Good afternoon. I want to thank the organizers of this meeting for giving me this opportunity. I plan to review a small sampling of the many cooperative clinical trials that have been performed in the VA since World War II. The pioneering study, the first we will discuss, was collaborative between the VA and the medical branches of the armed services. The studies I have chosen to talk about today are some of those that were particularly directed to the VA’s patient care population.

We will start with a rather full discussion of the VA-armed services studies of the treatment of tuberculosis. Even though the first of these had some technical flaws, it set the stage for a whole series of better-designed studies that came after it. Then we will discuss the VA studies of the treatment of psychiatric diseases, studies that were modeled after the tuberculosis studies. Next we will touch briefly on the VA’s landmark study proving the importance of control of severe hypertension. Finally, I hope to share with you a bit about a new type of VA cooperative study, studies directed to maximizing the quality and cost effectiveness of medical care delivery.

The Tuberculosis Studies

At the end of World War II, President Truman asked General Omar Bradley, the “GI’s general,” to take on the daunting task of upgrading VA services to meet the greatly increased demand. Bradley, in turn, enlisted General Paul Hawley to head his medical department.

One of the problems that faced Hawley from the start was the vast number of veterans who had tuberculosis. At that time there were some 12,000 veterans hospitalized in VA hospitals for tuberculosis, and the number was growing steadily. Hawley persuaded Dr. John Barnwell, a professor at the University of Michigan, to come to Washington to head the VA fight against tuberculosis.

In 1946, tuberculosis was treated by rest therapy. Patients were confined to special hospitals or to special units in general hospitals, and complete bed rest was the treatment of choice. This would often be supplemented by procedures, such as pneumothorax, to “rest” the diseased area. Typically, tuberculosis patients were hospitalized for a year or more. Because of the danger of infection, they were isolated from their normal environment. Even if their disease was eventually arrested, the personal and social impact of the disease was horrible. There was the specter of death, sometimes whole families wiped out by tuberculosis.

Streptomycin had been discovered in 1944, but very little of it was available by 1946. Its distribution to civilians was controlled by a central governmental agency, which, in early 1946, was allotting a total of 2 kg per month to the entire VA hospital system. General Hawley appointed a “Streptomycin Committee,” chaired by Dr. Barnwell, to distribute this scant supply to VA hospitals. At first, all of the streptomycin was used for nontuberculosis conditions such as tularemia, but manufacturers successfully increased their production, so that by April 1946, there was some left over to treat tuberculosis.

But no one really knew whether clinical tuberculosis would be helped by streptomycin treatment. Streptomycin was known to inhibit the tubercle bacillus in culture. However, tuberculosis is a very complex disease. The bacillus grows slowly, and it is often found in non-vascular sites, so that the antibiotic might not reach the infective agent. It invades many parts of the body and manifests itself in many ways. Patients frequently improved without specific treatment, and permanent arrests of the disease occurred, although true “cures” were thought never to happen. Whether streptomycin would alter the course of this complex clinical picture was doubtful. Barnwell, and his colleague Dr. Arthur Walker, set out to try to answer that question.

They chose seven VA hospitals and two military hospitals (Table I). Selection was based on the hospitals having tuberculosis experts who were interested in cooperating in a study to see what effect streptomycin had on moderately advanced tuberculous disease. These hospitals were given an allotment of the precious streptomycin adequate to treat those patients who qualified for the protocol. Barnwell and Walker worked together with representatives of the Army and the Navy to establish and follow a common protocol.

There was considerable discussion and worry about the use of controls. The statisticians felt that concurrent untreated controls were essential. However, there were ethical concerns about withholding the drug once clinicians became convinced that it worked, even though that had not been proven. So, less satisfactory methods were used:

(1) All patients were observed for at least 2 months before treatment, and their conditions were documented to be stable or worsening. No changes in other treatment parameters were allowed. The patients continued on what-
TABLE I
THE FIRST NINE HOSPITALS IN THE TUBERCULOSIS TRIALS

<table>
<thead>
<tr>
<th>VA</th>
<th>Hines, Illinois</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronx, New York</td>
<td></td>
</tr>
<tr>
<td>Livermore, California</td>
<td></td>
</tr>
<tr>
<td>Rutland Heights, New Jersey</td>
<td></td>
</tr>
<tr>
<td>San Fernando, California</td>
<td></td>
</tr>
<tr>
<td>Sunmount, New York</td>
<td></td>
</tr>
<tr>
<td>Army</td>
<td></td>
</tr>
<tr>
<td>Fitzsimons General</td>
<td></td>
</tr>
<tr>
<td>Navy</td>
<td></td>
</tr>
<tr>
<td>Sampson, New York</td>
<td></td>
</tr>
</tbody>
</table>

ever degree of bed rest they were receiving. Their chest X-rays were then compared by experts who were blinded to when the film was taken.

(2) A group of similar patients from a previous year was selected. Their serial X-rays were examined together with those of the streptomycin-treated patients, again by experts who did not know whether this was a treated patient or not.

Since the first question to be answered was whether streptomycin had any effect, Barnwell and Walker decided for the first study to use a dosage schedule that could be expected to maintain blood streptomycin levels for 24 hours. Based on previous experience with penicillin, patients in the first study received a total of 1.8 g. 0.3 g every 4 hours. As the authors state in their early paper describing the study, "These decisions concerning dosage and duration of treatment were admittedly arbitrary for there were no data on which to base an informed judgment but, in order that the study have any statistical significance, it was considered essential that this first group of patients be treated in accordance with a single regimen."

In December 1946, the participants in the streptomycin trial met in Chicago for the first Streptomycin Conference. At this meeting, everybody brought the records and chest films from the participating hospitals, and they were examined by a group of experts who had no knowledge of whether these were treated patients or not.

TABLE II
CLINICAL OBSERVATIONS DURING STREPTOMYCIN TREATMENT

<table>
<thead>
<tr>
<th>Percent</th>
<th>Weight increase</th>
<th>Appetite increase</th>
<th>Cough decrease</th>
<th>Sputum decrease</th>
<th>Temperature decrease (of 160 febrile)</th>
</tr>
</thead>
<tbody>
<tr>
<td>84.3</td>
<td>85.2</td>
<td>79.8</td>
<td>79.8</td>
<td>73.1</td>
<td></td>
</tr>
</tbody>
</table>

There also were adverse effects balancing the improvements (Table III). The most frequent and disturbing was vestibular damage, and this persisted after treatment, although patients generally adapted to it.

In addition to readings of the patients' chest films at each participating hospital and by the assembled participants at group meetings, a more objective assessment was provided by readings done by a jury of seven tuberculosis experts. They were chosen by the President of the American Trudeau Society, the premier society for the study of tuberculosis. These seven men met together for 6 consecutive days, reading and comparing films. They were presented with blinded film sets from patients with and without streptomycin treatment, each set containing three films. The first two of these were taken at a 2-month interval, the third after a 4-month interval. In the case of the treated patients, the first 2-month interval was the pretreatment observation period. The second, 4-month, interval was the period of streptomycin treatment in the treated group. They evaluated interval changes during the 2 months just prior to streptomycin treatment and during the 4 months of streptomycin in 222 lesions in 131 patients. The corresponding interval changes were judged in 142 lesions in 88 historical control patients.

The results of their review were dramatic (Table IV). First of all, it appears as if the historical controls chosen from the participating hospitals were, on average, less ill than the treated patients. Fewer of their exudative lesions worsened over a 2-month period than among the study patients during the 2-month pretreatment period. Among the untreated patients, the natural history of the illness was predictably stable, with about as many lesions worsening and improving over the next 4 months as during the first 2 months. On the other hand, in the treated patients, exudative lesions were much more likely to improve during the 4 months of streptomycin than during the

TABLE III
ADVERSE EFFECTS OF STREPTOMYCIN TREATMENT

<table>
<thead>
<tr>
<th>Percent of Patients</th>
<th>Vomiting and nausea</th>
<th>Eosinophilia</th>
<th>Dermatitis</th>
<th>Urinary casts</th>
<th>Vertigo</th>
<th>Diminished caloric test</th>
<th>Hearing loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0</td>
<td>69.5</td>
<td>19.8</td>
<td>67.3</td>
<td>91.5</td>
<td>77.1</td>
<td>0.5</td>
<td></td>
</tr>
</tbody>
</table>
April 1948, they began testing p-aminosalicylic acid in combination with streptomycin. However, just to be sure, I asked a member of the Stanford Biostatistics group to look at these data. By all of his tests, the chance of the null hypothesis is zero.

A more extensive analysis included all of the biweekly films of all 223 patients (Table V). In this study, physicians at the various participating hospitals read the films. Again, there was a dramatic improvement during the period of streptomycin treatment.

However, 8% of the patients (Table V) began to get worse while still on streptomycin, after an initial improvement. This pattern would not have shown up on the expert panel readings, as that panel didn't review any films taken in the middle of the treatment course. The pattern of improvement followed by worsening suggested that resistance of the organisms to streptomycin was developing. Bacteriological analysis (Table VI) confirmed that nearly two-thirds of the patients' organisms had become moderately or markedly resistant to streptomycin by the end of 4 months of treatment at 1.8 g/day. By May 1947, there were 21 active participating hospitals. Nearly 400 cases had been treated with 1.8 or 2 g of streptomycin per day. The group decided to try different treatment schedules in a search for one that would have a therapeutic effect but less toxicity and fewer problems with drug resistance. They compared the 2 g/day dose they had been using with 1 g/day and found the results to be comparable, but with less toxicity. In April 1948, they began testing p-aminosalicylic acid in combination with streptomycin, using the streptomycin-alone regimen for the control series. As soon as the streptomycin-p-aminosalicylic acid regimen was shown to be superior, it was taken as the control against which new treatments were tested. They went on to study many different treatment schedules and the best treatment for the variants of tuberculosis.

The name of the conferences, now annual, changed to reflect that streptomycin was no longer the only drug to treat tuberculosis. The group had a subgroup that pilot-tested newly reported drugs. Within 3 weeks of the first reports about the potential of isoniazid, in January 1952, 12 hospitals were studying it in comparison to the standard streptomycin-p-aminosalicylic acid regimen. In parallel with their efforts, the VA tuberculosis population began to decline (Fig. 1).

Soon the group was evaluating the need to keep patients on bed rest, introducing the revolutionary concept of ambulatory care of tuberculosis. They continued to try to improve the drug treatment of tuberculosis into the 1970s, when their final study, on rifampin, was reported. Each new variant was tested against the current "gold standard," the regimen that had given the best results to date.

In addition to studying the chemotherapy of pulmonary tuberculosis, this group also studied the treatment of many other forms of the disease. As time went on, their work led to advances in techniques that had impacts on a much wider group of patients, and the name of their conference was changed once again. A major outcome of these efforts was improvement in pulmonary function measurements.

Finally, after feeling their way along in the early days, negotiating with the statisticians, and coping with the realities of human behavior, in 1960 the group established their concept of the essential principles of a clinical trial:

1. The design of the trial is of critical importance.
2. Ethical considerations are essential, particularly in the selection of regimens to be investigated.
3. The "experimental" regimen to be studied should be compared with a "control" series, usually the best-known available form of therapy.
were sophisticated in research methods. Yet it was necessary to get everyone these were the ancestors of tests in common use today.

Setting up this study was a major organizational effort. Quantitative psychological tests were few at the time, and not well suited to the task of measuring the clinical course of schizophrenia. A group of tests had to be developed for this study. Some of these were the ancestors of tests in common use today.

The Behavioral Science Studies

We now turn more briefly to another series of cooperative clinical trials that also were carried out over many years in VA hospitals, these on the treatment of the major psychoses.

In 1953, Leo Hollister, M.D., who was Chief of Medicine at the Palo Alto VA Hospital, then a psychiatric hospital, noted that when he gave reserpine to treat hypertension in patients who were also schizophrenic, the patients' schizophrenic symptoms seemed to improve. He learned that others had made the same observation and decided to confirm his impressions with a double-blind study. He persuaded his psychiatrist colleagues to refer acutely ill schizophrenic patients to him. The patients were treated with reserpine or placebo, following a random-assignment design, and then sent back to the referring psychiatrist for evaluation. The result was a dramatic improvement, which Hollister reported in 1954.

By 1956, Thorazine (chlorpromazine) was being used to treat acutely ill schizophrenic patients, but no one knew whether it did more than simply sedate the patient. Hollister and others persuaded VA headquarters to call together a group of leading behavioral science researchers to design a study aimed at answering this question. They sought guidance from Dr. Barnwell and the tuberculosis studies group, which by now had 10 years of experience. The first of these studies involved 692 male patients from 37 VA hospitals. It compared chlorpromazine, promazine, phenobarbital, and placebo in a double-blind protocol. Setting up this study was a major organizational effort. Quantitative psychological tests were few at the time, and not well suited to the task of measuring the clinical course of schizophrenia. A group of tests had to be developed for this study. Some of these were the ancestors of tests in common use today.

From the beginning, conferences of participants were central to these studies. Few of the physicians in psychiatric hospitals were sophisticated in research methods. Yet it was necessary to get everyone participating in the study to agree about the protocol and the way in which the patients' clinical course was to be measured. The participants needed to learn about how to apply the protocol, and they needed motivation to carry out the extra labor. There was no money to hire assistants, as is done today—the study depended on volunteer labor as well as consenting patients. Despite the shortage of travel funds, which plagued them as it plagues us today, the Central Office staff managed to get everyone's name and what they said included. The first study carried out by this group clearly answered the outcome question posed. Chlorpromazine (and promazine less so) led to improvement in schizophrenia (Fig. 2). Phenobarbital was no better than placebo, clearly showing that the antipsychotic effects of chlorpromazine were not from sedation alone.

The landmark chlorpromazine study was followed by a series of studies that evaluated all of the important antipsychotic drugs available at that time. The group studied effects of different dosage schedules and of "drug holidays" or even complete discontinuation of treatment. The group studied psychotherapy and behavioral therapy as adjuncts to or substitutes for neuroleptic medication. It was largely through their efforts that drug treatment of schizophrenia has been based on a solid foundation of carefully acquired, objective data.

The Hypertension Studies

The VA has carried out a long series of cooperative studies of hypertension, masterminded until recently by Dr. Edward Fries of the Washington, DC, VA Medical Center. The study we will discuss here was designed to answer the basic therapeutic question: Does control of essential hypertension affect patient outcome?

To many of you in the audience who are younger, this may seem a silly question. You would never consider leaving a patient with significant, documented hypertension untreated. Yet, during my clinical training in the late 1950s, many of my attendings taught that hypertension was just a symptom and that changing it would not change the patient's clinical course. The goal was to find the cause of the patient's hypertension, a search that was usually fruitless. Reducing blood pressure nonspecifically with antihypertensive drugs was scornfully referred to by some as "treating the manometer." As late as 1966, a chapter in search was a source of pride for their hospitals, many of which had no other research. The conferences were held in VA hospitals, but the National Institute of Mental Health funded the travel for some of them. Proceedings were published, with everyone's name and what they said included.

The first study carried out by this group clearly answered the outcome question posed. Chlorpromazine (and promazine less so) led to improvement in schizophrenia (Fig. 2). Phenobarbital was no better than placebo, clearly showing that the antipsychotic effects of chlorpromazine were not from sedation alone.

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![Fig. 2. Life-table analysis of all morbid events in patients with mild to moderate hypertension (diastolic blood pressure 90 to 114).](https://example.com/fig2.png)
a book by Ingelfinger, Relman, and Finland vigorously defended the position that the drug treatment of essential hypertension was of no benefit.

Dr. Fries learned about cooperative studies and biostatistics from the VA tuberculosis trials. In the late 1950s, he assembled a team of collaborators from various VA hospitals to do a series of comparative studies of various drugs for treating essential hypertension. After a few years of rather unfocused effort, in 1964 the group began a completely new study designed to answer only one question: whether treatment reduces morbidity and mortality in mild to severe hypertension, excluding malignant hypertension. They were fortunate to have an exacting and unflappable biostatistician working with them, and they designed a very tight protocol.

They narrowed their study population to remove from it patients with labile hypertension and those who were noncompliant, both problems that have plagued other studies of hypertension treatment. To be included in the study, the patient’s hypertension had to persist through 1 week of in-hospital observation followed by a 3 week period of outpatient observation on placebo medication. Compliance was monitored by pill counts and by checking urine fluorescence to detect riboflavin, which had been added to the pills. Only patients who were compliant and who were still hypertensive after this exacting pre-protocol study were randomized.

The study itself was a double-blind, placebo-controlled study of the style we have become accustomed to in more recent years. The active treatment was the most effective combination available at the time. It had come out of the group’s earlier studies, and was the combination of hydrochlorothiazide, hydralazine, and reserpine. The randomization of the patients was stratified according to their diastolic blood pressure on entry to the study.

Starting about a year after randomization, the investigators began to notice a disturbing finding. In the stratum of patients who had entered the study with severe hypertension, those with diastolic blood pressures between 115 and 129 mm Hg, one of the groups began to show a disproportionate number of morbid events. The code was broken and the results were striking (Table VII). Twenty-seven of the 70 patients in the placebo group had serious adverse events, compared with only 1 patient out of 73 in the treated group. It did not take a statistician to tell that the higher the blood pressure on entry to the study, the greater the benefit of treatment. In the 90 to 104 group, the incidence ratio for adverse events was only 1.5 to 1, whereas in the group with diastolic blood pressures of 105 to 114, the incidence ratio was 4 to 1.

This study established the value of controlling moderate to severe hypertension, and the results have stood the test of time and of other studies in a broader population. However, at the time the study came out in JAMA in 1970, it caused little interest in the media or in the medical profession in general. This changed after Fries received the Lasker Award in 1971. Mary Lasker went to see Elliott Richardson, then Secretary of Health, Education, and Welfare, armed with reprints from the VA study. The result was a highly successful media campaign that made hypertension a household word.

### Health Care Delivery Studies

All of us in public medicine have long realized that our obligations include not only delivering the best health care to our patients but also doing so in the most cost-effective manner possible. Since we work within a defined budget, any waste will result in less benefits for our patients.

The VA has had a program of health services research since the late 1950s, and has had a separate Health Services Re-

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**TABLE VII**

| Morbid Events During 1.5 Years in Patients with Severe Hypertension (Patients with Entry Diastolic Blood Pressures 115-129 mm Hg) |
|---|---|
| **Control** (n = 70) | **Treated** (n = 73) |
| Accelerated hypertension | 10 | 0 |
| Stroke | 4 | 1 |
| Congestive heart failure | 4 | 0 |
| Renal damage | 3 | 0 |
| Myocardial infarction | 3 | 0 |
| Aortic rupture | 3 | 0 |
| Total adverse events | 27 (39%) | 1 (14%) |
| Fatalities | 4 (6%) | 0 (0%) |

**TABLE VIII**

| Fatal Outcomes, Mild or Moderate Hypertension, Average Follow-Up 3.3 Years (Diastolic Blood Pressure 90-114 mm Hg) |
|---|---|
| **Control** (n = 190) | **Treated** (n = 190) |
| Fatal stroke | 7 | 1 |
| Sudden death | 8 | 4 |
| Fatal myocardial infarction | 3 | 2 |
| Fatal aneurysm | 1 | 1 |
| Total cardiovascular deaths | 19 | 8 |
| Accelerated hypertension | 20 | 0 |

(dropped from study)
search Service since 1973. This Service has its own budget and a formal peer review process for research projects.

In 1990, the Health Services Research and Development Service announced its own program in Cooperative Studies. Each of these studies goes through a formal planning and review process and there is careful centralized supervision of its progress. Before planning by a biostatistical center can begin, the idea and proposed approach are peer reviewed. If the study passes that hurdle, the proponents work with a biostatistical center to develop a protocol, which then has an exacting peer review. If approved—and funded—the project is supervised jointly by the principal investigator and the collaborating biostatistician. Annual human studies review is at the biostatistical center and also at each participating medical center. Finally, the unblinded data are reviewed by a disinterested Data Monitoring Board, which may recommend changes in the study or even stopping it.

Ten of these Cooperative Studies in Health Services have been initiated, of which I would like to mention three that are specifically oriented to assessment of patient outcomes. All three concern outcomes of variants on the usual care currently delivered as follow-up to hospitalization of seriously ill VA patients.

Team-Managed Hospital-Based Home Care

The first of these originated from Hines VA Medical Center in Chicago. A research team there, which includes the physician medical center director, Dr. Joan Cummins, a social worker, Dr. Susan Hughes, and a social psychologist, Dr. Frances Weaver, developed a model for hospital-based home care in which care was delivered by a multidisciplinary team headed by a physician.

In a local study at Hines, they had shown a benefit of this model compared with the usual hospital-based home care model in treating severely disabled or terminal patients, both in patient outcome and in cost. The Cooperative Study extends the patient base and introduces the variable of different sites to determine whether the benefits stand up in different settings, still studying severely disabled or terminal patients. The hypothesis is that team-managed hospital-based home care will reduce the total cost of care compared with either the usual care or with the traditional hospital-based home care. In 15 sites, patients treated with this model are being compared with others not assigned to hospital-based home care, and the total costs of care are being compared for the 680 patients in the two groups. Fifteen other sites with traditional hospital-based home care units will also be studied for cost comparison with the team-managed units.

Primary Care

The study of primary care has been spearheaded by Dr. Morris Weinberger of the Indianapolis VAMC and Dr. Eugene Oddone, of Durham, North Carolina. This study has a different slant. We all know that, in the present day, to question the value of primary care, as against care in subspecialty clinics, is as bad as it would be to question the value of motherhood. Nevertheless, this team of VA investigators is doing an objective study of that premise. The hypothesis is that patients hospitalized with serious illnesses will maintain better health after discharge if they have ready access to a primary care provider, and that this improved health will be reflected in reduced readmission rates after discharge and reduced lengths of stay. A series of other benefits are also hypothesized, including improvements in health-related quality of life, satisfaction with care, time to readmission, frequency of emergency room visits, and total health care costs.

One thousand three hundred ninety-six patients with diabetes mellitus, chronic obstructive lung disease, and congestive heart failure have been recruited. The data collection is nearing completion in this study, and the results will be published soon. Look for it, as it will be interesting.

Telephone Care

The final study I want to tell you about this afternoon is just getting started. Its principle investigator is Dr. Gilbert Welsh from the White River Junction VAMC in Vermont. It is based on the hypothesis that substituting provider-initiated "telephone appointments" for selected clinic visits will lower the overall cost of care without impairing the patient's health status, and that both the patient and the provider will be satisfied with the results. In this study, patients who have agreed to participate will be assigned clinic return intervals by their primary providers before they are randomized. Those in the usual clinic care group will be given a return appointment at the interval assigned. Those in the telephone care group will have a return appointment at twice that interval. They will also receive three interim telephone appointments prior to the next visit, appointments for times when the provider will telephone them. Patients in either group may call in to their provider as needed, and they may be given out-of-sequence clinic appointments if needed.

This study is based on a single site study done at the White River Junction VAMC following this plan. It showed cost savings, no adverse health effects, and increased patient satisfaction among the patients in the telephone care group compared to those receiving usual clinic care. White River Junction is in a largely rural setting, and its clientele are primarily white. Before these results can be generalized, it is important to know how well telephone care works in other settings. The benefits to the rural patient of cutting down on clinic visits, saving travel time and costs, may not be so compelling to an urban patient. Patients in different ethnic groups may react differently to trying to relate to a health care provider on the telephone. If the results hold up in different settings, they could lead to important improvements in efficiency and economy. The cooperative study is about to kick off its pilot phase with three new sites.

Conclusions

Cooperative studies have come a long way since Barnwell and Walker felt their way along the path in 1946. The National Institutes of Health, which soon followed the VA's early example in setting up cooperative studies to answer important clinical problems, has supported landmark studies costing many times what the VA's modest research budget could support. These studies have provided important answers. One of the most recent was the finding that tight control of type-I diabetes does indeed reduce the incidence of complications. Even the drug companies, motivated by their commercial needs combined with the Food and Drug Administration's increasing scrutiny, have been planning and executing creditable cooperative clinical trials.
Where do the VA and the armed services fit into this picture in 1995? We still have advantages on which we can build. Even though each of our hospitals is unique, we have a lot in common. Our doctors, nurses, and technicians are loyal. Our patients are loyal, and many of them want to help others by participating in research. Let us continue to work together to solve the problems that we can solve best.

References
2. Minutes of the First Streptomycin Conference, December 12-14, 1946, Veterans Administration Branch Office, Chicago, IL.

Photos from Anaheim, the 102nd Annual Meeting