

**BIOMEDICAL EXPERIMENTATION INVOLVING
ELDERLY SUBJECTS: THE NEED TO BALANCE
LIMITED, BENEVOLENT PROTECTION WITH
RECOGNITION OF A LONG HISTORY OF
AUTONOMOUS DECISION-MAKING**

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INTRODUCTION

The age-related dependence experienced by many of the elderly raises fundamental questions that must be addressed in the context of their consent to participate in biomedical experimentation or other non-therapeutic medical procedures. There are those elderly individuals who have suffered a significant decline in cognitive capacity because of the insidious progression of dementia, particularly that of the Alzheimer type. These individuals will not meet the criteria for competence to consent to research and the obvious question that arises is whether they should be eligible at all for participation in experimentation. Other elderly adults may not have experienced any significant degree of cognitive impairment but they may be nonetheless in a dependent position because of factors related to their age. In their case, the question is how can we ensure that any consent that they may give to submit themselves to experimentation is, in fact, a genuinely free and informed consent?

The protective concern for the elderly as a distinct group is based on a developing bedrock of empirical research. There is little doubt that the elderly are peculiarly susceptible to a number of forms of abuse: in particular, physical abuse, emotional abuse, financial abuse, and neglect. It has been estimated that as many as 100,000 elderly Canadians¹ have recently suffered some form of serious maltreatment within

¹ E. Podnieks *et al.*, *National Survey on Abuse of the Elderly in Canada* (Toronto: Ryerson Polytechnical Institute, 1990).

their own homes. It has also been shown that abuse may be a significant problem in both public institutions and private facilities that provide care for the elderly in Canada.² Thus, research has unearthed cases where, in large proportions, those individuals and institutions that have been entrusted with protecting the elderly have in fact become their abusers. With respect to research, it is critical that exploitation and mistreatment by those engaged in biomedical experimentation should not be added to the list of abuses to which the elderly are vulnerable.

While the need for the protection of the elderly is becoming increasingly evident, it is also necessary to acknowledge that they have already enjoyed a great deal of decision-making autonomy during their lives. It has been noted that "an overdose of benevolence can be as harmful as the absence of protection and assistance" and that "limited, benevolent intervention" is needed in the case of vulnerable elderly adults to ensure that they "receive the most effective but least restrictive and intrusive form of assistance, support or protection necessary to meet their needs".³ In the specific context of consent to research, therefore, it is difficult not to agree with Cassel who warned that we should be careful not to permit well-intentioned paternalism to extend to the point where we do not allow the elderly "the choices and freedoms that we would allow other people, constricting their experiences unnecessarily."⁴

OVERCOMING A HISTORY OF NEGLECT

The elderly have experienced a history that, until recently, was marked by widespread indifference to their special health needs, and accordingly they have lagged behind other sectors of society in terms of medical advances that are of particular relevance to their health care. Indeed, one author has commented that geriatric research "has not been perceived as being as glamorous or rewarding as high-tech research in the acute care setting and has suffered from under-funding and limited visibility in the scientific community".⁵ Neglect of the elderly by researchers has also been a feature in the reports of various special commissions or learned bodies.⁶

² L. Belanger *et al.*, *Les Cahiers de L'Association Québécoise de Gerontologie* (Association Québécoise de Gerontologie, 1981).

³ R.M. Gordon & S.N. Verdun-Jones, *Adult Guardianship Law in Canada* (Scarborough, Ont: Carswell, 1995) at 1-28.

⁴ C.K. Cassel, "Informed Consent for Research in Geriatrics: History and Concepts" (1987) 35 *Journal of the American Geriatric Society* 543 at 543.

⁵ C.K. Cassel, "Ethical Issues in the Conduct of Research in Long Term Care" (1988) 28 *The Gerontologist Supplement* 90 at 91.

⁶ None of the leading reports in this area specifically included the elderly in their discussion of the special populations in need of particular protection in the context of the research process. See for example: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Research Involving Those Institutionalized as Mentally Infirm: Report and Recommendations* (Bethesda, Md.: The Commission, 1977) [hereinafter *National Commission: Research Involving Those Institutionalized as Mentally Infirm*]; Law Reform Commission of Canada, *Working Paper No. 61: Biomedical Experimentation Involving Human Subjects* (Ottawa: Law Reform Commission of Canada, 1989); and A.D. Milliken, "Position Paper: The Need for Research and Ethical Safeguards in Special Populations" (1993) 38 *Canadian Journal of Psychiatry* 681 at 684.

Traditionally, research with the elderly was regarded as highly unfeasible. There were intractable practical difficulties associated with obtaining their consent for research, and governments were unwilling to address those difficulties because of the prevailing apathy concerning the needs of the elderly in general. Although the National Commission's *Research Involving Those Institutionalized as Mentally Infirm: Report and Recommendations*⁷ — much of which might have applied to the elderly — was never officially approved, it effectively stifled much potential research “because investigators and administrators had real concerns about the regulations and about their own risk management concerns to avoid scandals”.⁸ Therefore, societal indifference to the special concerns of the elderly, their complexity as subjects for research, and the problems associated with gaining their consent all served historically to dampen the enthusiasm of the medical community for research into their needs.

Ironically, during the period when institutionalized populations were widely employed as research subjects to achieve medical advances of general application, universal neglect of the elderly resulted in their protection from much abuse. They were widely regarded as being unsuitable subjects because, often, they were suffering from multiple disorders or dysfunctions that would be likely to complicate or distort the experimental results.⁹ Thus, with the exception of the discussions of some notable examples of abuse among institutionalized populations, the elderly were neglected both as the topic of, and as potential participants in, research.¹⁰

Changing demographics and the elderly's “growing prominence . . . as a market for the therapeutics industry”¹¹ have sparked increased interest in geriatric research and have fostered a growing recognition of the need to face the problems associated with safeguarding their interests and obtaining consent for their participation. The obvious connection between a developing interest in research with a special population and a rising concern for that population's welfare has rendered further neglect unacceptable. It has been argued that “the exclusion of older people from

⁷ See *National Commission: Research Involving Those Institutionalized as Mentally Infirm*, *ibid.*

⁸ C.K. Cassel, “Research in Nursing Homes: Ethical Issues” (1985) 33 *Journal of the American Geriatric Society* 795 at 796.

⁹ As Swift has pointed out, “intersubject variability and the coexistence of confounding factors (such as concurrent disease and drugs) increases with age”. See C.G. Swift, “Ethical Aspects of Clinical Research in the Elderly” (1988) 40 *British Journal of Hospital Medicine* 370.

¹⁰ One notorious exception to the neglect of research among the elderly was a protocol from the Sloan-Kettering Cancer Research Center in New York. See E. Langer, “Human Experimentation: Cancer Studies at Sloan Kettering Stir Public Debate on Medical Ethics” (1964) 143 *Science* 551. Researchers from this Centre injected live cancer cells into long-term-care patients at the Jewish Chronic Disease Hospital to examine the immunologic response to malignant cells in those people likely to have suppressed responses owing to chronic illness. Twenty-two long-term-care patients were enrolled in the experiment but neither they nor their relatives were informed of the experimental nature of the study or of the fact that the injections contained cancerous cells. In reality, since many of the patients were demented, non-English speaking, or extremely deaf, it is likely that they were chosen precisely because they were not in a position to be informed of the nature of the experiment. When asked in a courtroom whether they had explained to the subjects that the injections contained malignant cells, the investigators replied, “[o]f course not; they never would have agreed to the study if we had told them that”. See Cassel (1985), *supra* note 8 at 796.

¹¹ See Swift, *supra* note 9.

clinical research is itself unethical;¹² it is unethical simply because “we know we can do a better job in the care of the elderly population if we do more research”.¹³

In keeping with this growing concern for the welfare of the elderly, recent interest on the part of the medical community in conducting research with this population has focused on areas of particular application to the elderly themselves. Thus, though the elderly may have been spared inclusion in unethical research in the past as a result of the complexity of their medical status, this very complexity is now the subject of ethically sound research into their needs. Research on the elderly has made progress in overcoming such obstacles as societal indifference and scientific complexity, but problems associated with obtaining the consent of the elderly to participate in research still remain.¹⁴

The Special Place of the Elderly and the Urgency of Caring for Their Needs

Questions of consent that arise in relation to biomedical experimentation involving a vulnerable population flow from a recognition of the particular social characteristics and needs of that population, and a sense of the urgency of attending to those needs, including research whose results may have a potential benefit for them.¹⁵ The recognition of both the urgency of extending the knowledge about their needs through research and the importance of guaranteeing them proper protections acknowledges the special place of these populations in society. Unfortunately, it has not been easy to identify the special needs of the elderly in the context of consent to biomedical experimentation because their special status has not, until relatively recently, been accorded the same degree of recognition as that given to, for example, children.¹⁶

Is the incentive to conduct research to be understood as being limited to the impact of changing demographics and the discovery of the elderly as a “market for the therapeutics industry”?¹⁷ How do the general public and the caregivers of the elderly view their efforts with respect to those adults who, while they were once full-fledged participants in society, now experience diminishing capacity? In terms of society’s pragmatic and varying commitments to different groups, one writer commented that,

we live in a highly urbanized, industrialized, technological society which emphasizes productivity and technical skills. Those who can contribute productively and skillfully to the economy are highly valued; those who no longer can, or are no longer allowed to, are

¹² *Ibid.*

¹³ See Cassel (1985), *supra* note 8 at 797.

¹⁴ See e.g. G. Hodge, “Ethics of Research with Dementia Sufferers” (1989) 4 *International Journal of Geriatric Psychiatry* 239; R.E. Kendell, “Ethics of Research with Dementia Sufferers: Comment” (1989) 4 *International Journal of Geriatric Psychiatry* 239; G. Langley, “Review of ‘The Clonidine Test in Patients with Dementia’” (1989) 4 *International Journal of Geriatric Psychiatry* 241.

¹⁵ For a general discussion of the notion of “vulnerability” in the research context, see Chapter 18.

¹⁶ See Chapter 19.

¹⁷ See Swift, *supra* note 9.

not valued. Predominant value orientations . . . leave the elderly in a vulnerable and devalued position.¹⁸

Thus, it may actually be that research into the needs of the elderly with the promise of finding solutions for their problems are just the result of a consequentialist approach. Such an approach would be founded on changing demographics that allow the elderly to have a voice like any other lobby group, and on concern that, eventually, the great majority among us will be joining their ranks. To reduce it to its basest level, the possible return on society's investment in the elderly is only now becoming clear.¹⁹ That return is encapsulated in the so-called "golden rule": do unto others as you would have them do unto you.

Recognition of the Elderly as a Special Population

Paradoxically, heterogeneity may be the common element that unites the elderly as a group.²⁰ Even a definition of age is controversial in relation to the elderly. For example, in establishing regulations for Institutional Review Boards in the U.S., "proposals to develop separate regulations for the elderly were dropped because it was impossible to define the aged as a population sharing any common characteristics".²¹ Furthermore, many elderly persons incapable of giving consent are institutionalized and/or may also be physically dependent on others for their daily care. All in all, definitions of the elderly as a class of individuals have traditionally waffled between recognition of their residual vigour and inapt, unfair comparisons with other vulnerable groups.

The emergence of a positive definition of "the elderly" from within the elderly population itself provides a key element for developing a cohesive understanding of the elderly as a population. Political activism among the elderly, such as "senior" and "grey power"²² movements, has contributed to an improved definition of the elderly as a community. This, in turn, has fostered the commitment of society as a whole to their welfare²³ and to an acknowledgment of their right to give or withhold consent in matters affecting their personal care. This is critical because, as has been

¹⁸ E. Ozanne, "Informed Consent and the Elderly: Professional Defence or Consumer Right?" in Law Reform Commission of Victoria, *Medicine, Science and the Law: Informed Consent* (Melbourne: Globe Press, 1987) 50 at 51.

¹⁹ See G.A. Sachs & C.K. Cassel, "Biomedical Research Involving Older Human Subjects" (1990) 18 *Law, Medicine & Health Care* 234 at 241.

²⁰ M.B. Kapp & A. Bigot, *Geriatrics and the Law: Patient Rights and Professional Responsibilities* (New York: Springer, 1985) at 177-8.

²¹ B. Stanley, ed., *Geriatric Psychiatry: Clinical, Ethical and Legal Issues* (Washington, D.C.: American Psychological Association Press, 1985) at 83.

²² See e.g. S.G. Rice, "Beyond War: Empowerment for Senior Citizens in a Nuclear Age" (1988) 15 *Journal of Sociology and Social Welfare* 73.

²³ "The law affecting the elderly is a reflection of how society regards older people, the relationships that exist between and among the generations, the views people have about growing old, and the passage of time in another era". See E.S. Cohen, "Realism, Law and Aging" (1990) 18 *Law, Medicine & Health Care* 183 at 184.

suggested, “special attitudes and assumptions regarding aging and the aged, whether emanating from a sincere altruistic instinct to protect those we perceive as vulnerable or from a perverse ageist bias akin to other irrational ‘isms’, shape the ways in which society uses law to define the rights and responsibilities of the elderly”.²⁴

The more important question remaining, however, is whether we can build on these positive trends in social attitudes towards the elderly and develop a process for obtaining consent that is appropriate to their special needs. How, then, might we begin to characterize a positive and cohesive view of the elderly, and in what ways may the various elements of this view affect the manner in which issues of informed consent are perceived by those involved in the research enterprise?

The Special Nature of the Elderly Population

Dubler characterized the elderly as being divisible into two categories. The first category covers “those persons who are chronologically advanced in life’s predetermined span of years, but who are otherwise vigorous, independent, and autonomous adults”. In Dubler’s view, “there are no logically compelling reasons for distinguishing these adult persons from those ten or even thirty years their junior” and they should, therefore, be subject to the general research procedures and regulations that are applicable to the adult population at large.²⁵ The second category, however, consists of “the elderly incapable” whose various cognitive deficits inevitably dictate the need for a degree of special treatment. Dubler, therefore, contends that there is a case for making a clear distinction between the “chronologically advanced” and the “elderly incapable”, and for treating the former in the same manner as those who are decades younger and devising special methods for dealing with the latter.

There are serious drawbacks to this bifurcated characterization of the elderly. First, as Dubler herself notes, splitting the elderly into two sharply divided groups does not adequately account for the “gray areas”, or the marginal and fluctuating competence that is common in those whose capacity is affected by the aging process.²⁶ In other words, it does not readily promote the development of “appropriate standards for the treatment of those with some compromised intellectual, emotional and judgmental capacities and some residual capacity . . .

²⁴ M.B. Kapp, “Introduction: Law and Aging” (1990) 18 *Law, Medicine & Health Care* 181.

²⁵ See N.N. Dubler, “Legal Judgments and Informed Consent in Geriatric Research” (1987) 35 *Journal of the American Geriatric Society* 545.

²⁶ A study by Stanley, Stanley & Pomara revealed that “[t]he elderly demonstrate poorer comprehension [than their younger counterparts] of each of the specific elements of informed consent information, that is, knowledge of risk, benefits, and purpose of the project and procedure. Thus, as a group, geriatric patients may have some impairment in their competency to give informed consent to research. However, this impairment does not appear to have a significant impact on the quality of their decisions”. See B. Stanley, M. Stanley & N. Pomara, “Informed Consent in Geriatric Patients” in B. Stanley, ed., *Geriatric Psychiatry: Clinical, Ethical and Legal Issues* (Washington, D.C.: American Psychological Association Press, 1985) 17 at 26–27.

precisely the situation that describes many elderly persons with some cognitive deficits".²⁷

In this regard, it is important to underscore the value of a functional approach to competency assessment, rather than on global determinations of competence.²⁸ This approach seems ideally suited to a class of individuals whose capabilities may gradually diminish in a piecemeal fashion, and who are otherwise entitled to be presumed competent.

Creating legal distinctions within the elderly population on the basis of global assessments of capacity can also have deleterious effects on the community itself. Although heuristically sound, legal distinctions do not promote a community of individuals cognizant of each others' strengths and supportive of each others' needs; instead, they exacerbate the historical situation in which there has been a tendency for the able-bodied and quick-witted to disavow any connection with, or sympathy for, those of similar years who are deemed to be less capable. The bifurcated approach would create a class of individuals identified by their weakness and dependency and who, accordingly, are not challenged to retain their abilities following the precipitous declaration of their incompetence, and another class of elderly persons who, though largely functionally independent, may suffer as a result of masked inabilities that they are afraid to reveal lest they be adjudged incompetent.²⁹

For the elderly, the rate of decline is a highly individualized process; there is very little correlation between the rates of aging from one individual to another. Many individuals in our society require assistance in managing their personal affairs in their sixties or seventies while others continue into their eighth decade as leaders in government or their chosen professions. Moreover, a rapid decline in functioning, such as that precipitated by the loss of a spouse, has often been observed in certain elderly persons while others experience a much more gradual decline in their abilities.

The marked variation in the observable onset, progress, and effects of the aging process all point to perhaps the central heuristic confusion with respect to the definition of the elderly as a special population: that, although incapacity is age-

²⁷ See Dubler, *supra* note 25 at 546.

²⁸ See D.N. Weisstub (Chair), *Final Report: Enquiry on Mental Competency* (Toronto: Queen's Printer, 1990) at 74.

²⁹ But see Dubler, *supra* note 25 at 548:

Should . . . [specific regulations] be for all elderly persons, as a class, or for the subset of persons of diminished capacity or mental infirmity? The latter option is preferable both for individual determinations and for public policy reasons. Designating all elderly persons as a class in need of special protection may tend to further separate and stigmatize all elderly persons. Ageism need not be provided with any further support.

This view addresses concerns that arise in an environment in which global assessments of (in)competence tend to stigmatize persons, and in which protections established through regulations tend to be inflexible. However, in the context of decisional capacity determinations, recognition of the possibility of diminished capacity among the elderly, sensitively handled, is neither disrespectful, nor does it promote ageism. Rather, it provides protection from the possibility of exploiting a consent obtained from those not yet deemed incapable of giving it.

related in the elderly, there is no clear correlation between chronological age and declining capacity.³⁰ That is, because we cannot easily determine at what age one becomes “elderly”, we have been reticent to acknowledge the elderly as a distinguishable class of persons. In the past, society has tended to make inapt comparisons with children and to regard the elderly as too heterogeneous to be understood as a special population with common needs and interests.³¹ In addition, it has tended to doubt that an age-based class of individuals can exist beyond strict chronological parameters. Nevertheless, despite these persisting tendencies, more positive images are gradually emerging of a cohesive community of elderly persons that is striving to retain and maximize their capacity for independence and self-determination — a capacity which society at large possesses and which they themselves once took for granted.

Alzheimer’s Dementia and its Influence on Models of Consent for the Elderly

In the preceding material, we have provided a characterization of our historical neglect with regard to the elderly. This neglect has been attached to a resistance to attend to their needs and even to the recognition of this population as deserving a special status.³² A disease such as Alzheimer’s, which especially inflicts the elderly, has become such a common occurrence, due to increased longevity, that there is a strongly-sensed need in our society to generate an effective response through research.

Alzheimer’s Dementia (AD) is “a condition marked by continued cognitive deterioration beginning with simple forgetfulness and ending with the inability to eat, to recognize loved ones, and to control one’s bodily functions”.³³ “The average

³⁰ As Bowsheer *et al.* note:

The diversity that exists among elderly people increases with age, owing to the effects of varied life events, environments and resources. Such effects influence the course of development of frail elderly people. Development is time and change dependent. For these reasons, the degree of change for any elderly person or group of elderly people can only be measured by taking measurements across time. . . . The false assumption of homogeneity, that is believing that 60-year-olds are like 90-year-olds, can be prevented by the selection of subjects by cohort groups. True differences between the “young-old” and the “old-old” will then be more clear. When subjects are “lumped” into broad age groups, the ability to generalize from the data obtained is seriously jeopardized.

See J. Bowsheer *et al.*, “Methodological Considerations in the Study of Frail Elderly People” (1993) 18 *Journal of Advanced Nursing* 873 at 874.

³¹ Glass reaffirms the view that “[i]t is legitimate to consider the elderly as a group for some purposes and to do so without stereotyping them”. In so doing, she emphasized the need to respect “the elderly person’s altered value system and perception of risk, whether ‘accurate’ or not”. See K.C. Glass, “Informed Decision-making and Vulnerable Persons: Meeting the Needs of the Competent Elderly Patient or Research Subject” (1993) 18 *Queen’s Law Journal* 191 at 204, 224.

³² R. Ratzan, “Being Old Makes You Different: the Ethics of Research with Elderly Subjects” (1980) 10:5 *Hastings Center Report* 32.

³³ A. Moorhouse, “Ethical and Legal Issues Associated with Alzheimer’s Disease Research and Patient Care: To do Good Without Doing Harm” in S.N. Verdun-Jones & M. Layton, eds., *Mental Health Law and Practice Through the Life Cycle: Proceedings from the XVIIth International Congress on Law and Mental Health* (Burnaby, B.C.: Simon Fraser University, 1994) 43 at 43.

duration of the illness, from first onset to death is 8.1 years, although the time from the diagnosis to death averages 3.4 years. The duration is unpredictable, however, and can last up to 25 years.³⁴ Among the many tragic consequences of AD is its effect on the ability of its sufferers to consent to participation in research that may yield valuable knowledge in the search for its prevention, treatment, and cure. AD diminishes global cognition and leaves the “capacity [to consent] progressively impaired and ultimately extinguished”.³⁵

Major ethical and legal problems arise in the context of research into AD because such research is generally of a non-therapeutic nature. Although AD research subjects may contribute to the advancement of scientific knowledge about this disease, they generally will not receive any direct and immediate benefit for themselves as a consequence of their participation.³⁶ Furthermore, given the short lifespan that may be expected by AD research subjects, any improvements in treatment that may flow from AD research are almost certain to be limited in their impact to future sufferers. This inevitably raises the question of whether incompetent patients should be permitted to participate in AD research at all.

In this respect, researchers find themselves perched uncomfortably on the horns of a dilemma. Since their research will, in many cases, be non-therapeutic in nature, there is, on the one hand, considerable uncertainty as to whether, at common law, a valid third-party consent can be given on behalf of incompetent subjects.³⁷ On the other hand, there is no doubt that the scourge of AD will only be fought on a more effective basis if we increase our scientific understanding of the disease through systematic research. A further difficulty regarding research on AD is that it has no acceptable animal model, thereby necessitating the use of human subjects.³⁸

Campion, among others, has identified the urgent need for AD research to continue notwithstanding the problems associated with obtaining the consent of subjects who are incompetent as a consequence of the disease itself:

Ultimately, the future care of SDAT patients and the hope of improving that care relies very largely upon research. The costs of the disease are staggering — in hard dollars and in human despair — that we cannot afford to let Alzheimer’s research become stalled or, worse, to die the death of a thousand qualifications. No disease affects us more profoundly nor threatens us more tangibly than Alzheimer’s. Because it is so common and so highly age-related, the care of the Alzheimer’s patient is closely linked to the health care of the elderly in general, and of the seriously impaired elderly in particular.³⁹

³⁴ Congress of the United States, Office of Technology Assessment, *Losing a Million Minds: Confronting the Tragedy of Alzheimer’s Disease and other Dementias* (Washington, D.C.: U.S. Government Printing Office, 1987).

³⁵ See V.L. Melnick *et al.*, “Clinical Research in Senile Dementia of the Alzheimer Type: Suggested Guidelines Addressing the Ethical and Legal Issues” (1984) 32 *Journal of the American Geriatric Society* 531.

³⁶ Moorhouse, *supra* note 33 at 43.

³⁷ See Chapter 8.

³⁸ See Melnick *et al.*, *supra* note 35 at 531–532; Moorhouse, *supra* note 33 at 44; E.W. Keyserlingk *et al.*, “Proposed Guidelines for the Participation of Persons with Dementia as Research Subjects” (1995) 38 *Perspectives in Biology & Medicine* 319 at 319.

³⁹ See E.W. Campion, “Ethical Issues in the Care of the Patient Involved in Alzheimer’s Disease Research” in V.L. Melnick & N.N. Dubler, eds., *Alzheimer’s Dementia: Dilemmas in Clinical Research* (Clifton, N.J.: Humana Press, 1985) 71 at 76.

The intractable difficulties associated with obtaining informed consent from AD patients to participation in research have considerably limited the range of potential subjects.⁴⁰ On the one hand, recruitment of research subjects in the early stages of the disease is inefficient because the early symptoms of AD are common to a variety of other conditions.⁴¹ On the other hand, recruitment in the later stages is problematic because cognition has usually deteriorated to such a marked extent as to render communication virtually impossible. Thus, researchers have largely been required to confine their recruitment efforts to a very narrow window of time between the making of the diagnosis and the onset of incapacity.

As disturbing as AD is, both the incentives that it creates for research and the problems that it presents for the ethical conduct of that research are only the more striking examples of the incentives and problems that are associated with cognitive-aging research in general. Elderly persons may experience a variety of physical dependencies and disabilities in common with members of other vulnerable populations; however, it is cognitive aging, found in the frighteningly unexpected, rapid and relentless shape of Alzheimer's Dementia, that is at the heart of the special needs of the elderly with respect to their participation in biomedical experimentation. Growing awareness of the suffering caused by AD has certainly instilled determination in the medical community to develop ways of treating those suffering from it and it has also created the incentive for legal and ethical experts to search for ways in which research into AD can be conducted with human participants who are actually suffering from it.

Many elderly persons have cognitive abilities that are just as sound as those of younger adults and many others have a range of health requirements that are unrelated to diminishing cognitive capacity. Nevertheless, AD patients are a compelling example of the typical challenges experienced by the elderly in the context of their ability to consent to participate in research that could assist in identifying their own particular needs. Consequently, it will be helpful to draw on examples from the experience of Alzheimer's research when discussing the various practical problems faced by many elderly adults, such as loss of memory and the

⁴⁰ For a discussion of the ethical justifications for involving elderly persons in research protocols, see generally, B. Brown, "Proxy Consent for Research on the Incompetent Elderly" in J.E. Thornton & E.R. Winkler, eds., *Ethics in Aging: The Right to Live, the Right to Die* (Vancouver: University of British Columbia Press, 1988) 183. See also H. Helmchen, "The Problem of Informed Consent in Dementia Research" (1990) 9 *Medicine and Law* 1206.

⁴¹ Stanley amplifies the discussion of the problems of recruitment in the early stages of Alzheimer's for research:

Generally, in the early stages, where the deficits are mild, the diagnosis is made with much less certainty than in its later stages. Therefore, it is possible that some individuals having mild cognitive impairment may not only be wrongly diagnosed as having Alzheimer's disease, but may also be enrolled in studies and subjected to unnecessary risks. Also, in progressive illnesses such as Alzheimer's disease, it may not be possible to detect underlying biochemical changes early in the course of the illness. This, in turn may yield inconclusive findings or falsely negative results.

B. Stanley, "Senile Dementia and Informed Consent" (1982) 1 *Behavioral Sciences & the Law* 551 at 562.

inability to read small print, as well as the more complex problems, such as those of assessing whether the individuals' dependency on others is a coercive influence on their willingness to participate in research, or whether a family member can be relied on to provide an accurate representation of the participant's competent wishes. In short, the growing understanding by the medical, ethical, and legal communities of the ways in which AD patients may participate in research can be used as a model for research on senility and other types of conditions specific to the elderly.

THE ELDERLY AND CONSENT TO PARTICIPATE IN RESEARCH

The ethical and legal communities face three principal concerns when searching for ways in which those elderly adults who are experiencing diminishing capacity as a result of cognitive aging⁴² may participate in medical research. The first concern relates to the ability of the elderly to consent; this can be compromised by a variety of practical problems, for which there may be equally practical solutions. Surprisingly, ways of making the potential harms and benefits of a protocol understandable to prospective patients who are cognitively impaired are only just now being developed. The second concern involves devising methods of responding to unpredictable, fluctuating and declining cognitive abilities and the presumptions or determinations of capacity to consent that are associated with these abilities. The third concern arises in those situations where there is either a serious doubt concerning the capacity of the elderly individual to consent, or where it is clear that the individual no longer has that capacity; in these circumstances, it becomes necessary to address the whole question of substitute decision-making and the potential role of the care-giver in the consent process.

Practical Problems and Solutions

It is now becoming evident that efforts to satisfy the requirements of informed consent with elderly subjects can teach researchers a great deal about the relationship between the capacity for self-determination and the more mechanical and mundane abilities of those who are asked to provide their consent. For the elderly, the appreciation of the nature of independent decision-making and the resulting capacity to consent may endure despite a decline in other abilities such as perception or memory.⁴³ Adults tend to consider the mechanics of the physical abilities they once took for granted only when they begin to experience difficulties with them or when they sense that new limitations are being imposed on their freedom of movement; in just the same way, careful attention to the ethical and legal aspects of the consent process in relation to the elderly has only recently been responsible for researchers acquiring more knowledge about the strictly mechanical aspects of obtaining informed consent.

⁴² Either normal or pathological aging (*i.e.* as a result of Alzheimer's Dementia).

⁴³ See Weissstub, *supra* note 28 at 28–29.

Several studies assessing the effectiveness of the consent process with respect to informing the patient have suggested that subjects “may have inadequate comprehension and memory of the materials even though they sign the consent document and state that they understand the information presented”.⁴⁴ However, “even though comprehension is assumed to be necessary for a rational decision about research participation, most evaluations have actually measured memory (e.g. immediate or delayed recall) . . .”. despite the fact that “poor memory or recall does not necessarily imply poor comprehension”.⁴⁵ Moreover, it has been pointed out that “(t)he fact that individuals forget information following a decision does not mean that they did not use it in their decision making”.⁴⁶ Indeed, the confusion caused by failing memory could be clarified by encouraging participants in research to retain and refer to the information sheets throughout the duration of the study in question.⁴⁷

Another study of consent with the elderly made the simple observation that many elderly persons “have slower reaction time and require more time to process complex information” and are more likely than others to have hearing or vision impairments,⁴⁸ and they may be more prone to experiencing comprehension problems arising from the questionable readability of consent forms.⁴⁹ The use of large-type forms, written in simplified language and presented in information sessions tailored to suit the time requirements of the prospective participant, provides an eminently practical method of maximizing the ability of individuals to engage meaningfully in the decision to participate in research. Furthermore, proper practical adjustments that enable the involvement of those who are experiencing diminishing capacity in relation to the consent process should no longer be considered optional.

In the last decade, researchers in California extensively examined the health care decision-making process as it affects both elderly and developmentally disabled subjects.⁵⁰ Tymchuk argued that the current understanding of the process of informed consent is flawed. Consent is currently conceived of as an “instantaneous

⁴⁴ H.A. Taub, “Comprehension of Informed Consent for Research: Issues and Directions for Future Study” (1986) 8:6 IRB 7.

⁴⁵ See H.A. Taub, G.E. Kline & M.T. Baker, “The Elderly and Informed Consent: Effects of Vocabulary Level and Corrected Feedback” (1981) 7 *Experimental Aging Research* 137. See also A. Meisel & L.H. Roth, “Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies” (1983) 25 *Arizona Law Review* 388; Weisstub, *supra* note 28 at 167–68.

⁴⁶ See Stanley, *supra* note 41 at 555.

⁴⁷ See Taub, *supra* note 44 at 8.

⁴⁸ R.L. Schwartz, “Informed Consent to Participation in Medical Research Employing Elderly Human Subjects” (1981) 75 *Journal of Contemporary Health Law & Policy* 15 at 24, 55.

⁴⁹ See Taub, *supra* note 44.

⁵⁰ A.J. Tymchuk, J.G. Ouslander & N. Rader, “Informing the Elderly: A Comparison of Four Methods” (1986) 34 *Journal of the American Geriatric Society* 818; A. J. Tymchuk *et al.*, “Medical Decision Making Among Elderly People in Long Term Care” (1988) 28 *The Gerontologist Supplement* 59; A. Tymchuk, L. Andron & B. Rahbar, “Effective Decision-making/Problem-solving Training with Mothers who have Mental Retardation” (1988) 92 *American Journal of Mental Retardation* 24; A. Tymchuk, “An Alternative Conceptualization of Informed Consent with People who are Elderly” (1992) 18 *Educational Gerontology* 135.

event”; this conception fails to consider the underlying “information processing framework”⁵¹ and it presumes that “one method would be satisfactory for all people”. Revision of the current conception is urgent because

... without such adaptations not only would there be a great likelihood that these populations would not understand what it is they are agreeing or disagreeing to but also limits would erroneously be placed upon our understanding of their capabilities. Both of these results would invariably lead to an abrogation of the principles of self-determination and autonomy on which the concept of informed consent is based.⁵²

Tymchuk recommended a model for consent based on a cognitive structure revolving around “three distinct phases: input, assimilation and output”.⁵³ By “operationalizing” each of the phases, it is possible to identify and attend to any difficulties experienced by the individual subject. For example, Tymchuk and his group found that elderly patients in long-term care facilities read on average at a grade-five level and that, by simplifying the information presented and questioning the participants after receiving it, the material was much better understood. In addition, one of these studies supported the contention that a storybook format incorporating large type would contribute positively to the acquisition of an overall understanding of the proposed medical procedure and its possible consequences.⁵⁴ One valuable study demonstrated that the exposure of nursing home residents to a simplified patient’s Bill of Rights significantly improved the understanding, and application, of the individual’s rights in the consent process.⁵⁵

As indicated by these studies and by the ongoing work of specialized teams such as that of the Competency Clinic for the Elderly at Baycrest Centre,⁵⁶ there is much to be learned about the effect of aging on cognitive processes and the relationship of cognitive aging to the capacity to consent. In 1990, the *Enquiry on Mental Competency* noted that a precise notion of psychiatric “normality” in the elderly was poorly understood because “cognition is usually measured in reference to the prototypic middle-aged adult”. Accordingly, it was recommended that cognitive parameters not be weighed as heavily in assessing decisional capacity, and that self-functioning and sedimented life preferences⁵⁷ be accorded increased significance in

⁵¹ See Tymchuck, *ibid.* at 138.

⁵² *Ibid.* at 136.

⁵³ This structure was derived from F. Craik & R. Lockhart, “Levels of Processing: A Framework for Memory Research” (1972) 11 *Journal of Verbal Learning and Verbal Behaviour* 671.

⁵⁴ See Tymchuk, Ouslander & Rader, *supra* note 50; Tymchuk *et al.*, *supra* note 50.

⁵⁵ The results of which were published in Tymchuk, Ouslander & Rader, *ibid.*

See also D.M. High *et al.*, “Guidelines for Addressing Ethical and Legal Issues in Alzheimer Disease Research: A Position Paper” (1994) 8:4 *Alzheimer Disease and Associated Disorders* 66 at 70–71 for a discussion of the importance of communication in obtaining the informed consent of elderly persons.

⁵⁶ See M. Silberfeld *et al.*, “A Competency Clinic at Baycrest Centre” (1989) 10 *Advocates Quarterly* 23; M. Silberfeld, “The Mentally Incompetent Patient: A Perspective from the Competency Clinic” (1990) 11 *Health Law in Canada* 33.

⁵⁷ See Weisstub, *supra* note 28 at 161, explained the nature and significance of “sedimented life preferences” as follows: “Sedimented life preferences are the established patterns of behaviour and choices of the geriatric person. Choices that comport with an individual’s life preferences should be recognized in the absence of serious cognitive or functional deficits”.

assessing whether the actions of an elderly person reflected a capacity for self-determination. In sum, further research is likely to yield valuable insight into what is now coming to be regarded as a complex relationship between cognition and self-determination; indubitably, elderly individuals, whose abilities in both areas⁵⁸ once passed unchallenged, are likely to be both valuable participants in, and direct beneficiaries of, such research.⁵⁹

Generational and Cultural Factors

“*Research* can be an emotionally laden term that frequently causes mistrust of the researcher’s objectives and arouses concern about the well-being of the patient”.⁶⁰ In addition, generational differences tend to result in the elderly’s being less accustomed to the formal consent procedures applicable to minimally invasive procedures and to the protocols employed in the highly regulated fashion of today’s research. Accordingly, images of the high-risk, poorly regulated research of past decades may be conjured up by any reference to “medical research”, and the resulting anxiety may be increased by the formality of a written consent procedure. In fact, it is only to be expected that those who were part of a generation that did not have the benefit of the requirement of informed consent, even for highly invasive or risky treatment decisions, would have difficulty grasping the fact that extensive information is being provided to them with a view to gaining their consent to a minimally invasive procedure such as, for example, venepuncture. Although misgivings such as these are likely to change only with time, it is also probable that much assistance may be derived from promoting efforts to educate the general public as to the nature and significance of currently-required safeguards in research and the associated process of obtaining informed consent.⁶¹

Special attention should also be given to particular cultural backgrounds of certain elderly communities. In her letter to the Editor of the *New England Journal of Medicine*, Barbara Mishkin, in commenting on one study of the feasibility of obtaining informed consent “by proxy”, noted that:

all the foreign-born proxies for residents in the Jewish nursing home were from Eastern Europe, and that of those, only 18% consented to their relatives’ participation in the research Surprisingly, the authors provided no further analysis of the extent to which

⁵⁸ And whose autonomous preferences are often remembered by family or otherwise documented.

⁵⁹ An elderly person’s sense of well-being may be impaired if an opportunity to participate in the consent process is refused. Accordingly, it is crucial for researchers to be sensitive to the differential requirements of the elderly, particularly insofar as the methods by which informed consent is obtained are viewed as a tangible demonstration of respect for their individual autonomy. It is also important to recognize the differences in the nature and extent of the dignitary harms experienced by members of different special populations whenever there is a failure to respect their autonomy.

⁶⁰ E. Schiaffino-Purvis, “To the Editor” (1987) 316 *New England Journal of Medicine* 1029.

⁶¹ M.S. Brod & R.I. Feinbloom, “Feasibility and Efficacy of Verbal Consents” (1990) 12 *Research on Aging* 364. See Eisch *et al.* who found that “signing a form was more threatening for some of the participants than acutally agreeing to the research”. J.S. Eisch *et al.*, “Issues in Implementing Clinical Research in Nursing Home Settings” (1991) 22 *Journal of the New York State Nurses Association* 18 at 19.

country of origin or sociocultural background affected attitudes toward biochemical research. It is equally surprising that no one commented on the fact that most . . . [were likely to be] holocaust survivors who understandably may have strong negative feelings about human experimentation. Had I been a member of the institutional review board that reviewed this protocol, I would have urged recruitment from a different facility, in part because of the possibility that immigrant Jewish families might be offended by the proposed research.⁶²

Similarly, other groups, based either upon a perceived physical vulnerability due to a trauma, or because of an espoused religious belief system which creates a hyper-sensitivity to potential violations, will differ with respect to levels of resistance to research interventions, even when there is a calculable benefit to the group itself or in its relation to a wider population. Owing to the impact of generational and cultural factors, the relationship between informed consent and autonomy is therefore a complex one. While a sense of autonomy may be critical to the well-being of many elderly persons, demonstrating respect for that autonomy may not always require a strict adherence to the current requirements of informed consent: the precise procedures to be followed may vary in light of the particular cultural or generational background of the elderly subjects concerned. This is by no means to argue for dispensing with informed consent in the absence of a participant's objections. Rather, it is to point out that many elderly persons are accustomed to a relationship with health care practitioners that involves a greater degree of trust and a lesser degree of information than is currently desirable; they are more comfortable delegating the sometimes complex assessment of small risks of harm or potential benefit to a family member or their physician than they are in reviewing the information in its entirety. They too should be respected for this choice. In other words, sensitive consideration of the generational and cultural factors affecting the participation of the elderly in the consent process reminds us that informed consent is not an end in itself, but rather a means to promote the sense of autonomy and self-determination in those individuals asked to provide it. The requirements of informed consent should be structured to achieve that end, and not just to meet purely abstract specifications.

Capacity: The Problem of Uncertainty and the Use of Presumptions

Uncertainty with respect to capacity to consent to participate in research is common in elderly persons for at least three reasons. First, the decision-making capacity of an elderly person may be in a process of gradual or rapid decline, or it may be subject to fluctuation as a result of a variety of environmental, emotional or even pharmacological reasons. Accordingly, elderly persons may remain in a state of questionable capacity for an extensive period. Second, a variety of perceptual and cognitive faculties only peripherally related to a sense of self-determination among the elderly may be subject to decline in ways that mask the elderly's underlying

⁶² B. Mishkin, "To the Editor" (1987) 316 *New England Journal of Medicine* 1030, commenting on J.H. Warren *et al.*, "Informed Consent by Proxy. An Issue in Research with Elderly Patients" (1986) 315 *New England Journal of Medicine* 1125.

ability to consent. Finally, as the decision to participate in research is not generally the kind of decision that forms part of an individual's daily routine, it may be difficult to determine the extent to which the elderly are capable of making this kind of decision through observation of their abilities in other areas.⁶³

The problem of uncertainty with respect to capacity is common to health care decision-making involving members of several special populations. In the past, this problem has been resolved through the use of presumptions. Both presumptions and determinations are "socio-legal" in nature;⁶⁴ in other words, they are very often a function of society's understanding of the nature and difficulty of the decision in question as well as society's appreciation of the consequences of permitting an individual of uncertain capacity to make such a decision.⁶⁵

The interests of society with respect to the treatment decisions of other vulnerable populations may vary as the balance shifts from emphasizing the concern to ensure a high standard of health care — regardless of the effect a presumption of incapacity may have on the individual's autonomy — to promoting a concern to ensure respect for that autonomy. In addition, the current integration of the underlying principles of personal autonomy, "best interests" and community concerns favours individual autonomy.⁶⁶ The result of this integration is that the presumption of incapacity, even in its explicitly rebuttable form, has been eliminated, for example, in current Ontario legislation.⁶⁷

In the context of participation in research, where the underlying principles of "best interests" and community concerns may be somewhat at odds with one another, the autonomy principle takes on an even greater significance. It is

⁶³ One significant factor favouring decision-specific capacity noted in the *Enquiry on Mental Competency* is the difference in the "situational parameters" of different kinds of decisions. See Weisstub, *supra* note 28 at 81.

⁶⁴ "Although much studied in the biological and behavioral sciences, the term competency is so inextricably linked to social norms that it has become a value-laden concept serving the socio-utilitarian ends of assuring conformity in society". *Ibid.* at 32–33.

⁶⁵ Children, for example, have been historically regarded to be incapable of making treatment decisions, regardless of the empirical data either supporting or discounting the incapacity of any individual child in particular. The prime consequence of presuming young children incapable is that treatment decisions will be made by their physicians and those legally responsible for their care.

⁶⁶ The *Final Report* argued the point as follows:

Practical difficulties aside, the integration of personal autonomy, "best interests" and community concerns must reflect the legal and philosophical context in which it is being performed. Since there is not, and cannot be, an objectively "correct" specification of this integration, one must attempt to structure the testing of decision making capacity in such a manner that the applicable social values, as decided through the appropriate democratic processes, are incorporated and reflected in both the substance and procedure of the test.

At present, although this integration favours individual autonomy and, therefore, requires that presumptions, burdens, etc. favour the protection of individual rights, clear evidence of functional incapacity will rebut the presumptions and facilitate an intervention to protect the "best interests" of the individual in question. The entire testing process must reflect the autonomy and "best interests" principles while conforming to social needs for proportionality, administrative simplicity and relevancy of decision making.

Ibid. at 54–55.

⁶⁷ *Health Care and Consent Act, 1996*, S.O. 1996, c. 2.

increasingly accepted that the involvement of persons in non-therapeutic research cannot be justified on the basis of their “best interests”, except insofar as it reflects respect for their autonomy. Accordingly, in some of these situations where capacity may be in question, society may put autonomy aside, and presume individuals to be incompetent so as to protect them from participation in research. This presumption, however, may not be necessary in the current context of comprehensive ethical review of protocols. Indeed, as participation by adults in research is required to be a purely voluntary activity, and since either the lack of a decision or a decision not to participate would exclude them from protocols, a presumption of incapacity would serve only to provide greater assurance of exclusion.⁶⁸ This virtually absolute preclusion of participation in research is problematic insofar as it may conflict with the discernible desires of the elderly. Thus, despite the fact that we are caught between “too readily accepting a person’s decision to participate and too readily rejecting it (because both can constitute a wrong to the person)”,⁶⁹ there are strong arguments against the use of presumptions of capacity or incapacity to resolve the problem.

Capacity Determinations — Distinguishing the Tests of Capacity and Reasonableness

There remain many concerns that the continuing presumption of capacity may result in the participation in experimentation of those who are not capable of consenting. Therefore, it becomes necessary to address the difficult issues surrounding the determination of capacity. Having already stated that capacity determinations may themselves have a deleterious effect on an elderly person’s self-esteem, the questions of when a determination should be sought, who should make it, and on what basis it should be made, are all important considerations in this regard.⁷⁰

Accordingly, the nature of decision-making must be examined in a variety of decisional contexts. In the context of research, it must first be acknowledged that the procedure is not proposed for the benefit of the individual but rather for research purposes. Secondly, the question of voluntariness is of particular significance. In considering a method for assessing capacity, the functional abilities of the individual should be the basis for the assessment of capacity, rather than the individual’s status or the outcome of the decision-making process.⁷¹

On this note, academics and jurists have been slow to meet the challenge presented by the need to distinguish the assessment of capacity from the

⁶⁸ That is, if the elderly were presumed incapable, they would have to both volunteer to participate in research and demonstrate their capacity to do so. It is not clear that risk levels prevalent in research currently justify a level of caution that would require challenging their capacity, and hence their autonomy, in order to permit them to be enrolled in a protocol.

⁶⁹ See K.C. Glass & M.A. Somerville, “Informed Consent to Medical Research on Persons with Alzheimer’s Disease: Ethical and Legal Parameters” in J.M. Berg, H. Karlinsky, & F.H. Lowy, eds., *Alzheimer’s Disease Research* (Toronto: Thomson Professional Publishing, 1991) at 38–9.

⁷⁰ See generally Weisstub at 28.

⁷¹ *Ibid.* at 83.

reasonableness of the decision. For example, in a recent consideration of competence to consent to research with Alzheimer's patients, one writer contrasted the level of difficulty of health care decision-making in the context of treatment with that of research, on the basis of the kind of critical thinking required to engage in an independent assessment of the recommendations of a practitioner. It was noted that "only modest competence is needed to decide to follow one's doctor's advice" since "a prudent person would" do so; and that it would be wise to set a low "threshold of entry to indicated medical care" because to do otherwise "might compromise the well-being of people of borderline or uncertain competence".⁷² However, "as the recommended treatment becomes more speculative and invasive, more prone to adverse side-effects and liable to prove unsuccessful, the balance of advantage between receiving and rejecting the treatment shifts, and deciding not to undertake it may require no more capacity than accepting it".⁷³

Nevertheless, acquiescing to the course of action proposed by one's physician is generally less demanding on the capacity and competence of the patient than refusing to follow such advice. It is, therefore, critical to find ways to construct an environment in which the prospective participant in research will feel equally comfortable whether accepting or declining the request to enroll in a protocol.⁷⁴ With respect to the ease of doing "what a prudent person would," it is acknowledged on an evidential level that the more reasonable a decision appears, the easier it is for others to recognize it as a capable and voluntary decision. However, neither the difficulty of expressing one's desire to refuse the request of the researcher to participate, nor the difficulty of recognizing as competent a wish to do something other than that which a reasonable person would do, shed any light on the actual difficulty of the decision itself. In other words, conflating the nature and difficulty of the decision with the question of whether a socially acceptable outcome is achieved by acquiescing to the proposal of the researcher creates a problem; it glosses over the critical issues raised by the difficulty of making the actual decision involved and the capacity required to make it.

Capacity assessments, based on the reasonableness of the outcome and on the difficulty of distinguishing a decision that is idiosyncratic from one that is the product of incapacity or coercion, have been common, for example, in Canadian jurisprudence.⁷⁵ Case law has held that the information necessary to consent to research "may considerably exceed what needs to be given for therapeutic care

⁷² See B.M. Dickens, "Substitute Consent to Participation of Persons with Alzheimer's Disease in Medical Research: Legal Issues" in J.M. Berg, H. Karlinsky & F.H. Lowy, eds., *Alzheimer's Disease Research* (Toronto: Thomson Professional Publishing, 1991) 60 at 62.

⁷³ *Ibid.* at 63.

⁷⁴ Morris, in his discussion of conflicts of interest, notes that "[t]he method of presentation, type of data chosen for discussion, level of enthusiasm in describing one alternative versus another, and other factors all may be used, knowingly or unknowingly, by the clinician to influence or coerce patients during recruitment for clinical trials". See J.C. Morris, "Conflicts of Interest: Research and Clinical Care" (1994) 8:4 *Alzheimer Disease and Associated Disorders* 49 at 52.

⁷⁵ See *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask.C.A.) [hereinafter *Halushka*]; *Weiss v. Solomon*, [1989] R.J.Q. 731 (C.S.).

alone, and it needs to be better understood . . .”;⁷⁶ that no therapeutic privilege applies to relax the standard of fully informed consent;⁷⁷ and, consequently, that “a patient sufficiently competent to consent to therapy may not be sufficiently competent to decide on entering a research study . . .”⁷⁸ The question that needs to be asked, however, is whether it is more difficult *per se* to make the decision to participate in research than it is to make the decision to consent to treatment, or whether the possibility of undue influence simply makes it more difficult to recognize the voluntariness of the decision.

In distinguishing the considerations underlying the need to determine the capacity of an individual consenting to participate in research from one consenting to treatment, one writer discussed the problem of undue influence as follows:

We must maintain a constant vigilance (or index of suspicion) that the subject is possibly not acting in the truest sense of autonomy and needs therefore our most careful protection. It may be easy enough to allow cognitively impaired subjects to agree to investigative procedures in the name of respecting their own autonomy, if that agreement furthers our own projects. [However,] “[r]easonableness” criteria have been used in situations of evaluating competence to consent to treatment, not to experimentation. We might, in certain cases, support a measure of competence when the patient’s well-being is at stake but participation in research is more optional, and therefore we have no overriding paternalistic duty pressing us to question the “reasonableness” of the patient’s decision.⁷⁹

In other words, setting aside the question of the actual difficulty of the decision in both cases, the concern with respect to individual subjects’ capacity to consent to treatment is ensuring that they receive adequate health care, whereas the concern in the context of participation in research is that they be protected from having their possible susceptibility to undue influence exploited.⁸⁰

In the treatment context, there is significant social concern with respect to the consequences for the individual of an outright rejection of recommended treatment or even of a failure to make a decision to consent to that treatment. However, in the research context, where no direct benefit is intended and where the ethical review of protocols is, in part, intended to reduce the risk of harm, the social concerns would be twofold: first, with establishing a context in which the individual is genuinely free to consent or to refuse to participate; and second, with establishing a viable method for ensuring that the individual’s participation in this voluntary activity represents an *affirmation* rather than a *violation* of their autonomy. Once again, the reasonableness of the patient’s decision does not count so much as its voluntariness.

Jurists have recently begun to require direct evidence of functional incapacity and not just mere evidence of an “unreasonable” decision before they will consider displacing the presumption of capacity in a variety of contexts, including that of

⁷⁶ See Dickens, *supra* note 72 at 64.

⁷⁷ See Halushka, *supra* note 75.

⁷⁸ See Dickens, *supra* note 72.

⁷⁹ See C.K. Cassel, “Research on Senile Dementia of the Alzheimer’s Type: Ethical Issues in Informed Consent” in V.L. Melnick & N.N. Dubler, eds., *Alzheimer’s Dementia: Dilemmas in Clinical Research* (Clifton, N.J.: Humana Press, 1985) 99 at 103–105.

⁸⁰ The need to guard against the possibility of undue influence in this context is very similar to that which exists in the capacity to make a gift or a will.

treatment. The right to refuse treatment has not been held to be dependent on the ability to demonstrate the reasonableness of the decision; rather, it has been viewed as the logical correlative of the requirement of informed consent.

Evidencing Voluntariness

The problem of *formally* evidencing voluntariness in a context in which there is the possibility of undue influence may be novel in the field of medical research, but it has arisen in several areas of law, such as the law of wills and estates. The challenge of evidencing voluntariness in the course of testamentary disposition is similar to that which arises in the process of obtaining consent to participate in research on the part of those who are considered to be (or seem to be) of uncertain capacity; one party receives a gratuitous benefit (*viz.* the subject's participation) in a situation in which it may not be possible to verify the donor's actual intentions directly.

Evidencing voluntariness in testamentary disposition is achieved most commonly through the use of witnesses to the signing of a will. It is worthwhile to employ this device in the context of obtaining consent for research from individuals who are of uncertain capacity. Family members frequently are able to assist in the consent process not only by ensuring that the prospective participant understands the procedure as completely as possible, but also by assisting them to articulate their wishes. It is not clear to what extent the understanding of the elderly individual's wishes by family members is based on their comprehension of the individual's contemporaneous expressions or their familiarity with the "sedimented life preferences"⁸¹ of the individual; however, this is probably not important because the contemporaneous willingness to participate is a prerequisite for continued enrollment in experimentation regardless of any signed consent form or the attestation of any third party.

SUBSTITUTE DECISION-MAKING AND THE ROLE OF THE FAMILY IN THE CONSENT PROCESS

Undoubtedly, there remains a great deal to learn about how we may best provide practical assistance to potential research subjects whose capacity may have been diminished by the aging process. Suitable adjustments in everything from the design of packages of information materials, through the conduct and approach of the individual seeking consent, to the nature of the setting and the role of those present, can assist potential participants whose interest in self-determination continues despite the loss of their ability to exercise it easily. Further, the practice of encouraging family members to witness the consent of elderly persons may achieve a great deal by enabling those of uncertain capacity to have their wishes respected without harming their dignity either through questioning their capacity or appearing to transfer their legal right to consent to someone else.

⁸¹ See Weisstub, *supra* note 28.

Nevertheless, there are occasions upon which research is proposed in relation to subjects who are no longer able to articulate their attitudes toward medical research and participation. As much as researchers have been encouraged, and should continue to be encouraged, to devise alternatives to the involvement of subjects who cannot consent, there will remain occasions on which valuable research cannot be conducted without the participation of such subjects. On these occasions, if the research is to be conducted at all, and if respect for the autonomy of these individuals is to continue to be a requirement satisfied through the process of informed consent, the question must be posed as to how the wishes of these individuals may be represented in that process.

Research directives provide individuals with a way to document their wishes in advance.⁸² Further, to the extent that they may stipulate or require the interpretive support of family members or other nominated persons, they encourage participants to discuss their wishes with others while they retain capacity to consent. Finally, they may provide comfort to those anticipating diminished capacity and increased dependence by giving them the opportunity to take positive steps for the future, and possibly to make a valuable contribution to medical advances in areas of significance to them.

However, in the absence of an advance research directive, there is bound to be considerable debate concerning the desirability of permitting family members to represent the wishes of an incapable person in the context of a request to enroll that person in a research project. For example, in the context of Alzheimer's Dementia and other illnesses in which it is suspected that there is a genetic element,⁸³ family members may have a keen interest in the advancement of medical understanding.⁸⁴

In conferring a gratuitous benefit, it is essential that those who witness the voluntariness of the consent be disinterested parties (i.e. those who are not potential beneficiaries of the decision). The potential for a conflict of interest should disqualify one as a witness to the consent of the individual.⁸⁵ In response to this concern, the Task Force established by the U.S. National Institute on Aging included the following recommendation in their suggested guidelines for research in dementia:

8. Authorization by a "legally authorized representative"
 . . . substitute decision-makers should possess the following characteristics:

⁸² See also Chapter 11.

⁸³ For a discussion of the genetic basis of Alzheimer Disease and some related ethical issues, see S.G. Post, "Geriatrics, Ethics and Alzheimer Disease" (1994) 42 *Journal of the American Geriatric Society* 782.

⁸⁴ Moreover, there may be other sources of conflicts of interest on the part of a family member. For example, an overburdened caregiver may find it difficult to make an impartial decision about the participation of an incompetent family member in an experiment that involves keeping the latter in a medical facility for a fixed period; clearly, the prospect of a degree of welcome release from the incessant pressures associated with looking after the incompetent family member would inevitably place the caregiver member in a situation of conflict of interest.

⁸⁵ See Melnick *et al.*, *supra* note 35.

- a. No evident or substantial conflict of interest that would be likely to lead to a decision contrary to the best interests of the patient.
- b. An ability to participate in a vigorous, informed and conscientious manner in the decision.
- c. An ability to remain a vigorous advocate of the incompetent's interest in maintaining control of decision-making throughout the course of the patient's participation in research.

Clearly, it may be difficult for devoted caregivers to avoid being offended by potential disqualification, and it is equally true that recognition of the potential benefit to a caregiver might be a strong motivation for competent persons to consent to participation in non-therapeutic research. However, the extension of the limits of permissible research to include those who cannot provide contemporaneous informed and voluntary consent can only be justified if it can be shown not to violate the interest in autonomy served by the requirements of informed consent. Since the person providing consent on behalf of the incapable individual must do so because of the difficulty of evidencing one's wishes created by incapacity, any factor that would cast doubt on the apparent disinterest of the witness would defeat the purpose of their participation in the consent process.

Despite the fact that questions have been raised about the reliability of family members accurately to represent the wishes of their incapable relatives, it is nevertheless not recommended that caregivers and family members be excluded from the consent process. Indeed, much research would be impractical in the absence of family support.⁸⁶ Rather, a method must be established for recognizing potential conflicts of interest and preventing family members from permitting participation in research that would be contrary to the interests of incapable subjects. The underlying societal considerations in research seem to favour retaining a duty of the researcher, or any other person participating in the consent process, to refuse to accept the consent of someone whom they believe has a conflict.⁸⁷

ETHICAL AND LEGAL PRINCIPLES

Very few of the international and national documents concerned with the regulation of biomedical experimentation contain provisions that are specifically concerned with ensuring the ethical conduct of experimentation with elderly subjects. However, some recent domestic and international ethical guidelines have given the

⁸⁶ American Psychiatric Association Task Force on Alzheimer's Disease, "Editorial: The Alzheimer's Disease Imperative — The Challenge for Psychiatry" (1988) 145 *American Journal of Psychiatry* 1550 at 1550–1551.

⁸⁷ A requirement that a family member representing the wishes of an incapable person make a declaration that there is no conflict of interest assists in two ways: first, by alerting them to the requirements for their eligibility to represent another's wishes, and, second, by ensuring that a potential conflict of interest does not lead to a decision to enroll a subject in a protocol whose interests would not be adequately served.

elderly some recognition as a distinct population.⁸⁸ For example, the World Medical Assembly in Hong Kong in 1989, with the publication of its *Declaration of Abuse of the Elderly*, contributed towards the recognition of the elderly as a population with special needs.⁸⁹ This declaration was a signal of a growing sensitivity both to the importance of conducting research with the elderly and to the principle that failure to respect the wishes of elderly participants should be considered a form of abuse.

In the United States, the guidelines from the Office for the Protection of Research Risks, although acknowledging that the DHHS regulations contain no specific provisions regarding research with elderly subjects state that:

it is generally agreed . . . that the elderly are, as a group, heterogeneous and not usually in need of special protections, except in two circumstances: cognitive impairment and institutionalization. Under those conditions, the same considerations are applicable as with any other, nonelderly subject in the same circumstances.⁹⁰

The OPRR also recognizes that the presence of elderly persons in institutions such as nursing homes or hospitals increases the chances of coercion and undue influence because of a lack of freedom. The *Guidebook* therefore recommends that research in these settings be avoided unless the involvement of the institutional population is necessary to the conduct of the research.⁹¹

⁸⁸ Specific mention of the elderly as a special population was made in the *MRC Guidelines*, which state that: "Research into disorders of the elderly pose special problems. Research into Alzheimer's disease, for instance, may require affected subjects to be exposed to uncomfortable and above-minimum-risk procedures. Subjects may not themselves benefit from results of individual studies, and they may lack competence to give consent". See Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Supply & Services Canada, 1987) at 31 [hereinafter *MRC Guidelines*]. Similarly, the *CIOMS Guidelines* recognize the special nature of Alzheimer's Dementia, which, of course, targets the elderly. See Council for International Organizations of Medical Sciences, in collaboration with the World Health Organization, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 1993) at 22. However, the *Guidelines* do not provide any additional safeguards aside from those which apply to persons suffering from behavioural or mental disorders. The Law Commission (UK), however, throughout its analysis of legal reform with respect to mentally incapacitated adults, included "elderly people with mental infirmity" among the four categories of adults identified amongst whom incapacity may occur. See The Law Commission, *Mentally Incapacitated Adults and Decision-Making: An Overview (Consultation Paper No. 119)* (London: HMSO, 1991); The Law Commission, *Mentally Incapacitated Adults and Decision-Making: A New Jurisdiction (Consultation Paper No. 128)* (London: HMSO, 1992); The Law Commission, *Mentally Incapacitated Adults and Decision-Making: Medical Treatment and Research (Consultation Paper No. 129)* (London: HMSO, 1993); The Law Commission, *Mentally Incapacitated and Other Vulnerable Adults: Public Law Protection (Consultation Paper No. 130)* (London: HMSO, 1993); The Law Commission, *Mental Incapacity* (London: HMSO, 1995).

⁸⁹ See "Hong Kong World Medical Assembly — Full Report" (1990) 37 *World Medical Journal* 4 at 13. For further discussion of the growing concern over the problem of elder abuse, see Council on Scientific Affairs, "Elder Abuse and Neglect" (1987) 257 *Journal of the American Medical Association* 966.

⁹⁰ See Office for Protection from Research Risks, National Institutes of Health, *Protecting Human Subjects: Institutional Review Board Guidebook* (Washington, D.C.: U.S. Government Printing Office, 1993) at 6–47.

⁹¹ *Ibid.* at 6–48. The problem of obtaining a voluntary consent from elderly persons who are also institutionalized was also recognized by the National Health and Medical Research Council in Australia. The Council clearly states that the elderly constitute a special group in a dependent relationship. See National Health and Medical Research Council, *Statement on Human Experimentation and Supplementary Notes* (Canberra: NHMRC, 1992) at 23.

The *Guidebook* also states that:

Despite [certain] difficulties, the inclusion of older persons in the research enterprise is important. IRBs should ensure that where they are excluded or treated specially, older subjects are in need of protection and are not the object of disdain, stereotyping or paternalism. Together, researchers and the IRB should enable older persons to share in the benefits and burdens of research.

The use of age as the criterion of ability to consent and therefore participate in research is not valid. Studies have shown that education, health status, and inadequate communication about the research rather than age contribute to the lack of comprehension and recall. While it is recognized that memory may be a problem for some elderly subjects (thus putting into question their ability to provide continuing consent), the question for the IRB is whether, despite some impairment to competence, subjects can make reasonable choices.⁹²

The conclusion to be drawn is that the elderly may be a population which merits special attention before participating in research to ensure that their consent is informed and free.

Finally, provisions concerned with whether the values of a competent adult regarding participation in research are respected when the adult becomes incompetent, are of particular relevance to the elderly, who may suffer from degenerative diseases, and therefore have a potentially decreasing capacity to give consent to participate in research. The MRC recognized that treatment involving mentally-incompetent adults must reflect their:

mature personalities and, in particular, avoid any procedure which the subjects would probably have refused, were they still fully competent. The ability of all incompetent potential subjects to exercise choice must be maximized, and their dignity must not be compromised by exposing them to procedures which demean them or exacerbate their dependency.⁹³

The above observation is especially applicable to the elderly, given the fact that, as mature adults, they have had ample time to develop their personal values and beliefs upon which a substitute decision, if necessary, could be based. Hence, various guidelines, including the present legislation in Ontario,⁹⁴ emphasize the need for substitute decision-makers to base their decisions on the previously expressed values and beliefs, thereby preserving the right of individuals to project autonomous

⁹² See *OPRR Guidebook*, *supra* note 90.

⁹³ *MRC Guidelines*, *supra* note 88 at 30. The revised *Code of Ethical Conduct for Research Involving Humans* reaffirmed this principle, namely in its assertion that although there might be concerns with respect to competence in the case of elderly persons, these concerns should be addressed in their own right and not on the basis of age. See Tri-Council Working Group, *Code of Ethical Conduct for Research Involving Humans* (July, 1997), at Part 2, p. 36. The Tri-Council consists of the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada.

⁹⁴ *Substitute Decisions Act, 1992*, S.O. 1992, c. 30, s. 66.

decisions into a future time where they may be mentally incompetent. Recommendations often suggest that this be accomplished through research directives.⁹⁵

CONCLUSION

The elderly are difficult to categorize as a distinct population — possibly because society has not until recently recognized them as an identifiable group. It is apparent, however, that a growing recognition of the needs of the elderly has emerged in response to changing demographics, an increasingly outspoken elderly population, and an improved awareness of the tragedy of Alzheimer's Dementia. These factors have all served to focus attention on the importance of medical research concerned with the health needs of the elderly.

One significant characteristic of the elderly in the context of health care decision-making is that the elderly might possess *uncertain and fluctuating capacity caused by diminishing cognitive abilities*. Because declining capacity in the elderly generally follows several decades of autonomous functioning, cognitive deficits often mask both a residual desire, and a continued capacity for, self-determination that should be respected. Accordingly, every effort should be made to eliminate, or at least reduce, practical impediments to the participation of the elderly in the process of providing informed consent. Similarly, since many members of the current generation of elderly persons have developed their perspectives as to the nature of an appropriate relationship between individuals and health-care practitioners in contexts that differ from that of the current concern for informed consent, deference should be shown to their standards of respect for persons in health-care decision-making.

While presumptions of capacity to consent to participation in research may place some elderly participants at risk, presumptions of incapacity nevertheless provide protection that is largely unwarranted and often offensive. Formal determinations of capacity are, in the same way, unduly intrusive. By distinguishing measures of capacity that focus on the decision-making process from those concerned with the reasonableness of the outcome, capacity to consent to research participation⁹⁶ emerges as the ability to appreciate that the proposed procedure is not intended to benefit oneself directly and that the giving or withholding of consent to participate should have no effect on one's current or future entitlement to health care. Thus, the capacity to consent to research essentially consists of the ability to appreciate it as an entirely voluntary and optional activity. Because the decision to participate in

⁹⁵ For example, the CIOMS Guidelines, *supra* note 88 at 23, suggest that persons who foresee cognitive impairment might make use of research directives — either by stating acceptable conditions for participation in research, or by designating a substitute decision-maker. Similarly, the guidelines presented by the task force sponsored by the National Institute on Aging encouraged the use of documentary methods of establishing a person's wishes, such as the use of "durable powers of attorney", and the conduct of long-range and long-term protocols so as to permit the enrollment of persons at a time when they were competent. See Melnick *et al.*, *supra* note 35.

⁹⁶ As distinct from the capacity to consent to treatment with which it shares the requirement that one be able to understand the nature of the proposed procedure and its relationship to one's physical condition.

research involves the conferring of a gratuitous benefit by one whose capacity to do so may be uncertain, the inherent challenges are to eliminate the possibility of undue influences and to ensure the provision of reliable evidence of the voluntariness of the decision. In the case of a participant of uncertain or borderline capacity, both can be accomplished through the witnessing of the consent of the participant by a person familiar with the individual and independent of the researcher. The involvement of a witness in the consent process in the event of any uncertainty with regard to capacity obviates the need for either presumptions or determinations of capacity and the threat they may pose to the dignity of elderly persons.

Although many persons retain capacity or borderline capacity throughout their lives, many others experience a period of incapacity at the end of their lives. In some cases, especially when this incapacity is a result of a degenerative condition such as Alzheimer's Dementia, these individuals or subsequent generations of elderly persons are entitled to receive the benefits of medical advances that may arise in the future as a consequence of their participation in research. If the commitment to informed consent is to be sustained, this research can only go forward if provision is made for substitute consent.

This should be accomplished through a legislative framework for substitute consent that may be applied in a variety of areas including that of consent to treatment. Such legislation should be, by and large, applicable to research participation and provisions made for encouraging the use of documentary methods, such as continuing powers of attorney, as a method of establishing the prior capable wishes of incapable persons, would be most helpful in determining the continuing wishes of those incapable of articulating them. Also, mechanisms should be enunciated for determining the substance of the incapable person's wishes and for selecting a person to represent those wishes should also be applicable to the decision whether or not to participate in research.⁹⁷

However, because research participation is a voluntary activity, unrelated to the therapeutic best interests of the individual, the legislative provisions relating to the therapeutic need for, or likely effect of, a proposed procedure are clearly inappropriate when considering the incapable person's wishes regarding their participation in a research protocol. Furthermore, because the possibility of conflicts of interest can extend to those who might be called on to consent on behalf of the incapable person, those with potential conflicts should be regarded as being ineligible to provide consent unless the factors that might affect their decision will not lead them to consent to research participation on the part of the incapable person against that person's wishes. Researchers should have a continuing obligation to decline the consent of those they feel ought be disqualified on this basis. A declaration to be signed by family members acting as substitute decision-makers, for example, should include an appropriate statement declaring that they are free from any conflict of interest.

⁹⁷ See also Chapter 8.

The elderly are coming to be recognized as a special population with health care needs requiring research with human participants. There is growing concern for the specific health care needs of the elderly and an increasing degree of recognition that respect for their dignity requires the establishment of mechanisms for determining their continuing wishes with respect to research participation.

SUMMARY

Geriatrics is, comparatively speaking, not a very old medical specialty. In the past, illnesses suffered by older persons gained the attention of health professionals for purposes of cure or maintenance of comfort; it was rare for individuals to live to a "ripe old age". The comparative rarity of old age delayed the recognition of the existence of a group of older persons with physiological characteristics and health requirements that were distinct from those of the general population. Longevity is a new social reality that has obliged us to regard old age as a second likely period of dependency. Indeed, it is now becoming increasingly apparent to society as a whole, including the medical and legal communities, that age-based incapacity is likely to affect many people not only at the beginning, but also at the end, of their lives. In the light of these major considerations, we make the following recommendations:

- (1) Non-therapeutic research should never be conducted on incompetent elderly subjects if it is possible to conduct the same research with competent subjects.
- (2) Although treated as a special population, the elderly must nevertheless be treated as adults whose autonomy of decision-making is strictly respected *unless* there is clear and convincing evidence of incapacity to give or withhold consent to participation in non-therapeutic experimentation. For this reason, there should be a presumption of capacity.
- (3) Where an elderly person is institutionalized in a hospital or nursing home, or where there is a reasonable doubt as to the person's ability to voluntarily consent to participate in research, the giving of consent should be witnessed by a family member or, if appropriate, a close friend. Where research is conducted in an institutional setting, the prospective subjects should be given the opportunity to discuss the relevant issues with an independent third party. There should also be a reduction of incentives that might cause a prospective subject to become involved in research where others would not.
- (4) Where an elderly person has been placed under the guardianship of an attorney for personal care, or where there is clear evidence of incapacity to give consent to participate in research, the consent must be obtained from the appropriate substitute decision-maker.
- (5) Those individuals qualified by their relationship to an incapable person to give a substituted consent to participate in research should be required to provide a statement that certifies the absence of any conflict that would be likely to lead to a decision contrary to the wishes of the incapable person, and

that they will assume responsibility for decision-making regarding continued participation throughout the protocol. A person unable to meet this requirement must be disqualified.

- (6) Where substitute consent is given, it must be based, wherever possible, on the *previously expressed wishes, values or beliefs of the elderly person concerned* — assuming that these were expressed at a time when the latter was competent to do so.
- (7) In no circumstances may non-therapeutic research be either commenced or continued where there is a clear objection on the part of the incompetent subject. Current objections must override any previous consent that may have been given to participation in such research.
- (8) Elderly persons should be encouraged to give advance research directives, especially when a person has been diagnosed as being in the early stages of a disease that is known to cause cognitive impairment. These directives should express the wishes of the person concerned and should appoint a substitute decision-maker of their own choice.
- (9) An objection on the part of the subject, or previously expressed wishes (such as an advance directive stating an unwillingness to participate in non-therapeutic experimentation), should override consent provided by a substitute decision-maker.