The growing number of individuals affected by dementia will intensify the ethical issues that emerge in clinical practice and research. Issues early in disease relate to genetic testing, use of medications in mildly affected persons, and diagnostic disclosure. Research issues relate to appropriate informed consent processes, conflict of interests, and research design issues, such as the use of placebos and the use of biological tissues. In the later stages of disease concern about appropriate therapeutic goals and end-of-life care is appropriate.

Research and clinical ethics in dementia are challenging because of the nature of the disease. Ethical analysis, particularly in the Western world, is based on interactions among rational autonomous individuals. Dementia threatens the rationality and independence of persons, and raises specific concerns about quality of life.

Ethical issues will become more evident in the future. First, considerably more individuals in both developed and developing countries will be affected by dementing illnesses, particularly Alzheimer’s disease (AD). The revolution in molecular medicine, particularly genetics, will continue to lead to new technologies with ensuing ethical issues. However, the recognition that our fascination with the power of genetic technology is distracting us from attending to public and environmental health issues will hopefully grow. Revolutions in health care systems in many countries, which are due in part to the aging of our populations, will continue to generate new value conflicts for physicians and other providers. The growth of managed care in the United States is one such example. In general, however, the recognition that health care systems around the world are facing economic constraints will be a major challenge and result in ethical issues relating, for example, to rationing of services. The frail and vulnerable elderly such as those with dementia will be at risk for being assigned low priority in such a rationing process.

In this paper, we will first discuss some of the approaches of modern biomedical ethics to orient the reader to language and methodology. Next, we will consider the ethical issues that emerge in research and practice involving persons affected by dementia in a chronological or disease-stage fashion. We will begin by considering issues early in the disease, in fact, even before individuals are identified as having a dementing disorder. Then, we will consider mid-stage ethical issues that relate to determining competency and participation in research and in health care. We will then attempt to consider the later stages of dementia, in which the patient is severely demented, and eventually becomes terminally ill. Finally, we will conclude with a discussion of some of the trends in research and health care that
will affect our consideration of value conflicts emerging in the future.

**Approaches in ethics**

The discipline of bioethics is only a little over 25 years old. The term “bioethics” was introduced into the English language by Potter. He coined the term to highlight the need for broad exploration of the relationship between biology and human values. The use for the term was modified and limited by the Kennedy Institute and others to focus more specifically on the value considerations associated with the introduction of new medical technology.

Bioethics itself is becoming more unified and professionalized. For example, in the United States, the merging of several organizations has led to the founding of the new American Society for Bioethics and Humanities. As an inherently interdisciplinary field, defining the knowledge base is challenging. Individuals approach bioethics through philosophy, medicine, nursing, law, empirical social sciences, anthropology, history, and other disciplines. Appropriate standards for bioethical consultation are being developed.

As mentioned above, ethical issues emerge when there are conflicts in what human beings value in a particular social context. They also relate to differences in opinion about what constitutes a virtuous individual or a good life. The dominant mode of ethics practice in the United States is based on an analytical philosophical approach and the application of principles, particularly autonomy, beneficence, and justice. In this secular approach, ethical situations are analyzed in terms of balance among these principles. Autonomy relates to preserving the rights of individuals to make decisions about their own lives. Beneficence relates to the shared responsibilities we have for each other, particularly the principle of nonmaleficence, ie, doing no harm. Justice addresses at the societal level questions of fairness in health care decision making. Ethical decisions are seen as weighing up these three principles to arrive at the best course of action in a particular circumstance.

Ethical analysis based on this principled approach is helpful. However, there are other complementary approaches to address biomedical ethical concerns. Discourse or communicative ethics is perhaps less abstract and focuses on the practical real-world struggles that individuals face caring for someone with dementia. The focus is on quality communication where the development of trust and clarification of the positions of different parties in the ethical dispute are critical. Casuistry and narrative ethics focus on the stories that are told by individuals involved in ethical disputes. These approaches focus on the richness of individual lives and their complex interactions. The focus again is on the particulars of a certain case and less on abstract principles.

It is also important to recognize that there are close relationships between ethics and law. As we consider ethical issues, we should be aware of any legal statutes that relate to the decisions that are being considered. However, laws often cannot be applied to ethical issues with certainty and the moral foundation of some laws can be questioned.

**Ethical issues in early disease**

Before we begin our discussion of ethical issues in persons who have been labeled with a diagnosis of dementia, we need to consider those without manifest disease, ie, people with subtle degrees of intellectual impairment who might be at risk for developing frank dementia such as AD in the future. As we age, many of us will develop changes in our intellectual abilities, some to the point that they could be labeled with a term such as mild cognitive impairment (MCI). The history of this term is interesting in that the initial identification of people who had mild impairment of thinking, particularly in memory, was by Krall when he coined the term benign senile forgetfulness. Other terms, such as aging-associated memory impairment and aging or related cognitive decline, have also been operationalized. MCI is the most popular term currently. The differentiation of those who have AD from those who have cognitive abilities at the extreme lower range of normal aging is arbitrary and accomplished by setting a threshold on scores on quantitative assessment batteries.

Ethical issues emerge in relationship to the treatment of people with MCI. Recognizing that many of these people will develop dementia, but have not yet, should we begin symptomatic treatment to try to improve even a mild degree of memory difficulties? How should we consider the risks and benefits of long-term treatment with agents that might prevent the onset of AD, such as vitamin E or nonsteroidal anti-inflammatory agents? How should we consider the ethics of cognitive enhancement using such a “pill” for individuals who are “normal”? 
Other ethical issues emerge in people who are at risk for AD. In many ways, that group includes literally everyone who is currently alive and who lives into old age, the period of maximum risk. The chance of getting AD increases for all of us as we approach the age of 85; perhaps as many as half will be affected. Moreover, it is possible that we will all develop AD if we live long enough.

There are some individuals for whom the risk is considerably greater in younger years, i.e., those who belong to families with the autosomal dominant forms of the disease. In families with identified mutations on chromosomes 1, 14, and 21, it is now possible to offer presymptomatic genetic testing and identify those individuals who carry the gene. These individuals can have their knowledge of risk of having the AD gene modified by genetic testing from 50/50 to close to either 0% or 100%. Moreover, genetic susceptibility testing with apolipoprotein E (apo E) is a form of genetic testing that is considered by some to apply to all of us. Those who carry the apo E allele are more at risk for the disease than those with apo E 2 or 3. However, the risk information in the case of susceptibility testing is not as clear-cut as in the autosomal dominant setting. Thus, ethical issues emerge as to how valuable information that is less precise is to individuals who consider themselves at risk. Risks of psychological harm and even suicide exist if bad news is given and especially if it is misinterpreted. Moreover, ethical issues follow genetic testing of both the susceptibility and autosomal dominant type as to who should have access to the information. For example, should insurance companies who might modify the costs or availability of health insurance based on the results of genetic tests on individuals be informed?

When a person crosses over the indistinct line from severe normal aging to mild AD, it is appropriate to consider “applying” the diagnosis to that individual. Diagnostic disclosure raises a number of ethical issues. Considerable cultural variation exists as to whether physicians and the public believe it is ethical to inform individuals of their diagnosis and prognosis. In the United States and Northern Europe, it is usually considered best to allow the autonomous individual access to that information, whereas in oriental and southern European cultures, the family is often told and the patient is protected from the diagnosis. One major issue not often considered in these discussions of the ethics of disclosure is what words are used when a diagnosis is given and how the information is actually processed by the individual and family. Their understanding of what is said by the physician is often different from what he or she intended the message to be. Individuals should be encouraged to develop advance directives early in the disease. A living will is a document describing the kinds of care that the individual would like later in the illness when they may not be able to make their own health care decisions. We are beginning to explore the use of such devices concerning decisions about research participation. In addition to a written document, the individual with dementia should identify the person, usually the caregiver, who will make decisions when the patient is not able to do so, i.e., a surrogate decision-maker. How a caregiver should make the decisions is also an ethical issue. Should a decision be a substituted judgment by attempting to mirror the decision that the affected individual would have likely made, or “best interest” reflecting what is considered optimal for the patient at the time the decision needs to be made?

### Mid-stage issues

In order for an advance directive to activate, the community needs to determine that the individual is no longer competent to make decisions and that the surrogate decision-maker needs to become more active. The assessment of competency is a complicated area for physicians. The actual decision about competency is made by a judge. However, physicians are often asked to provide data to inform the process. Formal neuropsychological testing can be administered. However, it is best to evaluate competency in a particular domain by asking the patient about the actual decision to be made or similar decisions using hypothetical vignettes. A judgment can be made about whether the patient can understand that a decision needs to be made and whether he or she is considering relevant factors that affect the decision or not.

In the mid-stages of disease, the patient may be given the opportunity to consider participation in research. A number of ethical issues are raised in this context. Informed consent involves providing information to an individual and allowing them to make a decision about research participation. Dementia affects an individual’s ability to both understand the purpose and process of research and...
to make the decision to participate or not. A variety of national and international groups are now examining the issue of informed consent for those who are cognitively impaired. The National Bioethics Advisory Commission in the United States has made certain proposals concerning additional protections for mentally ill research subjects that involve assessing the degree of risk and involving other national boards and patient representatives to assist review of research procedures. Alzheimer Disease International and The International Working for the Harmonization of Dementia Drug Guidelines have also issued recommendations. Major issues involved in these debates are how incompetence to make research decisions should be established, how a surrogate decision-maker should be identified, and what grounds the surrogate decision-maker should use to decide what kinds of research should or should not be permitted. Another issue relates to the monitoring process that should be in place to insure that the informed consent process is adequate and the research is conducted as approved by the Institutional Review Board.

Another active ethical issue in research relates to conflict of interest when physicians may gain personally—or their institution—based on their participation in research, particularly therapeutic trials. Inadequately disclosed conflicts of interest threaten to undermine the trust that the public has that the research is being conducted for the benefit of society and not for the personal or organizational financial betterment of researchers. Issues also relate to the control of the information collected in the research project. For example, is it ethical for drug companies to suppress negative studies? Other ethical issues in research design that are under active consideration at the moment include determining when use of a placebo is inappropriate. Research practice dictates that participants should be offered standard therapy as an option. Donepezil has become in many people’s minds the standard of practice for symptomatic improvement of cognition in AD. Are we at a stage that all studies should compare new drugs with donepezil rather than with a placebo? Most people do not believe that we are at this stage in the field with donepezil, but this is a point of contention.

In many research protocols, subjects are asked to donate tissues for analysis. For example, it is common in clinical trials to collect a blood specimen to allow determination of genotypes, such as Apo E4. The hope is to determine whether the genotypes in any way relate to responsiveness to the medication. However, if the affected person grants permission to obtain biological tissue, questions are raised as to how long the tissue can be stored, whether it can be used for analysis of other disease markers, and who can have access to this information.

In addition to opportunities to participate in research, individuals in the mid-stage of the disease are often involved in a great variety of services in the health care system. Managed care in the United States has changed the financial incentives for physicians and organizations providing health services. For example, in capitated managed care, providers are at risk for excessive use of services. Patients with dementia may be at risk of not being granted adequate access to services in a health care environment in which they threaten to consume more than average resources. The ethics of managed care has attracted considerable professional and public attention. For example, early attempts to stop physicians from sharing information about other therapeutic options not included in the patient’s plan with so-called gag rules were judged by most to be unethical.

End-stage ethical issues

As the disease progresses, patients with dementia may become unable to make any decisions and, in fact, unable to communicate with their loved ones and care providers. They often need placement in long-term residential care facilities. A variety of ethical issues emerge in this context. Many of them relate to the use of restraints, whether they are physical or chemical. As the dementia progresses from severe to profound, many consider it appropriate to think of AD as a terminal disease. In this context, ethical discussions emerge as to what kinds of interventions are effective and appropriate in the latter stage of the disease. Should we ever place a feeding tube in a severely demented patient? Do antibiotics alter the course of patients who are terminally demented and have developed infections?

Finally, there are active discussions in some countries concerning the role of physician-assisted suicide and euthanasia in dementia care. In the Netherlands, a recent report explored whether it is appropriate to allow an individual in the mild stages of dementia to commit suicide with a physician’s assistance if this is judged as being congruent with the patient’s conceptions of a good life. Quite a number of individuals in the Netherlands have also filled out advanced directives
asking doctors to kill them when they reach a certain severity of dementia. Clearly, we need to have appropriate forms of health care available to patients dying with dementia. Many hospice programs provide an appropriate model for such care. The options for end-of-life care should focus more on the quality of life than prolonging life. The spiritual aspects of life increasingly become important to many. Secular bioethics is often not comfortable when narrower religious or broader spiritual value issues are raised.

**Future trends**

Many changes are occurring in the clinical and research environment involving patients with dementia. As mentioned above, we will have a larger number of individuals affected by dementia because of the graying of our population. Moreover, because of population mobility, we will be called upon to involve increasingly cultural diverse individuals in our practices and research. Attending to the differences in ethical belief systems in different cultures will be even more important in the future than it is today. In some cultures, the principle of autonomy is not as dominant as in the United States and Northern Europe. In general, even in these Western countries, we are questioning whether such a strong focus on individual rights is appropriate as we recognize that attending to the health needs of the public and our communities requires reconsideration of the relationships that physicians have with individual patients.

As our health care systems continue to evolve to better integrated systems in which acute and long-term care will be coordinated in a smoother continuum, a variety of ethical issues will emerge. Many of them will have to do with the use of integrated clinical and financial information systems. As computers and information systems are increasingly involved in the care of patients with dementia, confidentiality will be an increasing issue. Moreover, as computers begin to actually play a role in supporting care, accountability for therapeutic decisions may become less clear.

As the number of individuals with dementia increases and health care resources are increasingly stressed, the level of support given to patients with dementia will be examined. It remains to be seen how expensive therapies to treat dementia will be prioritized when, for example, the deleterious effects of environmental pollution on the health of people of all ages continue to grow. At a personal and cultural level, dementia will challenge us as the disease of the millennium and a particularly postmodern one at that.7

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**Aspectos éticos en la demencia**

El progresivo aumento de sujetos que padecen de una demencia intensificará la discusión ética que surge desde la práctica clínica y de la investigación. Los temas éticos al inicio de la enfermedad se relacionan con pruebas genéticas, con el empleo de medicamentos en personas levemente afectadas y con la revelación del diagnóstico. Los temas éticos vinculados a la investigación se relacionan con los procesos para obtener el consentimiento informado, con la evaluación de los conflictos de intereses y con los diseños de investigación, tales como el uso de placebos y el empleo de tejidos biológicos. En etapas más avanzadas de la enfermedad los temas éticos se refieren al análisis de los objetivos terapéuticos y de los cuidados terminales del paciente.

**Problèmes éthiques posés par la démence**

Le nombre croissant d’individus touchés par la démence va amplifier les questions éthiques soulevées par la pratique clinique et la recherche. Les problèmes éthiques qui se posent précocément ont trait au diagnostic génétique, au traitement éventuel des patients atteints de détérioration mentale légère et à la révélation du diagnostic. La recherche est confrontée au problème du consentement éclairé adapté au patient dément, aux problèmes des conflits d’intérêts et des protocoles de recherche qui utilisent des placebos et des prélèvements biologiques sur les patients. Aux étapes ultimes de la maladie se posent les questions de choix thérapeutiques appropriés et de soins de fin de vie.
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