Chapter 3

Selected chronic Conditions, Technology, and Biomedical Research

Contents

Page

Introduction 61
Dementia: Social Problem , Medical Enigma, and Federal Burden 63
Causes and Prevalence 63
Effects on Patients and Their Families 64
Clinical and Scientific Background 64
Federal Roles Regarding Dementia 65
Urinary Incontinece 66
Definition, Prevalence, and Causes of Incontinence 70
Treatment 72
The Cost of Incontinence 76
Conclusion 77
Hearing Impairment in the Elderly 78
Prevalence 78
Types and Causes of Hearing Loss Among the Elderly 80
Impacts of Hearing Impairment 82
Treatment of Hearing Impairment 82
The Service Delivery System. 86
Funding for Treatment of Hearing Impairments 87
Federal Government Programs for the Hearing Impaired Elderly 88
Osteoarthritis 89
Definitions and Prevalence 90
What is osteoarthritis 90
Risk Factors 91
Diagnosis 91
Prevention of Disability and Treatment 92
Quackery 94
Social Factors 94
Osteoporosis 95
Introduction 95
Magnitude of the Clinical and Social Problem 95
Biology and Physiology 96

Page

Diagnosis 97
Treatment andPrevention 97
Summary 100
Policy for Basic Biomedical Research 100
Congressional Role in Supporting Research on Aging 101
Reasons for Supporting Biomedical Research on Aging 103
Resource Allocation: Who Decides What . . . 105
Conclusion 110
Congressional Issues and options Regarding Basic Biomedical Research 110
Chapter 3 References 111

Tables

Table No. *Page*

5. Common Reversible Causes of Dementia . . 66
6. Types of Incontinence. 71
7. Treatments for Urinary Incontinence 73
8. Causes of Conductive and Sensori-Neural Hearing Impairments 81
9. Treatments for Arthritis 92

Figures

Figure No. *Page*

13. Percent of Adults Aged 25 to 74 With Hearing Impairment, by Frequency of Tone in the United States, 1971 -75..... 79
14. Physiology of the Human Ear 80
15. Diagram of Knee Joint 91
16. National Health R&D, 1972 and 1982, as Related to Total R&D Cost and Total Health Cost 102
17. National Support for Health R&D by Source, 1972-83 103

Chapter 3

Selected Chronic Conditions, Technology, and Biomedical Research

Introduction

Improved sanitation, health care, environmental protection, and greater affluence all contribute to extending the average length of human life. Technology is an essential element of each of the factors that improve health and extend life. Modern sanitation methods, for example, are based on scientific evidence of their potential effectiveness and the technological innovation that makes the transport and treatment of sewage affordable. New medical technologies that extend life include the use of drugs to successfully treat hypertension, thus reducing mortality from heart disease and stroke, and sophisticated devices, like computer-assisted X-ray machines, that permit more rapid and specific diagnosis.

The second half of the 2~h century has seen a dramatic shift in the types of diseases afflicting people, especially in economically developed countries. The incidence of many infectious diseases has fallen sharply as sanitation has improved and vaccines have been developed; many of the remaining infectious diseases can be effectively treated with antibiotics. Death rates from diseases of the heart and blood vessels have also begun to change as a result of diet, personal habits, and improved health care. If trends contilme, several predictions can be made:

- life expectancy will continue to rise,
- diseases whose incidence rises with age will become more common,
- environmental and dietary factors affecting health may become more important because individuals will live through longer periods of exposure and have longer to develop symptoms, and
- new and unexpected medical syndromes **may** appear.

Each of these factors may boost the number of people affected with chronic health conditions. Dementia, arthritis, deafness, poor vision, and other currently incurable ailments are likely to rise in importance as death rates from vascular disease decline and the prevalence of various cancers shifts (see app. A). There are four general strategies for dealing with chronic health conditions:

- treatment of acute episodes of illness arising from underlying chronic illness;
- long-term treatment or long-term care;
- prevention; or
- research to improve diagnosis, treatment, and prevention.

Policies regarding each of these interventions, except routine medical care, are discussed elsewhere in this assessment. Medical care for acute episodes of chronic illness and other aspects of hospital and ambulatory health care are discussed only briefly in this report because they are covered in both OTA reports on Medicare and in reports by other Federal agencies. Certain aspects of medical care, however, are covered in chapter 8.

Long-term care is discussed in chapter 7 and prevention in chapter 4. Questions regarding Federal policy on biomedical research on aging are addressed in the final section of this chapter.

An important result of the rise of chronic disease is the likely increase in prevalence of conditions that lack both cures and means of prevention and that become more common with age, such as osteoarthritis and Alzheimer disease. The shift from infectious to cardiovascular to other chronic conditions has followed a path of progressively greater clinical ignorance: those disorders that are now becoming more common are those about which we know the least. We know far more about the cause of tuberculosis than

about the causes of Alzheimer disease. The most common causes of death and disability among Americans over 65 are reviewed in chapters 1, 2, 7, and in appendix A, which covers morbidity and mortality. The conditions selected for special review by OTA staff and the advisory panel for this assessment were chosen on the basis of several criteria:

- the condition is chronic and persistent;
- easily readable and current summaries of the state of science and medicine regarding the condition are not readily available;
- the elderly population is specifically affected due to severity or prevalence;
- technology is relevant to correction of or compensation for the condition;
- the condition contributes to the demand for long-term care, in line with the emphasis of the current assessment; or
- Congress has recently demonstrated a special interest in the condition.

The conditions identified by OTA staff and advisory panel members as most meriting discussion were dementia, urinary incontinence, hearing impairment, osteoporosis, and osteoarthritis, Visual impairments, diabetes mellitus, certain cancers, liver disease, and chronic lung disorders were also considered, but omitted due to limitations of space, which also dictated that the reviews be succinct and focused on policy.

Dementia was selected because Alzheimer disease and other dementing illnesses will soon become overwhelming health problems unless means for prevention or treatment are found. These diseases are severe, affect an important aspect of human function—mental ability—and are the most common determinants of need for long-term care. There are as yet no reliable or specific means of accurately diagnosing dementing disorders, although improvements have been rapid in recent years. Further, these disorders are probably not single entities, but combinations of related but biologically distinct diseases that have not yet been scientifically differentiated. The policy options relating to Alzheimer disease and dementia thus relate to long-term care for demented patients (see ch. 7) and to biomedical research. Although the ultimate solutions to dementing illness must come from research, they are not likely to be achieved in the short term, and the problem of caring for demented patients for the final few years of life cannot be avoided in the near future.

Urinary incontinence is a common problem. It is a symptom of many neurological, endocrine, vascular, and urological diseases that can now be treated with technologies ranging from absorbent pads to sophisticated mechanical devices. Because many of the relevant technologies are just coming to fruition, incontinence will be far more effectively treated in the future. Discussion of the problem of incontinence centers on the substantial delay in bringing technology to bear on the problem, and on possible drawbacks of present technologies. Improvements in this area could revolutionize nursing home care, and permit families to care for their incontinent dependents for longer periods before the patients become unmanageable. Even more important, great improvement can be made in individual patients' lives.

Hearing impairments affect 24 percent of those 65 to 74 and almost 40 percent of those over 75 in the United States. Many forms of hearing impairment can be improved by technological intervention—hearing aids and other devices. But the adaptation of appropriate technology to specific hearing defects of patients, especially elderly patients, has had only limited success. The potential for improvement of functional hearing impairments is substantial if patients can be convinced of the value of correction and if industry can adapt to better serving patients' needs. Technological innovation in this area promises to be rapid over the next decade. Federal policy issues include assurance of patient safety in public places (mandating alarms that can warn those with hearing impairments of danger), reimbursement policy for Medicare and Medicaid (which currently offer little support for those with hearing impairments), regulation of the hearing-devices industry, and sponsorship of training and research.

Osteoarthritis, which affects 16 million to 20 million older Americans, is the largest single cause of disability among the elderly. Technological

issues related to osteoarthritis include a relative lack of basic scientific knowledge about the biology of cartilage, a need for preventive strategies, the potential for reducing pain and suffering for a large proportion of patients, and the enormous expense of current therapies, particularly joint replacement surgery. Like dementia, osteoarthritis is in need of discoveries that could lead to effective prevention and cure.

Osteoporosis is a disease process involving thinning of bones. Its most devastating consequences are fractures of the vertebrae and long bones, which are especially common in elderly women. Fractures of the hip often result in death. Current evidence suggests that osteoporotic fractures are amenable to prevention by such methods as increasing calcium intake or postmenopausal administration of estrogens, but the definitive preventive protocol has not been established because the various regimens used in routine practice have not yet been rigorously compared. Federal policy centers on the need for support of research to determine optimum prevention and treatment methods, basic biomedical research, and oversight of elevating the dietary standards for calcium (Recommended Dietary Allowances) to conform to the requirements of older women.

In conjunction with this assessment, longer separate reports, with additional scientific and technical background, are being issued by OTA on the impacts of neuroscience, technologies for managing urinary incontinence, and the management of hearing impairments.

This chapter summarizes OTA findings regarding each of the five selected chronic conditions, and discusses Federal policy with respect to biomedical research on aging.

Dementia: social problem, medical enigma, and Federal burden

Dementia is one of the most important disorders leading to chronic disability among older Americans. It affects fewer people than osteoarthritis, and is not a major direct cause of death like cancer or cardiovascular disease. In epidemiological studies, however, life expectancy is reduced by half among demented patients, making it the fourth or fifth highest cause of death among older people. Yet the effects of dementia are so devastating to the patient and his or her family, and its prevalence is increasing so rapidly, that one medical authority, Lewis Thomas, has called it the “disease of the century. ”

Causes and prevalence

Dementia is a serious social problem, a difficult medical enigma, and a major Federal expense. The loss of intellectual and other “higher” functions that is referred to as dementia can be caused by many different diseases and environmental insults.

The most common type of dementia is Alzheimer disease, which accounts for 50 to 7s percent of all cases. Up to 20 percent of patients with dementia have a disease that is treatable, and proper treatment can improve mental function in many cases.1 Another 15 to 25 percent have dementia due to cardiovascular disease, stroke, or an accumulation of “mini-strokes. ” Another common cause is inappropriate drug treatment for other illnesses; many drugs used to treat cardiovascular diseases, psychiatric diseases, and insomnia lead to poor mental function. Mental function often improves when the offending medication is withdrawn, and failure to distinguish drug-induced dementia from true irreversible dementia can resuh in unnecessary mental confusion and inappropriate care. A substantial, but unquantified, number of older people suffer from transient confusion that spontaneously

Kommon treatable causes of dementia include drugs, depression, and some cardiovascular and endocrine ailments.

resolves or abates with medical treatment of another condition. Such acute confusional states pose a different set of medical problems than does chronic dementia; acute dementia is not explored further in this discussion. There are many causes of irreversible dementia, but the functioning of affected patients is generally similar regardless of cause; daily care techniques are thus also similar. Because stroke as a cause of dementia is, in general, treated as is stroke causing other symptoms, a scientific review of this type of dementia is not included here. In contrast, Alzheimer disease is the largest single cause of irreversible dementia, and little is known about its cause or means of prevention.

Alzheimer disease, first described in 1906 by German physician Alois Alzheimer, leads to progressive loss of brain functions over a period of years. The cause is unknown and there is no effective standard medical treatment.

Alzheimer disease affects between 1.2 million and 4 million Americans; its true prevalence cannot be accurately determined because of variations in regional and historical methods of diagnosis of dementing illnesses. The term "Alzheimer disease," for example, was until recently restricted to those cases beginning before the arbitrary age of 65. Best estimates suggest that severe dementia affects approximately 2.5 percent of those over 65, and moderate and mild dementia probably afflicts another 2.5 to 10 percent. The disease becomes more common with age, affecting 20 to 30 percent of those over 80. More than half of all nursing home residents suffer from dementia.

Effects on patients and their families

The patient is usually aware of intellectual decline in the early stages of the illness. As the disease progresses, the patient loses touch with the outside world, first through loss of memory and intellectual functions, then through loss of personality and speech, and finally through loss of the ability to recognize even close relatives and spouses.

The effect of dementia on family and friends is devastating. Families care for the vast majority of patients with dementia. For the most part, only those in the final stages of severe dementia are placed in nursing homes or other institutions of long-term care. Families and friends are estimated to attend to 80 percent of the long-term care needs of patients in the United States (see chs. 7 and 9).

Beyond the financial and medical burdens imposed by those who develop this disease are the severe emotional strains faced by families and friends. The progressive intellectual deterioration of a close loved one is a tragic experience that can only be fully understood by those who have gone through the process; it has been described by one family member as a "funeral that lasts for years." The arduous task of caring for patients with dementia is tellingly described in a book called ***The 36-Hour Day,***

Clinical and scientific background

The clinical changes of Alzheimer disease are associated with physical and biochemical changes in the brain. Accumulations of abnormal proteins and other material are found in "plaques" in the cerebral cortex of the brain, as are accumulations of abnormal fiber-like proteins within nerve cells. Specific populations of nerve cells in the nucleus basalis of Meynert, near the base of the brain, die for unknown reasons. The death of these cells is postulated to be related to the clinical symptoms.

Patients die with this disease, not ***of*** it. Patients with dementia have only half the usual life expectancy for a given age; not because it kills in and of itself, but because patients become susceptible to other diseases as a consequence of being unable to take care of themselves and because of immobility caused by the end stages of the disease. At present, its cause ***is*** unknown, and there are no means of prevention. The absence of effective medical intervention has diminished the incentives to physicians to provide accurate and welldocumented diagnosis; if the cause of illness does not affect treatment choices, there is less reason to identify it. Greater awareness of the fact that up to 20 percent of dementia is treatable could improve physician attention to accurate diagnosis of dementia. Growing public awareness

of Alzheimer disease has drawn medical attention to the disorder, yet one of the most important reasons for accurate diagnosis is often overlooked–families of patients know that something is wrong, but do not know what. The specific diagnosis of organic brain disease is unwelcome, but may reduce the anxiety and guilt felt by patients' families by identifying the problem as an organic brain disease rather than a problem of family or interpersonal dynamics.

The widespread belief in dementia as a normal concomitant of aging has historically served to lessen physician interest in the disease. The problem of diagnosis has been further hampered by physicians who inaccurately ascribed dementia to atherosclerosis or other cardiovascular dysfunction. Diagnostic methods are now changing rapidly, and heightened awareness has led to a dramatic increase in specific diagnosis by physicians. Nevertheless, there is great uncertainty about the real prevalence of Alzheimer disease.

Although there is a genetic form of the disease, which runs in families (much like such genetic diseases as Huntington disease), it is not yet certain how many cases of Alzheimer disease are of the familial type; estimates of the number of patients who have a genetic form vary from fewer than 10 percent to more than 60 percent. Determining the genetic basis of Alzheimer disease is an important objective for research, especially if a marker for the disorder could be found to aid in diagnosis in affected families. Various causes of the disease have been postulated, including unusual infectious agents ('(slow viruses")) aluminum toxicity, reaction of the body against itself (autoimmune disorder), and various biochemical abnormalities. Many research leads are promising, but none are yet conclusive.

Federal roles regarding dementia

The basis of Federal concern about Alzheimer disease is not only in its prevention and treatment, but in payment for the care of patients. Because dementing illnesses account for admission of most nursing home residents, they are a major aspect of long-term care and institutionalization (see ch. 7). The Health Care Financing Administration has estimated that the Federal Government spends over $6 billion annually in nursing home costs alone for those affected with Alzheimer disease (approximately 30 percent of the total Federal outlay—1982 data). An additional $2 billion to $4 billion in Federal funds are spent each year on acute hospital, home, and rehabilitative care for these patients.

Federal concern about Alzheimer disease is intensifying as its prevalence increases with the rapid growth of the oldest segments of the American population, The magnitude of health care costs, especially for long-term care, has focused new attention on the scientific and medical need to study this disease.

Concern among physicians, researchers, and other health care professionals has led to rapid advances in the study of Alzheimer disease in the last decade. A significant factor has been the creation of the National Institute on Aging (NIA), which has made a major commitment to the study of dementia. In 1984, for example, NIA earmarked $3.S million to establish up to five "centers of excellence" for the study of Alzheimer disease in response to congressional appropriations, The National Institute of Neurological and Communicative Diseases and Stroke (NINCDS) and the National Institute of Mental Health (NIMH) have also increased research on dementia. Total Federal research funds on Alzheimer disease for 1984 are estimated at $36.4 million to $37.8 million, up from $3.8 million in 1976. Recent discoveries of specific nervewell loss, of the nature of the anatomic abnormalities, possible infectious agents, and of biochemical changes have all emerged from federally funded research during the last decade.

Recent findings in neuroscience have led to experimental drug therapies directed at particular chemical nerve~ell connections in the brain. There has been preliminary success with drugs that allow the neurotransmitter acetylcholine to work longer at its anatomic site. The neuropeptide vasopressin has been shown to improve memory slightly in some patients with Alzheimer disease. The drug naloxone, which is used to treat some forms of acute opiate overdose, has also been reported effective in one small study, but following studies have not shown a significant effect. Tests have begun on drugs that might in-

crease the efficiency of releasing acetylcholine into its active site by altering calcium metabolism and other biochemical pathways. Federal policy regarding support of randomized clinical trials of various therapies will affect the pace at which effective drug treatments are identified and accepted by the medical community. Preliminary findings offer hope for at least a partially effective symptomatic treatment. Solving the problem of dementia may well depend on developing effective means of prevention, which will, in turn, depend on understanding its cause and the mechanisms of its progression.

There is also a role for the Government inpwtecting those who have Alzheimer disease. For example, who is to decide when it is proper to conduct research on a demented patient? The patient is by definition not able to give informed consent, which requires understanding of the purpose and process of experimentation. Obtaining informed consent can be a barrier to scientific investigation of just those treatments that are so needed. The dual role of the Federal Government in both preserving civil rights and supporting most biomedical research suggests that informed consent for Alzheimer disease research maybe an emerging Federal issue.

Treatment and prevention of this dread disease can only come from investment in neuroscience research (see table 5). The United States has a social, financial, and medical stake in the solution of this major health problem. The Federal Government already sponsors research, pays for acute care and diagnosis through Medicare, and is responsible for long-term care through Medicaid. Cost savings in health care for the rising population of demented patients depend on finding new, effective, and inexpensive treatments for dementia and determining methods of prevention for Alzheimer disease and other dementing illnesses.

Table 5.—Common Reversible Causes of Dementia

Drugs:
- Sleeping pills and sedatives
- Other psychopharmaceuti cals
- Anti-Parkinson's drugs
- Other neurological drugs
- Anti-hypertensive drugs
- Other cardiovascular drugs
- Opiate analgesics

c Many others

D@#VWSiOfl ***and psychosis***

/nfectlons:
- Colds
- Flu
- Lung (pneumonia)
- Brain
- Brain membranes
- Blood
- Kidney
- Digestive tract

c Many others

Stroke ***(often at least ~arfia//y reversible):***
- Blood clots in or around the brain
- Occlusion of blood vessels feeding the brain

Heart failure

Disorders of endocrine function:
- Thyroid hormone
- Parathyroid hormone
- Hormones and substances affecting blood volume control
- Stress-related hormones
- Others

Nutritional disorders:
- Vitamin BI~ deficiency
- Folate deficiency
- Protein deficiency

Anemia

Metaboiic and eiectrviytic imbalances:
- Calcium
- Sodium
- Potassium
- Others

Trauma:
- Head injury
- Shock

Toxicity:
- Occupational exposure
- Environmental exposure (lead, carbon monoxide)
- Household exposure (pesticides)

SOURCE: Office of Technology Assessment.

Urinary incontinence

Urinary incontinence is detrimental to the physical health, psychological well-being, and social functioning of those afflicted. This condition disrupts the lives of 5 million to 10 million Americans, their families, friends, and caregivers and is most common among those over age 65. Incon-

OTA Fact Sheet on Alzheimer Disease

How big is the problem?

- Alzheimer disease affects 5 to 15 percent those over 65 (1.2 million to 4 million Amer. icans).
- Alzheinwr disease is common with advancing age, affecting more than 20 percent of those over age 60.
- Alzheimet disease imposes severe financial medical, and emotional stresses **on** families:
  - –A full diagnostic evaluation cost $300 to *$2,000.*
  - –Families bear fractions of diagnostic therapeutic costs, and **almost half of** the overall cost of king-term care directly out-of-pocket.
  - –Families suffer loss of a ~ ~ , ‘ ‘ , often leading to sudden and substantial duction in income,

  Alzheimer disease accounts for an estimated 30 to 50 percent of those in nursing homas.
- **Alzheimer disease** is the most **frequent cause of** institutionalization for **long-term care.**
- Federal funds **for long-term care in 1980 were** $12 billion **($10.4 billion from** Medicaid, **$0.4** billion from Medicare, and $1.1 billion **from** the Veterans Administration). **These costs,** under present arrangements, **will escalate to $24 billion** by **1985, and $43 billion by 1990. Alzheimer** disease accounts **for** 30 **to 50 percent of this spending.**
- **Alzheimer disease accounts for an estimated 50 to 75 percent of dementia ("senility"). The remaining fraction is due to cardiovascular disorders, stroke-related diseases, and more than a dozen treatable causes of dementia.**
- **Alzheimer disease is often misdiagnosed; 8 to 23 percent of those said to have this disease may actually have depression or other treatable disorders.**
- **Chances are better than 50 percent that one of one's grandparents would develop the disease if all lived past age 65.**

What is it?

Alzheimer disease is an organic brain disease named after the German physician, Alois Alzheimer, who first described it in 1906. Alzheimer disease causes progressive loss of mental functions over a period of years. Its clinical progression is **usually** divided **into** three **stages:**

1. Mild cognitive deterioration **is quite difficult** to distinguish from normal **function, and** is **usually first detected by loss of memory for** recent events. Difficulties in speech and word-finding; loss of the ability to "think through complex interpret complex stimuli soon follow. The first signs noted can however, vary greatly among patients.
2. This is followed by worsening cognitive deterioration and personality changes, often **including** *tation as to time* and place. The patient's speech often remains fluent and grammat**ical' but the content** of what is said is often *inappropriate or eisconected from reality*
3. **Finally,** shows complete loss of **intellectual** leading to **a state of** vegetation. This includes the inability to speak or Recognize even close relatives, and complete loss of "world knowledge."

It is highly **probable that what is now called Alzheimer** or "senile dementia of the **Alzheimer** type" **is a *group* of several** distinct **diseases, with** causes and mechanisms. **is tremendous** variation in the duration **its fatellness and** progression. Younger **patients** tend to have more severe cases which **progress** apidly. **Alzheimer** disease can **last from** a **few** years to a few decades.

How is the diagnosis made?

The diagnosis of Alzheimer disease can now be made only by excluding other causes of dementia. Diagnosis is certain only when made at autopsy, by finding a profusion of the three pathologic indicators of Alzheimer disease:

- **"Senile" or Alzheimer plaques (neuritic plaques)—accumulations of proteins and cellular debris also found in other diseases, but not in such numbers or in the variety of anatomic locations as in Alzheimer disease.**
- **Neurofibrillary tangles—accumulations of fiber-like proteins inside of cells, also found in several other disease states, but with a different distribution and in lesser numbers.**
- **Granulovacuolar bodies—enclosed bundles (vacuoles) of material of uncertain origin found inside cells. They are restricted to specific regions of the brain, and are rare-in other diseases.**

None **of** the pathologic changes is unique to **Alzheimer** disease. The pathologic diagnosis is

based on seeing a large number of the plaques, tangles, and granulovacuolar bodies in places not usually associated with other diseases. There are, however, certain groups of nerve cells in specific anatomic locations that appear to be lost in Alzheimer disease much more than in other disorders. Correlation with clinical symptoms is essential to definitive diagnosis.

What are other important points?

- It is not clear whether Alzheimer disease is a consequence of aging or a specific disease which affects only a susceptible population. Present medical belief favors the latter hypothesis; historically, the relative dominance of these beliefs has alternated.
- All statistics on incidence and prevalence are highly uncertain because:
  - —Alzheimer disease patients die *with* the disease, not *of* it. This leads to underreporting on death certificates.
  - —Patterns of diagnosis of psychiatric and neurological diseases have changed drastically in the last decade. "Alzheimer disease" used to refer only to those patients affected before the arbitrary age of 65.
  - —Alzheimer disease patients often are not referred to a neurologist or psychiatrist for specific diagnosis. Terms such as "senility," "cerebral arteriosclerosis," "organic brain syndrome," "chronic brain syndrome," and "dementia" often serve as substitutes for an accurate and specific diagnosis. Nonspecific and uncertain diagnosis make data on dementia unreliable, especially when not gathered by neurology or psychiatry departments.
  - —There is no fully effective treatment at present, although several new drug therapies are promising.
  - —There is no specific "marker" for the disease. Thus the diagnosis is made by excluding other causes of poor mental function. This leads to diagnostic error. There is a need for accurate and cost-effective diagnosis.
  - —The disease starts as the patient's and ends as the family's: the patient's medical problem soon becomes a financial and emotional drain on the family. Many of the most distressing effects of the disease are borne by friends and relatives, not by the patient.
  - —Self-help groups, such as the Alzheimer Disease and Related Disorders Association, are trying to aid in family support and as information clearinghouses.
- There are no effective means of prevention.
- Because the ability of the patient to decide for himself or herself is often questionable, the procedure for obtaining informed consent may be unclear, leading to legal and ethical problems in research and treatment.
- Families are often prudent in seeking transfer of power of attorney well in advance of the time when medical and financial decisions must be made on behalf of the patient.

What are some possible causes?

- Loss of nerve cells in specific areas of the brain (nucleus basalis of Meynert, hippocampus, locus ceruleus) may be one cause, analogous to Parkinson's disease. The reason for the loss is unknown.
- Genetic factors may account for 10 to 60 percent of cases. The wide range in estimates is due to scientific uncertainty. There is definitely at least one genetic form, in which an affected person's sons or daughters are each at 50 percent risk, but the prevalence of the genetic form is controversial.
- An atypical infectious agent ("slow virus"), analogous to that which causes some other dementing diseases, has been suggested. The other diseases are caused by unusual infectious agents that remain dormant for years, and then cause unremitting neurological illnesses which terminate in death after a clinical course of one to a few years. Alzheimer disease is similar to these other diseases in several respects, but there is only circumstantial evidence of causal similarity at present.
- Contamination of fibrillar proteins in neurons, of unknown cause, may lead to interference with normal nerve-cell function, eventually resulting in cell death.
- Aluminum and silicon are found in high concentrations in the plaques of those affected with Alzheimer disease. One hypothesis is that cell death is due to some variety of "aluminum poisoning." There is no agreement on whether the aluminum accumulation is a cause or an effect of cell death and biochemical changes in Alzheimer plaques.
- It has also been suggested that Alzheimer disease may be an autoimmune disorder, caused by the immune system reacting against the brain, leading to cell death. This would be analogous

to Other diseases such as systemic lupus erythematosus *or* myasthenia gravis.
- A biochemical aberration of calcium metabolism may lead to insufficient release of neurotransmitter.
- There may be a disorder of glycolytic biocheroical pathways (pyruvate dehydrogenase) leading to decreased calcium influx into the cell and insufficient release of neurotransmitter.
- Disorders of neurotransmitters other than acetylcholine maybe involved as well. Those suggested include:
  —somatostatin,
  —norepinephrine (from the locus ceruleus),
  —vasopressin, and
  —endogenous opioid peptides. This last is supported by clinical reports of improvement by treatment with naloxone, a chemical blocker of opiate receptors.

What potential therapies are under investigation?

- Infuse drugs that simulate the actions of acetylcholine directly into the fluid surrounding the brain. Four patients, in a recent trial, received such drugs from a pump implanted in the patient% body and families reported improvement or stabilization of symptoms.
- Stimulate acetylcholine synthesis (lecithin, choline)—not very successful to date.
- Administer piracetam, a drug which improves some aspects of mental function, alone or in combination with other drugs.
- Use drugs that mimic the effect of acetylcholine, either alone or in combination.
- Stimulate acetylcholine release with 4-aminopyridine and related agents.
- Increase the *duration of action* of acetylcholine by inhibiting breakdown by anticholinesterase drug therapy. The best example is physostigmine.
- Chelate aluminum to prevent toxicity with fluoride, tetracycline, or deferoxamine.
- Use naloxone to block opiate receptors.
- Use vasopressin to improve memory.
- Breathe hyperbaric oxygen (not very successful).
- Use ergoloid mesylates (Hydergine—only marginally effective, used widely in Europe

Of these treatments, those affecting acetylcholine have shown moderate, but inconsistent improvement. Ergoloid mesylates administration has been shown to have an effect in numerous trials, but the effect is so minor that it may not be clinically relevant.

What are some potential developments in the long run?

- Research may yield a specific diagnostic test for Alzheimer disease. Such a test could develop from biochemical tests on tissue from brain biopsies, chemical metabolizes in cerebrospinal fluid, or monoclonal antibodies to proteins that are possibly specific to Alzheimer disease.
- Use of nerve-cell implants (so-called brain-cell transplants) is promising, but many technical obstacles remain. The treatment has worked in animals with a disease resembling Parkinson's disease, and human grafts have grown successfully in experiments conducted in Scandinavia. The human experiments have not yet been clinically useful, and many problems regarding what tissue to use as a source of implantable nerve cells must be solved. Successful implant therapy for Alzheimer disease also awaits knowledge of the nerve cells that need to be replaced.
- Understanding of the biochemical and neurotransmitter defects may allow specifically targeted therapy, based on the physiology of the affected parts of the brain. One promising avenue to learning about this is through development of animal models based on finding chemicals that specifically destroy certain parts of the brain or particular types of nerve cells.
- Understanding a cause or causes (whether viruses, other infectious agents, or environmental toxins) may permit effective prevention.
- Identification of genetic markers, analogous to those known for sickle cell disease or Huntington disease, would prove useful for investigating the putative molecular defect, as well as helping in diagnosis of members of affected families for family and personal planning.
- Genetic treatments sible, based on genes in other species (e.g., hamsters or mice), and identification and study of those genes, if any, that predispose to dementia may also be possible to deliberately engineer nerve cells with needed characteristics to replace or supplement cells that have died.

tinence also constitutes a costly health problem: the U.S. Surgeon General estimates that $8 billion is spent on incontinence in this country each year (37). Because it is often difficult for affected individuals and their families to cope with the condition at home, incontinence may play a pivotal role in the decision to enter a long-term care facility.

Despite the availability of many effective forms of treatment, incontinent persons are rarely evaluated thoroughly enough to determine the precise causes of the condition and are therefore not treated optimally. Some estimate that up to one-third of incontinent patients could be completely cured (38,73). Several factors contribute to the deficiency in care of incontinent persons in this country, including: 1) lack of knowledge about the specific diagnosis and optimal treatments for different types of urinary incontinence; 2) reluctance of affected individuals to seek medical help because of embarrassment, social stigma, and the misconception that it cannot be treated ('largely because of lack of awareness of available treatments); and 3) scant, inconsistent Federal and State reimbursement policies for urinary incontinence treatment and products, especially for the noninstitutionalized.

This section briefly explores these barriers to adequate medical care for incontinent persons, looks at the technologies available for treatment, and proposes some ways in which the government might act to reduce the magnitude of the medical, social, and economic impact of urinary incontinence in this country.

Definition, prevalence, and causes of incontinence

Urinary incontinence is defined as an involuntary loss of urine sufficient in quantity and frequency to be a social or health problem. The severity ranges from occasional dribbling to total loss of control over excretion of both urine and stool (fecal incontinence is much less common and is not discussed in detail here). Between 10 and 20 percent (2 million to 4 million)[2] of community-dwelling elderly have some degree of incontinence. The prevalence increases to between 40 and 50 percent of those elderly in nursing homes *(600,000* to **700,000).** In comparison, between 1 and 5 percent of those under age 65 (2 million to 10 million) have a persistent problem with incontinence.

Data subdivided by severity for community-dwelling elderly persons are scarce but British studies suggest that 5 percent are severely affected (one or more episodes daily) and 9 percent are less severely affected (68). More than two-thirds of affected individuals (or over one-third of the total patient population) in nursing homes have more than one episode a day (59). Although incontinence of both urine and stool is relatively uncommon in community dwelling persons, close to 50 percent of those in nursing homes who are incontinent of urine also have episodes of fecal incontinence (46,59). Most patients with both kinds of incontinence also have severe impairments of mental and/or physical functioning.

Disorders of the lower genitourinary tract, disorders of innervation and neurological control over genitourinary function, lack of mental awareness of the need to void, and limitations in mobility or environmental factors (e.g., restraints or **drugs) Can all** contribute to the development and persistence of incontinence. The many types of urinary incontinence can be divided into two general categories, acute and persistent (see table 6), for which the causes and the clinical approaches are distinct.

Acute incontinence refers to the sudden onset of episodes of involuntary urine loss that are usually associated with an acute illness, or environmental factors that impair the mental or physical ability to reach a toilet or toilet substitute. Especially common in hospitalized elderly, acute incontinence can be precipitated by impairment of mobility (as with hip fracture) or some type of bed restraints; such patients may recognize the need to void but may not be able to obtain timely help in getting to the toilet. other causes of acute incontinence include: acute urinary tract infections with bladder inflammation; metabolic dis-

[2]'Accurate, consistent prevalence data for urinary incontinence are scarce, especially for community dwelling persons, because of underreporting due to social stigma, reluctance to seek medical help, and lack of diagnosis. The figures given here are therefore rough and probably underestimates.

Table 6.—Types of Incontinence

Definition	Causes	Population(s) affected
Acute:		
Incontinence of sudden onset associated with an acute illness (and/or other factors) that subsides once the acute condition has been resolved or other factors have been removed,	Acute illnesses associated with one or more of the following: (a) immobility and/or environmental factors that diminish the ability to get to and use a toilet, (b) impaired mental function that diminishes toileting ability, (c) fecal impaction. Acute urinary tract infections. Drugs: (a) those that increase urine flow (e.g., diuretics), (b) those that inhibit bladder contractions and cause urinary retention and overflow (e.g., anticholinergics), (c) those that decrease mental awareness (e.g., sedatives, hypnotics). Metabolic—increased urine flow (polyuria) associated with poorly controlled diabetes.	Elderly, usually in acute hospitals.
Established:[a]		
Stress:		
Leakage of small amounts of urine with increases of intra-abdominal pressure (e.g., coughing, sneezing, laughing, exercise).	Weakened supporting tissue surrounding bladder outlet and urethra associated with: (a) lack of estrogen in postmenopausal women, (b) previous vaginal deliveries, (c) previous pelvic surgery (e.g., hysterectomy).	Women, especially those over age 40.
Urge:		
Leakage of urine caused by inability to delay voiding long enough to reach the toilet after urge to void is felt.	Neurological disease such as stroke, dementia, Parkinsonism, muliple sclerosis, spinal cord diseases. Genitourinary disorders such as unstable bladder ("detrusor instability"), bladder stones, diverticuli of urethra and bladder, atophic urethritis, vaginitis (females), chronic cystitis, mild outflow obstruction (usually males).	Men and women of any age; most common in the elderly.
Overflow:		
Leakage of small amounts of urine associated with obstruction to urine flow.	Hypotonic or acontractile bladder associated diabetic neuropathy, spinal cord injury, or drugs such as anticholinergics (which inhibit bladder contractions), smooth muscle relaxants, narcotics, and alcohol. Anatomic obstruction associated with prostatic enlargement or urethral stricture.	Older men with prostatic enlargement. Diabetes.
Functional:		
Inability or unwillingness to reach a toilet in time.	Impaired mobility. Impaired mental function. Inaccessible toilets (or caregivers). Psychological disorders such as depression, psychosis, anger or hostility.	Elderly in acute hospitals and nursing homes and those with acute or severe psychiatric illness.

a Incontinence is persistent and unrelated to an acute illness.

SOURCE: J Ouslander, R. Kane, S. Vollmer, and M Meneres, "Medical Devices for Urinary Incontinence: A Case Study," prepared for the Office of Technology Assessment, contract No. 333-6550, December 1983.

orders that increase urine flow, such as diabetes; fecal impaction that may mechanically obstruct normal bladder emptying or cause reflexive involuntary bladder contraction; and a variety of drugs. Drugs that can induce urinary incontinence include: diuretics that increase urine flow; sedative, hypnotic, and antipsychotic drugs that may diminish mental awareness of the need to void; and drugs that influence lower urinary tract functioning, such as anticholinergic drugs (that inhibit the bladder from contracting) and certain antihypertensive drugs (that decrease resistance in the bladder outlet) (36,64).

Persistent or established incontinence (i.e., repeated episodes not associated with an acute condition) can be divided into four types:

1. Stress ***incontinence*** usually occurs in women, especially those whose musculature has been weakened by multiple vaginal deliveries or

pelvic surgery. It involves the leakage of small amounts of urine with increased abdominal pressure such as that associated with exercise, straining, coughing, laughing, or sneezing.
2. ***Urge incontinence*** involves leakage of varying amounts of urine because of inability to delay voiding before reaching a toilet. It can be, but is not always, caused by a variety of genitourinary and neurological disorders such as involuntary bladder contractions, or local irritation of the bladder or the urethra.
3, ***Overflow incontinence*** involves leakage of small amounts of urine and is caused by anatomic obstruction to bladder emptying (as by an enlarged prostate in men) and/or impaired ability of the bladder to contract (as with diabetes, spinal-cord injuries, and certain drugs).
4. ***Functional incontinence*** occurs in those individuals who have chronic impairments of either mobility or mental function, are unable to use a toilet independently, or are unable to maintain continence because of psychological disturbances. This type of incontinence may also be induced by iatrogenic factors such as medication or environmental barriers (e.g., restraints).

Treatment

Determining the appropriate treatment for an individual with urinary incontinence requires a thorough evaluation of all relevant factors—genitourinary, neurological, psychological, and environmental—that could be causing or contributing to the condition. Unfortunately, health professionals commonly do not recognize incontinence, especially among community dwelling older persons, or fail to note it as a problem and therefore do not pursue an evaluation (59). The problem is compounded by the reluctance of many afflicted individuals who are too embarrassed to seek medical help or believe that nothing can be done about it.

Fewer than 5 percent of incontinent patients in a nursing home setting are estimated to have had any specific evaluation of their incontinence **(59).** Many could benefit from such an evaluation because it could lead to a cure or to treatment that significantly ameliorates their incontinence. Some experts estimate that one-third of incontinent patients can be completely cured and most others could be kept comfortable and dry with appropriate management technologies (38,73). Unfortunately, there have been very few studies on the relative efficacy of various treatments for different types of incontinence. Only a handful deal specifically with the elderly and most report on fewer than 10 patients (72).

When treated inadequately or inappropriately, incontinence can lead to skin breakdown and recurrent urinary infections. In addition, inadequate treatment can exacerbate the incontinence and thus increase the psychosocial impact, leading to further loss of self-asteem and withdrawal from social activities that may exacerbate isolation and depression. Studies in Great Britain indicate that incontinent individuals often are reluctant to utilize services available to them such as incontinence nurses, incontinence clinics, and laundry services (e.g., 67,68,74,75).

Many technologies are specific to a particular type or types of incontinence and attempt to cure the problem (e.g., artificial sphincters, electric stimulators, drugs, training procedures, and surgery). Diagnostic evaluation is thus critical to the appropriate use of these treatments. other treatment technologies are nonspecific and palliative rather than curative (bed pads, undergarments and, in some situations, catheters). In general, these technologies should be used as a last resort after diagnostic evaluation has excluded treatable conditions.

The various types of technologies for the treatment of urinary incontinence, along with their mechanisms of function and appropriate uses, are described in table 7. In order to discuss their advantages and disadvantages, these technologies are divided into four categories in the discussion that follows: devices, surgery, drug treatment, and training procedures. Again, little is known about the relative efficacy and long-term cost effestiveness of the various treatments for urinary incontinence.

Table 7.—Treatments for Urinary Incontinence

Examples	Mechanism	Uses
Devices:		
To collect urine before leakage occurs:		
Catheters	A flexible tube is placed directly in the bladder and drains urine into a collecting bag. Can be used continually or intermittently.	Inability to empty bladder (urinary retention) that cannot be corrected by surgical or drug treatment. (This may *or* may not be associated with overflow incontinence.) Incontinence associated with healing skin lesions.
*To collect urine after **leakage occurs:***		
NASA (female) Condom catheters (male)	Outflow is trapped and drained into a collecting bag.	Any type of incontinence.
Bed pads	Pad protects individual and mattress from contract with urine. These pads are disposable or reusable.	Any type of incontinence especially, useful as adjunctive therapy with other treatments.
Prevent or delay urine outflow:		
Artificial sphincters Inflatable cuff	Inflatable cuff is surgically implanted around urethra and inflated to prevent urine outflow.	Incontinence associated with sphincter weakness (usually stress incontinence or postprostatectomy)
Silicone-Gel prosthesis	Silicone-gel is inserted to replace existing urethra.	
Periurethral Teflon	Teflon paste is injected into tissues surrounding urethra.	
Electrical stimulators	Device inserted into vagina; produces electric impulses that (a) cause contraction of pelvic floor musculature (b) inhibit bladder contractions.	Incontinence associated with pelvic floor muscle weakness or bladder instability.
External clamp (male)	Penis is clamped to prevent urine flow.	All types of male incontinence.
Pessary (female)	Device is inserted into vagina, supporting tissues below bladder and around urethra.	Female incontinence associated with prolapsed pelvic structures (usually stress incontinence).
Other treatments:		
Surgical procedures:		
Bladder-neck suspension	Urethra and bladder neck are restored to a more normal intra-abdominal position.	Female stress incontinence.
Prostatectomy (transurethral resection and suprepubic)	All obstructing portion of prostate is removed.	Male overflow incontinence associated with anatomic obstruction.
Therapeutic bladder-neck transection	Bladder neck is surgically incised.	Urge incontinence associated with bladder instability.
Selective bladder denervation (cystolysis)	Nerves to upper bladder are cut so that there is no muscle control of bladder dome, but sphincter mechanism is intact.	Urge incontinence associated with bladder instability.
Therapeutic bladder distension	Bladder is distended under anesthesia for at least two hours to a pressure close to systolic blood pressure.	Urge incontinence.
Correction of other genitourinary pathology (e.g., bladder tumor or stone).	Removal of irritative or obstructive factors.	Urge incontinence associated with bladder instability. Overflow incontinence associated with outflow obstruction.
Drugs:		
Propantheline (Probanthine) Imipramine (Tofranil) Oxybutrin (Ditropan) Flavoxate (Urispas)	Diminish bladder contractions.	Urge incontinence associated with bladder instability.
Ephedrine (Sudafed)	Strengthen bladder outlet	Stress incontinence associated with sphincter weakness.

Table 7.—Treatments for Urinary Incontinence—continued

Examples	Mechanism	Uses
Phenypropronolamine (Ornade)		
Estrogen (Premarin) Oral or topical	Increases supporting tissue around urethra.	Stress incontinence.
Bethanechol Urecholine)	Promotes bladder contraction.	Overflow incontinence.
Training procedures:		
Habit training	Caretaker determines individual's pattern of incontinence and gets him/her to toilet according y.	Urge. incontinence. Functional incontinence.
Bladder retraining	Caretaker establishes routine of fluid administration and toileting with progressive lengthening of toileting intervals to increase bladder capacity or re-initiate normal voiding.	Urge incontinence. After catheter use. Overflow incontinence after overdistension injury.
Pelvic floor exercises	Exercises to strengthen pelvic muscles.	Stress incontinence.
Biofeedback	With specialized equipment, patient is trained to inhibit bladder contractions or contract pelvic muscles.	Mainly urge incontinence associated with bladder instability and stress incontinence associated with sphincter weakness.
Behavioral modification	Caretaker rewards incontinent individual for staying dry.	Incontinence associated with underlying mental or emotional disorders; some forms of functional incontinence.

SOURCE: J. Ouslander, R. Kane, S. Vollmer, and M. Medical, "Medical Devices for Urinary Incontinence: A Case Study," prepared for the Office of Technology Assessment, contract No. 333-6550, December 1983.

DEVICES

Four major types of devices are currently in use: bedpads and undergarments, catheters, electrical stimulation, and artificial sphincters.

Bedpads and undergarments range from those that are completely disposable to those with launderable components. Most acute care hospitals and long-term care institutions use "blue pads" for managing incontinence despite their relatively low absorbency and lack of odor control. More innovative forms, like the Kylie @ pad that is launderable and draws moisture away from the body, have been marketed widely in the United States only recently. The efficacy of these products in diminishing complications of incontinence such as skin irritation and urinary tract infection has not yet been carefully assessed.

The three types of catheters commonly used are chronic indwelling catheters, intermittent bladder catheterization, and, for men, external catheters. A chronic indwelling catheter is placed in the bladder and attached to plastic tubing that drains urine into an externally worn collection bag, This type of catheter can induce serious complications, however; urinary tract infection is the most common. It should only be used in patients with urinary retention that cannot be treated surgically, pharmacologically, or by intermittent catheterization, and for patients with skin conditions that are worsened by contact with urine.

There is evidence that indwelling catheters are overused in managing urinary incontinence, especially in elderly patients in long-term care facilities (10 to 30 percent of incontinent cases), probably because of the relatively low cost and convenience for the staff (50,53,57,61)69). Intermittent self-catheterization has a lower incidence of infection and other complications in younger patients (51), although its relative efficacy in the elderly has not been studied; this method also requires training on the part of the caregiver and/or patient. External (condom) catheters, used exclusively in men, may reduce infection but require frequent changing, often fall off, and may result in local skin irritation.

The National Aeronautics and Space Administration (NASA) has also developed an external female urine-collection device for use of women

astronauts. This and a similar adhesive device developed by private industry are still in the developmental stage for application to older women in the general population; both have already received approval by the Food and Drug Administration (FDA). The adhesive device has been marketed on a limited basis; the NASA product is scheduled for release onto the retail market in November 1984 under a nonexclusive licensing agreement with a small manufacturing company headed by the inventor of the device.

Electrical stimulation involves an external device that intermittently stimulates musculature associated with voiding to induce muscle contraction and maintain continence. This technique is most useful for incontinence due to stress and bladder instability (40,41)42)43), Between 50 and 80 percent of individuals treated in this way derive some short-term benefit from the treatment. The long-term effects of chronic electrical stimulation are unknown, however, and the patient must be willing and able to manage the device.

While artificial sphincters appear to improve or cure incontinence in 40 to 80 percent of patients treated (relatively few patients receive such implantations), there are several associated complications. The most common problems are erosion of the sphincter cuff into the urethra, persistent infection, and mechanical failure. Favorable results have been obtained with prostheses consisting of injections of silicone gel or Teflon", but there is again the risk of urethral erosion and Teflon" particles have shown a tendency to migrate to other major body organs.

SURGERY

Surgery is an essential treatment for certain types of incontinence and is effective, but not essential, for other types. An anatomic obstruction to urine flow (e.g., an enlarged prostate in men), for example, can lead to recurrent infection and even renal failure, necessitating surgery to relieve the obstruction. Yet surgery may not cure the incontinence and may even induce a different type of incontinence. Pathologic conditions in the lower genitourinary tract that irritate the bladder or urethra (e.g., bladder tumors, bladder stones, and diverticuli of the urethra or bladder) and cause incontinence can also be treated surgically. The most common surgical procedure for incontinence is bladder-neck suspension in women in which the bladder neck and urethra are repositioned to relieve stress incontinence. The success rate is generally reported as 70 to 90 percent (54,62,63,65,66). There have been no conclusive studies on the efficacy of surgery relative to other treatments for stress incontinence.

DRUG TREATMENT

Although drugs can be used to treat overflow, stress, and urge incontinence (36,56)64), they may be inappropriate for the elderly or have undesirable side effects. For example, cholinergic drugs used to treat overflow incontinence that promote bladder contraction may actually worsen incontinence in the elderly by creating urinary frequency and urgency; in addition, some of these drugs may cause cramping, diarrhea, and increased bronchial secretions. Drugs used to treat stress incontinence that promote muscle contraction around the bladder outlet may exacerbate hypertension. The topical and oral estrogens that are used in elderly women to strengthen the tissues around the bladder outlet may also exacerbate hypertension and increase the risk of cancer of the uterine lining. The most common and effective drug treatment involves substances that reduce bladder contraction to treat urge incontinence. Most studies show these drugs to be effective in 50 percent of the patients. Many, however, can have undesirable side effects, including dry mouth, constipation, and blurred vision. Unfortunately, there have been few studies comparing the efficacy of these drugs with other methods.

TRAINING PROCEDURES

"Training procedures" are broadly defined here to include pelvic-floor exercises, biofeedback bladder retraining, habit training, and behavior modification. Many of these have been reported as successful in managing various types of incontinence (47)71). Patients must have adequate cognitive function to use the pelvic-floor exercises (strengthening associated muscles by repeated contraction), biofeedback bladder retraining (learning to control muscle contraction, requiring specialized equipment and personnel) or blad-

der retraining (learning progressively to extend periods between voiding). Habit training involves developing a toilet schedule and can be used with patients who have mental and physical impairments. Behavior modification is similiar to habit training but incorporates positive and negative reinforcers and is used mainly for bed-wetting children and chronically mentally ill patients (39,60). Most studies of the efficacy of training procedures have involved some type of bladder retraining or habit training for urge incontinence and have found So to 80 percent of subjects cured or substantially improved (44,45,47,48,49,52). Again, there have been few studies of the relative efficacy of training compared with other treatments.

The cost of incontinence

The costs of incontinence go far beyond economic considerations. Withdrawal from social activities, psychological distress, burden on the family and caregivers, and the influence on the decision to institutionalize are all important potential effects of incontinence that are difficult to quantify (55). In one study of stress in caregivers of frail elderIy community dwelling persons, difficulties with toileting and incontinence were highly correlated with caregiver burden (55). Since the Federal Government plays an important role in assisting with medical costs, however, it is important to discuss the cost of incontinence and current Federal reimbursement policies.

The variety of incontinence products are discussed in detail in a separate OTA case study, "Technologies for Managing Urinary Incontinence. " One of the report's major conclusions is that promotion of these products has been targeted largely toward physicians and other health care professionals rather than toward the consumer. As a result, incontinence products are not widely available at the retail level and public awareness of the variety of treatments available is scant,

Two large paper-products firms have entered the market for disposable incontinence products, however, and have launched consumer-oiented advertising campaigns that may help destigmatize incontinence and lead to competitively low prices. Unfortunately, these promotional efforts, which emphasize management of incontinence through the use of undergarments, may lead consumers to believe that this is the most appropriate treatment. For other technologies such as catheters, electrical stimulators, and artificial sphincters, the delays and difficulties in obtaining FDA approvals could constitute a barrier to entry into the market for manufacturers. The case report points out that the Federal Government, as a disinterested party, could effectively promote consumer education about the importance of medical evaluation and the variety of treatments available.

FINANCIAL COSTS

The actual expense of incontinence management and the Federal role in providing financial assistance to care recipients is important since this can affect access to health care. Moreover, loss of productivity of both those afflicted and their caregivers can be substantial, It is important to note that, as has been mentioned, very few incontinent nursing home patients receive a specific evaluation of their condition. Although an extensive urologic evaluation for incontinence can be costly (about $600) and involve highly specialized personnel and equipment, it may save money overall by curing or mitigating the condition through more specific, effective treatment (58), and bring immeasurable improvement to the quality of life of both the patient and the caregiver. Research into the most practical and cost-effective methods of diagnosing different types of incontinent patients is sorely needed.

The U.S. Surgeon General has estimated that $8 billion is spent on incontinence in this country annually (37); the basis of this estimate has not been detailed, however. A recent report (58) divides estimates of the overall annual costs of incontinence in nursing homes in the united States into "firstarder costs" (i.e., the costs of managing incontinence without the costs of any complicating conditions) and "seconderder costs" (i.e., the costs associated with managing complications of incontinence and its treatment).

If only first-order costs are considered, incontinence adds between $3 and $11 to the daily cost of caring for a nursing home patient. The range

of cost is due to differing costs of various management techniques. of the three components of these costs (labor, laundry, and supplies), the labor involved in handling an incontinent patient is the major contributor,

Assuming that there are approximately 600,000 nursing home patients with some degree of urinary incontinence and that, in threequarters of these patients, the incontinence is of sufficient severity that catheters or other specific management techniques are used, the yearly first-order costs of incontinence in U.S. nursing homes can be estimated at between $0.5 billion and $1.5 billion. This represents between 3 and 8 percent of the total expenditure on nursing home care in this country (58). The costs of incontinence in the community are much more difficult to estimate and no studies have addressed these costs in detail.

First-order costs were estimated to be lowest for patients with indwelling catheters. Yet for these same patients the second-order costs were highest because of the high incidence of urinary tract infection associated with continuous use of these devices. A conservative estimate of the second-order costs of incontinence is between $2,000 and $3,000 per patient per year. The National Institute on Aging is currently funding a study on methods to reduce complications associated with indwelling catheters in order to reduce second-order costs and possibly render these catheters less costly alternatives to other treatments in the nursing home setting.

PAYMENT

Except for diagnostic evaluation and services delivered as part of an acute hospitalization,[3] Medicare coverage for incontinence products is quite limited. Part B of the plan only pays for a prosthetic device that replaces an inoperative body organ or function thereof. Thus sphincters or ileostomy bags would qualify, but catheters, bedpads, and undergarments would not. Medicare also does not pay for most bedpads and undergarments used outside of the hospital.

[3]Medicare coverage of acute hospital costs under Part A changed dramatically with the introduction of diagnosis-related groups in October 1983. The all-inclusive price will not specifically pay for an incontinence device.

Coverage for urinary incontinence products under Medicaid varies from State to State. Undergarments and other disposable products are least likely to be considered medical equipment and are therefore the least likely treatments to be covered. Medicaid covers these products in some States, such as New York, California, Florida, Illinois, and Michigan. In other States, such as New Jersey, these products are not covered. Even in those States in which Medicaid covers the products, the type and extent of coverage vary considerably. Furthermore, State requirements for coverage and payments change frequently.

Given present fixed reimbursement rates in most States, the first-order costs of incontinence ($3 to $11 per day) represent 7 to 27 percent of the daily per diem provided by Medicaid (about $41 per day in California for 1984). The result is often reluctance of nursing homes to accept incontinent patients. Several States have developed or are developing case-mix reimbursement strategies that recognize the rising costs of incontinence; the emphasis, however, is on managing such patients rather than on treatment to improve their condition.

Moreover, second-oder costs, as for treatment of skin breakdown or urinary tract infection, are largely covered by Medicare. The financial incentive for nursing homes is therefore to use the cheapest treatment in terms of first-order costs ***(e.g.,*** an indwelling catheter) regardless of possible resultant complications. An experiment conducted by the National Center for Health Services research is currently testing the effects of paying nursing homes an incentive to accept incontinent patients and a bonus if they improve their functional condition (70).

Conclusion

Urinary incontinence afflicts a significant percentage of our elderly population with detrimental effects on their physical health, psychological well-being, and social functioning, and constitutes a costly health care problem. There are several barriers to effective treatment, including lack of knowledge about the most effective treatment for particular types of incontinence, lack of public awareness of the variety of technologies available

(many curative), social stigma, and limited access to health care due to minimal, inconsistent government reimbursement for most of incontinence treatments and products, especially for the noninstitutionalized. Improving the quality and availability of treatment for urinary incontinence by reducing or removing these barriers could reduce the impact on affected individuals and their caregivers, as well as reduce costs through decreased institutionalization and reduced use of other health care resources.

Hearing impairment in the elderly[4]

Hearing loss is a major problem for the elderly. National surveys show that hearing impairment is the third most prevalent chronic condition among the noninstitutionalized elderly, exceeded only by arthritis and hypertensive disease (93,94).

As the older population grows, the number of hearing impaired individuals will increase rapidly. Because the over-75 population has a very high prevalence of hearing impairments and is growing at a faster rate than the elderly population as a whole, the total number of hearing impaired elderly individuals will rise dramatically. At present, more than 7 million elderly persons have significant hearing impairments. If current rates persist, there will be more than 10 million hearing impaired elderly persons by the year 2000.

Hearing impaired individuals include both those who are deaf and those who are hard of hearing. Hard of hearing refers to a degree of hearing impairment that interferes with comprehension of speech, although partial auditory function remains. Deaf refers to a degree of impairment that renders hearing nonfunctional for the ordinary purposes of life (90).

Only a small proportion of the elderly with hearing impairments are deaf, but even the partial loss of hearing that is often associated with aging can limit independence and negatively affect quality of life for the elderly. Hearing loss restricts the individual's ability to interact with others and to give, receive, and interpret information. Sound is important for self-protection and identification of hazards in the environment. Ultimately, hearing loss can affect mental and physical health, decreasing the ability of some individuals to function independently and increasing the need for formal and informal long-term care services.

Prevalence

The prevalence of hearing impairment is measured by two methods, interviews and audiometric testing. The interview method underestimates the prevalence of hearing impairment because many individuals, particularly the elderly, are not aware of their hearing loss or may deny or minimize its severity. Audiometric testing results in more accurate information about prevalence and also measures hearing at specific frequency levels; this is important because hearing acuity in the elderly varies greatly according to frequency. Audiometric tests that measure hearing of pure tones, however, underestimate the extent of dysacusis, a condition that is widespread among the hearing impaired elderly. Individuals with dysacusis can hear pure tones but have difficulty understanding speech because of deficits in auditory discrimination (84).

Prevalence of hearing impairment by age, gender, race, income, and institutional status is discussed here. These data reflect prevalence of hearing impairment in the total population but may not apply in a given geographic area. For example, the prevalence of chronic ear infections among certain ethnic groups in Alaska and in the Southwest increases the prevalence of hearing impairment in these areas, Similarly, in areas where high-noise industries are concentrated, hearing

[4]This section summarizes an OTA background paper, ***Management of Hearing Impairment in the Elderly***, which draws heavily on G. Becker, R. M. Flower, L. E. Glass, and R. J. Newcomer, ***The*** Management ***of*** Hearing ***Impairment in*** Older Adults and American Speech-Language-Hearing Association, Management of Hearing ***Impairment in Older Adults,*** OTA contract No. 333-8970.0, 1984.

loss is much more prevalent among the working age and older populations.

AGE

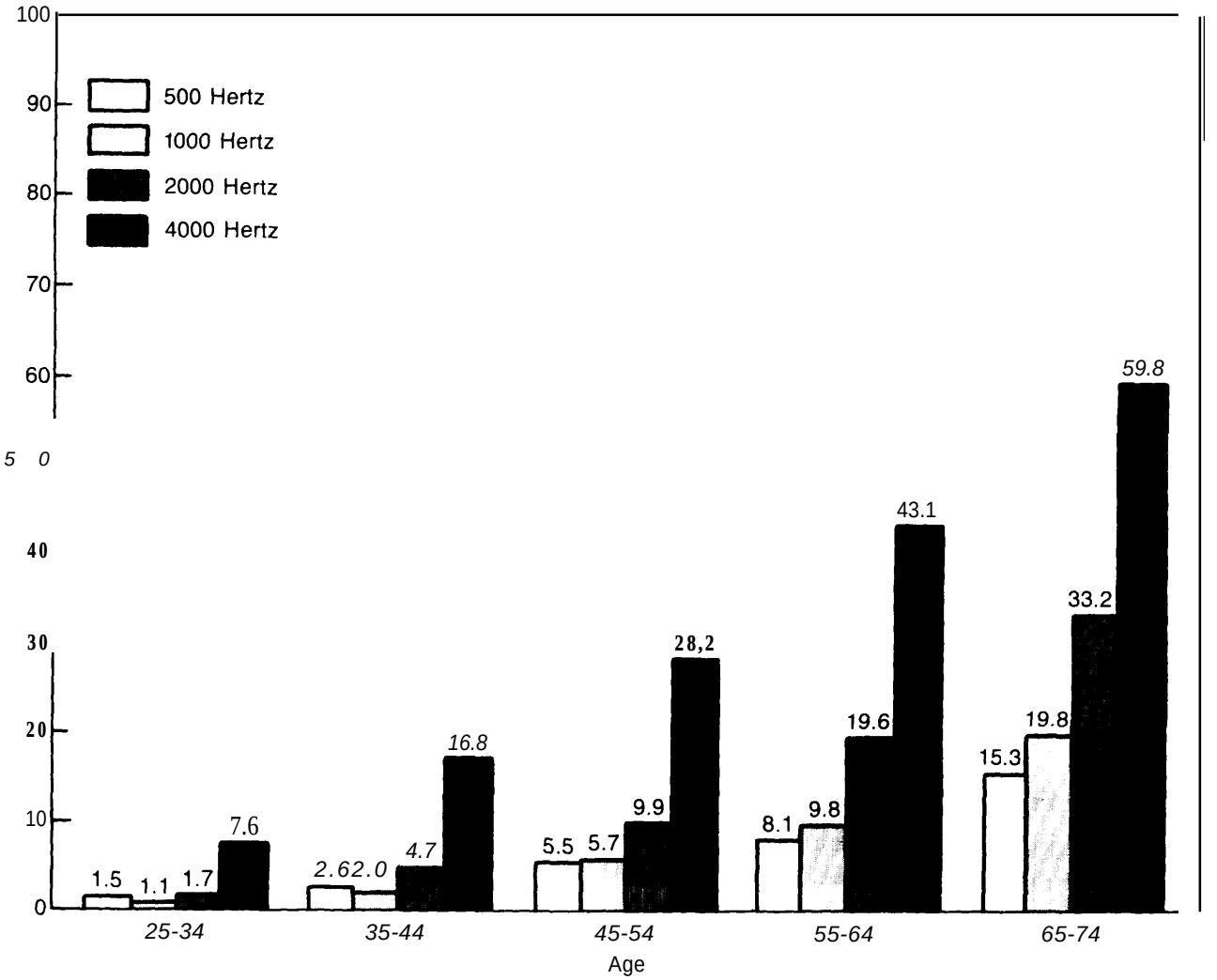
Interview surveys indicate that the prevalence of hearing impairment rises sharply with age, from less than 2 percent of those under 17, to about 12 percent of those 45 to 64, 24 percent of those 65 to 74, and about 39 percent of those over 75 (92). The severity of hearing impairment also increases with age (91).

Audiometric testing indicates that hearing impairment varies according to the frequency of the sound. As figure 13 indicates, the elderly have much greater hearing loss for high-frequency than low-frequency sounds. While most speech is in the frequency range of 500 to 2,000 hertz, sounds such as S, T, K, and P are heard at higher frequencies, and elderly persons with hearing impairments are often unable to hear these sounds.

GENDER

Interview surveys show that elderly men have a higher prevalence of hearing impairment than elderly women. For example, one study found that 29 percent of men ages 65 to 74 had hear-

Figure 13.—Percent of Adults Aged 25 to 74 With Hearing Impairment, by Frequency of Tone in the United States, 1971-75.



SOURCE National Center for Health Statistics, Basic Data on Hearing Level of Adults 25-74, Off Ice of Health Research Statistics and Technology, 1980

ing impairments compared with only 20 percent of women in that age group. Among those over 75, 44 percent of men but only 35 percent of women have hearing impairments (92). Some scholars suggest that these differential rates result from men's longstanding exposure to noise in heavy industry and other work-related situations.

Audiometric testing indicates that elderly men have a higher prevalence than women of hearing loss at high frequencies. One study showed that 49 percent of men over 65 had a moderate to severe hearing loss at 4,00 hertz, compared with only 17 percent of women over 65. Elderly women, however, have a slightly higher prevalence of hearing loss at low frequencies (95). The reasons for these differences are not known.

RACE

Interview surveys indicate a lower prevalence of hearing impairment among black persons of all ages than among whites. For example, blacks age 65 to 74 (bath sexes) showed an impairment rate of 18 percent, while whites in the same age group showed a rate of 25 percent (92). Audiometric testing shows that elderly blacks have a lower prevalence of severe hearing impairments than elderly whites, but a higher prevalence of moderate hearing impairments (95).

INCOME

Persons with low family incomes have higher rates of hearing impairment than their wealthier counterparts. For example, one interview survey found that the rate of impairment among persons 65 to 74 with annual family incomes below $3,000 was 30 percent. For the same population group with incomes in excess of $15,000, the rate was 20 percent. with only minor variation, this inverse relationship to income is sustained for all age categories (92).

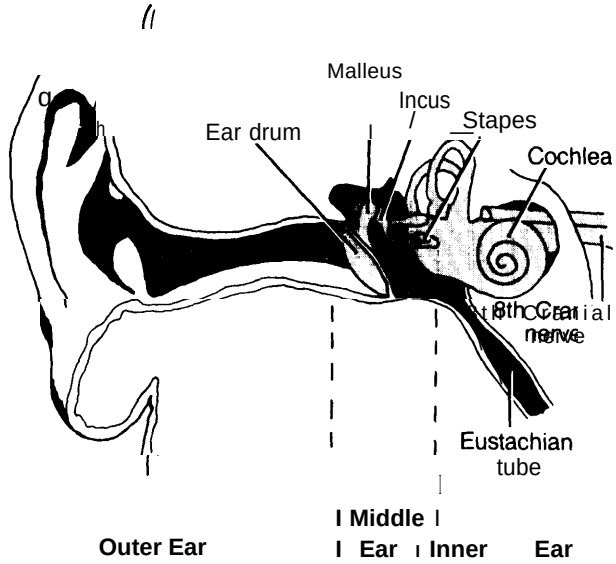
INSTITUTIONALIZATION

The prevalence of hearing loss among the institutionalized elderly is greater than among the noninstitutionalized elderly (88). Moreover, a recent study of an institutionalized older population (80) pointed out the inadequacy of self-reports for accurately assessing hearing impairment. Residents of a home for the aged were interviewed about their hearing and were given audiometric tests, Fifty percent of the residents acknowledged a hearing loss, but audiometric testing showed that 75 percent had hearing impairments; 8 percent of the residents reported hearing loss when there was no audiometric evidence of impairment, while 33 percent reported normal hearing but actually had clinically significant loss. These findings suggest that audiometric testing should be a routine procedure for elderly individuals admitted to long-term care facilities.

Types and causes of hearing loss among the elderly

Types of hearing impairment include conductive, sensori-neural, mixed, and central hearing impairments. These types are based on the site of structural damage or blockage (see fig. 14). ***Con-***

Figure 14.—Physiology of the Human Ear



In the healthy ear, the outer ear gathers sound waves and directs them to the ear drum, where three bones-the malleus, incus, and stapes—transmit the vibration to the cochlea. In the cochlea delicate hair cells translate the vibration into electrical current that passes through the 8th cranial nerve to the auditory centers of the brain.

SOURCE OTA From an original by V Friedman, Washington University Medical Center at St Louis.

ductive *hearing* impairment involves the outer and/or middle ear. ***Sensori-neural*** impairment involves damage to the inner ear, the cochlea, and/or fibers of the eighth cranial nerve. A mixed ***hearing impairment,*** as the term implies, is one that comprises both conductive and sensori-neural components. A *central* processing *disorder* a hearing impairment that influences the understanding of spoken language; the elderly person may hear the words but be unable to make sense out of them as a result of disorders of the auditory pathways in the brain.

Hearing impairment causes an inability to hear environmental sound without amplification. Hearing impairment is sometimes also characterized by an inability to discriminate or understand speech sounds even with amplification. This distortion of sound, which is common among the hearing impaired elderly, can result in the complaint, "I can hear you, but I can't understand you."

Tinnitus is often an accompanying complaint of those who have hearing loss. It is a ringing or buzzing in the ears or head, the cause of which is unknown. The prevalence of tinnitus increases with age, and is more common in women than men (84). Another problem often seen in older persons with hearing loss is ***recruitment,*** an inability to tolerate loud sounds. This condition can interfere with satisfactory use of a hearing aid.

Causes of conductive and sensori-neural hearing loss are listed in table 8. The most common type of hearing loss in the elderly is prebycusis, a sensori-neural loss resulting from changes in the inner ear. These changes can include decreased numbers of hair cells or nerve fibers in the cochlea and fibrous changes in the small blood vessels that supply the cochlea. Some researchers believe that presbycusis is associated with normal aging, while others believe it results primarily from disease conditions. Not all elderly individuals have presbycusis, and some people in their 90s and older retain acute hearing.

THE ONSET OF HEARING IMPAIRMENT

The onset of hearing impairment can occur before birth or in early childhood before language is acquired, during early or middle life, or during later life. People who have been deaf since childhood have had time to adjust to their hearing losses and to develop behaviors to cope with the social isolation resulting from deafness (77), but additional problems acquired late in life may seriously affect their functioning. For example, poor vision in old age may interfere with lipreading techniques the individual has used successfully throughout life.

The elderly who become hearing impairedl ate in life present different problems because they must acquire an entirely new and complex system of communication in order to maintain social

Table 8.-Causes of Conductive and Sensori.Neural Hearing Impairments

Causes of conductive hearing impairments:

External blockage: buildup of wax or presence of a foreign object in the ear, which is very common in the elderly.
Perforated eardrum: a hole or tear in the eardrum, which can occur **as a** result of injury, sudden pressure change, or infection.
Genetic and congenital abnormalities: malfunction and/or malformation of the outer and/or middle ear.
Otitis *media:* middle ear infection and accumulation of fluid.
Otosc/erosis: disease process affecting the mobility of the middle ear bones, which is thought to be hereditary.

Causes of sensor-nural hearing impairment:

Presbycusis: literally, "old hearing." The term has been used to describe hearing impairment that occurs with old age. Presbycusis may be sensory, neural, metabolic, or vascular in nature.
Hereditary *hearing loss:* includes a great variety of disorders that affect the sensori-neural mechanism and are usually present at birth.
Trauma-induced: caused by a severe blow to the head, an accident, or a stroke or brain hemorrhage that affects the ear, auditory pathways, and brain centers.
Tumors: acoustical neuromas and tumors that invade the eighth nerve.
Noise damage: brief or continued exposure to high-intensity sound, which irreparably damages the hair cells.
Vascular incidents: related to hypertension, heart disease, or other vascular problems that may alter blood flow to the inner ear.
Drug-induced hearing loss: drugs such as aspirin, and some antibiotics, diuretics, and certain powerful anti-cancer drugs can damage the hair cells or other vital parts of the inner ear.
Viral and bacteria/ illness: such as mumps, meningitis, or encephalitis, and rubella contracted by expectant mothers, are some common disease processes that are well-documented as etiologies for hearing impairment.
Meniere's disease: characterized by fluctuating hearing loss, dizziness, and tinnitus, the possible causes range from allergy to hypothyroidism and diabetes.

SOURCE: American Speech and Hearing Association, "Management of Hearing Impairment in the Elderly," prepared for OTA under contract No, 333-8970.0, 1984

interaction. Little information is available about the special problems of acquired hearing impairment among adults, and particularly the elderly.

Impacts of hearing impairment

Hearing impairment causes social and psychological difficulties by interfering with the individual's ability to communicate with family and friends. This can lead to withdrawal, social isolation, and depression. Loss of hearing interferes with the elderly person's ability to compensate for other losses that can occur with aging, such as loss of relationships due to the death of spouse, siblings, and friends, loss of a familiar home or community, and worsening health and mobility. Lack of easy communication means decreased access to new people, new activities, and new services.

Hearing impairment limits access to information that is normally available through personal communication, telephone, radio, and television. For elderly individuals who have both hearing and visual impairments, access to information is often severely Iimited, and some research indicates that restricted access to information can contribute to the progressive development of confusion; further research is needed in this area.

Perhaps more important than any actual confusion related to hearing loss is the widespread ***assumption*** that elderly persons who are hearing impaired are also confused. In a study conducted in a hospital, health care professionals described their impatience with elderly persons with hearing losses. Several respondents said the method they used in interactions was to "scream at them. " This behavior was considered acceptable since the patients were old, "and probably senile, too" (76).

DENIAL OF HEARING IMPAIRMENT

Many elderly individuals deny they have a hearing problem despite significant evidence to the contrary. Negative social attitudes about hearing impairment and growing old encourage denial, Hearing impairment is not visible, and in= visibility facilitates denial In addition, hearing impairment in the elderly is often characterized by very gradual onset that can make the impairment difficult to recognize.

For elderly persons with one or more life-threatening illnesses, hearing impairment may seem insignificant by comparison. The onset of depression and withdrawal associated with hearing impairment may be slow and insidious and may appear unrelated to hearing loss. Accidents that occur as a result of the elderly person's inability to receive aural cues are frequently ambiguous as to cause. Similarly, difficulties in communication and social relationships may not be attributed to hearing loss, even when the loss is acknowledged. As a result, hearing impairment is often not seen as important by the elderly, their families, and health care providers. Denial of hearing impairment and failure to recognize its impact on independent functioning are clear obstacles to effective treatment.

Treatment of hearing impairment

Treatment of hearing impairment includes methods to: 1) prevent hearing impairment or reduce its severity, 2) improve the individual's communicative competence through amplification or other electronic and mechanical devices, 3) adapt public facilities to accommodate the special needs of hearing impaired people, and 4) help people to manage their hearing problems by providing information about devices and other compensatory strategies to reduce communication handicaps.

Potential treatments for hearing impaired people are the same regardless of age, The suitability and effectiveness of each approach, however, differs considerably among the various age groups, because of the type of hearing loss most frequently encountered and because of other physical, psychological, and social characteristics of each age group.

PREVENTION

Prevention is an obvious first approach to treatment. At present, too little is known about the causes of hearing loss associated with aging to allow effective preventive measures. Dietary factors and circulatory changes have been impli-

cated, if not as direct causes, at least as accelerators of deterioration in the auditory system. More vigorous research efforts might identify specific factors that would ultimately lead to precise prevention strategies.

Some hearing impairments in older people result from preventable problems that began earlier in life, such as untreated infections and exposure to noise. Better health care throughout life and effective noise control procedures could ultimately reduce the prevalence and severity of hearing loss among older people.

Some drugs damage auditory mechanisms. The best known ototoxic drugs are the "aminoglycosides," a class of antibiotics that includes streptomycin; these drugs may be lifesaving but can adversely affect hearing. Aspirin can also be ototoxic, though probably only in the high dosage levels sometimes used in the treatment of arthritis. Aspirin-induced hearing loss is usually reversible if it is recognized early and dosage is reduced. Too little research has been done on the mechanisms of ototoxicity and the essential chemistry of ototoxic agents. Educational efforts have been effective in informing most physicians of the hazards of streptomycin, but the ototoxicity of other drugs is frequently not recognized.

MEDICAL AND SURGICAL TREATMENT

The likelihood of curing hearing impairments in the elderly with available medical or surgical treatment is limited because they are almost always sensori-neural losses most of which are currently not treatable. The exceptions include removal of acoustic tumors, and surgical treatment of Meniere's disease.

The cochlear ***implant is*** a relatively new treatment for sensori-neural hearing loss. This electronic device is surgically implanted in the inner ear to pick up sound waves, change them to electrical signals, and carry them past the cochlea to the auditory nerve (82). The purpose of the implant is neuroelectrical simulation of natural hearing, but full attainment appears far in the future. The sound produced by available implants has been described as fluctuating grating noises and buzzes that are not the same as normal sound (85), and users need extensive training to learn to interpret the sound. Research to improve the cochlear implant continues in the United States and other countries.

In its present form, the cochlear implant is not appropriate for most elderly hearing impaired people who usually have partial. hearing loss rather than the profound deafness for which the device is now used. In the future, as the cochlear implant is improved through research and testing, it may become an important treatment option for sensori-neural hearing loss among the elderly.

TECHNOLOGIES TO COMPENSATE FOR HEARING IMPAIRMENT

Since only a small proportion of the hearing impaired elderly can benefit from medical or surgical treatment, other approaches to treatment are needed. These approaches do not change the underlying condition but provide methods to compensate for hearing loss and maintain adequate communication. Such methods include the use of personal listening devices and amplification systems, adaptations of the telephone system, and signaling and alarm systems.

Hearing Aids—Hearing aids are amplification devices designed to compensate for partial hearing loss. They have benefited thousands of individuals, allowing them to function in communication situations that otherwise would have been impossible. Yet only about 13 percent of all persons with hearing impairments use hearing aids. The elderly are more likely to use hearing aids than younger people: about 20 percent of all hearing impaired persons over 65 use hearing aids, and those with more severe impairments are more likely to use them (91).

Deterrents to the use of hearing aids include problems in instrument design and performance, social and psychological factors, and cost. Hearing aids do not restore normal hearing for most users. The quality of sound is mechanical, and the amplification of distracting background noise is a problem for users of all ages.

Some specific hearing deficits that are common in the elderly, such as more severe hearing loss at high frequencies and distortion of sound due to abnormalities in the sensory cells, require tai-

loring of the hearing aid's operational specifications. Sound processing techniques are available to make these adaptations, but most of these techniques are not widely used, partly because of the difficulty of identifying the precise deficits experienced by each individual (85). Audiologists are trained to evaluate hearing deficits, but many elderly individuals buy hearing aids from hearing aid dealers without seeing an audiologist. Moreover, even when a comprehensive evaluation is done, the audiologist or hearing aid dealer may have difficulty selecting the appropriate hearing aid because of the lack of reliable technical information about different brands and types of hearing aids (79).

Social and psychological factors that discourage use of a hearing aid include reluctance to call attention to the hearing impairment and disappointment with the quality of sound provided by the hearing aid. Individuals who once had normal hearing often expect that a hearing aid will return their hearing to normal, and the disappointment they experience in trying to adjust to a hearing aid can create significant acceptance problems. Some experts believe that the elderly have more difficulty adjusting to hearing aids than younger people because of so-called age-related inability to adjust to something new, but it is also possible that many elderly individuals are not using their hearing aids because the aids are inappropriate for their hearing impairments.

other Personal Listening Devices.—Three other personal listening devices can compensate for hearing loss: audio loop systems, FM amplification devices, and infrared amplification devices. These devices transmit sound directly from the source to the listener, thus eliminating background noise that interferes with hearing. They have been used primarily in classrooms and public facilities, such as theaters and churches, and are often called "large room systems," but they are now being used by individuals for interpersonal communication and TV and radio listening. This use is particularly appropriate for the elderly because they usually have partial rather than complete hearing loss, and in many cases these devices can provide satisfactory amplification. Moreover, no training is needed to learn to use these devices. Audio loop systems, FM amplification devices, and infrared amplification devices can also be used with the hearing aid to eliminate bothersome background noise.

The Use of Devices for Public Access: The Rehabilitation Act of 1973 prohibits discrimination against disabled individuals by any program, activity, or facility receiving Federal assistance. The law requires that these facilities be accessible to people with all kinds of handicaps, including hearing impairment, but the emphasis has primarily been on adapting facilities for people with mobility problems. This has occurred even though the costs of providing access to the hearing impaired with technologies such as FM and infrared amplification devices are usually minimal compared with the costs of major modifications in architecture. While public funding has been available for architectural modification% the costs of improved accessibility for the heap ing impaired have been paid primarily by the private sector.

Telecommunications Systems. -Inability to use the telephone is one of the most common problems of hearing impaired individuals. For the elderly, particularly the great number who live alone, the telephone is a link to the outside world; inability to use the telephone can compromise safety and interfere with independent functioning.

Hearing over the telephone is difficult even for those with mild hearing loss because telephone signal transmissions omit very low- and high-frequency sounds that are important for understanding speech. Line noises and other sound distortions also interfere with the quality of sound transmission. In the future, as the need grows to transmit more conversations over limited channels, this problem may become worse. Methods for increasing channel capacity involve omitting parts of the speech message that are considered unimportant, but the standards for what is unimportant are based on the hearing ability of younger persons with normal hearing. Research is needed to document the effect of these omissions on the hearing ability of elderly and other hearing impaired individuals (78).

Devices to assist hearing impaired individuals to use the telephone include amplifiers that can be built into the telephone handset or attached

to the side of the telephone, and telecoils that are built into hearing aids to pickup electronic signals directly from the telephone receiver, bypassing the hearing aid microphone. The Telecommunications for the Disabled Act of 1982 requires that all telephones installed in "essential places" such as hospitals, hotels, and similar public facilities be compatible with hearing aids. Because there are no comparable requirements for hearing aids, however, aids can now be sold that are not compatible with these telephones.

For individuals with severe hearing impairments, other devices are available or in the development stage. These devices include:

- teletypewriters (TTYs) that allow individuals to type a message that is carried over phone lines,
- ***Teletex*** and ***Viewdata*** information retrieval systems for transmitting text and simple graphics to a television receiver, and
- ***Picturephone*** and ***Vistaphone*** devices that transmit a visual image of the speaker over an ordinary telephone line and allow communication through lipreading or manual sign language.

It is not known how many elderly individuals use or could use these devices. The TTYs and Viewdata systems require that the speaker type all messages. The Picturephone and Vistaphone are only helpful to those who communicate through lipreading or sign language. Since few elderly individuals use these methods of communication, the usefulness of these devices for the hearing impaired elderly is limited.

The development of effective computerized speech recognition systems could greatly simplify telephone use for the hearing impaired. These systems convert spoken words into printed output that could be displayed on a screen attached to the telephone. Currently available speech recognition systems have major limitations: they recognize only a few words and sometimes confuse words, and their performance varies widely from speaker to speaker. Future refinements of this technology could facilitate telephone use for the hearing impaired elderly.

Signaling and Alarm Systems.—Signaling and alarm systems that convert sound to visual or tactile signals are important for the safety and independence of hearing impaired persons. Flashing lights and vibrating devices that signal the ringing of a fire alarm, smoke alarm, telephone, doorbell, or alarm clock substitute for sounds the person cannot hear. ***Tactile Paging Devices*** use radio signals to generate vibrations in a portable receiver carried by the hearing impaired individual.

One serious block to use of these devices by the elderly is lack of awareness of devices that could be helpful. Information about these devices is available within the informal deaf community, which is primarily comprised of younger individuals who have been deaf since childhood or early adulthood, and their families. The elderly, however, are seldom part of the informal deaf community, so they lack access to this source of information. Since the elderly usually do not receive comprehensive aural rehabilitation services, they do not learn about available devices from hearing specialists.

Aural Rehabilitation.—Aural rehabilitation services are designed to help individuals communicate more successfully with or without the use of a hearing aid or other personal listening device. These services are usually provided by audiologists and are briefly described here:

- ***Hearing aid orientation*** includes instruction in the care and maintenance of the aid and earmold, practice inserting the earmold and batteries, and instruction in the use of amplification in a variety of listening situations.
- ***Auditory training*** involves systematic training in the use of residual hearing. The individual is taught to recognize and differentiate sounds and intonational patterns that give clues about the content and meaning of speech. This training is presently used almost exclusively with children, but the elderly, who usually have some residual hearing, could also benefit from this approach.
- ***Speechreading*** is the use of visual cues to facilitate understanding speech. It is similar to lipreading but involves attention to facial,

throat, and body positions in addition to lip movements (81,87). Few elderly individuals are taught speechreading techniques, even though these techniques are particularly effective for individuals who have only partial hearing loss. ***Cued speech*** is a method of communication that supplements speechreading and is being used with elderly individuals in a few places in the United States. Cued speech involves the use of hand signals and hand positions that clarify the lip and facial positions associated with speech sounds.

- ***Counseling*** can address negative attitudes that interfere with rehabilitation. It can help to develop strategies to manage social situations and other life activities in ways that will lessen the handicap (81). The elderly are particularly likely to believe that their hearing losses are hopeless, and some elderly individuals suggest that services be directed toward a younger person who could derive greater benefit. Counseling can help to overcome these feelings.

Despite the potential benefits of aural rehabilitation, few elderly individuals receive these services. Reasons for this include lack of awareness of the value of the services by the elderly and their families, the cost of the services, and the historical focus of hearing professionals on the needs of profoundly impaired children.

Environmental Desigm-Building design characteristics affect the behavior of sound and the relative ease or difficulty of hearing. For example, hard-surfaced walls and floors reflect sound, creating reverberations that interfere with hearing, while sound-absorbent wallcovering materials decrease reverberations (83). While much is known about design characteristics that affect hearing, this information is seldom applied in buildings used by the elderly. Reduction of reverberations and background noise in these facilities could ameliorate some of the problems of those with hearing loss.

The service delivery system

SERVICE PROVIDERS

Hearing services for the elderly are provided primarily by physicians, audiologists, and hearing aid dealers. Although few hearing impairments of older people respond to medical or surgical treatment, some elderly persons see a ***primary care physician*** as a first step in treatment. Depending on their symptoms, they may be referred to a specialist, who is usually an ***otolaryngologist.*** Physician evaluation is important to identify impairments that are medically treatable, but physicians usually receive little training in the management of hearing impairments and alternative approaches to compensate for hearing loss.[5]

Audiologists are nonmedical specialists trained in the identification and evaluation of hearing impairment and rehabilitation of individuals with hearing deficits. Audiological evaluation includes assessment of hearing threshold sensitivity, speech discrimination ability, and residual auditory function. Audiological testing helps to determine the type of hearing aid needed, and some audiologists dispense hearing aids. Audiologists also provide hearing aid orientation and counseling for hearing impaired persons, families, and health care providers in a variety of settings.

Hearing aid dealers sell hearing aids and hearing aid accessories, such as batteries, earmolds, and spare cords, and may also repair hearing aids. They often receive as little as 1 week's training from hearing aid manufacturers and much of this training focuses on sales management.

The National Hearing Aid Society (NHAS) offers a 20-week home-study course, but many dealers do not take the course. Moreover, an expert panel review of the home-study course found many deficiencies including incorrect, oversimplified, and outdated information. The review panel concluded that the home-study course was ***"not only inadequate but potentially dangerous.*** It is dangerous in the same way that 'quack' medicine is dangerous . . . it postpones or prevents adequate evaluation, diagnosis, and treatment of hearing loss and its accompanying pathology" (89).

[5]Otolaryngologists receive some training in hearing measurement techniques and amplification, but few otolaryngologists receive extensive training in sophisticated aspects of auditory processing and its relationship to communicative ability. Their training focuses pri. marily on medical diagnosis for and medical/surgical treatment of conditions affecting the ear, nose, throat, head, and neck, and on facial, cosmetic, and reconstructive plastic surgical techniques.

The National Hearing Aid Society confers the title "certified hearing aid audiologist" on dealers who pass the NHAS home-study course. This title can lead consumers to believe that the dealer possesses expertise that he does not have. The Federal Trade Commission (FTC) has proposed a rule that would prohibit the dealer's use of the term "certified hearing aid audiologist ." The use of this term by dealers is already prohibited in several States.

The most valuable aspect of the dealer's role in the hearing aid delivery system is that of a prosthetic dispenser. Dealers are trained and qualified to make earmold impressions, to fit the final earmold product and the hearing aid for comfort, and to provide hearing aid wearers with ***basic*** instruction concerning the operation and care of hearing aids. They are generally not qualified to provide the comprehensive auditory evaluation needed by the hearing impaired elderly.

Many elderly individuals enter the service delivery system through a hearing aid dealer. When they are fitted with hearing aids without consulting an audiologist they risk purchasing an aid that is of no value to them.

Speech therapists, social workers, psychologists, nurses, and other caregivers sometimes provide physical, emotional, and "informational" support to the hearing impaired elderly. These professionals often know very little about treatments, devices, and rehabilitative approaches that might ameliorate the hearing loss. The education of all human services professionals should include information about the causes and treatment of hearing impairments in the elderly.

FEDERAL REGULATION OF THE DELIVERY SYSTEM

Some aspects of hearing aid sales are regulated by the Food and Drug Administration. The FDA requires that the consumer must give the hearing aid dispenser a written statement from a physician, certifying that the hearing loss has been evaluated and that the individual may be a candidate for a hearing aid. However, consumers who are over 18 may sign a form waiving the requirement of a physician's evaluation. There is no objective information about the number of aids that are dispensed on the basis of these waivers, but it has been informally estimated that in some communities up to 80 percent of all aids are dispensed through waivers.

FDA regulations also require that the customer receive an instructional brochure describing the use and care of the aid, sources of repair and maintenance, and a statement that the hearing aid may be only part of a rehabilitative program that may also involve speechreading or auditory training. The regulations require a warning to dispensers and purchasers that certain conditions make medical consultation advisable prior to purchase of an aid.

While the FDA regulations were intended to address safety and effectiveness, they offer no assurance that any hearing aid that is sold will benefit the purchaser. Furthermore, in providing a waiver for even the requirement of physician evaluation prior to sale, the regulations surrender all semblance of quality control. Regulations that thus purport to offer consumer protection, but do not in fact do so, may be more dangerous than no regulations at all.

During the mid-1970s the FTC initiated a major effort to develop regulations for hearing aid sales. Recommended regulations, published in 1978, included restrictions on in-home sales, marketing of used hearing aids, and the use of testing programs to identify potential customers. The regulation that was most vigorously contested by the hearing aid industry would allow a hearing aid purchaser or renter to cancel the sale or rental within 30 days and receive a refund. These recommended regulations were strongly supported by consumer advocates and organizations for the hearing impaired, but no regulations have been promulgated as of october 1984, a full eight years after the rules were proposed. The FTC is presently sponsoring a survey of hearing aid users, and results of the survey will be used by the commissioners to determine the current need for regulations,

Funding for treatment of hearing impairments

Hearing services for the elderly are paid for by government programs, such as Medicare and Medicaid, private insurance, and direct out-of-

pocket payments. Medicare pays for medical and surgical hearing services provided by physicians, and some services provided by audiologists, but only when authorized by a physician. Medicare does not pay for audiological evaluations related to the prescription of hearing aids. Purchase of hearing aids and other assistive listening devices are also not covered by Medicare.

Hearing aids are the most common treatment for hearing impairment in the elderly, and lack of Medicare funding for hearing aids has a severe effect on the provision of effective treatment. Many elderly individuals purchase hearing aids, but few are also willing and able to pay for an audiological evaluation that could specify an appropriate aid. Without this evaluation it is likely that the hearing aid will be ineffective.

Medicaid pays for medical and surgical hearing services provided by a physician to low-income patients. some services provided by audiologists are covered by Medicaid in most States, and Medicaid pays for hearing aids in about half of the States. A major problem in many States that have Medicaid reimbursement for audiological services and purchase of hearing aids is that the reimbursement rates are so low that providers refuse to serve Medicaid patients. Another problem with reimbursement for hearing services by both Medicare and Medicaid is the complexity of Federal and State regulations that govern reimbursement, especially for audiology services.

Private insurance companies cover some hearing services, but each insurance policy is independently negotiated, and it is difficult to specify exactly which hearing services are covered by which insurers for which groups of beneficiaries. Most policies reimburse for hearing services provided by physicians and some hearing services provided by audiologists, but routine evaluations to detect hearing loss and services related to degenerative hearing loss are not covered. Hearing aid evaluations and hearing aids are also not covered.

Since Medicare and private insurance do not pay for audiological evaluation or purchase of hearing aids or other assistive listening devices, the elderly must pay for these services and devices themselves or do without.

Federal Government programs for *the hearing impaired elderly*

Hearing impairment among the elderly is a Federal Government concern because of its impact on the safety and quality of life of elderly people and because of the need for publicly funded health and social services for the hearing impaired. Federal initiatives to address these concerns have included funding for research and some hearing services, legislation to guarantee access to public services and facilities for the hearing impaired, and regulation of hearing aids. While these initiatives have benefited hearing impaired individuals of all ages, there is a need for programs that address the specific problems of the hearing impaired elderly.

The prevalence of hearing loss in the elderly far exceeds that of most chronic diseases and disabilities of later life, but the magnitude of this problem has not been reflected in the amount of research that has been conducted in pathology, prevention, treatment, and rehabilitation. Most hearing-related research has been directed toward the most severe hearing problems and particularly the problems of deaf children. In contrast to children, however, hearing impairment in the elderly is often mild or moderate, instead of severe, yet it is very widespread; it is often progressive; it usuaIly has a gradual onset and is frequently not recognized for some time; and finally, hearing impairment in the elderly often coexists with other health problems that complicate treatment and limit the effectiveness of available assistive devices. Research is needed on causes of hearing impairment in the elderly and appropriate treatment methods.

Denial of hearing impairment is a continuing obstacle to treatment. public education to increase awareness about the extent and type of hearing impairments among the elderly is needed,

Few of the hearing impairments of the elderly respond to medical or surgical treatment, and the most effective method of treatment available at present is the use of devices and techniques that compensate for hearing loss. The elderly, their families, and health care providers need information about the kinds of devices that are available to compensate for hearing impairment.

Assistive listening devices have been developed in the United States primarily by universities with rehabilitation programs and by commercial manufacturers. Marketing of new devices has been a problem, and testing procedures for devices have been inadequate. In some industrial countries such as Sweden, development, funding, dissemination, and repair of devices are considered a national responsibility, In the United States the Veterans Administration (VA) has a comprehensive program of device development, testing, and patient services, but outside of the VA, the delivery system is splintered and often ineffective. Extension of the VA model of services could stimulate device development and improved service delivery.

A final concern is the failure of the hearing impaired elderly to utilize aural rehabilitation services. Although hearing loss in the elderly is often mild or moderate, it is not simple, and its effects can be very serious. Government initiatives to increase the use of aural rehabilitation services could include increased funding and simplification of the complex requirements for these services under Medicare and Medicaid. In addition, public education programs are needed to increase awareness of the potential benefit of these services among the hearing impaired elderly and their families.

Osteoarthritis

osteoarthritis is one of the most important causes of chronic disability in the United States and other developed countries. The disease is found in all organisms with bony skeletons' (98). Although it is not a disease of modernity-evidence of it has been found in the skeletons of Neanderthal Man and even some dinosaurs—because the incidence of osteoarthritis rises with age, and because its prevalence increases as individuals live longer, it has become much more common in recent years. This rising prevalence may give osteoarthritis the "highest morbidity rate of all mankind's diseases" (98). Some evidence of the disease has been found in 90 percent of people by age 40 (in autopsy studies), but it causes symptoms only in a minority at that age.

Variations in diagnostic criteria render statistics on incidence and prevalence uncertain, as they are for many other disorders. All estimates, however, indicate that the process that underlies osteoarthritis occurs in almost everyone if they live long enough, and that symptoms become increasingly prevalent and more intense with age. The disease is severe enough in 16 million to 20 million Americans to cause symptoms (97,105). Some form of arthritis other than rheumatoid arthritis was reported as affecting 47.5 percent of those over 65 in 1981 (see ***Appendix A: Morbidity and Mortality Data)*** and osteoarthritis would constitute the vast majority of such cases. Osteoarthritis causing severe or moderate pain was noted in 6.6 percent of those 65 to 74 in the National Health and Nutrition Examination Survey (this includes only those cases for which patients reported symptoms) (112). Had older age groups been surveyed, the prevalence would have been far higher. Other surveys have found evidence of the disease in patients to dramatically increase with age; changes in joint X-rays can be found in only 4 percent of those aged 18 to 24, but in 85 percent of those 75 to 79 (105). Of those showing some X-ray evidence of the disorder, 23 percent reported moderate or severe symptoms. The prevalence of osteoarthritis is higher in white populations and lower in blacks, American Indians, and Asians living in Asia.

Osteoarthritis is a major factor in health care costs and patient morbidity, but, like dementia, is not a direct cause of death. osteoarthritis causes an estimated 46 million visits to physicians, 3.7 million hospital days, 185 days spent in bed away from the hospital, and loss of 68 million workdays per year in the United States (104). The Arthritis Foundation estimated the total costs of all forms of arthritis at $13.3 billion in 1983 (96),

[6]Sharks, which do not have bony skeletons, but do have cartilaginous ones, are evidently immune to the ravages of osteoarthritis,

of which osteoarthritis accounted for approximately 60 to 70 percent (more than $7 billion). Although it is only one of hundreds of causes of arthritis, it affects far more individuals than any other cause.

Osteoarthritis should not be confused with rheumatoid arthritis; only osteoarthritis is reviewed in this report. Rheumatoid arthritis is the second most common form of arthritis, affecting an estimated 6 million to 7 million people, but its prevalence in many younger age groups makes it less a disease of aging. Its cause is thought to be disrupted immune function, and is quite distinct from the process underlying osteoarthritis.

Definitions and prevalence

Arthritis means inflammation of the joint,[7] of which osteoarthritis is one cause, Other names for osteoarthritis include "degenerative joint disease, " "osteoarthrosis, [8] and "hypertrophic arthritis. " These alternative labels reflect a degree of medical disagreement about the disease process, but the debate over proper terminology is not germane to public policy regarding the condition itself. OTA has selected "osteoarthritis" because it is the most common term. Osteoarthritis, as used here, refers to the combination of biochemical and anatomical changes in the joint that cause symptoms in at least one joint.

Medical definitions of the disease are subject to some controversy. Most physicians consider the diagnosis if there is pain or stiffness and X-ray evidence of joint damage. There is disagreement, however, about the X-ray changes that indicate osteoarthritis. Some physicians look for unusual bone formations (osteophytes) around the affected joint. others do not make the diagnosis without evidence of joint narrowing and changes in the bone underlying affected joints.

What is osteoarthritis?

Osteoarthritis is the symptomatic disruption of joint function. Functional impairment arises from the biological changes described in this section, which provide an introduction to the biology and anatomy underlying osteoarthritis.

Joints are fluid-filled spaces lined by cartilage and separating bones; those found on the limbs (legs and arms) are adapted to permit easy movement. Limb joints are most affected by this disease, especially those responsible for weight-bearing (hips and knees), the vertebrae, and (for unknown reasons) the joints closest to the tips of the fingers.

Arm and leg joints are composed of a fluid-filled cavity, surrounded by a fibrous capsule (see fig. 15). The surfaces that move against one another are composed of cartilage. The cartilage sits over bone. The cartilaginous surfaces are extremely well adapted to ease of movement; they are four times as slippery as Teflon ", one of the most frictionless artificial surfaces (98). Disruption of the health of the cartilage tissue can reduce this ease of movement, leading to joint stiffness. Irritation of surrounding tissues leads to the symptom of pain, osteoarthritis is one of the causes of ill health of the joint cartilage.

Many types of injury to cartilage can lead to changes similar to those seen in osteoarthritis (102). Such changes include degeneration of the cartilage, faulty attempts at repair, anatomic clefts and blisters, and even complete exposure of underlying bone. Injury can be caused by imposed immobility, removal of tissues that support the joint, and extreme compression. The similarity of normal cartilage repair to osteoarthritis has led some to hypothesize that the disease is an abnormal response to constant minor injury.

Joint cartilage relies on adjacent tissues for its health. The surface of joint cartilage is coated with special long chains of sugars and proteins. Biochemical changes of these coatings have been associated with damage to cartilage, and can reduce the slipperiness of the surfaces, causing increased friction and yet more tissue damage.

Because cartilage does not contain blood vessels,g it gets its nutrients and other factors from the surrounding soft tissues and, more importantly, underlying bone. Proper cartilage repair ap-

T'rem: arthro-(joint) + -itis (inflammation).
'From: osteo-(bone) + arthro-(joint) + asis (process)

'Blood Vessels appear to be prevented from growing into cartilage by a molecule that is produced by the cartilage,

Figure 15.-Diagram of Knee Joint

SOURCE: National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases

pears to require access to cells in the bone marrow (102). The repair process may be sensitive to influences from other tissues as well, including hormones (thyroid-stimulating hormone and somatomedin have been postulated) and other chemical messengers (growth factors, growth suppressors, and certain nucleotides have all been suggested) (98)102), Osteoarthritis can, over a long period, lead to severe joint deformity, enlargement of surrounding tissues, and immobility.

Risk factors

The most important risk factor for arthritis is age, which cannot be controlled. Other uncontrollable factors include (105):

- body type (risk is increased in stocky individuals, decreased in tall thin people);
- . race (risk is increased in Caucasians over blacks, Asians, and American Indians);
- diabetes (which may be partially controllable when due to obesity) (98); and
- genetic traits (one possible form is influenced by sex chromosomes; another involves many genes).

There are also some controllable risk factors:

- obesity (many studies support this, but some do not) (98);
- occupation (risk is increased in coal miners, dock workers, and dominant hands of weavers, but not in pneumatic hammer drillers); and
- exercise.

one possible risk factor, exercise, deserves special mention. Many orthopedic surgeons fear that the current popularity of jogging and other vigorous exercises may exacerbate osteoarthritis. It would be ironic if strategies that could prevent some deaths (e.g., from cardiovascular disease and stroke) were to worsen disability due to osteoarthritis. There is ample evidence that overexercise can worsen the condition of those who have the disease. Evidence that exercise can precipitate it, however, is unclear. Studies of marathon runners did not show more osteoarthritis of the hip, and studies of soccer players showed some indications of the disease, but other signs and symptoms were absent (105). Whether osteoarthritis can be caused by exercise thus remains an important unanswered question.

Diagnosis

The diagnosis of osteoarthritis is made by correlating symptoms of pain and stiffness with X-ray evidence of changes in joints. other causes of arthritis must be eliminated by history, physical examination, and laboratory tests. Such other causes include infection, deposits of mineral crystals (from gout or other metabolic disorders), and some systemic diseases. one problem in making

the diagnosis is that some patients wait for prolonged periods before seeing a professional. Another problem is that physician and patient perceptions of the severity of the illness may differ. one study found that while physicians' and patients' judgments of the degree of disability agree for low levels, physicians may underrate the disability at higher levels (where such error may make a greater difference) (107). The authors point out that this can erode mutual trust, and can lead to a paradox in that the physician believes that treatment is successful, but the patient does not.

Prevent of disability *and treatment*

The Arthritis Foundation notes that patients with osteoarthritis wait an average of 4 years before seeking medical attention from a physician. This is unfortunate, because the progression of the disease can be retarded, and its symptoms ameliorated by routine treatments (table 9).

CHANGING THE PATIENT'S ENVIRONMENT AND HABITS

Some symptoms of osteoarthritis can be prevented by treatment and directed programs of exercise and physical therapy. Some simple interventions can greatly retard the progression of the disease. Use of a cane can, for example, reduce the stress placed on the hip during walking by a factor of 2 or 3 (113). Changing the environment by adapting beds and chairs for easier entry and exit, and arranging living space to avoid use of stairs can greatly diminish the demands on the individual, and can minimize the need for movements that exacerbate the disease (113).

Weight reduction is often recommended to reduce the weight strain placed on knees and hips. Job changes away from physically demanding occupations may reduce joint wear and tear, and altering sports activities may be necessary to prevent acceleration of joint degeneration.

Devices that compensate for diminished function, especially of the hand and major joints of the legs, could greatly improve the independent and relatively normal functioning of those affected by osteoarthritis. There appears to have been little attention given, for example, to designing computer keyboards to make them accessible to the millions of Americans whose hand mobility is restricted by this disease.

Table 9.—Treatments for Arthritis

Assistive devices:
• **Canes and devices that facilitate walking**
• **Special utensils**
• **Adapted furniture**
. **Special stairways**
• **Enlarged keyboards**
. **One-floor architecture**
Physical therapy:
• **Balanced program of rest and exercise**
• **Special movement and relaxation therapy directed at specific joints**
• **Weight loss**
Drug thearapy:
• **Aspirin**
• **Nonsteroidal anti-inflammatory agents**
• **Others (steroids, etc.)**
Surgical therapy:
• **Hip joint replacement**
• **Bone reshaping (osteotomy)**
• **Joint debridement**
Future possibilities:
• **Specific hormones or growth factors active on joint cartilage**
• **Joint surface replacement**
• Cartilage transplantation
• Improved joint replacement techniques and replacements for joints in addition to the hip
• More and better assistive devices

SOURCE: Off Ice of Technology Assessment.

PHYSICAL THERAPY

Treatment of osteoarthritis involves balancing joint movement with protecting the joint from excessive movement. This implies the need for a proper balance between exercise and rest. Weight bearing and movement are imperative for proper cartilage repair (98), but overexercise is a well-known cause of excess disability. Physical therapists, physiatrists (physicians engaged in physical therapy), and other providers can be effective in reducing muscle spasm and in training patients to exercise and rest specific joints.

DRUG THERAPY

There are several drug therapies for osteoarthritis. The most common is the use of high doses of aspirin. Aspirin has the unusual characteristic of being both a painkiller and an anti-inflammatory agent, which makes it suitable for treating

both the process that causes pain (inflammation), and the pain itself. Aspirin may also directly affect some biochemical processes involved in cartilage repair, thus improving the repair process. But because it can cause digestive disturbances, ringing in the ears, and other adverse effects, and some patients have violent reactions to it, aspirin cannot be used by all patients. Further, recent reports based on animal studies suggest that some effects of aspirin can inhibit proper healing of arthritic joints (101)108). Such studies have not yet been extended to research on humans, hence their relevance to standard therapy is not yet clear.

Among the other drugs used in treating osteoarthritis, the most common is a class of drugs called nonsteroidal anti-inflammatory drugs. These reduce joint inflammation and can prevent some of the resulting pain and stiffness. Many such agents are widely prescribed, including indomethacin (Indocin"), ibuprofen (Motrin®), naproxen (Naprosyn@), and others. These drugs are, in general, reserved for patients who cannot tolerate aspirin. They are more costly than aspirin, and have significant side effects (109). Several drugs in this group have recently been withdrawn from the market because of side effects, and two others are currently under investigation by FDA. Development of safer anti-arthritic drugs in this class is a high priority in the laboratories of many pharmaceutical manufacturers.

Steroid drugs are not generally used for routine treatment because of the many possible side effects, but they can be effectively used by local injection for flare-ups, or before surgery.

SURGERY

Total joint replacement is a relatively new technique, made possible by technological advances in low-friction materials, biocompatible plastics and metals, and development of cements that can function in bone. The joint most commonly replaced is the hip, but some centers are also performing knee replacement surgery, and surgery on other joints, such as fingers and shoulders, on an experimental basis.

More than 60 percent of the 75)000 total hip replacements done in the United States annually are done in those over 65, mainly because of osteoarthritis (110). Hip replacement is now a routine procedure, which can reduce pain, improve mobility, and has a low risk of failure. The risk of death during the operation is less than 1 percent, and the risk of infection is similarly low. Included in the l-percent risk are clot formation in leg veins (clots can cause severe problems if they break off and pass through the heart to the lungs). Temporary urinary retention is found in 15 to 30 percent of patients. A major conference on the subject at the National Institutes of Health (NIH) concluded that hip replacement "when done for incapacitating pain and dysfunction . . . gives a predictably excellent result in the vast majority of patients" (110).

The same conference found that present technology results in 90 percent of devices remaining functional 10 years after surgery (110). The main complication of total hip replacement is loosening of the apparatus. Fracture of the device occurs in approximately 0.5 percent of cases. A search for improved cements to keep the devices in place, and development of devices that do not require cement (by allowing bone growth into the device) are underway (105). New technologies also may permit detection of loosening by detecting sounds of the device under stress (111). Surgical replacement of hips and other joints is effective, but expensive.

It is estimated that $700 million was spent in 1979 for hip replacements alone, 59 percent of which was done to replace joints affected by osteoarthritis (103). The rising numbers of elderly in the U.S. population, especially of those who are very old, suggests a rapid increase in this total unless means of preventing osteoarthritis can be found. The potential for cost growth as more joint replacements are done is a topic of concern for health policymakers. There are large numbers of potential recipients, and as the technology advances, such surgery may well become more attractive to a larger proportion of those with osteoarthritis or osteoporosis, This raises the prospect of difficulty in establishing criteria for deciding who should be entitled to joint replacement, establishing publicly acceptable mechanisms for rationing or otherwise constraining access to joint replacement through Federal pro-

grams, or continued cost escalation driven by demand.

Osteotomy involves reshaping the bone to reduce stress, or to provide a more favorable anatomic orientation of the joint. It is now less commonly used because of the advent of total joint replacements. joint ***debridement*** is removal of unwanted tissue from the joint space, and can help when there is free cartilage or bone irritating the joint. Hip ***surface replacement*** is also being tried for some cases of arthritis, mainly in younger patients (106),

POSSIBLE FUTURE DEVELOPMENTS

Future prevention and therapy of osteoarthritis may include new drugs to promote cartilage growth and regeneration, production of growth factors and hormones through biotechnology, improved joint replacement, regrowth or replacement of joint surfaces, and development of devices to compensate for diminished function, Increased attention to this potentially large market by companies that produce devices could also greatly improve the functioning of arthritic individuals. Designers of chairs, stairways, beds, telephones, and computer keyboards are likely to adapt their designs for use by the growing numbers of those affected by arthritis. Development of "smart" technologies to assist in daily activities should prove highly marketable to this large subpopulation.

Quackery

A major problem in arthritis treatment is the proliferation of quack remedies and consumer fraud. The Consumers Union notes that "quackery thrives best on human illnesses for which there is no cure" (99). The persistent and unremitting symptoms of pain and stiffness also spur the search for remedy, or the promise of it. The large number of affected individuals encourages promoters to try to tap this potentially lucrative market. Both chronic discomfort and high prevalence contribute to the problem of quackery. Further, the episodic nature of the illness can breed personal anecdotes of "successful" treatments, when an individual happens to take action just at the time the symptoms are naturally subsiding.

one additional factor can render arthritis victims vulnerable to the attractions of useless substances, devices, and procedures: the patient's perception that traditional medicine has failed. This can be exacerbated by the frequent disparity between the patient own measure of discomfort and that acknowledged by medical practitioners.

The Arthritis Foundation has variously estimated the amount spent on false or unproven remedies as $950,000 and $1.8 million (96,97). Quackery can take many forms:

drugs;
- chemical mixtures (often containing hormones);
- diets;
special "clinics";
- devices; and
- "therapeutic" jewelry (e.g., copper bracelets, gold, etc.).

Examples of useless or unproven remedies include DMSO, a common chemical solvent, which has been heavily promoted for relief of arthritic symptoms, despite a lack of verifiable effects. Copper bracelets were popular for a time, and one patently fraudulent device, the "Vryllium Tube," consisted of $0.02 worth of salt and sold for $250. Special clinics in Mexico and the Dominican Republic have catered to the desperation of arthritis victims, and special diets and diet books can be found in profusion (99).

The creative marketing techniques sometimes used by American drug companies, encourage unenlightened self-medication. Promoting agents to the public for relief of arthritis symptoms can lead to inaccurate self-diagnosis, and, in the words of a 1977 FDA panel, "Consumers who self-treat with an over-the+ ounter pain reliever for these diseases, without first seeking medical attention, may be risking irreversible damage to joints and other tissues" (99).

Social factors

As with any other chronic condition, optimal patient functioning relies not only on physiologic change and medical intervention but also on social variables and public policy:

R is clear that patient motivation, patient compliance, education level, socioeconomic status, arrangement of health care resources in the community, payment mechanisms, public and patient education programs, and family support, among other factors, may be as important determinants of disability as are the biologic activity of the disease or the extent to which that biologic activity may be controlled by medicinal agents (loo).

Osteoporosis[10]

Introduction

Osteoporosis ("porous bone") is a major chronic disorder of older people. It is defined as a condition in which total bone mass is decreased while bone volume is unchanged; therefore the density of the bone decreases. This thinning of the bone increases its fragility and makes it more susceptible to fracture. Activities and stresses that would not harm normal bone can result in fractures of osteoporotic bone. Loss of bone mass occurs in all people as they age, but the rate of loss is higher in women for about 10 years immediately following menopause, This period of rapid loss causes women to be especially subject to fractures and the secondary problems that ensue.

This predisposition to fracture makes osteoporosis of significant importance to individuals over 40 and to the health care system.

Magnitude of the clinical and social problem

Osteoporosis is an important cause of morbidity and mortality in the elderly. It appears to be the underlying cause of about two-thirds of hip fractures in older people (132). The incidence of hip fractures due to osteoporosis was estimated to be 98 per 100)000 people in the United States in 1977 (130)132); their total annual cost (acute care only) was estimated to be about $800 million. The total cost of osteoporosis in the United States has been estimated at $3.8 billion annually, and osteoporosis affects 15 million to 20 million Americans (145)!

Greater life expectancy and rising health care costs are expected to sharply increase the costs related to hip fractures. The total number of patient days spent in general hospitals as a result of hip fractures now ranks 10th among conditions counted (131). Fractures of the wrist are also a problem in people with osteoporosis and can result from relatively minor stresses. Vertebral fractures are common; it is estimated that 25 percent of white women have at least one vertebral fracture by the age of 60 (122). Most of these fractures are compression fractures—''crush fractures" —in which the vertebra simply collapses from the weight of maintaining the body in the upright position. Vertebral fractures often go unrecognized as fractures but may cause considerable pain. The pain frequently is not restricted to the area of the fracture, but can be felt in other areas, such as the abdomen.

The immediate medical and surgical problems posed by these fractures frequently foreshadow a significant impact on the individual's lifestyle. A number of studies of patients who suffered hip fractures (117,122,125,131) indicate a 16- to 40-percent increase in mortality within the first year. Only about 50 percent of patients are likely to return to pre-fracture mobility; approximately one-third enter nursing homes and remain there permanently (127,129,131). Mortality rates related to hip fractures were found to be higher in older patients (over 80), males, and patients with dementia or confusion (131). Of those patients who were living at home prior to the fracture and ultimately returned home, about 20 percent had to spend some time in a nursing facility during the interim (127,131). This nursing care tends to incur considerable expense, which is generally not fully reimbursed by public or private health insurance. The social problems are also significant because the patient is separated from his or her friends, family, and regular activities, which can

This section written by Sheila Taube, Ph .D , as part of the ,XIH Grants ,Associates Training Program,

cause depression and other psychological problems.

Direct costs of osteoporosis include diagnostic tests, drugs, surgery, prosthetic devices, physical therapy, long-term care, and social rehabilitation. The indirect costs include productivity decreases from lost labor and its impact on the gross national product, although most osteoporotic patients are older women who are no longer in the work force.

Biology and physiology

Bone consists of a soft protein framework that is hardened by deposition of calcium salts. It is a dynamic tissue that is constantly being remodeled (reshaped and renewed) throughout a person's life. Bones provide the skeletal structure for the body and also serve as a repository of minerals such as calcium, magnesium, phosphorus, and sodium, which are required for a variety of the body's functions. This remodeling of bone is accomplished by simultaneous resorption (removal of structural components) and formation (redeposition). Any condition in which resorption exceeds formation results in decreased bone mass.

Resorption and formation are usually tightly coupled so as to maintain bone structure and function. This coupling appears to be a localized phenomenon; the cells responsible for the resorption and formation processes are active in the same bone surface at the same time. The resorbing cells are called osteoclasts, and the forming cells are called osteoblasts. The two cell types together are considered to be a "remodeling unit." Turnover of bone is high when there are many "remodeling units" present and low when there are few. The relative rates of activity of the two cell types determine whether there is net gain or loss of bone mass.

An individual's total bone mass generally reaches a maximum in the second to fourth decade of life and then begins to decline, The initial rate of decline is the same for both men and women, about 0.5 percent per year. When women enter menopause, however, the rate of bone loss increases to 1.0 to 1.5 percent per year for about 10 years and then begins to slow again to a rate similar to that in men (138,141). The rate of bone loss differs for different parts of the skeleton (138). Bones most affected include the metacarpal (the bones between the wrist and the fingers), the neck of the femur (that part of the thigh bone which forms the hip), and the vertebrae. Different bones lose mass in different ways; bones of the spine are more prone to losing their internal structure, while those in the limbs become thin near the edges.

The cause of age-related bone loss is not clear. It appears that the rate of resorption is increased, but it has been difficult to find a consistent cause underlying this increase. The metabolic interactions involved in bone turnover are complex, and normal function depends on a balance of calcium intake, absorption into the blood, deposition in bone, and excretion. These processes are controlled by hormones (particularly parathyroid and adrenocortical hormones) and by vitamin D and its derivatives. They are also affected by dietary components other than calcium, such as protein, phosphorus, fiber, and others.

Specific parameters that have been examined have not provided consistent correlations between metabolic changes and increased bone loss. There has been no direct evidence that increases in parathyroid hormone levels associated with age are any greater in osteoporotic patients (120). There appears to be no relationship between the degree of bone loss and the age of onset of menopause (128). There have been no consistent changes in adrenocortical function documented in osteoporotic individuals, although suggestions have been made that subtle changes in function of the pituitary, adrenal, or gonadal glands might play a role in osteoporosis (128). Osteoporotic patients generally have lower body weight and less muscle mass than nonosteoporotic controls, but the significance of this observation is unclear (118,128). It is possible that tall thin people can less afford to lose bone mass than stockier people.

Current research is directed toward a better understanding of the molecular aspects of bone remodeling, Growth factors have been identified that stimulate osteoblasts (the cells responsible for bone formation). Human skeletal growth factor, for example, may couple bone formation and resorption and may be involved in osteoporosis (144). Attempts are being made to define the cells

and molecules that affect activity of both the osteoblasts and the osteoclasts (135). With this knowledge, it may then be possible to manipulate the system to maintain the balance of activity necessary to prevent bone loss. Much of the current molecular research is on bone cells in culture, a technique only recently perfected; it will take time to relate findings in these experimental situations to events actually occurring in the body.

Diagnosis

The diagnosis of osteoporosis can present major difficulties. The diagnosis is made by exclusion; the doctor must determine that the patient has no other causes of bone loss, such as underlying metabolic disorders, metastatic cancer, malnutrition, or drug-induced disorders. The condition is frequently undiagnosed until a fracture occurs. Vertebral fractures are often detected by accident when a patient has an X-ray taken for some unrelated problem. Once fractures have occurred, examination usually reveals considerable bone loss. To make the diagnosis of osteoporosis, the physician must first exclude other possible causes of bone loss; if any specific disorders affecting bone are found, appropriate treatment is initiated. If no underlying cause is found, the condition is considered to be osteoporosis.

In order to attempt to prevent fractures resulting from bone loss, it must be possible to detect this loss early and to measure the rate of loss. Standard radiographic procedures are not sensitive enough to detect the early stages of the disease because 30 to 40 percent of the bone must be lost before osteoporotic changes can be detected by these techniques. Nevertheless, films of the spine and hand can aid in the differential diagnosis of osteoporosis by identifying other diseases, and are sensitive enough to detect later stages of osteoporosis. The characteristic changes in vertebral osteoporosis that distinguish this disease from other bone diseases generally occur in the lower portion of the spinal column (below the sixth thoracic vertebra, at the midchest level). Changes seen higher in the spine are usually due to other causes, such as cancer, trauma, or infection. The particular vertebral shape changes are also characteristic of osteoporosis; for example, the vertebral bodies may become increasingly biconcave and wedge-shaped. Other shape changes indicate that other disorders may be present. Similarly, hand films can provide clues for differential diagnosis since changes seen can distinguish between osteoporosis and underlying hormonal imbalances (137).

X-ray measurements are only useful once changes have occurred; a procedure that could detect very early losses and identify individuals at risk would be of far greater value. More sensitive methods for measuring bone density are being developed. Photon absorptiometry is a sophisticated method that employs a highly focused beam of light at one frequency to examine the total mass of bone in the path of the light. This technique is only useful for examining peripheral bones (in the arms and legs) and is not yet available at all medical centers. Dual photon absorptiometry, a modification of this technique, can be used to examine the spinal column but its availability is even more limited. Quantitative computerized axial tomography (CAT) scanning of the spine can be used to make careful density measurements of spinal bones, but is expensive and not widely used. All of these techniques are being improved in terms of precision and reduction of X-ray dose, but usefulness for routine screening must still be assessed. As yet there are no reliable markers in blood or urine that can be used to quantitate bone loss; some blood tests indicate metabolic disorders, but these do not measure the condition of specific bones.

Treatment and prevention

The ability to measure bone loss prior to fracture is likely to have important implications for prevention and treatment. The pattern of bone loss may provide physicians with clues concerning other underlying disorders as well as with prognostic information.

Treatment of osteoporosis is complex primarily because it involves care of problems arising from the underlying bone loss, that is, fractures and their sequelae. As discussed earlier, hip fractures are a major occurrence; surgical repair of the fracture or replacement of the hip is required.

Surgical techniques and prosthetic devices have improved, and death rates now appear to correlate more with age and predisposing disease than with common complications of surgery such as infections and embolisms. Total hip replacement is sometimes required. Fractures and the necessary immobilization following surgery further complicate the osteoporosis because lack of exercise results in further bone resorption and predisposes the individual to formation of clots in blood vessels.

Vertebral compression fractures cause pain, postural changes, and increased strain on the muscles of the torso. Treatment for pain and postural problems can include bed rest, analgesics, and orthopedic braces of various sorts. Bed rest must be balanced with a need for exercise because of the complications of immobility mentioned above, but rest may be necessary to remove the stress on the spine. Painkillers must be used carefully as well, because of side effects such as constipation and disorientation. orthopedic braces can be very uncomfortable, but they do relieve the pressure on the spine and permit somewhat more mobility. Younger patients tolerate the rigid supports better than older patients. There are exercises that can be performed safely to relieve pain, but these should include only extension exercises; flexion can cause more pain and may result in new fractures (140).

A major treatment issue concerns the measures that can or should be taken to prevent further fractures once it is clear that clinical osteoporosis is present. Most studies indicate that Iost trabeculae of bone (the spiny meshwork inside the bone) cannot be replaced, but significant research is being performed to determine how to decrease the rate of bone resorption, As more information is gained concerning the normal metabolism of bone, attempts are being made to enhance bone formation or decrease resorption. These include use of mineral supplements, vitamin therapy, hormonal therapy, and exercise. Aside from wide acceptance of calcium supplements, few, if any, of the “treatments” are accepted universally as effective. This is because more definitive studies are required to prove cause-and-effect relationships, or efficacy of treatments (121).

A consensus conference at NIH addressed the question of defining optimum treatment of osteoporosis in April 1984, and concluded that carefully monitored estrogen therapy, calcium supplementation, vitamin D administration or exposure to sunlight, and exercise are all potentially effective methods of treatment (145).

Vitamin D increases both bone resorption and formation. Experience with this vitamin and its analogs (all involved in calcium and bone metabolism) is limited, and the studies are inconclusive. The best results have been obtained with an activated form of vitamin D, but levels must be monitored with care since too high a dose can increase bone resorption (150), In general, vitamin D should be used carefully because it is easy to attain toxic levels.

Sodium fluoride (NaF) has been shown to increase bone mass, but the bone has unusual crystal structure and decreased elasticity. In addition, joint pain and severe gastrointestinal problems occur in as many as 50 percent of patients (139). Calcium supplements given with NaF result in more normal bone structure, but there are still side effects in one-third to one-half of patients, and it is not certain that the increased bone mass is associated with fewer fractures. A large clinical trial of NaF treatment is currently underway under sponsorship of NIH.

Hormone treatments may also prove effective in treating osteoporosis. Preliminary studies using parathyroid hormone or its active fragment have not been encouraging; both resorption and deposition increased (136). Use of estrogen, a female sex hormone, has received a great deal of attention. Most researchers now agree that estrogen therapy for the first few years following menopause slows the rate of bone loss to that of men or premenopausal women. why female sex hormones affect bone physiology is not clear, Nevertheless, empirical studies support a consensus that low doses of estrogen” are beneficial in terms of bone formation and resorption, and in preventing fractures of the hip, in the arm, and above

11Wh$_{en}$ given cyclically with progestins and periodic withdrawal of both hormones to allow bleeding, analogous to uses for contraception and menstrual regulation.

the wrist. **(124,133,149).** When to terminate treatment has not been agreed upon, and the minimum effective dose is under investigation (123). Another controversy arises over the dangers of estrogen treatment—the increased risks of both blood clotting and cancer of the lining of the uterus (endometrial carcinoma). For women who have had hysterectomies, estrogen therapy appears to be relatively safe because the risk of endometrial carcinoma is removed. A newly uncovered aspect of estrogen therapy, however, is encouraging; the overall mortality of women dying from all causes is lower for those treated w-ith estrogen than for those who are not (116). The questions about estrogen use as a routine measure in postmenopausal women cannot be answered without more long-term prospective studies. These studies are difficult to perform because women have to be followed over many years (perhaps as long as 20 or 30 years), and there are ethical questions as well. The relative risks and costs of osteoporosis and endometrial carcinoma have been compared (148), and it has been suggested that if osteoporosis is already present, the risks of further deterioration are greater than for endometrial carcinoma. Because the issue has not been resolved to everyone's satisfaction, estrogen therapy has not been recommended as a regimen and its use is being evaluated on a case-by-case basis. FDA has, however, approved estrogen for treatment of osteoporosis at the physician's discretion, and carefully monitored estrogen therapy was recommended for white women at the NIH Consensus Conference (145).

one recent finding may change treatments for osteoporosis. Thiazide diuretics, used in the treatment of heart failure and hypertensions, appear to be associated with reduced numbers of bone fractures among women taking them (147). Further investigation of this phenomenon may lead to a new strategy for treatment.

Calcium intake and absorption are widely accepted as important in preventing osteoporosis (134). Calcium alone is considered effective in slowing bone resorption, but the amount of calcium in the diet decreases as people grow older because of changes in the foods they eat (121), In addition, absorption from the gut appears to decrease. The cause of this decrease is not clear, Increasing the intake of calcium does appear to increase the total amounts of absorption, and calcium is not toxic in the amounts necessary to provide adequate absorption (143). However, there are some contraindications to calcium supplements: decreased blood flow through kidney (diminishing kidney filtration rate), or hyperparathyroidism, but these conditions can be assessed prior to prescribing supplements.

Proper calcium intake should be maintained as people age, and this may require supplementation of the normal diet. In order to achieve absorption of the recommended amount of calcium (800 to 1,000 mg per day), it is probably necessary to consume 1.5 to 2 times this amount (still within the safe limits). Active forms of vitamin D that enhance calcium absorption from the intestine are under investigation by the FDA, and may prove useful in preventing osteoporosis. Calcium may not be the only mineral involved in osteoporosis. Zinc deficiency has also recently been associated with osteoporosis, but its the link to the thinning of bone has not been established (115).

Another critical element in maintaining bone health is exercise, specifically weight-bearing exercise. Bone mass decreases when physical activity is reduced. Studies of immobilized subjects have indicated that loss of bone begins very soon after immobilization, and on full bed-rest the calcium loss is about 200 to 300 mg per day (about one-fourth to one-third of the Recommended Dietary Allowance) (119). Exercise has been shown to increase bone mass in normal individuals during recovery from immobilization (146) and in women after menopause (114, 142). Once osteoporosis has been diagnosed, the exercise program should be carefully designed to avoid stress to fragile bones.

Although this discussion has concentrated on treatment efforts aimed at further reducing bone loss and fractures once osteoporosis has been diagnosed, some comments also apply to prevention of the disease. Studies to date suggest that bone mass must be built and maintained prior to the fifth decade of life and that the greater the bone mass at its peak, the more the individual can afford to lose before the bone becomes subject

to fracture (121). Women especially should be sure to eat calcium-rich foods and to carefully assess their diets to assure proper calcium intake.[12] Nutrition is a complex science, and calcium absorption and excretion are affected by other components of the diet such as protein (high protein increases calcium excretion) and fiber [effects are not clearly understood yet) so that an individual's entire diet must be analyzed to assure proper nutrition. It is also important for women to maintain muscle and bone mass through regular exercise. The NIH Consensus Conference recommended that women take 1,000 to 1,500 mg calcium daily, starting well before menopause (145).

To determine the extent to which age-related bone loss can be retarded by calcium supplementation, studies must be performed over a period of time that is long enough to permit accurate rates of loss to be calculated. Studies are needed to assess calcium absorption under different conditions, i.e., high concentrations of calcium, effects of other nutrients, etc. Prospective longitudinal studies are required to establish a firm relationship between calcium nutrition in early life and development of peak bone mass as well as the relationship between peak bone mass and later susceptibility to fracture. The longitudinal studies necessary to prove cause and effect are almost impossible to carry out because of the long time span over which observations and measurements must be made. However, some of the necessary evaluations could be included in ongoing longitudinal studies such as the Baltimore Longitudinal Study on Aging. One longitudinal study, sponsored by NIH, started in 1967. Those in the study are just now entering the age of susceptibility to osteoporosis.

Because the various methods of preventing or treating osteoporosis have not been rigorously compared for relative efficacy (126), there is a clear need for randomized clinical trials.

Summary

Osteoporosis affects a significant number of elderly individuals. The morbidity and mortality associated with fractures are costly in terms of hospital care, long-term care, and rehabilitation, and the social costs to the individual and his or her family are substantial, although they cannot be precisely measured. Although research on bone physiology suggests the availability of preventive measures and treatments to those who are susceptible to osteoporosis, most prevention methods still require confirmation by research. Earlier diagnosis is considered important to a better prognosis, and such new technologies as photon absorptiometry make earlier diagnosis possible.

[12]Wood sources of calcium in food are dairy products, and vegetables such as parsley, soybeans, and spinach. For those who cannot tolerate milk easily, yogurt is an acceptable substitute. Calcium supplements are readily available as over-the-wounter products,

Policy for basic biomedical research

Provision of health care for the increased numbers of older individuals in American society will involve activity in many sectors: prevention of disease, promotion of health, good nutrition, delivery of health care, diagnosis and treatment of diseases, and research into all of these. This section focuses on that segment of the Federal Government's activity related to biomedical research.

In light of the aging of the American population, those diseases that are more common in the elderly will affect a higher proportion of the total population, Research on aging and diseases that affect older people will therefore become progressively more important, and funds expended in this area are likely to benefit more individuals. The Federal Government devotes 27 percent of its funds to services for older citizens and disburses $53.5 billion for Medicare and Medicaid, the two largest health care programs for older Americans (154). In the most recent inventory of Federal research specifically on aging (but not including all research on diseases common in older people), a task force found Federal spending for biomed-

ical research on aging was $177 million in 1980[13] (163). The agency supporting the largest amount of research on aging was the National Institute on Aging (NIA), which spent $42.3 million, or 24 percent of the total. These figures do not, however, include all research on such disorders prevalent among the older population as stroke, atherosclerosis, or arthritis. In terms of other disorders, such as dementia, NIA has taken the lead. Research figures on the diseases for which most research is performed at institutes other than NIA would significantly expand the totals. Precise figures cannot be given because surveying research on diseases important to the elderly population would entail making difficult judgments about which diseases to include, and would necessitate another, much larger, inventory effort.

It is clear, however, based on research expenditures compared to health care costs, cited in other sections of this chapter, that research on several chronic conditions of older Americans is relatively neglected. Federal research expenditures on Alzheimer disease, for example, total less than $40 million, compared to $8 billion to $10 billion Federal outlays for acute and long-term care, and roughly equal contributions from private sources.

While there is no complete accounting of the resources devoted to research on all diseases of importance to the older American population, it is possible to make rough estimates of the relative Federal costs of health care and biomedical research for the total population. In 1982, costs of health care were $322 billion nationwide, accounting for 10.5 percent of the gross national product. In this same year, estimated total Federal and non-Federal funding for health research and development was $9.2 billion, or 2.9 percent of total spending on health care. Appropriations for the National Institutes of Health (NIH) were $3.6 billion, or 1.1 percent of the total spending for health care nationwide. NIH sponsors the vast majority of federally sponsored biomedical research (comprising 37 percent of all health research, and 69 percent of Federal support for overall biomedical research). An approximate figure for relative Federal spending for health care v. biomedical research might thus be estimated by comparing NIH funding to spending for federally funded health care through the two largest programs, Medicare and Medicaid. In 1982, these two health programs disbursed $83 billion from Federal sources. The NIH budget would constitute 4.4 percent of this total (see fig. 16).

Federal funding for biomedical research has remained fairly constant in real dollars over the past decade, but has declined as a proportion of health care costs from 3.9 percent in 1972 to 2.9 percent in 1982. Funding for biomedical research has also failed to keep pace with overall trends in research and development: the proportion of dollars going to biomedical v. other types of research declined from 12.4 percent in 1972 to 11.7 percent in 1982. The proportion of funding for health research provided by the Federal Government declined from its 1977-79 peak of 41 percent of all health research support to 36 percent in 1982, and is now approximately the same as the Federal share a decade ago (when it was also 36 percent) (see fig. 17).

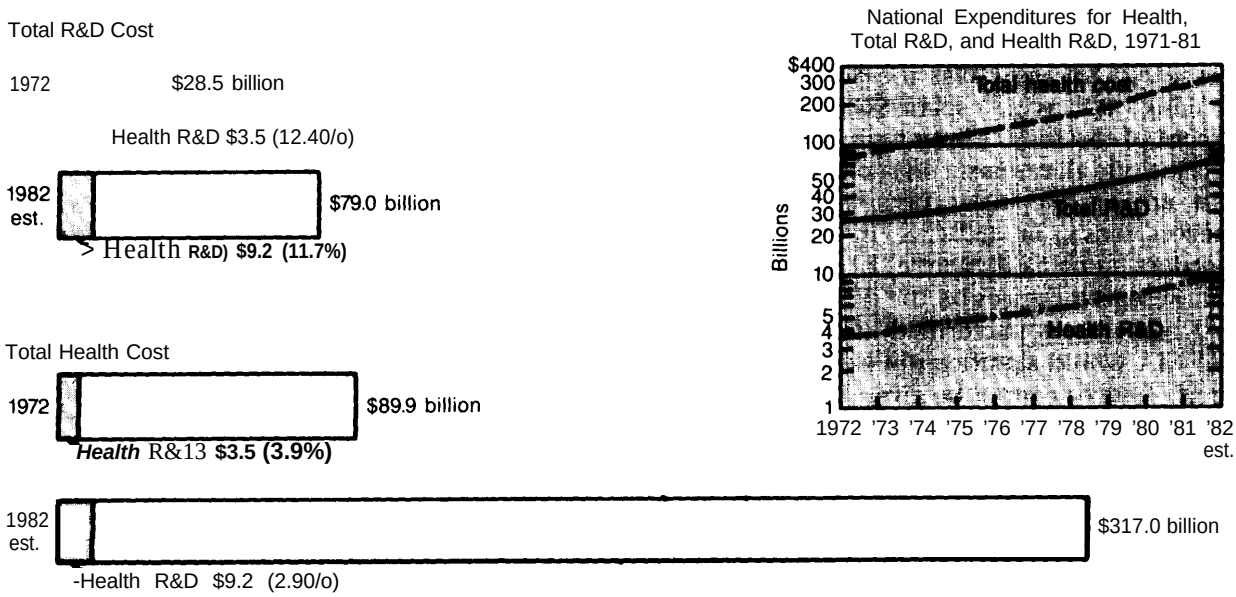
There is no method of determining an optimal level of Federal spending for biomedical research overall or even for a particular disease or class of diseases. There is no competitive market that can establish an equilibrium among spending for prevention, diagnosis, treatment, delivery, and research. In the absence of such a self-correcting mechanism, decisions about the relative levels of support are made administratively, based on a calculus of mixed economic, biological, ethical, medical, and political considerations.

Congressional role in supporting research on aging

The growth of biomedical research in the United States has depended on action by Congress to authorize and fund the Federal agencies responsible for performing and coordinating research, especially at NIH, The NIH budget has grown from $48,000 in 1933 to $55 million in 1953 to $4.3 billion in 1984. This growth has oc-

[13]This inventory was done primarily by computer search of abstracts for aging-related terms. This procedure would miss many basic science and clinical projects relevant to diseases highly prevalent in the older population that not did not include such terms,

Figure 16.– National Health R&D, 1972 and 1982, as Related to Total R&D Cost and Total Health Cost



SOURCE NSF and NIH
SOURCE HCFA, with adjustments of R&D (and theretore of totals) to conform to NIH data

curred as a consequence of wide acceptance among congressional leaders of the importance of biomedical research. In 1974, Congress created a new institute at NIH, the National Institute on Aging, "for the conduct and support of biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged" (Public Law 93-296).

NIA has taken a clear lead in research on some disorders. For example, it supports the largest effort on Alzheimer disease and dementia. NIA obligated $9.3 million out of a total of $22.3 million spent on Alzheimer disease in fiscal year 1983. This proportion will further expand with the substantial increase of funds designated for research on Alzheimer disease and related disorders in fiscal year 1984 ($36.4 million to $37.8 million). NIA was intended to focus its efforts on the disorders and problems of older Americans. NIA coordinates research among the various institutes, and incorporates biological and social science research into a national research plan on aging.

NIA has convened panels of experts to formulate planning for national research on aging. Their most recent report entitled, ***A National Plan for Research on Aging (165),*** has played a pivotal role in determining current research priorities.

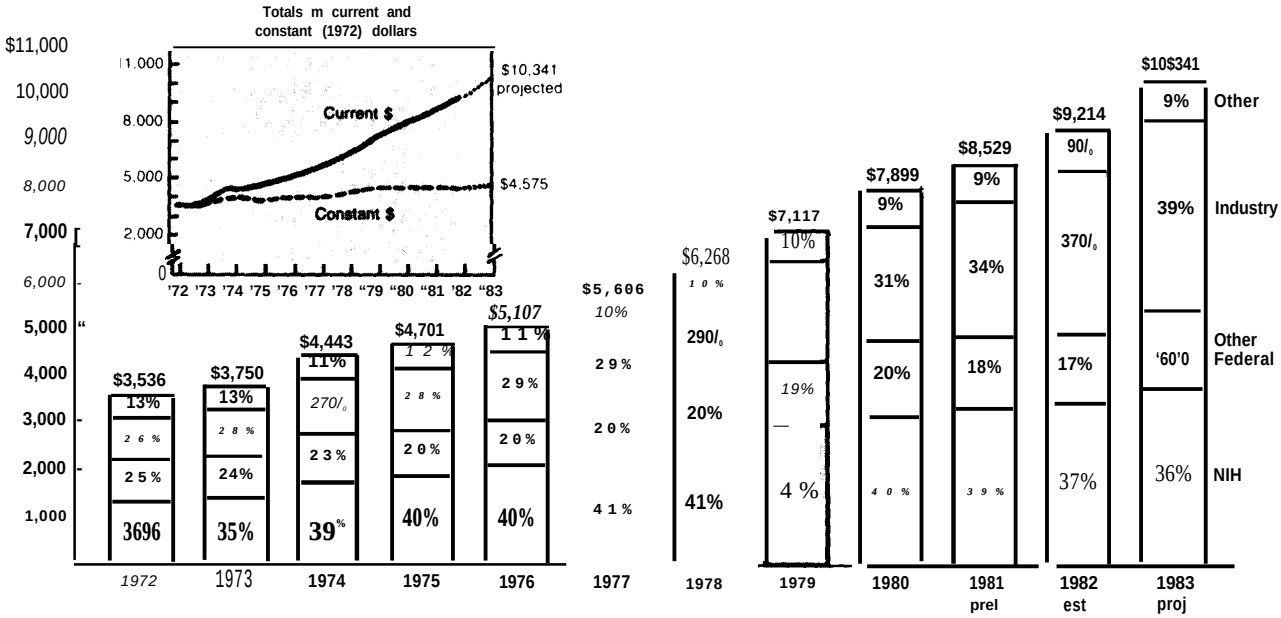
Congress has supported growth at NIA over the past decade. The appropriations figures itemized below show the rise in funding for NIA. Although these figures have not been adjusted for inflation, they do show an increase in the proportion of NIH funding devoted to aging research. But because NIA remains the second smallest of the institutes, the increase at NIA has little proportionate impact on overall NIH funding allocation. (For example, the 1983 appropriation of $91.6 million for NIA compares with $595.7 million for the National Heart, Lung, and Blood Institute (NHLBI) and $962.6 million for the National Cancer Institute.)

Appropriations for the National Institute on Aging
(millions of dollars)

Fiscal year 1976	$ 19.3
Fiscal year 1977	30.0
Fiscal year 1978	37.3
Fiscal year 1979	56.9
Fiscal year 1980	70.0
Fiscal year 1981	75.6
Fiscal year 1982	81.9
Fiscal year 1983	91.6
Fiscal year 1984	112,3

SOURCE Fiscal years 1976-82 NIH Data Book, NIH publication No 83.1261, final year 1983 and 1984 Congressional Record H 8445, Oct 20, 1983

Figure 17.—National Support for Health R&D by Source, 1972-83
(Dollars in Millions)



*Constant dollars based on biomedical R&D price Index 1972–1 982 Projected to 2260 for 1983, based on percentage Increase In estimated GNP implicit price deflator
SOURCE: National Institutes of Health (164).

NHLBI provides most of the support for research on cardiovascular and respiratory diseases, disorders that are responsible for most deaths among older populations. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) expends most of the funds that support work on arthritis and osteoporosis, conditions that are major causes of disability among the elderly. The National Cancer Institute funds research on cancer, one of the most feared killers of older Americans,

Reasons for supporting biomedical research on aging

HEALTH AS A JUSTIFICATION FOR BIOMEDICAL RESEARCH

The most compelling reason for supporting biomedical research is the future health of the American population. Investment in research now is a means of conferring improved health on present and future Americans, and providing information for use by all populations in the world.

The primary product of research is information that is freely available to all—that is exclusive to no particular group. This aspect of research places it in a category economists call "public goods." For example, a successful treatment of arthritis would improve society as a whole by decreasing demand for social services, and by improving the quality of life of countless individuals who cannot now be identified. Much as we all benefit from free access to information about weather, we are all better off for knowing how to prevent ill health. Most biomedical research is funded by the Federal Government because market mechanisms cannot serve to adequately allocate resources to long-term research. Market mechanisms fail, in part, because of both the high degree of uncertainty associated with basic research and the general applicability of many research results (a company does not gain relative advantage from investment if all companies can apply the results of its research). Progress in research is most rapid when there are many groups investigating closely related topics, and when research information is freely disseminated, another

reason that private corporations cannot support research as easily as the public sector. An individual company's incentive to invest in research is reduced to the extent that it cannot control its use and dissemination: wide dissemination yields greater research efficiency overall, but provides less direct benefit to the sponsoring company. Further, no single company can support a research program large enough to assure a balanced program of research in large scientific areas. Since World War II, the Federal Government has adopted the responsibility for supporting basic biomedical research because of this absence of an adequate market mechanism.

The main justification for basic biomedical research is future reduction of mortality and morbidity. Reduced illness can reduce overall health care costs through:

- more effective prevention;
- reduction in the severity of disability leading to increased productivity;
- prolongation of productive life span;
- improved diagnosis allowing more specific treatment or prevention;
- reduction in the cost of a particular disorder (e.g., poliovirus vaccine reduced the need for supportive therapy of the victims of poliomyelitis);
- improved function in individuals permitting less use of medical care (e.g., treatment of cardiovascular illness permitting patients to remain at work, while also improving their quality of life);
- replacement of expensive treatment by a cheaper form (e.g., replacement of some surgery by new drugs for peptic ulcer disease, or replacement of coronary bypass surgery by drugs or catheter surgery);
- reduction in the number of useless therapies, incorrect diagnoses, or errors in treatment; and
- improved delivery of services.

Historical analysis suggests that each of these justifications for biomedical research can be supported in particular instances. Research can also, however, increase health care costs through:

- increased life span leading to a longer period of incurring health care costs for any particular condition;
- increased life span leading to acquisition of more disabilities;
- replacement of a lesser health cost with a greater health cost (e.g., those who would have died from polio have lived long enough to develop arthritis, coronary artery disease, and dementia[14]);
- discovery of new treatment modalities (e.g., new treatments for disorders that would previously have gone untreated, such as drug treatments for certain cancers);
- discovery of new methods of diagnosis (thereby incurring increased costs required to confirm or eliminate treatment alternatives);
- development of more complex therapy (e.g., multiple drug therapy for cancer in place of a single drug);
- requirement of testing for effective prevention (e.g., requiring a laboratory test for monitoring drug treatments);
- increasing medical errors by making diagnosis, treatment, or prevention more complex; or
- increasing the complexity of health care provision, thus requiring new capital outlays, new types of service providers, and more specialized education.

Basic biomedical research does not, therefore, necessarily lead to savings on health care costs in all cases. The goal of biomedical research is health, not parsimony. Federal investment in biomedical research can assure future generations of improved health, but reduction in the cost of health care is not guaranteed. Even improved health is not guaranteed, although it becomes increasingly probable as more resources are devoted to biomedical research.

ECONOMIC JUSTIFICATIONS FOR BIOMEDICAL RESEARCH

Future Savings in Health Care Costs.—While the most widely accepted reason to support biomedical research is the promise of better health in the future, there are also economic

14 Prevetion of polio, therefore, may actually increase lifetime health care costs for any particular individual. However, those who would have died of polio would also have been prevented from contributing to society. Premature mortality, conversely, may actually reduce health care costs but increase overall costs to society. Dead people cost less, but neither can they contribute.

arguments for supporting basic biomedical research. In addition to the possible savings in health care costs for some technologies, several other economic results can follow from progress in biomedical research.

Restoration of health can also permit a return to normal life, including contributing to economic or industrial productivity. Many studies of cost/benefit analysis relating to health take this factor into account. In the case of many older Americans, however, many of their activities are not included in standard economic calculations of productivity because they are retired. In such cases, cost/benefit analysis may underestimate the total benefits to society. Further, if the "human capital" approach of calculating lost wages were to be rigorously applied to health care resource allocation and research priority setting, resources would be preferentially assigned to younger working populations.

Industrial Applications.-One of the most exciting new developments in industry is biotechnology, The new biological technologies promise to become an important part of the international economy (161). The new industrial techniques comprising biotechnology all grew from biomedical research. Applications of biomedical research have thus spun off into the fields of environmental protection, food production, food processing, energy production, and even submarine detection. Such industrial changes constitute national returns on investment in biomedical research. These alone might provide sufficient justification for the investment, and at least provide additional reasons for funding basic research at the national level.

The health care industry is one of the largest in the United States, accounting for 10.5 percent of the gross national product. The health industry is highly labor-intensive, employing large numbers of service workers. Health care is one economic sector promising to produce many new jobs in the coming decades.

one important force driving the growth in health care is new biological and medical knowledge. New knowledge has led to new technologies for enhancing health and for industrial production. Examples of industries based, at least in part, on knowledge derived from biomedical research include pharmaceuticals, diagnostic device manufacture, hospital equipment production and distribution, and new biotechnology firms. Those employed include scientists, technicians, physicians, nurses, pharmacists, educators, social workers, administrators, and government regulators.

REASONS FOR SUPPORTING RESEARCH SPECIFICALLY ON AGING

NIA was created in response to a need perceived by Congress to focus research specifically on aging. This perception arose from the demographic pressures of anticipated growth in the older American population, the potential increase in health costs due to increasing numbers of chronically ill persons in this population, and neglect of research on aging (Public Law 93-296). Several functions distinguish research on aging from other biomedical and social science research.

Older individuals have biological characteristics that differ from younger cohorts. Examples cited in this report include their special susceptibility to side effects of drugs, increased incidence of particular disorders, and vulnerability to concurrent diseases and multiple organ failure. Older people are also more likely to suffer functional impairments for those conditions that they have, and are thus more vulnerable to limitations on their independence. The reasons underlying the reduction in functional reserve [15] that occurs in many organs are not known, and the fundamental processes that cause the phenomenon of aging are not understood. The primary goal of research on aging is resolution of these problems.

Resource allocation: who decides what

Congress determines funding levels for NIH and other research agencies through its budget process. As part of this process, decisions must be made about:

- how much research money is devoted to research overall;

[15] Functional reserve is the ability of a tissue or organ to respond to new stresses without affecting the individual. A good example is the heart's response to vigorous exercise that diminishes with age.

- how many resources are given to biomedical v. other varieties of research;
  allocation among the various institutes;
  division within the institutes into intramural or extramural research (that done at NIH or elsewhere);
- division into basic research and clinical research;
- duration of support for each grant;
- division within the institutes into programs for disease groups or scientific areas; and
- allocation among research projects, training, investigator grants, institutional grants, clinical projects, technology transfer, development of applications, public information dissemination, and special activities.

Congressional debate about proper mechanisms for funding of biomedical research has intensified in recent years. Concerns have been expressed about how to properly allocate funds, how to organize research, and how to determine how much research should be in basic science and how much devoted to other activities (e.g., promoting development of new treatments, supporting clinical trials of new drugs or treatments, or disseminating information about health).

CRITERIA FOR ALLOCATION DECISIONS

There are at least four important determinants of successful biomedical research. Each of these is advocated by different groups in support of funding for a particular area of science or focused on a particular disease or group of disorders.

Scientific ***opportunity*** is important in productivity of any research. one cannot successfully study even the most important health problems if there are no scientific techniques with which to address the relevant questions. The study of bone diseases, for example, was inhibited until recently by the absence of tissue culture methods for studying bone and cartilage cells. Study of Alzheimer disease is still hampered by absence of an adequate animal disease model. In some instances, such scientific roadblocks can be creatively circumvented; in other cases, the barriers resist scientific inquiry. Scientists can, for example, develop new instruments or tests that permit information-gathering directly from affected patients (e.g., noninvasive new technologies for visualizing the living human brain), but cannot deliberately cause Alzheimer disease in animals or laboratory cells in order to study it.

The process of peer review by scientists has arisen to measure the scientific validity of individual grants or programs, thus promoting efficiency in research. Peer review is by no means flawless; studies have shown that there may be a substantial factor of luck and reviewer bias in some methods of peer review (162). Eliminating the peer review process would, however, sacrifice evaluation of factors that are ***not*** attributable to luck. Peer review might be improved, but is unlikely to be replaced, because there appears to be no other effective means of identifying scientific priorities.

Personnel and environment are also essential. Those doing the research must be properly trained, have access to necessary equipment, and have an environment of support from peers. In several areas there is a shortage of personnel trained to do research on a particular topic, which makes research less robust than it could be. Few medical researchers are trained to do computer research, for example, and still fewer Federal sources of fellowship provide support for training them. Many of the arguments in favor of functional assessment and prevention initiatives, cited in chapters 4 and 7, presuppose training and support of new researchers in these areas.

The environment for doing the research must provide needed support services and an intellectual atmosphere conducive to productive enquiry. Evaluation of both the adequacy of institutional support and aptitude of the individual researchers is another aspect of peer review.

One important reason for sponsoring intramural research at NIH and for the support of "centers of excellence" is the enhanced productivity achieved by concentrating groups of researchers close to one another. For example, it is not uncommon at many major research universities to find ready exchange of ideas at seminars, lectures, and through informal laboratory interchanges. This rapid and easy diffusion of ideas causes spread of new techniques into diverse fields, proliferation of approaches to scientific questions, and intensification and broadening of research training. There is thus a "critical mass"

phenomenon associated with biomedical research: it is most productive where there is a sufficient number of highly qualified scientists available to exchange ideas. Not all research, however, is conducted at major research universities. Some scientists are more productive when left on their own, and many important ideas arise from those who take a completely fresh approach to a scientific problem, without being restrained by the ideas of those around them. There are different research styles, just as there are different styles of management.

Importance of solving a problem is a factor in allocating resources for research. Those problems that cause the most social disruption, the greatest number of deaths, or the highest levels of disability are those that society most wishes to solve. The "burden of illness" can be measured by numbers of people affected, severity of disability, public fear of developing a disorder, and untoward social and health effects associated with a given disorder. For example, cardiovascular diseases are the most frequent causes of mortality among the elderly; the severe symptoms of stroke and dementia cause distress for the patient and his or her family; arthritis causes chronic pain for a vast number of individuals, but kills few; and the prospect of cancer provokes widespread fear. Each of these aspects of disease bears on the political and administrative calculus of deciding how to distribute research dollars. Recent congressional debate has focused on how best to organize distribution of funds to NIH, Some prefer distributing funds along scientific lines (for research in neurobiology, metabolism, genetics, or for basic cell biology), while others favor increasing the focus on particular diseases or disease groups.

Duration of grant support: the length of time a research project is supported affects how science is performed. Shorter periods of grant support permit greater flexibility of resource allocation at the national level because long-term grants obligate funds in future years that cannot be redirected to new projects. Shorter grants also, however, require scientists to apply for funds more often, thus detracting from their primary function of investigation. Short-term grants also increase the paperwork associated with research support because of the necessity of filing more grant applications during the same period than would be needed for long-term commitments. Long-term grants also permit more stable assurance for research personnel and stable development of coordinated research programs. Decisions about grant duration at the national level thus balance the advantages of flexible yearly research priority assessment against the need to provide stable and reliable support for scientific investigation.

SPECIFIC CONGRESSIONAL INVOLVEMENT IN BIOMEDICAL RESEARCH

Congress creates new research institutions, annually authorizes and appropriates funding for research, and has control over some aspects of how funding is allocated. Congress makes decisions about resource allocation at three levels:

- Congress determines how much total funding to set aside for all biomedical research at the Federal level.
- Congress may also choose to play a role in allocating funds among the various institutes .[16]
- Congress may also ensure execution of particular projects or research plans.

The level of congressional involvement varies from allocating money to be used at the discretion of the Secretary of Health and Human Services (usually delegated to the Director of NIH) to specific funding for particular types of grants. Specific congressional involvement differs among disease groups, scientific areas, and executive institutions that support research. There have been historical variations in the intensity and specificity of congressional action. Examples of general actions include creation of the NIH and the larger institutes. Less general was the creation of NIA, which was intended to encourage research in an area of perceived neglect. Specific actions are common in support of particular diseases or disease groups. For example, there were several proposals for research specifically on Alzheimer dis -

[16]ongress must specifically authorize and fund the ,National Cancer Institute and the ,National Heart, Lung, and Blood Institute because of the character of the legislation that created these two largest institutes at NIH. Other institutes are authorized under an "umbrella" authorization that provides spending authority if authorization has not passed Congress,

ease in the most recent session of Congress. Decisions about congressional involvement in determining research priorities involves debate about the criteria named earlier: scientific opportunity, personnel, and social importance. It also involves judgments about the administrative costs of particular actions, and who is best able to decide questions of a particular type. In general, Congress is best at ascertaining the social and personal costs of a particular problem, while scientists, through the peer review process, are expert in assessing scientific validity. Congress can direct resources to important problems, and scientists can emphasize the importance of using the tools available.

Judgments about proper allocation of resource funding are thus political in that they can involve resolution of sometimes conflicting contentions. There may often be no one right answer. When there is only one right answer, it may not be possible to identify it. The present system of allocating research funds incorporates the tension between the expertise of scientists, who assess scientific opportunity and research priority in a given area, and Congress, which establishes overall funding and general research priorities.

EXAMPLE OF CONGRESSIONAL POLICY DEBATE: A PROPOSED ARTHRITIS INSTITUTE

A prominent example of congressional debate about research policy surrounds creation of a new institute for the study of arthritis and musculoskeletal disorders, which was under consideration as this report was written (151,152, 158,160).

Those opposed to creation of a new institute cite increased administrative costs that would detract from money available for basic research (such costs are estimated by the Office of the Director of NIH at $4 million) (156) and express concern that proliferation of the number of institutes at NIH will make the organization difficult to manage. Those in favor of creating a new institute assert that research on arthritis is relatively neglected, and the presence of a new institute would focus scientific attention on this severe medical and social problem and facilitate efforts to garner support for arthritis research in Congress (thus increasing total funding for research, rather than merely reallocating funds from other areas) (159).

Proponents of the arthritis institute point out that spending is 22 times higher per affected patient for cancer research and 12 times higher for heart research than for arthritis research (153). By these same criteria, however, mental illness could be considered even more underfunded than arthritis, yet the presence of a National Institute of Mental Health (NIMH) has not remedied this. Some believe, in this context, that funding for NIMH would have been greater if NIMH had not been separated from NIH in the late 1960s (155). Differences here center on whether creating an institute at NIH in fact attracts increased resources for the topics investigated at that institute. The historical analysis in the upcoming Institute of Medicine study of the NIH (see below) may provide information that can contribute to resolving this issue.

Within the field of arthritis research, there is debate about the current distribution of funding. Some aver that funding is now too focused on immunology and away from basic cartilage and bone research. They advocate increasing research on the major causes of disability of osteoporosis and osteoarthritis with less emphasis on rheumatic arthritis and immunological disorders. Others counter that scientific opportunities in bone and cartilage research are restrained by the absence of adequate scientific methods and shortage of trained researchers in this area. They point out that research on immunological mechanisms has been extremely productive, and should continue to be so. Those favoring research on osteoarthritis counter that the productivity of immunological research is due to availability of Federal funding for it, and that bone and cartilage research would have been equally productive if it had been as well supported over the last decade.

Such debates highlight the difficulties of allocating funding in the absence of a natural market. Targeting of research on particular diseases emphasizes the importance of the problems to be addressed, while targeting on particular methods of scientific approach or organ system stresses scientific opportunity. In most cases, these values do not conflict, but when they do, there are usually good arguments on both sides of the debate.

Congress is then forced to make an administrative decision fraught with a high degree of uncertainty. High levels of spending for heart and cancer research arose from congressional action and concerted public efforts persistently pursued since the 1950s. The present high level of scientific achievement in these fields and the industrial spinoffs (biotechnology and medical technology) of such research are the beneficial effects of more than two decades of committed Federal support. Whether creation of an institute for the study of arthritis and musculoskeletal disorders will achieve its goals of scientific excellence and amelioration of disability may depend as much on the consistency of support from Congress over the next decade as on the establishment of a new institutional home for musculoskeletal research.

The status of a new institute for the study of arthritis, musculoskeletal, and skin diseases is uncertain as this assessment is written. The Senate and House of Representatives of the 98th Congress passed S. 540 authorizing the creation of such an institute, but the bill was vetoed by President Reagan on october 30, 1984.

ANOTHER EXAMPLE: PROGRAMS FOR PREVENTION RESEARCH AND EDUCATION

Concern that research on disease prevention and health promotion has been relatively neglected prompted Congress to mandate Associate Directors for Prevention Research at the National Cancer Institute, National Institute on Child Health and Human Development, and the Office of the NIH Directopr, in addition to the one already in place at the National Heart, Lung, and Blood Institute. The function of these new offices would have been to assure that research on prevention, health-promoting behavior, epidemiology, and disease causation was given high priority at the respective institutes.

In addition, passage of S. 771 authorized a revision and extension of the Office of Health Promotion and Disease Prevention of the Public Health Service. The bill included provisions to create a network of centers for health promotion and disease prevention, The centers were to perform basic applied research in preventive health. The bill contained authorization sufficient to support 13 center grants in fiscal years 1985, 1986, and 1987, The arguments for this new legislation in the structure of NIH were similar in type, although different in detail from those urging establishment of the arthritis institute. These other health research bills were also vetoed on October 30, 1984.

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH: IOM STUDY

The proposed institute on arthritis is only one of many changes in NIH debated over the past decade. As a result of this debate, the organization of the National Institutes of Health is being studied by the Institute of Medicine (IOM). The results of this study, ***The Organizational Structure of the National Institutes of Health,*** was released on November 15, 1984. The study focused on criteria for creation of institutes, how to support solid basic science, and how to best respond to medical needs and social burdens (157).

The study has three components:

- a historical review of how institutes were formed, how association with or dissociation from NIH has affected different institutes, and how institutes have split or had new functions added to existing institutes;
- a survey of the current organization of NIH, including how priorities are set and a review of potential additions to NIH, and review of proposed alternative organizational structures; and
- an analysis of alternative means of organizing NIH, including criteria for goal setting, decisionmaking, priority setting, and budget authority.

Conclusion

The prevalence of major chronic diseases is expected to rise over the next decade. If current trends continue, dementia, hearing impairments, urinary incontinence, osteoporosis, and osteoarthritis will continue to increase in incidence and prevalence as the population ages and as the average age at death continues to rise. Effective treatment for prevention of these disorders is needed, and adaptation of technology to compensate for the ravages of chronic disabilities will be more and more in demand in the future. For conditions that may be ameliorated by existing technologies, such as hearing impairment and incontinence, application of such technologies is a priority. Research on chronic diseases, however, provides the only possibility for ultimately eliminating them.

Congressional issues and options regarding basic biomedical research

Support for basic biomedical research is growing rapidly. It has resulted in the creation and growing budget of the National Institute on Aging and support of research in other NIH institutes and Federal agencies on diseases prevalent among the older population. Such research has not, however, attained the status or level of support enjoyed by other groups of disorders, such as cancer or heart disease. Increasing efforts by private citizen organizations such as the Alzheimer Disease and Related Disorders Association and the Arthritis Foundation have begun to change this, encouraging Federal policymakers to invest more research dollars in studying the diseases that cause severe disability among older Americans. Such increases in funding can be achieved by diverting funds from other areas of basic biomedical research, by increasing total funding for biomedical research, or by a combination of these strategies.

Issue 1: Should Congress increase support for basic and clinical biomedical research on aging?

Options:

1.1; Congress could continue present levels of support for aging research.

1.2: Congress could increase support for basic biomedical research on aging by devoting a larger share of the NIH budget to it.

1.3: Congress could increase support for basic biomedical research on aging by devoting more overall Federal funds to it.

Some believe that present levels of funding for aging research are adequate, and that devoting increased funds to this area could detract from research now going on in other areas. Others believe that the growing proportion of the older segment of the American population will necessitate a commensurate increase in knowledge about the biology of aging and about conditions highly prevalent in older Americans.

If Congress chooses to support more research on aging, it can take one of three general courses: either increase the overall NIH budget, earmarking more funding for aging, increase the proportion of the NIH budget devoted to aging research, or a combination (the combination would conform to recent trends).

Issue 2: Should Congress exercise more control over the direction of basic biomedical research?

Options:

2,1: Congress could delegate major decisions regarding biomedical research to the Director of NIH, the Public Health Service, and the Department of Health and Human Services.

2.2: Congress could increase its level of involvement in selected areas, such as general aging research,

creation of new institutes, and mandating new programs.

2.3: ***Congress could increase its level of involvement by changing the methods of authorizing and appropriating funds for NIH.***

Examples of option 2.2 would include the proposed new institute on arthritis and musculoskeletal disorders, new centers of excellence for Alzheimer disease, earmarking of funds for particular types of disease-oriented research, and mandating programs for disease prevention and health promotion. Examples of 2.3, involving regular reauthorization and appropriation of each institute and increased oversight of institute programs, were at the heart of debate about the original version of H.R. 2350 in 1983, before a compromise was reached with competing bills. The basic arguments were those noted above in the discussion about the specificity of congressional involvement in basic research policy and in the discussion about the proposed arthritis institute.

Increased congressional involvement in research policy would tend to favor more sensitivity to the needs of diseasearianted interest groups, which may represent the needs of their constituents; leaving administrative decisions to the present NIH hierarchy favors attention to scientific opportunity as assessed by peer review.

Chapter 3 references

Dementia

1. Appel, S. H., "Alzheimer Disease and Dementia)') ***Neurol. Clin. 4:3-11, 1982.***
2. Ball, M. J., "Alzheimer Disease," ***Arch. Pathol. Lab. Med.*** 106:157-162, 1982.
3. Beck, J. C., et al., "Dementia in the Elderly, the Silent Epidemic, " ***Annals. Int. Med.*** 97:231-241, ***1982.***
4. **Brody, J. A., "An Epidemiologist Views Senile Dementia—Facts and Fragments, " *Amer. J. of Epidem.*** 115:155-162, ***1982.***
5. **Cook, R. H., Ward, B .E., and Austin, J. H., "Studies in Aging of the Brain, IV: Familial** Alzheimer **Disease—Relation to Transmissible Dementia,** Aneuploidy, **and** Microtubular **Defects)"** *Neurol.* 29:1402-1412, **1979.**
6. Cowell, **D. D., "Senile Dementia of the** Alzheimer **Type: A Costly Problem,"** *J. Am. Geriat. Soc.* 31:61, 1982.
7. Coyle, **J. T., Price, D. L., and DeLong, M., "Brain Mechanisms in** Alzheimer **Disease,"** ***Hosp. Pract.*** 17:55-63, ***1982.***
8. **Dunn, A. J., "Neurochemistry of Learning and Memory,"** *Annu. Rev. Psychol.* 31:343-390, ***1980.***
9. Folstein, **M. F., and** Breitner, **J. C. S., "Language Disorder Predicts Familial** Alzheimer **Disease, " *Johns Hopkins Med. J.*** 149:145-147, ***1981.***
10. Gajdusek, **D. C., "Unconventional Viruses and the Origin and Disappearance of** Kuru," ***Nobel Lecture,*** **Dec. 13, 1976.**
11. Gibbs, C. J., "Virus-Induced Subacute Degenerative Diseases of the Central Nervous System, " *Ophthalmology* 87:1208-1218, ***1980.***

ha. Harbaugh, **R. E., Roberts, D. W.,** Coombs, **D. W., et al., "Preliminary Report: Intracranial** Cholinergic **Drug Infusion in Patients With** Alzheimer's **Disease,"** ***Neurosurgery*** 15:514-518, 1984.

12. Hokfelt, **T., et al.,** "Peptidergic Neurones," ***Nature*** 284:515-521, ***1980.***
13. Housman, **D. E., and** Gusella, **J. F., "Molecular Genetic Approaches to Neural Degenerative Disorders, " *Molecular Genetic Neuroscience (New* York: Raven Press, 1982), pp. 415-434.**
14. **Hyden, H., and** Egyhazi, **E., "Nuclear RNA Changes During a Learning Experiment in Rats," *Proc. Nat. Acad. Sci.*** 48:1366-1373, ***1962.***
15. Iversen, **L. L.,** Nicoll, **R. A., and Vale, W., "Neurobiology of Peptides,"** *Neurosci. Res. Prog. Bull.* 16:211-370, **1978.**
16. Iversen, **L. L.,** "Neurotransmitter **Interactions in the Substantial Nigra: A Model for Local Circuits,"** *The Neuroscience: Fourth Study Program,* F. O. **Schmitt and F. G. Worden (eds.) (Cambridge, MA: MIT Press, 1979).**
17. Katzman, **R., "The Prevalence and Malignancy of** Alzheimer **Disease,"** ***Arch.*** *Neurol.* 33:217-218, ***1976.***
18. **Kety, S. S.,** "Neurochemical **and Genetic Bases of Psychopathology: Current Status,"** *Behav. Genet.* 12:93-100, **1982.**

19. Lijmaer, H., Fuld, P. A., and Katzman, R., "Prevalence and Malignancy of Alzheimer Disease," *Arch. Neurol.* 33:304 (letter), 1976.
20. Martin, J. B., "Huntington's Disease: Genetically Determined Cell Death in the Mature Human Nervous System," ***Molecular Genetic Neuroscience,*** F. O. Schmitt, S. J. Bird, and F. E. Bloom (eds.) (New York: Raven Press, 1982), pp. 407-414.
21. McAllister, T. W., and Price, T. R. P., "Severe **Depressive Pseudodementia With and Without Dementia,"** *Am. J. Psych.* 139:626-629, 1982.
22 McGaugh, J., and Thompson, R. (eds.), *Neurobiology of Learning and Memory (New* York: Plenum Press, 1982).
23 McKinstry, D. W., "Diagnosis, Cause, and Treatment of Alzheimer Disease," ***Research Resources Reporter*** NIH 6:1-7, 1982.
24. Mortimer, J. A., Schuman, L. M., and French, L. R., **"Epidemiology of Dementing Illness,"** *The Epidemiology of Dementia,* J. A. Mortimer and L. M. Schuman (eds.) (New York: Oxford Press, 1981), pp. 3-23.
25. Phelps, M. E., Mazziotta, J. C., and Huang, S. C., "Study of Cerebral Function With Positron Computed Tomography," *J. Cereb. Blood Flow Metab.* 2:113-163, 1982.
26. Shashoua, V. E., **"Role of Specific Brain Proteins in Long-Term Memory Formation,"** *Changing Concepts of the Nervous System (New* York: Academic Press, 1982), pp. 681-716.
27. Stenevi, U., Björkland, A., et al., **"Cross-Species Neural Grafting: Survival and Function in an Animal Model,"** *Nature* 298:652-654, *1982.*
28. Task Force Sponsored by the National Institute on Aging, **"Senility Reconsidered,"** *J. Am. Med. Assoc.* 244:259-263, *1980.*
29. Thoenen, H., **"Strategies for Application of Molecular Genetics to Neurobiology)"** *Molecular Genetic Neuroscience,* F. O. Schmitt, S. J. Bird, and F. E. Bloom (eds.) (New York: Raven Press, 1982), pp. 459-466.
30. Traub, R., Gajdusek, D. C., and Gibbs, C. J., Jr., **"Transmissible Virus Dementia,"** *Aging and Dementia, M.* Kinsbourne and L. Smith (eds.) (New York: Spectrum, 1977), pp. 91-146.
31. Varon, S., et al., "Neuronotrophic Factors: Problems and Perspectives," *Prog. Clin. Biol. Res.* 79:225-242, *1982.*
32 U.S. Department of Health and Human Services, Health Care Financing Administration, June 1983.
33 Whitehouse, P. J., et al., "Alzheimer Disease—Evidence for Selective Loss of Cholinergic Neurons in the Nucleus Basalis," *Annals Neurol. 10:122-126, 1981.*
34. Yesavage, J. A., **"Opportunities for and Obstacles to Treatments for Dementias,** *J. Am. Geriatrics Soc.* 31:59-60, *1983.*
35. *Yoe,* M. R., "Dementia," *Johns Hopkins Magazine,* December 1982, pp. 23-31.

Urinary incontinence

36. Bissada, N. K., and Finbeiner, A, E., **"Pharmacologic Treatment of Lower Urinary Tract Disorders, "** in *Lower Urinary Tract Function and Dysfunction: Diagnosis and Management, N.* K. Bissada and A. E. Finkbeiner (eds.) (New York: Appleton Century Crofts, 1978).
37. Brazda, J. F., "Washington Report," *The Nation's Health,* p. 3, March 1983.
38. Castledon, C. M., Duffin, H. M. , and Answer, M. J., **"Clinical and Urodynamic Studies in 100 Elderly Incontinent Patients",** *Brit.* Med. J. 282:1103-1105, 1981.
39. Collins, C. W., and Plaska, T., "Mowrer's Conditioning Treatment for Enuresis Applied to Geriatric Residents of a Nursing Home, " *Behav. Ther. 6:632-638, 1975.*
40 Erlandson, B. E., Fall, M., and Carlsson, C. A., **"The Effect of Intravaginal Electrical Stimulation on the Feline Urethral and Urinary Bladder: Electrical Parameters,"** *Scand. J. Urol.* Neph. 44(Suppl):5-18, 1977.
41. Erlandson, B. E., Fall, M., and Sundin, I., "Intravaginal Electrical Stimulation: Clinical Experiments in Urethral Closure," *Scand. J. Urol. Neph.* 44(Suppl):31-39, *1977.*
42. Fall, M., Erlandson, B. E., Carlsson, C. A., et al., "The Effect of Intravaginal Electrical Stimulation on the Feline Urethra and Urinary Bladder: Neuronal Mechanisms," *Scand. J. Urol. Neph.* (Suppl):19-30, *1977.*
43. Fall, M., Erlandson, B. E., Nilson, A. E., et al., "Long-Term Intravaginal Stimulation in Urge and Stress Incontinence," *Scand. J. Urol. Neph. 44* (Suppl):55-63, *1977.*
44 Fantl, J. A., Hunt, W. G., and Dunn, L, J., "Detrusor Instability Syndrome: The Use of Bladder Retraining Drills With and Without Anticholinergics, " *Am. J. Obset. Gynecol.* 140:885-890, *1981,*
45. Frewen, W. A., "A Reassessment of Bladder Training in Detrusor Dysfunction in the Female, " *Br. J. Urol.* 54:372-373, *1982.*
46. Garibaldi, R. A., Brodine, S., and Matsumiva, S., "Infections Among Patients in Nursing Homes—Policies, Prevalence, and Problems," N. *Engl. J. Med.* 305:731-735, *1981.*

47. Hadley, E., "Bladder Training and Related Therapies," prepared for the National Institute on Aging's Workshop on Bladder Training, Washington, DC, April 1983.
48. Jarvis, G. J., "The Management of Urinary Incontinence Due to Primary Vesical Sensory Urgency by Bladder Drill," *Br. J. Urol.* 34:374-376, 1982.
49. Jarvis, G. J., "A Controlled Trial of Bladder Drill and Drug Therapy in the Management of Detrusor Instability," *Br. J. Urol.* 53:565-566, 1981.
50. Jewett, M. A. S., Fernie, G, R., Holliday, P. J., et al., "Urinary Dysfunction in a Geriatric Long-Term Care Population: Prevalence and Patterns," *J. Amer. Ger. Soc.* 29:211-214, *1981.*
51. Lapides, J., and Diokno, A. C., "Clean, Intermittent Self -Catheterization," in *Female Urology*, S. Raz (cd.) (Philadelphia, PA: Saunders, 1983).
52. Mahady, I. W., and Begg, B. M., "Long-Term Symptomatic and Cytometric Cure of the Urge Incontinence Syndrome Using a Technique of Bladder Reeducation," *Br. J. Obset. Gynecol.* 88:1038-1043, 1981.
53. Marron, K. R., Fillit, H., Peskowitz, M., et al., "The Nonuse of Urethral Catheterization in the Management of Urinary Incontinence in the Teaching Nursing Home," *J. Am, Ger. Sac.* 31:278-281, *1983.*
54. McDuffie, R. W., Litin, R. B., and Blundon, K. E., "Urethrovesical Suspension (Marshall-Marchetti-Krantz)—Experience With 204 Cases," *Am. J. Surg.* 141:297-298, *1981.*
55. Noelker, L. S., "Incontinence in Aged Cared for by Family," *Gerontol.* (Abstract) 23:258, 1983.
56. Ouslander, J. G., "Lower Urinary Tract Disorders in the Elderly Female," in *Female Urology*, S. Raz (cd.) (Philadelphia, PA: Saunders, 1983).
57. Ouslander, J. G., and Fowler, E., "Incontinence in VA Nursing-Home Care Units: Epidemiology and Management," *Gerontol.* (Abstract) 23:257, 1983.
58. Ouslander, J. G., and Kane, R. L., "The Costs of Urinary Incontinence in Nursing Homes," *Medical Care* 22(1):69-79, 1984.
59. Ouslander, J. G., Kane, R. L., and Abrass, 1. B., "Urinary Incontinence in Elderly Nursing Home Patients," *J. Am. Med. Assoc.* 248:1194-1198, *1982.*
60. Pollock, D. D., and Liberman, R. P., "Behavior Therapy of Incontinence in Demented Patients," *Gerontol.* 14:488-491, *1974.*
61. Priefer, B. A., Duthie, E. H., and Gambert, S. R., "Frequency of Urinary Tract Infection: Study in Hospital Based, Skilled Nursing Home," *Urology*, 20:141-142, 1982.
62. Raz, S. (cd.), *Female Urology* (Philadelphia, PA: Saunders, 1983).
63. Raz, S., "Modified Bladder Neck Suspension for Female Stress Incontinence," *Urology* 17:82-85, 1981.
64. Raz, S., "Pharmacologic Treatment of Lower Urinary Tract Dysfunction, *Urol. Clin. N.A. 5:323-334, 1978.*
65. Stanton, S. L., and Cardozo, L. D., "Surgical Treatment of Incontinence in Elderly Women," *Surg. Gyn. Obstet.* 150:555-557, *1980.*
66. Stanton, S. L., and Cardozo, L. D., "Results of the Colosuspension Operation for Incontinence and Prolapse," *Br. J. Obstet. Gyn.* 86:693-697, 1979.
67. Thomas, T. M., Plymat, F. R., Blannin, J., et al., "Prevalence of Urinary Incontinence," *Brit. Med. J.* 281:1243-1245, *1980.*
68. Vetter, N. J., Jones, D. A., and Victor, C. R., "Urinary Incontinence in the Elderly at Home," *Lancet* 2(8261):1275-1277, *1981.*
69. Warren J. W., Muncie, H. L., Berquist, E. J., et al., "Sequelae and Management of Urinary Infection in the Patient Requiring Chronic Catheterization, *J. Urol.* 125:1-7, 1981.
70. Weissert, W. G., Scanlon, W. J., Wan T. T. H., et al., "Encouraging Appropriate Care for the Chronically Ill: Design of the NCHSR Experiment in Nursing-Home Incentive Payments," paper presented at the Annual Meeting of the American Public Health Association, Detroit, MI, Oct. 19-20, 1980.
71. Wells, T. J., and Brink, C. A., "Urinary Incontinence: Assessment and Management," in *Nursing and the Aged,* I. M. Burnside (cd.) (New York: McGraw Hill, 1981).
72. Williams, M. E., "A Critical Evaluation of the Assessment Technology for Urinary Incontinence in Older Persons," *J. Am. Ger. Soc.* 31(11):657-664, *1983.*
73. Williams, M. E., and Pannill, F. C., "Urinary Incontinence in the Elderly," *Ann. Int. Med. 97:895-907, 1982.*
74. Yarnell, J. W. G., and St. Leger, A. J., "The Prevalence, Severity, and Factors Associated With Urinary Incontinence in a Random Sample of the Elderly," *Age Aging* 8:81-85, *1979.*
75. Yarnell, J. W. G., Voyle, G. J., Richards, C. J., et al., "The Prevalence and Severity of Urinary Incontinence in Women," *J. Epidem. Comm. Health* 35:71-74, *1981.*

Hearing impairment

76, Becker, G., *The Disability Experience: Educating Health Professionals About Disabling Conditions*

(Berkeley, CA: University of California Press, 1981).
77. Becker, G., *Growing Old in* Silence (Berkeley, CA: University of California Press, 1980).
78. Bergman, M., "Assistive Listening Devices, Part I: New Responsibilities," *Asha*, pp. 19-23, March 1983.
79. *Consumer Reports,* "How To Buy a Hearing Aid: What Consumers Should Know," pp. 346-352, June 1976.
80. Corbin, S., Reed, M., Nobbs, H., Eastwood, K., and Eastwood, M. R., "Hearing Assessment in Homes for the Aged," *J. Am. Geriat. Soc.* 32(5):396-400, *1984.*
81. Davis, J. M., and Hardick, E. J., *Rehabilitative Audiology for Children and Adults (New* York: John Wiley & Sons, 1981).
82. House, W. F., "The Cochlear Implant," *Shhh*, pp. 12-13, January/February 1982.
83. Leib, R. K., "The Chronically Impaired Elderly in Institutions and in the Community Care System: Technological Applications Leading to New and Improved Products," *Conference Papers, National Research Conference on Technology and Aging*, the Gerontological Association of America and The Western Gerontological Society, AoA grant No. 90-AR-0025, 1982.
84 Leske, M. C., "Prevalence Estimates of Communicative Disorders in the U. S.: Language Hearing, and Vestibular Disorders," *Asha* 23(3):229-237, *1981.*
85. Pickett, J. M., "Hearing Through Sight and Feeling," *IEEE Spectrum,* pp. 37-41, April 1982.
87. Ross, M., *Principles of Aural* Rehabilitation (New York: The Bobbs-Merrill Co., 1972).
88. Schow, R. L., and Nerbonne, M. A., "Hearing Levels Among Elderly Nursing Home Residents)" *Journal of Speech and Hearing Disorders 45:124-132,* February 1980.
89. U.S. Department of Health, Education and Welfare, U.S. Congress, U.S. Senate Report of Review of NHAS Home-Study Course, US. Senate Permanent Subcommittee on Investigations of the Committee on Government Operations, 1975.
90. US. Department of Health, Education, and Welfare, National Institute of Neurological Disease and Stroke (NINDS), National Institutes of Health, *Human Communication and Its Disorders: An Overview,* Bethesda, MD, NINDS monograph No. 10, 1969.
91 U.S. Department of Health and Human Services, National Center for Health Statistics, P. W. Ries, "Hearing Ability of Persons by Sociodemographic and Health Characteristics, " *Vital and Health Statistics,* DHHS publication No. (PHS) 82-1568, series 10, No. 140, Hyattsville, MD, August 1982.
92. US. Department of Health and Human Services, National Center for Health Statistics, B. A. Feller, "Prevalence of Selected Impairments, U. S., 1977," *Vital and Health Statistics,* DHHS publication No. (PHS) 81-1562, series 10, No. 134, Hyattsville, MD, February 1981.
93. U.S. Department of Health and Human Services, National Center for Health Statistics, S. S. Jack, *Current Estimates From the National Health Interview Survey, U.S., 1979,* DHHS publication No. (PHS) 81-1564, series 10, No. 136, Hyattsville, MD, April 1981.
94. U.S. Department of Health and Human Services, National Center for Health Statistics, unpublished data from the 1981 Health Interview Survey, 1981.
95 U.S. Department of Health and Human Services, National Center for Health Statistics, M. Rowland, "Basic Data on Hearing Levels of Adults 25–74, U.S. 1971 -75," USDHEW publication No. (PHS) 80-1663, series 11, No. 215, Hyattsville, MD, January 1980.

osteoarthritis

97. Arthritis Foundation, So *You Have osteoarthritis,* November 1982.
96. Arthritis Foundation, *Arthritis: Basic Facts,* June 1983.
98. Bloccol, J. J., "The Reversibility of osteoarthritis: A Review," *Amer. J. Med.* 74(64):16-26, *1983,*
99. Consumers Union, "The Mistreatment of Arthritis," *Health Quackery, 1980.*
100. Fries, J. F., "Toward an Understanding of Patient Outcome Measurement," *Arthritis and Rheumatism* 26:697-704, *1983.*
101. Gay, R. E., Palmoski, M. J., Brandt, K. D., and Gay, S., "Aspirin Causes in Vivo Synthesis of Type 1 Collagen by Atrophic Articular Cartilage, " *Arthritis & Rheumatism* 26:1231-1236, October 1983.
102. Hulth, A., "Experimental Osteoarthritis," *Acta Orthop. Scand.* 53:1-6, *1982.*
103. Kelsey, J. L., "Epidemiology and Impact," *Total Hip Joint Replacement–Program Abstracts,* NIH Consensus, Mar. 1-3, 1982.
104. Kramer, J. S., Yelin, E. H., and Epstein, W. V., "Social and Economic Impacts of 4 Musculoskeletal Conditions," *Arthritis & Rheumatism* 26:901-907, *1983.*
105. Moskowitz, R. W., "osteoarthritis)'" prevention

Conference on Arthritis, Airlie House, VA, July 19-22, 1983.
1064 Moskowitz R., "Management of Osteoarthritis," *Bull. Rheum. Dis.* 31:31-35, 1981.
107. O'Connor, G. T., and Olmstead, E. M., "Agreement Between Clinical Judgment, Patients' Assessment and Responses to Functional Health Status Questionnaire," paper presented at the San Antonio Meeting of the American Rheumatology Association, June 1-4, 1983.
108. Palmoski, M. J., and Brandt, K. D., "In Vivo Effect of Aspirin on Canine Osteoarthritis Cartilage)" *Arthritis & Rheumatism* 26:994-1001, August 1983.
109. Shrier, R. W., and Henrich, W. L., "Nonsteroidal Anti-Inflammatory Drugs: Caution Still Indicated," *J. Am. Med. Assoc.* 251:1301, *1984.*
110. National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Office for Medical Applications of Research (OMAR), National Institutes of Health, USDHHS, *Total Hip Joint Replacement,* Consensus Development Conference Summary, No. 4, 1982.
111. U.S. Department of Health and Human Services, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health, "Arthritis, Rheumatic Diseases, and Related Disorders," Special Report to Congress, 1981.
112. U.S. Department of Health and Human Services, National Center for Health Statistics, *Basic Data on Arthritis: Knee, Hip, and Sacroiliac Joints in Adults Ages 25-74, 2971-1975,* USDHEW publication No. (PHS) 79-1661, series 11, No. 213, 1979.
113. Wright, V., "Mobility in the Elderly: The Problem of Arthritis, " *Current Med. Res. and Opin. 7,* Suppl. 1:28-32, 1982.

osteoporosis

114. Aloia, J. F., "Exercise and Skeletal Health." *J. Am. Geriat. Soc.* 29:104-107, *1981.*
115. Atik, O. S., "Zinc and Senile Osteoporosis," *J. Am. Geriat. Soc.* pp. 790-791, December 1983.
116. Bush, T. L., Cowan, L. D., Barrett-Connor, E., et al., "Estrogen Use and All-Cause Mortality," *J. Am. Med. Assoc.* 249:903-906, *1983.*
117. Crane, J. G., and Kernek, C. B., "Mortality Associated With Hip Fractures in a Single Geriatric Hospital and Residential Health Facility: A Ten-Year Review," *J. Amer. Ger. Soc.* 31:472-475, *1983.*
118. Dequeker, J., Goris, P., and Uytterhoeven, R., "osteoporosis and osteoarthritis (Osteoarthrosis): Anthropomorphic Distinctions, " *J. Am. Med. Assoc.* 249:1448-1451, *1983.*
119. Donaldson, C. L., Hulley, S. B., Vogel, J. M., et al., "Effect of Prolonged Bed Rest on Bone Mineral," *Metabolism* 19:1071-1084, *1970.*
120. Gallagher, T. C., Riggs, B. L., Jerpbak, C. M., and Arnand, C. D., "The Effect of Age on Serum Immunoreactive Parathyroid Hormone in Normal and Osteoporotic Women, " *J. Lab. Clin. Med.* 95:373-85, *1980.*
121. Heaney, R. P., Gallagher, J. C., Johnston, C. C., Neer, R., et al., "Calcium Nutrition and Bone Health in the Elderly)"Amer. *J. Clin. Nut.* 36:986-1013, 1982.
122. Heaney, R. P., "Estrogens and Postmenopausal Osteoporosis, " *Clin. Obstet. Gynecol.* 19:791-803, 1976,
123. Horsman, A., Jones, M., Francis, R., and Nordin, C., "The Effect of Estrogen Dose on Postmenopausal Bone Loss," *N. Engl. J. Med.* 309:1405-1407, *1983.*
124. Hutchinson, T. A., Polansky, S. M., and Feinstein, A. R., "Post-Menopausal Oestrogens Protect Against Fractures of Hip and Distal Radius: A CaseControl Study," *Lancet* 2:705-709, *1979.*
125. Jensen, J. S., and Tondevold, E., "Mortality After Hip Fractures)" *Orthop. Scand.* 50:161, *1979.*
126. Kanis, J. A., "Treatment of Osteoporotic Fracture," *Lancet* 7:27-33, January 1984.
127. Keene, J. S., and Anderson, C. A., "Hip Fractures in the Elderly: Discharge Predictions With a Functional Rating Scale," *J. Am. Med. Assoc. 248:564-567, 1982,*
128. Krane, S. M., "Metabolic Bone Disease," *Harrison's Principles of Internal Medicine,* 8th cd., G. W. Thorn, R. D. Adams, E. Braunwald, K. J. Isselbacher, and R. G. Petersdorf (eds.) (New York: McGraw-Hill, 1977), pp. 2028-2037.
129. Lawton, J. O ., Baker, M. R., and Dickson, R. A., "Femoral Neck Fractures—Two Populations," *Lancet* 9:70-72, July 1983.
130. Lewinnek, G. E., Kelsey, J., White, A. A., III, and Krieger, N. J., '(The Significance of a Comparative Analysis of the Epidemiology of Hip Fractures," *Clin. Orthopedics. Rel. Res.* 152:35-43, *1980.*
131. Miller, C. W., "Survival and Ambulation Following Hip Fracture," *J. Bone& Joint Surg.* 60-A:930-934, 1978.
132. Owen, R. A., Melton, L. J., III, Gallagher, J. C., and Riggs, B. L., "Hip Fractures Associated With Osteoporosis)" *Clin. Orthopedics. Rel. Res.* 150: 172-176, 1980.
133 Paganini-Hill, A., Ross, R. K., Gerkins, V. R., et al., "Menopausal Estrogen Therapy and Hip Fractures," *Ann. Intern. Med.* 95:28-31, *1981.*

134. Parfitt, A. M., "Dietary Risk Factors for Age-Related Bone Loss and Fractures," *Lancet* 2:1181-1184, November 1983.
135. Raisz, L. G., "Osteoporosis," *J. Amer. Geriat. Soc.* 30:127-138, *1982.*
136. Reeve, J., Hesp, R., Williams, D., et al., "Anabolic Effect of Low Doses of a Fragment of Human Parathyroid Hormone on the Skeleton in Postmenopausal Osteoporosis," *Lancet* 1:1035-1038, 1976.
137, Resnick, N., and Kantrowitz, F. G., "Senile Osteoporosis," *Arch. Int. Med.* in press, 1983.
138. Riggs, B. L., Wahner, H. W., Dunn, W. L., Magess, R. B., et al., "Differential Changes in Bone Mineral Density of Appendicular and Axial Skeleton With Aging," *J. Clin. Invest.* 67:328-335, *1981.*
139, Riggs, B. L., Hodgson, S. F., Hoffman, D. L., et al., "Treatment of Primary Osteoporosis With Fluoride and Calcium," *J. Am. Med. Assoc. 243:446-449, 1980.*
140, Sinaki, M., "Postmenopausal Spinal Osteoporosis Physical Therapy and Rehabilitation Principles," *Mayo Clin. Proc.* 57:699-703, 1982.
141. Smith, D. M., Khairi, M. R. A., Norton, J., and Johnston, C. C., Jr., "Age and Activity Effects on Rate of Bone Mineral Loss," *J. Clin. Invest.* 58:716-721, 1976.
142. Smith, E. L., Reddan, W., and Smith, P. E., "Physical Activity and Calcium Modalities for Bone Mineral Increase in Aged Women," *Med. Sci. Sports Exercise* 13:60-64, *1981.*
143. U.S. Department of Health and Human Services, Food and Drug Administration, "Report on Over the Counter Preparations," *Fed. Reg.* 44:16175-16178, 1979.
144. U.S. Department of Health and Human Services, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, "Arthritis, Rheumatic Diseases and Related Disorders," Special Report to Congress, 1982.
145. Office of Medical Applications of Research, National Institutes of Health, U.S. Department of Health and Human Services, *osteoporosis,* Consensus Development Conference Statement, vol. 5, No. 3, 1984.
146, Vogel, J. M., and Whittle, M. W., "Bone-Mineral Content Changes in the Skylab Astronauts," *Amer. Jour. Rheumatol.* 126:96-97, *1976.*
147, Wasnich, R. D., Benfante, R. F., Yano, K., et al., "Thiazide Effect on the Mineral Content of Bone," N. *Engl. J. Med.* 309:344, *1983.*
148. Weinstein, M. C., "Estrogen Use in Postmenopausal Women-Costs, Risks, and Benefits," N. *Engl. J. Med.* 303:308-316, *1980.*
149. Weiss, W. S., Ure, C. L., Ballard, J. H., et al., "Decreased Risk of Fractures of the Hip and Lower Forearm With Postmenopausal Use of Estrogen," N. *Engl. J. Med.* 303:1195-1198, *1980.*
150 Whedon, G. D., "Recent Advances in Management of Osteoporosis," *Phosphate and Minerals in Health and Disease, S. G.* Massry, E. Rity, and H. John (eds.) (New York: Plenum Press, 1980).

Biomedical research policy

151. Arthritis Foundation, policy statement, 1983.
152. Arthritis Foundation, policy statement, 1982.
153. Arthritis Foundation, *Annual Report, 1982.*
154. Borzilleri, T., "The 'Graying' of the Federal Budget: Income and Expenditures of the Elderly," prepared under contract for the Office of Technology Assessment, October 1983.
155. Goodwin, F., Address to Institute for Alternative Futures, April 1983.
156. Salans, L. B., Response to a Question, *Departments of Labor, Health and Human Services, Education, and Related Agencies: Appropriations for 1984, 1983.*
157. Stoto, M., Study Director, Institute of Medicine, National Academy of Sciences, December 1983.
158. Sun, M., "A New Arthritis Institute Nears Approval," *Science* 217:610-612, 1982,
159. Sun, M., "Mary Lasker's Latest Pet Project," *Science* 217:611, 1982.
160. U.S. Congress, House debate on H. R. 2350, Nov. 17, 1983.
161. U.S. Congress, Office of Technology Assessment, *Commercial Biotechnology: An International Analysis, OTA-BA-218,* January 1984.
162. U.S. Congress, Office of Technology Assessment, "Appendix B: Grants, Contracts, and Peer Review on NSF Grants)" *Technology Transfer at the National Institutes of Health—A Technical Memorandum,* OTA-TM-H-lO, March 1982,
163. U.S. Department of Health and Human Services, "Inventory of Federally Supported Research on Aging," Administrative Document, March 1982.
164. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Office of Program Planning and Evaluation and Division of Research Grants, *NIH Data Book, 1983,* NIH publication No. 83-1261, June 1983.
165, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Aging, *Toward an Independent Old Age: A National Plan for Research on Aging,* NIH publication No. 82-2453, September 1982.