Canadian Institutes of Health Research–Institute of Aging: Profile

Ethics, Health Research, and Canada's Aging Population*

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Introduction

Canada's population is getting older. Statistics Canada estimates that by 2031 there will be nine million persons over the age of 65, accounting for 25 per cent of the population. Within the same approximate time frame, the number of Canadians with Alzheimer's disease or related dementia is expected to double to more than one million persons. The aging of the Canadian population has significant policy implications for all levels of government in Canada. In April 2009, the Senate Special Committee on Aging released a report with 32 recommendations concerning health care, income security, housing, and other services (Senate, Special Senate Committee on Aging – Final Report, 2009). The 2010 fiscal sustainability report of the Parliamentary Budget Officer emphasised the economic implications of the demographic transition: "The ageing of the population will move an increasing share of Canadians out of their prime working-age and into their retirement years. With an older population, spending pressures in areas such as health care and elderly benefits are projected to intensify" (Office of the Parliamentary Budget Officer, 2010, p. ii).

While debate persists about the impact of an aging population on health care costs, it is clear that older persons generally require more health care than younger people. The Canadian Institute for Health Information reports that "spending concentrates among the elderly, and toward the end of life" with per capita expenditures rising sharply for those over age 70 (Canadian Health Services Research Foundation, 2002; Canadian Institute for Health Information, 2009, p. 48).

These realities raise important issues for health research, and this commentary discusses several ethical issues concerning health research at the societal (macro) level and individual (micro) level. Provision of appropriate services to optimise the health and well-being of older Canadians depends on research to elucidate biological, psychological, social, and other aspects of aging. Timely knowledge and technology transfer processes to apply research outcomes to practice is also a crucial step. From a macro-level perspective, underinclusion of older persons in some areas of research raises concern about the ethical allocation of research investments and the application of potentially "age inappropriate" health research knowledge to a large segment of the population. Ethical considerations of distributive justice may call for more research that is specific to older persons, yet, at the individual level, elders may face special vulnerabilities as research participants. Studies of conditions that involve mental decline (e.g., Alzheimer's disease, age-related dementia) or involving persons living in institutional care settings raise ethical concerns about voluntary and informed consent, and about substitute decision making

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on behalf of participants who lack mental capacity at the time of recruitment, or whose capacity deteriorates during the study.

Issues at the Societal Level

From a macro-level perspective, research on aging has been neglected compared to other areas of health research, raising concern about the ethical allocation of research investments and the "orphaning" of certain groups and/or conditions. The British Geriatrics Society has pointed out that research funding, and health resource allocation in general, has "been skewed towards higher tech treatments and 'sexier' conditions such as cancer or ischaemic heart disease which affect younger people and away from the needs of older people with incurable long term conditions" (British Geriatrics Society, 2009, p. 128). This criticism is borne out by a recent analysis of studies on long-term conditions published since 2002: 23.5 per cent of the studies focused on cancer, 17.6 per cent studied cardiovascular diseases, while 1.4 per cent concerned dementia (Knapp & Prince, 2007).

This gap in research is being addressed to some extent by longitudinal studies that follow older participants for a number of years to examine various factors that impact health and other aspects of aging. For instance, the Canadian Longitudinal Study on Aging aims to follow approximately 50,000 Canadians aged 45 to 85 for at least 20 years to examine physical, psychological, social, economic, and other changes that affect individuals as they grow older (see http://www.clsa-elcv.ca). Studies with older adult participants are important not only to acquire new health-related knowledge but also to inform the ethical conduct of research. Researchers who include older participants can share knowledge learned about communicating and interacting with these participants. As one example, an ongoing U.S. study (Samelson, Kelsey, Kiel, Roman, Cupples, Freeman et al., 2008) involving participants aged 70 and older has reported that:

> To recruit older individuals, face-to-face interactions are more effective than less personal approaches. … Assuring a safe and warm environment for elderly participants and offering a positive experience are a vital priority. Adequate funding, planning, and monitoring are required to provide transportation and a fully accessible environment in which to conduct study procedures as well as to select personnel highly skilled in interacting with elders (p. 1444).

Strategies for recruiting older persons newly diagnosed with cancer have also been reported (Puts, Monette, Girre, Wolfson, Monette, Batist et al., 2009).

Greater investments in health research are still being sought regarding older persons. For instance, the Senate report on aging called for research investments in palliative care, elder abuse and neglect, and issues related to mental capacity and competency, and the Alzheimer's Society of Canada advocates for more funding in all areas of dementia-related research (Alzheimer Society of Canada, 2009). A major challenge is to determine how to allocate funding among areas of research that will benefit distinct age groups (e.g., neonatology research vs. geriatrics research) and, in research concerning older persons, how to allocate resources among different types of research (e.g., basic research, research into new treatments, prevention-oriented research, social science research). Allocation of health research resources raises ethical complexities that are mirrored by debates about distribution of health care services.

Much literature has focused on the ethics of age-based rationing. Some condemn such rationing as "fundamentally ageist [and] discriminatory in a morally objectionable sense" (Fleck, 2010, p. 27), while others argue that notions of having achieved a "natural life span" or having enjoyed "fair innings" may permit ethically acceptable age-based rationing (Callahan, 1987; Harris, 1985). Ethics principles advanced to guide allocation of scarce health care resources such as prioritarianism (favouring the worst off), utilitarianism (maximising total benefits), and egalitarianism (treating people equally) (Persad, Wertheimer, & Emanuel, 2009) may be applied to help make determinations about allocating health research resources. A single principle, however, can never take account of all relevant considerations; thus decision makers and funders must consider and compare multiple principles and, most importantly, should establish and make public a reasoned basis for the distribution of research funds. As Daniels and Sabin (2008) have urged:

> To hold decision makers accountable for the reasonableness of their decisions, … the process must be public (fully transparent) about the grounds for its decisions; the decision must rest on reasons that stakeholders can agree are relevant; decisions should be revisable in light of new evidence and arguments; and there should be assurance through enforcement that these conditions (publicity, relevance, and revisability) are met (p. A1850).

From the Societal to the Individual

Macro-level debates and decisions about health research funding intersect with research ethics issues at the individual level. While under-investments in research regarding aging ought to be remedied, the autonomy, dignity, and welfare of individual participants must be respected in all research projects. Researchers, and research ethics boards (REBs), require guidance on principles to guide the ethical conduct of research involving older participants, especially those who may have special vulnerabilities arising from lack of mental capacity or dependent living circumstances.

Various studies report that older people are unjustifiably excluded from participation in some research. For example, a 2000 U.K. analysis of 155 protocols submitted to an REB found that 85 of the studies (55%) unnecessarily excluded older participants (Bayer & Tadd, 2000). A 1997 study of clinical trials revealed that "a third of the original research papers in major medical journals excluded elderly people without justification" (Bugeja, Kumar, & Banerjee, 1997, p. 1059). This analysis was repeated in 2004 and revealed that "although matters have improved a little, almost 15% of papers still unjustifiably excluded older people, and that fewer than 5% of the papers published were specific to older people" (Habitch & McMurdo, 2008; McMurdo, 2005, p. 1036). An analysis of exclusion criteria for randomized controlled trials published in high-impact medical journals between 1994 and 2006 found that 38.5 per cent of trials excluded persons over age 65 (van Spall, Toren, Kiss, & Fowler, 2007).

Exclusion of older people from research may stem from: (a) concerns that older people will be difficult or vulnerable participants; (b) worries about additional complexities and costs of recruiting and retaining older individuals; and (c) the potential for co-morbidities and poly-pharmacy. Such exclusion may compromise the generalisability of research findings, meaning there is inadequate evidence to support evidence-based medicine for older populations (Scott & Gyatt, 2010). Several strategies have been proposed to overcome these issues: (a) regulators should look for evidence that the target population for a new therapeutic has participated in clinical trials; (b) research funders and REBs should require reasons for age-based exclusions and "should recognise as unethical applications proposing to apply arbitrary and unjustified age restrictions" (McMurdo, 2005, p. 1037); and (c) funding agencies should ensure that resources are available to address barriers to research participation by older persons (e.g., transportation and communication aids).

In Canada, the Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans (TCPS) addresses unfair exclusion from participation in research on the basis of age, noting that the principle of justice requires that REBs and researchers consider the need for accommodations to remedy barriers that hinder older persons' participation in research. The TCPS also provides guidance on consent to participate in research. Researchers have a legal and ethical duty to obtain valid consent from individuals prior to their participation in research. For consent to be valid, it must be fully informed and be given voluntarily by a person with capacity. Where an older person lacks capacity to consent, a substitute decision maker (SDM) may have authority to permit the elder's participation in research, subject to provincial legislation and ethics guidance provided by the TCPS.

Researchers should be aware of any requirements or limitations under provincial laws. For example, British Columbia's *Health Care (Consent) and Care Facility (Admission) Act*, R.S.B.C. 1996, c. 181, and Alberta's *Personal Directives Act*, S.A. 2000, c. P-6, preclude an SDM from giving consent to remove tissue for research purposes and to consent to experimental procedures that offer little or no therapeutic benefit. In general, SDMs have an obligation to act in the best interests of the older person and to take account of any known wishes or beliefs that may be relevant to participation in research.

A participant who does not have capacity to give consent may nonetheless have the ability to express some preferences about research activities. Researchers must attempt to seek the participant's input or assent, and where the individual indicates she or he does not wish to participate, this dissent should preclude participation, even if an SDM has given permission (Black, Rabins, Sugarman, & Karlawish, 2010).

It is also important to note that capacity may fluctuate during the course of a research project. Where an older person regains capacity after an SDM has authorised participation in a research study, researchers must seek informed consent from the participant regarding their continuing participation. Participants with capacity have the right to make their own choice about research participation and to withdraw from a study.

Advance directives are tools that allow a person to express their wishes about health care and other personal matters in anticipation of a future state of incapacity. All Canadian provinces and territories, except New Brunswick and Nunavut, have legislation on advance directives (Dalhousie University's Health Law Institute has a useful website with links to relevant legislation across Canada: http://as01.ucis.dal.ca/dhli/cmp_advdirectives_faq/default.cfm). Whereas some provincial laws imply that advance directives may address research participation, it has been noted that "absence of official guidelines regarding ARDs [advance research directives] renders this mechanism susceptible to misuse, under-use, or non-use in instances where it could be advantageous for individuals, their families/caregivers, and progress in dementia research and treatment" (Pierce, 2010, p. 623). The draft second edition of the TCPS (which is not yet in effect as of September 1, 2010) proposes to give more guidance on advance directives for research participation. Although the advance directive allows an individual to express preferences regarding future research participation, consent of an SDM would still be required to authorize participation of a person who does not have capacity.

The TCPS also provides guidance for research involving persons who live in institutional settings or situations of dependency. Researchers and REBs must ensure that a potential participant's living situation does not compromise

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the ability to give voluntary and informed consent to research. At the same time, stereotypes about vulnerability should not lead to inappropriate exclusion from opportunities to participate in research.

Conclusion

The aging of the population is a key policy issue confronting Canadian governments, funding agencies, researchers, and health and social service providers. The health care and other needs of this aging demographic is best guided by research that provides findings and evidence relevant to older persons. Research from multiple disciplines that appropriately includes older participants with due attention to ethical issues related to consent and capacity will help inform best practices in health care, social supports, and other important areas. At the macro level, calls for more investments in aging-related research must be addressed through decision processes that meet standards of fairness and accountability for reasonableness.

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