Implications for Research and Policy

Economic Considerations That Influence Health Policy and Research

William R. Harlan

Cardiovascular conditions account for more medical costs than any other diagnostic category in the United States. Increasingly, economic constraints will shape policy related to health care and research. Hypertension is the most common cardiovascular condition, and despite low unit health care costs, the aggregate costs are considerable. However, the unit and aggregate costs of the complications of hypertension are fourfold greater and, in this economic perspective, aggressive approaches are warranted to prevent complications. Treatment and research strategies should be identified that could have considerable potential economic impact. Several strategies are suggested as a prospective guide to policy development. Economic considerations will be important and should be incorporated in the planning of hypertension care and research. (Hypertension 1989;13(suppl I):I-158–I-163)

In the United States, cardiovascular diseases are responsible for more medical costs than any other diagnostic category. Moreover, these costs are certain to increase because of the aging population, increasing expenditures of chronic care after success in preventing mortality, and proliferation of new but expensive technology for diagnosis and treatment. It is no surprise, therefore, that the increasing national concern with cost containment will have important implications for those involved in cardiovascular care and research. Major attention has already been directed to cost-effective practices in managing acute myocardial ischemia because of the profound cost impact of intensive care. Currently, most cost-containment efforts are directed to eliminating or constraining inpatient care and the use of expensive technology, but ambulatory care and the conduct of clinical trials research will also receive increasing scrutiny. Hypertension is managed primarily in an ambulatory care setting, but the high prevalence of hypertension and its precursor relation to target-organ morbidity and mortality magnify its economic importance. In this context, it is useful to examine economic considerations that will impact on research and treatment and to formulate a prospective agenda that anticipates the constraining economic forces. The alternative to addressing economic constraints prospectively is to sacrifice the latitude for responding. In addressing economic issues, I will sketch the cost origins of cardiovascular disease, suggest implications related to medical care and research, and then examine how clinical research may be performed more cost-effectively.

Costs of Cardiovascular Disease

The allocation of health care costs provides a useful framework for appreciating economic forces. The data discussed here have been taken from the National Medical Care Utilization Expenditure Survey, which was conducted by the National Center of Health Statistics in 1980. The survey sample comprised a nationally representative sample of the civilian noninstitutionalized US population, and national estimates of care, costs, and disability can be made. In Figure 1, the most common diagnostic categories for two age groups (45–64 years, ≥65 years) of adults are plotted by the proportion of total direct medical care costs. These categories account for about 75% of all costs for the US population. Circulatory conditions account for the greatest costs in both age groups, but the cost impact is particularly striking for those 65 years of age and older. For this age group, circulatory conditions account for more than twice the cost for the next predominant category, neoplasms.

The per capita costs for specific diagnostic conditions within the circulatory category are shown in Figure 2. For this analysis, the reported diseases have been grouped into four mutually exclusive categories: hypertension alone, hypertension and cardiovascular disease, cardiovascular disease alone, and hypertension plus complicating diseases. The complicating diseases include renal disease, diabetes, and so forth. Cerebrovascular disease is included with cardiovascular disease.
Hypertension alone is the most prevalent cardiovascular condition and is the leading reason for physician visits. The total costs for care were more than $11 billion in 1980. However, the per capita costs of care for persons with this diagnosis was no greater than the average per capita cost of care for all US adults (bar at the top of Figure 2). The distribution of costs among hospital services, physician fees, and medications differed between the two groups, with medication costs being higher for those with hypertension (shaded areas within the bars). The relatively low per capita costs for persons with hypertension alone reflects the primary reliance on diuretic agents for treatment at the time the survey was performed (1980) and also reflects the fact that office visits for hypertension averaged 2 visits/yr.

The mean attributable cost for hypertension was $125. On the other hand, whenever hypertension was associated with cardiovascular disease or with complicating diseases, the per capita costs were fourfold greater than for hypertension alone. The costs for persons with hypertension complicated by comorbid conditions (diabetes or renal disease) approximates the costs for persons with arteriosclerotic, cardiovascular, or cerebrovascular disease. The higher costs in the latter categories result primarily from hospitalization, with its attendant high costs and from more frequent ambulatory visits. To complete the overview of costs, it should also be noted that there were no significant age, race, or gender differences in expenditures for care, although women tended to have greater expenditures for hypertension alone, and men had cardiovascular surgery more frequently. In terms of disability and work loss, persons reporting hypertension alone had slightly but significantly higher functional disability scores (2.3 vs. 1.7) than the adult US population and also had slightly more work-loss days. More importantly, disability measures were two- to fourfold greater when hypertension was complicated by target-organ damage. Thus, the personal and social costs of illness follow the same relative pattern as the costs of illness.

**Therapeutic Strategies With Economic Impact**

These cost allocations lead to some general observations and suggest some economic strategies that are outlined in Tables 1 and 2. The aggregate costs for treating hypertension in the total population are great, but the per capita costs are relatively low. However, the advent of target-organ damage or of complicating disease carries a major economic as well as health impact. Therefore, considerable economic benefit derives from focusing on the prevention of damage of complications and on identifying ambulatory rather than hospital approaches to managing complicating conditions. Several therapeutic strategies are outlined in Table 1. Treatment of hypertension has proven valuable in averting stroke, but the value of lowering blood pressure in averting ischemic heart disease is less clear. Therefore, the therapeutic approach should be broadened to include...
TABLE 1. Therapeutic Strategies With Potential Economic Impact

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<thead>
<tr>
<th>Strategy</th>
<th>Economic benefit</th>
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<tbody>
<tr>
<td>Broaden intervention approach to include other cardiovascular risk factors for complications of hypertension (e.g., cigarette smoking, weight, and hyperlipidemia)</td>
<td>Forestall or avert major medical and disability costs associated with ischemic heart disease</td>
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<tr>
<td>Broaden concept of hypertension as a risk factor to include treatment of hypertension to forestall morbidity of noncardiovascular conditions (e.g., diabetic microangiopathy, renal disease, and congestive heart failure)</td>
<td>Forestall or decrease disability costs and medical costs associated with target-organ failure</td>
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<td>Cost-effective selection of antihypertensive therapy and better matching of treatment to individual patient profiles (e.g., using age, race, gender, and compliance characteristics)</td>
<td>Find the most cost-effective therapeutic approach for patient groups and improve compliance of providers and patients with least-cost drugs that assure long-term management</td>
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<td>Appropriate selection of persons needing or not needing antihypertensive treatment</td>
<td>Decrease costs associated with inappropriate treatment</td>
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<tr>
<td>Primary prevention of high blood pressure and proving and improving nonpharmacological approaches, especially in the elderly</td>
<td>Decrease the prevalence of hypertension, the attendant costs of care, and the disability from treatment</td>
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<td>Focus on hygienic approaches that may have several beneficial effects (e.g., weight reduction and reduced dietary fat)</td>
<td>Greater economic efficiency of treatment and broadened potential to prevent major cardiovascular and noncardiovascular problems and costs</td>
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other risk interventions that will impact on the development of heart disease. For example, interventions on cigarette smoking, hyperlipidemia, and obesity should increase the economic effectiveness of hypertension management by preventing the morbidity that complicates hypertension and that thereby minimizes associated treatment costs. This scheme does not depreciate the importance of treating elevated blood pressure; rather, it places the treatment of the individual in a context of the best and ultimately most economic care. Lowering systolic and diastolic blood pressures remains the most important manageable risk for stroke, but a broader approach is needed for other complications.

Hypertension and its effective management can have important effects on conditions other than cardiovascular disease. For example, hypertension is a manageable risk factor for microvascular disease in diabetes mellitus and probably has considerable potential for delaying or ameliorating the retinopathy and nephropathy that are major contributors to the morbidity and costs of diabetes. A focus on early identification of elevated pressure and aggressive long-term therapy could have important economic and health benefits through avoidance of blindness and end-stage renal disease. Currently, diabetes is the main cause of these conditions in the United States, and an indication of the cost can be gained from Figure 2, which shows that "hypertension plus comorbidities" (primarily diabetes and renal disease) have annual per capita medical costs four times those of hypertension alone. Additionally, the indirect and social costs of these complications are important. Disability, work loss, and economic dependency are common when blindness and end-stage renal failure develop.

TABLE 2. Research Strategies With Potential Economic Impact

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<th>Strategy</th>
<th>Economic benefit</th>
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<tr>
<td>Include estimates of direct medical costs and measures of morbidity (work loss, bed disability, and inability to work) as study variables</td>
<td>Acquire data to estimate cost-effectiveness and efficiency of alternate approaches</td>
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<tr>
<td>Increased use of nonfatal end points in clinical trials</td>
<td>Cost savings from decreased sample size and duration of trial</td>
</tr>
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<td>Large trials with simple protocols and end points</td>
<td>Cost savings from simple and fatal clinical observations and no expensive technology</td>
</tr>
<tr>
<td>Increased use of available cohorts to address new issues related to epidemiology or intervention</td>
<td>Cost efficiency because a major cost of large studies is cohort recruitment and retention</td>
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<tr>
<td>Improved translation of clinical trial findings into medical care practice and increased public acceptance</td>
<td>Broader impact on mortality, morbidity, and medical costs through greater and more rapid adoption of effective approaches by health professionals and public</td>
</tr>
<tr>
<td>Collaborative design and funding of large clinical trials by public and private sectors</td>
<td>Cost sharing of expensive but important therapeutic trials</td>
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The large number of persons receiving antihypertensive agents and the long duration of therapy provide a large multiplier that increases even relatively low unit costs when treatment duration is long and mortality is prevented. Therefore, appreciable savings can result from efficient use of therapy. Introduction of new agents has broadened the physician's armamentarium and increased the cost of medications.\(^5\) Low-cost treatment strategies must be balanced with the selection of agents that are most effective for age-race-gender groups to maximize effectiveness at minimal doses with the smallest number of agents while maintaining long-term compliance. Currently, most drug trials do not address the issues of costs, nor do the usual drug trials include enough demographic diversity to assess appropriateness of therapy for specific groups. However, there is considerable economic importance in finding the best and least expensive match of drug to patient. The current cost for hypertensive care is estimated to be more than $8 billion and climbing rapidly as expensive new agents are introduced.\(^5\)

In the context of cost-effective therapeutic selection, Stason\(^6\) has highlighted the uncertainty of the risk–benefit ratio in the pharmacological therapy of patients with "borderline" (86–90 mm Hg) or "mild" (90–94 mm Hg) high blood pressure. Part of the problem relates to a lack of information about the medium-term (weeks to months) and long-term (months to years) variability of blood pressure. Numerous studies of newly treated hypertensive patients or of long-term pharmacologically treated hypertensive persons indicate that about 15% will attain normal blood pressures without treatment after a year or more of observation and will not require further treatment.\(^6\) Others will have progressive increases in blood pressure and will need further treatment. Currently, practitioners tend to treat all patients with elevated blood pressures after a brief period of observation. Thus, many persons will be treated inappropriately. The potential number of patients is great because the borderline and mild portions of the blood pressure distribution contain large numbers of persons. Improving patient selection for initiation of long-term therapy could have considerable economic savings nationally, and such savings would increase cumulatively each year as unnecessary treatment is not initiated or not continued. The problem is partially due to our imperfect knowledge about the variability of blood pressure over long periods and partially due to our uncertainty about whether nonpharmacological therapy can be successful in maintaining a lower pressure or in attaining adequate compliance.

Numerous important questions with economic import remain to be answered about nonpharmacological therapy. Even a cursory examination of blood pressure distribution at older ages makes it clear that about one half the aging population will have blood pressures requiring close observation or treatment because they exceed the current threshold for treatment. As the number of older Americans increases, the economic burden of pharmacological treatment will increase progressively and markedly during the next several decades. Primary prevention of blood pressure elevation with aging and the development of effective nonpharmacological approaches to high blood pressure in older persons could have major cost implications. The high prevalence of hypertension in this age group provides a multiplicative effect, so that even small individual savings in treatment can have great potential payoffs. The economic value of research investment to address these issues is also clear.

Investigating nonpharmacological approaches to the management of high blood pressure should focus on interventions that have the broadest potential health and economic benefits. For example, weight reduction is not only effective in lowering blood pressure but also has other salutary effects like lowering plasma lipid levels, improving glucose tolerance, and lessening the risk of coronary heart disease. Successful intervention on this single factor could convey multiple health benefits efficiently and lower total health costs. Cessation and maintenance of cigarette smoking and reduction of alcohol intake are other examples of health behavioral interventions that can affect more than one aspect of health and can carry multiple potential economic benefits. However, the maintenance of these behaviors over long periods is difficult and may be costly.

The strategies in Table 1 have important potential to improve health and to decrease direct costs for care. However, there are several caveats: these approaches would be implemented primarily in ambulatory care settings; the potential beneficiaries are numerous; and, if mortality is forestalled, the numbers would increase cumulatively. Therefore, the duration of treatment, whether pharmacological or nonpharmacological, would be long, and the total costs would be considerable and greater than are present costs, although presumably, such costs would not be as great as the hospital and mortality costs that would be averted. However, without data on the effectiveness and costs, it is not possible to compare the cost-effectiveness of these strategies with current approaches. Although cost containment is an attractive goal of these strategies, it is possible that cost shifting from hospital to ambulatory care settings could occur without net cost savings. The national data suggest considerable financial benefit from these interventions when compared with hospital and technology costs associated with target-organ damage. However, actual analysis has not been performed, and in many cases, the data are insufficient.

Assumptions about effectiveness and cost of alternate cost-effective approaches are based on acceptance of such alternatives by health providers and the public and translation into practice behavior. This scheme requires gaining the interest and commitment of physicians who remain the final arbiter.
of patient management. To gain this commitment to change requires development of scientific evidence about the value of the therapy. Financial constraints or disincentives are probably less successful in constructively changing physicians' practice behaviors. A preferable approach is demonstration of medically effective interventions through clinical trials. Perhaps the best example is the effect of two large hypertension therapy trials, the VA Collaborative Trial in Hypertension and the Hypertension Detection and Follow-up Program. The recommendations from these trials included specific drug regimens, were therefore widely accepted by the medical community and public, and were rapidly incorporated into practice. The result has been an expansion of hypertension treatment, which has become the most common reason for visits to physicians and has been financially rewarding as well. Therefore, it is important to test these and other promising strategies in a clinical setting to determine effectiveness, cost, and relative efficiency. Testing in a clinical setting will provide scientific support and practice-oriented guidelines for incorporation into practice behavior.

**Improving Efficiency and Economic Impact in Clinical Trials**

Putting cost-effective treatment strategies into practice should have a rational linkage to the design and conduct of research. In part, large clinical trials are expensive because they test treatment effectiveness in circumstances that mimic practice settings and thus, provide information directly relevant to and adoptable by practitioners. This study design contributes to their cost but increases their utility. Another source of high costs is the complexity of many trial protocols and the demand for expensive technologic measurements. However, the increasing costs of large clinical trials threaten the ability to develop and sustain new trials. Economies in clinical trials should be sought, and an economic perspective can be used in trial design and analysis. Some proposed economic considerations in the planning and conduct of clinical trials are given in Table 2.

Generally, clinical trials focus on proof of effectiveness and are not designed to collect financial data. However, financial data have several uses, including use as a surrogate measure for the burden of morbidity in terms of treatment cost, work loss, disability and lost productivity, and diminished functional capacity. These assessments comprise a part of the assessment of quality of life. Additionally, estimates of cost could form the basis for cost-effectiveness or cost-efficiency analysis and could be used to influence selection of the most cost-effective strategy. However, the research costs must be identified and removed from consideration. The process for separating research and treatment costs (financial and human) should be set up prospectively and become a part of ongoing data collection. Cost data could also be used as summative measures that would allow comparisons of alternate approaches to therapy. Although it is possible to estimate treatment costs and disability estimates retrospectively, the estimates are neither as accurate nor as complete as prospectively collected data.

In the design of large clinical trials, there are often two competing strategies: a large sample trial with a simple protocol and fatal end points, and a trial with smaller sample size with a more complex protocol and nonfatal end points. Improved cost efficiencies in the cost of conducting clinical trials may be realized by greater use of nonfatal end points. As life expectancy increases and conventional therapy becomes more successful, trials of new therapies will require successively larger sample sizes and longer follow-up intervals to disclose significant differences in mortality. Therefore, consideration should be given to the use of nonfatal events as primary end points. For example, intervention trials in hypertension require increasingly larger sample sizes when mortality is the end point. The use of more frequent end points like left ventricular mass or arteriosclerotic lesions and events may decrease the required sample size. However, the added cost of these measurements may increase overall costs and not make this the most cost-effective strategy. Moreover, the nonfatal end point must be "important," that is, clearly linked to the disease process and related to the risk of mortality. These competing strategies should be subjected to rigorous cost-effectiveness analysis. The results of this analysis may help in design selection although the scientific question remains paramount in determining approach.

Clinical trials characteristically have a defined stopping point when proof of effectiveness has been confirmed, but termination of observations in the trial cohort may be an extravagance rather than a savings. Consideration should be given to innovative use and reuse of cohorts that have been developed after the initial trial or study has ended. In large clinical trials, the recruitment and retention of cohorts may comprise as much as one fourth or one third of the total cost of the trial. Considerable savings could be realized if these costs could be foregone in a second research effort by using the same cohort. Numerous examples of NHLBI studies illustrate the value of continued follow-up. Surveillance of the Multiple Risk Factor Intervention Trial, Lipid Research Clinics-Coronary Primary Prevention Trial, Hypertension Detection and Follow-up Program, and Coronary Drug Trial after formal conclusion of the trial have yielded valuable, often unique, data at a fraction of the cost of developing a new cohort. Using the same or supplemented cohorts for successive trials of therapies for the same condition also merits attention.

The final outcome of large clinical trials is the adoption of effective therapy or behavior by health professionals and the public. The translation of trial results into practice behaviors deserves greater attention than it has received. It is the widespread use of
this information that will impact on mortality, morbidity, and medical costs, so attention to translating trial findings into practice has positive economic potential.

Finally, funding large clinical trials can become a collaborative venture between federal agencies and the private sector, primarily pharmaceutical firms. The private sector funds smaller-scale drug trials but also has a potentially important financial stake in the extension to large trials that can broaden the market for these drugs. Obviously, this collaboration needs to be approached carefully and monitored continuously, so that the scientific and public interests are not subordinated to the promotion of a product. In general, this would mean that design, recruitment, monitoring, and analysis be under the exclusive control of the governmental sector. The potential cost saving is great and sufficient to warrant the effort.

Summary

Economic constraints have become increasingly important in shaping policy and research in medicine. Although hypertension is treated primarily in an ambulatory care setting at relatively low unit cost, the high prevalence of this disease in the population and its long duration of increasingly costly management make aggregate costs an important economic consideration. Taking a proactive constructive approach to economic realities will allow practitioners and researchers to find the best accommodations to increasing economic constraints.

References


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