2.
Funding for Clinical Trials

2. Funding for Clinical Trials

Clinical trials, like all good research, can be expensive. The more participants they engage and the longer the trial runs, the more expensive they become. Two recent multicenter randomized clinical trials (RCTS) sponsored by the National Heart, Lung, and Blood Institute (NHLBI) are budgeted at over $100 million (240). While these are the most expensive trials undertaken in this country, costs over $1 million are common. The cost of clinical trials is one of the main factors driving the search for alternate methods to answer the same questions. Nevertheless, RCTS are now the superior means to evaluate the efficacy of medical technologies. Insofar as RCTS contribute to more rational decisionmaking in health care, halting the adoption and hastening the abandonment of ineffective technologies, their immediate costs may be justified. Nonetheless, only a limited number of trials can be funded. At the moment, the funding of clinical trials is concentrated in biomedical research and drug development programs. In the coming years, however, judging from current discussion related to funding, their costs may be more widely spread throughout the health care system.

A large number of clinical trials in this country are supported by the Federal Government. The drug industry is also a major supporter of trials of proprietary drugs, the results of which are used to gain approval of new drugs by the Food and Drug Administration (FDA) (table 1), Many other private health and medical groups, such as the American Cancer Society and the American Heart Association, fund a small number of trials, but generally these are not the large-scale, multicenter trials like those that the Federal Government or industry can support.

In 1979, the companies represented by the Pharmaceutical Manufacturers Association (PMA) (over 90 percent of companies in the industry) spent about $212 million on clinical evaluation, a figure including phase I, II, and 111 clinical trials (182). RCTS are generally conducted in phase III, but no more detailed breakdown of expenditures for RCTS is available from PMA. In any case, it is a substantial sum of money.

Table 1.—Studies Required in FDA's Premarketing Drug Approval Process

Phase 1:
Studies in normal volunteers or relatively healthy patients to determine safety and pharmacologic effects.
Small studies in patients to determine clinical effectiveness.
Total number of subjects—up to 80 administered the investigational drug.
Phase II:
— Controlled clinical trials to determine appropriate doses, safety, and effectiveness.
— Total number of patients—about 200 administered the investigational drug.
Phase III:
— Controlled and uncontrolled clinical trials to determine safety and effectiveness and to support labeling claims.
— Total number of patients—about 500 to 3,000 administered the investigational drug.

SOURCE U S **Food and Drug Admininstation**

The largest supporter of clinical trials in the Federal Government is the National Institutes of Health (NIH). The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) finances RCTS under its Treatment Assessment Research Program. The Veterans Administration (VA) supports multicenter RCTS in VA medical centers through the Cooperative Studies Program.

The U.S. Department of Defense (DOD), largely through the Department of the Army, supports a large field studies program, conducting RCTS mainly of vaccines and prophylactic drugs and of some treatments.

Academic institutions also support RCTS, mainly in the form of researchers' salaries. The dollar value of this contribution is not known (158).

Of equal interest is who does not fund clinical trials. Third-party payers for medical care generally do not. Because clinical trials, and RCTS in particular, are important in assessing technologies

and in better decisionmaking, they should be of great interest and value to third-party payers. The accelerating costs of health care have led to concern of third-party payers about costs and about covering only those medical practices of proven value. The RCT is the best method for gathering evidence on the effectiveness of a practice, in cases where the method is appropriate.

The greatest expense in conducting RCTS is patient care. At present, the VA system excludes from the research budget nearly all patient care costs in RCTS. Under most other funding arrangements, research money covers varying percentages of patient care and institutional (hospital) costs in RCTS as well as the associated costs of trials. The research community is now active in encouraging private third-party payers to increase their contributions to patient care costs in RCTS.

Through the Medicare program, the Federal Government directly pays about one-quarter of all third-party medical payments in the United States. The large and ever-rising cost of health care, symptomatic of today, is a powerful incentive toward more informed decisionmaking. Congress, in the Social Security Act Amendments of 1983, recognized the need for reliable assessments of medical technologies by, for the first time, allowing the Health Care Financing Administration (HCFA) to fund RCTS relevant to their needs for information (for a fuller discussion of policy decisions under HCFA, see ch. ***3).*** HCFA'S will undoubtedly bean important contribution to RCT financial support.

TRENDS IN FUNDING CLINICAL TRIALS

Trends in Federal funding of clinical trials were encouraging through the ***1970's.*** Between 1971 and 1974, 4 of the 11 NIH institutes—NHLBI, the National Cancer Institute (NCI), the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), and the National Eye Institute (NEI)—nearly tripled their obligations for major clinical trials, including RCTS (225). In 1979, NIH expenditures for clinical trials totaled $136.2 million, in support of ***986*** trials. The numbers have increased steadily since 1975 when ***$87.8*** million went to support 755 trials. The amount spent on clinical trials as a percent of total NIH expenditures, 4.3 percent in 1979, has changed relatively little during that time, however. Since 197'9, comparable data have not been compiled, but evidence suggests a downturn in the support of clinical trials, brought about by budgetary constraints and policies concerning the total number of competing grant awards ***(235).*** In the Akitional *Institutes of Health Research Plan, A' 198.3-85,* NHLBI states ***(239):***

> . . . the most severe impact [of holding the number of grants constant] will be felt in clinical trials and targeted research, funded under the contract mechanism, where no new efforts can be implemented in 1980-1982. . . . The contract mechanism is best suited to fund clinical trials, and rapid advances in research and developments in cardiovascular and pulmonary treatment techniques necessitate clinical evaluation at a time when no new contracts can be awarded.

borne of the other institutes make similar statements (235).

Funding for VA's multicenter clinical trials increased throughout the 197'0's. In fiscal year 1970, VA spent $1.8 million, 3.1 percent of its total budget for biomedical research and development, on clinical trials. By 1981, the figure was $9.7 million, representing 7.1 percent of this VA budget.

THE NATIONAL INSTITUTES OF HEALTH

The major biomedical research agency in the United States, NIH, is also the largest supporter of clinical trials.

Clinical trials included in NIH statistics cover more than just RCTS. According to the NIH+ Inventory *of Clinical Trials,* clinical trials are defined as follows **(242):**

> . . . a scientific research activity undertaken to define prospectively the effect and value of prophylactic/diagnostic 'therapeutic agents, devices, regimens, procedures, etc., applied to human subjects. It is essential that the study be prospective, and that the number of cases or patients will depend on the hypothesis being tested, but must be sufficient to permit a definite result to be anticipated. Phase 1, feasibility, or pilot studies are excluded.

Of NIH trials active in 1979, about 60 percent were RCTS (158), up from about 50 percent in 1975 (225).

The emphasis given to clinical trials varies considerably from institute to institute. NCI and NHLBI, the largest institutes, are also the largest supporters of clinical trials (table 2). These NIH institutes differ somewhat from the others as they are the only ones specifically mandated by acts of Congress, and clinical research is specifically mentioned in their legislation. The other institutes are guided by the general research authority of the Public Health Service Act, which provides a less specific mandate (235).

NIH institutes least active in clinical trials are the National Institute for Environmental Health Sciences (NIEHS), which supported no clinical trials in 1979, and the National Institute of General Medical Sciences (NIGMS), which supported one, NIEHS is mainly concerned with the adverse effects of environmental factors on human health. Such effects are not readily studied in clinical trials. NIGMS primarily supports undifferentiated basic research, that does not necessarily focus on a specific disease. Technologies ripe for clinical trials are usually no longer in the purview of NIGMS.

The seven remaining institutes fall between the two extremes, their *use* of clinical trials dictated to some degree by the state of knowledge of the diseases they study, and to a large extent by the importance accorded clinical trials by key individuals within the individual institutes. The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK), for example, supports a great deal of clinical research on the mechanisms of the chronic diseases. NIADDK is now testing some promising treatments for these diseases (e.g., apheresis for a number of conditions), but there are not within its purview at this time as many promising technologies ready for clinical trials as there are, for instance, in the areas of heart disease and cancer. NCI has strongly supported RCTS since the late **1940's,** even before very many promising cancer treatments had been developed. It was farsighted statisticians and other researchers working in the cancer field that provided the impetus. NEI supported no RCTS 15 years ago; it now supports more than 20, stimulated in large part by a few motivated advocates (see box B).

In the mid-1970's, NIH began to compile an annual inventory of the clinical trials supported by all its institutes. Data were collected in 1974, and the first published compilation covered trials active in fiscal year **1975.** The last compilation was of trials active in fiscal year **1979.** NIH no longer compiles these data on clinical trials. Some but not all of its institutes have continued inventories for their own purposes, in the same form as they did for the NIH-wide inventory. NCI publishes a *Compilation of Experimental Cancer Therapy Protocol Summaries,* which includes phase 1, 11, and III studies, a much broader range of trials than were included in the NIH inventory.

NIH inventories summarized data from each trial on a standard survey form. Clinical trials were defined to include more than RCTS, but to exclude very small trials, phase I drug studies, and feasibility and pilot studies. The data collected described the trials purpose, starting date, type and amount of support, subject population, administration, and other characteristics. The summaries classified trials by type and amount of support, number of participants, type of experimental design (e. g., randomized or nonrandomized assign-

Table 2.–NIH Support for Clinical Trials, Fiscal Year 1979

A.–Amount of NIH Support for Clinical Trials Active in Fiscal Year 1979, by institute for Type of Support

Institute	Extramural support				Intramural Supportb	Total amount of support
	Grant	Contract[a]	Grant and contract	Total		
NIH	$47,304,588'	$75,738,768	$1,954,960	$124,998,316	$11,161,800	$1 36,160,116C
NEI	3,141,547	5,378,262		8,519,809	85,800	8,605,609
NHLBI	4,006,736	50,933,477	159,788	55,100,001	1,423,500	56,523,501
NIAID	2,435,341	3,827,597		6,262,938	234,000	6.496,938
NIAMDD	1,927,658	5,226,975		7,154,633	1,085,500	8,240,133
NICHD	3,074,448	556,296		3,630,744	552,500	4,183,244
NIDR	221,977	557,672		779,649	999,050	1,778,699
NINCDS	1,786,449	439,000		2,225,449	435,500	2,660,949
NIGMS	225,750	—		225,750	—	225,750
NC I	30,484,682[c]	6,819,489	1,795,172	41,099,343	6,345,950	47,445,293[c]

[a]Contract includes Interagency agreements without intramural suPPort
[b]Intramural support includes intramural suppo.tin combination with Interagency agreement s
[c]One trial did not report amount Of support

SOURCE National Institutes of Health. 1979 *Inventory of Clinical Trials*

B.–Number of Clinical Trials Supported by NIH in Fiscal Year 1979, by institute for Type of Support

Institute	Number of trials supported extramurally				Number of trials conducted-intramurally	Total number of trials
	Grant	Contract[a]	Grant and contract	Total		
NIH	592	212	11	815	171	986
NEI	20	3	—	23	3	26
NHLBI	3	13	1	17	3	20
NIAID	80	34	—	114	6	120
NIAMDD	30	22	—	52	15	67
NICHD	24	6	—	30	2	32
NIDR	2	11	—	13	13	26
NINCDS	17	3	—	20	20	40
NIGMS	1	—	—	1	—	1
NCI	415	120	10	545	109	654

[a]Contract includes interagency agreements without intramural support Two trials were supported mostly by contract with some intramural support
[b]Intramural support includes intramural support in combination With interagency agreements One trial was supported most ly by Intramural support with some contract support

SOURCE National Institutes of Health, 1979 *Inventory of Clinical Trials*

ment of participants to groups, use or lack of a control group, type of control group) and type of intervention (e.g., therapeutic, diagnostic, or prophylactic).

The NIH inventory was managed by the Division of Research Grants which, for the first 2 years, supported it with funds designated for evaluation. As resources and personnel became scarcer, funding the inventory became increasingly difficult. Collecting the information itself was not easy, although the institutes experienced different degrees of difficulty in providing the needed information. The future of the inventory is unclear, but without some measure like the inventory, trends in clinical trials are hard to document.

In 1979, total NIH clinical trials of therapeutic interventions, 494, far outnumbered those of prophylactic interventions, 118, and diagnostic ones, 53 (table 3). Among the 1979 trials, however, prophylactic trials cost most, $59 million, compared with the $51 million NIH spent on therapeutic trials and the $3 million it spent on diagnostic ones. The discrepancy in order between the two sets of figures arises because the large-scale multicenter prevention trials funded by NHLBI, while few in number, are relatively expensive. In

Box B.—The National Eye Institute

Soon after the National Eye Institute (NEI) was established in 1968, it began the Diabetic Retinopathy Study (DRS). First recommended by the Advisory Council to the then National Institute of Neurological Diseases and Blindness, the study assessed laser treatment used to halt the progress of vision loss in patients with proliferative diabetic retinopathy. Retinopathy, one of the major complications of insulin-dependent diabetes, is a leading cause of blindness in this country. Assessing such laser therapy by an RCT was extremely important.

The significance to ophthalmology of DRS is even greater, marking the beginning of a trend in the field's clinical research. Since the mid-1950's, when RCTS confirmed that high dosages of oxygen to infants in incubators caused retrolental fibroplasia, no major RCT'S had been carried out in ophthalmology in this country. DRS established the use of RCTS in the field. NH shortly thereafter funded two more large RCTS under contract, one a direct successor to DRS. NH now funds more than 20 RCTS, most grant-supported.

There are some readily apparent reasons for the success of RCTS at NEI, many of them related to DRS. The first and present Director of NEI, Carl Kupfer gave high priority to clinical trials generally, and believed it part of NEI's mission to carry out RCTS. He established the Office of Biometry and Epidemiology to manage contract-supported RCTS, which became a national focal point for RCTS in eye disease.

The DRS was well designed and well run. It had an unequivocally positive outcome: Laser treatment did prevent blindness by almost 50 percent over the S-year period of the study. Finally, it involved a large number of ophthalmologists in 15 clinical centers. Participating in or knowing about the study sensitized ophthalmologists to RCT methods. This accounts, to some degree, for the increased number of NEI grant applications for RCTS.

In addition to supporting RCTS, for nearly a decade NEI has taught an annual short course on clinical research methods at the American Academy of Ophthalmology. .

Table 3.-Number and Amount of Support for NIH Supported Clinical Trials Active in Fiscal Year 1979, by Institute for Type of Intervention

	Total trials supported in fiscal year 1979a		Type of intervention					
			Therapeutic[a]		Prophylactic[a]		Diagnostic[a]	
Institute	Number[b]	Amount[b]	Number	Amount	Number	Amount	Number	Amount
NIH	666	$112,847,367	494	$50,540,964	118	$58,875,770 53		$3170.625
NEI	26	8,605,609	22	4,890,194	2	3,415,997	2	299,418
NHLBI	20	56,523,501	10	9,726,605	10	46,796,896	—	—
NIAID	120	6,496,938	57	2,992,347	39	2,697,064	24	807,527
NIAMDD	67	8,240,133	60	7,680,072	4	246,798	3	313,263
NICHD	32	4,183,244	16	2,532,054	15	1,629,175	1	22,015
NIDR	26	1,778,699	7	779,051	17	776,871	2	222,777
NINCDS	40	2,660,949	35	1,565,020	2	959,429		136,500
NIGMS	1	225,750	–	—	1	2 2 5 , 7 5 0		—
NCI	334	24,132,544	287	20,375,621	28	2,127,798	18	1,369,125

[a] Trials in cooperative groups not included
[b] One trial did not report amount of support One trial did not Specify type of intervention

SOURCE National Institutes of Health, 7979 *Inventory of Clinical Trials*

1979, the average cost of a clinical trial at NHLBI was about $2.8 million, the highest average cost of all the institutes. The National Institute of Allergy and Infectious Diseases (NIAID), for example, spent an average of $54,000 per trial.

Most NIH-sponsored clinical trials are conducted extramurally. In 1979, of all 986 NIH trials, only 171 were conducted intramurally (by a scientist on the NIH campus). Extramural trials are funded through either grants or contracts, with the mix in types of funding varying among institutes. Overall, they spend about twice as much on contracts as on grants, although this statistic may disproportionately reflect the pattern of one large institute, NHLBI. The institutes together fund a larger number of trials by grants (592 v. 212) though again this reflects the large number of smaller trials funded by one institute, NCI. Larger, multicenter trials are probably more appropriately funded under contracts, which presumably give the sponsoring institute more control over the trial, while small, single institution trials probably are more appropriately funded by grants.

NIH has greatly fostered the use and development of RCTS from the early work in cancer chemotherapy, to the large-scale trials in heart disease. These trials have contributed not only to that body of knowledge of medical practices derived from testing with RCTS, but also to the improvement and sophistication of the RCT method itself. Specific trials and groups of trials of particular medical significance are discussed in chapter 5.

THE ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

ADAMHA, an agency of the U.S. Department of Health and Human Services, is composed of three institutes, each devoted to programs of basic and applied research, service, and training, in its own area: the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH). ADAMHA and its predecessor agencies have conducted research to establish the safety and efficacy of medical technologies since the 1950's. In 1975, however, ADAMHA established Treatment Assessment Research (TAR) as a separate kind of research, to study the relative safety and efficacy of various therapeutic substances and procedures applied to human subjects. This research includes clinical trials, case reports, retrospective surveys, and reanalysis of early data (225). In 1982, the total TAR budget was $18.5 million (125). Table 4 gives a breakdown of expenditures by institute. The amount spent specifically on RCTS is not available. Of the three institutes, however, NIMH most actively promotes clinical trials (see box F in ch. **5).**

Table 4.—ADAMHA Treatment Assessment Research Fiscal Year 1982 Expenditures

Institute	Millions of dollars
National Institute of Mental Health	$12.778
National Institute on Drug Abuse	4.995
National Institute on Alcohol Abuse and Alcoholism	.774
Total	$18.547

SOURCE" R Kopanda, ADAM HA, personal communication

THE VETERANS ADMINISTRATION

The VA Cooperative Studies Program (CSP) supports multicenter clinical trials within the VA medical care system. As of September 1982, CSP had 19 studies in the implementation stage (all but 2 RCTS), 11 in active planning, and 12 in final analysis. The technologies the VA studies reflect the medical problems of the veteran population. Of ongoing and recently completed studies, the greatest number treat cardiovascular disease. VA research also emphasizes alcohol-related diseases, and dental and mental conditions. Other VA trials treat acute infectious diseases, diabetes, epilepsy, and conditions associated with disabling injuries. The largest number of trials have tested drug therapies, followed by those that have tested types of surgery. While most trials have concerned treatments, many have focused on the prevention of cardiovascular disease through control of hypertension. The mix of VA clinical trials is much like that of NIH, except that fewer VA trials focus on cancer treatment.

CSP is centrally administered at VA headquarters in Washington, D. C., and has four centers to coordinate data and one experimental drug unit located in different parts of the country.

CSP trials follow a well-defined pathway from inception to final analysis and publication. Ideas for studies come from physicians and investigators in VA installations around the country. They are considered by VA panels and outside advisors, and if judged appropriate for VA research and worthwhile are planned and carried out. Each study is assigned a coordinating center for help in design and conduct of the trial including final data analysis. This procedure ensures the high quality of the study's design and implementation, and obviates the need that the principal investigator be an epidemiologist or statistician.

Up to the present, all the ideas for VA studies have flowed from the "provinces" to the central office. The CSP office in Washington is now beginning to encourage studies that are important, as well as continuing to receive ideas from the field.

The deceptively small budget of CSP, about $12 million per year, goes mainly to support the coordinating centers and other nontreatment aspects of the trials. In contrast to the funding procedure for clinical trials through other mechanisms in this country, in VA trials the participants' treatment in trials is paid for entirely through a different channel, in this case, as VA medical benefits.

CSP only supports trials that require the participation of more than one VA hospital. Other clinical trials are conducted within single VA hospitals, and VA is involved in trials funded by other sources (e. g., NIH, pharmaceutical companies), but there is no central register of these activities.

THE DEPARTMENT OF DEFENSE

DOD is a major supplier of health care in this country. Many of the health problems it must treat, however, differ from those of the civilian population. DOD also conducts much health-related research, most of it directed toward developing and testing drugs and, especially, vaccines. A significant part of this research is conducted entirely by DOD, particularly by the Department of the Army, from drug and vaccine development all the way through large-scale field testing in RCTS.

The Department of the Army is now conducting between 60 and 70 drug and vaccine studies in humans, including studies in phases I, II, and 111. RCTS are now under way on a vaccine for gonorrhea, the use of steroids in life-threatening typhoid, antileishmania agents, and antibiotic

prophylaxis of leptospirosis. For the past 20 years, the Army has supported a development program for antimalarial drugs that relies heavily on RCTS for final recommendations on prophylaxis and treatment. These recommendations form the basis for practice worldwide (34).

Results of DOD vaccine trials and some drug trials have provided information for DOD policy-making, and DOD's recommendations are often adopted by the civilian population. Among the vaccines developed and tested wholly or in part by DOD are those for meningococcus, adenovirus, typhoid, yellow fever, Rift Valley fever, Venezuelan encephalitis, Rocky Mountain Spotted fever (now in late stages of field testing), and gonorrhea (soon to be tested). DOD is also involved in national efforts to develop influenza vaccines. All of its modern vaccine developments have included large-scale field testing in RCTS.

DOD has no central mechanism to track RCTS in its system. In theory, individuals at any DOD installation can carry out trials, and each branch of service is autonomous in conducting RCTS, unless the cooperation of other branches is required, e.g., for trials that require large subject populations. DOD has no regular coordinating body or mechanism to facilitate multicenter or multibranch trials. Each trial is done ad hoc. The Department of the Army keeps most of its financial information on RCTS by subject area (e. g., malaria, typhoid, etc.), so the total amount of money it spends on clinical trials is not easily compiled.

HEALTH INSURERS AND SUPPORT OF RCTS

A growing recognition of the value of RCTS in making sound coverage decisions by both public and private third-party health insurers has manifested itself recently in a number of ways, and has brought several basic issues to the fore. A central issue is to define the appropriate role for third-party payers in supporting RCTS. It is probably unrealistic to expect insurers to underwrite RCTS entirely. A more reasonable expectation is that they cover a greater share of the costs of treating trial participants. Currently, a prohibition against paying for experimental or investigative procedures exists in most private health insurance contracts. Insurers do reimburse for some patients in RCTS receiving "standard" care. This might mean patients in control groups, or even patients in "experimental" groups if the RCT is evaluating a practice already in use. RCTS often require more lab tests and closer observation of all patients, experimental and control, than a patient would receive under nontrial conditions. These excess costs, which may be substantial, are not generally covered by third-party payers.

A more significant reason for lack of sponsorship of RCTS by private health insurers is the administrative structure of those companies. The Blue Cross and Blue Shield Association, the largest private health insurer, is not capable of requiring that individual plans (State and local) and individually insured groups contribute to clinical trials in general or particular trials. This is because each group that seeks health insurance through local Blue Cross or Blue Shield Plans contracts for coverage for that group alone. Some of these groups may be as small as 50 enrollees while others are national accounts with hundreds of thousands of employees spread across several States (169).

In one of the few examples of third-party reimbursement for both the study treatment and sham treatment, five State and local Blue Cross/Blue Shield groups and other third-party payers agreed to reimburse five centers involved in an RCT of plasmapheresis v. sham pheresis for multiple sclerosis. HCFA and the State Medicaid groups, on the other hand, are not participating. Thus, patients' eligibility for the trial depended not only on medical criteria, but also on the type of health insurance they had. The administrative and other research costs of the trial are funded through an NIH grant. While the trial is successfully under way, getting agreement from the third-party payers was a cumbersome and time-consuming process.

In another example, all funds for patient care are being provided by third-party payers in a trial

of "extracranial/intracranial bypass, " a surgical procedure to prevent stroke in patients with cerebrovascular disease. This multicenter study involves 20 major medical centers in this country and three outside the United States (147). The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) is supporting the administrative costs of the central office and the data center, and the costs of entering and following up patients. Hospitalization and medical fees are covered by the third parties **(97).**

Some of the current activities concerning third-party payers and RCTS are described below. The Institute of Medicine of the National Academy of Sciences is considering the role of third-party payers in clinical trials as one aspect of its project on "Evaluating Medical Technologies in Clinical Use. "

The Arthritis Foundation and the National Multiple Sclerosis Society are sponsoring a meeting (to be held in July 1983), at which they hope to develop a proposal for the participation of third-party payers in funding clinical trials. Representatives of the private insurers as well as the Government will attend the meeting.