting it. You know it might be your doctor. You might have greater confidence in your naturopath.” “I don’t think the researcher’s job is to interpret for us.”

A number of participants recognized that returning results would present a logistical challenge for the study: “Logistically, would that be very difficult for the research teams?” There was also an understanding on the part of some that their participation was for the “greater good” and that while results would be nice to have, they had to be balanced against the cost and complexity of providing them.

“I think that often in research there is a volunteer aspect; you don’t necessarily expect something in return. Although I want to see the results, if possible, I understand that it may be too big a task to inform 50,000 people about their individual results.”

“...so you’d have to take a hard look at the cost and the time involved in sending out all these results. If it’s worth it fine, if not... I mean there’s all kinds of guinea pigs in the world, so if I’m another one, why not; if they can do something for research, why not?”

While there was a general desire to have individual results returned, some participants would agree to participate regardless: “I’d like to have the results but if the study group feels that is costly or whatever, I would still agree to participate.” “I would prefer it, yeah, but I don’t think I’d decline to participate if they said: ‘no, we’re going to keep them all to ourselves.’” Others were inclined to participate but were specifically concerned about not receiving results that could indicate a serious condition: “I’d be curious.

Would it stop me from participating? No, but I think you never know when you're withholding information that could have made a difference." A few participants tied their participation specifically to the receipt of results:

"I definitely feel that you should have the information back. I feel very strong about it. It is about yourself and I would not participate in it if I wasn't going to be given the opportunity of having the information back."

3.3.2. Personal Feelings

As already indicated, most participants had difficulty in separating the question of whether studies that incorporate health measures should return results to participants from their own personal feelings on the subject. When asked specifically about whether they would want their own personal results back, an overwhelming majority indicated that they would want to personally receive their test results or have them sent to their doctor. The only variation was between the results of routine testing or results which were in the normal range and non-routine tests or those which indicated a potentially serious problem. Some participants were not interested in receiving the results of tests which they had done on a regular basis by their own physicians: "I go to the doctor every few months...that's why I said I wouldn't need them back because I get it every 3 months..." "I mean if it's just straightforward blood pressure/blood tests and that sort of thing, I don't need to have that back." "...if I wanted specific results about my health, I would just get them from my physician." I'm OK with that if they keep it confidential, but if there's anything extreme, then I would expect to be advised..."

Most participants accepted that they would not receive the results of DNA analysis but expressed a desire to receive DNA results if, in the future, they had diagnostic value and specifically if it indicated any cause for concern: "It would be treated like any other diagnostic tool then and I think you should know if it shows up anything adverse."

Speaker A: "So if they found out 10 years into the study that this particular gene... is a precursor to say, diabetes or something, would they tell you or not?"

Moderator: "Would you want to be told?"

Speaker A: "Yes"

A few participants felt that they would rather not have DNA results that indicated the potential for a serious illness unless there was something they could do about it: "...what good is it going to do me to know that I'm likely to get cancer unless you got something that I can do that might prevent that?"

3.3.3. Reasons for Not Returning Results

Participants were asked if they could think of any reasons why results should not be returned to those taking part in the CLSA. Focus group participants were able to articulate a comprehensive list of factors that might impact the decision to not return individual results. The most frequent response and the first to be mentioned in most groups was that the results, if adverse or even if misunderstood, might worry, alarm or

panic some participants: “I wouldn’t want to get information about a catastrophic illness in the mail.” “Yeah, kind of a shock... if you find out by mail that you have 6 days to live...”

“Well, for some people it will be worrisome... the idea of just getting a bunch of numbers sent to you in the mail that you can’t understand, yeah, I think for some people that would be stressful.”

Because of the possibility of alarming information, most participants felt that results should go to a physician rather than the individual: “Some people may not have the inner strength to handle some of the things... so maybe all of them should be released to a trusted physician.” “...if it was really, really bad news maybe it should go directly to their doctor or something, rather than getting that directly in the mail.”

Several people also brought up the possibility of false positives: “Is there also the danger of a false positive or something like that? It could get people more disturbed than they need to be.”

“So you get that back... in a cold letter... you got prostate cancer, you know it would make you jump unnecessarily. So that would be the kind of case where it should actually go to the doctor first... so that if it is a false positive he can allay the fears before they’ve even started.”

For many participants, a reason not to return test results was that they might indicate a non-treatable disease or condition: “There’s tests for genetic markers and stuff now that they’re doing that I don’t necessarily want to know because if they find it, there’s nothing they can do about it.” “...you know what? That’s some of the information where you want it until you get it and then you wish you didn’t have it.” “Some things you don’t know, you’re better off for it because there’s nothing you can do about it.”

Another reason put forward for not returning individual results was that those receiving them would not be able to properly interpret the results: “If they don’t have the background to be able to understand it.” “...just to get the results back without an ability to understand this is within the normal range or if you really need to do further exploration here...”

A few participants conjectured that sending results back to individuals might even lead some people to initiate self-treatment:

“...if the results indicated an abnormality and there was some commercial on the television that told you to buy this product for this particular abnormality, now you’re taking some medicine... that might not be the appropriate thing to do; whereas if you hadn’t gotten the results you wouldn’t have done that.”

One participant brought up the possibility that some of those in the study might not be competent to receive results: “...there is a possibility that someone that is in the study

would develop Alzheimer's disease and then sending them the information will have no meaning to them..."

Cost and logistics were cited in a few groups as reasons to not return results. "I think I would like them, but you know there's a big cost involved too... it's a major component of the study costs; money would be better spent on getting more participants." Despite this recognition, however, there was still a desire to have adverse findings returned to participants or their physicians.

"...if you have 50,000 people, there have to be...enormous costs associated with sending all of that stuff out. So can I think of a reason why I wouldn't want to send it out and why I would want to be selective on what I send out, then that would be it, it would probably just be cost and logistics. ...if anything is outside defined parameters, we'll send them to the family doctor and the family doctor contact the individual and go from there, and that way you focus on your study and go forward."

A few participants felt that returning results could lead study participants to modify their behaviour, thus skewing the study findings. However, this recognition did not lead to the conclusion that results should not be returned.

"Yes, because they would act differently after getting these results. I don't think that is that important though. ...I think they should get the results back and I also think they should have the choice, though. Some don't want it back. It would be really simple for them to sign a waiver."

A few participants cited concerns about privacy and confidentiality as reasons to not return results. For some the concern was with the physician having access to the information while for others it was a more general concern: "...what if you start throwing things in like HIV tests? I mean would people want those kind of results being sent to their physician first? "Perhaps if some participant is worried about privacy and thinking that if you're sending it out then more people might be seeing it, I don't know, because some people get kooky about that."

3.3.4. Usefulness of Results

This theme captures comments by participants related to the potential utility of receiving individual test results as a consequence of participating in a study that incorporated health measures. One frequently mentioned benefit was increased knowledge or information about personal health matters: "I think I'd be giving my results to my doctor to add to my file to just enhance what they already know about me." "It would be interesting to compare results with what our doctor was giving us..."

"...it would be neat to personally track how you yourself have aged over time because I know we notice things as years go on... I think if you got involved in this study you'd have a curiosity [about] yourself so it would be adding to that."

Several participants were interested in comparing their results with others in the study group: “I think we should also be able to compare the results to those of the group in general to see where we’re at.” “...am I where I should be at? Am I above average with this, am I below average?” “I can always go to my doctor and say: ‘what are my individual results’ but I can’t go to my doctor and say: ‘what are the average results?’”

One participant was particularly interested in the overall results of the study and what they indicated about the aging process. “But I would like to see something in the study where people physically change or when they start slowing down or when they have less energy and things like that...”

A number of participants pointed out that the usefulness of the results would depend on the interpretation of those results, a task they largely entrusted to their health care providers. “But you could take them to your doctor and say: ‘I’m in this study, here are the numbers; what do they mean?’” “I think that if we had the results... [we could] go to the doctors to get things explained.”

Several participants felt that involvement in the study would be useful because the various tests might reveal something of which they and their doctor were unaware: “...they do all these wonderful tests and now, you know, they’re picking up on anything that my doctor may not have sent me for because there was no suspicion ahead of time.” “So I think if you send a report back saying, these are the numbers, this one is in red bold because it looks dangerous. We suggest you take it to your doctor.” “So that’s why I feel strongly on the red flag situation because... physicals are often sort of rushed in some aspects and not everything is covered in this detail.”

Participants overwhelmingly felt that, in general, those involved in health studies should receive their own results or at least have the option of receiving them. While acknowledging that there were difficulties associated with receiving these types of results and the fact that they might not always be useful and potentially even harmful, participants generally felt that those involved in such studies had a right to choose whether or not to receive personal test results.

This view was reinforced when participants were polled about whether they would want their results back if they were involved in the CLSA. A large majority indicated that they would like to receive them personally and/or have them sent to their health care provider. While results that were within the normal range were viewed as nice to have, those outside the normal range, especially if they indicated a potentially serious problem were viewed as essential. The study was clearly seen as having an obligation to participants to provide these “red-flagged” results.

Participants identified a number of reasons why the study might not return individual results to participants including alarming participants, cost and logistics, skewing the results and the need to have results interpreted. None of these reasons, however, was compelling enough to make participants question their desire to receive results,

especially “red-flagged” results. In fact participants were quick to point out ways in which the task of returning results could be effectively managed.

Participants clearly saw the benefits to their own health of being part of a study which involved various health measures. Many saw it as a way of monitoring their own health, and being able to make comparisons over time and with the entire study group. Perhaps, most importantly, participants saw study participation as possibly allowing for the early detection of a serious condition or disease that they would otherwise be unaware of.

3.4. Responsibility for Health

Participants were specifically asked if they felt that a study like the CLSA had a responsibility to provide health information to participants. This probe, as well as other, related, questions produced a great deal of debate about the roles and responsibilities of studies that incorporate health measures, the individuals that participate in those studies and their physicians. In some ways these discussions are at the very centre of the debate about returning individual results. Participant feelings about who is ultimately responsible for their health care, underpin their views on whether individual test results should be returned.

3.4.1 Responsibility for Health Care

In some groups, initial responses to this question centered on the possibility of adverse results and the “duty of care” owed to participants by the study. Some participants even felt that the study could be liable if they failed to disclose adverse results. For many participants the phrase “health information” was interpreted as potentially conveying bad news and their responses tended to focus on this possibility. “[My] main incentive is to participate in the study and to collaborate, if only minimally, in a large project but that means that those who have information about me have a duty to share it with me.” “I think it’s kind of a moral obligation of being your brother’s keeper.”

“I think they have an ethical and moral obligation to give the results to the person... If they find a growth in a person’s abdomen the size of a grapefruit, to suggest that they’re going to go: ‘well that’s interesting’ and shuffle it off into the research bin, I think defies a lot of common sense.”

“If somebody had an indication of a serious illness and you took the position that you were not going to tell them and something happened shortly afterwards, wouldn’t you be liable for having this information and not disclosing it?”

Participants seemed most concerned about test results that might reveal a serious condition of which they were unaware. It was this specific possibility that placed the greatest onus on the study to disclose information. In other respects most participants generally felt that they were responsible for their health, either individually or in partnership with their health care providers. This included monitoring their health,

seeking advice and interpretation from health care providers, or other sources, and making decisions about treatment: “I think it’s our personal health, it’s our personal responsibility.” “...you should be really responsible for your own [health], which everybody is. If you don’t do anything about it, well too bad; that’s your problem.”

“It’s not the researcher’s responsibility. We’re supposed to be taking care of ourselves. We’re supposed to be checking up on ourselves. If we decide to take part in a study, it’s to help, like you said, with research. It’s not to then give the responsibility of our health to somebody else.”

Most participants felt that the study should notify physicians directly or advise participants to see their physicians when results were outside the normal range. Others, specifically in two of the focus groups, felt that individuals should make that decision on their own. “Maybe suggestions should not be made, but here are your tests... if you want them. Discuss it with your doctor.”

Speaker A: “I would like to know whether good or bad. It’s up to me to do something about it afterwards.”

Speaker B: “Yes, I don’t want a diagnosis.”

Speaker C: “No, just [a] red flag to say that based on what they know, you are not doing well; take the necessary steps.”

However, some participants identified that being informed by the study of adverse results could be problematic.

“Maybe they have an obligation to suggest that they see a doctor... And I don’t quite know how you’d actually say that to somebody because... you’re going to set off all kinds of alarm bells. Maybe cause some problems.”

For this reason, most participants felt that results should go directly to physicians. However, in a few groups, participants also wanted the results communicated to them directly. A majority of participants concluded that individuals should be given the choice to receive or not receive results and to whom those results should be sent.

“So I’d like to get a form saying: ‘who would you like these results sent to – yourself, your doctor?’ Would you like to be informed if there’s... we’d break them up with five or six conditions...”

While participants in most groups felt that participants should have the right to choose not to receive any results under any circumstances, not everyone agreed with this view. One participant felt that agreeing to receive results should be a condition of participating in the study but this view was not shared by others. Several other participants felt that the duty to report adverse results took precedence over the expressed wishes of participants.

Speaker A: "...I think that the study should at least call them and say: 'I know you said you didn't want to know, but we have some information that you might want to know.'"

Speaker B: "You're not going to believe what we found."

Despite these minority views, most participants felt that those selected for the study should be offered the choice of whether or not to receive results, who they should go to and whether to receive all results or only those indicating a potentially serious problem. Most also felt that those wishes should be respected regardless of outcomes.

Although most participants did feel that the study had an ethical obligation to return results, there was understanding and appreciation on the part of some that the study was being conducted for research purposes: "This is for research; now why should the research people be responsible for your health, my health, her health?" "...it is a study; we do not go there for a check-up. Should we have expectations in terms of results? I am not sure of that."

"But I think the purpose of the study is not to inform us. The purpose of the study is to do research... If you want that kind of information then you go to your doctor and say: 'okay, can you do these tests?'"

"...I don't see why we, as individuals, would get that information. If you agree to be part of the study, you're doing it so that all the research data that's collected is used to apply to the general population."

A few participants commented on the logistical challenges of providing individual test results in a study of this size: "...on the other hand too it's a study and it probably costs a heck of a lot more money to start giving everybody results..." "...you guys have got 30,000 people to process. How are you going to do that if you're going to have a consultation for everyone?"

However, even most of those who understood the purpose of the study and the logistical constraints still felt that adverse results should be disclosed to participants who had requested them. Some other participants envisioned a study which would provide much more comprehensive health information and in which the well-being of participants would take precedence. In some groups this resulted in a debate between participants.

Speaker A: "Because in the end, this could save a life and I think that's the bottom line."

Speaker B: "I think the bottom line is this is a research study. This isn't a way for people to save a life because it's a research study."

Speaker A: "From my perspective it doesn't matter whether..."

Speaker B: "No, the bottom line is it's a research study. Could the benefit be a life is saved? Yeah."

Speaker A: "Okay."

Speaker B: “But it’s not their bottom line, though. Their bottom line is to research longitudinal aging in the Canadian population. ...possible benefits could be red-flagging information for an individual earlier than normal, but I think their focus and their baseline is the research study.”

A few participants were aware that providing test results could result in behavioural changes that could affect the validity of the study. However, most felt that the ethical duty to inform someone of a serious outcome was more important than maintaining strict validity.

Speaker A: “...once you put up the red flag and now they go and get treatment, you’re skewing the results of your 20 year study probably, if you’re trying to have a totally objective study.”

Moderator: “And is that problematic, do you think?”

Speaker A: “I don’t think it’s as problematic as not letting somebody know that they have a possibly terminal illness that they need treated.”

While acknowledging the likelihood that the study will uncover serious medical conditions, participants generally did not feel that the study would be perceived as a substitute for regular health care: “That’s not the purpose of the study group. They don’t replace your doctor.”

“...if we participate... we’re doing it for the sake of the study. We’re not doing it for our health... I don’t think we’re relying on this study to find something, we go to our own physicians; we get our own testing done...”

There was concern expressed, however, that for some study participants, specifically those without a family physician or those who seldom see a physician, the tests done in the course of the study might be the only medical testing they receive: “...you’re going to have people in this study who may not see a doctor or may not have any tests except when they do this three-year study and there will be people like that.”

3.4.2 Role of the Study

Participants were presented with two hypothetical scenarios, one involving the receipt of blood pressure readings in the normal range and one involving the receipt of blood cholesterol readings outside the normal range. Participants were queried about their expectations relative to these results. Participants were also asked if their expectations would change if the blood pressure reading was outside the normal range. This sub-theme captures any comments, from these specific questions, or other related questions, relative to participant perceptions of the responsibility of the study to provide interpretation, counseling, additional information or referrals based on the test results.

When asked about their expectations in terms of interpretation, participants in some groups immediately wanted to know if a physician would be doing the testing: “I don’t know who is going to be doing the test, but will they have doctors for that kind of thing?”

“Who is actually going to be carrying out the study? Are they university students, are they medical students or are they full-stream doctors?” Participants were told that tests would likely be carried out by health professionals such as medical technicians or nurses but probably not by doctors. Based on these comments and their reactions, these participants did not have high expectations in terms of having their test results interpreted: “So therefore the people looking at the results wouldn’t necessarily be able to analyze whether or not some of the results were serious health problems.”

- Moderator: “Would you expect that the blood pressure reading be interpreted to you?”
- Speaker A: “My reaction is no.”
- Speaker B: “The person is not a doctor.”
- Speaker A: “Exactly. Not a physician.”
- Speaker C: “But it could be a nurse when you say a health professional... and nurses can know just as much as doctors in some cases...”
- Speaker A: “...so now you’re assuming that this medical technician is able to interpret that in terms of your health and your lifestyle. I’m not sure if that’s an appropriate situation or not.”
- Moderator: “So you’d have some concerns about interpretation?”
- Speaker A: “Well I have concerns when doctors do it, let alone medical technicians.”

Participants did not seem to view these measures as either particularly interesting or important, in part because many indicated that they already had access to their results and understood the normal ranges. “Well blood pressure is fairly standard. It’s acceptable within this range” “...if someone says to me 120/70, I say thank you very much and I know.” As a result most participants did not expect these results to be interpreted to them. “I don’t think the researchers’ job is to interpret for us.” One participant even felt that providing interpretation could result in problems for the study: “I think there could be liabilities if it’s interpreted by people in the study.” Some participants, however, did feel that the results should be interpreted: “...interpret the test for me because I am not trained for that... Tell me in words I can understand, not just medical terms.” “I think they should be explained in... layman’s language... and if there is some disturbing and concerning information on them, then they should definitely let you know all that too.”

Despite the fact that most participants did not see the need for detailed interpretation of test results, there was an expectation on the part of most that they be informed of the actual reading, whether it was normal, higher than normal or lower than normal and told to follow up with their physicians, if necessary. “I’m not sure if I understand, when you say ‘interpreted’; there’s information and advice. I would like to be informed that it’s high but I don’t expect a technician to give me advice on it.”

Most participants felt that the study had an obligation to advise them to see a physician if test results revealed anything out of the ordinary. “I guess someone should tell you depending how far outside the norm it is... ‘...your blood pressure is a little high... and I

suggest you see your doctor at your earliest opportunity’.” “If it was a red flag area, I think you should say: ‘I would recommend you make an appointment with your doctor’.” Others wanted their physicians notified directly: “...if something’s extraordinary send it to my doctor and I’ll go through him.” Some participants felt that advising participants to see their physicians would satisfy ethical concerns and relieve the study of any potential liability. The decision to follow up the study’s recommendation with a visit to a physician would be left entirely with the participant.

“...to make it as simple as possible from the study’s perspective, couldn’t they just say: ‘we would advise you to see your doctor’. It could be that simple. If you’re not in the business of being diagnosticians, can’t you just say: ‘well we’ve seen some results here that are not quite in the normal range’... and then say: ‘we would advise you to...’ and then... the study’s liability is over.”

“...if it is a health risk, is far enough out of the parameters, yeah. Whether they actually do go or not is their responsibility as an adult, but from an ethical point of view, yeah. Your blood pressure is way out of whack. You should go see your doctor and do something about it.”

Most participants did not expect the study to provide them with written materials on things like high blood pressure or cholesterol. A number indicated that this type of information was already widely available.

Moderator: “Do you want to get literature on BP and if so what type of materials?”

Speaker A: “No.”

Speaker B: “Think of the Internet; you have everything you need.”

Speaker C: “That is not their role.”

Moderator: “Would you expect to receive any written materials on blood pressure?”

Speaker A: “No, there’s enough out there for God’s sake.”

Speaker B: “Well, it’s a research study; I’m there to give you the information, not to get information.”

Several participants felt that additional information might be “nice to have” and could be made available by the study either in written form or over the Internet. However, there was no expectation that it be provided in the form of an information package to specific participants based on their test results.

Speaker A: “I mean there’s a difference between providing and having it available, so if you want to have certain things available, maybe on a website or a kiosk or whatever...”

Speaker B: “Yeah, on your website, you could have links to all of these reputable places that have discussions on these things, but the

person would make the decision themselves whether they wanted the information.”

“On your way out we have the wall of pamphlets here... heart disease, cholesterol, blood pressure... But I don’t think you’d have to have: ‘here’s your information package’ because, again, that’s not your focus. You’re not there as a diagnostic tool.”

Most participants did not expect the study to provide any counseling relative to their test results, preferring to receive this information from their own physicians. Participants reasoned that since physicians were unlikely to be performing the physical assessment and conducting tests, study personnel would probably not be qualified to provide counseling: “Well, the person that’s doing that test isn’t a doctor. They shouldn’t be giving you medical advice.” “...I don’t think you should be given advice right then and there because you should be talking with a doctor who’s familiar with you and [can] put everything in context. That’s just one reading.” Participants simply expected to be told that results were outside the normal range and advised to consult a physician: “...the person who is doing that test, their job is to say: ‘hey, this is outside of the normal range. It’s too high. It’s too low. You should go and see your doctor about it’.”

A few participants expected counseling but the expectations seemed quite limited and were placed in the context of a recommendation to see a physician: “...if it’s way out of normal, yeah, you should be given some counseling or a pamphlet and again, probably referred to go back to your doctor.”

3.4.3. Adverse Findings

Participants felt that the obligation of the study increased if results fell outside the normal range and were greatest when indications of life threatening diseases or conditions were found. “...if there’s a red flag, let me know.” “...if they find something wrong and they know it’s wrong and you don’t, I mean that’s... withholding knowledge that would benefit me to know.” “...send a report back saying: ‘these are the numbers, this one is in red... because it looks dangerous. We suggest you take it to your doctor’.”

Some participants did not feel the study should inform them of their results but only suggest that they see their doctor: “...rather than saying anything specific about it just say it’s beyond what is considered normal and you should see a doctor.” “Others felt that it would be irresponsible to inform participants directly of potentially serious results: “...is it responsible for the people doing the study to give an adverse report to me? Would that be responsible? I don’t think so.” “I’d hate to get a letter at home saying: ‘Oh you have leukemia’.” For this reason suggestions were made to have the results go directly to physicians: “Now if there was something that came up... that was of concern, I think it would be incumbent on the study itself to just provide that information to the person’s doctor without them being involved.” “I think that’s important... that you don’t get results in that kind of a situation but definitely the doctor should be informed so that he or she can figure out how to handle it.”

A few participants commented on the fact that returning out of range or potentially serious results would be important for study participants who didn't see a physician on a regular basis or take care of their health. "...there would be a certain percentage of your study's population... that doesn't monitor their health." Most participants agreed that the study's purpose was not to monitor the health of participants but this did not lessen the responsibility to report adverse findings.

Speaker A: "...people shouldn't be depending upon this because it is a research study. They shouldn't be depending on this for monitoring their health."

Speaker B: "I agree they shouldn't be depending on it but if a big red flag pops up, then the sooner that person knows the better."

Participants who wanted to be personally informed of their test results expressed concern over the manner in which the study would communicate this information to them. In particular, they wanted sensitive or disturbing information communicated in a humane manner: "...have someone competent explaining it to me... who knows how to present facts, something humane; do not just throw it in my face; a bit of humanism, that is what I would like." "Do you send something in the mail saying you've got cancer? That would be an issue. That has to be handled appropriately."

Some participants also felt that there was an obligation on the study to return potentially serious results in an expedited fashion: "...if they are mailing out results it makes sense that the ones that have a red flag should go out first." "...the results six months later would be worthless. I might be dead by then."

Speaker A: "Yeah, there might be a mechanism to get serious results out faster."

Speaker B: "Yeah, the 'Holy Crow' factor you know."

However, a few participants felt that this might be an unreasonable burden for a research study: "I just don't think there should be any moral obligation imposed on the researchers for not getting the study [results] out faster."

Focus group participants generally accepted responsibility for their health but also felt that the study owed them a duty of care to disclose information pertinent to their health that might be revealed in the course of clinical testing. In essence, participants felt that they had a right to information the study might uncover about their health status. This responsibility was greatest in the case of results falling outside the normal range and/or indicating a potentially adverse disease or condition. Most participants did not view participation in the study as a substitute for health care but did view it as a supplement to their health care with the potential to reveal something of which they and their physician were unaware. There was also an acknowledgement that for some participants the study tests might constitute the only health care they receive.

Generally participants felt that those selected to take part in the study should be offered the choice of whether or not to receive results, who they should go to and whether to receive all results or only those indicating a potentially serious problem. Most also felt that those wishes should be respected regardless of outcomes.

Most participants did not expect the study to provide them with interpretation of test results or counseling, preferring to deal with their own physicians. However, participant views on interpretation of results and counseling need to be viewed in the context of both the subject matter of the hypothetical scenarios and the fact that testing would be done by technicians as part of a research study. Blood pressure and cholesterol measures are probably not viewed with the same level of concern as other diagnoses which could be more immediately life-threatening and participants clearly did not have the same level of confidence in medical technicians as they had in their own physicians. Most participants did not expect the study to provide written materials such as pamphlets on various diseases but some considered these as nice to have and reasoned that it would be relatively easy for the study to provide such information as a courtesy.

Although most groups wanted results to go to their physicians directly, a few groups wanted to receive their results personally. These participants expected that the study would inform them of any potentially serious result in a sensitive and humane manner. Most participants also felt that if a serious result was identified, there was an obligation on the part of the study to communicate it more quickly than results which were in the normal range.

Although there is recognition by a number of participants that this is a research study, there is still a clear expectation that potentially adverse results be communicated to participants or their physicians. While other aspects of the study's relationship with participants are seen as beneficial, desirable or "nice to have", this element of disclosure of adverse results was considered essential.

3.5. Receipt of Test Results

Focus groups participants were asked a number of questions based on the premise that some results would be returned to study participants. Specifically, they were asked for their views on whether participants or their health care providers should receive results, what should happen in the case of a serious health concern, and how and when results should be communicated to participants.

3.5.1. Who Receives Results

There was considerable variation on the question of who should receive test results. While there were a few minor differences between individuals within a group, almost all of the variation occurred between the various focus groups. Essentially, two of the groups felt that test results should go to the individual's physician, two felt they should go to the individual and two felt they should go to both the individual and their physician.

Additionally, three groups came to the conclusion that study participants should be given the choice of who receives results.

In groups where the doctor was the preferred choice, participants felt that individuals would not be able to understand or interpret the results and that they would prefer to hear any bad news from someone they knew: “Well I would have mine sent to the doctor. I wouldn’t want them myself because there might be things in there I wouldn’t understand...” “...you could take them to your doctor and say: ‘I’m in this study, here are the numbers, what do they mean?’” “...if something’s extraordinary, send it to my doctor and I’ll go through him.” “...if something’s off the radar screen or something, my doctor should be notified...then it’s coming from someone you’re familiar with... you hear you’re dying.”

Some participants felt strongly that individuals should not have the option of receiving results directly: “I think the study’s responsibility is to say if you want the results we will release them to a competent medical person. Otherwise we’re not going to release them to you... I don’t think we should be our own physician.” “We have to be responsible and release it to a medical person because you might be liable to go off the deep end if you find out something...”

Several participants felt that there were distinct advantages in sending the results to a physician. It could help avoid the panic resulting from false positives or measurement errors and also enhance the information available to the doctor: “...it could be something went wrong with some measurement there and the doctor could at least say this person doesn’t have that problem, something’s wrong.” “I think I’d be giving my results to my doctor to add to my file to just enhance what they already know about me.”

In the two groups in which the preference was for individuals to receive their results directly, participants felt that they had a right to their own information and would decide themselves whether to share it with their physicians or not: “Participants, because it is your health, your body, and you can do whatever you want with them afterwards; if they don’t want to go to the doctor’s they don’t have to.” “From my perspective that’s their private personal stuff. That should come directly to them.” “...they’re the person who’s made the commitment to be in this study and it is their health and the information relates to them...” Other participants felt that they were personally responsible for their health and therefore should get the results: “We are adults. We are responsible.” “I’d still want to see the results myself. I’d want it to be within my control to take it.”

“But I believe that the person that’s in charge of my health is me. Not my doctor. And they may send him test results and he’s on vacation and just doesn’t quite get to it. That’s why for me I’d like to see the test results, good bad or indifferent, because I’m the one responsible.”

In several groups participants first of all suggested that results should go to both the individual and their physician:

Speaker A: "I think both would be a good idea."
Speaker B: "Yeah, I agree with that."
Moderator: "Both?"
Speaker C: "That's what they're doing now with your Pap test. They send the result to you and to your doctor."

This discussion of providing results to participants and their physicians rapidly evolved into the concept of giving participants the choice of who should receive their results. This concept also came up in one of the groups which favoured results going to individuals: "I think the participants should be able to decide whether it goes just to them, just to their doctor or both... you've got to give participants the option, I think." "...why not give people the choice? You know, send it to the person; send it their doctor or both. And they can choose..."

3.5.2. What Type of Results are Returned

As previously discussed under the Responsibility for Health theme, participants were much more concerned about adverse findings than those falling within the normal ranges. While normal test results are seen as "nice to have", results indicating a potentially serious disease or condition are essential and participants want to be notified or have their physicians notified in a timely manner: "I think it depends upon the findings too... Coming back and telling me I've got a cold, I don't need to know that information. If I have a life threatening disease, I'd like to know that." Some participants didn't feel it was necessary for results within the normal range to be communicated at all: "...if it's routine and there's nothing serious, I don't think my GP wants another piece of paper flowing through his desk. If there's nothing significantly different, I don't think anything needs to go anywhere." This was especially true for participants who saw their physicians on a regular basis for routine testing: "No, especially if you go to a doctor... I go for blood tests every two months and I have my blood pressure done..." A few participants wanted normal results sent to them personally and only potentially serious results sent to their physicians: "If they're just routine... why bother the doctor? Just get them to send them to me."

Although there was variability in terms of who should receive adverse results, all participants felt that they needed to be communicated. Responses broke down into those who felt that participants should simply be advised to see their physicians and those who felt that physicians should be notified directly: "I think you... should be notified that there is a problem with your test and your doctor has been notified and we suggest that you go and make an appointment to see your doctor about this." "The doctor should tell me that." Some participants felt that the study should inform them personally of their results and let them decide what to do: "If you send them to me, I now have the choice of either going to my doctor or saying... [I] don't need to discuss those with the doctor...my option." Others felt that adverse results should be communicated by the study but in a sensitive manner. "...when you have to tell someone something as serious as this, the way you say it is more important than the information itself." "...I mean the person has to know and I don't know; how does a research company go about telling somebody that...?"

3.5.3. How and When Results are Returned

Participants were asked how they would like to receive results, if they were to be returned to them. Suggestions ranged from regular mail to registered letters, e-mail, phone calls and in person visits. There was also the suggestion that results be posted on a secure website: “I would prefer mail.” “I’d say a registered letter because people change addresses and lots of stuff in the mail doesn’t come all the time.” “E-mailing wouldn’t be bad either because that’s instantaneous.” “As far as how I want it delivered, I’d like the option of having it by mail or e-mail” “Sometimes things can get lost in the mail so I think... there should be an effort made to call the person and talk to them” “[A] nice voice on the phone.” “Unless you go to a site that’s password protected, then you can get them there.”

Based on their responses a few participants seemed to find this question quite amusing: “A singing telegram.” “Probably not a Hallmark card...”

In most groups participants had different expectations depending on whether the results were “serious” or not. “I would say that the more serious it is, the more personal the communication should be.” “I wouldn’t want to get information about a catastrophic illness in the mail...” “I was thinking that if there is nothing mail is fine. If there is something serious I would like to be called in.” Often these expectations also involved having the results sent to their physicians: “If they find something that’s pretty serious for me, I don’t think I’d like to get a letter in the mail about it. I’d like my doctor to be contacted specifically...” “...if there is something serious I would rather hear about it from my doctor versus a stranger.” Participants in some groups expected that potentially serious results be communicated in a sensitive manner: “Not on the first line... ‘You have cancer’. Show a bit of empathy.” “You have a serious heart problem. Like how do you get that information to that individual in a comforting fashion?”

When asked for a reasonable time frame in which to receive the results of a blood test, participants in most groups initially said a week, probably based on the time it usually takes to get results from physician-ordered blood tests. However, in the course of discussion and clarification that the blood tests were being done for research purposes and in large numbers, most participants settled on a figure of around a month: “I’m thinking two weeks but I don’t know if that’s feasible with the amount of people and the results.” “Anywhere between one and two months I’d say...” “...it would depend on how many people you are testing as to how soon or how long it might take to get results back, I would think.”

“I don’t think you could expect... the same timeframe because this is the study, it’s not like going and getting the test done and it goes immediately to your doctor. So I wouldn’t expect it in a week or even two weeks. I’d probably expect it in a month.”

However, as already indicated, a number of participants had an expectation that potentially adverse results should be returned more expeditiously: “If everything is normal, do nothing, but if there is something then the results have to be faster.” “But if

they are mailing out results, it makes sense that the ones that have a red flag should go out first.”

A number of participants did appreciate the fact that returning study results to participants could present a logistical challenge: “...it’s a study and it probably costs a heck of a lot more money to start giving everybody results and postage and this and that...”

“...if you have 50,000 people, there have to be...enormous costs associated with sending all of that stuff out. So I can think of a reason why I wouldn’t want to send it out and why I would want to be selective on what I send out...”

3.5.4. Physician Role

A number of participants commented on the role of personal physicians in the study as interpreters, diagnosticians and counselors, as previously documented. Many participants felt that most people would not have the skills to interpret medical information and so would need to consult with a physician: “...one of the choices should be to have the results sent to your physician. He would know you were in the study so... you actually read it with him.” “...a lot of people who get the information aren’t going to be medical doctors so they wouldn’t be qualified to do medical evaluations...” A few others, however, saw a much more limited role for physicians or even questioned their role entirely: “I don’t see the doctor’s role in this study; he was not picked.” “I don’t need a doctor to deal with the results. There’s lots of information available [about] medical issues: books, Internet.”

There were also comments on the difficulty presented by study participants who had no physicians: “...we’re saying a report should go to your doctor. If you don’t have a doctor where does it go then?” Some participants felt that having a doctor would be critical but still left the decision up to the individual: “If they had something that was important, they would have to get a doctor. I mean it would be their choice if they didn’t, if they didn’t want to get better...”

The variance in views on whether participants, their physicians or both should receive test results underlines the wisdom of leaving this choice up to participants. In several groups participants came to this conclusion independently after debating the merits of the other choices. While this view was not universal, it does represent an evolution of thought that occurred in some groups in which a dichotomous view (individual or physician), was superseded by an inclusionary view (both), and finally resolved by leaving the decision up to the participant.

Many participants viewed results that were in the normal range as “nice to have” but not a necessity and some even felt that they should not bother their physicians by sending such results. However, results indicating a potentially serious disease or condition were seen as essential information that had to be reported to the individual or their physician as quickly as possible. While some participants had expectations that the study should inform them of any serious results in a sensitive humane manner, most participants

limited the study's responsibility to communication. A majority of participants felt that potentially "serious" results should be returned more quickly than results falling within the normal range but this view is somewhat at odds with a research study in which tests would likely be analyzed much more slowly than those ordered by a physician for diagnostic purposes. It is unclear whether participants clearly understood this constraint and it would be critical to have this clearly explained to potential participants to prevent any reliance on health measures conducted by the study as diagnostic tools.

Participants were divided on the role of physicians in the study. While most saw them as recipients and interpreters of study results, a minority reserved their right to receive results and consult their physicians at their own discretion. Most participants felt that anyone selected for the study should have a personal physician or should get one so that they could serve as a conduit for any potentially serious results.

3.6. Receipt of DNA Results

A scenario in which DNA was extracted from a blood sample and analyzed was read to participants. They were told that the DNA would be used to study the aging process and that currently DNA tests had no diagnostic value. They were then told that they would not receive the results of their DNA tests and asked how they felt about that. Probes to this question explored their concerns, especially around privacy and confidentiality and asked about their expectations if, in the future, new DNA analysis techniques were developed that did have diagnostic value.

3.6.1. General Views on DNA

Some participants were initially taken aback by this question: "...DNA was the last thing I thought would be brought up here." Others seemed confused by this question either because they did not understand why the study would want their DNA or because the statement: "...tests using it currently have no diagnostic value..." was at odds with their perception of DNA analysis: "If it has no diagnostic value, why would you take it?" "Well, what results are there to get?" "I don't really understand... they're taking a DNA test but... they're not going to tell you because they don't know either?" "Are you saying there are no medical tests based on DNA now?" Generally speaking, this question, more than any other, engendered suspicion and feelings of discomfort among participants. A number wondered why their DNA was required and how it would be used: "I don't know. My immediate reaction would be why would you want my DNA?" "I want to know what this is going to be used for... It has to be specific: what is it going to be used for, before I sign the agreement..." Some others were uncomfortable with the idea of giving a DNA sample: "I'm not so sure about the DNA. I don't feel comfortable about the DNA part." "Yeah, I don't feel comfortable... DNA is something so personal..."

While a few participants mentioned fear of cloning, these comments were offered in a humorous manner. "You know I wouldn't want to be cloned or anything like that. I wouldn't want another one of me around." Several participants wanted to know how their DNA would be extracted and if it would be painful: "How would they take that kind

of sample? What methodology would they use..?” “I’d be more concerned if it was painful.”

A number of participants saw the value in DNA analysis as a component of the study: “I think it’s very cool, what they can do with that.” “This is... research to help future aging people too.” A few participants were pragmatic about providing a DNA sample: “...if someone wanted your DNA they can get it. It’s not a secret, you are who you are, and so for the sake of maybe finding something that could change something in the medical field, I would go with it.” Despite being told that they would not receive the results of DNA tests, some participants thought that they might benefit personally from having their DNA analyzed: “I think it would be wonderful because we would have access to a diagnostic tool that ordinary people do not have access to.” “...they might find something in your DNA that’s hereditary.”

Regardless of the concerns expressed, most participants appeared willing to provide a DNA sample even though they would not initially receive any results. Although some wanted reassurances about what it would be used for and guarantees of confidentiality, others had no reservations: “I’m not comfortable but I’d agree to it.” “I’m just trusting that there’s a valid medical reason why you need it, and assuming there is, then...” “I don’t see a difference between giving blood and giving DNA; same thing to me.” “It’s fine with me. I mean it’s all part of a study...” “I wouldn’t have a problem.” “But really, I have no concerns. I mean my DNA is my DNA. And if I was murdered or something it would be nice to have it stored somewhere.” One participant summed up his motivation for providing a sample in this way: “...if I enter a study like this, I’m going into it for altruistic purposes. I’m thinking that someone down the line is going to benefit...”

Several participants demonstrated a sophisticated understanding of the challenges associated with obtaining consent to collect and analyze DNA samples: “...if you’re going to actually analyze people’s DNA, I think they need to know that when they consent to participate in the study.” “...your consents may need to be updated over the years as new tests become available and you can do more with that DNA.”

3.6.2. *Non-Receipt of DNA Results*

Participants had mixed feelings about not receiving the results of their DNA test. Most were relatively unconcerned: “...it wouldn’t be a test you’d normally have anyway, so I wouldn’t care if I got it back or not.” “...it does not bother me...”

“If we’re in this... study, we’re going to be giving bodily fluids left, right and centre from the sounds of it. I mean, if you’re going to do a DNA test and keep it secret, well I don’t have a problem with that. I don’t know what harm it could cause me...”

Several participants expressed a desire to have their DNA results although they were informed that they would not be returned: “I would like to get the DNA results just out of curiosity...” “...if I had 50 or 60 percent likelihood of having such and such a disease, I want to know.” “I would probably want mine back... I mean it belongs to you so why not

have it back?” One participant expected to be informed if the DNA testing revealed any serious health conditions: “I’m OK with that if they keep it confidential, but if there’s anything extreme, then I would [expect] to be advised...” Several participants anticipated the question probe about receipt of DNA test results in the future, if more advanced analysis techniques prove diagnostic, and felt that, in these circumstances, DNA results should be returned to participants:

“...20 years from now, you know, it’s conceivable that persons with certain DNA would be highly susceptible to certain diseases. If that is part of the research then are you saying that you wouldn’t divulge that...?”

“...there might be, over the 20 year course of the study, quantum leaps in testing abilities that would say... you, as an individual, might be prone to this disease or that... in which case knowing this information, having it back, might make us... more proactive in certain respects... with diet, exercise or other things within our control. We wouldn’t be able to do that if we didn’t have the information.”

Some other participants rationalized not receiving DNA results on the basis that it would probably be of little use to them at this point: “I’m not sure what good it would be to my doctor or to me... I might want it but I don’t know what I’d do with it.” “It would be lovely to know, but it’s realistic that you won’t get that.” “I wouldn’t know what to do with it anyway.” “Like you said, there is nothing to know at the beginning. They can’t say: ‘OK, well we got this from your DNA so 10 years from now this is what is going to happen to you.’” One participant reasoned that if you wanted to have the results of a DNA test, they are available privately: “Well, I mean, if you really want your DNA you can pay to have it done. It’s about 700, 800 bucks. It would be a ‘nice to’, but it’s not a big deal.”

3.6.3. Views on Potential Future Receipt of DNA Results

When asked about their expectations if new DNA analysis techniques were developed in the future with greater diagnostic value, most participants wanted their results: “Yes, we would want the results; we would want to know.” “Then I would want to know, just like my blood tests and stuff.” A few only wanted to know if the results indicated something serious: “It would be treated like any other diagnostic tool then and I think you should know if it shows up anything adverse.”

Interestingly, in most groups, the initial desire for DNA results was soon tempered by the reality of having information about a disease or condition for which there was no effective treatment: “If you’ve got something they can’t fix, then you’re better off not knowing it seems like.” “I’m not sure I want to know if I have a 60% chance of developing cancer.” “I don’t know if I would want to know what the future held all the time.”

“Yeah, I’m not sure I want to know about something that might happen that I can’t do anything about, really... On the other hand, if you can say there’s a

lifestyle change that would prolong my life because of something that you discovered in the DNA, that's a different scenario.”

3.6.4. Privacy and Confidentiality

Participants raised a number of issues relative to the privacy and confidentiality of their DNA samples. Some wanted to know what would happen to their DNA, and in particular, its storage and destruction: “What would they do with the samples after they were done with the research?” “Yes, but then I'd also want to know what you did with the sample. Do you just take the test now and destroy it, or are you going to keep it for each test over the 20 year lifetime?”

Speaker A: “OK, what are you going to do with it once you finish with the tests?”

Speaker B: “Yeah, I want to know when you're going to destroy it all.”

A number of specific concerns were expressed about the confidentiality of DNA data. Some participants were concerned that their DNA would positively identify them: “Well, my first concern here is you said these things are confidential and my DNA identifies me.” “It would have to be very, very confidential... They would have to guarantee that this is in a safe and that it will stay in the safe.” “...confidentiality would be of utmost importance.” A few others seemed to object to DNA collection on principle but could not clearly articulate their concerns beyond discomfort:

Moderator: “So what are your concerns specifically, [name omitted], about DNA?”

Speaker A: “I don't even know that. I can't really articulate that. It's just; I don't believe that there is complete total confidentiality... I've got nothing to hide; it's just a basic right.”

Moderator: “You think that somebody else might get access to it, that you hadn't intended?”

Speaker A: “Maybe. I don't, see I don't even know. It's just more of an intuitive thing; I just don't feel comfortable.”

Moderator: “Makes you feel uncomfortable.”

Speaker A: “Very uncomfortable.”

Some participants felt that the study could not guarantee confidentiality in part because of the nature of computer systems: “...there's no guarantees on security today.” “Don't misunderstand me. I respect what you're doing, but, I mean, look at the security out in the world today. Nothing is secure, right?” “Nothing's confidential when it's in a database. They just create the perception it is.” However, this view was tempered by others who trusted the study to maintain the confidentiality of their DNA: “I have to trust that the system works.” “I wouldn't be worried about it. When I looked how many forms I had to sign just to come and how many things I had to sign really just to sit and chat...”

A few of participants wondered whether their DNA profiles could be accessed by insurance companies or employers: “...if your DNA showed a predisposition towards a

medical problem and you wanted to apply for insurance and the information went to the insurance company; that could be used to refuse insurance.” “I would have no problem supplying that but, indeed, it has to be confidential and in five years not tell my insurer that I am likely to get this disease or that, or my employer.”

The most frequent specific concern raised by participants was around the availability of DNA samples to police agencies. While a few of these comments appeared to be offered ‘tongue in cheek’ most were raised in a serious manner: “Would it ever be shared with... the FBI or CIA, CSIS, RCMP?” “If I was arrested for something and if my DNA is in a bank and available to the RCMP...without my consent...” Several participants were concerned whether the guarantee of confidentiality offered by the study would be respected in the event of a criminal investigation:

“But if I’m charged with something and they call you up and say: ‘hey, we want this guy’s DNA because he is not giving it voluntarily’, I want to be sure that you say: ‘no, we have a confidentiality agreement, you cannot have his DNA.’”

“It doesn’t really matter whether you’re going to do a DNA analysis on the sample or not, if you’re keeping the sample, and it’s subpoenaed, they can do it. I mean the prosecutor’s office can do that if a sample is required.”

3.6.5. DNA Sampling as a Reason to not Participate

Only one participant indicated that they would refuse to participate based on the collection of a DNA sample:

Speaker A: “...in my particular case, if you were looking for volunteers... I wouldn’t go.”
Moderator: “Because of?”
Speaker A: “The DNA test.”

Although most participants found the prospect of not receiving the results of an initial DNA test acceptable, the whole topic of DNA testing was controversial and sparked considerable discussion. While participants generally would not refuse to participate based on DNA sampling they raised many questions and concerns. For a significant number, their willingness to participate hinged on the study successfully addressing these questions and concerns. It appears that some concerns were raised by the manner in which the question was worded. Indicating that results would not be returned seemed to engender a feeling that the study was being secretive or withholding information. Some participants also questioned the statement ‘...tests using it currently have no diagnostic value.’ A minority of participants appeared to be quite well informed about the potential value of DNA analysis for population health while some others seemed to have learned about DNA from television crime dramas.

Participants, while generally accepting that results would not be returned were, nonetheless, eager to receive them when offered. Several even anticipated the question about future receipt of DNA results by pointing out that medical advances

would, no doubt, improve the diagnostic value of DNA analyses. However, this desire for results was somewhat tempered by the realization that knowing about an untreatable disease or condition would not be desirable.

There was a great deal of concern expressed about storage and destruction of DNA, security and who might be able to access DNA data. Some participants did not feel that it was possible to offer strict guarantees of security either because of the possibility of computer systems being breached or because DNA profiles could be subpoenaed in a court proceeding.

It is clear that most participants would be willing to take part in a study that involved the collection and analysis of DNA but only if they know the purpose and are assured of the confidentiality of their DNA sample. They also expect to receive relevant information from their DNA analysis if and when it becomes diagnostically useful.

3.7. Return of Results as a Benefit of Participation

Participants were asked if getting the results of some individual tests would make them more or less likely to participate in a 20 year study such as the CLSA. This theme also captures other comments on the benefits to participants of receiving results, including the benefit of receiving aggregate results.

3.7.1. Perceived Benefit of Receiving Individual Results

At several points in the focus group discussions, participants volunteered comments on the potential value of receiving individual results. A number of these comments have been captured in the context of other themes and some are repeated here. A few participants remarked on the value of study results as a comparator with results ordered by their physicians: "...our doctors have comparisons to make between what they've observed and what somebody else has observed, you know; and it might just pay off..." "...the advantage of having a second opinion..." "It would be interesting to compare results with what our doctor was giving us." Value was also seen in being able to compare individual results over time: "...it's a longitudinal study on aging, so it would be neat to personally track how you, yourself, have aged over time..." Some others saw the benefit in receiving results that might reveal something of which they were unaware: "I wouldn't be against taking any tests but, if possible, I'd like to get the results because you never know... you can get sick or drop dead or get a heart attack..."

"...you could treat it like a screening tool, like every x number of years... they do all these wonderful tests and... they're picking up anything that my doctor may not have sent me for because there was no suspicion ahead of time."

Several participants mentioned the value of receiving results for those who do not see a physician on a regular basis: "For a lot of people it will mean doing something that they already do, but I would say it would enlighten a lot of those who don't consult regularly. I guess that would already be a plus."

3.7.2. Impact of the Offer of Results on Participation

When asked directly about the effect of receiving individual results on their participation, most participants indicated that they would be more likely to participate. In several groups this view was unanimous: “yes, it would be an incentive.” “...if I can get some results I would like that.” “...I don’t think it would matter but I think if I was going to be persuaded, it would make me more likely.”

Moderator: “So it would be beneficial to get your results back if you were participating?”
Speaker A: “Absolutely.”
Speaker B: “Motivating.”
Speaker C: “Yes.”
Speaker D: “Yes.”
Speaker E: “Yes.”
Speaker F: “Hands up, unanimous.”

Several participants thought the offer to return results would motivate them: “It is additional motivation; you learn about yourself, your health...” “...you do need, in effect, a little bit of a carrot, so having some feedback in is a good idea.

Only one participant tied their participation directly to receiving their results: “I wouldn’t participate unless I got my results.”

For a minority of participants, the decision to participate would not be affected by the offer of results: “I would participate regardless if I was asked.” “I’m fine whether I get them or not.” “...I’m completely neutral in getting the results... getting the results isn’t a factor.

Several participants indicated that some people would participate in the study for altruistic reasons rather than the offer of individual results: “I think some people would participate just totally altruistically... you talk about giving blood; I’m sure you do that just because you want to do it.”

“...it is not getting test results that will necessarily motivate you to participate in the study. I think that it is for science, knowledge, because it will serve the next generation, medicine as a whole, for society. Getting the results... that is not why I would participate.”

3.7.3. Participant Suggestions for Increasing Recruitment and Retention

Independent of the question about the likelihood of participation increasing with the offer of individual results, a number of participants suggested that offering results would encourage participants initially and provide an incentive for ongoing involvement: “It would be a reward for those who participate in the study, to keep them informed.” “I think, in terms of retention rate, you need to give people feedback. If you’re looking at a 20 year project and people are going year after year and getting nothing back, what’s motivating them?”

Speaker A: “If you’ve gone through all of those tests and get no results, I think that will raise your blood pressure and give you a lot of stress.”

Speaker B: “I think it will also destroy the study because a lot of people will drop out. They’ll say: ‘hey if we’re not going to get any feedback, what’s the point?’ Just drop out.”

Some participants also made specific suggestions for diagnostic tests which they felt would encourage greater participation: “What if you were to offer ECG and MRI?” “With the ECG... it’s such a simple thing... and it only takes a couple of minutes...”

“I would think it would be a very interesting part of the study to see how many seemingly healthy people out there have things wrong with them that you couldn’t find out any other way except... using a tool like MRI.”

3.7.4. Benefit of Receiving Overall Results

One participant, in particular stressed the importance of receiving aggregate results in addition to individual results for comparative purposes. He also felt that such information would be important in informing research and practice because they would be derived from such a large study population:

“I’d like to see some numbers published somewhere so I can see where I stand on it. ...these numbers might be useful to me, if for nothing else than saying: well, I’m at least on the average... and they might be useful to doctors too for the same reasons.”

“What are the actual results of that many people? This kind of information would be quite useful because I don’t think some of the numbers out there are based on large studies.”

A number of participants indicated that they saw value receiving some of their results even before they were asked if receiving them would make them more likely to participate. Among other reasons, participants viewed a “second opinion” as desirable, wanted to be able to track their own health status over time and felt that the tests they underwent as part of the study could potentially reveal a serious condition of which they were unaware. When asked if the receipt of results would make them more likely to participate, most agreed. However there were some for whom the offer of results would make no difference in their decision to participate. A few of these cited altruistic reasons for participating in the study. Only one participant indicated that their participation would hinge on receiving their individual results. Several participants felt that generally the offer to return results would be an incentive for participants to both enroll and continue to participate in the study. Some participants felt that the offer of desirable diagnostic tests, such as MRI, would encourage greater participation. One participant in particular was interested in aggregate results as a comparator for his own

individual results but also as a contribution to medical science based on a large study population.

3.8. Behavioural Change

Several questions revolved around the topic of behavioural change. In the context of health information, participants were asked if they felt the information they received about their health changed their behaviour in any way. Additionally, participants were asked if they would change their behaviour either prior to, or subsequent to, having a physical assessment as part of the CLSA. They were also asked if they would cancel or delay seeing their own physician as a result of having this physical assessment. This theme also captures other comments about behavioural change.

3.8.1. Lifestyle Changes

Participants spoke generally about the effect of health information on their behaviour and gave a number of specific examples of lifestyle changes they had made. Most felt that, while difficult, it was possible to make changes to improve health and fitness: “I think that information at any time enables you to make better quality decisions... I guess it gives me enough information to at least ask better quality questions.” “We’re already doing the best we can... it takes little steps... it’s all baby steps to keep going until you come up with a really healthy regimen of eating.” “I think it changes my behaviour. I’m interested in exercises especially, and so I try to keep up.”

“I don’t always do even though I know I should, but I think, over time, it’s just going to get to be more and more of following what you’re hearing and what you know you should be doing and getting rid of some of these bad habits that I’ve been carrying on with for too many years.”

When asked if they would change their behaviour before coming in for a physical assessment as part of the study most participants replied in the negative. A few were unsure of what was meant by this question and sought clarification while others even scoffed at the idea or felt it was dishonest: “No, I wouldn’t do anything unusual.” “Only if there was instructions like fasting for eight hours... I couldn’t see going to the gym for the month of February!” “It would be dishonest... I would find that childish, irresponsible.”

“I don’t think it would change my behaviour significantly, especially if you’re doing this... every X number of years, it becomes part of your routine and I’m not sure how drastically I could change the results within a month or so of the appointment anyway.”

However, after some consideration, some admitted they might alter their behaviour in order to ‘do well’ on the tests: “Well, maybe I would watch myself.” “well I think, personally, it would because it’s like being monitored...” “I’d do a few more exercises before I went so my blood pressure wouldn’t go up.” One participant even remarked that he would try to do badly on the test in order to show improvement over time: “I’d

actually go the other way... I'd say: 'how bad can I be?' so that I know when I go to normal, I have to do better than those scores."

When queried about behavioural changes subsequent to a physical assessment, most participants indicated that it would depend on the seriousness of the results: "Depends on the results." "That would depend on the results. If you found out that your cholesterol was high or something, you might think about doing something to fix that so that it goes down." "If there were results I didn't know about before, yes..." "Yes, if they tell me I have to improve this or that, that my cholesterol is high, of course I will take the necessary steps to improve it..." "Well, it has to. I mean, if it doesn't you're not using much sense. Of course it does; unless there is nothing untoward, but I mean if there is something wrong, you have to change, yeah." A few participants were more philosophical about their reactions, even commenting that too much information can create its own problems: "I feel that information is nice, it all depends what you do with it. If you worry about it, you fret about it, you take it to heart too much..." "I think we're inundated an awful lot with the media... and I hate that they can get people very disturbed and very worried about themselves because it brings on complications that they maybe wouldn't have had."

3.8.2. *Difficulty in Initiating and Maintaining Lifestyle Changes*

A number of participants commented on the difficulty of making lifestyle changes and maintaining them over time: "People are creatures of habit and the older you get; the harder your habits are to break." "I was heavy for 30 years. I read all kinds of articles on weight loss, and I was never motivated to do it, even though I knew the consequences." For some it was a case of 'paving the road to hell': "It changes my intention." Some others felt that it was difficult to maintain any type of change in the long term and that reversion to former habits was almost inevitable: "But I'm like everybody else. It will last for about six months or eight months and then I begin to forget, and I begin to go back to my old way." "When I would go to my doctor and he'd say lose weight, I'd probably behave myself for a couple of weeks, and then eventually the old habits would creep back in."

"I'll confess short term. You're overweight; your blood pressure is a little too high. You've got to do something. So I'll start exercising a little bit more, or join a gym for a short period of time and then, unfortunately, it tails back and like most people, I go back to the norm of what I've been doing..."

One participant described the process of personal change as 'an inside job', dependent on individual motivation: "I think it's an inside job, really. You know you can read everything. On the cigarette packages, it says that it kills you, and people still smoke, so you know, I think it's a personal choice, really."

A few participants felt that lifestyle changes could only be maintained if there were serious consequences to not doing so: "So unless it was something fairly serious, I doubt if I would make a sustained change."

“I think it would have to be something alarming that happened to me, you know, that would really make me sit up and take notice and change my behaviour. It’s horrible to say but I think that’s the truth.”

3.8.3. Study Validity

A few participants felt that any behavioural changes in advance of undergoing a health assessment could affect the validity of the study: “I wouldn’t. A lot of the point of the study is to find out where we’re at, what we’ve done about it. If you change everything, then it doesn’t represent, really, our situation.” “...what is important for me is not to affect the national average. These are my results so I would go there exactly the same way I would when I go and see my doctor.”

“...I was thinking you would not get the true picture. Like if you’re watching what you’re eating and not smoking, not drinking a week before the tests, and then you go back right after the tests, it’s not a true picture of your health”

3.8.4. Health Care Changes

Participants were specifically asked if they would cancel or delay seeing their own physicians because they knew they would be tested as part of the study. Initially, most respondents denied that they would make any changes. “No, not at all.” “Definitely not.” “I would do nothing differently.” However, as the discussion unfolded, some admitted that they might, in fact, postpone or cancel their physician appointments if they knew they would get results from the study: “I might tend to delay my other test.” “Yeah, if I was getting the results, then I would postpone my doctor’s appointment so that I could add those results to my review. If I wasn’t getting the results, then I wouldn’t change my appointment at all.” “Well, it depends how the study is conducted. If they say you will have blood tests, super complete ones, I would not go and have the same tests done again at the hospital for nothing...” “Well, if this is not a very nice process, would you want to have it twice? ...If the results are going to the doctor within a reasonable period of time, I mean you could consider it sort of like your yearly physical.”

Many participants felt that they were able to change their behaviour as a result of health information that they became aware of. Many spoke of lifestyle changes they had made and often described the transition as a gradual process bounded by the level of their concern and the difficulty of changing old habits. While most felt they would not change their behaviour prior to having a physical assessment as part of the study, this was not universal. For most, behaviour change subsequent to a physical assessment was predicated on the seriousness of the results. Participants were well aware of the difficulty of initiating and maintaining lifestyle changes, with a number citing examples of changing their habits with the best intentions only to later revert to previous behaviours. Several felt that the ability to change old habits was related to the consequences of not doing so. While most participants would not alter a physician appointment because of having a physical assessment as part of the study, a few saw no point in duplicating the process if the study was returning their results. Others saw the availability of study results as a benefit and would delay an appointment in order to have these results

available to their physician. The description of behaviour change as ‘an inside job’ accurately sums up many of the views expressed by participants.

3.9. Consent to Receive or not Receive Results

As part of three questions on returning results, participants were asked their views on what should happen if participants had chosen not to receive any results. Additionally, participants made a number of comments on the consent process, the right to choose to receive or not receive results, waivers, litigation and re-consent.

3.9.1. Consent Process

Virtually all participants felt that they should have a choice to receive or not receive results. Most also felt that they should be able to decide who received those results: individuals or their nominated health care provider: “I think the person who is involved in these studies should have the right to say yes, I want the results or no, I don’t.” “I think the participants should be able to decide whether it goes just to them, just to their doctor, or both... So you’ve got to give participants the option, I think.” “...there will be those who don’t want to know. It can be left up to each person to decide, like tonight when you asked if we wanted the results; we were free to say yes or no.” “But if we sign a release and say we’ll participate and help you with the study and I don’t want any information, that’s what I said, I don’t want any, then that’s it.”

In most groups participants expected to be offered these choices as part of the overall consent process, similar to the consent process for the focus groups: Basically what you’ve done tonight when we came here... you’ve covered a lot of bases with all the signatures, so why couldn’t it be done for this?” “...look at the forms we had to fill out just to sit in this room. So to do a 20 year study, I can only imagine... could there be another form that says: ‘yes, I want the results; no, I don’t want the results’.” “Maybe they have to know going in. Or maybe you ask them going in: ‘if we find something important do we tell you?’ Maybe people don’t want to know.” Some participants had specific concerns that they felt should be addressed in the consent process, specifically DNA testing and confidentiality of test results: “...if you’re going to actually analyze people’s DNA, I think they need to know that when they consent to participate in the study.” “...would you have an opt-out clause that: ‘no, I don’t want these results being passed on to my physician’?”

Several participants expressed concern about the liability of the study and felt that those who chose not to have any results returned under any circumstances should sign a waiver to that effect: “I also think they should have the choice, though. Some don’t want it back. It would be really simple for them to sign a waiver.” “I think the study should have the participants sign a waiver... I agree not to know.”

Participants showed awareness of the fact that individuals should be able to reconsider the decisions they originally made during the consent process. This point was made several times in the context of discussions around the potential for new DNA tests with greater diagnostic power: “...at the beginning of the study I had said that I don’t need

this information. Then I would like to be able to revisit that.” “And the other thing is your consents may need to be updated over the years as new tests become available and you can do more with that DNA.” A few participants felt that those enrolled in the study should have the opportunity to revisit their choices at regular intervals: “Then ask the person again and say: ‘do you want to know?’ That was based on when I was 43 and now I’m 55, it might be a little different.”

Speaker A: “And so I think part of every three years could be... ‘We need you to fill this out, do you want these results? You don’t want these results or you only want them if there is a ‘red flag’ and it’s a form we fill out every 3 years.”

Speaker B: “There should be the opportunity there for individuals.”

Moderator: “To change their mind?”

Speaker B: “Yeah.”

3.9.2. Ethical Considerations

Participants were asked about the return of potentially adverse results to someone who had elected not to receive any results. There was considerable debate and difference of opinion on this question with some participants taking the view that a person’s expressed wishes had to be respected: “...you should respect my wish, whatever my wish is, you should respect it. You shouldn’t override it.” “...of course you respect their wishes; if they’ve said that, how can you go against them?” “If they don’t want to know, and they just want to carry on and suffer the consequences... that’s free will, that’s a free choice.” Some participants felt that the right to choose had to be respected even if the consequences of the decision were questionable: “It’s still their legal right, whether... it’s ethically or morally wrong... if they’re of sound mind and they say I don’t want to know anything...” “But as an adult, don’t you have a right to choose? I mean, even if it’s the wrong choice, it’s still your choice.”

A number of other participants took the view that the greater ethical obligation was to inform someone of a potentially life-threatening disease or condition and that this should override the wishes of those in the study who had elected to not receive results: “...the ethics of the thing would be that even if the person said I don’t want to know any results, they have to send that to his doctor. That’s just all there is to it.” “No, I wouldn’t sleep at night, my conscience wouldn’t be clear... they go to the doctor, and even though they don’t want it, that’s the right thing to do.” “But isn’t there an ethical issue here, and the ethical issue is that... this person has a major medical issue and... you’re not taking a positive step to help them.”

“...you’re sitting on a ticking time bomb inside this individual’s body, and even though they signed a consent to say: ‘no I don’t want to know’, there is a certain medical ethic that I would think, at least to make one or two proactive attempts to say: ‘you really should go to see your own doctor’.”

Some participants were very creative in coming up with solutions to this dilemma. While questionable, they demonstrate how much they struggled with this issue: “Well, they

wouldn't be getting them; their doctor would." "And it might be a very, very thin line also, when you sign the form that said you don't want to know, did it say anything about letting your doctor know?" "...but I think the way around that one is to have them nominate a doctor or something, then that person would be advised to the concern, and he can deal with it." "Put in another little box and say, even though you told us not to contact you, if we find something really serious, would you like to see your doctor...?" The following discussion is illustrative of the debate that took place in some focus groups around this issue:

- Moderator: "...you did a test and you found a serious health concern that they were not aware of. What should happen?"
- Speaker A: "I think the same thing that they go straight to the doctor."
- Moderator: "But they said they don't want the results."
- Speaker A: "*They* don't want the results."
- Moderator: "Well, maybe they've said up front they don't want any results sent to anybody."
- Speaker A: "Well then, I guess you should respect their wishes."
- Speaker B: "I think I would contact them and say: 'I really think that you should have some results. Would you like them now?'"

Several participants pointed out potential problems with trying to get around the issue of not having consent to release any results, citing confidentiality:

"I don't see how you can go ahead and provide that information when they have said no; you're breaching medical confidentiality by passing it on to another physician. I think you'd legally have a problem with doing that even if it were something serious; they said no up front."

Proponents on both sides of this debate cited legal arguments to support their views: "But even if someone said... that they didn't want to know anything, and then something came up that was a threat to their health, I think the responsibility of the study is to let them know or they could probably sue them, right?"

- Speaker A: "In these days of litigation... If they found out something serious about me and didn't tell me, even though I had said I didn't want the information sent back, and it turned out I had a terminal illness, can I now turn around and say, now if they had let me know a little bit sooner, I could have lived longer, therefore I'm suing for malpractice or something"
- Moderator: "Well, that's what we'd like to avoid."
- Speaker A: "I guess the suggestion is that whatever you put down on the questionnaire when they are either giving permission or withdrawing permission, it better be legally binding."
- Speaker B: "I think the greater danger is if you said: no I don't want the results and they said: but you have this disease, we're telling you or we're telling your physician, then... the research team has violated your

expressed written intent and that puts them in a higher litigation risk than the scenario you just...”

Several participants felt that because of the potentially serious consequences of not receiving results, the study had to take great care in ensuring that the consent process was truly an informed one: “...there would have to be a disclaimer on the form saying: ‘By saying I don’t want this I am understanding that all of my medical information will be kept confidential’.”

- Speaker A: “And presumably that would be in the question up front. You would ask me and say: ‘now if this is something serious do you still not want to know?’ And if they’ve had an opportunity to consider that question and still say no, I think you’ve got it.”
- Speaker B: “Make them sign a waiver, right?”
- Speaker A: “Make them sign a waiver.”

3.9.3. Consent to Receive as a Condition of Participation

One participant felt strongly that participants should be required, as a condition of taking part in the study, to consent to receive potentially serious results:

- Speaker A: “I think that people should have to sign a consent form to say that if, in fact, something serious shows that the results will be sent either to them or to their doctor. Because I think ethically the people who are doing this study can’t leave that information in limbo...”
- Moderator: “So are you saying that a person wouldn’t have the option to say: ‘I don’t want any results under any circumstances’ and if they didn’t agree to take the results, they couldn’t participate in the study?”
- Speaker A: “That’s what I think, yes”
- Moderator: “Okay.”
- Speaker B: “I disagree strongly with that. I think, as an adult, you have the right to be as stupid as you want... as we prove over and over.”

However, another participant observed that such a requirement might affect the validity of the study: “If you weed out those people who don’t want to know the results... then your study’s not going to be a random sample by any means. It has to be done in such a way that the testing is reasonably valid.”

For many participants choice was a key aspect of the consent process. They wanted to be able to decide not only who should receive their test results but also whether to receive them at all. While almost all participants wanted their own results, with few exceptions they felt that this choice should not be forced on anyone. While participants clearly understood the concept of informed consent and wanted to fully comprehend their rights, responsibilities, and their options before agreeing to participate in the study,

they did not want these choices to be cast in stone, preferring regular opportunities to revisit their decisions.

Participants struggled with the question of not returning potentially serious results to someone who had elected to not receive any results. Some participants advocated respect for the decision while others argued that the study had an ethical responsibility to inform the participant regardless of their decision. While this debate was not resolved by any means, there appeared to be movement towards the principle of respecting a participant's informed decision not to receive any results. This view was certainly not shared by everyone and there was also considerable concern expressed that the consent be formulated in such a way as to protect the study from any liability arising from the non-return of adverse results. Participants felt that the potential consequences of choosing not to receive any results had to be made very clear and that anyone choosing this option should sign a waiver to release the study from any potential liability.

Although there was a suggestion that accepting results be a condition of participation, most participants did not agree with this view. Some even felt it would affect study validity by restricting participation to those willing to receive their results.

3.10. Conduct of the Study

Participants were very curious about the study, asking numerous questions and offering many comments and suggestions. These questions and comments covered a broad range of topics but have been organized around several themes including: confidentiality, policy implications, validity and reliability, factors influencing participation and suggestions for improving the study.

3.10.1. Questions about the Study

Generally participants were very curious about the CLSA and asked numerous questions related to all aspects of the study. Many questions were simply seeking information or clarification and will be dealt with in a perfunctory way. Other questions illuminate specific concerns and will be discussed in greater detail.

Participants were interested in various particulars about the study such as how many people would be asked to participate, how they would be selected and whether they would be a part of it by virtue of participating in a focus group. They also wanted to know what was meant by 'longitudinal', if the study was focused exclusively on health issues and whether other, similar studies were being conducted in other countries. There was interest in the start date for the study and whether it would represent all Canadians, specifically ethnically and geographically. Several participants wanted to know why the study was being done now and speculated that it had to do with the aging baby boom generation. Others asked about attrition, particularly what would happen if a participant became seriously ill, incompetent or died during the course of the study.

A number of participants commented on the challenges associated with mounting such a large, involved study: "Well, I suspect it's quite the noble idea, this study. I just see it

as a logistical nightmare; 50,000 people, that's the size of a small city." Participants wanted to understand the rationale behind the study and its overall goals and objectives: "This research study, what is it set up to accomplish in the long run and for who?" "What are they hoping to achieve and understand in this? It's a very generic statement saying they want to learn more about aging, but what... is there any specific objectives that they're looking for?"

There was also interest in the funding sources for the study, whether the funding was in place and who might benefit from it financially. "And is it being funded by the three universities?" "The funding for the study, is it all in place now?" "And why are they doing this? I mean the obvious, but it's horrifically expensive. How is it being paid for and ultimately who is going to benefit?" "So the three universities aren't ending up down the road going to make a big bundle out of this?" There were also concerns that the study findings be available to the public: "Because it is done by a university it will be public information when the summary comes out, right?" A few participants were hopeful that the study could lead to more research being conducted: "And it could lead to further research, right, once you look at the findings, then it might pinpoint areas to do more research."

Participants asked numerous questions about the testing that would be done as part of the CLSA. They wanted to know what tests would be performed, at what intervals and who would be carrying out the testing: "How thorough... sort of tests would you be talking about, because I had the impression that it was blood pressure and simplistic sort of things." "What information do you expect to retrieve from the health testing...?" "We talked a lot about taking your blood pressure and blood samples. Is there going to be anything else in this study?" Several wanted to know if the study would have its own doctors: "I don't know who is going to be doing the tests, but will they have doctors for that kind of thing?" "...do you have medical staff that are doing this?" "Who is actually going to be carrying out the study? Are they university students, are they medical students, or are they full-stream doctors? One participant felt that not having doctors performing the tests removed some of the ethical obligation to inform participants of serious results: "You don't have a doctor with a dilemma looking at my results saying: 'should I call his home doctor or not?'" Participants also asked questions about the logistics of testing including location and scheduling: "Would it be done, everybody at the same doctor?" "...are you doing all 50,000 people at the exact same time or is this staggered?"

There were also a number of questions about interpretation of the results with concern expressed that those carrying out the tests may not be able to identify a potentially serious result: "So therefore the people looking at the results wouldn't necessarily be able to analyze whether or not some of the results were serious health problems."

Participants asked a lot of questions about DNA testing and many did not seem to understand why they would not receive results or could not reconcile the phrase 'currently have no diagnostic value' with their knowledge of DNA testing: "...they're taking a DNA test but... they're not going to tell you because they don't know either?"

“For cancers, certain types of cancers; he has a marker that makes him more susceptible to those types of cancers... like significantly higher... so some of that information is available today...” Some participants thought that DNA results were not being returned because of concerns over validity: “...do you mean that they wouldn’t want to tell you... because then it would skew the study?”

Return of results was a topic that generated many questions and comments. Participants were concerned about both the logistics and cost of returning individual test results: “Logistically, would that be very difficult for the research teams?” “...it would be a huge administrative thing to try to distribute that information... specifically to individuals.” “Because that could hugely add to the cost of the study, right; it would be prohibitive if we asked for too much, right?” Several participants were interested in the overall results of the study: “But I certainly would want to know what the study says in its conclusions.” However, some doubted that they would personally benefit from these findings: “...people around this table... may be dead in 20 years, so what good is that going to do us?”

3.10.2. Privacy and Confidentiality

Most participant concerns about privacy and confidentiality were related to access issues with a number of questions about the availability of data to persons or agencies outside the study. In some cases participants were simply curious about research use: “So once this research is done, who would it be available to?” “The results will be made available just for researchers only, biomedical field or any researchers?” In other cases participants had concerns about access by insurance companies or pharmaceutical companies: “Would something like this be... sold to insurance companies?” “OK, but for instance, if there is a private company who wants to create an anti-aging enzyme, will they have access to this research? There was also some concern about who would actually own the data: “Who owns this information; the Canadian government?” Some participants also wanted to know what would happen to their bio-samples: “...I’d also want to know what you did with the sample. Do you just take the test now and destroy it, or are you going to keep it for each test over the 20 year lifetime?” Although most participants seemed to trust the study to protect their confidentiality, some wanted assurances:

- Moderator: “So even if you were given a guarantee that the information would be kept confidential, you’d still have some concerns?”
- Speaker A: “I would have a confidentiality agreement signed.”
- Speaker B: “You’re the lawyer.”

3.10.3. Participant Suggestions

A number of suggestions were made by participants on how the study could be improved. Some of these have already been noted in previous sections. Participants suggested that the study incorporate certain diagnostic tests because of their diagnostic value but also because they would encourage participation:

“...there’s a lot of seemingly healthy people out there who have found out... that they got things wrong with them as a result of having an MRI. It would be interesting if you had a percentage of that 30,000 who could be given an MRI...”

Several participants suggested anonymizing all the data in order to remove the dilemma of having to return results: “The way the study could avoid a problem is not to identify the individuals... That way you come across somebody with a really bad result, you don’t know who they are.”

There was also a suggestion that the study not perform its own testing but recruit family physicians to undertake this task on behalf of those enrolled in the study: “If this test group was going to all go out and have all the blood tests... and so on done, have our own doctors do it. Have our doctors do the test, inform us and then pass the results to you doing the study.”

There were several suggestions that the study make available overall or average results to participants so that individual results could be compared: “...I think we should also be able to compare the results to those of the group in general, to see where we’re at.”

One participant in the Montreal focus group was very concerned about the language issue: “...all the personnel of the study should be of the language of the person who will be tested, and that is important, that is very, very, very important... the language question is important, I am not making anything political out of this, OK.”

A number of comments were made about the consent process and, in particular, ensuring that participants were aware of what was being asked of them: “...you’d have to make it very clear what kind of things are going to be done to someone. I mean are you going to take a urine sample, a blood sample, put them on a treadmill, this, that or the other? Some people might be receptive to this but not that.”

There were several suggestions about making general health information available to participants on a voluntary basis: “On your way out we have a wall of pamphlets here... heart disease, cholesterol, blood pressure, you know. You’re welcome... [to] have any information.” “...on your website you could have links to all of these reputable places that have discussions on these things, but the person would make the decision themselves whether they wanted the information.”

3.10.4. Policy Implications

Participants showed a basic understanding of population health and the potential value of the study in the long term: “And is the purpose of the study... to direct money in specific directions to improve health? Is that the long term purpose?” “...if it is not useful to improve the aging process; to make things easier; what is the point of the study?” “I think we can’t expect too many personal benefits from this; it is with an objective: the collectivity.” Examples of potential uses of the study findings were offered by some participants. Some thought it would show regional variations in health: “But

this study is probably going to show tons of stuff. It's going to maybe show that people in British Columbia are probably healthier than the people living... in Ontario..." "But what if... they find pockets of disease in parts of Canada that may be caused by environmental things... where should they go?" Several participants felt that the study findings could influence much more than health policy: I think that... housing policy can be affected by a study like this. I think that's one of the best things you can do to maintain people's health is to make sure they're not alone..." "For instance that could influence how old folks homes are built; we are not in the medical field anymore, we are in architecture and engineering..."

3.10.5. Study Validity

Somewhat surprisingly, a number of participants commented on possible effects on study validity. Some were concerned over the effect of returning test results on behaviour: "...if you're monitoring disease development over the longitudinal span of the study and if you're suddenly in there where you've got to go to the doctor and you'd better get this checked out, then you're... skewing the results." However, most participants saw this as less problematic than the alternative: "I think what [name omitted] said is literally true but I don't see the problem with... skewing, as you say, the results. You're going to save a few people's lives..." Several participants commented on the fact that they thought the study would attract those with an interest in their own health, resulting in a non-representative sample: "...I would have to assume that the people... are going to be people who are curious and fairly aware of their own medical situation and medicine in general."

The validity of testing procedures, particularly blood pressure was questioned by a number of participants who felt that white coat syndrome could affect results: "But the numbers... in blood pressure don't always mean anything because of the white coat syndrome." "I think some people really get worked up about certain things: getting their blood pressure done, having a needle... blood work or whatever." "The reading is accurate for that time; the question is: what does it mean?"

3.10.6. Participation

Participants expressed their views on a number of incentives and disincentives to study participation. One participant framed the whole question of study participation in this way:

"Why does the research group think that they are going to get 50,000 people to participate in this? And what I mean is that what would the incentive, the motivation be for 50,000 people to participate in a 20 year study? That's a significant commitment."

By way of response, participants outlined a number of factors that would they felt would aid in recruitment and retention: The availability of certain diagnostic tests was mentioned by a few:

Speaker A: “Can I just ask: what if you were to offer ECG and MRI? Would that increase your chances of being in the study?”

Speaker B: “Absolutely.”

Speaker A: “You’d want to participate?”

Speaker B: “Absolutely yes.”

As previously discussed, returning results was an important incentive for most participants to enroll in the study and conversely, not receiving results was a disincentive: “I think it will also destroy the study because a lot of people will drop out. They’ll say: hey, if we’re not going to get any feedback, what’s the point? Just drop out.” Some participants also commented on other factors that might cause someone to withdraw from the study: “...a lot can change in 20 years. I mean, you can start into this study... being healthy and fine and at the end of it you got some major illness or in the hospital. You might not be interested in any more needles...” There was also concern about discomfort that might be associated with test procedures: “I’d be more concerned if it was painful.”

For some participants their motivation for participating was altruistic and it appeared that there was little else that would motivate or de-motivate them: “I mean there’s all kinds of guinea pigs in the world and if I’m another one, why not. If they can do something for research, why not?” “I think that it is for science, knowledge, because it will serve the next generation, medicine as a whole, for society.” “If I enter a study like this, I’m going into it for altruistic purposes. I’m thinking that someone down the line is going to benefit.”

Most participants seemed enthusiastic about the study and eager to participate: “I want to sign up right now, by the way.” However, at least one would refuse to participate outright. In this particular case the reason was DNA sampling: “I guess in my particular case, if you were looking for volunteers... I wouldn’t go.”

Participants were very curious about virtually all aspects of the study and asked many questions both during the discussions and after the focus group in question and answer sessions. This indicates a strong level of interest in the study among most focus group participants. However, not all questions were informational and it was clear that for some, at least, they were seriously considering their own participation in the study. Participants seemed to appreciate the logistical challenges of mounting such a large study and were interested in how these challenges would be met. All the questions were not innocuous, however, with some participants questioning the purpose of the study and what it would achieve. Some even wondered if the benefits would justify the expense. There were also questions about who would benefit from the study which may have been indicative of some level of suspicion about the motives for carrying out the study and who might profit from it.

There was a significant amount of discussion about the types of tests the study would incorporate and who would be carrying them out. While not explicitly stated, some participants seemed to be weighing the level of effort and inconvenience against the

personal benefits, such as return of results that might accrue to them. The questions about who would be doing the testing also seemed to underlie fear of someone other than a doctor or health professional performing a physical assessment and other tests. The topic of DNA testing and non-return of results provoked a number of questions. As previously stated, this area of inquiry was rather controversial and statements in the moderator guide about DNA appeared to be at odds with participant perceptions of its current value.

Some participants felt that returning test results would present a logistical challenge and wanted to know how the study would accomplish this task and speculated as to the cost. A number of participants were interested in overall study results as a way of comparing their results with study averages.

Concerns about privacy and confidentiality were largely centred on who would have access to the data. Participants asked about insurance companies and commercialization, but also issues such as data ownership and data destruction. Some were clearly looking for very clear and legally binding guarantees to protect their confidentiality.

Participants made a number of suggestions that they felt would make the study more attractive, such as offering particular diagnostic tests, which they felt would increase recruitment and retention. In the Montreal group, participants pointed out the importance of having francophones involved in all aspects of testing and communication with participants. The importance of having a comprehensive consent process to ensure participants knew exactly what they were signing up for was also mentioned.

The policy implications of the research were not lost on participants who recognized the potential value, not only in the area of health, but also related fields. Participants showed a good understanding of several issues affecting study validity including the importance of a representative sample and the effects of behavioural change on study results. There was also discussion of factors which would impact study participation with recognition that participants may need incentives to begin and continue to participate in a 20 year study. In line with other feasibility study results, altruism was an important motivating factor for some participants.

3.11. Experience of Aging

Participants made a number of comments about their specific experience of aging and also some general observations on the aging process. While not connected to any particular line of questioning, these comments offer a glimpse into the attitude of participants towards aging.

A few participants made reference to the fact that they were not very proactive when it came to their health: “I sometimes feel like my body is like a car and I wait for two or three things to happen and then I go in.” “Until I got diabetes, my annual [check-up] came about every seven years.”

A few participants related negative experiences with physicians, commenting on their callous attitudes and indifference. "...when we were younger, the doctors did not speak to us at all, not one word... as if they are gods! They did not see us as clients. I never got the answer; it was abhorrent." "I had the same experience... 'Here are the results, you have cancer.'"

A few participants talked about other aspects of aging besides physical health. For some mental health was as important as physical health: "...the mental condition is as important as the physical." Others had more specific concerns: "I guess the other thing I would question is depression, living with depression... is it connected to the aging process? I'm curious to know..." "I kind of forget things and... I'm very interested to know why." A few people brought up financial issues: "...what about finances, because that is a part of aging... people have to live, have enough money...coming in." A number of participants spoke about the importance of having a positive attitude towards aging: "I am looking for balance... to stay healthy, to have more experiences, to grow in wisdom..." "...I always say it is one thing to grow old but it is another thing for that individual to accept it." "And even when I had my heart surgery, sure, I was scared and everything else, but I figured, well, if my time is to be then, that's to be. If it isn't, I'll survive and carry on."

"I know I am aging but I'm trying to age gracefully... if I'm going to... go through a depression because I have a couple of wrinkles, it's going to kill me, so that's why I read a lot, I exercise, I live my life, I enjoy my life..."

A few participants admitted that the prospect of aging and its consequences was frightening to them: "...yes, I am very afraid of disease." "...now I'm 60 and I feel that I'm old, but not that old, so I'm scared... what's going to happen. I'm really scared to be 70."

Ageism was mentioned by a few participants: "...they've just been forgotten, they've dropped through the cracks... And so we... focus on one side of the generation gap and we forget this side." "...especially if you live in Vancouver... like we are invisible because we are older..." "The TV sets teach people that they're full of nonsense, kids don't listen to you."

While many people related anecdotes about their own experiences with aging in order to illustrate their various points, a number of these personal experiences illustrate important facets about the aging process in Canadian society. Participants related their experiences with unsympathetic physicians and spoke of their difficulty in being more proactive about their health. They also saw aging as a multidimensional process involving mental and economic health as well as physical health. Participants spoke about the need for a positive attitude towards aging but also expressed their fear of what the future might hold for them. There was also awareness of the negative images of the elderly in the media and lack of respect among the younger generations.

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Appendix A

Moderator Guide

Canadian Longitudinal Study on Aging

Feasibility Study 10

November 2005

Introduction

Hello everyone, welcome, my name is Geoff Strole and I'm the moderator for tonight's group discussion. Helping me is Steven Dukeshire who will be taking notes during the discussion.

We appreciate you taking time to participate in tonight's session. The goal of this discussion is to "get" your perspective on a number of topics related to the Canadian Longitudinal Study on Aging. This is a proposed national study on healthy aging that will follow a large group of Canadians over a 20-year period. We have some questions for you about how you would feel if you were asked to participate in a study like this. In particular, we are interested in your views about whether large health studies like this should return information to participants about themselves and how this should be done.

Before we get started I want to review some information and go over your role in the group discussion.

Disclosures

Confidentiality: First off, all persons involved in carrying out this research will keep everything you say here confidential. Nothing you say will be associated with any individual by name. We also want to emphasize that it is very important that you similarly maintain the confidentiality of what is said by others during the discussion. You can talk about the focus group with other people in general terms, but you should not reveal any personal information that may come up during tonight's discussion to anyone outside this focus group.

Voluntary Participation: Your participation in this group is entirely voluntary. You may stop participating or withdraw at any time. You do not have to speak about any topic that you do not wish to discuss.

Audio-taping: This session is being audio-taped so that we can write an accurate report about the issues raised during the discussion, not to identify who said what.

Participant roles

1. Only one person should talk at a time. Please speak in a voice as loud as mine.
2. Avoid side conversations with your neighbours.
3. We would like to hear from everyone during the course of the evening but you don't have to respond to every topic.
4. Feel free to respond to someone directly. You don't have to address your comments to me.
5. All points of view are welcome. We want to hear your personal views whether or not anyone else shares them. We are not looking for everyone to agree.
6. Finally a note on my role. I'm here to ask questions and guide the discussion but not to participate in the discussion. We are here to listen and learn from you. However, we do have a number of topics we need to cover so I may need to interrupt in order to move the discussion to a new topic or keep us on track. If you have specific questions about the study there will be an opportunity to ask them at the end.
7. One more thing, if you have a cell phone could you please turn it off or put it on vibrate. If you have to take a call I would just ask you step outside the room.

Group Introductions

Please introduce yourself by telling everyone your first name, and a little about yourself.

OK, I'd like to begin by telling you a little more about the Canadian Longitudinal Study on Aging.

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The Canadian Longitudinal Study on Aging, which I will refer to as the CLSA, is a proposed study that will follow 50,000 Canadians 40 and over for a period of 20 years. For this study, participants will be asked to take part in an assessment that could take up to four hours of time approximately every three years. During this assessment, participants would complete questionnaires, have a physical assessment, and provide blood and urine samples. What we want to ask your opinion about tonight is what types of information about yourself, if any, you would like to receive if you were to participate in a long-term study, such as this. However, before we address that specific question, I would first like to ask you:

1. What types of health information about yourself are you most interested in and...
 - a. Where would you typically get this information?
 - b. When you visit a doctor do you ask for specific information such as blood pressure readings?
 - c. When you discuss the results of a test such as a blood test with your doctor do you ask for specific information such as cholesterol readings?

- d. Do you ever try to get health information from sources other than a doctor or nurse? For example, do you ever take your own blood pressure? Look up information on the Internet; ask a naturopath, chiropractor, salesperson in a health food store?
- e. What do you do with information that you receive about yourself? Do you think it changes your behaviour in any way?
- f. What types of information do you not get now that you would like to get about yourself?

30

2. Many of those selected to participate in the CLSA will be asked to have a physical assessment involving routine procedures, such as a blood test for cholesterol or having their blood pressure taken. These tests are conducted for research purposes in order to better understand the aging process. Some people think that participants should get the results of their own tests back and some people don't. What do you think?

Probe, if necessary:

- a. Do you think this type of information would be meaningful to most people?
- b. Do you think the test results would have to be explained?
- c. Do you think a study like this has a responsibility to provide health information to participants?
- d. Can you think of any reason why this information should not be returned to participants?
- e. Would you want your own personal results back? (monitor health behaviour, just want to know more about self)

40

3. In a research setting such as that proposed for the CLSA, the results of a physical assessment are typically not as useful as they would be in the hands of a family doctor who can put the results into context because of medical knowledge, knowledge of the patient and the patient's history. Does knowing this change how you feel about receiving your own test results?

Probe, if necessary:

- a. Why? Why not?

45

4. Assuming that individual test results were to be returned, who do you think should get this information, individual participants or their family doctors or both?

Probe, if necessary:

- a. Why? Why not?

5. What do you think should happen if a test result is found to be in a range that indicates a serious health concern?

Probe, if necessary:

- a. How do you think the person should be notified?
- b. Who do you think should be notified; the participant and/or the family doctor?

- c. What should happen if the participant requested not to receive individual test results?
- d. Is there anything else you would expect should happen?

50

6. If you had requested the results of routine tests how would you like to receive results?

Probe, if necessary:

- a. e.g. by phone, mail, in person, through doctor's office, the Internet
- b. What do you think would be a reasonable amount of time in which to receive the results of a routine test such as a blood test?
- c. Would you want the results sent just to you or also sent to your doctor?

55

7. If you knew you were going to have a physical assessment as part of a study such as the CLSA, would this affect your behaviour in any way?

Probe, if necessary:

- a. Before you came for the assessment?
- b. What about after having the assessment?
- c. Would you cancel or delay seeing your family doctor?
- d. Why? Why not?

60

Now I'd like to present you with some different scenarios. I'll describe a hypothetical situation and get your reactions.

8. As a participant in a research study you have your blood pressure taken by a medical technician, not a doctor. The readings taken during the visit are in the normal range. What would you expect to happen next?

Probe, if necessary: Would you expect:

- a. the blood pressure reading to be given to you? What about if you had not agreed to receive individual test results?
- b. the blood pressure reading to be interpreted to you?
- c. to receive written materials on blood pressure? What type of material?
- d. the results to be sent to your family doctor (if you previously agreed to have this information released)?
- e. a health professional (such as a nurse or nurse practitioner) to speak with you at the time?
- f. Just as before, you have your blood pressure taken but this time the readings are outside the normal range. Would your expectations about what should happen be any different?

70

9. As a participant in a research study, you have a blood test which is not immediately analyzed. Three months later the test shows blood counts that may indicate a very high level of cholesterol. What would you expect to happen next?

Probe, if necessary: Would you expect:

- a. to receive the results? what about if you had not agreed to receive individual test results?
- b. to have the test result interpreted to you?
- c. to receive written materials on the test result? What type of material?
- d. to be advised to make an appointment to see your family doctor?
- e. the results to be sent to your family doctor (if you previously agreed to have this information released)?
- f. a health professional (such as a nurse or nurse practitioner) to speak with you at the time?
- g. how would like to receive the results (mail, in person, telephone, from doctor)

75

10. As a participant in a research study you provide a blood sample from which your DNA is extracted. The DNA is only used to study the aging process and tests using it currently have no diagnostic value, i.e. it is not something a doctor could use to inform you about your health. You would not get your individual results back from any tests done using your DNA. How would you feel about this?

Probe, if necessary:

- a. What would be your concerns? Would you be concerned about how it is used? Do you have any concerns about privacy?
- b. Why do you feel this way?
- c. If in the future, new DNA analysis procedures are developed which have diagnostic value, what would your expectations be?

80

11. Would getting the results of some individual tests make you more likely or less likely to participate in a 20 year study such as the CLSA?

Probe, if necessary:

- a. Why? Why not?

85

12. Is there anything else you would like to say that you haven't had a chance to so far? Do you have any questions about the CLSA?

90

Thank-you

Appendix B

Consent Form for Focus Group Participants

The Return of Individualized Test Results to Study Participants and/or General Practitioners

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Inspiring Innovation and Discovery

1. Introduction

We invite you to take part in a study being conducted by Susan Kirkland, Ph.D., who is an Associate Professor in the Departments of Community Health and Epidemiology, and Medicine at Dalhousie University in Halifax, Nova Scotia, Christina Wolfson, Ph.D., Professor in the Departments of Epidemiology & Biostatistics, and Medicine at McGill University in Montreal, Quebec, and Parminder Raina, Ph.D, Associate Professor in the Department of Clinical Epidemiology and Biostatistics at McMaster University in Hamilton, Ontario. Your participation in this study is voluntary and you may withdraw from the study at any time. The study is described below. This description tells you about the risks, inconvenience, or discomfort which you might experience. Participating in this study will likely not benefit you, but we might learn things that will benefit others. You should discuss any questions you have about this study with (the CLSA staff person).

2. Purpose of the Study

The purpose of the research is to try and understand what people's expectations are regarding the return of individualized test results in a long-term study like the Canadian Longitudinal Study on Aging. The information provided will be used primarily to help develop the Canadian Longitudinal Study on Aging.

The Canadian Longitudinal Study on Aging is a large, national, long-term study that will follow approximately 50,000 Canadian men and women aged 40 and older for a period of at least 20 years. For additional information on the CLSA please see the enclosed brochure.

3. Study Design

This study will consist of 6 focus groups conducted in 6 cities: Halifax, Montreal, Winnipeg, Calgary, Vancouver and Hamilton. You have been asked to participate in one of these focus groups. The focus group will consist of a discussion guided by a moderator. Discussion topics will include asking you about your thoughts and feelings concerning a number of issues related to the return of individualized test results to participants and/or general practitioners in a proposed long-term research study of health and aging. There are no right or wrong answers.

4. Who can Participate in the Study

You can participate in this study if you are an adult living in Canada who is 40 years and older.

5. Who will be Conducting the Research

The Principal Investigators for this study are Susan Kirkland, Ph.D (Dalhousie University), Parminder Raina, Ph.D (McMaster University), and Christina Wolfson, Ph.D (McGill University). The focus group you will be taking part in will be guided by Geoff Strople. Notes will be taken by Steven Dukeshire.

6. What you will be asked to do

You will be asked to take part in a group discussion about issues related to returning individualized test results to research participants and/or general practitioners in the context of a research study. A moderator will guide the discussion through a series of topics. During the discussion, you will be asked to share your thoughts and feelings about each of these topics. Because we are asking for your opinions, there are no right or wrong answers. It is expected that the discussion will last for approximately *two hours*. Prior to the focus group discussion, you will be asked to complete a very brief written questionnaire to provide some background information on yourself. The information you provide will remain anonymous, that is, we will not ask for your name or any other identifying information.

The focus group will be audio-taped and notes taken. The focus group is audio-taped to ensure that we do not miss any information and to ensure that we report all information accurately.

7. Possible Risks and Discomforts

There are no known serious risks or hazards involved in this study. However, all participants will be asked to respect the confidentiality of the information shared during the focus group. To protect your confidentiality, you will only be identified by your first name during the focus group. There is also the possibility that you may feel some stress or negative emotion if a topic is discussed that is of a highly personal nature to you. If this happens, or you wish to leave the focus group at any time for any other reason, you may do so.

8. Possible Benefits

There is unlikely to be any direct benefit to you for participating in this study, although you may learn about issues related to health research. The main benefit will be to researchers who use the information you provide to help develop better long-term research studies.

9. Compensation / Reimbursement

If you choose to become involved in this research study you will receive \$40.00 to assist you with 'out of pocket' expenses for travel, or other related expenses such as child care or elder care. If during the focus group you decide that you do not want to continue, you may withdraw from the study without penalty and will still receive the same amount (\$40.00).

10. Confidentiality & Anonymity

All information, which you provide, will be held in strict confidence. Only persons involved in transcribing the audio-tapes and analyzing the results of the focus groups will have access to and be able to listen to the tapes or read the transcripts. Audio-tapes, transcripts, questionnaires and field notes will be stored in locked cabinets in locked rooms at CLSA offices in the Department of Community Health and Epidemiology at Dalhousie University. Electronic files will be password protected. Tapes, transcripts, questionnaires and field notes will be maintained in a secure environment until they are destroyed. This period will be for a minimum of 5 years after the study findings are published. Only CLSA Principal Investigators and CLSA staff will have access to these tapes and transcripts. The summaries of the focus group will be circulated to key individuals including the principal investigators, co-investigators, moderators hired by the CLSA, and CLSA staff members directly working in this project.

Any summary of the results or published reports will not identify you by name, nor will any information be included that could be used to identify you. Although we will emphasize to all focus group participants the extreme importance of keeping information discussed during the focus group private, we cannot guarantee that all people involved in the focus group will do so. In an effort to protect your identity, we will only use first names during the focus group.

11. Questions

If you have questions about this study, you may contact any of the following:

- Project Coordinator, Geoff Strople, MA – 1-866-515-5252, geoff.strople@dal.ca
- Lead Principal Investigator, Susan Kirkland, Ph.D. – 902-494-1235 susan.kirkland@dal.ca

12. Summary

The research you are being asked to take part in has as its goal to better understand people's views on their expectations regarding the return of individualized test results if they were to participate in a long-term study of health and aging, such as the proposed Canadian Longitudinal Study on Aging.

If you choose, you may provide your name and address after this focus group has ended and a summary of the research results of the focus groups related to the study you participated in will be mailed to you after this series of focus groups is finished.

13. Problems or Concerns

In the event that you have any difficulties with, or wish to voice concern about, any aspect of your participation in this study, you may contact Patricia Lindley, Director of Dalhousie University's Office of Human Research Ethics Administration, for assistance (902) 494-1462, patricia.lindley@dal.ca.

Title of the Research Project:

The Return of Individualized Test Results to Study Participants and/or General Practitioners

PARTICIPANT CONSENT: I have read or had read to me this information and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the nature of the study and I understand the potential risks. I understand that I have the right to withdraw from the study at any time. I have received a copy of the information and Consent Form for future reference. I freely agree to participate in this research.

Name of participant: (print) _____

Participant Signature: _____

Date: _____ / _____ / _____
Day/ Month/ Year

I understand and agree to the fact that this session will be audio-taped. I understand that if I do not consent to be audio-taped I cannot participate in this focus group.

Participant Signature: _____

I hereby give consent to the use of my exact words (quotations) for any publication that may come out of this research study. I understand that no identifying information will be included in any reports.

Participant Signature: _____

STATEMENT BY PERSON OBTAINING CONSENT: I have explained the nature of the consent process to the participant to ensure that they understand that participation is voluntary and that they may withdraw at any time from participating.

Name: (print) _____

Signature: _____ Position: _____

Date: ____/____/____
Day/ Month/ Year

Appendix C

Focus Group Participant Questionnaire

Canadian Longitudinal Study on Aging

Feasibility Study 10

November 2005

Please tell us a little bit about yourself by answering the following questions. The information you provide is completely confidential and will only be used for the purposes of interpreting the results of this focus group. If you would prefer not to answer a question you may leave it blank.

1. How old were you on your last birthday?

___ Years old

2. Are you male or female?

- Male
- Female

2. What is the highest level of education you have completed?

- Less than high school
- Some high school
- Completed high school
- Vocational training or community college
- Some university
- University graduate
- Post-graduate degree or diploma

4. In what country were you born?

- Canada
- Outside Canada (please specify) _____

5. While most people in Canada view themselves as Canadians, this question refers to the origins of your ancestors. To which ethnic or cultural group did your ancestors belong? (Check all that apply)

- British Isles origins
- French origins
- Aboriginal origins
- North American origins
- Caribbean origins
- Latin, Central and South American origins
- European origins
- African origins
- Arab origins
- West Asian origins
- South Asian origins
- East and Southeast Asian origins
- Other... please specify _____

6. What is your current marital status?

- Single
- Married, including common law
- Divorced or separated
- Widowed

7. Do you have any children living at home?

No Go to Question 9

Yes
↓

8. What are their ages?

___ Child 1

___ Child 2

___ Child 3

___ Child 4

9. What is your current employment status?

Working full-time

Working part-time

Student

Homemaker

Unemployed

Retired

10. What is/was your occupation?

11. What is your household income?

- Less than \$25,000
- \$25,000 - \$49,999
- \$50,000 - \$74,999
- \$75,000 and over

12. What is your postal code?

_____ Postal Code

Thank you for completing this questionnaire.