Hypertension and the Department of Health and Human Services

ROBERT J. RUBIN, M.D., AND CHRISTOPHER BLADEN, M.SC.(ECON.)

SUMMARY Hypertension affects from 17% to 25% of all Americans. Because of its fundamental charge to help protect the public health, the Department of Health and Human Services (HHS) is substantially concerned with the condition. Additionally, hypertension represents a significant source of underwriting risk to which HHS is exposed in its role as health insurer of the poor and the elderly. HHS has invested hundreds of millions of dollars in hypertension research, development and testing of treatment regimens, and education of health care providers and consumers. However, much of the etiology of hypertension still eludes us. Sodium's apparent importance as a "causal" agent to the development of hypertension, and in its treatment, has waxed and waned over the past several generations; research to date has not yet finally settled the issue. Is sodium or some other cation the key? While research on this issue continues, HHS is currently faced with deciding whether and how to require inclusion of sodium content in nutrition labelling. In the debate, attention has to be given not only to the current best evidence on sodium; additional issues of consumer choice, costs, and education are also of importance. (Hypertension 4 (supp III): III-152—III-156, 1982)

KEY WORDS • hypertension • sodium • labelling • regulation

HYPERTENSION represents a disease of substantial interest to the federal government, and especially to the Department of Health and Human Services (HHS). HHS' interest is twofold: first, in its public health role, for hypertension really is the "silent killer" of the public service advertisement; and second, in its role as health insurer to the elderly through Medicare, and, in partnership with the States through Medicaid, as frequent health insurer of the poor.

Let me give you some figures that help define the problem of hypertension from the Department's perspective. While not directly comparable with one another, and in part "best guesses," what is important is that these figures are conservative, they mount very rapidly, and they present an order-of-magnitude outline of the hypertension problem.

Numbers

Based upon the criteria used to define hypertension, and the age groups considered to suffer from it, 23 to 60 million Americans are hypertensive. The publication, Nutrition and Your Health. Dietary Guidelines for Americans, jointly issued by the Departments of Agriculture and Health and Human Services, indicates that approximately 17% of all Americans have definite hypertension (160/95 mm Hg). The National Heart, Lung, and Blood Institute (NHLBI) estimates that 25% of all Americans have borderline (140/90 mm Hg) or definite hypertension.

In addition to those whose health is directly damaged by hypertension, many more individuals suffer and die from diseases and disabilities associated with hypertension: e.g., kidney failure; stroke, the third highest cause of death; and ischemic heart disease, the number one cause of death in the United States.

National Center for Health Statistics figures for ischemic heart disease death rates in 1977 among those persons 35 to 74 years old show blacks have a significantly higher death rate than whites, and males have a rate more than double that of females.

Estimates based upon the Framingham, Massachusetts, Longitudinal Study indicate that men between 45 and 64 years of age having elevated blood pressure (170 mm Hg) are at least twice as likely to experience coronary events as those with normal blood pressure (130 mm Hg).

Costs

In 1977, the most recent year for which reliable Medicare program expenditure data are available, care given for essential hypertension, the primary diagnosis (ICDA 40.1), accounted for 535,000 reimbursed inpatient days. Limiting this count to cases in which hypertension was the primary diagnosis results in very serious under-reporting of hypertension's effects, e.g.,
most hypertension-related hospitalizations for the elderly show another primary diagnosis.

Nonetheless, despite being limited by the primary diagnosis criterion, these data still show that hospitalizations for hypertension represented nearly 1% (0.8%) of total discharges; more than half of one percent (0.6%) of total hospital days of care; an average length of stay of 8.2 days; an average cost per discharge of $1,050; total hospital charges of $92 million; and reimbursement costs to the Medicare Trust Fund of $69 million.

It is important to remember that these calculations are based on 1977 data, when the average cost, inclusive of the hospitals' daily rate, was $130 per day. And, these costs cover only Medicare.

In 1979, NHLBI considered the cost of illness related to hypertension, using cost of illness methodologies developed in large part by Dorothy Rice and others at the National Center for Health Statistics. These cost of illness figures typically do not include imputed costs of pain and suffering, nor unpaid services provided by the immediate family. On the other hand, discounting to account for secondary and tertiary diagnosis is not often done either. Consequently, these estimates should be considered only in order of magnitude, and not exact calculations.

For the nation as a whole, NHLBI calculated indirect mortality costs to be approximately $736 million, direct morbidity cost to be $2.2 billion, and direct costs, inclusive of treatment, to be $5.88 billion. The sum of these illness costs related to hypertension, in 1979 dollars, was more than $8.8 billion!

An Aside

Let me remind you of the original work done on the costs of hypertension. The first well-founded, reliable data on the health risks of hypertension were developed by the Society of Actuaries. In its 1959 Build and Blood Pressure Study, the Society examined the records of nearly 4 million policy holders between 1935 and 1954. The finding, now taken for granted, was that mortality increases with increases in both systolic and diastolic blood pressure. This vast epidemiological study was undertaken to answer an applied economics question: insurers were concerned about the risk exposure associated with life policies and health care.

This has special pertinence for me as the Assistant Secretary for Planning and Evaluation. My staff consists of generalists, economists, social scientists, not members of the health professions. Much of their and my activity is devoted to similar economic issues.

Past Research

In response to the problems of public health, and public costs associated with hypertension, the federal government has undertaken a variety of activities. The most consistent and diverse effort has been in research about the causes, detection, and treatment of hypertension. Hundreds of millions of dollars have been channeled into that mode. Most of these research support resources have come from the National Heart, Lung, and Blood Institute.

In addition to demonstrating the increased risk for heart disease and stroke for persons with hypertension, research of the late 1950s and 1960s also built the foundation for major change in treatment options — including the drug revolution that introduced chlorothiazide in 1957, followed shortly by guanethidine in 1959, alpha-methyldopa in 1960, and then clonidine, and the vasodilators. The drug revolution itself was the result of prior private and public research funding.

As a result of the drug revolution, the federal government began to fund research to test the newly available hypertension drug therapies: The Veterans Administration (VA), through its Cooperative Study Group, published in 1967 and 1970 the results of its randomized, double-blind, placebo-controlled clinical trial which demonstrated the effectiveness of antihypertensive drugs in reducing morbidity and mortality in middle-aged hypertensive males.

In summary, research had demonstrated the increased risk for heart disease and stroke for persons with hypertension. And, the VA's clinical trial successfully demonstrated the utility of drug therapy to control many cases of hypertension, with consequent reduction in morbidity and mortality.

In 1972, Mary Lasker and Elliot Richardson, then Secretary of HEW, sought a mechanism for bringing the product of research to the lay and professional public. Their efforts resulted in the organization of the National High Blood Pressure Education Program. In addition to its research and other programmatic responsibilities, NHLBI was made the lead agency within the Department, to coordinate the National High Blood Pressure Education Program initiative. Legislative support for the Program's education and prevention emphasis was provided to NHLBI by Congress the same year (via PL 92–423).

In reality, the core of the National High Blood Pressure Education Program has been a coalition of some 15 federal agencies, 50 state health departments, 150 major national organizations including provider organizations, and 2000 organized community control programs. The purpose of the coalition has been to make available to health professionals, unions, industry, affected minority populations, hypertensives, and the general public the best information on: 1) the need for better identification and diagnosis of hypertension; 2) appropriate hypertension therapies, including diet management; and 3) the importance of therapy maintenance.

The thrust of the National High Blood Pressure Education Program has been to bring to health care providers and consumers the pertinent results of hypertension research in a format appropriate to their varied needs and roles in the community. Thus, when research results demonstrated the interconnection between nutrition, smoking, exercise, and hypertension, the program accepted the challenge of broadly disseminating these results.
Concurrently, in 1972 NHLBI initiated the Hypertension Detection and Followup Program\(^5\) to address questions raised by the VA study. One question, for example, was whether the findings of the VA study were generalizable to other populations. The 5-year Hypertension Detection and Followup Program followed nearly 11,000 hypertensives aged 30 to 69 years of age. Results of the study, published\(^6\) in 1979, demonstrated that:

1. Blood pressure can be substantially reduced using appropriate therapies.
2. Certain intervention patterns work significantly better than others. For instance, "stepped care," or intensive treatment in a highly organized clinic setting, was more successful than "referred care," or standard community medical services in long-term control of hypertension.
3. Even with the multidose/day requirements of available drugs, patient compliance with therapy can be brought to and maintained at a high level.
4. Mortality, even for patients with only mild hypertension, can be significantly decreased by treatment.

Monitoring the population of the Hypertension Detection and Followup study will continue into 1983, to obtain even longer term data on morbidity and mortality patterns.

Susceptibility to Information

The evidence for what was happening elsewhere while this research was going on is mixed. Untreated hypertensives in the nation fell 10% over the 1962–1974 period. In 1974, significant resistance to clinical acceptance of antihypertensive therapy still existed. Some\(^7\) claimed that treatment of hypertension in the elderly was not warranted because the dangers of hypertension were minimal. I know of no source that still maintains such a position.

In 1974, half of the hypertensive population surveyed claimed they knew, by some symptom or other, when their blood pressure was high. By 1979, one-third of hypertensives still thought that hypertension was accompanied by symptoms.\(^1\) In 1974, 75% of those respondents reporting themselves as having high blood pressure said that an antihypertensive medication had been prescribed at least once. Of the 75%, one-quarter had stopped taking the medication, and, of them, half had stopped the medication on their doctors’ order. In 1979, the only difference was that the proportion stopping without a doctor’s direction increased. In other words, the rate of therapy compliance decreased.\(^1\)

In 1974, two out of three hypertensives had not been advised by their physician to stop smoking. By 1979 the proportion of hypertensives who had been advised not to smoke increased. Unfortunately, at the same time the number of cigarettes consumed by hypertensives who smoke also increased.\(^1\)

The Stanford Heart Disease Prevention program, initiated in 1972 as an experimental intervention project in two communities with a third acting as their control, had monitored cigarette smoking, uncontrolled hypertension, and serum cholesterol levels. The health promotion intervention, using media and, for high risk individuals, direct counseling, led to a 25% reduction in the risk for heart disease while the rate actually increased in the control community.

The Stanford program and the NHLBI Hypertension Detection and Followup study have shown that increasing numbers of hypertensives can be identified, treated, and controlled. These, as well as other studies, have indicated, however, that follow-up to achieve long-term compliance is important and often costly. In examining cost/benefit of alternative resource allocation strategies for hypertension, Weinstein and Stason\(^8\) conclude:

"Despite the much greater cost of enhanced [post-treatment] follow-up for a given yield of patients . . . the treatment and enhanced follow-up strategy still results in a larger number of controlled hypertensives within a limited budget than the strategy in which a larger number of hypertensives are detected and treated only."

Thus, a major area of inquiry is: how can long-term therapy compliance be improved, and its costs reduced? Drug companies’ research may prove to hold a fundamental key: development of antihypertensive medications that require only one dose per day may significantly improve patient compliance. It is important to recognize how limited our knowledge is regarding the cause, cure, and prevention of hypertension. As NHLBI acknowledged in its September 1979 report\(^4\) to the Senate:

"The specific causes of 90 to 95 percent of hypertension remain unknown."

In quoting that statement, I am not suggesting that resources devoted to hypertension research have been wasted. Indeed, we know better how to control hypertension, despite our ignorance regarding its cause, than we do some other diseases whose etiology we better understand. Moreover, the degree of our ignorance has probably been decreased by a few percentage points since 1979. Nonetheless, the gaps in our knowledge remain vast.

The FY 1982 resource commitment planned by the Department to address these gaps of knowledge includes:

1. Approximately $82 million specifically in hypertension research at NHLBI, an increase of more than $1 million over FY 1981. We hope the increase in FY 1983 will be even greater.
2. An estimated $35 million in nutrition research at NHLBI specifically, a sizable part of which will be relevant to hypertension.
3. A total nutrition research budget for NIH of approximately $150 million, much of which will be relevant to hypertension issues.
In addition to these research components, this Administration has given substantial attention to folding many formerly categorical service programs into block grants to the States. We believe that decisions regarding the expenditure of these funds are most appropriately made at the state and local level, where specific community needs are best known.

The Prevention Block Grant will be of primary interest to this audience. Through the Prevention Block, approximately $80 million will be placed under the control of state governments and their locally elected representatives. Congress has accepted the Administration's position that maximum flexibility should be provided to states in their use of these resources; federal "strings" are virtually nonexistent. Prevention Block resources may be used by states to support a variety of hypertension-relevant activities, including detection programs. Hypertension is a major threat to health, and detection and treatment regimens can save a lot of needless suffering. Making your views, as citizens, researchers, and health professionals, known to your local and state governments can be effective in increasing their activities in hypertension.

**Sodium**

Before concluding, I want to consider the historical waxing and waning of interest in dietary sodium, to set the scene for policy decisions currently being made. The first identification of a relationship between salt and blood pressure seems to have been made in 1904. From that identification came the first recommendation for salt-free diets for hypertensives; however, not until 1920 was it established that sodium caused water retention. The Kempner rice diet of 1944 renewed and significantly reinvigorated interest in limiting sodium intake. Following development of the first generation of antihypertensive drugs, interest in sodium again flagged, except for those patients with severe renal problems.

By the late 1970s, salt restriction was again becoming popular:

"Freis in 1976, for example, contended that a decrease in dietary salt consumption to less than 2 grams per day would eliminate essential hypertension as a public health issue." (1980)

The 1979 Surgeon General's Report, *Healthy People*, represents one useful summary of this position:

"High dietary salt intake may produce high blood pressure, particularly in susceptible people. Unequivocally, studies in genetically predisposed animals show a cause-effect relationship between high salt intake and elevated blood pressure. Studies in man also suggest such a relationship. . . ."

One year later, in 1980, the position of the Department of Health and Human Services, and Agriculture, in their joint publication, *Dietary Guidelines for Americans*, was slightly less trenchant:

"The major hazard of excessive sodium is for people who have high blood pressure; not everyone is susceptible. . . . [S]odium intake is but one of the factors known to affect blood pressure. . . ."

On April 13, 1981, NHLBI Director Dr. Levy noted in testimony given to the House Committee on Science and Technology that genetic differences in the population distinguish how individuals tolerate sodium. Some strains of rats are sodium-sensitive, others sodium-resistant. While we can tell the rats apart, we have no easily discernable way to differentiate the human strains. While some sections of the scientific community are looking for "markers" for sodium susceptibility, others are considering whether, and for whom, calcium or potassium levels rather than sodium consumption might be the key. Might sodium be irrelevant, and another cation all-important?

The Surgeon General's 1979 position regarding sodium was based in substantial part on the Federation of the American Societies for Experimental Biology's review of the scientific literature. The Federation's review, submitted in final form in mid-1979, but in draft in 1978, was performed for the Food and Drug Administration as part of FDA's Generally Recognized as Safe (GRAS) review of sodium chloride. The science reviewed by the Federation strongly indicted sodium, but failed to prove its causal role in hypertension. The Federation, on the basis of its review of the literature, recommended to FDA that labelling of foods' sodium content would be appropriate.

**Current Activities**

As a result of the Federation's review and the Surgeon General's pronouncement, several things began to happen. First, the Federal Trade Commission, the Department of Agriculture, and the Department of Health and Human Services jointly proposed regulations in December 1979 that would have required all food products to be labelled for their sodium content. Second, FDA began to seriously consider whether to remove sodium from the GRAS list of food additives. Third, implementation plans for HHS' *Goals for the Nation: 1990*, placed considerable stress on the reduction of dietary sodium as a mechanism for reducing hypertension.

At this time, the Carter Administration was replaced by the Reagan Administration. The new President almost immediately decided to place a "hold" on all new regulatory activities, while a review of their costs and benefits was undertaken.

During that review, HHS has given serious consideration to the sodium issue. As I previously noted, the Department's concern regarding hypertension is real, legitimate, and substantial. Consequently, there has been significant internal debate about the ties between sodium and hypertension. I anticipate that several notices will soon be published in the *Federal Register* that will summarize the results of this debate.

I want to briefly outline some of my own views pertinent to the debate. First, as previously noted,
proof of sodium’s causal role in hypertension is absent. To remove sodium from the GRAS list would require either presentation of such proof or the details of studies appropriate to its derivation. Because it is not known what kind of studies would succeed in proving either sodium’s ultimate safety or harm, we are stymied on that front.

Second, it is my view that consumers should have the power to decide the levels of sodium they wish to consume, but that providing necessary information through which to exercise that choice should not be at a cost of limiting foods from which to choose. Therefore, information should cause neither the pricing of products off the market, nor out of consumers’ reach. The path toward these goals is narrow. One way to hold to that path may be to require manufacturers who voluntarily label their product’s nutritional content to label also for sodium content. A requirement that nutrition labels indicate sodium content can be implemented at a fairly nominal cost to the manufacturer — and thus, to the consumer. At present, producers who provide nutrition labelling do so voluntarily, for either real or perceived competitive market advantage. The same situation would exist with sodium labelling. Manufacturers of low sodium foods would hope to gain a competitive advantage by advertising them as such, via the label.

A reasonable goal is not to label every package of every product for sodium, but to have available a wide enough choice of labelled products for the consumer to exercise his sovereignty. The March 15, 1982 issue of Time featured a cover story on “Salt: A New Villain?” When Time runs such a cover story, you can be certain that it’s indicative of a growing consumer awareness. That story alone may account for a significant increase in voluntary sodium labelling of food products, as manufacturers jockey for the consumer’s food dollar.

Disease prevention and health promotion are issues of prime concern to Secretary Schweiker and to the entire Department. I earlier noted that, beyond regulations, many people in the Department accepted the Federation’s position that reduced sodium intake is desirable as a preventive measure. Thus, the report was instrumental in setting reduced consumption of sodium as one of the Goals for the Nation: 1990.

Further, numerous meetings have been held with food industry representatives, to explore whether the sodium content of food products can be reduced. The makers of Campbell’s Soups are among those with whom we have talked. Their new line of low sodium soups is one indication that voluntary labelling and competition incentives will make sodium content information available.

**Summary**

In summary, the pieces are in position for federal, state, and local governments, health providers, the private sector and researchers to work as partners toward the more effective control and elimination of hypertension as a major public health problem.

**References**

3. Effects of treatment on morbidity in hypertension, II. JAMA 213: 1143, 1970
4. National Heart, Lung, and Blood Institute: An Overview of the National High Blood Pressure Education Program, prepared for the Senate Blue Ribbon Committee for Evaluation of the National High Blood Pressure Education Program, September, 1979