NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES
UNITED STATES SENATE

NINETY-FIFTH CONGRESS

SECOND SESSION

ON

S. 2466

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO ESTABLISH THE NATIONAL INSTITUTES OF HEALTH CARE RESEARCH; TO EXTEND AND REVISE THE ASSISTANCE PROGRAMS FOR HEALTH SERVICES RESEARCH AND HEALTH STATISTICS; TO ESTABLISH THE NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY, AND FOR OTHER PURPOSES

FEBRUARY 7, 1978

Printed for the use of the Committee on Human Resources

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NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

TUESDAY, FEBRUARY 7, 1978

U.S. SENATE,
SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE COMMITTEE ON HUMAN RESOURCES,
Washington, D.C.

The subcommittee met, pursuant to notice, at 9:42 a.m., in room 357, Russell Senate Office Building, Senator Edward M. Kennedy (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Schweiker, and Javits.

Committee staff present: David Blumenthal, M.D., majority staff, and Mary Frances Lowe, minority.

Senator KENNEDY. We will come to order. I apologize for being late. The full committee was hearing the administration's nominee for Commissioner of the Administration on the Aging, and we were interested in pursuing some issues in the areas of nutrition with him in the title III programs of the Older Americans Act. So I apologize for being late and look forward to this hearing.

Today, the Subcommittee on Health and Scientific Research holds a hearing on S. 2466, the National Institutes of Health Care Research Act of 1978.

I introduced this bill last week, with the cosponsorship of Senators Schweiker, Williams, and Javits. The purpose of this new legislation is to give focus, strength, and vitality to a series of research and statistical activities aimed at improving the quality, efficiency, and effectiveness of health services in the United States.

Americans have an abiding faith that new knowledge can improve their lives. I share this belief. I am proud that our country has had the wisdom to invest generously over the last 30 years in biomedical and behavioral research aimed at the conquest of disease.

Hard as it is to believe now, there was a time when these research areas were neglected and undeveloped. It took a combination of unstinting public funding and careful institution-building to bring them to the point they are today. That national effort is now paying generous dividends.

The history of Federal involvement in biomedical and behavioral research offers important lessons for the Congress and the American people. For despite our Nation's commitment to health research, some areas of health-related inquiry are still neglected.

Health services research, health statistics, and epidemiology, the evaluation of new and existing medical technology—these disciplines are supported meagerly, if at all, by the Federal Government. And where money is available, it is often scattered haphazardly among uncoordinated and competitive programs.

The result, I believe, is that valuable opportunities to improve the lives of our citizens are being lost. It is time to start building these areas of inquiry into powerful partners of basic biomedical sciences. It is time to complete the job of building our Nation's capacity to improve the health of its citizens through research.

That is why I am proposing to create the National Institutes of Health Care Research. It would provide an institutional home for health care research and related activities, an advantage which the biomedical sciences have enjoyed for decades.

It would provide increased authority and direction for the Department to draw together scattered programs in the areas of statistics and health services research.

It would provide moderate increases in funding for these activities, give HEW money and authority to expand and systematize its work in the area of evaluating health technologies. And it would provide an institutional umbrella which could be expanded to include other research missions as appropriate. These could include, for example, selected areas related to disease prevention and control.

Specifically, the bill would accomplish the following: It would create a National Institutes of Health Care Research modeled upon and parallel to the National Institutes of Health. This umbrella organization would provide overall policy guidance and coordination for its component institutions.

It would create a National Center for the Evaluation of Medical Technologies, a new agency located in the National Institutes of Health Care Research. The purpose of this new center would be to assess the cost and effectiveness of medical practices and procedures.

It would expand, redirect, and rename the National Center for Health Statistics. This agency would take on important new functions in the conduct of epidemiologic research and in the coordination of health statistics work. It would become a component institute of the National Institutes of Health Care Research.

Finally, S. 2466 would expand, redirect, and rename the National Center for Health Services Research. This agency would also become a component institute of the National Institutes of Health Care Research.

[The text of S. 2466 follows:]

95TH CONGRESS
2D SESSION

S. 2466

IN THE SENATE OF THE UNITED STATES

JANUARY 31 (legislative day, JANUARY 30), 1978

MR. KENNEDY (for himself, Mr. SCHWEIKER, Mr. WILLIAMS, and Mr. JAVITS) introduced the following bill; which was read twice and referred to the Committee on Human Resources

A BILL

To amend the Public Health Service Act to establish the National Institutes of Health Care Research; to extend and revise the assistance programs for health services research and health statistics; to establish the National Center for the Evaluation of Medical Technology, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE; REFERENCE TO ACT

SECTION 1. (a) This Act may be cited as the "National Institutes of Health Care Research Act of 1978".

(b) Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act.

SEC. 101. Section 304 and the heading thereto are amended to read as follows:

"NATIONAL INSTITUTES OF HEALTH CARE RESEARCH

"SEC. 304. (a) The Secretary shall establish, in the Department of Health, Education, and Welfare, the National Institutes of Health Care Research (hereinafter in this section referred to as the "Institutes"). The Institutes shall be headed by a Director appointed by the President, by and with the advice and consent of the Senate. The Director, with the approval of the Secretary, may appoint a Deputy Director and may employ and prescribe the functions of such officers and employees as are necessary to administer the activities to be carried out through the Institutes.

"(b) (1) The Secretary, acting through the Institutes, shall conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

"(2) In carrying out paragraph (1), the Secretary, acting through the Institutes, shall give appropriate emphasis to research, demonstrations, evaluations, and statistical and epidemiological activities respecting—

"(A) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for the delivery of health care,

"(B) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

"(C) the collection, analysis, and dissemination of health related statistics,

"(D) alternative methods to improve and promote health statistical and epidemiological activities,

"(E) the safety, efficacy, effectiveness, cost effectiveness, and social, economic, and ethical impacts of medical technologies, and

"(F) alternative methods for disseminating knowledge concerning health and health related activities.

"(3) The Secretary, acting through the Institutes, shall (through National Research Service Awards) undertake and support manpower training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects as set forth in sections 305, 306, and 306A.

"(4) The Secretary, acting through the Institutes, shall supervise the administration and operation of the National Institute for Health Policy Research, the National Institute for Health Statistics and Epidemiology, and the National Center for the Evaluation of Medical Technology in order to assure that (A) the programs carried out through each such Institute and Center receive appropriate and equitable support, and (B) there is cooperation among the Institutes and the Center in the implementation of such programs.

"(c) To implement subsection (b), the Secretary may, in addition to any other authority which under other provisions of this Act or any other law may be used by him to implement such subsection, do the following:

"(1) utilize personnel and equipment, facilities, and other physical resources of the Department of Health, Education, and Welfare, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals;

"(2) secure, from time to time and for such periods as the Secretary deems advisable, the assistance and advice of experts and consultants from the United States or abroad. In addition, the Director of the National Institute for Health Policy Research and the Director of the National Institute for Statistics and Epidemiology, in order to assist each of them in carrying out the functions set forth in sections 305 and 306 respectively, and without regard to any other provision of this Act, are each authorized to obtain the services of not more than fifteen experts or consultants who have appropriate scientific or professional qualifications; and

"(3) acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

"(d) The Secretary shall coordinate all research, evaluation, demonstration, and statistical and epidemiological activities referred to in subsection (b) undertaken and supported through units of the Department of Health, Education, and Welfare. Such coordination shall be carried out through the Institutes.

"(e) The Director of the Institutes shall submit a report to the Secretary for simultaneous transmittal, not later than October 30 of each year, to the President and to the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the

House of Representatives setting forth the program accomplishments of the Institutes in the preceding fiscal year and the objectives and priorities for the current fiscal year.".

SEC. 102. (a) The heading for section 305 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH".

(b) Section 305(a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Policy Research (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 305(b) is amended by—

(1) striking "304(a)" and inserting in lieu thereof "304(b)";

(2) striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may undertake" and inserting in lieu thereof "shall undertake";

(4) striking "and" after "evaluation," and inserting in lieu thereof "and/or";

(5) striking "technology," in paragraph (1);

(6) striking "and" after "manpower;" in paragraph (2);

(7) striking the period in paragraph (3) and inserting in lieu thereof ", and"; and

(8) adding at the end thereof the following new paragraph:

"(4) the uses of computer science in health services delivery and medical information systems.".

(d) Section 305 (c) is amended by striking "Center" and inserting in lieu thereof "Institute".

(e) Sections 305 (d) (1) and 305 (d) (2) (A) are amended by inserting ", acting through the Institute," after "Secretary" each place it occurs.

(f) Subsection (e) of section 305 is redesignated subsection (f) and is amended by (1) striking "304 (b)" and inserting in lieu thereof "304 (c)" and (2) striking "(b), (c), and (d)" and inserting in lieu thereof "(b), (c), (d), and (e)".

SEC. 103. (a) The heading to section 306 is amended to read as follows:

"NATIONAL INSTITUTE FOR HEALTH STATISTICS AND EPIDEMIOLOGY".

(b) Section 306 (a) is amended to read as follows:

"(a) There is established in the National Institutes of Health Care Research the National Institute for Health Statistics and Epidemiology (hereinafter in this section referred to as the 'Institute') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.".

(c) Section 306 (b) is amended by—

(1) striking "304 (a)" and inserting in lieu thereof "304 (b)";

(2) striking "Center" and inserting in lieu thereof "Institute";

(3) striking "may" and inserting in lieu thereof "shall";

(4) striking "and" after "dissolution" in paragraph (1) (H);

(5) inserting "or both" after "contract" in paragraph (2);

(6) striking "and" after "demonstrations," in paragraph (2) and inserting in lieu thereof "and/or"; and

(7) adding at the end thereof the following new paragraph:

"(3) undertake and support (by grant or contract or both) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1).".

(d) Section 306 (c) is amended by—

(1) striking "Center" and inserting in lieu thereof "Institute";

(2) by inserting "and epidemiological" after "statistical" each place it occurs; and

(3) striking "Labor and Public Welfare" and inserting in lieu thereof "Human Resources".

(e) Section 306 (d) is amended by striking "Center" and inserting in lieu thereof "Institute".

(f) Section 306 (e) is amended by—

(1) inserting ", through the Institute," after "Secretary";

(2) inserting "to be known as the Cooperative Health Statistics System" after "levels" in paragraph (1);

(3) striking "such cooperative system" each place it occurs and inserting in lieu thereof "such System";

(4) inserting "or both" after "contract" in paragraph (3);

(5) striking "system" in paragraph (5) and inserting in lieu thereof "System".

(g) The first sentence of section 306 (f) is amended by inserting ", through the Institute," after "Secretary".

(h) Section 306 (g) is amended by inserting ", through the Institute," after "health data, the Secretary".

(i) Section 306 (i) (1) is amended by striking "United States".

(j) Section 306 is amended by adding at the end thereof the following new subsection:

"(j) In carrying out the requirements of sections 304 (d) and paragraph (2) of subsection (e), the Secretary, acting through the Institute, shall coordinate health statistical and epidemiological activities of the Department of Health, Education, and Welfare by—

"(1) developing in consultation with the National Committee on Vital and Health Statistics, promulgating by regulation, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b) (1),

"(2) after consultation with the National Committee on Vital and Health Statistics, establishing, by regulation, standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis,

"(3) reviewing periodically all existing health statistical data collections of the Department that were previously approved pursuant to the Federal Reports Act of 1942 to determine whether such collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such collections are found not to be in conformance, the Secretary shall take the necessary action to assure that any future collections (effective ninety days after the review) are in conformance,

"(4) reviewing all proposed health statistical data collections of the Department that require approval pursuant to the Federal Reports Act of 1942 to determine whether such proposed collections conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (1) and (2). If any such proposed collections are found not to be in conformance, the Secretary shall take the necessary action to bring them into conformance before such proposed collections are initiated.".

SEC. 104. Title III is amended by adding after section 306 the following new heading and section:

"NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY

"SEC. 306A. (a) There is established in the National Institutes of Health Care Research the National Center for the Evaluation of Medical Technology (hereinafter in this section referred to as the 'Center') which shall be under the direction of a Director who shall be appointed by the Secretary and supervised by the Director of the National Institutes of Health Care Research.

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"(b) The Secretary, acting through the Center, shall—

"(1) establish, in consultation with the Council for the Evaluation of Medical Technology, priorities for research, demonstrations, and evaluations of medical technologies as prescribed by paragraph (2) (A). In establishing such priorities, particular emphasis should be placed on—

"(A) the actual or potential risks and the actual or potential benefits to patients associated with the use of the medical technology,

"(B) per use and/or aggregate cost of the medical technology,

"(C) the rate of utilization of the medical technology, and

"(D) the stage of development of the medical technology; and

"(2) undertake and support (by grant or contract or both) research, demonstrations, and evaluations concerning—

"(A) the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular medical technologies;

"(B) the factors that affect the utilization of medical technologies throughout the United States;

"(C) alternative methods for disseminating information on medical technologies to health professionals;

"(D) alternative methods for measuring the quality of health services; and

"(E) the effectiveness, administration, and enforcement of quality assurance programs.

"(c) To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the National Institutes of Health, the Veterans' Administration and any other interested Federal departments or agencies and with State and local health departments and agencies.

"(d) (1) The Secretary, acting through the Center, shall, by grants or contracts, or both, assist public and/or private nonprofit entities in meeting the costs of planning and establishing new centers, and operating existing and new centers for multidisciplinary research, evaluations, and demonstrations respecting the matters referred to in paragraph (2) of subsection (b). To the extent practicable, the Secretary shall take such actions, in accordance with the requirements of this subsection and section 308, to assure that three such centers shall be operational by September 1, 1981.

"(2) (A) No grant or contract may be made under this subsection for planning and establishing a center unless the Secretary, acting through the Center, determines that when it is operational it will meet the requirements listed in subparagraph (B), and no payment shall be made under a grant or contract for operation of a center unless the center meets such requirements.

"(B) Each center shall meet the following requirements:

"(i) there shall be a full-time director of the center who possesses a demonstrated capacity for sustained productivity and leadership in research, demonstrations, and evaluations respecting the matters referred to in paragraph (2) of subsection (b), and there shall be such additional full-time professional staff as may be appropriate;

"(ii) the staff of the center shall have expertise in the various disciplines needed to conduct multidisciplinary research, evaluations and demonstrations respecting the matters referred to in paragraph (2) of subsection (b);

"(iii) the center shall be located within an established academic or research institution with departments and resources appropriate to the programs of the center; and

"(iv) each center shall meet such additional requirements as the Secretary may by regulation prescribe.

"(e) (1) There is established in the Center a National

Council for the Evaluation of Medical Technologies (hereinafter in this subsection referred to as the 'Council') to be composed as follows:

"(A) the Surgeon General, the Director of the National Institutes of Health, the chief medical officer of the Veterans' Administration, the Chairman of the National Professional Standards Review Council (or their designees), and three other employees of the Department of Health, Education, and Welfare (or their designees) appointed by the Secretary, shall be ex officio members of the Council.

"(B) Sixteen members appointed by the Secretary. Seven of the appointed members shall be selected from among leading medical or scientific authorities; two of the appointed members shall be selected from members of the general public who are leaders in the field of economics; two of the appointed members shall be selected from members of the general public who are leaders in the field of law; and five of the appointed members shall be selected from outstanding members of the general public who, based on their interests, disciplines, and/or expertise, would be appropriate members of the Council.

"(2) (A) Each appointed member of the Council shall be appointed for a term of four years, except that—

"(i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

"(ii) of the members first appointed after the effective date of this section, five shall be appointed for a term of four years, five shall be appointed for a term of three years, five shall be appointed for a term of two years, and three shall be appointed for a term of one year, as designated by the Secretary at the time of appointment.

Appointed members may serve after the expiration of their terms until their successors have taken office.

"(B) A vacancy in the Council shall not affect its activities, and twelve members of the Council shall constitute a quorum.

"(C) Members of the Council who are not officers or employees of the United States shall receive for each day they are engaged in the performance of the functions of the Council compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS-18 of the General Schedule, including traveltime; and all members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

"(3) The Council shall annually elect one of its appointed members to serve as Chairman until the next election.

"(4) The Director of the Center shall (1) designate a member of the staff of the Center to act as Executive Secretary of the Council, and (2) make available to the Council such staff, information, and other assistance as it may require to carry out its functions.

"(5) The Council shall meet at the call of the Chairman, but not less often than four times a year.

"(6) The Council is authorized to—

"(A) advise, consult with, and make recommendations to the Secretary, the Director of the National Institutes of Health Care Research, and the Director of the Center with respect to carrying out the provisions of this section;

"(B) after consultation with appropriate public and private entities, advise the Secretary concerning the safety, efficacy, effectiveness, cost effectiveness, and the social and economic impact of particular medical technologies;

"(C) after consultation with appropriate public and private entities, develop, when appropriate and to the extent practicable, exemplary standards, norms, and criteria concerning the utilization of particular medical technologies;

"(D) publish, make available and disseminate, through the National Library of Medicine, promptly in understandable form and as widely as possible, but, at a minimum, to all health systems agencies, to all Professional Standards Review Organizations and to the health facilities of the Veterans' Administration the standards, norms, and criteria developed pursuant to paragraph (C); and

"(E) review and approve any grant that the Center proposes to make and any contract the Center proposes to enter pursuant to this section if such grant or contract is in an amount exceeding $35,000 of direct costs.

"(f) For purposes of this section, medical technology means any discrete and identifiable medical or surgical regimen or modality used to diagnose or treat illness, prevent disease, support life, or maintain patient well-being.".

SEC. 105. (a) The heading to section 308 is amended by striking "304, 305, 306, AND 307" and inserting in lieu thereof "304, 305, 306, 306A, and 307".

(b) Section 308 (a) (1) is repealed.

(c) Section 308 (a) (2) is amended by (1) redesignating it as section 308 (a) (1), and (2) striking "the National Center for Health Services Research and the National Center for Health Statistics" and inserting in lieu thereof "the National Institutes of Health Care Research".

(d) Section 308 (a) (3) is redesignated as section 308 (a) (2).

(e) Section 308 (b) (1) is amended by inserting "306A," after "306".

(f) Section 308 (d) is amended by (1) inserting "306A," before "or 307" and (2) by inserting "or epidemilogical" after "statistical" in paragraph (1).

(g) Section 308 (e) is amended by inserting "306A," after "306" each place it occurs.

(h) Section 308 (f) is amended by striking "or 306" and inserting in lieu thereof "306, or 306A".

(i) Section 308 (g) (2) is amended by striking "and 306" and inserting in lieu thereof "306, and 306A".

(j) Section 308 (h) (1) is amended by striking "or 306" each place it accurs and inserting in lieu thereof "306, or 306A".

(k) Section 308 (i) (1) is amended to read as follows:

"(i) (1) For health services research, evaluation, and demonstration activities undertaken or supported under section 304 or 305, there are authorized to be appropriated $34,000,000 for the fiscal year ending September 30, 1979;

$40,000,000 for the fiscal year ending September 30, 1980; and $45,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year, at least 15 per centum of such funds shall be available only for health services research, evaluation, and demonstration activities directly undertaken by the National Institute for Health Policy Research and at least 5 per centum of such funds or $1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken by the Center.".

(l) Section 308 (i) (2) is amended to read as follows:

"(i) (2) For health statistical and epidemiological activities undertaken or supported under section 304 or 306, there are authorized to be appropriated $60,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $70,000,000 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1978, at least 15 per centum of such funds shall be available only for health statistical and epidemiological activities directly undertaken by the National Institute for Health Statistics and Epidemiology.".

(m) Section 308 (i) is amended by adding at the end thereof the following new paragraph:

"(3) For medical technology research, evaluation, and demonstration activities undertaken or supported under section 304 or 306A, there are authorized to be appropriated $25,000,000 for the fiscal year ending September 30, 1979, $35,000,000 for the fiscal year ending September 30, 1980, and $50,000,00 for the fiscal year ending September 30, 1981. Of the funds appropriated under this paragraph for any fiscal year commencing after September 30, 1980, at least 15 per centum of such funds shall be available only for medical technology research, evaluation, and demonstration activities directly undertaken by the National Center for the Evaluation of Medical Technology.".

SEC. 106. (a) Section 472 (a) (1) (A) is amended by—

(1) striking "and" after "private institutions," in clause (iii);

(2) redesignating clause (iv) as clause (vii); and

(3) inserting after clause (iii) the following:

"(iv) research at the National Institutes of Health Care Research,

"(v) training at the National Institutes of Health Care Research to undertake such research,

"(vi) research on the matters set forth in section 304 (b) (2) at public institutions and at nonprofit private institutions, and".

(b) The last sentence of section 472 (a) (1) is amended by inserting ", National Institutes of Health Care Research," after "National Institutes of Health".

SEC. 107. Part K of title III is repealed in its entirety.

SEC. 108. Title IV is amended by adding at the end thereof the following new section:

"SEC. 477. The Director of the National Institutes of Health shall make available annually to the National Center for the Evaluation of Medical Technology and the Council for the Evaluation of Medical Technology a list of all technologies (as defined in section 306A (g)) of which he is aware that are under development and that appear likely to be used in medical practice in the near future.".

Senator KENNEDY. Before hearing testimony, I would like to comment on several of these proposals. The creation of a National Center for the Evaluation of Medical Technologies is a key element in our bill and deserves a few words of explanation.

Last summer, the subcommittee heard 2 days of testimony on a problem which is of growing concern not only to the Congress, but to many thoughtful medical and social scientists throughout the country.

It has been estimated that one-half of the annual increase in the cost of 1 day of hospital care can be attributed to the use of more technology in medical practice. That means that between 1966 and 1976, expenditures on medical technology added between $8 and $12 billion to our national hospital bill.

What are we buying with this outlay of funds for additional technology? Are these expenditures improving the health of the American people? According to the testimony we heard last summer, in many cases, we simply do not know.

I yield to no one in my desire to see the products of biomedical research transferred rapidly and appropriately to the bedside. But we must recognize that we also pay a high price for the overly rapid application of new technologies.

The creation of a National Center for the Evaluation of Medical Technologies, like the one proposed here, seems to us a reasonable and essential first step toward assuring that the health practices commonly employed in the United States are efficacious and cost effective.

Just one more point. S. 2466 makes changes in the mandate, location, and authorization of the National Center for Health Statistics. I view the gathering of health statistics as a vital function of Government.

Statistics are the Nation's window on its own health. They tell us what our health problems are, and how to begin solving them.

In this regard, I would like to say how impressed I was with the recently published HEW report, "Health, United States, 1976–77." It is an example of Government statistical reporting and analysis at its very best.

It is because of the importance of health data-gathering that I am so distressed at the Department's continuing inability to coordinate its own data-gathering activities.

The Federal Paperwork Commission has commented on this problem. It estimates that the Nation would save $200 million if the current overlap and duplication in health data-gathering were eliminated at the Federal level.

S. 2466 addresses this issue by increasing the authority of the revised National Center to coordinate health statistics. We will be interested to hear the administration's plans for dealing with the statistics coordination problem.

In health statistics, as elsewhere, S. 2466 has ambitious goals. Institution building is no easy job. It will be argued that the proposal moves too fast and too far, that it is too disruptive of established organizations, that the health disciplines involved are underdeveloped and need time to mature.

Unfortunately, the situation could hardly be worse than it currently is. The burden is on those who would go slow to prove they can do the job without a comprehensive new initiative.

S. 2466 will give us a solid start at completing the job of building our Nation's health research capacity. I look forward to the comments of our witnesses.

Our first witnesses are good friends of this committee, Dr. Julius Richmond, accompanied by Ruth Hanft, Dorothy Rice, Dr. Gerald Rosenthal, and Carol Emmot.

Dr. Richmond is, of course, the Assistant Secretary for Health, Surgeon General of the Public Health Service. We have enjoyed having you in the past and look forward to your testimony this morning.

STATEMENTS OF DR. JULIUS B. RICHMOND, ASSISTANT SECRETARY FOR HEALTH, SURGEON GENERAL OF THE PUBLIC HEALTH SERVICE, ACCOMPANIED BY RUTH S. HANFT, DEPUTY ASSISTANT SECRETARY FOR HEALTH POLICY, RESEARCH, AND STATISTICS; DOROTHY P. RICE, DIRECTOR, NATIONAL CENTER FOR HEALTH STATISTICS; DR. GERALD ROSENTHAL, DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES RESEARCH; AND DR. CAROL EMMOT, OFFICE OF LEGISLATION, DHEW, A PANEL

Dr. Richmond. Thank you very much, Mr. Chairman. I am pleased to appear again, along with my colleagues——

Senator Kennedy. I am sorry you are so far away from us here, but I can see you and hear you well.

Dr. Richmond. Fine. We are pleased to appear before you today to discuss the renewal of authorization for the national centers for Health Statistics and Health Services Research, and to discuss issues of technology assessment and use, and the proposal for certain changes in the structure of these programs embodied in your bill, S. 2466, which you have just described for us.

Research and statistics expenditures—as you have already indicated—are an investment in the future—in our ability to make sound decisions that can improve our health care delivery system. Your support, and that of your subcommittee over the years for our health services research and statistics activities, is greatly appreciated by all of us in the Department.

Your continuing concern with both the promise and problems of health technology has been a catalyst for important new actions in the Department, which I will outline in my remarks.

I might just mention, Senator, that the hearings we participated in last summer, which you referred to, set in motion a chain of events which have been very important to all of us and, we think, to the health of the Nation, ultimately.

The work of the centers makes invaluable, although, unfortunately, not always visible, contributions to policy deliberations, health legislation, Federal health programs, and the decisions of health care providers.

The comprehensive program of the National Center for Health Statistics includes more than 20 data systems, which produce information on health status of the population, health resources, utilization of health services, nutrition, family growth, and the Nation's patterns of births, deaths, marriages, and divorces.

You have already mentioned "Health, U.S.A." as one of the publications, Senator. I would also call your attention to the "Chartbook on Health, U.S.A." which are important products and which represent, I think, some of the most comprehensive data on health statistics presented anywhere in the world, nationally.

A few examples will illustrate the importance of these activities. Among the specific contributions of the information that has been generated is an awareness of the health care trends that form the factual backdrop for many important decisions in the health field, in cost containment, quality, distribution of services, and control of toxic substances.

For example, the Hospital Discharge Survey has shown the incidence of hysterectomies rising substantially from 734 per 100,000 females 15 years and older in 1971, to 850 in 1974.

More recently, there appears to be a downturn, perhaps due to heightened visibility of the phenomenon, stimulated in no small measure, we think, by the data which have become available.

The Health and Nutrition Examination Survey measures the prevalence of hypertension among adults——

Senator KENNEDY. Have tonsillectomies done the same thing, Doctor? Both were targeted problems.

Dr. RICHMOND. Yes. Indeed, there has been a very significant decline since this has been made more visible—a very significant decline, and we will mention that, perhaps, later.

The Health and Nutrition Examination Survey measures the prevalence of hypertension among adults and indicates that the prevalence rate among blacks is nearly twice as high as that among whites.

New epidemiologic techniques in mapping infant mortality and other mortality rates to determine geographic differentials can identify variations due to lack of access to care or exposure to environmental hazards.

We intend to make much more use of these kinds of geographic differentials in our planning for health services as we move forward.

The National Center for Health Services Research plays a parallel role in services research. The National Center for Health Services Research-supported research and demonstration activities produced the factual justification for new legislation which provides for reimbursement of physician assistants and nurse practioners practicing in rural clinics.

Other National Center for Health Services Research research has produced the health scarcity index for identifying shortage areas.

The Experimental Medical Care Review Organization project initiated in 1970 provided the working model for the professional standards review organizations.

The Center has become increasingly sensitive——

Senator KENNEDY. That budget went down this year; did it not?

Dr. RICHMOND. Yes.

Senator KENNEDY. It went down in real terms, and of course, with inflation, it went down about 10 percent, in terms of real——

Dr. RICHMOND. Yes, that is true.

The Center has become increasingly sensitive to the demand for policy-relevant research and is preparing to fund research on cost containment specifically tailored to the needs of local health systems agencies.

It has initiated a series of national medical care expenditure studies as a major component of its intramural program.

Data for this study is being developed in collaboration with the National Center for Health Statistics. The product of this effort will provide valuable information for evaluating alternative financing mechanisms for health care in the United States.

More detailed information about the activities of the Centers is being submitted for the record.

[The following material was subsequently received for the record:]

For the Record - Supplement to
Dr. Richmond's Opening Remarks

Ever since the term "statistics", meaning the numbers describing the situation in the state, came into use it has been recognized that statistics are essential to statecraft. Man manages his affairs better if he has access to quantitative information on the condition of the state. The National Center for Health Statistics has an illustrious history in providing such quantitative information in the health field.

The National Center for Health Statistics was organized in August 1960 upon the recommendation of the Surgeon General's Study Group on Mission and Organization of the Public Health Service. In its final report in June 1960, the Study Group cited a real need for such a statistical operation to serve as the health statistical arm of the Public Health Service with this statement:

> "The needs of the Nation and the responsibilities of the Public Health Service require broad regional and national data with respect to the character and dynamics of health problems, their trends and implications. While States and other organizations contribute valuable data, national intelligence requires a center for the collection, evaluation, analysis, and interpretation of data from many sources. The Public Health Service has primary responsibility at the Federal level to provide national intelligence on matters relating to health - births, deaths, illness, disability, health services, marriages, divorces."

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Although the Center was formed in 1960, some of its activities developed much earlier. For example, questions about births, marriages and deaths were included in the 1850 census and in the century that followed the Bureau of the Census (Department of Commerce) was given increasing responsibility to collect, compile and publish vital statistics.

In 1946 these functions were transferred to the Public Health Service, and the National Office of Vital Statistics was established to administer the program and provide a single authority for collecting vital records at the Federal level.

As early as a century ago it was recognized that records of deaths alone could not provide a complete picture of the impact of illness and disease on the population. In 1878, the Congress authorized the collection of data on cholera, plague, smallpox, and yellow fever, and in 1893 a bill was passed to collect weekly morbidity data from States and cities throughout the United States. This system of notifiable disease reporting has continued until the present time.

Development of vital registration and of the system of notifiable disease reporting still left large gaps in our health intelligence. Information was needed which could be obtained only from the people themselves, from examinations of samples of the population, or from the providers of health services. Particularly missing was knowledge of those conditions that do not have high rates of fatality but which have high impact in terms of disability, economic loss, and the social and environmental concomitants.

The establishment of survey methods to measure morbidity has occurred only in recent years because the techniques and tools did not exist earlier. During the 1940's and 1950's research conducted within universities, as well as methodological work sponsored by the Federal government, resulted in refinements of questionnaire design and interviewing techniques which substantially reduced errors in survey data. The theory and application of techniques for sampling of human populations was developed to a point where relatively small samples of the population could provide information about the population as a whole, within stated margins of error and at reasonable cost. And finally, the electronic computer had proved its worth in processing of large volumes of complex survey data, in converting the answers to estimates for the entire population, and in tabulating and analyzing the results. By the time the National Health Survey Act was passed in response to increased demands for health information, the basic methods had been devised for producing the data. Continued improvements have been made in sampling, survey, analytic, and computer technology, concurrent with the development of new health statistical systems.

Pioneers in such survey techniques applied these methods to study the impact of the influenza epidemic of 1918 and in a number of community based surveys on child health, nutrition, dental disease, tuberculosis, costs of medical care, and many other aspects of morbidity that were of concern during the first third of this century. The economic depression of the 1930's provided the impetus for a national health survey in order to try to relate nutrition, physical growth, health status and health services to the economic conditions of the times. Results of this survey, conducted in 1935-36 in over 700,000 households in 83 urban areas, were used during the next 20 years to provide baseline data to the health professions, and to plan and promote public health programs.

By midcentury dramatic changes had taken place. The country had pulled through a major depression and a major war; the post-war baby boom and migration had resulted in population shifts; the growth in health insurance and in use of specialist services had changed the patterns of medical care; and the success of immunization programs and of new therapeutic products had altered medical practices and modes of treatment. Results of the earlier urban survey and community studies were no longer relevant to the emerged and unfolding problems of injuries, disability, chronic illness, and the provision of resources to cope with them. In 1956 Congress passed the National Health Survey Act to "provide for a continuing survey and special studies to secure on a non-compulsory basis accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services received for or because of such conditions." The basic household interview survey started in July, 1957, has been in continuous operation since that date and has been emulated by many countries of the world. Throughout the years information has been collected on a very large number of health conditions in relation to the social and economic characteristics of the nation's people.

In 1960 the National Office of Vital Statistics and the National Health Survey were administratively joined in a new organization, the National Center for Health Statistics. During ensuing years this Center has successively added new data systems to fill the many gaps in health information. A Health Examination Survey was started in 1960 to obtain data on chronic diseases, physiological norms and ranges, distributions and abnormalities of vision and hearing, growth and development of children, physchological test measurements and, in recent years, levels of nutritional status. Lack of uniform national hospital data about the number of patients, length of stay, diseases, and services received led the Center to establish a Hospital Discharge Survey in 1965. Other national surveys have been established within the past decade to determine the characteristics of residents of nursing homes, the diagnoses and services to patients seen in physicians' offices, and the expectations for family size and other factors affecting fertility and future population change.

In July, 1974, the Health Services Research, Health Statistics and Medical Libraries Act (P.L. 93-353) statutorily established the National Center for Health Statistics and provided the Center with extensive authority for the collection, analysis, and publication of health statistics by consolidating and revising fragmented and out-dated sections of the Public Health Service Act. The law also provided authority for coordination of DHEW health statistical activities through the Center and strengthened the mandate for developing a cooperative system for producing comparable health statistics at the National, State, and local levels including a specific provision for providing to States, through grants or contracts, the Federal share of developing and operating health statistical systems.

The chronology of development of the National Center for Health Statistics shows clearly three plans in evolution. That is, an early period of 10-15 years devoted to developing the armory of continuous, comprehensive, flexible, and sound health statistical systems to provide a continuing source of high-quality health information about the health of the American people, the health services they receive, and the health resources available to provide these services.

Another ten years of effort, 1962-1972, was a period of concencious efforts to both improve the basic systems to assure their continued productivity, and at the same time develop methods, techniques and demonstrations of the application of these data to: increasing our knowledge based in health matters; guiding health policy development; directing health program policy and evaluation; and, providing the research community with the grist of basic research direction.

More recently, the direction of the Center has shifted once again in response to health data demands. In keeping with the movement towards more local and State automony in the provision and financing of health care, the National Center for Health Statistics has begun to decentralize many of it's data systems to assure that data is collected in such a way as to meet needs for such information at lower levels of geo-political decision-making in health.

The major health data programs of the National Center for Health Statistics today include:

National Vital Statistics Program: This program plans and administers activities to provide statistics on births, deaths, fetal deaths, marriages and divorces reported in the national registration system. This program promotes the uniform collection of data on these vital events, provides technical assistance to the registration areas, conducts followback surveys to expand the scope of national vital statistics, and prepares life tables. This program also conducts the biennial Family Growth Survey. This household interview survey collects data on fertility, family planning, and infant and maternal health from a probability sample of ever-married women.

The Health Interview Survey: Oldest of the Center's surveys, the Health Interview Survey was started in 1957 to provide a continuous flow of health data from interviews of a sample of households spread across the Nation. Data are collected week after week. Questionnaires are revised annually so that information on new health topics can be compiled as the need arises.

About 42,000 interviews are conducted annually, covering about 134,000 persons, by skilled interviewers from the Bureau of the Census. They use questionnaires to obtain a general health history of each family. Questions designed to produce "yes" or "no" answers are asked on a variety of health subjects.

For example, questions might include asking if any member of the household had experienced such diseases or conditions as asthma, tuberculosis, chronic bronchitis, high blood pressure, or heart trouble. If they have, then more detailed information is sought.

Data from this survey measure the social rather than the physiological dimensions of health; the total amount of illness, how it affects people's lives, what actions they take to prevent or cure illness, and what the relation of health and medical care is to a wide variety of social, economic and demographic variables.

<u>The Health and Nutrition Examination Survey</u>: In contrast to the Health Interview Survey, the Health and Nutrition Examination Survey collects nutritional, physiological and diagnostic data through specially designed health examinations, using objective measurements and tests. Like the Health Interview Survey, this is a continuing operation. Direct health examinations are given to pre-selected samples of persons of various age groups. The sample in each case represents national proportions of race, economic and educational levels, as well as rural areas, small towns, medium-sized cities, and metropolitan areas.

Recent data from the survey includes information on dietary intake, clinical findings, growth and development measurements, laboratory test, results on blood and urine, prevalence of emphysema, dermatologists' findings on skin disease, measures of auditory acuity, and assessments of pulmonary function.

<u>The Health Resources and Health Resources Utilization Programs</u>: These programs are designed to develop statistics on national resources in health manpower and health facilities and the uses made of these resources. The specific surveys include:

- Master Facility Inventory: Maintains a file containing Census-type data on the nation's health facilities, their services, and staff. This file serves as a universe from which probability samples may be selected for particular surveys and it also services as a current source of baseline statistical data. Because censuses are conducted on the facilities, data are available for small geographic areas. This file is the only source of comprehensive data on health facilities that is available and suitable for local health planning.

- Resident Places Survey: Data is collected through interview surveys from a sample of long-term inpatient facilities listed in the Master Facilities Inventory. Statistics are published on the services provided by these facilities, the education and experience of their staff, and the expenditures they incur in providing care. Statistics are also developed on the socio-demographic characteristics and health status of residents in these facilities. The results of these biennial surveys are used for planning purposes at both the national and local levels.

- Hospital Discharge Survey: Demographic and medical data on persons discharged from short-stay, non-Federal hospitals is collected, analyzed, and published. The data is collected through a survey of hospital summary sheets and ledger records. Reports are prepared and published providing information on demographic and medical characteristics of the patients as well as data on type and location of hospitals participating in the survey.

- National Ambulatory Medical Care Survey: The purpose of this survey is to provide statistics describing services to ambulatory patients including statistics on demographic characteristics, diagnoses, diagnostic procedures, and patient management. Physicians' offices are the site of the greatest volume of health care and this survey provides information that has been insufficient in the past, about this important segment of the health care system. This annual survey collects data from a sample of approximately 3,000 physicians.

- Family Planning Statistics: This activity develops statistics on the utilization of family planning facilities and services. Statistics are also developed on the number, characteristics, services offered, and staff of all current facilities offering family planning services. These statistics will be used to efficiently implement expanding family planning programs.

The Cooperative Health Statistics System: The development of this System is the newest endeavor of the National Center for Health Statistics. The purpose of the System is to provide uniform, high quality, comparable, health data at the National, State and local levels. It will provide for the collection of any particular data element by that level of government best equipped to collect it, and the information then will be shared with the other levels. As now envisioned, when the Cooperative System is in full operation it will include seven components in the area of health and vital statistics.

Some examples of major areas of application of Center data to support DHEW health programs are:

Access and Unnecessary Utilization

There has been a great deal of concern in recent years with ensuring equal access to medical care among all subgroups of the population. By monitoring trends in the National Center for Health Statistics data over the past several years, it is apparent that the large increases in Federal health programs have had a substantial impact on accessibility. For example, data from the Health Interview Survey shows that in 1964, before the enactment of Medicare and Medicaid, the poor averaged 17 percent fewer doctor visits per person than the nonpoor (age-adjusted). By 1976, however, the poor reported 10 percent more visits per person than the nonpoor (age-adjusted). Similarly, a recently published study (C. Bombardier, et al., NEJM 297: 669-705, 9/29/77) based on the 1963 and 1970 Health Interview Surveys show large increases in surgical operations among disadvantaged groups: the aged, the lower educated and non-whites in urban areas.

Despite these encouraging results, however, there is clear evidence that substantial gaps in access remain. For example, a special supplement to the 1974 Health Interview Survey collected information about usual source of medical care. Seventy-eight percent of the poor reported that they had a usual source of care compared to 82 percent of the non-poor. Yet, when asked about the provider of their usual source of care, 35 percent of poor blacks in metro areas identified a hospital clinic or emergency room compared to only 3 percent of non-poor whites in metro areas.

Another indication of unequal access is provided by data from the 1973 Health Interview Survey supplement on preventive care. Among black women aged 45-64, 30 percent have never had a Pap smear to detect cervical cancer compared to only 16 percent of white women in the same age group. Since cervical cancer is amenable to effective treatment if detected at an early stage, the health consequences of this type of unequal access are particularly revealing: the death rate among Black women in this age group due to cervical cancer is more than three times the corresponding white rate.

The other side of the access issue is the question of unnecessary utilization of medical services. This issue has been raised most seriously in the hospital sector and particularly with respect to unnecessary surgery. The rate of surgical operations per 100,000 population has increased nearly 25 percent between 1971 and 1976. Careful monitoring of specific procedures, however, is needed to better understand the reasons for and possibly control the increase. For example, in 1971 tonsillectomy was the most frequently performed operation, with a rate of 478 per 100,000 population. A number of reports dealing with the appropriateness and demonstrating the lack of effectiveness of tonsillectomy led to a dramatic 40 percent decline in the rate by 1976. It still remains, however, one of the more frequently performed procedures and shows marked variation by region: the region with the highest rate (North Central) showed nearly 60 percent more tonsillectomies per 100,000 than the region with the lowest rate (Northeast).

A procedure which has shown marked increases over the years is Caesearean section. In 1971, 6 percent of all deliveries were by Caesearean section. This rate doubled to 12 percent by 1976. Regional variation is also large: from 11 percent in the North Central region to 15 percent in the Northeast. The increase from 6 percent to 12 percent represents 188,000 additional Caesearean sections per year and (based on the 3.2 additional days per delivery for Caesearean section) 6 million hospital days.

Of course, these data raise a number of questions which require further study. What was the reason for the increase? Why did it vary by region? Does the regional varation in the incidence of Caesearean section relate to regional differences in the incidence of conditions which are indications for surgery or to regional differences in surgical practice? Finally, before implementing policy to control unnecessary surgery, even more difficult questions must be addressed: what are the appropriate indications for the procedure? Under what conditions will this procedure improve the individual's health? What are the potential risks? How do alternative therapies compare in terms of risks and benefits?

Finally, it should be emphasized that not all increases in surgery are "unnecessary." The Bombardier study cited earlier illustrated increases in surgical rates which may have reflected greater access to needed services.

Prevention

Another example of the Center's statistical support of the Department's program planning and evaluation activities is in the area of health promotion. The Department is attaching top priority to the reduction of the incidence and the abatement, through secondary prevention, of the burden of disease and injury. Given the vast number of options that might go into a health promotion program and the scarcity of resources, it is imperative that the component initiatives be systematically articulated in a structure which minimizes redundancy and attacks as broad a range of preventable illness as possible.

The Center's surveys provide information that has been extremely valuable in targeting health promotional efforts. Knowledge of the extent and nature of the burden caused by various health conditions is needed in establishing preventive program priorities. The Center's statistics are also used to determine the modifiable personal habits and environmental factors that occur with sufficient frequency and consequences to warrant intervention. In planning a program, it is necessary to identify the population groups with the greatest need for preventive activities of various types. For instance, the Health and Nutrition Examination Survey points to women in low-income households as being particularly prone to obesity. Obesity has been shown to increase the risk of early death. Information regarding eating habits, physical activity, attempts to lose weight, and other considerations relevant to prevention is obtained through several of the Center's surveys. Similarly, the Center provides data essential to planning, monitoring, and evaluating prevention activities aimed at smoking, control of high blood pressure, accidents, and a variety of other personal and environmental factors.

Small-Area Data for Local Health Planning

The national health planning legislation passed in 1974 (P.L. 93-641) explicitly states that where possible, the newly-created planning agencies use existing data, including those provided by national programs, for planning activities. Furthermore, the high cost of conducting surveys and collecting data increases the demand among local areas for reliable data specific to their areas for health planning. Questions arise as to the feasibility of using data derived from national surveys for local purposes, if such use is deemed feasible, and to the appropriate methodology to be employed in utilizing national data.

Over the past fifteen years the National Center for Health Statistics has responded to these requests for small-area data in several ways. First, the Health Interview Survey (HIS) was designed to provide estimates of illness, disability, utilization of medical resources, periodic estimates of medical care costs, and other health-related topics for the Nation, four broad geographic regions, and the 31 largest standard metropolitan statistical areas (SMSA's). In addition, state estimates of disability based on HIS data have been published for 1962-4, and similar State estimates of disability and utilization of medical services have been published for 1969-71. Both of those publications employed the "synthetic" estimation technique, which operates as follows. Many of the health characteristics referred to above are related to age, sex, race and other demographic factors. The HIS can provide national and regional estimates of the particular health variable for each demographic (age, sex, race, etc.) group. These national (or regional) rates are then disaggregated to the State level by multiplying by the proportion of the State's population in the demographic group and adding over all demographic groups.

It is recognized that there are numerous problems associated with synthetic estimates, not the least of which is that they are subject to biases which are, to date, not quantifiable. A large empirical study recently conducted by the National Center for Health Statistics has indicated that improved estimation of small-area health characteristics can be achieved by combining a synthetic estimator with an estimator directly derived from survey observations taken in the local area of interest. A publication using this improved methodology with 1974-76 data from the HIS is currently in press.

The application of the methods described above to areas smaller than States (except for the 31 SMSA's already mentioned) is still in the research stage. The following two examples, however, illustrate uses of NCHS data at the local level in somewhat different contexts, one involving HIS data, the other using data from the vital statistics registration system.

Our National concern for equal access to health care has been translated into a large number of Federal laws which give special emphasis to medically underserved or health manpower shortage areas. The most comprehensive attempt to go beyond health manpower to population ratios in identifying underserved areas is the Index of Medical Underservice (IMU) which is used to designate medically underserved areas (MUAs) under the HMO Act and other health service programs. The IMU is a composite of four variables (infant mortality rate, physician to population ratio, percent of population below poverty level, and percent of population over 65). These variables are weighted to predict the areas that a group of informed experts would judge as medically underserved.

The use of such indirect measures to designate MUA's is the result of a lack of uniform small-area indicators across the United States which are more directly related to access to medical care. Although the HIS collects a great deal of information on utilization of health resources and, in 1974, included a special supplement on medical care needs, it does not provide sufficiently reliable geographic detail to directly designate MUA's.

It is possible, however, to use the HIS data to assist in critically examining MUA designations. Such a study is now in progress, and the preliminary results for non-metropolitan areas show that the differences between MUAs and non-MUAs are not as great as might be expected. For example, there was little difference between MUA and non-MUA respondents in the proportion with a usual source of care (80 percent in MUAs vs. 83 percent in non-MUAs). The proportions with no physician visit within the past year were also similar (29 percent in MUAs vs. 27 percent in non-MUAs), and the numbers of physician visits per person per year were identical (4.5).

It is possible to go even further and use the HIS data together with Census data, vital statistics, and manpower data, which are available for small areas, to define an index which is better able to discriminate between underserved and non-underserved areas. By choosing a few key variables which reflect access (e.g., availability of a usual source of care, absence of problems which delayed or prevented needed care, etc.), it is feasible to use multivariate statistical methods to choose those variables available at the local level which best predict medical underservice.

The use of natality and infant mortality data in planning maternal and child health programs is an areas in which health status data is relevant to health planning. For example, despite the large decreases in infant mortality in recent years, there remain very large geographic variations in mortality during infancy. In fact, during the period 1974-1975, the infant mortality rate for certain medium-sized non-metropolitan counties was 19 percent higher for both white and black infants than the corresponding rates for suburban counties of large metropolitan areas. The white/black differences also remain large: in 1975 the black infant mortality rate was 85 percent higher than the white rate. The black rate was fully 25 years behind the white rate! These considerations have led to a new effort on the part of the Bureau of Community Health Services to revitalize State maternal and child health programs. The vital statistics system allows the planner to examine county infant mortality rates over long time periods. Thus, the planner can identify areas with consistently high rates or unusual shifts in rates which indicate the need for appropriate intervention.

Natality data can also be useful to the planner for a number of purposes. First, in 42 States, data on the birth certificate indicate the month or trimester in which prenatal care began and the number of prenatal visits. These data provide an indication of areas or population subgroups (e.g., teenage mothers with no high school education) who are not receiving adequate prenatal care. Furthermore, intervention to improve the level of prenatal care can be evaluated rather quickly and inexpensively by using birth certificate data. Although the evidence is not conclusive, there are indications that adequate prenatal care is a determinant of healthy newborns.

Another example of the use of natality data at the local level is in planning and evaluating family planning programs. A priority of family planning programs is the reduction of birth rates among mothers at highest risk of infant loss (e.g., teenagers, women over 35 or 40, women with large numbers of children, etc.). The distribution of births by these characteristics can be used in targeting programs to meet the needs of high-risk women, and by following births over a period of time, in evaluating the success of the programs. It is also relatively easy to "translate" the distribution of births into expected infant mortality rates which can then be compared with actual rates.

Finally, the infant's birth weight (which is given on the birth certificate) provides another health status measure which should be examined to identify those mothers at risk of low birth weight infants.

Still another example of the uses of mortality data which goes beyond the population of mothers and infants is the examination of small area death rates for specific causes. Dr. David Rutstein and his colleagues have listed causes of death which are preventable under current medical knowledge. Thus, areas with high rates for these causes could be examined to detect any deficiencies in their health care delivery system. We are beginning to study geographic variations in these cause-specific death rates.

Epidemiology Program

Under the Public Health Law 93-353 discussed earlier, the National Center for Health Statistics (NCHS) is authorized to become involved in environmental and social studies that are related to health; "The Center may collect statistics on environmental, social, and other health hazards; determinants of health." For many reasons, NCHS has not emphasized these aspects during its first few years of implementation of the law. However, changes are underway.

The July, 1977, report of the Technical Consultant Panel to the U.S. National Committee on Vital and Health Statistics, on Statistics Needed for Determining the Effects of the Environment on Health, contains eight detailed recommendations. These include the establishment of a National Death Index, the strengthening of the epidemiologic capabilities of the NCHS, mainly concerned with analyzing, and interpreting epidemiologic data related to environmental exposures, and the resultant health status. The panel encouraged the use of the Health Interview Survey and the Health and Nutrition Examination Survey for the collection of data on environmental exposures, morbidity, and other environmentally relevant effects. They also recommended collecting more detailed information on occupational and industrial exposures in such national surveys.

The Center is responding to each of these recommendations. A national working group has been formed to implement the establishment of a National Death Index. This development is of great importance to the epidemiologic community for it will facilitate followup of persons exposed to suspected health hazards without violating standards of confidentiality.

Another major initiative in this area is the establishment of an epidemiology program at NCHS. While epidemiologic activities to varying degrees exist throughout the Center, there will be a focal point in the Office of Statistical Research. This office has already undertaken several epidemiologic studies.

A major purpose of this new program is to integrate the data needs of researchers in environmental health with the resources available at the National Center for Health Statistics. Toward this purpose it is proposed to more extensively analyze the existing data available at NCHS to answer questions currently arising in the field of environmental epidemiology. It is also proposed to alter some of the ongoing surveys within NCHS to provide explicit new information useful to epidemiologists.

Another important new epidemiologic activity is establishing a national health monitoring program on a more systematic basis. This involves developing statistical and computer methodology for displaying and detecting unusual disease time trends and levels by age group, race, sex, and geographic region. The forthcoming (1978) National Atlas of Mortality depicting race-sex-disease specific age-adjusted death rates for all major diseases by State Economic Areas is a first step in this direction by NCHS. This publication is a followup to the innovative mortality atlases published by the National Cancer Institute.

Such monitoring of primary cause of death, combinations of contributing causes, and unusually young deaths, will be conducted on a age-specific as well as age-adjusted basis. Hopefully, the methodology can be extended to birth defects from birth and infant mortality records, the Hospital Discharge Survey, and to morbidity mapping of Health Interview Survey data as well. There is evidence that important epidemiologic clues are being missed by failure to systematize such monitoring.

Should unusual disease patterns present themselves such that field studies appear warranted, epidemiologic investigation units in appropriate Federal agencies would be notified.

Valuable data that has been and is now being collected at the National Center for Health Statistics can be analyzed and interpreted in the light of known and potential environmental hazards. There are also surveys in existence that could be supplemented or altered in order to obtain additional information on the relationship of environmental factors to health status. Table I lists the relevant ongoing data systems at NCHS. Table II describes possible new data collection areas for environmental epidemiology which could be handled within the existing data systems.

Clearly new analyses of NCHS morbidity and mortality data, in combination with demographic and health habits information, will contribute significantly to epidemiology. Also, new information on national health habits will be invaluable in evaluatin-g prevention programs aimed at maintaining and improving health.

It should be pointed out that the Center can work collaboratively with the many Federal agencies whose primary functions involve environmental conditions. NCHS can provide for these agencies the outcome or the effect that has been produced by hazardous agents existing in the environment. Some reimbursable work programs in this area have begun with the Environmental Protection Agency.

TABLE I

NCHS DATA IN ONGOING SYSTEMS AVAILABLE FOR EPIDEMIOLOGIC ANALYSES

DATA SYSTEM	SELECTED DATA ITEMS	TYPES OF ANALYSES
1. Vital Statistics	Mortality (primary and secondary causes) Infant Mortality	Time-space mapping
	Natality (birth records)	Investigation of birth defects possibly related to environmental effects.
2. Health Interview Survey	Morbidity	Relate prevalence of acute respiratory or other illness with personal characteristics such as health habits and occupation. Morbidity mapping.
3. Hospital Discharge Survey	Morbidity and Mortality	Identify unusual patterns.
4. Health and Nutrition Examination Survey (HANES)	Blood and urine samples	Detection of environmental exposures and relate to health status characteristics.

TABLE II

POTENTIAL NEW STUDIES IN EPIDEMIOLOGY

UTILIZING EXISTING DATA SYSTEMS

DATA SYSTEM	NEW DATA ITEMS	TYPES OF STUDIES
1. Vital Statistics	Occupational data from death certificates	Analyses of rates by occupation.
	Infant Mortality and Births	Follow-back surveys to identify risk factors related to birth defects. Some may involve environmental conditions.
2. Health Interview Survey	More details on health habits. Leisure time activities.	Morbidity rate analyses.
3. Health and Nutrition Examination Survey (HANES)	New environmental exposure markers	Sub-surveys to answer specific questions in environmental epidemiology.

Statistical activities conducted by the National Center for Health Statistics are the major Department efforts in the collection, analysis, and dissemination of a wide range of general purpose health statistics that shed light on current and projected health problems of the Nation, the resources available to address those problems, the types of health services provided, and the quality and costs of those services.

The Center has a unique standing in its position as an impartial fact-finder, free of either actual or perceived dictation by others with respect to what its findings should be. There is widespread recognition within the Department and throughout the health community that NCHS is the principal health statistical agency in the Department of Health, Education, and Welfare. The Office of Management and Budget (OMB) has designed NCHS as one of the five general purpose statistical agencies in the Federal Statistical System--the one charged with carrying out major intelligence programs in the health field. OMB has urged that NCHS assume an even larger role in this area, still rbcognizing that numerous other agencies have important data gathering and analysis functions that are closely related to specific substantive health and social programs, and which often arise as by-products of those programs. The concept of Federal General Purpose Statistical Agencies is central to the government's desire--almost necessity--that there exist in each broad social and economic area an impartial fact-finding organization that embraces high standards, top professional and technical capability, and acceptance by both those who must supply information and those who use statistics for planning and management. A few agencies, notably the Census Bureau, the Bureau of Labor Statistics, and the National Center for Health Statistics meet these specifications, and have established themselves as invaluable sources of unprejudiced quantitative background and baseline data. These general purpose statistical agencies are a precious asset. Because they are impartial and protect the confidences of respondents, they are able to secure truthbul reporting from persons and establishments, and thus to provide evidence that is pertinent and closer to the truth than is otherwise obtainable.

It is essential for NCHS to continue to meet these broad needs for health data, such as in local areas and in Federal program management; medical audit and utilization reviews; planning and policy making; epidemiological investigations; production of Official U.S. Life Tables; actuarial projections by the Social Security Administration; intercensal population estimates and population projections by the Bureau of the Census; ana a multitude of uses by private industries dealing not only in health services and resources, but also in many other kinds of consumer services and products. NCHS produces data for or related to all of these purposes.

THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Since the National Center for Health Services Research was established in 1968, this organization has been the principal source of support in this country for general research on problems in the delivery of health services. Although other Government agencies support health services research, the NCHSR has been and remains unique. For in contrast with research undertaken in conjunction with operating programs, the research of this organization is not constrained by the needs and defined policies of a given program. As a result, it is possible for the NCHSR to undertake studies that rigorously question existing policies, that explore new areas and that generate analyses that will contribute to policy decisions in the future as well as the present.

When the NCHSR was given a statutory base in 1974, the legislation not only provided a broad mandate for research but added additional responsibilities in the form of a required Research Centers Program and an intramural research effort.

Research supported by the NCHSR program has directly influenced policy deliberations, health legislation, Federal health programs, and operational health service delivery systems.

It is possible to identify several projects supported by the NCHSR that have directly influenced the provisions of recent health legislation. The studies of Lester Breslow on health status and life style, long supported by this Center, are specificatlly cited by committee reports as justification for the National Disease Control and Consumer Health Promotion Act of 1975. A study by Robert Weiss and others, supported in part by the NCHSR through its research centers program, provided direct evidence of the problems associated with the influx of Foreign Medical Graduates and is cited as a basis for the FMG provisions in the Health Professions Education Assistance Act of 1976.

Recent amendments to the Social Security Act, P.L. 95-210, the Rural Health Clinic Services Act, permit payment of physician assistants or nurse practitioners when services are rendered by such individuals. The National Center for Health Services Research, through its early support of the Primex, Medex, and various other physician extender research and demonstration programs has been directly responsible for the acceptance of these physician substitutes. A substantial number of the articles used in the report, "Issues in Physician Extender Reimbursement," prepared by the Congressional Research Service and used by the Committees which initiated this bill, were funded by the NCHSR. The projects described in that report provided evidence that physician extenders are cost effective, represent no threat to quality, and are acceptable to the populations they serve.

Various committees and agencies of the Congress have made extensive use of findings from research projects supported by the National Center for Health Services Research in their policy and working documents. The report entitled, "Catastrophic Health Insurance", published by the Congressional Budget Office in 1977 is based largely on information provided by a series of studies funded through contract by the NCHSR. The report on the "Policy Implications of Medical Information Systems", prepared by the Office of Technology Assessment and published November 1977, is based entirely on projects initiated and funded by the NCHSR. Extensive use if made of research findings from NCHSR supported projects in a working paper, "Adult Day Facilities for Treatment, Health Care, and Related Services," prepared in 1976 by the Special Committee on Aging, United States Senate.

It is also possible to document the impact of the National Center for Health Services Research on the programs of the Department of Health, Education and Welfare. This Center supported the development of the health scarcity index, which is now being used to identify those shortage areas that must by law be given priority in resource allocation decisions. This index is used in setting priorities for Community Health Centers, in determining priorities for Health Maintenance Organization grants, and in assigning priorities for grants for health care facilities developed under the Planning Act. The NCHSR developed and demonstrated the feasibility of the Cooperative Health Statistics System which is being implemented by the National Center for Health Statistics. The Medical Care Review Organization project initiated in 1970 provided the working model for the Professional Standards Review Organizations (PSRO). The NCHSR is responsible for the initial development of a simulation model for generating national health insurance estimates which the Health Care Financing Administration is now employing in a modified version to examine the potential costs of various NHI proposals.

The direct influence of this research program on operating health care systems and consumers is more difficult to document. But it is possible to cite at least a few examples. A medical information system currently being employed by the Harvard Community Health Plan to provide most of the information required for patient care, patient management, and administrative support was developed with funds from the NCHSR. Research demonstrating the feasibility and cost-effectiveness of computer assisted electrocardiographic analysis can be attributed to this organization. The growth in the use and acceptance of physician extenders can be traced to the research and demonstration projects of this program. Finally, a management information system, whose demonstration and evaluation was funded by the NCHSR, has been shown to result in savings of $3.00 to $5.00 per patient day. Were such systems in use generally, the savings from this one innovation would be in excess of $1.0 billion annually.

Perhaps more important, but harder to document, is the general impact of the NCHSR program. A substantial part of the expert testimony provided in Committee hearings is given by researchers who, by virtue of support from this organization, have been able to acquire their information and expertise. The influence of this small but active program is pervasive in the health area and its efforts are crucial to the formulation of sound and responsible legislative and program initiatives.

In a very real sense, the NCHSR is a service organization which, on the one hand, has the responsibility for identifying the information needed by various kinds of decision makers and, on the other, for stimulating and supporting both the production of that information and its dissemination to those with a need to know. The NCHSR has, therefore, expended considerable effort in developing a process for identifying the relevant issues and critical questions that need to be addressed by the research community. In conjunction with this process, the organization has moved from a role of passively accepting research proposals submitted according to the preferences of researchers to an active role as a solicitor of research on crucial problems.

The progress made in improving the dissemination of research findings has paralleled the progress made in the planning area. The NCHSR now has a regular and extensive publication program. The emphasis in these publications is on brevity and comprehensability. More than 30 titles have appeared in the past year, with circulation ranging between 10,000 and 20,000 copies depending on the nature of the material. To complement the publication activity, the NCHSR has initiated a program of dissemination workshops. These meetings are being held in various parts of the country with small groups of state and local officials that have expressed their interest in hearing researchers discuss problems of immediate interest.

Finally, I would like to note that one of the most significant provisions of P.L. 93-353 is the requirement that the National Center for Health Services Research establish an intramural research program. This activity has resulted in attracting a number of prominent researchers to take positions with the NCHSR as visiting scientists or Service Fellows. The presence of this talent, not heretofore available to the Public Health Service, has made it possible to expand the analytic capability of this organization to the advantage of the Department and the general research program of the Center.

I believe it is critical to emphasize the importance of maintaining an independent research program in the Department of Health, Education and Welfare. It is important, indeed essential, to develop and maintain a research program that produces scientific, valid information for future as well as immediate needs, that is free to be innovative rather than constrained by current program efforts and policy initiatives or decisions.

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HEALTH TECHNOLOGY MANAGEMENT

AT THE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Final Phase I Report for the Secretary

Prepared by

Office of the Assistant Secretary for Planning and Evaluation

and the

Office of the Assistant Secretary for Health

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** These appendix items are attached

INTRODUCTION

-- How many tonsillectomies performed in this country are necessary?

-- What are the health outcomes from coronary bypass surgery versus drug therapy ?

-- How can new laboratory findings be linked with bedside practice?

-- What institutional or professional qualifications should be required of those proposing to perform open heart surgery?

-- What market incentive mechanisms can be used to stimulate development of lagging or absent beneficial and cost-saving health technologies?

The Problem

There is widespread agreement that twentieth century biomedical research and technological innovation have been responsible for profound improvements in human health. Some diseases have been eradicated; others can now be prevented; life itself has been extended; and much pain and suffering has been alleviated.

There is now emerging, however, a consensus that many technologies have been widely adopted into medical practice in the face of disturbingly scanty information about their health benefits, clinical risks, cost-effectiveness, and societal side-effects; that the use and overuse of other technologies has persisted long after it was evident that they were of marginal utility, outmoded, or even harmful; and that still other well-validated innovations have been inordinately slow in finding their way to patient care.

The consequences of such failures -- including spiraling costs with less than commensurate health improvements and iatrogenic health problems -- are now posing major dilemmas for providers, planners, patients and third party payers about the uses of existing and emerging technologies .

The Health Technology Environment

Evidence of a raised health technology consciousness is accumulating:

-- Dozens of articles about the use and abuse of technology have been written recently by prominent health officials and researchers;

-- Blue Shield has announced that it will no longer reimburse routinely for 28 medical and surgical procedures;

-- Two National commissions on biomedical research have been created in recent years one of which was Presidentially appointed;

-- Senator Kennedy has held a series of hearings, and Congressman Moss has proposed technology control-related legislation;

-- The Office of Technology Assessment has issued five reports on medical technology, and the Institute of Medicine will soon publish the results of a year-long study on the process of adoption and diffusion of hard technology;

-- Public interest groups are demanding increased consumer protection;

-- Private insurers and employers are searching for guidance on the relationship between the use of technology and soaring health care costs.

While there is increasing (though far from universal) advocacy for managing health technology toward serving the public more efficiently and effectively, there are divergent perspectives on who would take the lead role in integrating efforts toward that end and the means to be employed. For example:

-- Many research scientists view a stronger government role as a threat to beneficial technological innovation;

-- Many practicing physicians view such efforts as compromising the physician-patient relationship and their independence of professional judgement;

-- Many drug and device manufacturers are concerned about government interference with the marketplace and additional restrictions with which it is costly to comply;

-- Still others are concerned about overmanagement and its potential for increasing delays in the flow of beneficial innovations to bedside practice.

The multiple problems arising from technology development and utilization have not emerged overnight, and even the most carefully devised Department initiative is unlikely to provide a "quick fix" to the extraordinarily complex set of problems involved. This report proposes a major management initiative, but it is only one step toward a long-range solution that must take into account the complexities of technology development/transfer/utilization, and the divergent priorities, perspectives, and values of the various parties-at-interest.

The alternative to adopting a new strategy is to continue the current essentially laissez-faire approach which too frequently leaves development and adoption of technologies to the intellectual curiosity of researchers, the marketing strategies of manufacturers, the slowly evolving consensus of practitioners, the demands of usually uninformed consumers, and the incentives of the relatively unconstrained health market.

The Department of Health, Education, and Welfare

This report focuses on medical technologies (drugs, devices, and medical and surgical procedures) with which this Department is involved in three primary ways:

-- it develops technologies both intramurally through employee scientists and innovators, and extramurally through support of research and development activities;

-- it evaluates existing and emerging technologies to attempt to understand their value and their implications for health and society;

-- it recognizes technologies by regulating them, by buying them, by reimbursing for them, or by otherwise contributing to their use or non-use.

Yet for all of its involvement, the Department has no strategy for systematically linking the life cycle of technology development, evaluation, transfer, diffusion, utilization and phase-out. Nor has it either expected such a strategy of its agencies (with the exception of FDA) or provided resources to construct one. Consequently,

-- the "knowledge development" agencies (like NIH and NCHSR) each decide independently which technologies they will examine, how they will examine them, and how they will handle the results;

-- the "action agencies" (such as HSA, Medicare, Medicaid, and the PSRO program) lack both the technical information to carry out their responsibilities and the links to the knowledge development agencies through which to negotiate examination of the technologies for which they need action-supporting information;

-- results of technical evaluations appear in the research literature, but often do not come to the attention of practicing physicians or those officials responsible for making reimbursement decisions, and developing regulations, legislation and standards;

-- technology evaluation activities are extensive, but existing technologies (particularly medical and surgical procedures) receive too little attention;

-- considerable effort is focused on efficacy and safety evaluations, but little is done about the cost-benefit and cost-effectiveness implications and virtually nothing is done to examine general societal impacts;

-- the linkages between technology studies and action to impede or stimulate technology transfer and utilization are ad hoc and often fail.

As a result, DHEW is currently seeking a new strategy for handling medical technologies to assure that they are more carefully scrutinized for their efficacy and effect on health outcomes, more rapidly introduced or phased out of practice, more efficiently organized and equitably distributed, and more appropriately and effectively used. Such a strategy must be able to provide a balance between controlling costs of health care and over-controlling technological innovation at the expense of quality of health care.

From our past experience with drugs, it is known that expanding technology management will place difficult and sensitive decisionmaking authorities in the hands of government. Although extensive intra-Departmental and extra-Departmental consultation is planned, in the final analysis DHEW officials will have to weigh uncertain evidence of scientific inquiry against their estimates of the value of quality of life and costs. Such decisions cannot be made without their inevitable risks and errors. Nevertheless, the Study Team believes that the systematization of currently fragmented processes and the rendering explicit of presently implicit decisions and actions sum to a justified and responsible step.

The Charge to the Study Team

On July 20, during his testimony before the Senate Subcommittee on Health and Scientific Research, Assistant Secretary for Health Dr. Julius Richmond was asked by Senator Kennedy if the Department could develop an outline for a DHEW systems approach to technology management. At the same time, Assistant Secretary for Planning and Evaluation Henry Aaron had advised Secretary Califano that his staff was preparing a decision memorandum on technology management in the Department. As a result, the Office of the Assistant Secretary for Planning and Evaluation (P), in collaboration with the Office of the Assistant Secretary for Health (H), was asked to conduct a month-long Phase I study of this issue. P and H staff met jointly with representatives of the Department's health agencies and asked them to produce, within ten days, reports of their agencies' technology-related activities. (See Appendix Tab 2 for the Agency Report Outline.) The resulting reports (Appendix Tabs 3 through 11) were analyed and compared with the Study Team's conceptual framework for technology management to form the basis of this report.

Focus of the Phase I Study

The focus of this study is the development of a Departmental strategy for ensuring that emerging or existing health technologies are systematically evaluated and that results of those evaluations are linked to explicit actions -- using intervention mechanisms available to the Department -- to stimulate or retard development; encourage/discourage/or place constraints on utilization; or effect phase-out.

The Study Team examined current Departmental activities to discern (1) whether there exists in the Department structures and processes for systematically evaluating and acting to influence the development and use of technologies, and (2) whether technologies are in fact being systematically addressed. It was concluded that neither was the case. The Team then developed a linked, six-component conceptual design through which systematic action could occur, compared current Departmental technology-related activities to that design, identified deficiencies, and recommended remedial actions. It was recognized that the Department's resources could not support such thorough scrutiny of all the new, existing and developing health technologies (expert estimates of which range from 8,000 to 150,000) and that many did not require that level of attention. While the agencies would continue to address other important technologies through development of their own analytic agendas, this report proposes that the Department, through a broad-based, participatory process, annually select a small number of high-priority technologies, and subject them to an especially rigorous evaluation and action process.

The Study Team concluded that in order for such a system to operate effectively, it should be managed by an office at the Department level whose functions would include the following:

-- develops operational procedures in collaboration with DHEW agencies, other Federal agencies (e.g., VA, DOD, OSTP, NASA, NSF) and outside parties at interest (e.g., academic health science centers, medical specialty groups, providers, insurers, public interest groups, Institute of Medicine, manufacturers);

-- manages the annual process related to high-priority technologies;

-- provides technical assistance to DHEW agencies in their management of non-priority technologies (based on experience with the high-priority system and targets of opportunity);

-- serves as a catalyst for formulating Departmental policies on technology management issues;

-- functions as the Department's focal point for (though not exclusive agent of) liaison with other Federal agencies and outside parties at interest;

-- functions as a "switching point" for incoming inquiries related to health technologies being addressed within the Department and for Departmental inquiries about related activities outside the Department;

-- monitors DHEW agencies' management of technologies on an ad hoc basis to obtain feedback on agency-based techniques, and to identify gaps and targets of opportunity for technical assistance or the need for further conceptual development or formal evaluation.

Limitations of the Phase I Study

The Phase I study is not intended to result in a full-fledged prescription for DHEW technology management, but to produce a conceptual framework to be used as a foundation for designing such a system in the future. Consequently, this report does not attempt to provide information on (1) the technical abilities of the knowledge development agencies and their staffs to conduct or sponsor the types of technical studies that need to be applied; (2) the quality of such studies as are now being done; (3) the abilities of the action agencies or their staffs to wield the intervention mechanisms through which DHEW can impede or stimulate development or utilization of a technology; (4) the various options, with their pros and cons, for resolving the deficiencies identified by the study team.

Important study limits were:

(1) information was limited to reports prepared by the agencies within ten days; the Study Team had no time to do independent data gathering or verification;

(2) activities within DHEW only were examined excluding significant and relevant activities of such Federal agencies as the VA, DOD, NSF, NASA, OSTP, and OTA, and such private entities as manufacturers, medical specialty groups, academic health science centers, the Institute of Medicine, and provider and consumer groups;

(3) analysis was restricted to programmatic and systems approaches and specifically did not consider which organizational elements within DHEW might be assigned such functions or the levels of any additional staffing or funding that might be required;

(4) medical technologies only were examined; thus, health care system management, rehabilitation, mental health and environmental technologies were excluded as were research and development activities per se.

Consequently, it is recommended that a Phase II study be promptly initiated and that it focus on those aspects which will not be included in this first report. The dimensions of the Phase II study are described in Appendix Tab 13.

Two Important Distinctions

The technical terms used in this report are presented in the Glossary (Appendix Tab I). However, two distinctions are needed at this point to sharpen the discussion:

(1) the technology system vs. "technology assessment"

This report focuses on a management process and a structure (a system) for examining and influencing technologies as they move from development into practice. The popular term "technology assessment" refers only to one type of technical study that may be applied to a given technology, and it is addressed as one part of Section IV.

(2) knowledge development agencies vs. action agencies

For the purpose of this report, the Study Team has come to view agencies (or parts of agencies) as having as a primary orientation either the development of knowledge about technologies (e.g., NIH or NCHSR) or the use of that knowledge to undergird or justify actions taken to impede, promote, or otherwise set conditions on the use of a technology (e.g., HSA or HCFA). It is recognized that this distinction is oversimplified -- most knowledge development agencies have some action dimension (even if it is confined to publication of information) and some action agencies have developed considerable knowledge development capability (e.g. OPPR in HCFA). Subsequent studies of management changes will need to weigh the desirability of maintaining these duplicative and overlapping functions. The typing of agencies' primary functions is useful for purposes of examining missing or ineffective linkages and their costs.

A Note About Legislative Steps in the Process

Several legislative authorities will expire this Fiscal Year (e.g. NIH, BHPRD, NCHSR, NCHS). The Study Team believes that no new legislative authority is required for the initial steps necessary to initiate the proposed technology management process and structure. They are within the Department's administrative authority, and there is considerable Congressional interest in having the Department move forward on the matter. However, should new legislation prove desirable for such proposals as targeted appropriations and positions, the time available to advance them for Congressional consideration will be very short.

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I. THE CONCEPTUAL FRAMEWORK FOR A PROPOSED TECHNOLOGY SYSTEM

Medical technologies frequently move from a developmental stage through a fragmented and haphazard process into utilization in the health care system where they may assume a life of their own unrelated to proven efficacy, costs, risks, or benefits. Similarly, the process of technology development and transfer within DHEW is at least as fragmented and haphazard. Different types of technology studies are scattered throughout the Department, and there is no central clearinghouse to provide information about existing, new, and emerging medical technologies. Moreover, study results from knowledge development agencies are not linked systematically to action agency mechanisms to restrict or stimulate transfer and utilization of technologies, and no Departmental unit is responsible for addressing these issues comprehensively.

Recognizing that the Department currently has neither a strategy for managing medical technology nor an analytical paradigm upon which to develop such a strategy, the Study Team has designed a proposed technology system and has structured this report in terms of the proposed system. Figure 1 on the next page depicts the conceptual framework for the system which includes a six-component process:

1. Identification and screening of candidate technologies
2. Centralized priority setting of technologies to be scrutinized
3. Conduct or monitoring of the technical studies
4. Translation of technical findings for relevant users
5. Coordinated decisionmaking to restrain or stimulate the technology
6. Intervention mechanisms to implement the decisions

As shown in the following sections of this report, two of the six system components have a reasonably strong base of activities within the Department while four others are absent or very weak. The Study Team has concluded that it is important to correct the deficiencies of the existing components and to establish the absent components because all of them are needed to assure that medical technologies are examined and that explicit decisions are made about their values and limits.

The components of the proposed system and an analysis of what is now being done, as well as what is not being done, within each component constitute the subsequent sections of this report:

Monitoring and Screening (Section II): proposes development of a technology information base, and a process for "coarse screening" of health needs and existing and developing technologies to be analyzed or tested.

Development of an Analytic Agenda (Section III): proposes a process of subjecting technologies which pass the "coarse screen" to a fine screen resulting in approval of an Annual Technology Analysis Agenda for the Department. It also includes decisions about what types of studies are to be conducted and their assignment to appropriate agencies.

Analysis and Testing (Section IV): outlines five classes of technical studies by which medical technologies might be scrutinized.

Review and Synthesis (Section V): discusses synthesis and "translation" of results of technical studies and other expert opinion into a format for policy and program actions.

Decisionmaking (Section VI): proposes development of a process for explicit departmental decisions which link findings with coordinated interventions to restrain development or stimulate technology transfer and utilization.

Implementation/Intervention Mechanisms (Section VII): outlines intervention actions flowing from coordinated agency decisions and feedback of the intervention impacts to the monitoring and screening component.

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II. MONITORING AND SCREENING

- What system is available to identify and catalog existing and emerging technologies?
- How could existing and emerging technologies be screened to determine which might warrant high priority scrutiny?
- How can the Department identify and monitor the health needs in order to judge which problems warrant high priority scrutiny?

A. Description of Monitoring and Screening Component

The Monitoring and Screening component identifies those technologies which should be regarded as serious candidates for detailed study. This component consists of three elements. The first is a data base of information about existing and emerging technologies, which sets the first rough boundaries on the range of technologies to be considered.

The second element is an inventory of the causes of health impairments and disabilities. This inventory would not only rank the causes of death for various age groups, but also array the causes of various levels of impairment such as inability to work or confinement to bed. Information from the monitoring of health impairments would thus help in selecting those technologies which deserve serious consideration for intensive study. Information from the impairments inventory could also help provide guidance for new technology development efforts.

The third element in the Monitoring and Screening component is a set of criteria for "coarse screening" to identify specifically the technologies that are candidates for detailed study. The screening criteria might be based on such factors as magnitude of the health problem to which the technology addresses itself, the potential dollar and social costs of the technology, prominence of problems concerning the utilization of an existing technology, or the urgency of safety concerns. After candidate technologies have been identified through the application of "coarse screening" criteria, they would move on to the phase of Agenda-setting (See Section III) where they would be subjected to "fine screening" criteria to produce the Annual Analytic Agenda of technologies which would actually be studied in detail.

B. Agency Activities and Deficiencies

1. Monitoring and Screening of Technologies:

Analysis of the agencies' reports reveals that there is currently no system to identify existing and developing technologies or to provide the "coarse screen" to select candidate technologies to be studied. Not only is there no catalog of such technologies, either in or outside of the Department, but expert estimates of the total number involved range widely from 8,000 to 150,000 major and minor procedures and products. While none of the agencies has a systematic monitoring and screening mechanism, four of them report activities which could contribute to the development of the needed system.

NCHS reports that its 20 data systems include considerable macro data on utilization and diffusion of selected existing medical technologies and that it would be feasible to add to its ongoing surveys some questionnaire items about additional technologies. For example, NCHS can currently provide macro data which show increases or decreases over time of different types of surgical procedures such as cardiac catheterization and hip arthroplasty. Similarly, the annual hospital survey supported by NCHS includes items which enable the center to track the diffusion rate of such hospital-based technologies as open heart surgery units, radioisotope facilities and hemodialysis (Appendix Tab 9, pages 3-6).

FDA reports that it maintains a computerized system for post-market surveillance of approved drugs. This system stores adverse drug reaction reports received from manufacturers, hospitals, physicians, the World Health Organization and other sources, including the literature. FDA also has a system that lists approved drug products.

NIH reports that developing technologies are under continuous surveillance by the Institutes as part of their ongoing cycle of program planning, but this surveillance activity is informal.

NCHSR reports that its intramural staff have developed a concept design for an "ideal system" to identify, screen, track, and forecast developing technologies, and that this concept design for a computerized system has now been embodied in an RFP in order to have an outside contractor examine both its feasibility and its cost-effectiveness. The system is designed to provide NCHSR with a systematic way of identifying the universe of public and privately funded emerging technologies that should be candidates for its technology studies program and, more particularly, to provide the base for determining the optimal time at which to conduct these studies--i.e., before the technology is too far advanced to modify through public policy intervention and yet sufficiently developed so that it is possible to obtain adequate information about the technology and its potential applications. Since it will take some time to demonstrate the feasibility of such a system, the agency has also developed an interim informal approach for identifying and setting priorities for the study of developing technologies.

Thus, it appears that considerable work is already under way to determine the feasibility of the systematic monitoring of developing technologies which might warrant serious study, but that comparable conceptual work has not been done for existing technologies. Such a mechanism needs to be designed and tested for feasibility in the near future.

2. Monitoring and Screening of the Causes of Health Impairment: Analysis of the agencies' reports reveals that the Department also does not have a systematic inventory arraying the causes of health impairments and disabilities which could be used as a basis for the selection of high priority technologies for study. Nevertheless, there is considerable activity in the collection of mortality and morbidity data, and agency efforts in these areas could provide the foundation for an expanded monitoring program.

NCHS reports that it is collecting a large volume of data concerning the causes of death and, through survey questionnaires, data on the causes of illness as well. NIH, CDC, and HCFA are also collecting information on the incidence and prevalence of disorders which are relevant to their missions. However, there is not enough information with which to correlate the incidence of the various diseases with the degrees or levels of impairment that they produce. For example, one would want to know how many people with heart disease are symptomatic but working, how many are unable to work but ambulatory, and how many are so incapacitated that they are confined to bed. Determining the true "cost" of a disorder, and thus value of a technology to alleviate it, depends to some extent on knowing these impairment levels, and not simply the brute causes of death or illness. The morbidity and mortality data currently being collected NCHS, NIH, CDC, and HCFA can serve as the basis for a more systematic inventory and array of the causes of impairment levels. Such a mechanism for systematically collecting, analyzing, arraying, and displaying the causes of health impairments needs to be developed since it, together with the system for monitoring the technologies themselves, constitutes the front end of a systematic Departmental approach to technology management. Without such a system, it is quite possible that the most critical technologies will be overlooked, or that the limited funds available will be invested in the study of lower-priority technologies.

C. Recommended Approaches

It is recommended that the Department determine the feasibility and cost-effectiveness of developing within one or more of the agencies, a system to: (a) identify and monitor technologies; (b) inventory and monitor the causes of health impairments; and (c) screen the existing and developing technologies to select candidates for intensive study. The system should be capable of serving both the knowledge development and the action agencies of the Department. Since it may not be possible to design and launch such a system in less than two years, an ad hoc interim approach will need to be conceptualized and employed.

III. THE ANALYTIC AGENDA

- How are the highest priority technologies selected for scrutiny from among the pool of candidate technologies?
- How can a better balance be struck between the information needs of the action agencies and the research interests of the knowledge development agencies?
- How can it be assured that those agencies capable of conducting the needed studies will apply them to the priority technologies in a timely manner?

A. Description of the Analytic Agenda Component

This component comprises the annual preparation of a Technology Analysis Agenda which reflects the Department's priority needs for technical information about existing, new, and emerging technologies. Managed at the Department level, the collaborative agenda-building process includes agency staff, representatives of other Federal agencies, and outside parties-at-interest.

The process of developing the analytic agenda serves as a "fine screen" which subjects the list of candidate technologies (identified earlier through the Monitoring and Screening component) to a more selective set of criteria such as the resources and skills of the knowledge development agencies, the information needs of the action agencies, the researchability of the problem, and the time constraints. For each technology that passes through the fine screen, the process also determines what types of studies are most appropriate to the technology to be studied, which agencies will be responsible for conducting the studies, and which potential users are likely to be most interested in implementing the study results. The Agenda formalizes the Department's intent to carry out 15-20 high priority studies per year, but does not replace the development of analytic agendas by the individual agencies. After the Agenda is approved by the Secretary, or his designate, the Departmentally-assigned studies form the core and first priority of the analytic responsibilities of the agencies.

B. Agency Activities and Deficiencies

Agenda-setting occurs at the agency and sub-agency levels, influenced by priorities (not necessarily technology-related) identified through some of the following:

- the annual Departmental Planning Guidance
- OS review of the Agencies' evaluation plan submissions
- Congressional mandates and requests
- staff, peer and constituent contacts

Proposed agency agendas filter up to bureau and agency heads coordinated by review committees or by the agency planning office. Decisions are made in consideration of resource availability and perceived salience of the candidates, with the decisions then remanded to the working staff for implementation.

The primary deficiencies of this agency-based process are:

1. The needs of the action agencies for studies of specific technologies are not being incorporated into the agendas of the knowledge development agencies, and there are no interagency mechanisms to reach consensus on agency priorities or to provide arbitration in the absence of consensus.

2. There is no assurance that the types of studies initiated are conducive to policy-relevant questions being raised about the target technologies.

3. Opportunities for potentially valuable collaborative efforts are often missed because agencies are not aware of each other's capabilities and needs.

4. There is no Department-wide clearinghouse which serves as an information point for the agencies and private sector groups which need to know what studies are in progress or have been conducted on a particular technology-based problem.

These deficiencies give rise to action agencies attempting to develop staff capability to conduct studies relating to their own needs, or awarding technology study contracts that may duplicate other efforts, or remaining without the technical information to undergird their mandated functions.

C. Recommended Approach

It is recommended that the concept of a Departmental Technology Analysis Agenda be adopted, and that the responsibility for management of the annual process be lodged at the Department level.

IV. ANALYSIS AND TESTING

-- What types of technical studies should be used to examine technologies?

-- Does the Department currently conduct such studies, and where is improvement required?

A. Description of the Analysis and Testing Component

The Analysis and Testing component develops technical information and data about existing, new, and developing medical technologies. This information will include that which is now unknown, as well as the validation or refutation of what is believed.

In the preceding component (setting the Analytic Agenda), the Secretary, or his designee, would decide which types of technical studies should be applied to given technologies, and would assign responsibility for their conduct to certain agencies. Different types of studies are employed to address the diverse questions germane to different medical technologies. Classes of studies conducted are:

-- efficacy and safety

-- cost-benefit or cost-effectiveness

-- standards development

-- comprehensive technology assessment

-- cross-cutting and methodological

Each type of study is designed to provide information about a different facet of a technology; each is conducted using different methods and analytic tools; and each type requires different combinations of skills, disciplines and resources.

B. Agency Activities and Deficiencies

The one month time constraint limits this report to: (1) specifying whether or not such studies are now being conducted and (2) identifying what the agencies and the Study

Team perceive as the problems associated with their conduct. Independent judgments about the availability of resources and the quality of studies or staffs could not be made without on-site evaluation. Problems include the following:

-- Agencies doing the analysis and testing are seldom linked effectively to action agencies. As a result, questions of interest to action agencies are usually not incorporated into the study designs;

-- Action agencies frequently do not have the time or expertise to overcome chronic state-of-the-art limitations that compromise the quality of the studies they undertake themselves. Hence, they hesitate to implement the results of studies they sponsor;

-- Similar types of studies are conducted or sponsored in several agencies, but a "critical mass" of skills are not necessarily assembled in one place to conduct or sponsor such studies.

-- Current limitations of the state of the art of analysis and testing techniques pose barriers to obtaining definitive answers to many questions (e.g., health outcomes, long term risks).

<u>Efficacy and Safety Testing</u>

Efficacy and safety studies are conducted to obtain evidence about the medical usefulness and risks of drugs, devices and procedures. Since neither efficacy nor safety measures are absolute, these studies weigh probable health benefits against probable risks. Agency reports indicate a strong base for the conduct of efficacy and safety studies, particularly of new drugs and medical devices:

-- NIH, in FY 1975, conducted some 750 clinical trials at a cost of over \$100 million (about 60% were solely drug, vaccine, or biologics trials);

-- FDA evaluates the results of drug and device testing conducted by applicant manufacturers. In addition, it has a small intramural program to evaluate performance of such technologies as radiological equipment, cardiac pacemakers, and intraocular lenses. The agency is required by law to determine the safety and efficacy of new drugs and devices before they are marketed; and

-- CDC attention is mainly on tuberculosis and VD therapies. These include both testing and epidemiologic studies of efficacy and effectiveness.

The major deficiency identified by the Study Team is that the vast majority of the efficacy and safety studies are focused on new or developing technologies. Rarely are studies conducted on existing technologies to determine if they are outmoded or as effective or safe as generally believed (except when they are used as controls in testing developing technologies). This deficiency is particularly applicable to medical and surgical procedures.

Cost-Benefit (CBA) and Cost-Effectiveness (CEA) Analysis

These primarily economic analytic tools are employed to (1) produce measures of costs relative to the economic value of benefits (CBA), and (2) compare costs of alternative ways of achieving a given level of effectiveness or compare levels of effectiveness when a given cost is invested through alternative approaches (CEA). Agency reports suggest that little of this kind of analysis is being conducted:

-- NCHSR spent about one-fourth of its FY 76 budget in applying such analyses to computer-based screening, diagnosis and treatment technologies as part of comprehensive evaluations of demonstration projects;

-- HCFA's Office of Policy, Planning, and Research staff have previously been involved in CBAs related to arthritis, specific cancers, and motor vehicle accident prevention, but HCFA itself is not currently conducting such studies.

-- NIH reported small scale efforts hampered by state-of-the-art problems in applying such studies to disease research. NIH's report expresses the opinion that such studies are more appropriately the responsibility of other DHEW agencies.

-- CDC reports studies on costs and effectiveness of different venereal disease tests, screening techniques, and treatment schedules.

CBAs and CEAs are highly technical, specialized techniques that should be conducted by personnel trained in quantitative and economic analysis. Considerably less is known about their reliability and methodological pitfalls than risk benefit studies. Thus, they should be located in an environment where staff can collaboratively address state-of-the-art problems, and where a "critical mass" of experience and knowledge can collegially sustain a high quality initiative. This objective suggests the centralization of such activities rather than their partition among several biomedical or health services research-oriented agencies.

Development of Standards

Standards development activities usually proceed from a base of technical information developed through one or more of the previously described types of testing and analyses. But the analysis and synthesis of that information creates new information that justifies the categorization of standards development as a class of studies.

-- FDA sets standards for the quality, efficacy, and safety of drugs and devices being considered for market approval;

-- HCFA develops medical necessity, quality, and appropriateness standards to guide PSROs in their local review activities, e.g., the agency awarded contracts totalling $1.8 million to eight health professional groups to develop sample criteria and standards sets for medical necessity of hospitalization and appropriateness for use of a variety of procedures, tests, and drugs; and

-- BHPRD develops standards for access, supply and distribution (through the National Health Planning Guidelines) to assist State and local health planning bodies.

A major problem cited by nearly every agency developing or using standards is the need to implement and/or update viable standards as quickly as possible and the inadequacy of the technical knowledge base for doing this. It is in large part this mismatch between the important need and the lack of available data which makes this area of analysis particularly deserving of attention.

Moreover, the absence of linkages between agencies responsible for standards development and other knowledge development agencies means that the data necessary to undergird standards development is not being produced; the methodology for transferring technical data into standards is weak and the process for doing so superficial. As a result, the standards evolved are more normatively than empirically based. In part, this state of affairs can be attributed to recent pressures to produce multiple standards for PSROs and HSAs without delay. However, these shortcomings will not be overcome without a far more integrated process that recognizes the need for continuous updating in response to new data, increased study efforts including methodology, and increased realism about the current limitations of the state-of-the-art.

Comprehensive Technology Assessment

Comprehensive technology assessments examine holistically the potential future consequences of new or emerging technologies on such societal systems as the economy, the physical environment, the law, institutions, mores, ethics, and broad social fabric. These interdisciplinary assessments scrutinize what the proposed technology is intended to achieve, whether those achievements are socially desirable, who might benefit or lose from the achievement, what unintended consequences are likely, and what policy options are available to either avert side effects or to prepare more effectively for the unintended social change likely to be triggered by the new technology. Currently, there are isolated instances of examinations of discrete societal areas:

-- economic impacts have been examined by NIH, FDA and NCHSR. (For example, FDA examined the cost to manufacturers and consumers of complying with new performance standards of x-ray machines);
-- behavioral aspects of venereal disease carriers and treatments have been studied by CDC;
-- environmental impact assessments have been conducted by NIH (on Recombinant DNA Molecule research) and FDA (on radiation technology); and
-- societal impact has been examined in three NIH studies. The study on the totally implantable artificial heart is considered a forerunner of comprehensive technology assessment despite its small scale because it involved a multidisciplinary team which analyzed a broad range of societal implications of the device.

No agencies are currently conducting comprehensive technology assessments. This deficiency should be remedied in light of the increasing recognition that societal impacts of some technologies may be more profound than their direct economic cost. Lack of technical knowledge, resources, and a mandate for such analysis have apparently precluded its development, although last year NCHSR examined the feasibility and utility of such studies (see Part D of this section) and NIH has considered "preliminary" impact assessments as part of its "consensus building" strategy (see Section V-D).

Methodological and Cross-Cutting Studies

These studies are typically undertaken to provide background information to the agency or to overcome state-of-the-art research limitations. Agency-reported activities of this type include:

-- case studies of technology adoption and diffusion by HRA and NCHSR;

-- use of computers for biomedical information transfer by NIH;

-- development of models for assessing the quality, safety and performance of drugs, devices and biologics by FDA;

-- identification of new technologies and their implications for manpower, operating costs and capital expenditures by BHPRD;

-- development of models to predict treatment outcomes, control measures, and prevalence of venereal disease by CDC; and

-- development of a model to forecast net social value of dental caries prevention procedures by NIH.

No significant work is being done to relate magnitude and seriousness of health problems to absent or lagging technology development and allocation of R&D resources. For example, heart disease is by far the leading cause of death, but it commands approximately 10 percent of the R&D allocations. Very little theoretical work is being done on adoption and diffusion of medical technologies, and this is particularly important since comparable studies in other technological fields which show slow rates of diffusion may be misleading in light of the absence of a classical market structure in the health field.

C. Recommended Approaches

It is recommended that:

-- there should be a new pilot program initiative for cost-benefit and cost-effectiveness analyses and a similar program for comprehensive technology assessment. Both efforts should be evaluated after three years to determine their reliability and utility to the health system and other relevant societal systems;

-- increased attention should be paid to studying the efficacy and safety of existing technologies, particularly medical and surgical procedures;

-- increased R&D emphasis should be placed on health problems for which the current incentive structure does not suffice; and

-- increased emphasis is needed on methodological studies to improve the reliability and validity of technology-based analysis and testing.

D. NCHSR Proposal for Comprehensive Technology Assessment

The NCHSR has advanced a proposal calling for the creation of a 3-6 person Technology Studies Group to add the capability for conducting comprehensive tehnology assessment to NCHSR'S existing capabilities for studying cost-benefit, cost-effectiveness, and technical feasibility. The NCHSR proposal states:

> "Unlike the more discrete studies which concern themselves with particular aspects of a health technology, the new interdisciplinary technology assessment strategy provides a comprehensive analysis of their likely future effects.
>
> "NCHSR proposes to conduct holistic assessments, representing significantly different levels of effort ranging from $10,000 to $350,000 per study. The research strategy is to use micro or mini-technology assessments as a small scale screening tool to refine the research problem involved in the candidate technology and to decide what type and scope of follow-up study is really appropriate.

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"Thus, for example, a micro assessment conducted on a computerized EKG is likely to result in a judgment that it is a straight forward technology which raises no significant societal questions and the appropriate follow-up study might be a cost-effectiveness study. On the other hand, a similar assessment conducted on a nuclear powered heart is likely to reveal that it raises profound questions about the environmental radiation impacts, the psycho-social side-effects, the ethics of allocation, the dollar costs, the technical feasibility, and political-legal problems for which a full scale follow-up assessment is warranted."

The proposal for a pilot program has obvious advantages: it would provide the Department with a needed capability which is now absent, and it fits into the mission of NCHSR. There are also negative aspects: significant dollar costs are involved, and there may be overlaps in function between this proposal and NIH's OMAR proposal (see Section V). There was insufficient time to evaluate this proposal or develop alternative options for institutionalizing comprehensive technology assessment. We recommend that this be done in Phase II. If Phase II takes an extended period of time, however, we then recommend that a decision paper be prepared on the NCHSR and NIH proposals.

V. REVIEW AND SYNTHESIS

-- How can the Department collect and reduce to a useable form the technical information needed to make Departmental decisions regarding a technology?

-- How can the Department facilitate the flow of technology-related technical information to those outside the Department who affect and are affected by medical technologies?

A. Description of the Review and Synthesis Component

DHEW decisionmakers and other users are unable to effectively locate and use much of the new and existing information about technologies because they are unaware of its existence; it is not in a form understandable to them; or they lack the resources to integrate such information and bring it to bear in a timely manner.

This component is designed to review and synthesize (1) reports generated during the preceeding analysis and testing stage, (2) other reports and technical information, and (3) advice and recommendations from various parties-at-interest (such as manufacturers, providers, physicians, and consumers). The resulting syntheses are (1) presented to the Secretary (if they deal with a high priority technology) or other Departmental decisionmakers in a form suitable for making reimbursement, standard-setting, R&D funding, and other decisions that promote or impede technologies; and (2) transmitted to other Federal and non-Federal entities to encourage collaborative and consistent responses to technologies. The Department-level technology management unit would stimulate and coordinate the review and synthesis process for high-priority technologies, and provide technical assistance to the agencies to promote improvement in their handling of lower priority technologies.

B. Agency Activities and Deficiencies

The agency reports indicate an increasing awareness of the need for structured review and synthesis, but it is clear that additional emphasis and new initiatives are needed.

NIH, in some instances, provides the results of its studies to other agencies needing this information -- for example, vaccine research findings are given to the FDA and CDC. NIH has, as a result of their increasing awareness, recently begun to synthesize test results. A recent project involved synthesis of existing information on hypertension in order to develop consensus-based recommendations for diagnosis and treatment.

A similar exercise, on breast cancer screening, has just been completed. NIH has also submitted a formal proposal (see part D of this section) to OASH for a major "consensus-building" initiative which is designed to increase the agency's capability for synthesizing and transferring scientific findings to the health care community.

NCHSR reports that it channels the results of studies to decisionmakers and other users through two mechanisms: 1) by involving them actively in the setting of research priorities and in the development of individual projects, and 2) by issuing an ad hoc series of non-technical reports which synthesize research findings from several related projects in progress or shortly after completion.

CDC has an explicit process by which test results are reviewed and synthesized. In some cases recommendations are given to other agencies (for example, FDA or State agencies) but they are primarily used in CDC program planning.

FDA has the most formal and structured synthesizing processes. These are legislatively mandated reviews of efficacy and safety test results. These technical reviews result in recommendations to approve or not approve marketing of the product, with such recommendations then being acted upon within the FDA itself. Thus, for premarket approval, the review, synthesis, and decisionmaking at FDA constitute a continuous formal process. No similar process exists for review of data resulting from market surveillance. FDA is aware of this deficiency and is investigating ways to solve it.

OQS. When a Medicare coverage question is triggered by a claim for a new or unusual medical service, the former Office of Quality Standards (now the Office of Health Practice Assessment) synthesizes available efficacy and safety information on that service to develop recommendations for reimbursement. The Office (which recently assumed the responsibility) reported five serious deficiencies with the current ad hoc approach to synthesis:

1) it is a reactive approach which provides no structured way to anticipate questions about technologies about to enter medical practice;
2) coverage questions are not being raised about outmoded or ineffective technologies;
3) dollar costs of the technologies are not included in the review criteria;
4) the ad hoc process of searching the literature, or telephoning experts, to respond to the coverage question, provides no assurance that the best and most reliable data are obtained; and
5) there is no pathway for raising the question of whether the technology warrants a serious study to produce currently unavailable data.

To respond to this current set of deficiencies, the Office of Quality Standards is sponsoring a Medical Practice Information Demonstration Project in collaboration with NIH, HCFA, and ADAMHA (See addendum to Appendix Tab 11). This project is an attempt to demonstrate the feasibility of gathering, validating, and synthesizing the most authoritative data on three disease categories (depression, malignant melanoma and rheumatic heart disease). The findings are designed for use in three ways: in quality assurance programs (such as PSRO), in setting biomedical and health services R&D priorities, and in medical education. If the project is successful, it may be desirable to replicate it on a larger scale.

The problems cited by OQS were also raised by HCFA, which is both a major user of study findings and a potential feedback agent to the front end of a technology management process (by articulating the need for studies and identifying types of technologies which should be developed for more effective medical practice). HCFA is especially interested in a more structured approach to review and synthesis of the findings of cost-benefit and cost-effectiveness studies. HCFA would like this synthesized information channeled to the PSROs for use in their reviews of medical necessity, quality, and appropriateness of those health services funded by Medicare, Medicaid, and the Maternal and Child Health programs.

In addition to these agency-based problems, there are a number of Department-level deficiencies. Within DHEW, very few inter-agency agreements exist by which study findings are transferred from the agency conducting the study to an agency which will use the findings. In general, there is no mechanism for assuring systematic "translation" of bulky scientific and technical information into a form relevant for policymaking or for ultimate users such as providers and consumers. This deficiency has serious consequences for the Department. If the results of a study are not channeled to relevant decisionmakers and other users, much of the cost of conducting that study is wasted. Department decisions may be delayed or made without the benefit of information which is, in fact, available; studies may be started which duplicate existing or recently conducted efforts; and medical practice may remain unaffected by relevant findings.

C. Recommended Approaches

It is recommended that a Department-level capability be established to stimulate and coordinate the following: 1) agency-based technical review and synthesis activities; 2) translation of technical material into policy relevant form for decisionmakers and into understandable form for other non-technical users; and 3) dissemination of results to relevant parties.

D. NIH Proposal for an Office for Medical Applications of Research

NIH proposes to establish a capability in each Institute for reaching a "technical consensus" on specific medical technologies or disease areas. Consensus-building involves: 1) identifying and evaluating new information on a technology, 2) reaching technical consensus on the validity and significance of research findings and on their readiness for wide clinical use, 3) preliminarily assessing non-medical implications, and 4) producing recommendations in a form for ready acceptance and application by the health care community. Central support and coordination would be provided by an Office for Medical Applications of Research (OMAR) in the Office of the Director of NIH. The proposal has both positive and negative aspects: For example, it would complement a Department-level review and synthesis function, and is aimed at an area in critical need of improvement. On the other hand, NIH does not specify what criteria are to be used in selecting technologies for examination; significant dollar costs are involved; and the preliminary impact assessments appear to duplicate proposed activities of NCHSR (see Section IV, Part D).

In Section IX of this report, the Study Team recommends a follow-up (or Phase II) study relating to the implementation of recommendations for overcoming the deficiencies that have been identified. We believe NIH's OMAR proposal (and the NCHSR proposal) should be evaluated in the context of an array of alternative approaches to overcoming these deficiencies. If it should be decided, however, that the Phase II study should take place over an extended period, we recommend that these two proposals be presented to the Secretary as decision papers. While approval of the proposals would limit future alternatives, continued absence of the capabilities proposed would have adverse effects on the Department's interest in improving its technology-based activities.

VI. DECISIONMAKING

-- How are technology evaluation results converted into reimbursement, market aggregation, certificate of need and other kinds of technology impeding or stimulating actions?

-- Who should have the responsibility for taking the study findings and expert opinion collected during the review and synthesis process, and choosing among action alternatives?

A. Description of Decisionmaking Component

Decisionmaking is the bridge between the development of technical information about a technology and the action steps which might be taken to impede or promote use of a technology. The preceding review and synthesis component presents a technology for decision; this component assures that decisions are made and that they are coordinated.

Once the Secretary (or his designate) has reached a decision about a technology on the Department's high priority list, he would select which intervention mechanism(s) to employ, and would charge the relevant action agencies to alter regulations, draft standards, reallocate R & D funds, design a targeted practitioner education initiative, etc. Implementation would be coordinated by the Departmental-level management unit, and would be related to budget and legislative decisions and integrated, if feasible, with actions of other Federal agencies and private sector parties at interest. For technologies not on the Department's high priority list, the Department-level unit will monitor the agency-based decisionmaking processes on an ad hoc basis to promote coordinated and consistent decisionmaking.

B. Current Agency Activities and Deficiencies

Where a single agency develops knowledge about a technology, internally decides on the significance of that information, and then exercises intervention mechanisms over which it has control to influence the use of the subject technology (a "closed loop" process), the process typically appears to be relatively well-defined, integrated and purposeful. For example, where FDA's multi-disciplinary technical staff makes a recommendation to a Division Director regarding a new drug application, the Director knows (based on its degree of innovation classification) whether he can make the final decision or must raise it to the Bureau's Associate Director for New Drug Development. The action lever--approval/denial to market, and associated conditions--lies wholly within FDA's control, and the transition from decision to action is integrated and routine. As we have stated previously, FDA is exceptional in this regard.

On the other hand, the decision-implementation relationship becomes significantly less efficient and effective where, for a given technology,

-- the pertinent response mechanisms are located outside the knowledge-development agencies; or

-- the intervention mechanisms are scattered across several action agencies; or

-- there is no external pressure (as there is from the applicant drug or appliance manufacturers) to reach a clear, timely and supportable decision.

Examples of problems culled from Agency reports include:

-- "At the NIH, explicit formal processes have not generally been utilized in dealing with decisions concerning medical technologies and assessment results." Although some interagency agreements and coordinating committees are alluded to, it is clear that NIH confines its implementation activities to the information dissemination process, and that findings are not well-linked to external action agencies.

-- Medicare obtains reimbursement guidance from the PHS Office of Quality Standards through working staff contacts. The recommendations appear to have been generated in an ad hoc manner which failed to assure that useful complementary actions are employed by other arms of the Department. (This is expected to improve under the PHS reorganization and the establishment of the Office of Health Practice Assessment which is now working on an improved process.)

-- HRA's Bureau of Health Planning and Resources Development developed technical standards and criteria monographs relating to 16 technologies as guidance for health planning agencies. While these monographs are available through NTIS, "There has been no final determination as to the value of the monographs (and) they have not been endorsed..." In addition, although case studies have been developed under contract for eight other technologies, only one has been released (in response to high demand) and it has received no endorsement.

-- PSRO: "Unfortunately, (efficacy/outcome information on medical technologies) is generally not available, and the more difficult and time consuming approach of attempting to get a (standard-setting) consensus based on practice experience must be used." "From the perspective of (HCFA's Health Standards and Quality Bureau), decisions on results of technology assessment research are not systematically occurring, nor is there a structured approach for feeding decisions into medical practice."

The Study Team believes that there needs to be a visible and predictable decision-making process which converts the weight of technical information and expert opinion into broadly coordinated interventions which affect the generation, adoption, diffusion, or phase-out of technologies. For high-priority technologies, such decisions should be made by the Secretary or his designee to lend the influence of his office to agencies' commitments to take indicated actions, and to promote collaboration by other Federal and key non-Federal entities.

C. Recommended Approach

It is recommended that one of the primary functional responsibilities of a Department-level unit be to assure that (1) Secretarial decisions on high-priority technologies are implemented; (2) relevant decisions of one agency are consistent with those of another; (3) agency decisions take into consideration potential for collaboration with other Federal agencies and non-Federal entities; and (4) that agency decisions are consistent with Departmental policies or are used as triggering devices for formulating new policies.

It is also recommended that the Department level unit should monitor agency based decisionmaking processes on an ad hoc basis to promote coordinated and consistent decisionmaking.

VII. INTERVENTION MECHANISMS

-- What mechanisms does the Department have to impede or stimulate development, utilization and phase out of medical technologies?

A. Description of Overall Component

Intervention mechanisms are the Department's means to affect the development, adoption, diffusion, utilization, and phase-out of medical technologies to ensure the availability of quality health care. Specifically, policy, fiscal, educational and other mechanisms can be used to ensure that:

-- needed cost-effective technologies are brought into appropriate use more quickly;

-- existing technologies which are outmoded, inefficacious, or inappropriately used are curtailed;

-- developing technologies which may impact negatively on the health care system or on society are appropriately modified or arrested.

Four classes of intervention mechanisms need to be employed by the Department:

- o Regulatory mechanisms
- o Transfer and/or phase-out mechanisms
- o Pre-market incentive and/or disincentive mechanisms
- o Market incentive mechanisms

These classes of mechanisms and the specific types within each class come into play at different stages of the life cycle of a technology. Further, the role of responsible departmental agencies in the administration of the specific controls varies. In some cases, the agencies have direct responsibility, while in other cases, primary responsibility is at the State and local level and the Federal agencies only provide guidance, exemplary standards, and oversight.

Figure 2 is a matrix of technology life cycle stages and specific types of controls and incentives within each class of intervention mechanism which may be applied to them at various stages of development.

The potential application of current intervention mechanisms is depicted on the figure. The matrix shows that there are numerous controls applicable to the adoption, use and replacement stages and only three for the research and development stages. This apparent imbalance implies that the Department has considerably more power to affect later stages of the life cycle. In fact, this is misleading. It is not the number of controls applicable to the various stages which is important; rather it is how effectively those controls are used. R&D resource allocation controls, for example, are a powerful mechanism if their full potential is realized through effective policy and decisionmaking. These considerations are addressed in more detail in the following sections.

Further, when considering intervention mechanisms, it is important to realize that medical technology development, adoption, diffusion and utilization are driven by the following factors:

- Most hospitals are paid retrospectively and on a cost basis for technology-based capabilities, and, therefore, may tend to be indiscriminate in their purchase and use practices.

- The medical ethic essentially says that there is "nothing too good for the patient" and this, coupled with financial benefits to the physician for technology based services, contributes to overuse of technology.

- Consumers generally are not sensitive to, or responsible for financial aspects of medical care and, therefore, may be similarly indiscriminate in their demands. A large portion of medical services, for example, are

STAGES OF DEVELOPMENT / INTERVENTION MECHANISMS	BASIC RESEARCH	APPLIED RESEARCH	ENGINEERING/ FEASIBILITY	VALIDATION	MANUFACTURING/ MARKETING	ADOPTION/ TRANSFER/ DIFFUSION	UTILIZATION/ PRACTICE	REPLACEMENT/ OBSOLESCENCE
Regulatory Mechanisms								
*Market Approval/Disapproval					o	o		
*Certificate of Need/Sec. 1122						o	o	
*Professional Standards Review							o	
*Reimbursement						o	o	o
*Health Planning Guidelines							o	o
Transfer and/or Phase Out Mechanisms								
*Demonstrations				o		o	o	o
*Information Dissemination	o	o	o	o	o	o	o	o
*Professional Education						o	o	o
*Consumer Education						o	o	o
*Patent and Licensing Policy		o	o	o	o	o		
Pre-Market Incentive and/or Disincentive Mechanism								
*Allocation of R&D Funds	o	o	o	o				
Market Incentive Mechanisms								
*Development Subsidies			o	o	o	o		
*Tax Subsidies					o	o		
*Market Aggregation					o	o		

Figure 2: Relationship between Intervention Mechanisms and Stages of Technology Development

reimbursed by third party payers, and many consumers are covered by insurance programs where all or a part of the premium is paid by their employer.

Basically, these factors operate as uncontrolled incentive mechanisms. The Department presently is taking initiatives, including legislative action now pending, to deal with problems resulting from these factors.

REGULATORY MECHANISMS

A. Description of Component

There are five specific regulatory controls employed by the Department:

(1) Market Approval/Disapproval

FDA approves or disapproves the introduction of drugs and medical devices into the marketplace based upon a determination of the efficacy and safety of the technology. FDA also may issue conditional approvals which restrict where and how the technology can be used, and may recall technologies on the basis of subsequent adverse information.

(2) Certificate of Need/Section 1122

Certificate of Need (CoN) and Section 1122 require the review and approval of specified capital expenditures and proposed changes in health services. States implement these mechanisms with input from local health planning agencies and in accordance with minimum regulations established at the Federal level by BHPRD. CoN regulatory authority and practices vary across the States. Only one State has neither.

(3) Health Planning Guidelines

The forthcoming National Guidelines for Health Planning will have to be considered by local health planning agencies in developing their plans, and in conducting appropriateness reviews and the review of proposed services. Although not strictly a regulatory mechanism, the guidelines will affect decisionmaking at all levels through their expression of national policy on the appropriate supply, organization and distribution of health resources.

(4) Professional Standards Review

Professional Standards Review, conducted by local Professional Standards Review Organizations (PSROs), determines the necessity, quality and appropriateness of health services (and, therefore, medical technologies) reimbursed under Medicare, Medicaid and the Maternal and Child Health Program. PSROs receive guidance from the Health Standards and Quality Bureau within HCFA in the form of sample sets of norms, criteria and standards but may adapt these to local practices. Of the 203 PSRO areas, there are 62 at the planning stage, and 120 are conditional. They have concentrated their initial activities on the use of hospitalization.

(5) Reimbursement

Reimbursement mechanisms employed by the Department are limited to the approval or disapproval of reimbursement under Medicare for health services and technologies. HCFA makes such determinations, which can have a multiplier effect on the reimbursement practices of Medicaid and other third party payers.

B. Agency Activities and Deficiencies

Overall roles and responsibilities of the various agencies were discussed above. Specifically, the problems reported by the action agencies are of two types: those inherent in the regulatory mechanisms themselves and those resulting from analytic deficiencies, notably the difficulty in establishing standards. Many of the regulatory mechanisms, although available, are currently in a developmental state either because their legislative mandate is relatively new (Medical Device Amendments; P.L. 93-641), or because established policies and procedures are not adequate to address the complex issues posed by modern medical technologies. As shown below, these constitute a major set of deficiencies.

The Bureau of Medical Devices has not yet completed formulation of pre-market and post-market assessment procedures and performance standards which are comparable to those of the Bureau of Drugs. Though the state-of-the-art of developing standards for technologies was identified as a limiting factor, the Bureau of Medical Devices also reported that FDA procedures and the process of promulgating regulations have further hampered the process.

Health Systems Agencies (HSAs) and State Health Planning and Development Agencies (SHPDAs) are new State and local planning agencies in many cases, and the resource materials and technical assistance structure which will support their regulatory functions are not all in place. Appropriateness Review is not yet a required HSA and SHPDA function, and issues surrounding its regulatory aspects are unclear. The draft National Guidelines for Health Planning are too recently issued to have had an effect on the health care system. PSROs are established in only a little more than half the designated areas and sample criteria sets have been issued only for pre-admission and continued-stay-review for hospitalization. From the agency reports, it is obvious that the newness of these regulatory mechanisms or their present state of development constitute a major set of deficiencies.

Other programmatic problems identified by the Study Team include an overall lack of coordination and the exclusion of some medical care providers from regulation. Further coordination is needed between the various regulatory mechanisms in order to assure consistency. DHEW was ridiculed when CT head scanning was approved under Medicare while BHPRD was stating it did not have sufficient information to issue guidelines about CT services even though technicians understood the Medicare decision was based on efficacy and safety data while the guidelines are based on cost-benefit and cost-effectiveness findings. The Study Team also considers that the regulatory mechanisms of CoN and Section 1122 approval are weakened by the exclusion of physicians' offices and other ambulatory care providers from the requirements.

Without the authority to control the acquisition of technologies outside health care facilities, local and State planning agencies cannot, in our opinion, effectively plan and regulate the health care delivery system for which they are responsible.

The action agencies identified the lack of technical consensus about emerging and existing technologies as a major analytic problem to their regulation. Although BHPRD has developed monographs addressing 16 health services and has a contractor working on a series of case studies describing specific technologies, neither of of these efforts resulted in specific standards that planning agencies could use for decisionmaking under CoN and Section 1122 because of lack of consensus. HCFA also reported the lack of technical consensus as a major problem in the development of model sets of standards for PSRO's to use in reimbursement decisions and quality assurance. The recently issued National Guidelines established quantitative standards which (when issued in final form) must be considered by health planning agencies. These may contribute to a movement towards consensus about medical technologies and assist in the development of standards on which to base CoN and Section 1122 approval.

The scarcity of data about existing technologies was identified by the agencies as a factor contributing to the difficulty of reaching consensus. Information was reported to be urgently needed for State and local health planning decisions and for PSROs. The inadequacy of the existing knowledge base and the lack of dissemination of research findings also were cited by BHPRD, HCFA, and OQS as major impediments to the development of standards.

HCFA identified a need for more comprehensive review of new technologies in order to assist in the development of Medicare reimbursement policies. In addition, HCFA reported that additional research on the appropriate conditions for use of particular technologies is needed to assist PSROs and reimbursement mechanisms in the development of standards-for-use and thus the establishment of payment policies.

Lastly, it should be noted that, while the Study Team agrees with the action agencies about the need for a more structured approach to obtaining technical information about medical technologies, we are in no position to comment on the extent to which the current lack of this information affects their performance, since evaluation of their performance and productivity is beyond the scope of this Phase I inquiry.

TRANSFER AND/OR PHASE-OUT MECHANISMS

A. Description of Component

There are five specific types of mechanisms employed by the Department to stimulate the transfer or diffusion of a desirable technology and/or to phase-out an outmoded or unsafe technology:

- o Demonstrations
- o Information dissemination
- o Professional education
- o Consumer education
- o Patent and licensing policy

Demonstration projects are undertaken primarily to obtain information from which the future course of development and application of a technology can be determined. Demonstration projects also have the potential for directly stimulating or arresting the diffusion of the technology.

Information dissemination and professional and consumer education activities, which are often interrelated, are intended to influence the decisionmaking of practitioners, other health professionals, researchers and consumers on the use of medical technologies. This is accomplished by using such media as medical journals, pamphlets, professional meetings, and conferences to inform these parties about the important positive and negative aspects of technology.

Similarly, patent and licensing policy may be used to encourage or discourage the introduction, diffusion or application of drugs and devices developed with Federal support.

B. Agency Activities and Deficiencies

The agencies' reports overall indicated only limited use of these mechanisms to systematically transfer technologies, and virtually no use to curtail or phase out outmoded or inefficacious technologies.

NIH, however, reported substantial and increasing activity in the dissemination of information, physician and consumer education, and demonstration projects. For example, NIH established a Task Force on Communications in 1975 in the Office of the Director to recommend steps to improve the dissemination of information to health professionals and the general public. The various Institutes sponsor a variety of meetings for biomedical researchers and medical practitioners; publish journals, monographs, bibliographies and pamphlets; write a monthly section for the Journal of the American Medical Association dealing with emerging technologies relevant to medical practice; produce radio and television announcements; conduct seminars for scientific writers; and operate an information clearinghouse in specific disease categories (e.g., the Cancer Information Clearinghouse at NCI). NIH also undertakes the majority of demonstration activities of the Department. The NHLBI and NCI, in particular, are required by their legislation to conduct demonstrations and education programs for professionals and the public. Further, under the auspices of the various Institutes, more than 50 research centers have been established throughout the country. In addition, the NIH's National Library of Medicine is able to provide continuously updated information from its guide to Medical Literature, Index Medicus, by means of the computerized "Medline" system. This is available nationwide through 750 terminals in hospitals, medical schools, and libraries, and is backed up by 11 Regional Medical Libraries.

NCHSR funds demonstration projects of various computer-based diagnostic, therapeutic and screening technologies. These projects focus on obtaining further information about validity, efficiency, cost-effectiveness, and user acceptance, but also aid in the diffusion of worthwhile innovations. To facilitate adoption of some of its projects and elimination of barriers to the transfer of viable innovations, NCHSR has produced user guidelines and supported "user group organizations."

An Office of Health Information and Health Promotion was established recently in OASH to provide the Department with a focus for consumer education activities. This office, which plans to concentrate its efforts in areas where there is an absence of current activities, will assist the agencies in carrying out any aspects of their missions which involve or could involve consumer education, and will develop programs for the "education of the public in the maintenance of personal and family health and in the appropriate use of the health care system." This program is likely to encounter many of the problems commonly associated with the inadequacy of hard technical information about the effectiveness of many technologies. Also, the methodologies used in affecting consumer behavior are imperfectly developed.

These same informational and methodological problems apply to professional education activities. In this case, the problems are compounded because there is no departmental focus for activities relating to the continuing education of physicians and other health professionals. Practicing physicians currently do not have an adequate source of information about the technologies that they are using or could use, and medical literature often is not directed towards the needs of practitioners or written in terms familiar to them. In fact, the quality of that literature has been called repeatedly into question.

Recently, there has been increased recognition of these inadequacies, and various DHEW agencies have been encouraged to remedy them. Several activities discussed in this report (e.g., the Medical Practice Information Demonstration Project and the Department-level Review and Synthesis component described in Section IV) could aid in resolving these information and education problems.

NIH, however, reported that any further involvement in professional education might be inappropriate or infeasible. Since NIH currently is the most active agency in this area, it appears unlikely that substantial improvements in professional education will take place without a new locus for such activity elsewhere in the Department.

There was no explicit request in the Agency Report Form for information on patent and licensing policies or activities. Agency reports, therefore, provided no basis for discussion of these mechanisms. The Study Team is aware, however, that the Department has not articulated a policy which recognizes the dual use that patent and licensing policy can perform in encouraging or discouraging innovations resulting from DHEW-funded R&D.

PRE-MARKET INCENTIVE AND/OR DISINCENTIVE MECHANISMS

A. Description of Component

The allocation of R&D resources is an effective means for directly affecting technology development. Pre-market mechanisms can be used to stimulate, retard or redirect technology development. Decisions on the type and amount of R&D resources to be applied in any given area would be based, for example, on criteria such as the overall mission of the Department, the nature of the problem, the importance of the problem, targets of opportunity, and the availability of funds.

B. Agency Activities and Deficiencies

Agencies reported no conscious or formal use of R&D resources allocation policies as pre-market incentive or disincentive mechanisms. Such policies, however, are de facto control mechanisms, which reflect major judgments about health needs and national priorities. The problem for the Department is that the agencies simply do not review allocation of R&D as an intervention mechanism even though the Agency Report Outline explicitly labeled it that way.

This gap in the agencies' perception and planning is particularly striking since it occurs despite the recent barrage of criticism of DHEW for overemphasis of what Dr. Lewis Thomas has termed "halfway technologies" such as renal dialysis which is palliative , and underemphasis of technologies such as vaccinations which are preventive, or nutrient therapy which is curative.

It indicates that one of the Department's most powerful intervention mechanisms is not being employed to manage technology effectively.

MARKET INCENTIVE MECHANISMS

A. Description of Component

Market incentive mechanisms are intended to encourage private corporations to develop and commercialize medical technologies which meet a unique public need but which lack a sufficiently attractive market from the perspective of the industry. Such mechanisms include:

- o Development subsidies
- o Tax subsidies
- o Market aggregation

Development subsidies essentially are direct payment schemes by which all or a part of the costs to take a technology from the "breadboard" or prototype model to the production stage are paid by the Government.

Tax subsidies basically are indirect reimbursement schemes by which all or a part of the costs to develop actual manufacturing capabilities and/or produce a technology can be deducted from the taxable income of the organization.

Market aggregation refers to Government action to guarantee an exclusive market for a given technology which it desires, but which private corporations consider not cost-effective (i.e., manufacturing and sales costs cannot be sufficiently recovered and/or free market profit margins are too small or uncertain). This mechanism, therefore, assures a minimum sales volume and/or exclusive access to specific interested buyers (e.g., VA, PHS, DOD, GSA) for a given length of time.

B. Agency Activities and Deficiencies

Agencies essentially reported no activities to develop and apply market incentive mechanisms. The Study Team concluded, therefore, that either little was being done with this class of intervention mechanisms, or that the utility of such activities have not been recognized by agency managers. The situation appears to be comparable to the agencies' lack of a strategy for allocation and reallocation of R&D resources as an intervention mechanism.

While the agency reports demonstrated considerable concern with the problem of restricting technology use, they demonstrated no comparable concern with identifying and stimulating beneficial but lagging technologies which are not being developed because they fall between the cracks of the health care market. For example, preventative, rehabilitation, mental health and environmental technologies could reduce costs, but many are lagging in development because the normally overgenerous medical reimbursement system does not cover their use.

This gap in agency planning should be addressed at the Department level. It calls first for systematically identifying lagging or absent beneficial technologies and then, on the basis of the identification, for developing a more balanced strategy for managing technology development.

It is worth noting that the Experimental Technology Incentives Program of the Department of Commerce has the explicit mission of helping Federal agencies conceptualize and implement experimental approaches to technological innovation. This Federal resource should be used, particularly because some of the lagging technologies mentioned above are likely to fall beyond the traditional purview of DHEW (e.g., air pollution and automobile safety) and these call for collaborative efforts with other Federal Departments.

The Study Team believes that there are unrealized opportunities for the Department to promote incentive actions within its purview and to influence incentive actions in areas in which it does not have direct responsibility but which may impact both departmental resources and the overall health of the American public.

C. <u>Recommended Approaches</u>

Overall, we recommend that the Department undertake a comprehensive review to determine why most of its intervention mechanisms are not working effectively; and then to develop and implement policies to expand their scope and improve their effectiveness. In addition, we recommend that:

- o The research requirements to establish standards and policies for departmental regulatory mechanisms be clearly articulated and given consideration as research funds are allocated. All of the action agency reports identified some research needs, and we recommend that they be asked to prepare a proposed research agenda for consideration.

- o Formal linkages be established between HCFA and other reimbursement organizations in both the public and private sector in order for reimbursement decisions to be more consistent, and therefore effective as a regulatory device. All third party payers should have access to information relevant to the establishment of policies, and although private third party payers and Medicaid programs can not be compelled to act in concert with Medicare, further coordination between payers should be encouraged to increase the likelihood of a consistent approach to the regulation of technologies through reimbursement.

o The acquisition of technologies by private physicians and other ambulatory care facilities be subject to the same CoN and Section 1122 review and approval as other prospective purchasers.

o Current information dissemination and professional and consumer education activities be evaluated from the standpoint of their output (e.g., quality of information disseminated and relevancy of subjects covered), and their impact on the target audiences (e.g., consumers and physicians).

o A new locus for professional education be developed to coordinate activities among the agencies and to stimulate needed new program initiatives. We recommend that the responsible organization develop a collaborative relationship with the Medical Specialty Boards and academic health centers so that departmentally-generated information may be systematically channelled to them for use by physician recertification programs and other relevant activities.

o Specific departmental and agency policy be developed for identifying absent or lagging medical technologies and that R&D allocation plans take greater cognizance of health needs in relation to research targets of opportunity.

o A Departmental policy be developed relating patent and licensing actions to decisions to encourage or discourage innovations resulting from HEW funded R&D.

- A study be conducted to identify those beneficial technologies which are not being developed because current health care policy overlooks them. For example, prevention, rehabilitation, environmental and system management technologies offer the potential for improving health and reducing health care costs, yet HEW appears to be underinvesting in their development.

- A study be conducted of other Government organizations to determine the effectiveness of their activities to promote development and commercialization of critical health-related technologies. As part of this study, the Department should identify both those technologies and activities in other fields may impact beneficially on health problems (e.g., pollution control technologies), and those technologies and/or fields where the application of appropriate incentives might be encouraged to reduce the occurrence or severity of specific health and medical problems.

VIII. DEVELOPMENT AND MANAGEMENT OF A DHEW TECHNOLOGY SYSTEM

A. Development of the Proposed Technology System

Chapters II through VII compare the Study Team's concept for a DHEW technology management system with the current activities of the Department. To consider how the Department could move from the existing fragmented arrangements to a coherent management system, it is useful to summarize the current deficiencies and the types of needed initiatives.

COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
nitoring/Screening	- Three agencies report some activities which could contribute to an identification and monitoring system for existing technologies and NCHSR has concept design for developing technologies	- no catalog of existing, new, and developing technologies - no systematized approach to identifying and screening technologies to be studied	- develop and implement system for identifying, monitoring, and coarse screening of technologies to be scrutinized
nda-setting	- Agenda-setting occurs at individual agency levels based primarily on those agencies' perceptions of their missions, ad hoc Congressional Requests, and on resource availability	- imbalance between needs of action agencies and interests of knowledge development agencies - no assurance of agencies' focus on Nation's priority needs - no clearinghouse for information and data about technology-based studies	- create a Department-level mechanism and a fine screening process for an annual technology analysis agenda of 15-20 high priority studies
alysis and Testing	- There is a strong base for technology-based studies in several agencies - NIH conducted in FY '75 clinical trials of efficacy and safety at a cost of over $100 million; FDA and CDC are also involved in efficacy and safety analysis - NCHSR spent one-fourth of its budget for FY '75 on cost-benefit and cost-effectiveness analysis as part of comprehensive evaluations; NIH, HCFA, and CDC report small-scale efforts in this area - FDA sets standards for quality, efficacy, and safety of drugs and devices, and reviews data and testing procedures of developers; HCFA develops medical necessity, quality and appropriateness standards to guide PSROs; BHPRD develops standards for organization, supply and distribution of health technologies and services. - There are isolated instances of discrete societal impact studies (by FDA, NIH, CDC, NCHSR), and NCHSR has developed a proposal for comprehensive technology assessment. - Examples of cross-cutting and methodological activities: studies of diffusion by HRA; use of computers for information transfer by NIH; development of models to predict treatment outcomes by CDC and to assess technologies by FDA	- insufficiency of studies of existing technologies, particularly medical and surgical procedures - lack of critical mass of skills for conducting cost-benefit and cost-effectiveness studies - imbalance between action agencies' needs for standards development and knowledge development agencies' capabilities for providing them - no comprehensive technology assessments being conducted and insufficiency of discrete societal impact studies - insufficient effort to identify lagging and absent beneficial and cost-saving technologies - little theoretical work being done on adoption and diffusion of medical technologies - insufficient emphasis on methodological studies to improve the state-of-the-art of technology-based analysis and testing studies - ineffective linkage between study findings and agency actions to stimulate or impede technology development	- correct current imbalance of agency agendas - launch new analysis and testing efforts in appropriate agencies - evaluate quality of agency studies and staff capabilities and use findings as basis for realigning agency responsibilities - consider NCHSR proposal for comprehensive technology assessment

COMPONENTS	CURRENT ACTIVITIES	DEFICIENCIES	PROPOSED INITIATIVES
...iew and Synthesis	- NIH has begun to formally synthesize test results (e.g., on hypertension and breast cancer screening) and has developed a proposal for extensive review and synthesis activities - FDA has a formal, structured synthesizing process for reviewing efficacy and safety test results - NCHSR has begun to issue ad hoc non-technical reports synthesizing research findings from related projects in progress - OHPPE [illegible]	- primarily conducted retrospectively in response to ad hoc questions e.g., reimbursement for Medicare - no mechanism for assuring systematic "translation" of scientific and technical information for DHEW policy and decision-makers or for non-DHEW users	- create a Department-level capability for oversight and management of review, synthesis and translation of study findings to relevant users in and outside of DHEW - consider NIH proposal for creation of an Office of Medical Applications of Research
...cisionmaking	- FDA has an explicit process for decision-making regarding approval for marketing of drugs and devices	- no mechanism to assure consistency and coordination of agency decisionmaking - no mechanism to assure that relevant study findings are used to formulate new Departmental policies integrated across program lines	- assign responsibility to Department-level unit to facilitate coordinated agency decisionmaking and policy development and to involve outside parties-at-interest in collaborative efforts
...tervention Mechanisms	- FDA approves or disapproves the introduction of drugs and devices into the marketplace - National Guidelines with quantitative standards have recently been published in Federal Register - Planning agencies, BHPRD, and PSROs are in early stages of implementing their respective programs - HCFA makes ad hoc decisions about Medicare reimbursement for questionable technologies - NIH reports substantial technology transfer activities in information dissemination, professional and consumer education and demonstration projects - NCHSR supports user groups to facilitate adoption of validated technologies - An Office of Health Information and Health Promotion was recently established in OASH	- most intervention mechanisms still in developmental stages standards for medical devices not yet developed - PSROs not yet established in close to half of the designated areas - appropriateness review standards not yet developed - National Guidelines for Health Planning delayed, and technical assistance structure for HSAs and SHPDAs still evolving - regulatory decisions hampered by lack of technical consensus on standards for efficacy, safety, cost-benefits, and cost-effectiveness, and appropriate conditions for use of technologies - professional education efforts insufficient to needs of practicing physicians for information about appropriateness and effectiveness of technologies - information dissemination effort inadequate to need - consumer education efforts still in definition stage - allocation and reallocation of R&D not perceived by the agencies as an intervention mechanism - inadequate attention paid to market incentive mechanisms to stimulate lagging or absent beneficial and cost-saving technologies which fall between the cracks of health system incentive structure	- create a Department-level capability for oversight and management of a balanced strategy for impeding and/or stimulating technology development, adoption, and utilization - evaluate and strengthen action agencies' capabilities for management, adoption, transfer, utilization and phase-out of technologies - create a new locus for professional education on utilization of technology - establish formal linkages between Department and other Federal entities and private sector to develop collaborative efforts for managing technology - launch a new initiative to identify lagging and absent beneficial technologies which fall outside of the health system incentive structure - develop a Departmental policy for relating patent and licensing actions to DHEW decisions to encourage or discourage innovations resulting from DHEW funded R&D

To emplace the proposed technology management system, there will need to be jurisdictional clarifications and realignments among the agencies as well as assignment of new responsibilities and authorities and resources. There are two general approaches to development of the proposed system:

(1) A "tabula rasa" approach is the most free form (but it might be considered politically naive). It would assume no constraints on shifting existing institutional capabilities or responsibilities, and would thus be unfettered in developing a set of jurisdictional assignments, component linkages, etc. The agencies' roles would then be reformed around the new responsibilities.

(2) An "organizational-change-on-the-margin" approach would adhere to legislated missions, existing professional skills, experience, and so forth, and would design options that fit around existing arrangements and propose marginal changes in the agencies. It is the least disruptive and quickest approach, though the one most likely to be compromised by agency momentum.

The Study Team has concluded that elements of each will be required: marginal change where agencies have demonstrated competence (e.g., efficacy and safety testing of drugs and devices; implementation of certain action mechanisms), and totally new development of such components as agenda-setting, monitoring and screening, review and synthesis, and technology transfer mechanisms.

This month-long Phase I study did not include independent assessments of agency performance or staff capabilities. To advance organizational change alternatives that attempt to overcome current agency deficiencies and, at the same time, take best advantage of existing capabilities would therefore overstep the Study Team's knowledge base. The Team believes it would be more appropriate to assign precisely this responsibility to a Phase II study as recommended in Section IX.

B. Management of the Proposed Technology System

Does the proposed system require direct management or can its operation be left to the participating agencies? Departmental systems process requirements (like the annual evaluation agenda or the forward plan) typically assume a very low priority for agencies which are constantly trying to discharge major substantive responsibilities. In addition, institutional histories, fragmenting constituent pressures, interagency territoriality, etc. create centrifugal forces that tend to drive agencies apart and frustrate even such simple goals as information exchange. Where they do interact, their understandable jockeying for bureaucratic advantage siphons energy away from the enterprise. For these reasons, the alternative of leaving the management of the proposed technology system to a joint undertaking of the agencies is not presented for consideration.

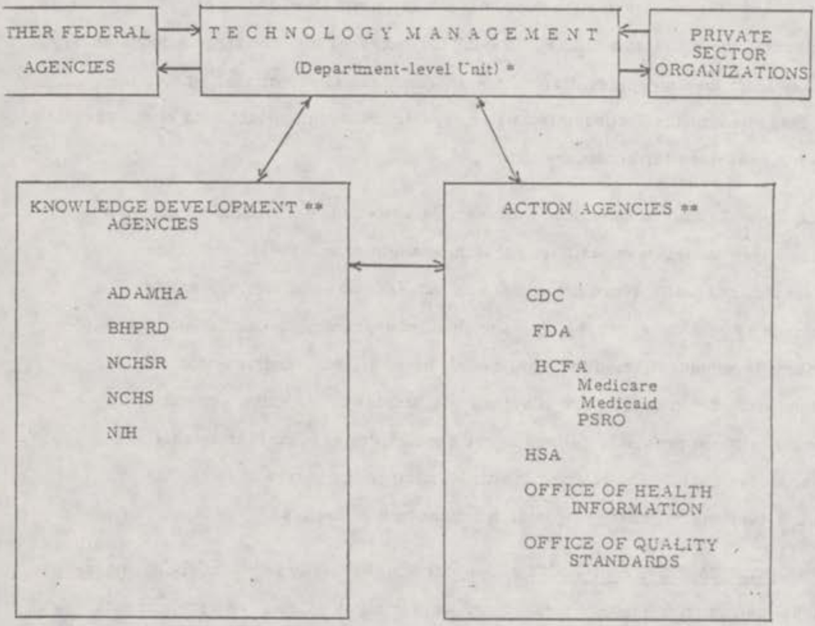
The Study Team has concluded that there is a need for establishment of a new technology management unit, and that such a unit should be located at the Department level. The functions of this unit (as shown in figure 3) might include system development, management, coordination, technical assistance, policy development, monitoring and evaluation, liaison, and information clearinghouse. The following are illustrative examples of the unit's activities; they would be more precisely defined by the Special Project Manager's decision memo (See Section IX) relating to unit location and resources, and by the unit's evolving definition of goals, functions and priorities.

<u>SYSTEM DEVELOPMENT</u> - The unit would initially focus on giving operational definition to the conceptual framework, and on guiding the developmental activities related to integrating the six-component system with Departmental structures and processes. Examples of the unit's developmental activities would include:

-- determination of the feasibility and cost-effectiveness of developing a system to (a) identify and monitor technologies; (b) inventory and monitor health needs; and (c) screen the existing and developing technologies to select candidates for intensive study;

Figure 3

Functions and Relationships of Proposed
Technology Management Unit



*PRIMARY FUNCTIONS
-System Development
-Management
-Coordination
-Technical Assistance
-Policy Development
-Monitoring and Evaluation
-Liaison
-Clearinghouse

** Agencies are identified in terms of their primary mission vis-a-vis technology-based knowledge development or action

-- in collaboration with the agencies, definition of the leadership, coordination and technical functions through which the agencies would participate in the technology management system and the six-component process;

-- development of a process through which the Department can collaborate on technology management problems with other relevant Federal Departments (e.g., VA, DoD, NASA, NSF, OSTP) and the private sector parties at interest (e.g., health insurers, providers, technology developers, Institute of Medicine, academic institutions, medical specialty groups and public/consumer interest groups);

-- preparation of a timetable for the annual technology agenda cycle.

These system development activities would be undergirded by information obtained from the Phase II study which is initiated by the Special Project Manager and transferred to the technology management unit staff as soon as they are appointed. As shown in Appendix Tab 13, the Phase II study would be structured so that the tasks that provide technical data and information needed for the system development activities are "front-ended", thereby giving the new unit's staff a major head start.

MANAGEMENT OF HIGH-PRIORITY TECHNOLOGIES - In the operation of the six-component system for addressing selected high-priority technologies, the unit would maintain timetables, convene or coordinate convocation of DHEW agencies and extra-Departmental participation, monitor and report progress, etc.

-- Monitoring and Screening: oversee generation of a list of "coarse screened" candidate technologies and health problems;

-- Agenda-setting: in collaboration with the agencies and outside parties at interest, convene expert judgment to "fine screen" the choice of candidate technologies; prepare an Annual Technology Analysis Agenda proposal that recommends to the Secretary the

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high priority technologies to be studied, the types of studies to be performed and by which agencies, the schedule for their completion, etc.; advise relevant parties of Secretarial decisions;

-- Analysis and Testing: while the agency assigned to conduct a study will be responsible for the technical design, the unit will, where necessary, coordinate inter-agency participation in study design; it will monitor timetables of the studies and act as an information clearinghouse on studies' progress--particularly for potential extra-Departmental users;

-- Review and Synthesis: scheduling, monitoring, and providing technical assistance to the agency(ies) responsible for preparing user oriented syntheses of high priority studies and other relevant information and data;

-- Decisionmaking: prepare (in collaboration with both action and knowledge development agency staffs) a decision memo for the Secretary recommending a conclusion based upon the weight of technical findings and judgment, and a series of coordinated action steps to convert that conclusion into policy and program changes; following the Secretarial decisions, communicate decisions to relevant parties;

-- Intervention: monitor and periodically report on agencies' progress toward effecting implementation actions (e.g., reimbursement changes, professional education initiatives, new draft legislation); facilitate liaison with parties at interest outside of the Department to encourage complementary actions.

GENERAL ACTIVITIES

-- Coordination: Where needed, the unit would help design linkages between action and knowledge development agencies to facilitate exchange of information needs, technical findings, etc. for those technologies not a part of the annual high-priority process.

-- Technical Assistance: The unit would respond to requests from the agencies for technical assistance in the operation of their internal technology management systems; it would advise agencies of the lessons learned (both positive and negative) from the operation of the high-priority system; it would request technical assistance from the agencies or from outside the Department relating to continuous refinement of the Department's technology management system; and it would provide technical assistance to other Federal and non-Federal parties on their technology management interests.

-- Policy: The unit would function as a catalyst and Departmental focal point for the development and refinement of policies relating to technology management, and would participate in preparation of legislative, budget, and management proposals to implement those policies.

-- Monitor and Evaluate: The unit would monitor (on an ad hoc basis) agencies' management of non-priority technologies and identify where technical assistance is needed and where there is need for formal evaluation activities; it would identify conceptual gaps in knowledge development and intervention activities and participate in the development of model approaches to overcoming those deficiencies.

-- Liaison: The unit would function as the Department's focal point for (though not the exclusive agent of) liaison with outside parties and agencies with which to link our technology management activities; to develop collaborative working relationships through which to facilitate joint action on specific technologies; to monitor other agencies' research and technology management activities and relate them to the Department's activities; to explore opportunities for interagency agreements and joint funding; to participate in improving the evolving state-of-the-art of technology management.

-- Clearinghouse: Depending upon the capacity, location(s) and structure of the monitoring and screening component, the unit might take on "switching point" activities for incoming inquiries related to health technologies being addressed within the Department and for inquiries within the Department relating to other Federal or non-Federal health technology-related activities.

Several alternatives for the organizational locus suggest themselves: OASH (given the health orientation of this initiative) in its program unit, its policy unit, its special health initiatives office, or, because of its signal importance, in the Assistant Secretary's immediate office; OASPE if considering extending the system to educational technology, telecommunications policy, etc.; or some direct staff arm of the Secretary or Under Secretary. The scope of this study does not permit evaluation of these and other alternatives. The Special Project Manager's 45-day analysis (see Section IX) of the unit's location, staffing, authorities, etc., should make a recommendation from among an evaluated set of options.

C. Recommended Approach

It is recommended that the Department adopt in principle both the technology system as outlined and the emplacement of a Department-level technology management unit; and that further definition of the unit be sought through a Decision Memo (45 days) and refinement of the system through a Phase II Implementation Study (6 months).

APPENDIX 1: GLOSSARY

MEDICAL TECHNOLOGIES: The drugs, devices, medical and surgical procedures used in medical care. Some definitions of this term include the organizational and supportive systems within which such care is delivered. For this study, however, only the former definition is used.

KNOWLEDGE-DEVELOPMENT AGENCIES: Those agencies in the Department whose primary mission is the development of knowledge relating to health or health care. These agencies conduct or sponsor analysis and testing activities. While their primary mission is knowledge development, they may have some significant action functions.

ACTION AGENCIES: Those agencies in the Department whose primary mission is the administration of programs which can affect the development, diffusion, or utilization of medical technologies. These agencies manage the Intervention Mechanisms. They may however, have some knowledge-development capabilities and functions.

EFFICACY: Potential benefit from a medical technology applied for a given medical problem to individuals in a defined population. Efficacy is sometimes used to refer to benefit under ideal conditions of care to differentiate it from effectiveness, which would then be benefit under average conditions of care. We have not made that distinction here; instead, we regard benefit under ideal conditions as a special class of efficacy.

SAFETY: The probability that a medical technology applied for a given medical condition to individuals in a defined population will not cause disease, injury, or harm.

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COST-BENEFIT ANALYSIS: Analysis which compares the monetary value (usually in present value terms) of future benefits with the monetary value of all immediate and future costs (usually in present value terms).

COST-EFFECTIVENESS ANALYSIS: Analysis which relates resource costs to the levels of effectiveness of alternative technologies under study. Their goal is to identify: 1) the alternative that maximizes effectiveness for a given resource cost, or 2) the alternative that involves the least resource cost to attain a specified level of effectiveness.

TECHNOLOGY ASSESSMENT: A relatively new approach to comprehensive policy studies which has a relatively defined set of conceptual parameters. The most commonly accepted definition of technology assesment (TA) is:

> "TA is a class of policy studies which systematically examines the effects on society that may occur when a technology is introduced, extended, or modified with special emphasis on those consequences that are unintended, indirect, or delayed..." (J. Coates)

This term is increasingly being used to refer to any technology-based policy analysis or planning. We have restricted our use of the term to the first sense because the term was coined explicitly by the Congressional Office of Technology Assessment to distinguish comprehensive technology assessment from other technology-based studies which examine such discrete aspects as efficacy, cost-benefit, or cost-effectiveness.

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Terry Shannon	BHPRD, HRA	436-6852
Donald Goldstone	NCHSR, OASH	436-8915
Sherry Arnstein	NCHSR, OASH	436-8963
Seymour Perry	OD, NIH	496-2500
Bruce Carson	OD, NIH	496-3152
Robert Kennedy	BMDDP, FDA	427-7900
Richard Terselic	BD, FDA	443-4154
Ronald Klimberg	BD, FDA	443-3557
Anthony Bruno	BCHS, HSA	443-1994
Dennis Tolsma	OPPE, CDC	8-236-3243
David Kefauver	OA, ADAMHA	443-4266
Howard Davis	NIMH, ADAMHA	443-6165

Office of the Secretary

Karen Davis	DASPE/H	245-7148
Carol Emmott	Legislation	245-2966
James Hinchman	General Counsel	245-7721
Barbara Holland	Executive Secretariat	245-7036
Dana Martin	Management & Budget	245-8846
Peter Sherer	Management & Budget	245-6477

APPENDIX 13

Outline of Analyses to be Included in Phase II Study

Several types of analyses will have major implications for the early refinement of the Departmental system, for the functioning of the technology management unit, and for the expeditious initiation of the high-priority technology process. Consequently, the following items should be initiated very early ("front-ended") in the Phase II Study under the aegis of the Special Project Manager:

— assessment of the perspectives of and potential for collaboration with outside groups (e.g., consumer and public interest groups, private insurers, academic heal science centers, medical specialty groups, providers, labor, Institute of Medicine);

— assessment of the approach of other Federal agencies to technology evaluatic and management, particularly NASA, Commerce, VA, NSF, DOD, OSTP, and OTA;

— evaluation of approaches to incorporating into the technology management system those health technologies excluded from the present study such as disease preven ion, systems management, environmental technologies, mental health, and rehabilitation;

— evaluation of alternatives and recommendation of an approach for implementi the "monitoring and screening" component (e.g., the feasibility and cost-effectiveness of a formal and centralized vs. ad hoc and decentralized approach).

Other types of analyses that should be undertaken by the technology management unit during the Phase II Study should include

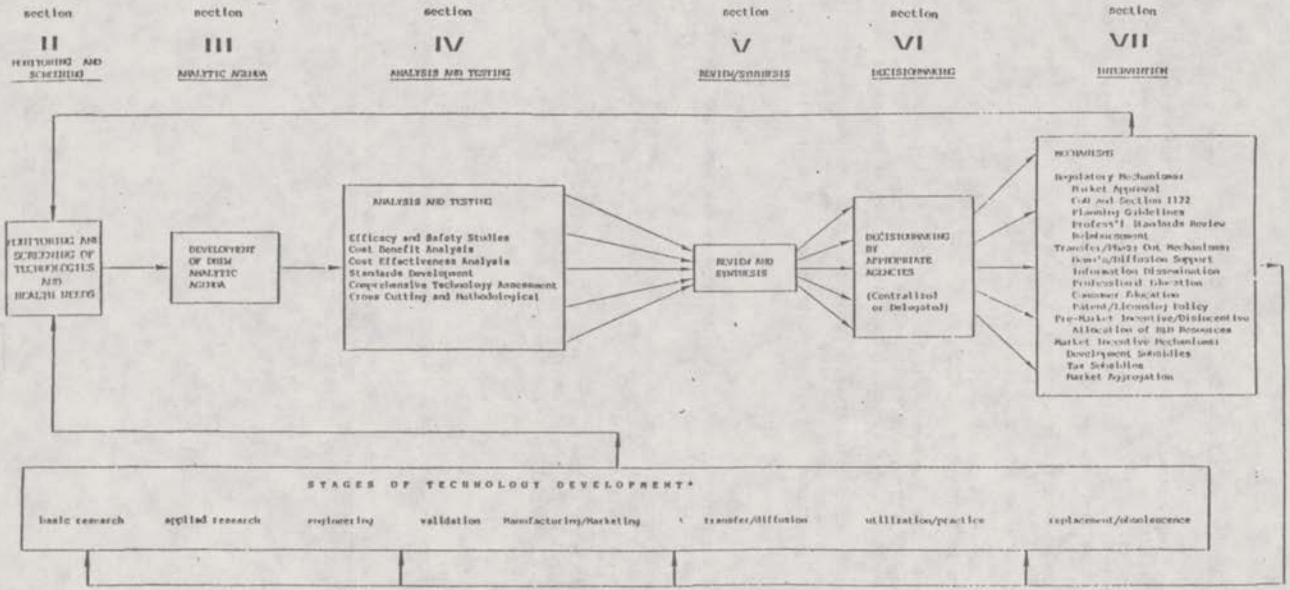
— development of formal mechanisms and processes for generating extensive participation in the high-priority process by other Federal agencies and extra-governmental parties at interest;

— evaluation of the institutional and staff capabilities of "knowledge development agencies" for conducting the types of technical studies described, and of "action agencies" for utilizing effectively the Department's intervention mechanisms, and recommendation of appropriate distribution of responsibilities and staffs among the Agencies;

— operational definition of processes, linkages, and responsibilities for emplacing and exercising the high-priority technology system (i.e., "rough screening" agenda-setting, analysis and testing, review and synthesis, decisionmaking and intervention);

— review of the agency-based deficiencies and the component-by-component recommendations contained in the Phase I report, and development of a work plan for addressing those deficiencies not incorporated into the above analyses.

FIGURE 1: CONCEPTUAL FRAMEWORK FOR HEALTH TECHNOLOGY MANAGEMENT AT THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE (section I)



* Because Technology Development is not a linear process, a technology does [illegible] through

Dr. RICHMOND. I consider the research functions performed by these Centers to be extremely significant. Only if their full potential is realized will we have sound factual and conceptual bases for the management of the health care system at every level, from Federal, State, and regional policy level to the individual provider of health care.

In order to assist these Centers in meeting this challenge, I have recently moved them into my office, where their activities will be coordinated more effectively with the other agencies in the Public Health Service as well as the Health Care Financing Administration.

We fully recognize the need to improve coordination of these critical activities. We have established a Public Health Service Committee for Coordination of Health Statistics Systems, chaired by the Director of the National Center for Health Statistics.

To address the need for Department-wide coordination, we have established a Health Data Advisory Committee, which will serve as a permanent and formal body to advise the Secretary on major crosscutting health data issues. All of these important activities can be carried out under existing legislative authority.

Senator KENNEDY. Just before you go on, isn't that the one that cannot agree on a Chairman, and they have not met?

Dr. RICHMOND. Yes. That is a Committee that did tend to fall into disuse, but we are now taking steps to reorganize and redirect that Committee.

Senator KENNEDY. That is hopeful, because I am sure you are impatient about its functioning and functioning well.

How does this sort of new, coordinated effort that you refer to work with HCFA? I understand that this is still a problem in terms of working out an effective coordinating process.

Dr. RICHMOND. Well, we are integrating our activities with the Health Care Financing Administration, Senator. And I have asked, from the Public Health Service vantage point, Mrs. Hanft, to direct that effort for us, and perhaps she can elaborate on that for you, if you would like.

Mrs. HANFT. We have a research committee that consists of the principles in health services research, including the Office of the Assistant Secretary of Planning. That committee has met once in the last 4 weeks. We viewed the agendas of both the HCFA research programs and the National Center research programs.

We have a second meeting next week. We are working on the charter right now of the Health Data Advisory Committee and hope to have that set up fairly soon.

We also have regular meetings with the Health Care Financing Administration about an every 2-week basis, to discuss mutual problems, overlap, and coordination. I hope in the future that we will even be able to undertake some joint research projects of interest to both organizations.

Senator KENNEDY. OK. We might come back to that later.

Dr. RICHMOND. Yes. I would only reenforce, Senator, what Mrs. Hanft has indicated. This Committee did fall into disuse, and as I came into my office and became aware of this, we have taken steps, with the support of the Secretary and the Under Secretary, to really reactivate this and to make it more functional.

We are working hard to give both Centers the substantive and managerial support which they need to perform their functions and to assure that they can meet the substantial demands that will be put upon them by our efforts to improve the health care system in this country.

Now, Mr. Chairman, I would like to turn to the issue of health technology. Your proposal for a National Institutes of Health Care Research has, as you know, spurred considerable thought through its use of the renewal of the Centers' authorizations to address a problem of which we are all aware, but which has not received the attention it deserves.

When I testified before your subcommittee last July, you expressed dissatisfaction with the Department's ability to link systematically laboratory bench findings to bedside practice.

You urged us to examine the problem and to develop a more systematic approach to technology development and use. We concurred in your assessment and, in concert with the Office of the Assistant Secretary for Planning and Evaluation, the Secretary created a joint team to conduct an analysis of the problem.

We asked the team to survey the technology-based activities which are now taking place in the agencies, to identify the gaps and deficiencies in those activities, and to outline a strategy to cope more effectively with those deficiencies.

While many share a commitment to come to grips with the "technology problem," our analysis quickly showed this seeming consensus to belie many different conceptions and priorities.

To some, it has seemed a problem of cost containment, because technology is perceived as a major culprit in the spiralling costs of health care.

To others, it has seemed a problem of reducing the time that it takes to get effective new technologies into medical practice.

To others, it has seemed a problem of preventing premature transfer of technologies which are unproven and perhaps even harmful.

To others, it has seemed a question of harnessing the techological imperative in order to enhance, rather than endanger, our social and ethical values.

All of these concerns illustrate that the technology problem is a grossly misleading form of shorthand. In fact, there are many technology problems.

Furthermore, important parties at interest have conflicting and competing priorities. Their views must be taken into account if we hope to develop a better balance between controlling the costs of health care while not stifling technological innovation and improvements in the quality of care.

Our study, which we are submitting for the record, Mr. Chairman, has also made us keenly aware that while the Department is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to link systematically stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization and phaseout.

In summary, while departmental agencies currently engage in many technology-based activities, an enlarged evaluation capacity is clearly needed.

The achilles heel, however, is our present incapacity to provide coordination and linkages among the activities.

Senator KENNEDY. Why is that so, do you think, Doctor?

Dr. RICHMOND. Well, I think, Senator, as our task force studied this and looked at the complexity, which is in the report which we are submitting, and in this chart which you have before you, when one breaks down the various components of health technology management, one identifies a high order of complexity. And, as I have indicated, various people have various perceptions of which pieces of this ought to be tackled first and, indeed, which issues are of the highest priority.

In our Department, we have in the National Institutes of Health, in the Food and Drug Administration, and the Center for Disease Control, many activities which deal with various pieces of this. And heretofore, we have not had a systematic way of dealing with this, and what our task force has recommended is a way of systematizing this approach, Mr. Chairman, so that we can begin to deal with all of the pieces which are ongoing in the Department and which also are ongoing in the extramural community across the country, in the universities and industry and in laboratories throughout the country and, indeed, in medical practice.

And what we have not had heretofore is a focal point for bringing these together.

Senator KENNEDY. Doctor, do you come later in your testimony to what they are doing at the present time?

Dr. RICHMOND. Yes; we will come to some of that.

Senator KENNEDY. Okay.

Dr. RICHMOND. Even the most carefully devised technology initiative is unlikely to provide a "quick fix" to the extraordinarily complex set of problems involved.

Nevertheless, we have developed and plan to implement shortly a new technology strategy which we believe will enable us to reduce significantly the gap between analysis and action.

As you can see from the diagram which I have already referred to, we have developed a technology management strategy that is comprised of six linked steps:

First, the identification and screening of candidate technologies and health needs for analysis;

Second, an annual priority setting for a departmental study agenda;

Third, the conduct or sponsorship of studies;

Fourth, the translation and synthesis of technical findings;

Fifth, explicit decisionmaking to restrain or to stimulate development and use of a target technology; and

Sixth, the implementation of decisions through a spectrum of such intervention mechanisms as allocation of R.&D. resources, market approval, incentives, utilization guidelines, and professional and consumer education.

Since such a strategy will require considerable orchestration among the agencies and extensive collaboration with the private sector, a Department-level locus is needed to provide the managerial leadership and coordination.

The Secretary has assigned that responsibility to my office, and I have already taken important steps to establish an Office of Health Technology.

One of the major tasks of the new Office will be to conduct a pilot demonstration of the technology assessment and management strategy, with four to seven high-priority technologies.

These demonstrations will focus on technologies which typify such current concerns as premature or delayed transfer from bench to bedside practice, unwarranted cost in relationship to anticipated benefits, and the need for early warning on controversial societal side effects.

Senator KENNEDY. Of course, there is no question about the importance of the managerial function in this area. On the coordinating aspect, what I consider to be the most important ingredient in making this case is your own personal leadership. Our real problem is from an institutional point of view as over any period of time, what is going to happen; whether you are able to get the kind of people to come down to work in this area for 2, or 3 years, until it gets on its feet, with the idea of being spun off, and get the support from the administration, in terms of OMB. We would have that difficulty, as well, I am sure.

But just in terms of the managerial setup, outside of what I consider to be a strong team in the Department at the present time, that is not an inconsiderable problem. I do not think from a structural point of view, it is going to make a tremendous difference. In the areas of responsibility, do you have an advisory committee working with you.

Dr. RICHMOND. We are planning, Senator, to first of all try to get the advice of the Institute of Medicine to the report of our task force, and on the basis of their recommendations, if we are successful in enlisting their cooperation, get their advice about the kind of advisory committee structure to set in place.

But we are looking for the widest kind of consultation.

Senator KENNEDY. So you will have some form or structure of an advisory council?

Dr. RICHMOND. Yes. I have discussed this pointedly with the Secretary and he is very eager for us to have some broad advisory group, that would be not alone from within the Public Health Service or the Department, but broadly representative of the scientific and health community.

Senator KENNEDY. Do you think OMB will give you the go-ahead on that?

Dr. RICHMOND. Well, as you know, they are very sensitive about advisory committees, Senator, but we think that this is an instance where it will be extremely important to be in the proper place.

Senator KENNEDY. You also talk about pilot demonstrations. Do you need a pilot or really something bigger? Or is that more descriptive of the buildup that you see?

Dr. RICHMOND. Well, we think, Senator, it is very important to try to focus on some high priority technologies and to essentially carry those through some pilot testing. We have already begun that. I have developed an Office of Health Practices Assessment, which is currently in the process of reviewing three health technologies. We are reviewing the management of manic-depressive psychoses, rheumatic heart disease, and malignant melanoma.

These are three areas that we think lend themselves to comprehensive review, and we think the results of such studies will have important implications to the management of these disorders.

We are piloting those. We think there are many others. We think if such things as the CT scanner had been piloted in this fashion earlier and more effectively that we perhaps would have had a more ordered approach to the development of these technologies.

Senator KENNEDY. If you had to draw a flow chart for the next 3 to 5 years, where would you be in your proposal; say, in 5 years, what sort of things would you be doing—or would you have spun this off by then?

Dr. RICHMOND. Well, I think, Senator, my thought is that in the institutionalization of this program which you have referred to and you see developing a center, I think we would think that such a development would be extremely important to policy development in the Department. Policy development at the highest level takes place in the Office of the Assistant Secretary, and my view is that since such an office would have to draw on the technologies which are being developed in various agencies of the Department, that it would be important—for a time, at any rate, until we gain more experience—for us to keep this at the level of the Office of the Assistant Secretary, to see how effectively this feeds into policy development.

Senator KENNEDY. Of course, that has all the limiting factors, does it not, from an institutional point of view? There is so much that you can do as the Assistant Secretary. But it seems to me by definition it would be a more limited function, quite frankly. I mean, OMB is not going to let your whole operation just expand and develop, I would not think, given the past record, the numbers in people and personnel and all the rest.

I think that it creates some really important organizational institutional problems just about how far you can go over what period of time. And I think probably there are men and women with differing views about that.

Dr. RICHMOND. Well, I think you are raising a very important question. Since I have come into my office, Mr. Chairman, what I have perceived is the need for strengthening our policy development capacity. And, as Mrs. Hanft has come into that office and taken on that responsibility, I think we have increased our capacity. But I think along with the two existing centers, if we had this third center ultimately, which would enhance our policy-generating capacity, I think it would be an extremely valuable addition at that level.

What I am suggesting, Senator, is that there may be another way to institutionalize this function, rather than the creation of another agency. I am not suggesting that perhaps several years from now, I might not come to that conclusion, but I think I would prefer to see us gain some experience in strengthening our policy developmental capacity at the present time, and I think we are on the road to doing that.

You have raised, Mr. Chairman, the question of recruitment. I think we would want to recruit ahead for this Office of Health Technology. We would hope to recruit an outstanding scientist, with credentials in both the research and the health care community.

We think that it is possible to recruit at that level if this Office is located at the level of the Assistant Secretary's Office.

To support this demonstration phase, we plan to redirect $5 million of Public Health Service funds in fiscal 1978 to support the necessary studies and evaluate innovative approaches to the communication of findings to such diverse users as practicing physicians, consumers, and policymakers.

To expedite establishment of the Office, staff for the first 6 months will be comprised of 22 detailees, drawn from different disciplines including health professionals, biomedical scientists and engineers, statisticians, policy scientists, ethicists, economists, behavioral scientists, and communication experts.

Other functions we would see in this new Office for Health Technology would include serving as a catalyst and Departmental focal point for policy formulation; development of a process through which the Department can collaborate on technology decisionmaking with other Federal agencies and the private sector; provision of technical assistance to departmental agencies; evaluation of technology assessment and transfer activities throughout the Department in order to identify gaps and deficiencies; the assessment of the feasibility and cost-effectiveness of developing a long-range system to identify and screen technologies and health needs; provision of recommendations to the Health Care Financing Administration on the advisability of reimbursement for drugs, devices, and procedures under the medicare and medicaid programs; and finally, the Office of Health Technology will be charged with developing recommendations regarding possible institutional changes that might contribute to achieving our technology management objectives.

In closing my remarks, Mr. Chairman, I would like to certainly commend you and the members of your subcommittee for the innovative approach to technology evaluation embodied in your bill S. 2466.

Once again, you have forced policymakers both inside and outside of government to focus their efforts on developing an effective technology management strategy.

I recognize that the plan of action I have just outlined may appear conservative by comparison. Institutional change along the lines embodied in your bill may indeed be warranted as we gain more experience and perspective on the technology problem.

We are unprepared, however, to endorse your proposal at this time, because we believe that it would be premature for the Department to undergo such a major structural change without a more fundamental understanding of the complexities involved.

Be assured, however, that we do plan to move quickly. We believe that the efforts of this pilot Office of Health Technology will provide essential information that will enable us to return in 2 years with recommendations for major structural reform.

Apart from what we believe is the prematurity of reorganization at this time, we are troubled by some of the specifics related to the National Center for Health Statistics and the National Center for Health Services Research.

The proposed institutes would have within their purview activities which are integral to other Public Health Service operations.

As mentioned earlier, the National Center for Health Statistics is now undertaking some epidemiologic analyses designed to complement the ongoing activities of the National Institutes of Health, the Center for Disease Control, the FDA, and ADAMAH.

The epidemiological activities of the National Institutes of Health and the Center for Disease Control are closely intertwined with the other activities of those units and coordination or control of them from outside would interfere with the place of these activities in the overall mission of NIH and CDC.

Further, the proposed change in orientation from health services research to health policy research obscures real differences between these disciplines. They are not the same. Both are necessary, and both need support.

It is our goal to provide research that is responsive not only to short-term policy considerations, but to independent and long-range research needs as well.

In addition, we have recently begun a major study of the National Center for Health Services Research's research agenda and structure. A list of experts serving as consultants in this review is being submitted for the record. The Institute of Medicine, as you probably know, is also conducting a broad-based study of health services research that will not be completed for several months.

Because we intend to move as rapidly as possible in these efforts, in improving the existing centers, and in developing plans for a large-scale technology management program, we would support a reduction in the extension of these programs to 2 years.

By 1980, we believe we would have the information necessary to evaluate adequately options for reorientation and would look forward to working with the subcommittee to develop a sound proposal.

In closing, Mr. Chairman, I would like to say that the Department shares your commitment to develop a technology management capability.

We concur in your assessment that the Department currently directs inadequate resources to technology evaluation, but would argue that a viable technology strategy must also address the management need to better link knowledge development and intervention strategies.

Thus, while we are presently unprepared to endorse major institutional reordering, we appreciate the contribution of S. 2466 in stimulating a broad discussion of alternatives, and we hope that differences in the timing of our strategies will not preclude the meaningful collaboration required for creative solutions to the whole range of problems imposed by technology in the health care system.

This concludes my prepared testimony at this time, Mr. Chairman. My colleagues and I would be happy to respond to questions.

[The prepared statement of Dr. Richmond follows:]

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

STATEMENT

BY

JULIUS B. RICHMOND, M.D.

ASSISTANT SECRETARY FOR HEALTH

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

TUESDAY, FEBRUARY 7, 1978

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to appear before you today to discuss the renewal of authorizations for the National Centers for Health Statistics (NCHS) and Health Services Research (NCHSR), issues of technology assessment and use, and the proposal for certain changes in the structure of these programs, embodied in your bill, S. 2466.

Research and statistics expenditures are an investment in the future--in our ability to make sound decisions that can improve our health care delivery system. Your support and that of your Subcommittee over the years for our health services research and statistics activities is greatly appreciated. Your continuing concern with both the promise and problems of technology has been a catalyst for important new actions in the Department, which I will outline in my remarks.

The work of the Centers makes invaluable, although not always visible, contributions to policy deliberations, health legislation, Federal health programs, and the decisions of health care providers. The comprehensive program of the National Center for Health Statistics includes more than 20 data systems, which produce information on health status of the population, health resources, utilization of health services, nutrition, family growth, and the Nation's patterns of births, deaths, marriages, and divorces. A few examples will illustrate their importance.

Among the specific contributions of such information is an awareness of the health care trends that form the factual backdrop for many important decisions in the health field, in cost containment, quality, distribution of services, and control of toxic substances. For example, the Hospital Discharge Survey has shown the incidence of hysterectomies rising substantially (from 734 per 100,000 females 15 years and older in 1971, to 850 in 1974). More recently, there appears to be a downturn, perhaps due to heightened visibility of the phenomenon. The Health and Nutrition Examination Survey measures the prevalence of hypertension among adults and indicates that the prevalence rate among blacks is nearly twice as high as that among whites. New epidemiologic techniques in mapping infant mortality and other mortality rates to determine geographic differentials can identify variations due to lack of access to care or exposure to environmental hazards.

The National Center for Health Services Research plays a parallel role in services research. NCHSR-supported research and demonstration activities produced the factual justification for new legislation which provides for reimbursement of physician assistants and nurse practitioners practicing in rural clinics. Other NCHSR research has produced the health scarcity index for identifying shortage areas. The Experimental Medical Care Review Organization project initiated in 1970 provided the working model for Professional Standards Review Organizations. The Center has become increasingly sensitive to the demand for policy-relevant research and is preparing to fund research on cost containment specifically tailored to the needs of local health systems agencies. It has initiated a series of National Medical Care Expenditure studies as a major component of its intramural program. Data for this study is being developed in collaboration with the National Center for Health Statistics. The product of this effort will provide valuable information for evaluating alternative financing mechanisms for health care in the United States.

More detailed information about the activities of the Centers is being submitted for the record.

I consider the research functions performed by these Centers to be extremely significant. Only if their full potential is realized will we have sound factual and conceptual bases for management of the health care system, at every level--from Federal, State, and regional policy level to the individual provider of health care.

In order to assist these Centers in meeting this challenge, I have recently moved them into my office, where their activities will be coordinated more effectively with the other agencies in the Public Health Service as well as the Health Care Financing Administration. We fully recognize the need to improve coordination of these critical activities. We have established a PHS Committee for Coordination of Health Statistics Systems, chaired by the Director of the NCHS. To address the need for Department-wide coordination, we have established a Health Data Advisory Committee, which will serve as a permanent and formal body to advise the Secretary on major cross-cutting health data issues. All of these important activities can be carried out under existing legislative authority.

We are working hard to give both Centers the substantive and managerial support which they need to perform their functions, and to assure that they can meet the substantial demands that will be put upon them by our efforts to improve the health system in this country.

For the National Center for Health Statistics, we intend to complete the first three components of the Cooperative Health Statistics System for all States during the next several years. We plan to reinstitute follow-back surveys to add to our knowledge of epidemiologic and health status data. We have plans to expand the analytic capability of NCHS to mine the wealth of available data.

For the National Center for Health Services Research, we plan an expansion of their technology program during fiscal year 1979. We are reviewing the allocation of research efforts between intramural and extramural activities. We plan to develop a capability to evaluate the impact of health services programs. Our organizational arrangements are being directed toward more effective coordination of research and statistical activities.

Now, Mr. Chairman, I would like to turn to the issue of health technology. Your proposal for a National Institutes of Health Care Research has, as you know, spurred considerable thought through its use of the renewal of the Centers' authorizations to address a problem of which we are all aware, but which has not received the attention its deserves.

When I testified before your Subcommittee last July, you expressed dissatisfaction with the Department's ability to systematically link bench findings to bedside practice. You urged us to examine the problem and develop a more systematic approach to technology development and use. I concurred in your assessment and, in concert with the Office of the Assistant Secretary for Planning and Evaluation, created a joint team to conduct an analysis of the problem. We asked the team to survey the technology-based activities which are now taking place in the agencies, to identify the gaps and deficiencies in those activities, and to outline a strategy to cope more effectively with those deficiencies.

While many share a commitment to come to grips with "the technology problem," our analysis quickly showed this seeming consensus to belie many different conceptions and priorities:

- To some, it's a problem of cost containment, because technology is perceived as a major culprit in the spiraling costs of health care.
- To others, it's a problem of reducing the time that it takes to get effective new technologies into medical practice.
- To others, it's a problem of preventing premature transfer of technologies which are unproven and perhaps even harmful.
- To others, it's a question of harnessing the technological imperative in order to enhance, rather than endanger, our social and ethical values.

- o Still others are particularly concerned about our under-investment in efficacy and safety studies, cost-benefit and cost-effectiveness analyses, or comprehensive technology assessments.
- o Additional divergent objectives include the need to address:
  - Obsolescent technologies;
  - Inappropriate utilization of technology;
  - Maldistribution of technology;
  - Inadequate market incentives for promotion of preventive, system management, and mental health technologies; and
  - The need for public input into technology decisions.
- o Finally, there are those who fear:
  - Federal intrusion into medical practice;
  - Federal interference in the health market; and
  - Suppression of technology development.

All of these concerns illustrate that "the technology problem" is a grossly misleading form of shorthand. In fact, there are many technology problems. Furthermore, important parties-at-interest have conflicting and competing priorities. Their views must be taken into account if we hope to develop a better balance between controlling the costs of health care while not stifling technological innovation and improvements in the quality of care.

Our study (which I am submitting for the record) has also made us keenly aware that while the Department is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to systematically link stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization and phase-out. Consequently,

- o The "knowledge development" agencies (such as NIH, NCHSR and NCHS) each decide independently which technologies they will examine, how they will examine them, and what use will be made of the results;
- o The "action agencies" (such as HSA, Medicare, Medicaid, and the PSRO program) lack adequate technical information to carry out their responsibilities and effective links to the knowledge development agencies which would promote development of action-supporting information on technologies of interest;
- o Results of technical evaluations appear in the research literature, but often do not come to the attention of practicing physicians, consumers, or those officials responsible for making reimbursement, regulation, or standard development decisions;

- Considerable effort is focused on efficacy and safety evaluations, but little is directed to evaluation of cost-benefit and cost-effectiveness implications, and virtually nothing is being done to assess unintended societal side effects;
- Inadequate emphasis is placed on methodological studies to improve the reliability and validity of technology-based analysis and testing; and finally,
- Ad hocracy reigns in the absence of explicit linkages between technology studies and public or private actions to impede or stimulate technology transfer and utilization.

In summary, while DHEW agencies currently engage in many technology-based activities, an enlarged evaluation capacity is clearly needed. The Achilles heel, however, is our present incapacity to provide coordination and linkages among the activities.

Even the most carefully devised technology initiative is unlikely to provide a "quick fix" to the extraordinarily complex set of problems involved. Nevertheless, we have developed and plan to implement shortly a new technology strategy which we believe will enable us to significantly reduce the gap between analysis and action.

As you can see from the diagram attached to my testimony, we have developed a technology management strategy that is comprised of six linked steps:

1. Identification and screening of candidate technologies and health needs for analysis.
2. Annual priority setting for a Departmental study agenda.
3. Conduct or sponsorship of studies.
4. "Translation" and synthesis of technical findings.
5. Explicit decisionmaking to restrain or stimulate development and use of a target technology.
6. Implementation of decisions through a spectrum of such intervention mechanisms as allocation of R&D resources, market approval, incentives, utilization guidelines, and professional and consumer education.

Since such a strategy will require considerable orchestration among the agencies and extensive collaboration with the private sector, a Department-level locus is needed to provide the managerial leadership and coordination.

The Secretary has assigned that responsibility to my office, and I have already taken important steps to establish an Office of Health Technology. One of the major tasks of new office will be to conduct a pilot demonstration of the technology assessment and management strategy with four to seven high-priority technologies. These demonstrations will focus on technologies which typify such current concerns as premature or delayed transfer from bench to bedside practice, unwarranted cost in relation to anticipated benefits, and the need for early warning on controversial societal side-effects.

To head the new Office of Health Technology, we will recruit an outstanding scientist with credibility in both the research and health care community.

To support this demonstration phase, I plan to redirect $5 million of Public Health Service funds in FY 1978 to support the necessary studies and evaluate innovative approaches to communication of findings to such diverse users as practicing physicians, consumers, and policymakers.

To expedite establishment of the Office, staff for the first six months will be comprised of 22 detailees, drawn from different disciplines including health professionals, biomedical scientists and engineers, statisticians, policy scientists, ethicists, economists, behavioral scientists, and communication experts.

Other functions of the new Technology Office include:

- o Serving as a catalyst and Departmental focal point for policy formulation;
- o Development of a process through which the Department can collaborate on technology decisionmaking with other Federal agencies and the private sector;
- o Provision of technical assistance to DHEW agencies;
- o Evaluation of technology assessment and transfer activities throughout the Department in order to identify gaps and deficiencies;
- o Assessment of the feasibility and cost effectiveness of developing a long-range system to identify and screen technologies and health needs;
- o Provision of recommendations to the Health Care Financing Administration on the advisability of reimbursement for drugs, devices, and procedures under the Medicare and Medicaid programs;
- o Finally, the Office of Health Technology will be charged with developing recommendations regarding possible institutional changes that might contribute to achieving our technology management objectives.

In closing my remarks Mr. Chairman, I would like to commend you for the innovative approach to technology evaluation embodied in S. 2466. Once again you have forced policymakers both inside and outside government, to focus their efforts on developing an effective technology management strategy.

I recognize that the plan of action I have just outlined may appear conservative by comparison. Institutional change along the lines embodied in your bill may indeed be warranted as we gain more experience and perspective on the technology problem. We are unprepared, however, to endorse your proposal at this time because we believe that it would be premature and disruptive for the Department to undergo such a major structural change without a more fundamental understanding of the complexities involved. Be assured, however, that we plan to move quickly. We believe that the efforts of this pilot Office of Health Technology will provide essential information that will enable us to return in two years with recommendations for major structural reform.

Apart from what we believe is the prematurity of reorganization at this time, we are troubled by some of the specifics relating to NCHS and NCHSR.

The proposed Institutes would have within their purview activities which are integral to other PHS operations. As mentioned earlier, the NCHS is now undertaking some epidemiologic analyses designed to complement the ongoing activities of the NIH, CDC and FDA. The epidemiological activities of the National Institutes of Health and the Center for Disease Control are closely intertwined with the other activities of those units, and coordination or control of them from outside would interfere with the place of these activities in the overall mission of NIH and CDC.

Further, the proposed change in orientation from health services research to health policy research obscures real differences between these disciplines. They are not the same. Both are necessary and both need support. It is our goal to provide research that is responsible not only to short-term policy considerations, but to independent and long-range research needs as well.

In addition, we have recently begun a major study of NCHSR's research agenda and structure. A list of experts serving as consultants in this review is being submitted for the record. The Institute of Medicine is also conducting a broad-based study of health services research, that won't be completed for several months.

Because we intend to move as rapidly as possible in these efforts, in improving the existing Centers, and in developing plans for a large-scale technology management program, we would support a reduction in the extension of these programs to two years. By 1980, we believe we would have the information necessary to adequately evaluate options for reorientation and would look forward to working with the Subcommittee to develop a sound proposal.

In closing, Mr. Chairman, I would like to say that the Department shares your commitment to develop a technology management capability. We concur in your assessment that the Department currently directs inadequate resources to technology evaluation, but would argue that a viable technology strategy must also address the management need to better link knowledge development and intervention strategies.

Thus, while we are presently unprepared to endorse major institutional reordering, we appreciate the contribution of S. 2466 in stimulating a broad discussion of alternatives and hope that differences in the timing of our strategies will not preclude the meaningful collaboration required for creative solutions to the whole range of problems imposed by technology in the health care system.

That concludes my prepared testimony at this time, Mr. Chairman. My colleagues and I will be happy to respond to any questions you may have.

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Senator KENNEDY. Thank you very much.

Dr. Richmond, I think we are hopefully moving into a time frame with health insurance where health information and research and technology assessment is going to be extremely important.

We will get the administration's program later this spring, and we intend to have quite extensive hearings on it during the period of the summer, and hopefully have action on it in the very near future with the kind of information that will be gathered by our proposal and the kind of information that I think you also recognize is of great importance is absolutely urgent at this time.

There is a greater sense of urgency about it, I think, now than really any time in the past—there should be, rather. Perhaps there is not, but there should be.

One of the factors that troubles me with the administration's proposal is it would seem that you would be moving along for 1, 2, perhaps even 3 years, trying to shift people around within the Department, and I think there would have to be some legitimate questions as to the types of training and the background and experience that these people would have, being loaned to various agencies, focusing on this problem; the difficulty of attracting people from outside that would come down to the Department for 1 or 2 years, with the idea that there is going to be a change in administrative structure of this particular program and unsure where that is going to lead. It is the question about what we are going to find out, even through experimentation and even through this kind of administrative setup that you talk about, that we really will not know in a couple of years.

I think really the legitimate question is: If we have some ideas and views about these issues, why doesn't it make sense to set up this process now and get about the business which we should be about, in terms of technology, in terms of information, in terms of the types of research? Let's give it the kind of visibility, get it moving in the private sector, with insurance companies and the private areas, and give it the support, both congressional and administration support, get the quality people in there, and get about the business of doing it.

That is really what I think needs to be done. I am just troubled—and you make a case, and it is an appealing one, that with your own personal leadership and the leadership of the people at this table, who are highly qualified and have a view about this particular issue, that you will be able to develop it through its early process, and perhaps be able to spin this off when it gets on its feet.

I am just troubled whether, from an administrative point of view and organizational point of view, and the sense of urgency that this particular issue demands, whether that is as effective.

I do not know, with all respect, that the proposals and the comments that were advanced putting forward this issue this morning are going to change my mind. Maybe you did not expect to, but that is where we come out.

I do not know whether you would want to make any general comment——

Dr. RICHMOND. I think I would, Mr. Chairman. I think your proposal is—as I indicated in my formal testimony—very innovative. Conceptually, it makes sense. And I suppose I feel that way because it is going in the direction that we are moving in as well.

Senator KENNEDY. You know, these ideas have been around. I think we have attempted to package them, but among thoughtful people, both in your Department and other areas that are thinking about it, we recognize it.

Dr. RICHMOND. I think I would just also indicate, Mr. Chairman, that we have been moving in the direction of explorations. The Office of Health Practices Assessments, to which I referred, we set up to try to accomplish some of the objectives that you had in the Center for the Evaluation of Medical Technology—or in the proposed Center.

We have also, we think, improved our capacity to evaluate various health technologies for the administration of the medicare and medicaid programs, and we have begun to systematize that.

We do feel, however, that there are many activities, many programs ongoing within the Department in the various agencies, that are very relevant to the management of health technology.

And we do indeed need to learn how to bring all of that together at a focal point in the Department more effectively. It is for that reason that we want to move quickly, even to the point, of course, of redirecting, as I indicated, some $5 million to get started immediately.

Our task force, as is, I think, well-illustrated in this diagram which you have before you, identified the inordinate complexity of this problem.

The whole matter of moving from basic research all the way to the practice and applications end of the spectrum—and there are many, many stages in between.

And we think in order to recruit the kind of competence that you are talking about, Mr. Chairman, in order to develop this on a sound basis, in order not to replicate what is going on in the existing agencies, but to develop some way of tapping into the good work that is going on there, as well as in the broader community outside of the Public Health Service, will take some really creative kind of effort. And we need to bring some people in to work on that. We do not think that that can happen instantly.

Senator KENNEDY. We are going to have to recess for about 10 minutes, and then I have some other questions and we will continue along.

[Whereupon, a short recess was taken.]

Senator KENNEDY. We will come to order.

Dr. Richmond, you have indicated that you would probably get $5 million for this project within HEW; is that correct?

Dr. RICHMOND. That is correct.

Senator KENNEDY. Could you tell us where that $5 million will come from?

Dr. RICHMOND. We were planning to redirect those funds from several of the agencies—some from the National Institutes of Health, some from the Center for Disease Control, some from the Food and Drug Administration, and some from the National Center for Health Services Research.

Senator KENNEDY. Well, I think we ought to find that out. You know, we spent a lot of time last year to get the increased budget, for example, in FDA, because of all of their responsibilities in terms of investigating and drug testing. And I would expect that they will probably have additional responsibilities in the area of cosmetics before this session is over. So I wonder how we can do it in terms of FDA.

The CDC has all the programs now with regards to the Russian flu and other factors. Do they have loose money around? The NIH, I would like to see where that is coming from, in terms of the program. Health services is the same way. All of those programes are heavily pressed with their budgets in any event.

So I think we ought to get some idea of where this is coming from and what you see as to where it will come from over any period of time, the next 2 years, 3 years, and how you see the growth of that particular kind of program within HEW.

You can submit that, unless you want to make a comment on it now.

Dr. Richmond. Well, we would, Senator, plan to come to you with some requests for new funds for this program before very long.

The redirection of the $5 million was largely in an effort to get something moving immediately, rather than waiting for the next budgeting cycle. But we will be glad to submit a plan to you for the record.

[The following material was received for the record:]

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

TO : Special Assistant for Legislation, HEW

DATE: August 3, 1978

FROM : Associate Director for Medical Applications of Research

SUBJECT : Preliminary Implementation Plan for the Office of Health Technology (OHT)

Attached as requested is a copy of a memorandum, dated April 25, which provides a preliminary implementation plan for the OHT. It was prepared in response to a request from the Office of the Secretary. The request which led to this memorandum is also attached (Memorandum from Fred Bohen, dated April 14, 1978).

The preliminary nature of this plan must be emphasized. One obvious possible change would be to have only one intradepartmental group instead of the two under I. IMPLEMENTATION.

It should also be noted that attachments No. 1 and 5 were prepared based on an earlier draft of the functional statement for OHT, in which the Office of Health Care Quality Assurance (OHCQA) was included. In the version signed by the Secretary portions dealing with OHCQA were deleted.

If I can be of any further help, please let me know.

Seymour Perry

Seymour Perry, M.D.

Enclosures

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

April 14, 1978

MEMORANDUM FOR DR. RICHMOND

At the close of the April 12 Health Technology meeting, it was agreed that you would initiate action to:

* Draft an implementation plan for the Office of Health Technology (OHT). The implementation should take account of the April 5 draft functional statement for OHT submitted by Karen Davis, and spell out as clearly as possible OHT's anticipated role in relation to NIH's Office for Medical Application of Research (OMAR).

* Assemble an intra-departmental work group to advise on and assist in the continuing colaboration of the OHT implementation plan. The group should be made up of the principals in H's prior health technology activities, especially HCFA and P as well as other agency representatives who will together reflect the full range of the Department's interest in OHT (L, AMB, OGC).

It would be helpful to have at least a preliminary implementation memorandum and a report on the initiation of the Task Force by April 21.

Fred Bohen
Fred Bohen
Executive Secretary

cc: HCFA
P
L
AMB
OGC
H

TRACER 44103

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

APR 25 1978

Executive Secretary, OS

Assistant Secretary for Health

Preliminary Implementation Plan for the Office of Health Technology (OHT)

In response to your memorandum of April 14, I am submitting the following preliminary implementation plan for OHT, along with a description of the relationship between OHT and Office for Medical Applications of Research (OMAR), National Institutes of Health (NIH).

I. IMPLEMENTATION

Immediately after approval and publication of the functional statement for OHT and appointment of Acting Deputy Assistant Secretary of Health for Technology (DASHT), the following will be undertaken:

1. An Intradepartmental Advisory Group will be established.

   This group will be chaired by DASHT and will consist of representatives from the Office of the Secretary (OS)-- Planning (P), Management and Budget (MB), Office of General Counsel (OGC); Health Care Financing Administration (HCFA); Office of Health Care Quality Assurance (OHCQA); Office of Health Programs (OHP-OASH); Office of External Relations (OER-OASH); and Office of Health Policy Research and Statistics (OHPRS-OASH). This group will provide overall guidance and advice to the operating group in the development of the implementation plan.

2. The Operating Group will be convened.

   This group will be the regular functioning body of OHT and will consist of representatives from PHS agencies, OS, OHCQA, and OHPSR, with a liaison member from HCFA. It will be chaired by DASHT, and will have the responsibility of developing the implementation plan with advice from the Intradepartmental Advisory Group.

3. Identification of High Priority Technologies

   OHT with advice of the foregoing will proceed to identify

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high priority technologies which urgently require consideration. It will set in motion the studies to provide the necessary information to enable it to develop recommendations regarding these technologies for conveyance to those agencies and others that need such input.

4. National Advisory Board

OHT will promptly proceed to identify and recommend for approval, candidates for the National Advisory Board to OHT and will include representatives from professional societies, the public, industry, third party payers, and others as appropriate and ex officio members from governmental bodies involved in health (e.g., the Veterans Administration, PSRO, etc.).

II. RELATIONSHIP BETWEEN OHT AND OMAR

1. Functions of OHT - (attachments 1 and 2)

The functions and responsibilities of OHT are described in the functional statement for OHT as reflected in the April 17 memorandum from the Deputy Assistant Secretary for Health Policy, Research and Statistics (attachment 3). In essence, OHT will systematize and manage the diverse technology-based activities which take place in the Public Health Service agencies (e.g., monitoring, evaluation, review/synthesis, transfer and intervention).

2. Functions of OMAR - (attachment 4)

This office has the lead responsibility for coordinating all NIH activities with respect to the evaluation of medical applications of research. In concert with the BID directors, OMAR has developed criteria for identifying health technologies which are ready for consensus development. Together with the BIDs, OMAR develops and refines procedures for consensus development regarding the safety, efficacy, and effectiveness of such technologies. It oversees selection of topics and consensus activities. OMAR has the responsibility of assuring that the results of consensus development exercises are conveyed in an understandable form to those that require such information (e.g., other PHS agencies, the practicing community, etc.).

3. OHT-OMAR Interaction - (attachment 5)

OHT is an office with management responsibilities for technology and deals particularly with High priority technologies

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

from a comprehensive perspective encompassing technical and ethical aspects, cost impact, reimbursement, standard setting, regulation, etc.

In contrast, OMAR is a scientifically oriented office drawing on all the resources of NIH to assess large numbers of health technologies with respect to safety and efficacy and their readiness from that standpoint for introduction into the health care delivery system. In its role, OMAR provides (1) technical input to OHT regarding establishment of priorities, (2) readiness of a given technology for assessment, and (3) technical information on safety and efficacy for use by OHT in its broader responsibility for comprehensive technology assessment. OHT furnishes to OMAR results of these assessments for consideration by the research community in setting research priorities.

In developing these interactive roles, both OMAR and OHT will consider the recommendations contained in the Department's Technology Management Report.

s/ Julius B. Richmond

Julius B. Richmond, M.D.

Attachments

Prepared by SPerry
Typed: ES/PHS:peh:4/25/78

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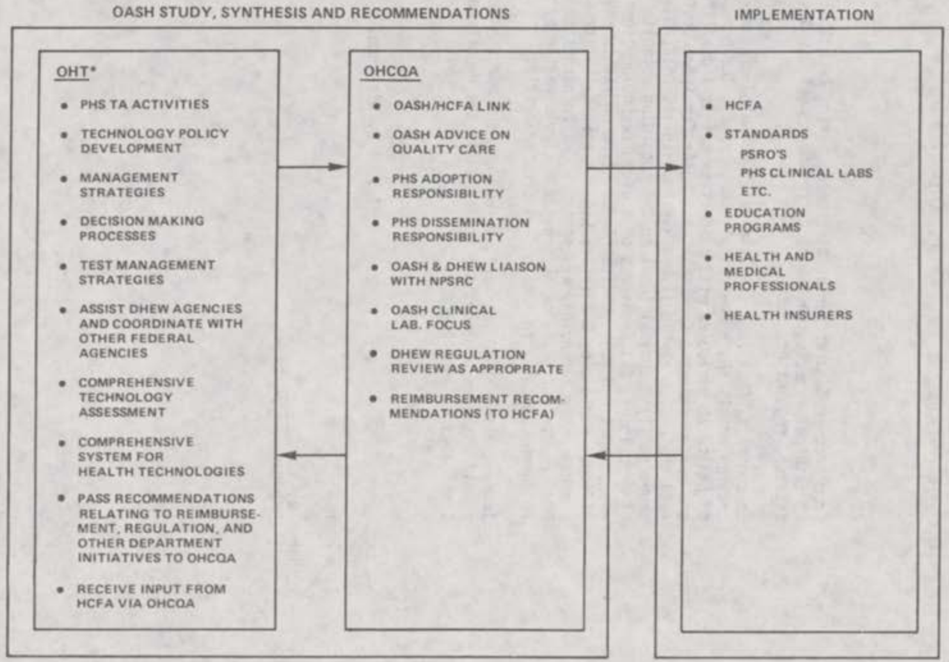
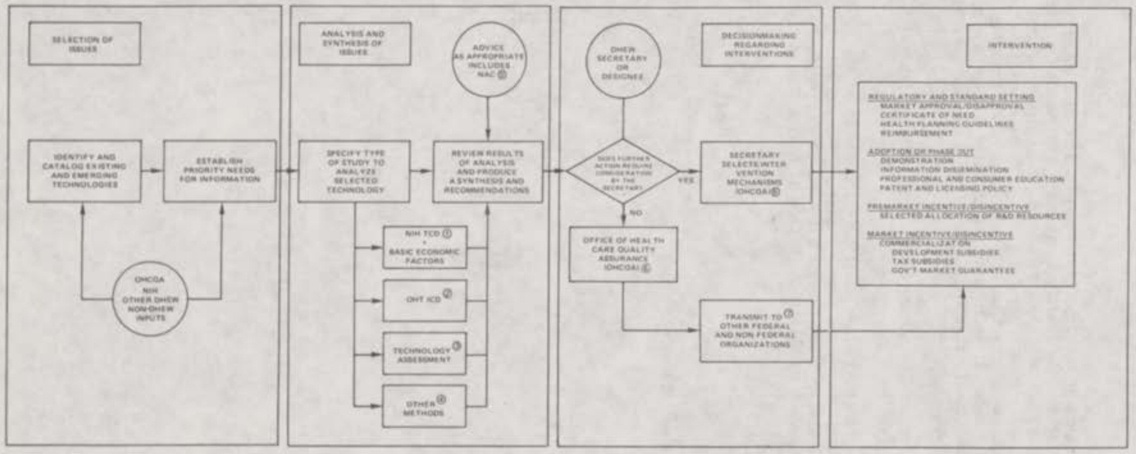
SUMMARY FUNCTIONS OF THE OFFICE OF HEALTH TECHNOLOGY
AND THE OFFICE OF HEALTH CARE QUALITY ASSURANCE (DHEW)



*PRINCIPAL ADVISOR TO THE ASSISTANT SECRETARY FOR HEALTH ON HEALTH TECHNOLOGY MATTERS; RESPONSIBLE FOR HIGH PRIORITY TECHNOLOGIES.

DRAFT

ROLE OF THE OFFICE OF HEALTH TECHNOLOGY



OHT FUNCTIONS–

- FOCUS FOR TECHNOLOGY POLICY FORMULATION AND COORDINATION IN PHS
- IDENTIFY DEFICIENCIES IN DHEW'S HEALTH TECHNOLOGY POLICY AND PROPOSE IMPROVEMENTS
- DECISIONMAKING PROCESS DEVELOPMENT AND TESTING
- ASSIST DHEW AGENCIES IN TECHNOLOGY ASSESSMENT AND TRANSFER ACTIVITIES
- EVALUATE DHEW TRANSFER AND ASSESSMENT ACTIVITIES
- LONG RANGE MONITORING AND SCREENING FEASIBILITY AND COST EFFECTIVENESS STUDY
- TRANSMIT RECOMMENDATIONS TO APPROPRIATE DHEW COMPONENT SUCH AS OHCQA, HCFA, NIH, CDC, FDA, ETC
- SUPPORT STUDIES OR DEMONSTRATIONS WITH BENEFIT OF ADVICE AS REQUIRED THROUGH DIRECT SUPPORT, TRANSFER TO NIH OR OTHER DHEW COMPONENT, OR BY COFUNDING WITH DHEW ORGANIZATION OR INDUSTRY AS APPROPRIATE
- DEVELOP RECOMMENDATIONS FOR INSTITUTIONAL CHANGES TO BETTER ACHIEVE HEALTH TECHNOLOGY OBJECTIVES
- TEST THE APPLICATION OF COMPREHENSIVE TECHNOLOGY ASSESSMENTS TO EFFECTIVE TECHNOLOGY MANAGEMENT
- TEST APPLICATION OF MANAGEMENT STRATEGIES ON SOME TECHNOLOGIES (PILOT DEMONSTRATION PROJECTS)
- COORDINATE DEVELOPMENT OF PROCESSES FOR COLLABORATION BETWEEN DHEW AND OTHER FEDERAL AGENCIES REGARDING TECHNOLOGY DECISIONMAKING

FOOTNOTES–

1. TCD - TECHNICAL CONSENSUS DEVELOPMENT (NIH)
2. ICD - INTERFACE CONSENSUS DEVELOPMENT (OHT)
3. TECHNOLOGY ASSESSMENTS BY OTHER ORGANIZATIONS–
   - VARIOUS GOVERNMENT AGENCIES, E.G., NCHSR, CDC, FDA, ETC.
   - VARIOUS NONGOVERNMENT ORGANIZATIONS SUPPORTED BY GRANT OR CONTRACT, E.G., SCHOOLS OF PUBLIC HEALTH, NAS, INDUSTRY, NONPROFIT ORGANIZATIONS, ETC.
4. INCLUDES OTHER EXISTING AND YET TO BE DEVELOPED STUDY METHODS
5. A NATIONAL ADVISORY COUNCIL
6. INTERVENTION PROCEEDS THROUGH THE OFFICE OF HEALTH CARE QUALITY ASSURANCE AS APPROPRIATE
7. SOME INTERVENTIONS COULD BE APPLIED BY DHEW ORGANIZATIONS, E.G., NIH, CDC, FDA, ETC.

DRAFT
4/19/78

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service

TO : Deputy Assistant Secretary for Planning and Evaluation/Health/OS

DATE: APR 17 1978

FROM : Deputy Assistant Secretary for Health Policy, Research and Statistics

SUBJECT: Revised Functional Statements for the Proposed Office of Health Technology

We have reviewed and accept the functional statements proposed by your communication of April 5, 1978. One modification has been made for further clarity. In functional item (3), the words "the selected" have been inserted between "relating" and "technology" to distinguish those high priority technology decision documents commanding the Secretary's attention from those that do not. Also, the functional statements have been edited to continue the item numbering sequence through the functional items included on page 2 of your proposal. Copy with changes is enclosed.

The revised functional statements have been cleared with the Assistant Secretary for Health.

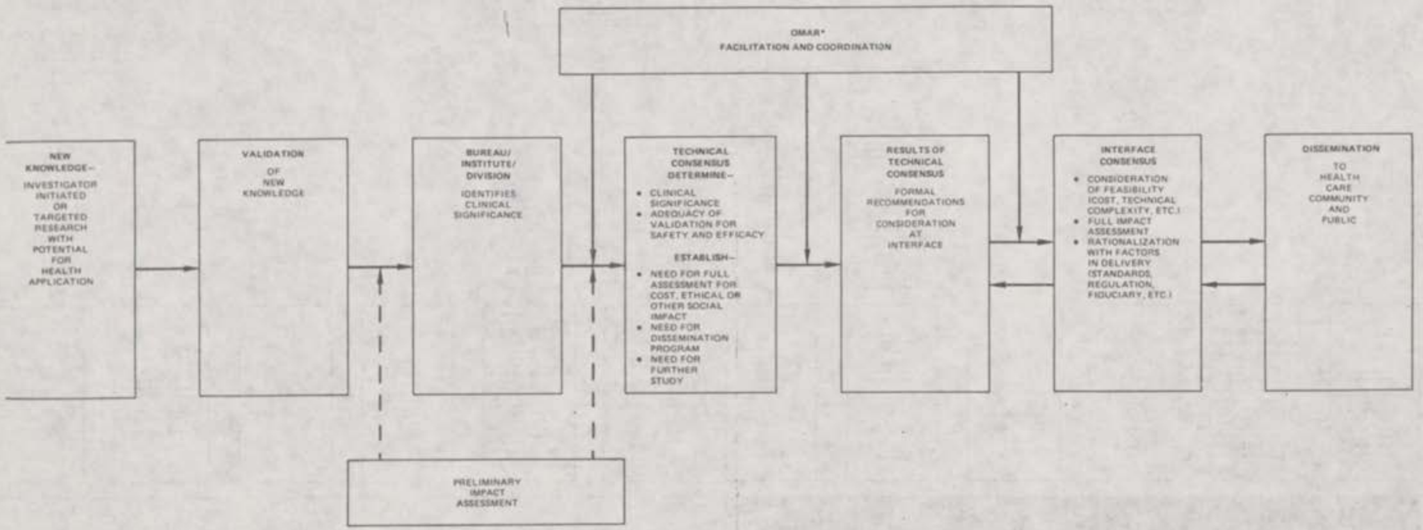
Under separate memorandum, we are forwarding copies of the revised functional statements to the Deputy Assistant Secretary for Management Analysis and Systems/OS for substitution for those previously forwarded with our proposal to establish the Office of Health Technology.

Ruth S. Hanft
Ruth S. Hanft

Enclosure
Revised functional statements

Office of Health Technology (HA1). The Office of Health Technology is a multidisciplinary unit under the direction of the Deputy Assistant Secretary of Health for Technology (DASHT) in the Office of the Assistant Secretary for Health. This Office functions as the Department's lead agency for health technology management, and the DASHT and his staff; (1) identify deficiencies in the Department's health technology policy and propose improvements; (2) coordinate the development of processes for DHEW collaboration with other Federal agencies regarding technology management activities; (3) manage the Department's process for selecting high priority technologies, for proposing assignment of technology analysis responsibilities, for overseeing convocation of professional judgments about selected technologies, and for preparing for the Secretary necessary decision documents relating the selected technology findings to reimbursement, regulation, and other Departmental initiatives; (4) conduct or oversee the conduct of formal evaluations of components of the Department's technology management systems; (5) analyze or monitor analysis of studies to determine the feasibility and cost-effectiveness of a comprehensive system for monitoring and screening health technologies; (6) direct and/or conduct tests of the application of comprehensive technology assessments (including evaluation of ethical, economic and social consequences) to effective technology management; (7) direct and conduct pilot demonstration projects to test the application of a technology management strategy to a limited number of high priority technologies; (8) establish liaison with extra-Departmental parties and agencies with which to link our technology activities in order to develop collaborative working relationships and to facilitate joint action; (9) propose linkages between Departmental agencies to promote increased coordination on technology issues and on specific technologies; and (10) in addition, the Deputy Assistant Secretary of Health for Technology serves as principal advisor to the Assistant Secretary for Health on health technology matters, and (a) reports to him on the technology activities of the offices and agencies under his direction, proposing such changes as may be considered appropriate; (b) provides the results of technology assessments to the Office of Health Care Quality Assurance for use regarding reimbursable (covered) services and for transfer of health care information to health professionals, educators and Professional Standards Review Organizations (PSROs); and (c) receives recommendations from the Office of Health Care Quality Assurance regarding selection of high priority technologies for assessment.

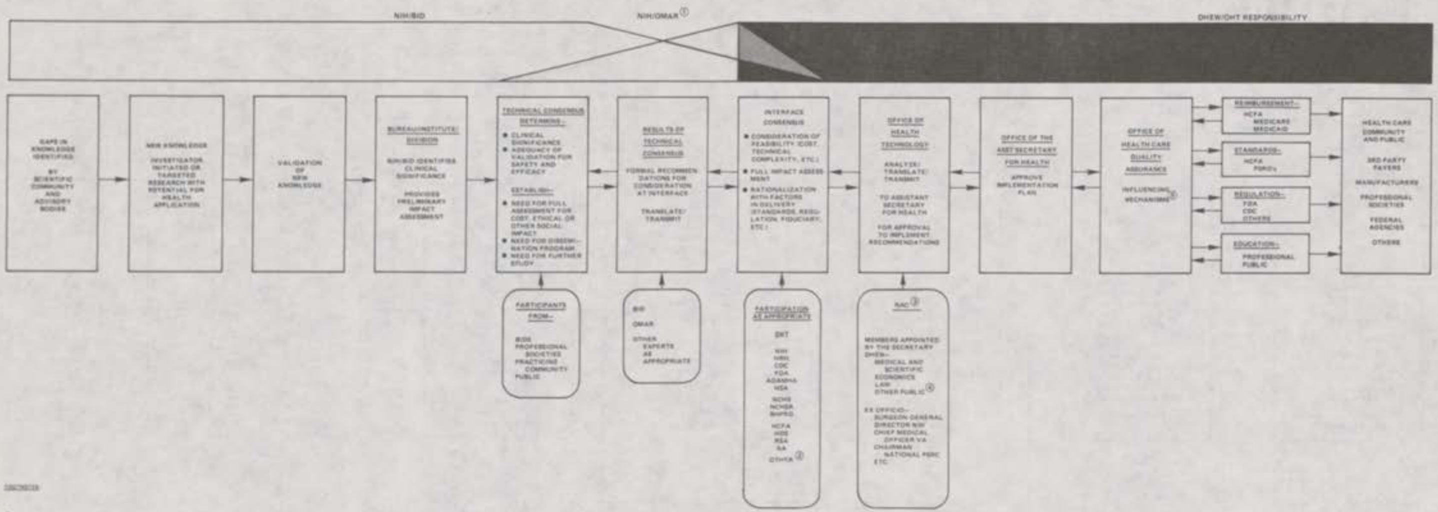
CONSENSUS DEVELOPMENT AND HEALTH RESEARCH/HEALTH CARE INTERFACE



*OMAR – OFFICE FOR MEDICAL APPLICATIONS OF RESEARCH

DRAFT

A PROCESS FOR DHEW HEALTH TECHNOLOGY DEVELOPMENT



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Senator KENNEDY. I mentioned just before we recessed the importance of getting the private sector, both the manufacturing industry, as well as other aspects of the health industry that are in the private sector, very much involved. And I am just wondering how you intend to do that.

I think that, quite frankly, there is probably greater opportunity with an independent posture and position than within the Department, but maybe you have got some ideas on that.

Dr. RICHMOND. As I indicated earlier, Mr. Chairman, we certainly plan to seek the advice of all appropriate groups. And certainly, in terms of research and development, industry is very significantly involved.

This is a place where we do hope to, as I indicated, gain the advice of the Institute of Medicine. We are hoping that the Institute will review the document which our task force has produced and that they will advise us on the best way to proceed with getting appropriate planning and policy development representation from all sectors.

We certainly, in addition to industry, would want to have university groups, the scientific and professional community, certainly professional organizations—I might note, Senator, that organizations like the American College of Physicians, the American Surgical Association, the American Academy of Pediatrics and many other groups are very actively involved in one or another aspect of technology assessment and transfer, and we would want to build those deliberations in.

This is part of what I meant earlier when I said we would not want to replicate what is ongoing. Many of these groups have very significant contributions to make in this development.

Senator KENNEDY. Let me ask you about how long is it going to take to get the cooperative health statistics system in place?

Dr. RICHMOND. I think, Senator, I would like to ask Mrs. Rice if she would make some comments on that, since she has that under her supervision.

Mrs. RICE. We are quite pleased with the development of the system. There really is quite an active interest and acceptance and support of the system in most of the States.

By the end of this fiscal year, we will have 44 States participating in the cooperative health statistics system. Of these, we will have 11 in the hospital care data component, 27 in health facilities, 26 in health manpower, and 38 in biostatistics.

We expect, with the planned budget for fiscal 1979 submitted to the Congress, to have almost all of the States fully operational in the biostatistics component, and to have about 42 States in the health manpower data and health facilities data components.

We are going more slowly in the hospital care component, with additional funds, we could do much more than we have in the past.

Senator KENNEDY. That was one of the questions. On this last point, you indicate with additional funds you could move more rapidly. That is, basically, you feel there is a hindrance to greater progress; is that correct?

Mrs. RICE. Yes; we do need additional funds to get the program going in the hospital care component. We expect that these data consortium, in many cases, for the collection of hospital discharge

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data would be self-supporting within a period of about 3 to 4 years after the initial funding.

The proposal is that the States actually collect the data through this nonprofit organization or a public agency and then the consortium could be self-funding by funds from the PSRO's, the HSA's, and the private organizations.

Senator KENNEDY. What kind of administrative problems or bureaucratic problems do you have, if any—or don't you have any?

Mrs. RICE. I know you are referring, Senator, to some of the problems we have been having with the coordination with the Health Care Financing Administration.

In New York, NCHS had in 1976 entered into a contractual arrangement with the New York State Health Department to design and test a statewide hospital discharge data system. And in carrying out the work of the health department, they had subcontracted to this New York Data Consortium, which is a nonprofit organization representing the public agency, the private insurers, the physicians, hospitals, and PSRO's, the local planning agencies, as well as the State of New York.

The work of the consortium had been substantially performed through the contract, at a cost of about $190,000. Last year, back in September, in anticipation of the enactment of the Medicare/Medicaid Fraud and Abuse Act that mandates uniform reporting system, we learned that HCFA was making a grant to the State Department of Health in New York. After learning about this grant, we communicated our concern to the Health Care Financing Administration and successfully arranged that a set of provisions be inserted into the grant, that they coordinate and cooperate with the Cooperative Health Statistics System.

We are meeting with the New York State people and the consortium next week, to resolve some of the problems that have emerged.

I do think that the proposal that Dr. Richmond had indicated would be for a health data advisory committee will assist in settling some of the problems that have emerged between the Health Care Financing Administration and the National Center for Health Statistics.

We hope to bring these issues for discussion between us at that forum and then, if there needs to be a resolution, to bring them to the Under Secretary and the Secretary of HEW for resolution.

Senator KENNEDY. Well, would you let us know what the results of that meeting are?

Mrs. RICE. We would be very pleased to inform you after the meeting.

Senator KENNEDY. Fine. I have no further questions.

Dr. RICHMOND. Thank you very much, Mr. Chairman.

Senator SCHWEIKER. Mr. Chairman, I apologize for being late. I had some trouble getting in this morning because of the snow.

Mrs. Rice, I understand you have already commented a bit on the epidemiological activities of your Center. My first question is, What do you see as the impact of this bill on the epidemiological work that is being done now, and is there—well, maybe I will just ask that question first and see what your response is.

Mrs. RICE. The bill does emphasize, of course, the expansion of the epidemiological activities of the National Center for Health Statistics.

The fact is that we are currently involved in a variety of epidemiological activities, and we can do this under the current legislative mandate.

We are in the process of developing a set of maps, comparable to those that were prepared by the National Cancer Institute, to apply to all diseases. In that way, we would be identifying high risk areas for various causes of desk. This will be a way of identifying these diseases, and for the CDC, for example, to go in to find out what can be done to improve the situation.

We are in the process of developing a national death index. This has been requested by the Congress, as well as the Nalional Institutes of Health.

We are in the process of examining our data and our data systems to be able to do more epidemiology work. We think we can do this under our mandate. Of course, with additional staff and additional funds, we could do even more.

Senator SCHWEIKER. Specifically, what kind of epidemiology studies are you doing now?

Mrs. RICE. Well, I mentioned the mapping and the——

Senator SCHWEIKER. Relating to any specific diseases?

Mrs. RICE. All causes of death. This is a presentation of the maps of all causes of death, by specific cause of death, so that we can look at the reasons for the variations across the country for different death rates.

The Cancer Institute has prepared, using our data, maps showing the differentials across the country in cancer deaths. We expect to produce a volume that will identify all causes of death.

Senator SCHWEIKER. How about morbidity data, diseases short of death?

Mrs. RICE. We have a variety of data systems, Senator, that can be used and are being used to produce data on morbidity and on the health of the Nation.

Our health examination and nutrition survey, a survey where we go out and examine the population over a period of time, we produce information about the health status of the population through that survey.

For example, we have identified, as Dr. Richmond indicated in his testimony, that there is a significant differential in hypertension among the blacks compared with the whites. We have been producing such information from our data systems.

Senator SCHWEIKER. Is there any duplication with CDC's work in the epidemiology area? Has that been much of a problem?

Mrs. RICE. Senator, I do not see that there is any duplication at all with CDC.

Senator SCHWEIKER. Let's take the example of Legionnaires' disease. I have been very active and interested in that case. CDC has acted as the lead agency, I believe, and has done some rather thorough epidemiological work. What, if anything, has your organization done in that case, in terms of epidemiology?

Mrs. RICE. We simply provided some information to them on the deaths from those diseases. We were able to identify the deaths in the past from diseases like Legionnaires' disease. And CDC went into the area to learn firsthand what the problems were, how they arose, and what were the factors associated with that disease.

We use our data systems in a broad way by identifying high risk areas. CDC goes into that area to find out more about the specifics of the disease.

Dr. RICHMOND. Senator Schweiker, if I might just elaborate on Mrs. Rice's comments, what her epidemiologic data do is chart the course of morbidity and mortality in the Nation, and CDC, with its capacity for laboratory and field investigation then moves in on the leads that are provided.

Just as an example, one of the reasons why we become concerned about potential outbreaks of influenza is that complications of influenza rank among the 10 leading causes of death.

We know that with outbreaks we can have those morbidities and mortalities rise considerably. So CDC then moves in to give us the advice on how we ought to proceed to try to minimize the increases in morbidity and mortality from a cause like that.

I would like to just comment, too, on the data collection systems that Mrs. Rice and her staff have developed, which give us now much more detailed pictures of the loci of high infant mortality rates, for example.

We now are beginning to use those data in the planning for health services, so that we are not firing our service resources like buckshot, but we are beginning to try to find ways of concentrating those resources at target areas where the outbreaks or the rates are high.

Senator SCHWEIKER. I would like to ask you or Mrs. Rice about the current supply of epidemiologists. Do we need more? Should we train more? What are the implications, if we do expand epidemiological activities and training?

Dr. RICHMOND. Well, as the former chairman of the Department of Preventive and Social Medicine at the Harvard Medical School, I think I can tell you, Senator, that we are in very short supply. For a variety of reasons, young physicians in particular have not been attracted to this field in sufficient numbers, and I think this is something that we are going to have to attend to.

I do not mean by that to indicate that physicians are the only ones who can do good epidemiology, but they constitute one significant source.

Senator SCHWEIKER. Are we able to take steps under existing legislation to attract more people into the field and expand training, or is this something that new legislation is needed for?

Dr. RICHMOND. Well, I think we have the authority, and we do have some programs in preventive medicine which enable us to do some training. I think we should expand these programs, however.

Senator KENNEDY. Would the Senator yield on that point?

Senator SCHWEIKER. Yes.

Senator KENNEDY. We did not get into this in the other question period, but as Senator Schweiker understands, this is one of the important ingredients that compels our particular approach, because each of the institutes has a strong training function, and for the reasons that you have outlined here, we stress the importance of that.

And I think it is not as apparent in terms of your proposal—I know that you know it is necessary—but we have really tried to target that as an important ingredient in our legislation, for the reasons that you have just mentioned here.

I thank the Senator.

Senator SCHWEIKER. I have just one more question. Dr. Richmond, you may ask one of your associates to answer it—I am not sure who in the group would handle it.

Where would the program support funds for health statistics and health services research activities come from, according to the administration's budget proposals?

In other words, would the money have to come from authorization specifically tied to the centers, or would it come from the Assistant Secretary's Office, or some place else?

Dr. RICHMOND. I think I might ask Mrs. Hanft to comment on that.

Mrs. HANFT. The centers' personnel and their staffing are targeted at each individual center. The entire budget appears in the budget of the Office of the Assistant Secretary of Health.

The supporting functions, such as management, contracts, financial management, and personnel are part of the overhead of the Office of the Assistant Secretary of Health, which serve all his functions.

But each center has an identified budget for their research and their statistical operations, their salaries and expenses and the costs of their various programs, both intramural and extramural programs.

Senator SCHWEIKER. Well, straighten me out if I am wrong, but I thought in the past, that NCHS and NCHSR "program support" funds, as the President's budget calls them, did not come out of the specific authorizations for appropriations for the centers, but actually came out of other channels. Now, maybe I misunderstood.

Mrs. HANFT. They have a separate appropriation for each of the centers. We also, in the Office of the Assistant Secretary for Health, provide them with certain supporting services in the way of financial management, personnel, and contracts.

But they have their own authorization, each center has its own authorization for salaries, expenses, grants, contracts, and their total costs.

In addition, the National Center for Health Statistics performs certain reimbursable services for other agencies, and they are reimbursed for those services out of the other agencies' budgets.

Senator SCHWEIKER. Oh, the other agencies reimburse them for their services?

Mrs. HANFT. For certain services that are done on a reimbursable basis by NCHS and by NCHSR. For example, the emergency medical services research is funded under the emergency medical services bill; yet the National Center for Health Services Research performs that research for the Health Services Administration.

Dr. RICHMOND. I think Dr. Rosenthal may want to make a comment on this, too.

Dr. ROSENTHAL. Only to note briefly that up until we were transferred to the Office of the Assistant Secretary, the program management budget for the National Center for Health Services Research and for the National Center for Health Statistics showed up in the appropriation for program management for the Health Resources Administration.

It was not in the line labeled "National Center for Health Services Research," or in the line labeled, "National Center for Health Statistics." And the authorization levels which were alluded to in our legislation did not include the program management resources.

Now, there was some discussion over whether that was the best strategic way to do that, but I think the way the law is written, those program management funds now will be part of the Office of the Assistant Secretary for Health, and the appropriations made against our authorizations will specifically refer to the research that we are undertaking, the statistical activities that we initiate, and in our case, only those things related to the direct management of the intramural program, which comes also ou of that legislation.

But the program management generally—my salary and those of our own administrative staff—are not included in that number. I think that is the nature of that question.

Senator SCHWEIKER. Thank you very much.

Senator KENNEDY. Thank you very much. We will be staying in touch with you and working closely with you.

Our next witness is David Hamburg, who we are pleased to welcome before the committee. He is the distinguished president of the Institute of Medicine, and his advice is always valued and always helpful.

Our only regret is that we do not get you down here more often, Dr. Hamburg. We look forward to your testimony.

STATEMENT OF DR. DAVID HAMBURG, PRESIDENT, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, WASHINGTON, D.C.

Dr. HAMBURG. Thank you, very much indeed.

Mr. Chairman, I am very grateful for the invitation to testify before this remarkable committee, which has contributed so much to the health of our Nation.

I have admired for years the deep interest this committee has taken in health care, research, and education. Your work has had a highly constructive and stimulating impact on the health sciences and health professions in the United States and abroad.

I recognize that the occasion for this hearing is the introduction of S. 2466. I believe this bill is timely and significant; it addresses constructively some of the major issues of the next decade in health policy.

The Institute of Medicine shares many interests and concerns of this committee. Our charter specifies that our mission is to protect and promote the health of the public and to examine health policy issues objectively, from multiple perspectives.

Today, I testify as an individual, expressing my own views. In doing so, I am fortunate to be able to draw upon a number of studies, papers, and conferences undertaken by the Institute during the past 2 years. They are listed in my statement, Mr. Chairman, but I am not going to read them, and indeed, there are other parts of my statement that I will simply submit for the record. I want to make my statement as brief and, I hope, useful as possible.

These activities of the Institute of Medicine listed in the statement deal with problems believed by our council, members and our staff to be of crucial importance in health science policy, in health services, and in disease prevention.

In addition to these materials, I draw upon my own background of 30 years active work in basic science, clinical investigation, and health care.

The essential point I want to make today is that we stand on the threshold of a great opportunity to improve the health of the public.

That opportunity rests on an extension of science to the whole of the health care system. In the next decade, I think we can greatly increase the extent to which the health system is based on scientific attitudes, methods, and principles.

To take advantage of this opportunity, we must provide conditions that will strengthen needed disciplines and foster novel collaboration among the disciplines in addressing the great problems of health and disease.

Circumstances have really changed rapidly in the past few decades, and we must make institutional changes to deal effectively with the new circumstances.

This will require that we construct a powerful chain of research from laboratory bench to patient bedside to the communities and homes—with every link in the chain strong. That is the essential point I want to make—broadening of science through the whole of the health care system.

I want first to discuss some explorations toward this wider range of scientific underpinnings for the health of the public.

It is important to bear in mind that there are three general classes of factors affecting the health of the public, and they are all very important.

One is medical care and other personal care by health professionals; another is environmental conditions, which have been very important historically in matters such as sanitation; and, no less important now, although in somewhat different ways than let us say in the last century; and finally, the effect of individual behavior on health. All three are very important, and all three have to be addressed scientifically.

In this context, let us consider the science base for improving the health of the public. We know that the establishment and maintenance of very high standards of scientific quality by the National Institutes of Health has served the Nation well over the past quarter century.

There now exists in this country a general appreciation of the importance of supporting strong fundamental biomedical sciences, such as biochemistry, genetics, physiology, pharmacology and related fields.

Indeed, Mr. Chairman, wherever I have gone throughout the world—Europe and Africa and elsewhere—I have found very great respect for the NIH. It is a visible symbol of high-quality achievement in biomedical research.

Now today, I think we are seeing the emergence of additional elements that build upon that base created primarily, though not exclusively, by NIH; the emergence of interest in other sciences to add on to the established fields, in pursuing the goal of improved health.

These include but are not limited to epidemiology, biostatistics, bioengineering, the behavioral and social sciences as they relate to health, health services research and prevention research.

Increasingly, we see that each of these lines of inquiry has great potential value for improved health and well-being, and are therefore deserving of supporting and nurturance.

And some of the newer or renewed sciences do indeed require careful nurturing.

Epidemiology, for example, has a valuable and in fact pioneering history in health and has been revived recently, particularly in the context of chronic diseases.

The most recent HEW forward plan points out that epidemiology is emerging as the first line of defense in detecting new cancer hazards that may be missed in various screens, and appear for the first time in humans.

Most of the clearly identifiable environmental causes of cancer have been found first through epidemiological studies and confirmed later through laboratory studies.

Now, this is not to argue in any way for epidemiology as a substitute for research on basic biological mechanisms. It is to argue for the strengthening of this old discipline in a new context. Also—and I would emphasize this point, Mr. Chairman—we have to find ways to bring about effective integration of epidemiology with laboratory sciences such as biochemistry and with clinical medicine. That is a special area where the training programs you spoke of a moment ago may be quite pertinent.

As we learn more about the burden of illness in this country, the importance of behavioral factors for health becomes increasingly clear.

Whereas infectious diseases used to be the most burdensome illnesses, we now see cardiovascular diseases, cancers, lung diseases, accidents, homicide, and other violence as the major assaults on life and health. Because such burdens clearly have strong behavioral factors, approaches to the prevention or management of these problems must obviously include a strong behavioral science perspective.

As the burden of illness changes, the sciences needed to lessen the burden also must change. We must find out how we can bring the best in behavioral science, whatever that may be at a given moment—and it will develop over time—to bear on these serious health problems.

Here I refer to the relationships of factors like heavy cigarette smoking, heavy alcohol use, risky driving, prolonged stress, peculiar diets, and lack of exercise, to cardiovascular diseases and some cancers, especially lung cancer—as well as to mental illness. And these are, of course, among the very heaviest burdens of illness we have.

Now let us briefly consider health services research. This is a field of study concerned with the practical delivery of health services. The mode in which services are provided, their cost, their quality, their availability—all have a great bearing in the long run on health status of the population.

To the extent that health services research can increase understanding leading to positive change, both in the content and in the organization of health services, it shows a relevance to health that is of great potential importance. And I am sorry to say that that potential importance has not been fully appreciated, even in the health professions and the health sciences, let alone in the general public, but that day is coming.

The key point being made here is that a whole spectrum of health research is needed in order to meet America's long range problems.

An exclusive or heavy focus on only one component of the spectrum is unwise. We must try to help the Nation test out the extent to which the methods of science could be brought to bear, not just on some pieces of the health system, but over the entire range of the health system.

Senator KENNEDY. Just to illustrate, the area of biomedical research and the support that it has received is an example, obviously, of excellence which has gotten strong support from this committee. But is your point here that what has been done in that area ought to be replicated in these other areas?

Dr. HAMBURG. Yes; it is, precisely. And I would like to——

Senator KENNEDY. And that if you just have that sort of tower standing in and of itself, that even its full potential might not be as realized if we do the other kinds of things which you have outlined here.

Dr. HAMBURG. Let me give two or three concrete examples that I think are tangible and down to earth in the next few minutes, that show really how this spectrum can work, if only we provide the conditions to make it work over the whole range of health problems.

Let us talk about hypertension. That was referred to by Dr. Richmond and some of his distinguished colleagues very well. It is a terribly serious problem. It is a very important disorder and a risk factor for stroke, coronary disease. It is concentrated heavily in the black population, as you have heard.

It has been a stimulus for and a beneficiary of a great deal of basic research which this committee has fostered in cardiovascular and kidney physiology and biochemistry, as well as research in endocrinology and in the neurosciences.

Now, out of that basic research came first small-scale clinical explorations, and then well-designed large-scale clinical trials, mainly in the VA.

And it was found that under these optimal conditions of the clinical trials that there were indeed several good treatments in the way of medication for hypertension that would reduce blood pressure over an extended period of time.

When these clinical trials demonstrated the effectiveness of medication, we who were interested in hypertension felt a lot of satisfaction, and the problems appeared to be largely solved.

But, in fact, it was not solved. To our distress, it turned out that only about half the patients did in fact adhere to the therapeutic regimen. Half of them simply did not take the medication.

Hypertension is by no means unusual in that respect. Now, it became important to ascertain, through behavioral and health services research, why patients were not taking medication that was manifestly good for them, and demonstrably able to prevent strokes.

And I may say with some feeling, Mr. Chairman, that my father this past week had a stroke related to hypertension, and I regard this as one of the major problems we have in this country. We have within our grasp the ability to prevent a great deal of this human suffering, and yet having the biochemical and pharmacological capacity in itself is not sufficient.

Now, health services research has brought about some clarification in this situation. And some of these factors may appear mundane, but I can assure you that they are very important to hypertension patients and their families.

Failure to take the medication depends partly on such factors as these: Long waiting times for the doctor and at the pharmacy; inadequate followup by doctors and clinics; overcomplicated and confusing dosage schedules; unsatisfactory doctor-patient relationships; unexplained side effects—that is, when nothing has been explained about what is likely to occur, particularly when the patient has not had symptoms prior to medication, even though his blood pressure was not elevated.

Now, recognizing that, learning those facts through health services research, there has recently been some careful work on the utility of nonphysician medication counselors, who focus specifically on these issues. And it has been shown that such medication counselors can markedly enhance the adherence to the therapeutic regimen in hypertension.

Senator KENNEDY. The point is that if we do not deliver the service which is the result of the basic research, we really perhaps minimize the achievement.

Dr. HAMBURG. That is right. We can have a wonderful treatment, but if we do not get it there in a sensible way, it is not going to do us much good. It is wonderful for us to know about it in the Institute of Medicine or somewhere like that, but in the communities where people actually live, it has to get there more or less in the way that it is prescribed.

Following out this hypertension-cardiovascular disease problem, another type of essential effort which I know this committee has been interested in involves trying to prevent the disease in the first place.

We do not know enough about the mechanisms to prevent the disease in the most fundamental sense. But on the other hand, some of the risk factors in the way we live our lives can be modified. For example, the study of heart disease prevention based at Stanford, which utilized three communities in California, was centered around public education. And I think we are going to need much more public education.

What that group did was to take two experimental communities and a control community. All three were very similar communities in northern California——

Senator KENNEDY. We had a very good visit at Stanford, Doctor, and we were very well briefed on that program. It is a very exciting program, with profound lessons for the rest of the country. We were very impressed with what we observed there, and I think the California program will be an important model for the type of research which ought to continue.

Dr. HAMBURG. My own judgment is that we need an intensification of research to learn how to do that effectively, nationwide. Just 10 days from today, we are having a conference at the Institute of Medicine whose focus is to a considerable extent on this kind of question. Now, in the California case, the two experimental communities clearly had a decrease in risk factors through public education using—whether one used mass media alone or mass media plus some personal contact with high risk individuals—either way, you did better than the control communities in respect to lowering blood pressure, lower blood cholesterol and lowering cigarette smoking.

Now, the Stanford study does not yet have measures that help outcome. But there was a similar study recently from Finland which does have measure of health outcome and shows, for example, a really historic change in the trend of coronary attacks, a decrease in the coronary attack rate.

So there is reason to believe that community-based programs can be effective, and we must now clarify the conditions under which such programs are likely to be most effective.

So this sketch of research on hypertension is meant to suggest the need for fostering the full spectrum of research from laboratory bench to patient bedside to the communities were we live and die.

Now I would like very briefly to turn to a couple of other paths of progress which I believe require intensified research efforts and more adequate institutional facilitation.

These are directions in which useful research on health care and disease prevention can be built on the solid foundations of biomedical science. They deal with practical, common problems that constitute an important part of today's burden of illness.

For example, the organization of health care efforts for specific purposes can be remarkably effected even under harsh and difficult conditions.

We all know the plight of the Indians in this country. Yet, in the 20 years from 1955 to 1975, a time in which intensive and systematic effort was made to bring public health and preventive care to Indian mothers and infants, through the Indian Health Service, there were striking health status improvements.

In those 20 years, the infant mortality declined about 70 percent; maternal mortality declined about 80 percent. The infant and maternal mortality among the Indians in this country today is below that if the black population, which has not had on the whole such intensive and highly organized efforts to deal with these issues.

Now, taking advantage of current knowledge based on public health and biomedical research, prenatal and perinatal care can clearly decrease not only infant mortality and maternal mortality, but also birth defects and premature births, which so often have unfortunate aftereffects.

Similarly, recent studies have shown that well-organized programs for children can decrease the days of illness, decrease expensive hospital time, and prevent later complications of childhood disease. In one such program, there was a 60-percent reduction in the incidence of rheumatic fever by virtue of prompt and appropriate use of antibiotic therapy. This means that these persons were spared the heart disease that you remember used to kill so many in young adulthood. When I was in medical school, we used to see those cases all the time.

Now, here we have a clear example of the value of modern biomedical research or preventive care that truly improves health. And yet, once again, the matter is not so simple as it appears at first glance.

A recent pediatric study shows an alarming problem that requires careful investigation if we are really going to fulfill the potentiality of science-based health care.

In the clinic where this study was done, a 10-day course of penicillin was prescribed for children with streptococcal throat infection. But by the 3d day of this putative 10-day course, 56 percent of the children were no longer taking the penicillin, and by the 6th day, 71 percent were no longer taking it.

This means that much of the value, much of the preventive potentiality of the penicillin is in actual fact being lost. Now, we need to know how widespread are such problems, what can we do to cope with them more effectively.

To answer those practical questions, we require clinical investigation, health services research, epidemiology, and behavioral science.

A study done last year by the Institute of Medicine is very revealing in this regard. It suggests that missed opportunities in childhood disease prevention are neither rare nor trivial.

This study was an analysis of the large body of scientific evidence bearing on the efficacy and safety of polio vaccines. And I may say, Mr. Chairman, that the study was in no small measure stimulated by the activities of this committee.

Now, while the polio vaccines are remarkably effective, their actual use in this country is disappointing. In 1974, only about 67 percent of white children and 45 percent of nonwhite children in the United States, ages 1 to 4, had been vaccinated against polio.

The comparable figure in northern European countries and the Scandinavian countries is above 90 percent. Why is this so? To what extent does it apply to other potentially valuable vaccines? What can be done to increase utilization?

I submit, Mr. Chairman, that these are not trivial questions. They are not beneath the dignity of science or beyond the range of scientific methods in the 1980's.

Some of the problems are easily overlooked. We have in this country a sort of romance with youth. We glorify youth. And yet, curiously, the adolescent age group, and especially the early adolescents, 10 to 15, tend to be poorly served and poorly researched, regardless of position in society. But this is a critical period for the formation of health-relevant behavior patterns that have lifelong significance. I refer here to cigarette smoking, alcohol use, risky driving, adolescent pregnancy, sexually transmitted disease, and habits of nutrition and exercise.

And of course, there are still major problems of the elderly, largely cutting across socioeconomic lines, but most poignant among the poor.

In connection with problems of adolescents and of the elderly and also of the mentally ill in general, we must learn more not only about the basic nature of the difficulties, but also how to integrate health services with social services in the communities where people actually live and get their care.

This committee has heard ample testimony in recent months, and I will not dwell on it, about the need for greater emphasis on research which assesses both the risks and benefits of diagnostic, therapeutic, and preventive interventions—particularly before their widespread dissemination, although there certainly is a problem about procedures in common use, as has already been referred to this morning.

It is true that the health professions strive continuously to improve their quality of care; there is a strong tradition in that respect. And yet, much of clinical care has not been based on modern scientific methods. It is necessary to determine more than we have done in the past the efficacy and safety of diagnostic, therapeutic, and preventive interventions.

I submit that the cost and ethical implications of not conducting such research are very serious. There are hopeful signs that this matter is now being discussed and taken seriously and the introduction of S. 2466 should greatly enhance these considerations.

Mr. Chairman, it is exceedingly important that the American people understand the need to build a firm foundation for dealing with the newer problem areas of health in practical, useful ways.

What I am trying to do today is primarily to clarify the need for a broadened approach to the health sciences.

These new frontiers involve many forms of clinical investigation, health services research, both at the institutional and individual level.

Such investigations involve complex biological, behavioral, statistical, epidemiological, and ethical considerations. To be done effectively, they need a secure home that can do for this field what NIH has done for basic biomedical research.

So we ask, Who can provide the right conditions? NIH probably could, but for reasons of its traditional strengths and boundaries, NIH is not likely to do more than a part of what needs doing.

ADAMAH already does some of it and could do more. The same applies to the FDA, CDC, and perhaps other health agencies as well.

The existing health agencies deserve vigorous support for their traditional missions, and for some, widening of their horizons. But if they cannot, or should not, do the whole job that needs doing—that we have been discussing this morning—then another agency of comparable stature must be developed to strengthen and apply a wider range of sciences and activities to improving the Nation's health.

The NIH has not until very recently accorded a high priority to research explicitly directed toward disease and trauma prevention, especially in regard to the behavioral and environmental aspects of health.

This situation, I am glad to say, has begun to change, and other agencies have taken an interest also. But there is, in my judgment, still a long way to go.

It may well be that new institutional arrangements are necessary to foster research on near-term prevention. The Institute proposed in S. 2466 could make a great contribution to this regard.

I might add, Mr. Chairman, I would welcome a little more language in that bill addressing prevention explicitly.

Now, let me summarize briefly and make a concluding comment. The biomedical science effort of the United States has earned worldwide respect. In fact, the principal source of new information since World War II on the nature of living organisms has been the American life sciences community, much of which has been biomedically oriented.

We now have growing concerns about finding ways in which the social utility of this great effort can be further enhanced. To do that, it is appropriate to broaden the traditional concept of biomedical sciences to include centrally, not marginally, the sciences associated with public health, with the environment, and with behavior. This broadened field may usefully be designated as "the health sciences."

The health sciences must be concerned in a major way not only with deepening the base of fundamental knowledge, but with continuous monitoring of these advances for applications that are promising in regard to clinical problems.

Furthermore—and I would emphasize this—arrangements are needed to insure that there will be feedback loops from the clinical and social needs that can stimulate the research enterprise.

The entire continuum of high quality research from basic science to clinical investigation to health services research should be fostered by any comprehensive national health policy.

If a higher research priority is to be assigned to work of the sort we have been discussing this morning, as I think it must, then I want to say a word about what I believe we will need. We will need a nationwide cadre of high quality scientists, qualified to tackle these difficult problems—not just a fine group of people here in Washington. We will need an ability to collaborate across disciplinary lines that exceeds most of what we have so far seen in the health sciences.

For example, health services research is not a single field. It is a combination of disciplines brought to bear on health care problems.

To do this sort of thing, we will need both extramural and intramural programs. We will need work relevant both to near-term policy problems and to long-range changes in health and society.

We will need for such efforts high visibility and respect, first class intellectual leadership, a clear organizational focus, and a determination to persist over many years in what is necessarily a complex and difficult enterprise.

Mr. Chairman, I believe the conditions are now exceptionally favorable to move forward expeditiously in providing the institutional arrangements that will complete the spectrum of health research and development.

The chain can be made strong in all of its links during the next few years. I say this for several reasons. One is the thoughtful. constructive, far-sighted interest of this committee as reflected in S. 2466 and in other committee activities. I say it also because today's leadership in the Department of Health, Education, and Welfare is keenly aware of these problems and ready to create new opportunities.

Dr. Richmond and his distinguished colleagues here today understand these issues very well and are deeply committed to dealing with them effectively.

This is also true to an unusual extent of the current heads of the health agencies in DHEW. In this, I believe they have the keen interest and full backing of Secretary Califano and Under Secretary Champion.

They have already taken constructive steps, of which I mention two briefly. One is the recent elevation in status of the National Center for Health Statistics and the National Center for Health Services Research, which we discussed earlier. And another is the intensive, systematic effort to focus on disease prevention throughout the entire Public Health Service in an unprecedented way. This includes major strengthening of research relevant to prevention in the foreseeable future.

It is my belief that this committee can work toegther with the Department of Health, Education, and Welfare in ways that will provide strong institutional arrangements to complete the spectrum of health sciences.

This can contribute in a major way to the continuing improvement of health care, a perennial quest. It can make our health services as rational, compassionate, and science based as is humanly possible.

Although I do not believe in any single right way to achieve such a goal, I believe that S. 2466 is a landmark pointing toward future progress in the health of our people.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Hamburg follows:]

SENATE SUBCOMMITTEE ON

HEALTH AND SCIENTIFIC RESEARCH

Statement of

DR. DAVID A. HAMBURG

President, Institute of Medicine

National Academy of Sciences

Washington, D. C.

February 7, 1978

Mr. Chairman, I am very grateful for the invitation to testify before this remarkable committee which has contributed so much to the health of our nation. I have admired for years the deep interest this committee has taken in health care, research, and education. Your work has had a highly constructive and stimulating effect on the health sciences and health professions in the United States and abroad.

I recognize that the occasion for this hearing is the introduction of S. 2466. I believe this bill is timely and significant; it addresses constructively some of the major issues of the next decade in health policy.

The Institute of Medicine shares many interests and concerns with this committee. Our charter specifies that our mission is to protect and promote the health of the public, and to examine health policy issues objectively from multiple perspectives.

Today, I testify as an individual, expressing my own views. In doing so, I am fortunate to be able to draw upon a number of studies, papers and conferences undertaken by the Institute of Medicine during the past two years. These include:

1) Policy Issues in the Health Sciences;
2) Perspectives on Health Promotion and Disease Prevention in the United States;
3) Evaluation of Poliomyelitis Vaccines;
4) A Policy Statement on Computed Tomographic Scanning;

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5) Assessing Quality in Health Care: An Evaluation;
6) Technology and Health Care;
7) Invited papers prepared for the President's Commission on Mental Health;
    a) The Relationship of General Health and Mental Health Services, and
    b) The Assessment and Improvement of Mental Health Services;
8) The 1976 Annual Meeting of the Institute of Medicine, (entitled The Health Sciences and The Burden of Illness) which led to the publication The Current Burden of Illness by Dorothy Rice, Kerr White and Jacob Feldman;
9) A Survey of Current Problems in Clinical Investigation (currently underway); and
10) An Assessment of Health Services Research (also underway).

These activities deal with problems believed by our Council, members, and staff to be of crucial importance in health sciences policy, health services, and disease prevention.

In addition to these materials, I draw upon my own background of thirty years' active work in basic science, clinical investigation, and health care.

The essential point I want to make today is that we stand on the threshold of a great opportunity to improve the health of the public. That opportunity rests on an extension of science to the whole of the health care system. In the next decade, we can greatly increase the extent to which the health system is based on scientific attitudes, methods, and principles. To take advantage of this opportunity, we must provide conditions that will strengthen needed disciplines and foster novel collaboration among the disciplines in addressing the great problems of health and disease. Circumstances have changed rapidly in the past few decades, and we must make institutional changes to deal effectively with the new circumstances. This will require that we construct a powerful chain of research from laboratory bench to patient bedside to communities and homes--with every link in the chain strong.

I want first to discuss some explorations toward a wider range of scientific underpinnings for the health of the public. It is important to bear in mind that there are three general classes of factors affecting the health of the public: 1) medical care and other personal care by health professionals; 2) environmental conditions, important for health historically and no less so now; and finally 3) individual behavior.

In this context, let us consider the science base for improving the health of the public. The establishment and maintenance of very high standards of scientific quality by the National Institutes of Health has served the nation well over the past quarter-century. There now exists in the United States a general appreciation of the importance of supporting strong fundamental biomedical sciences, such as biochemistry, genetics, physiology, pharmacology, and related fields. I refer here to the sheer fascination of understanding the nature of the human body, how it works, the tiny components of which it is constituted, and the way they relate to each other. Such understanding has great merit in its own right, and also has much relevance to disease.

However, the time scale of "payoff" in effective diagnosis, treatment, or prevention is very difficult to predict. Some developments can be foreseen on a time scale of a few years, but many are indeterminate. There are a few examples that are dramatic in the rapidity of movement from basic discovery to clinical application. One is the discovery of brain amines, their distinctive distribution within the brain, their relevance to Parkinson's disease, and the emergence of the first reasonable treatment of this serious disease--all this in about a dozen years. One wishes that there were many stories of discovery and clinical utility on that time scale. There are some, but integrity demands that we be candid about the inherent upredictability of the rate at which the acquisition of basic knowledge will be pertinent to treatment and prevention. There is a sense in which all basic research in the life sciences has long-run preventive implications. The more we understand about the nature of the organism, the more in principle we ought to be in a position to affect crucial mechanisms so as to prevent cancer and cardiovascular disease and mental illness. But in 1978 we are a long way from understanding most of the mechanisms that would offer that kind of prevention, and when we talk about prevention in today's context, it often has to do with modifying risk factors, even though we understand very little about the mechanisms by which those risk factors do their damaging work. Still, knowledge of risk factors may be extremely useful in devising near-term strategies for prevention of disease.

Today, there is an emergence of new interest in other sciences to add onto the established fields of biomedical research in pursuing the goal of improved health. These include, but are not limited to epidemiology, biostatistics, bioengineering, the behavioral and social sciences, health services research and prevention research. Increasingly we see that each of these lines of inquiry has great potential value for improved health and well-being, and are therefore deserving of support and nurturance. Epidemiology, for example, has a valuable, indeed pioneering history in health and has been revived recently, particularly in the context of chronic diseases. The most recent HEW Forward Plan points out that epidemiology is emerging as the first line of defense in detecting new cancer hazards that may be missed in various screens, and appear for the first time in humans; and it points out that most of the clearly identifiable environmental causes of cancer have been found first through epidemiological studies and confirmed later through laboratory study. Now this is not to argue in any way for epidemiology as a substitute for research on basic biological mechanisms. It is to argue for the strengthening of this old discipline in a new context. Also, and of special significance, is the need to find ways to bring about effective integration of epidemiology with laboratory sciences such as biochemistry and with clinical medicine.

As we learn more about the burden of illness in this country, the importance of behavioral factors for health becomes increasingly clear. Whereas infectious diseases used to be the most burdensome illnesses, we now see cardiovascular diseases ,cancers, lung diseases, accidents, homicide and violence as the major assaults on life and health. Because such burdens clearly have strong behavioral factors, approaches to the prevention or management of these problems must obviously include a strong behavioral science perspective. As the burden of illness changes, the sciences needed to lessen the burden also change. We must find out how we can bring out the best in behavioral science, whatever that may be at any given moment, to bear on these serious health problems. Here I refer to the relationships of factors like heavy cigarette smoking, heavy alcohol use, risky driving, prolonged stress, peculiar diets, and lack of exercise, to cardiovascular disease and some cancers, especially lung cancer--as well as to mental illness.

Now let us briefly consider health services research. This is a field of study concerned with the practical delivery of health services. The mode in which services are provided, their quality, their cost, their availability, all have a great bearing in the long run on health status of the population. To the extent that health services research can effect positive change both in the content and the organization of health services, it shows a relevance to health that is of great potential importance.

The key point being made here is that a whole spectrum of health research is needed in order to meet America's long-range problems -- an exclusive or heavy focus on only one component of the spectrum is probably unwise. We must try to help the nation test out the extent to which the methods of science could be brought to bear, not just on some pieces of the health system, but over the entire range of the health system.

Let me briefly talk about hypertension to make the research spectrum more meaningful. Hypertension is a very important disorder and a risk factor for stroke, coronary disease, and kidney disease. It affects millions of Americans, particularly in the black population. It has been a stimulus for and a beneficiary of a great deal of basic research in cardiovascular and renal physiology and biochemistry, as well as research in endocrinology and in the neurosciences. Out of that basic research came small-scale clinical explorations and then well-designed large-scale clinical trials, mainly in the VA. Under optimal conditions, we now have several good treatments in the drug sphere.

After the randomized clinical trials demonstrated the effectiveness of medication, we felt much satisfaction. The problem appeared to be largely solved. But, in fact it was not. About half the patients simply did not adhere to the therapeutic regimen. Hypertension is by no means unusual in that respect. It became important to ascertain, through behavioral and health services research, why patients were not taking medication that was manifestly good for them and demonstrably able to prevent strokes. A certain amount of clarification has emerged; some of it may appear mundane but very important to hypertensive patients and their families. Failure to take the medication depends partly on such factors as: long waiting times for the doctor and at the pharmacy; inadequate follow-up by doctors and clinics; over-complicated and confusing dosage schedules; unsatisfactory doctor-patient relationships; unexplained side effects, particularly in patients who had no symptoms prior to medication.

Recently there has been some careful work on the utility of non-physician medication counselors who focus specifically on these issues, and it has been shown that they can markedly enhance the adherence to a therapeutic regimen in hypertension.

Still another kind of essential effort involves trying to prevent the disease in the first place. We do not know enough about the mechanisms to prevent it in the most fundamental sense, but on the other hand, some of the risk factors in the way we live our lives can be modified. For example, the study of heart disease prevention based at Stanford which utilized three communities in California was centered around public education in two experimental communities and a control community. These were very similar communities -- one had mass media alone providing information about cardiovascular risk factors, one had mass media plus some personal contact with high-risk individuals, and the third had no intervention. In both experimental communities there was a very considerable decrease in the risk factors achieved over two years -- risk factors including lowering of hypertension, lowering of blood cholesterol, lowering of cigarette smoking. That study, however, did not measure actual changes in health outcomes as a result of modifying these risk factors.

There is, however, a similar study recently reported from Finland which has not only documented a similar reduction in risk factors, but has also tracked changed in health outcomes -- e.g., a decrease in the coronary attack rate. Thus, community-based programs can be effective. At the Institute of Medicine, we are currently trying to clarify the conditions under which such programs are likely to be most effective.

Once again, this sketch of research on hypertension is meant to suggest the need for fostering the full spectrum of research -- from laboratory bench to patient bedside to the communities where we live and die.

In considering our contemporary burden of illness, and the lines of inquiry needed to reduce the burden, we should learn as many lessons as we can from past experience. We must try to sort out what has worked well and what has not, where gains have been made and why, and the gaps in research most urgently needing to be addressed.

During the past centry, our health has benefited greatly from advances in agriculture, sanitation, infectious disease, family planning, and maternal and child care. Yet much remains to be done. I want now to give several illustrations of paths of progress. These are directions in which useful research on health care and disease prevention can be built upon the solid foundations of biomedical science. They deal with practical, common problems that constitute an important part of today's burden of illness. We can deal with them more effectively by broadening the range of sciences brought to bear on them.

For example, the organization of health care efforts for specific purposes can be remarkably effective, even under harsh and difficult conditions. We all know the plight of the Indians in this country, yet in the twenty years from 1955 to 1975, a time in which intensive and systematic effort was made to bring public health and preventive care to Indian mothers and infants through the Indian Health Service, there were striking health status improvements. In those twenty years, infant mortality declined about 70 percent, maternal mortality declined about 80 percent. The infant and maternal mortality among the Indians in this country today is below that of the black population, which has not had on the whole such intensive and highly organized efforts to deal with those issues.

In the past decade, considerable evidence has also accumulated indicating that organization of health care for specific groups with particular problems can reduce mortality, hospital costs, and the multiple burdens of chronic illness. Taking advantage of current knowledge based on public health and biomedical research, prenatal and perinatal care can clearly decrease not only infant mortality and maternal mortality, but also birth defects and premature births which so often have unfortunate after-effects. Clinical investigation and health service research in the past decade have shown that such programs need not be complex or expensive in most instances.

Similarly, recent studies have shown that well-organized programs for children can decrease the days of illness, decrease expensive hospital time, and prevent later complications of childhood disease. In one such program, there was a 60 percent reduction in the incidence of rheumatic fever by virtue of prompt and appropriate use of antibiotic therapy. This means that these persons were spared the heart disease that used to kill so many in young adulthood. Here we have a clear example of the value of modern biomedical research for preventive care that truly improves health.

Yet the matter is not so simple as it appears at first glance. A recent pediatric study reveals an alarming problem that requires careful investigation if we are to be truly effective in fulfilling the potentiality of science-based health care. In the clinic where this study was done, a ten-day course of penicillin was prescribed for children with streptococcal throat infection. But by the third day, 56 percent of the children were no longer taking the penicillin, and by the sixth day, 71 percent were no longer taking it. This means that much of the therapeutic and preventive potentiality of the penicillin is in actual fact being lost. How widespread are such problems? What can we do to cope with them more effectively? To answer such practical questions, we require clinical investigation, health services research, epidemiology, and behavioral science.

A study done last year by the Institute of Medicine suggests that missed opportunities in childhood disease prevention are neither rare nor trivial. This study was an analysis of the large body of scientific evidence bearing on the efficacy and safety of polio vaccines. While the vaccines are remarkably effective, their actual use in this country is disappointing. In 1974, only about 67 percent of white children and 45 percent of non-white children in the U.S. ages 1 to 4 had been vaccinated against polio. The comparable figure in northern European countries is above 90 percent. Why is this so? To what extent does it apply to other potentially valuable vaccines? What can be done to increase utilization? I submit that these are not trivial questions, not beneath the dignity of science nor beyond the range of scientific methods in the 1980s.

Some of the problems are easily overlooked. For example, even in the midst of our romance with youth, the adolescent age group tends to be a poorly served and poorly researched cohort, regardless of position in society. Yet this is a critical period in which health relevant patterns of lifelong significance are formed: cigarette smoking, alcohol use, risky driving, adolescent pregnancy, sexually transmitted disease, and habits of nutrition and exercise. And there are still major problems of the elderly, largely cutting across socio-economic lines, but most poignant among the poor. In connection with problems of adolescents and of elderly persons, as well as those of the mentally ill, we must learn much more about the nature of their difficulties, and how to integrate health services with social services in fostering their well-being.

This committee has heard ample testimony in recent months indicating the need for greater emphasis on research which assesses both the risks and benefits of diagnostic, therapeutic, and preventive interventions -- particularly before their widespread dissemination. Though the health professions strive continuously to improve their quality of care, much of clinical care has not been based on modern scientific methods. It is necessary to determine more than has been done in the past the efficacy and safety of diagnostic, treatment and preventive interventions. The cost and ethical implications of not conducting such research are exceedingly serious. There are hopeful signs that this assessment issue is being widely discussed in both the public and private sectors. The introduction of S. 2466 should greatly enhance these considerations.

Mr. Chairman, it is exceedingly important that the American people understand the need for building a firm foundation for dealing with the newer problem areas of health in practical, useful ways in years to come. My remarks today are mainly concerned with trying to clarify the need for a broadened approach to the health sciences.

These new frontiers involve many forms of clinical investigation and the emerging field of health services research, dealing with the "firing line" where research advances are applied to the actual provision of health care on both an institutional and individual level. Such investigations involve complex biological, behavioral, statistical, epidemiological, and ethical considerations. To be done effectively, they need a secure home that can do for this field what NIH has done for basic biomedical research.

Who then can provide the right conditions? NIH probably could, but for reasons of its traditional strengths and boundaries, NIH is not likely to do more than a part of what needs doing. ADAMAH already does some of it and could do more. The same applies to the FDA, CDC, and perhaps other health agencies as well. The existing health agencies deserve vigorous support for their traditional missions and for some widening of their horizons. But if they cannot, or should not, do the whole job that needs doing, another agency of comparable stature must be developed to strengthen and apply a wider range of sciences and activities to improving the nation's health.

The NIH has not until very recently accorded a high priority to research explicitly directed toward disease and trauma prevention, especially in regard to the behavioral and environmental aspects of health. This situation has begun to change, and other agencies have taken an interest also. But there is, in my judgment, still a long way to go. It may well be that new institutional arrangements are necessary to foster research on near-term prevention. The Institute proposed in S. 2466 could make a great contribution in this regard.

Let me summarize briefly and make a concluding comment. The biomedical science effort of the United States has earned world wide respect. The principal source of new information since World War II on the nature of living organisms has been the American life sciences community, much of which has been biomedically oriented. We now have growing concerns about finding ways in which the social utility of this great effort can be further enhanced. To do that, it is appropriate to broaden the traditional concept of biomedical sciences to include centrally, not marginally, the sciences associated with public health, with the environment, and with behavior. This broadened field may usefully be designated as the health sciences. The health sciences must be concerned in a major way not only with deepening the base of fundamental knowledge, but with continuous monitoring of these advances for applications that are promising in regard to clinical problems. Moreover, arrangements are needed to insure that there will be feedback loops from the clinical and social needs that can stimulate the research enterprise. The entire continuum of high-quality research from basic science to clinical investigation to health services research should be fostered by any comprehensive national health policy.

If a higher research priority is to be assigned to work in this area, as I think it must, then we will need (a) a nationwide cadre of high-quality scientists qualified to tackle these difficult problems and (b) an ability to collaborate across disciplinary lines that exceeds most of what we have so far seen in the health sciences. To do this, we will need both extramural and intramural programs; work relevant both to near-term policy problems and to long-range changes in health and society. We will need high visibility, first-class intellectual leadership, a clear organizational focus for these efforts, and the determination to persist over many years in a complex and difficult enterprise.

The conditions are now exceedingly favorable to move forward expeditiously in providing the institutional arrangements that will truly complete the spectrum of health research and development. The chain can be made strong in all its links during the next few years. I say this for several reasons. One is the thoughtful, constructive, far-sighted interest of this committee as reflected in S. 2466. I say it also because today's leadership in the Department of Health, Education, and Welfare is keenly aware of these problems and ready to create new opportunities. Dr. Richmond and his distinguished colleagues here today understand these issues very well and are deeply committed to dealing with them effectively. This is also true to an unusual extent of the current heads of the health agencies in DHEW. In this, I believe they have the keen interest and full backing of Secretary Califano and Undersecretary Champion. They have already taken constructive steps of which I mention two briefly: (1) the recent elevation in status of the National Center for Health Statistics and the National Center for Health Services Research; (2) the intensive, systematic effort to focus on disease prevention throughout the entire Public Health Service; this includes major strengthening of research relevant to prevention in the foreseeable future.

It is my belief that this committee can work together with the Department of HEW in ways that will provide strong institutional arrangements to complete the spectrum of health sciences. This can contribute in a major way to the continuing improvement of health care, a perennial quest. It can make our health services as rational, compassionate, and science-based as is humanly possible.

Although I do not believe in any single right way to achieve such a goal, I believe that S. 2466 is a landmark pointing toward future progress in the health of our people.

Senator KENNEDY. Thank you very much, Dr. Hamburg, for a marvelous survey of the landscape, in terms of the types of research and the focus of research that really needs to be done. I think you gave us a perspective which made it clear and compelling, and we are very grateful to you for it.

I am wondering whether you think we ought to have an additional institute on prevention. Are you suggesting that as well?

Dr. HAMBURG. Well, I do not think there is any one right way to get at that. It is certainly conceivable. It is plausible; indeed, to me, it is personally even attractive to have an institute sharply focused on prevention.

On the other hand, we are seeing right now that Dr. Richmond, with Secretary Califano's backing, has really mobilized the entire Public Health Service first to do an inventory of what is going on in the way of prevention in various health agencies and what else they would like to do, what latent potentiality there is. And it is very impressive, that with this kind of leadership, you can do a great deal.

And I am inclined to think that the prevention efforts are so pervasive in the Public Health Service that we ought to give that effort a chance. But I would say, Mr. Chairman, we should keep in mind the possibility of a distinct institute for prevention, but let us see how the present effort goes, because it is getting the kind of leadership now that it has not had before.

Senator KENNEDY. Do you think we can get these kinds of results within the existing framework, within the NIH? I think you have already commented on it. Or, do you think that inherently—as I understand their position, at least in the past, it has not had a very aggressive program into this type of factor. Yet, I think they are probably a little nervous about establishing this institute, as well. It almost appears they want it both ways. I do not know if that would be a fair characterization, and we will hear from them, but——

Dr. HAMBURG. The NIH is vast in scope. It is high in quality; it has tremendous responsibilities and heavy burdens. The issue is whether one wants to add this whole set of responsibilities onto the Institute.

A couple of years ago, I thought that was the way to go. I thought that primarily because of the very high quality of the Institute. I spent some of the happiest years of my life there in the intramural program, and was an extramural beneficiary for many years at Stanford, so I love the place.

On the other hand, I have come to feel that it is really adding too much. NIH has taken progressive steps in the last couple of years to bring the benefits of biomedical research right up to the edge of practice. But for NIH to take on the whole health care system pervasively, through the communities where people live in the ways that I was discussing, I think would be too much.

There is a lot of concern, I think, within NIH and the scientific community that has been closest to NIH, that it would perhaps diffuse the efforts of NIH and perhaps even undermine its basic mission, if it were to take on the whole set of responsibilities delineated in your bill.

Therefore, I think the NIH itself might be better off not to have this additional set of tasks. Because, although the dollars involved right now are small, the responsibilities are large, and ultimately I think the dollars would be large and the tasks would be very heavy.

I would add, Mr. Chairman, that there is more than the NIH involved here. There certainly is much to be said for a role, a significant role, for ADAMAH, FDA, and CDC, at least those agencies, in the kind of thing we are talking about this morning. And inevitably, however it is done, I think the Assistant Secretary and the Surgeon General will have to have a major active coordinating role, because there will be a certain healthy competition, even if the new institute is established.

Senator KENNEDY. Well, the question of coordination is a legitimate one. I think, for the reasons that you outlined earlier, in terms of the visibility, the focus, the attention, it seems to me that the institutional setup, at least as far as I believe, is best served by the way that we have outlined it in 2466.

Let me ask you, in terms of the study that you did on technology and the need to evaluate it further, is there anything in this legislation that is inconsistent with the recommendations and the findings of the institute?

Dr. HAMBURG. No.

Senator KENNEDY. Let us put it the other way. Is it consistent with the recommendations, or do you think it helps to carry them forward?

Dr. HAMBURG. Yes; I think it does. It seems to me—without getting into the details of it—the broad thrust of this legislation would indeed be very helpful, in terms of the problems that we have identified and discussed in the Institute of Medicine studies.

All I am saying is it is not the only way. I could conceive of other ways to do it. Dr. Richmond and his colleagues make a plausible case.

It may be that the two approaches can be combined, in fact. That is, you can view the recent organizational arrangements in HEW as a transitional step toward the kind of institute proposed in the bill, and then the question becomes what would be the rate of the transition and what steps could be taken expeditiously to make that transition work well.

Senator KENNEDY. Off the record.

[Discussion off the record.]

Senator KENNEDY. Let me just ask, on the clinical trials, do you think the center should do some clinical trials, as well?

Dr. HAMBURG. Now, which center are we talking about?

Senator KENNEDY. We are talking about the new one that we are proposing.

Dr. HAMBURG. Yes; I would favor that. Clinical trials have been a thorny issue. To be done well—there are very difficult scientific questions and ethical questions. When should you start a trial—when should you stop a trial. They tend to be expensive, very technical problems.

It is very understandable that there has been a certain amount of concern in the existing agencies about heavy commitment to technical trials. That is reflected in the President's Panel on Biomedical Research. In fact, in that report, they do not categorize clinical trials as research. But if it is not research, I do not know what it is. It might be some kind of an art form. But we certainly need more clinical trials.

Now, I think the NIH should and is doing a lot of clinical trials. ADAMAH is doing some and probably will do more. But in effect, the full range of what is needed, I think, will call for some additional bases for design in support of clinical trials beyond those we have now.

Senator KENNEDY. For our other witnesses, we are going to have to recess until 2:15, because President Sadat is here. I know it is inconvenient. But we have some important testimony and I want to hear it. So if that is convenient, we will resume the hearing at 2:15.

The subcommittee stands in recess.

[Whereupon, at 12:10 p.m., the subcommittee recessed, to reconvene at 2:15 p.m. this same day.]

Senator KENNEDY. We will come to order.

We are delighted to hear from Dr. Philip Lee, who is a former Assistant Secretary of Health, currently director of health policy program, School of Medicine, University of California, San Francisco.

I might ask Dr. Remington if he would like to come on up and we will have a panel. We had meant to have Kerr White, who could not be here, and Dr. Pomrinse, who is unable to be here.

Dr. Remington is the dean of the University of Michigan School of Public Health, and immediate past president of the Association of Schools of Public Health.

STATEMENT OF PHILIP R. LEE, M.D., PROFESSOR OF SOCIAL MEDICINE AND DIRECTOR, HEALTH POLICY PROGRAM, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO; AND RICHARD D. REMINGTON, PH. D., DEAN, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF MICHIGAN

Dr. LEE. Mr. Chairman, it is a pleasure to be here. I am very happy to respond to the committee's request to testify on the National Institutes of Health Care Research Act of 1978.

I wish to make it clear, as Dr. Hamburg did, that the testimony is my own and does not necessarily reflect that of my colleagues at the health policy program or the University of California.

I will not read through my testimony in detail, but will submit it for the record, and just highlight several points in the testimony and then leave it to you to ask the questions as you wish.

Senator KENNEDY. Fine.

Dr. LEE. I think that the act may require some minor modifications, such as the level of authorization for appropriations for health services research, but I want to express my strong support for S. 2466.

I think the proposed revisions of the Health Services, Health Statistics, and Medical Libraries Act are imaginative and well thought out.

I believe that the changes proposed in authorities and organizational structure are needed to reverse the years of neglect of health services research and health statistics by the Nixon and Ford administrations.

Tragically, despite what we have heard this morning, the Carter administration, through the stranglehold on the budget and personnel exercised by the Office of Management and Budget, is compounding the errors of earlier administrations.

The Carter administration has proposed to cut the appropriations for health services research for fiscal 1979 to a level that cannot possibly allow the center to meet the goals established by the Congress.

Although the support for health statistics is stronger, it is still well below what is needed, as Dorothy Rice pointed out this morning. Funds are needed for various phases of the health statistics programs that are vital to do the job that must be done.

I think that the proposal to establish a National Center for the Evaluation of Medical Technology is sound, and the appropriation authorizations there reasonable.

In my testimony, Mr. Chairman, I review some of the historical factors relating to the development of the National Center for Health Services Research. I have been close to that development for the past decade, and I have also observed with some interest the work of the National Center for Health Statistics.

In my testimony, I have described some of the things that have occurred with the new leadership in the center since 1974: The kind of policy direction that is now being given to health services research, the priorities that have been established, as well as some of the contributions that health services research has made, both to health policy and to improvements in health care.

One important point which I make on page 7 of the testimony is that the National Center for Health Services Research has been the principal supporter for health services research in the country. It has been and remains a unique institution, because it is not constrained by the needs or the defined policies of a specific program, such as medicare or the Health Care Financing Administration, with specific limitations on its authority.

It is possible for the National Center for Health Services Research to support studies that question existing policies, explore new areas, and generate research that will contribute to future policy decisions.

An example was the contribution that the work of Dr. Lester Breslow and his associates at the Human Population Laboratory in Alameda County made to the evolution and the development of the Health Information and Health Promotion Act of 1976. I consider this act to be a piece of landmark legislation, probably representing a turning point in national policy, shifting from our past emphasis on medical care to a more balanced approach. The research that Dr. Breslow did was supported as investigator-initiated, without any policy relevance at the time, unconstrained by any policies at the time, because the center could support investigator-initiated research.

That kind of support was also provided the Center for Health Administration studies at the University of Chicago, under Dr. Odin Anderson and that group. The Chicago group have carried two decades of survey research on the utilization of medical care services, medical care expenditures, and access to care. There is a recent special report published by the Robert Wood Johnson Foundation, describing the results of some of their recent studies. Critical to the work of the Chicago group has been support from the National Center for Health Services Research, over 10 years' time, including support of the recent study. The recent study will provide all of those concerned with national health insurance very basic data about access to care, current barriers to care, as well as the public's attitude about medical care and the kind of care they are receiving. That was the investigator-initiated research which will have significant impact for policymakers, even though it was not designed as a specific policy study.

It is the ability to support that kind of work that is really critically important for the Center.

With all this good work done by the National Center for Health Services Research—and I could cite a number of other areas, and I do in the testimony—why do I think that a National Institute for Health Care Research should be created? Why should the organizational structure be changed?

I came to this notion rather slowly. When I saw the Carter administration's decisions on the health services research budget for fiscal year 1979, I was absolutely convinced that some action had to be taken by the Congress to strongly communicate to the administration the importance of health service research, health policy research, health statistics, and technology assessment.

I am aware of the fact that this is not an Appropriations Committee hearing, Mr. Chairman, but if you look at the record of appropriations in the last 6 years, the appropriations have dwindled from $58 million to $23.8 million for fiscal year 1979.

In the appropriations budget, the administration has a figure of $31 million for health services research. That figure includes $7.2 million for personnel and other costs what I would call overhead items. There is only $23.8 million to actually support the research of the center.

During the last 3 years, the Department has included personnel and other administrative costs in the appropriations request, so it gives, I believe, an inflated figure when we compare it to earlier figures.

Senator KENNEDY. Those statistics are obviously enormously revealing, and it has gone through Republican as well as Democratic administrations. What is the mentality, when we see all of the needs and the explosions of costs and inflation in these other areas; I mean, what is the problem there?

Dr. LEE. I think that one of the problems has been a lack of understanding—and the problem lies principally with the Appropriations Committees. There has not been a lack of support in the Health Subcommittees in either the Senate or the House, but the Appropriations Committees have been more interested in disease-related research—cancer research, particularly—and the emphasis and the payoff that they see from that research. We have not been able to effectively point out the payoffs of health services research. How does health services research help an indiivdual? Members of the Appropriations Committees know when disease related research has help a member of their family or a member of families that they know. The benefits are very personal and very demonstrable.

Senator KENNEDY. I suppose also, with regard to basically various research grants, there is some latent suspicion and perhaps even hostility toward that. I mean, there should not be, but I think this gets caught up in that. And it is not only the administration. OMB, of course, has a similar attitude.

We were down there and spent an hour and a half with McIntyre down there, on this very issue. And you would think that people who were not just listening to the special pleaders—and I think all of us obviously plead some guilt to that—but people who are looking at it and have some degree to look at it from an assistance point of view, it just is incredible to me that we cannot do better.

Dr. LEE. Since 1973, the Center has requested $100 million more than has been authorized by OMB.

Senator KENNEDY. There is no question in your mind that it could be spent effectively, is there?

Dr. LEE. Absolutely no question in my mind, and that significant increases in the present authorizations should be made.

Groups like the University of Chicago's Center for Health Administration Studies used to receive continuing core support from the National Center for Health Services Research. It no longer receives that support because there is not enough money. And it is one of the best health services research groups in the country. It has made very important contributions, and contributions that I think would more than pay for all the money we have put into health services research.

The request by the Carter administration for this coming year is $23.8 million. When President Johnson established that Center, in 1968, he asked for $20 million in appropriations. And at that time, national health expenditures were $43 billion. This year, the Federal Government alone will spend $6 billion more than that. It would be a joke if it were not so serious. And it is unfortunate that the issue has to be brought repeatedly to the Congress, rather than finding some avenue within the administration to deal with it.

Although Dr. Julie Richmond has made some organizational changes and Ruth Hanft is doing a superb job helping the Center improve the internal management and giving greater visibility and status to both centers, is not the answer.

And after hearing the testimony this morning, I am really even more enthusiastic than I was when I wrote my testimony about the proposal.

I have one suggestion. I think it is an excellent proposal. I think it should be enacted promptly.

Senator KENNEDY. Let me ask you, though, why not do it through the current HEW system, under the wing, for example, of an Assistant Secretary and the team that is assembled, and they can give it the kind of encouragement, get it off the ground, and then spin it off after it has got some life to it. What is the principal trouble there?

Dr. LEE. The problem is time and priorities. If the Assistant Secretary for Health has to address issues of technology assessment, if he has to be involved with the details of organization, if he has to be personally involved, as he obviously will have to be involved if it is in his office, he simply is not going to be able to address himself to a number of the other major health policy issues that he has to be inolved in.

That is why I like the idea of creating an institute, creating a director who is a Presidential appointee, and giving the Director responsibility to do that job. Under those circumstances it should be possible to recruit one of the top people in the country to do the job—provided it has the kind of congressional support that this would envision and that this would imply.

If it was done purely by administrative action—say, Secretary Califano wants to reorganize, and he does that—I think it would not bring with it the same kind of support. We know that it is difficult. The Institute of Child Health and Human Development is an example of a congressionally mandated institute that has taken years to develop the kind of support that is needed.

Without the congressional support, we really would not see the thing fly in a viable way, even if it were done administratively, with strong support from the Secretary.

The one suggestion I would make in the legislation—well, two really—one is to increase the level of authorization for health services research. The proposed levels are seriously below what could presently be spent very, very adequately, very, very soundly.

The second suggestion relates to the timing or the timetable to achieve the full development of the National Institutes of Health Care Research and the individual institutes within the National Institutes.

I think it may take from 18 to 24 months to fully implement the legislative intent. It will be necessary to get appropriations, personnel ceilings, and to do the recruiting. If unrealistic expectations are raised we are going to be disappointed again. That has been one of the problems. Our early expectations for health services research exceeded what was possible to achieve.

You are proposing, Mr. Chairman, what we should have done in 1968; provide the kind of support that is needed, link health services research and health statistics to policy, but insulate them enough from the day-to-day demands of the Secretary's office, so that they will not be politicized. I think it is a superb proposal, I am fully supportive and certainly will work as vigorously as I can for its enactment.

Thank you for the opportunity.

[The prepared statement of Dr. Lee and additional material follows:]

STATEMENT BY

PHILIP R. LEE, M.D.*

BEFORE THE

SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH

OF THE

COMMITTEE ON HUMAN RESOURCES

UNITED STATES SENATE

NINETY-FIFTH CONGRESS

ON

NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978 (S.2466)

FEBRUARY 7, 1978

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*Professor of Social Medicine, Director, Health Policy Program, School of Medicine, University of California, San Francisco

Mr. Chairman and members of the Subcommittee on Health and Scientific Research:

I am pleased to respond to your request to testify on the National Institutes of Health Care Research Act of 1978 (S.2466). I wish to make it clear that the views I express are my own and do not necessarily reflect those of my colleagues in the Health Policy Program, School of Medicine, University of California, San Francisco or those of the campus or university administration.

Although some details of the Act may require modification, I want to express my strong support for S.2466. The proposed revisions in the Health Services Research, Health Statistics, and Medical Libraries Act (P.L. 93-353) are imaginative and well thought out. I believe that changes proposed in authorities and organizational structure are needed to reverse the years of neglect of health services research and health statistics by the Nixon and Ford Administrations. Tragically, the Carter Administration, through the stranglehold on the budget and personnel exercised by the Office of Management and Budget, is compounding the errors of earlier administrations. The Carter Administration has proposed to cut the appropriation for the National Center for Health Services Research to a level that cannot possibly allow it to meet the goals established by the Congress. Although the support for health statistics is stronger, it is still well below what is needed. The proposal to establish a National Center for the Evaluation of Medical Technology is sound and the appropriations authorization reasonable.

In my testimony, Mr. Chairman, I will focus on health services and health policy research because I have been concerned about the development of these fields and their effective application for more than a decade.

I am more familiar with the needs and opportunities in these fields than in health statistics, although I fully support your proposals regarding the creation of a National Institute of Health Statistics and Epidemiology.

HISTORY AND BACKGROUND

Ten years ago in his Health and Education Message to the Congress President Johnson stated:

> America's annual spending for health and medical care is more than \$43 billion. But despite this investment our system of providing health services is not operating as efficiently and effectively as it should.

He went on to note:

> Research and development could help eliminate these conditions by pointing the way to better delivery of health care. Yet the government-wide total investment in health services research amounts to less than one-tenth of one percent of our total annual investment in health care.

The President directed the Secretary of Health, Education, and Welfare to establish a National Center for Health Services Research and Development. He also recommended doubling the appropriation for health services research from \$10 million to \$20 million annually.

This proposal received strong support from the Congress. In enacting the Partnership for Health Amendments of 1967 (P.L. 90-174) specific authorization was provided for the support of health services research and development. After careful planning, the National Center for Health Services Research and Development was established on May 2, 1968 during my term as Assistant Secretary for Health and Scientific Affairs. Although the Center was established in 1968, it was not until 1974 that it was provided a specific statutory base.

With the passage of the Health Services Research, Health Statistics, and Medical Libraries Act of 1974 (P.L. 93-353), the Center was required to meet certain conditions and carry out certain specific programs. Unfortunately, neither the Ford nor the Carter Administration has requested the funds or the positions needed to do the job adequately.

The law specifies that the Center must use not less than 25 percent of its annual appropriation to conduct intramural research. This was very sound judgment and in the long run will do more to strengthen the quality of the health services research supported by the Center than any other single step that can be taken. The second Congressional mandate required that the Center support at least six special emphasis health services research centers, totally independent of the Federal government. One of these centers must concentrate on health care technology and another on management. (In 1976, Congress added a center for health services policy analysis to the list of special emphasis centers.) The third requirement of P.L. 93-353 is that no more than 20 grants, or $5 million, may be used in any one year to study a particular aspect of health services. In addition, all grants and contracts involving direct costs in excess of $35,000 must be reviewed for scientific merit by groups of non-Federal experts. Finally, the Congress gave the Secretary of the Department of Health, Education, and Welfare explicit authority to support health services research training. This is a most needed authority, but the Administration has refused to request funds to implement the needed training programs.

With this new Congressional mandate and new leadership in the National Center for Health Services Research (NCHSR), the difficult job of translating Congressional policy into more useful results was begun in 1974. When we first established the Center in 1968, we made a serious mistake: we tried to isolate the Center from the day-to-day demands of policy makers. We felt that the nation would be best served if the Center supported health services research in an independent fashion, without regard for the immediate policy problems that we faced, such as the rapidly increasing costs of medical care. There were a number of people, including my deputy Dr. George Silver, who felt that just the opposite course should have been taken. In retrospect, it is clear that we should have done what this Subcommittee is now proposing -- link the NCHSR and the National Center for Health Statistics to the health policy process, but provide an effective buffer from the immediate demands by policy makers for short-term policy analyses.

During the past three years the staff of the NCHSR has designed and implemented a research planning process that is responsive to the policy needs of the Department of Health, Education, and Welfare and Congress. It cannot possibly meet these needs, however, with current levels of support. The research planning process developed by the NCHSR is issue oriented. The purpose is to identify critical health care problems, to formulate the research questions relevant to those problems, and to design research strategies for gathering and analyzing the information pertinent to questions that policy makers might find useful.

MAJOR RESEARCH AREAS AND POLICY IMPACT

The NCHSRs research program is organized to address specfic health services delivery problems. Major areas, such as long term care, primary care, and the application of technology are all addressed within the targeted or applied program areas. The eight issues that have emerged as areas of special emphasis are:

(1) Inflation and Productivity;

(2) Health Manpower;

(3) Emergency Medical Services;

(4) Health Care and the Disadvantaged;

(5) Health Insurance Plans;

(6) Quality of Care;

(7) Planning and Regulation Methods; and

(8) Long-term Care.

In each of these broad areas specific issues are being addressed.

For example, in the area of health manpower one of the goals is to develop more reliable techniques to estimate the adequacy of manpower supply, and the need, as well as the demand, for health services. Further research in this area is critical and must include studies of the effects of national health insurance on the demand for services. Research supported by the NCHSR in the field of health manpower has much more clearly identified the needs in the area of dental health manpower; it has provided much of the support for the pioneering work in the development of nurse practitioners and physicians assistants; it has provided critically needed information to the Congress on Foreign Medical Graduate (FMGs) during the deliberations on the Health Professions Educational Assistance Act of 1976 (P.L. 94-484); and it is improving an understanding of factors affecting georgraphic and specialty maldistribution. In my judgment, the ultimate cost savings in medical care expenditures that will result from the decision of the Congress to restrict the entry of FMGs into the United States will exceed all the federal expenditures to date for health services research.

Within the large category "health insurance plans" the present NCHSR plan calls for special study of the potential cost and impact of the catastrophic insurance provisions, and for the investigation of natural experiments involving health insurance benefit changes, such as the addition of co-insurance or deductibles to a group practice prepayment plan. The potential usefulness of this information to policy makers is apparent.

Research and analysis on the effectiveness of emergency medical services continues to be a high priority. Studies are examining specific procedures or methods of emergency care as well as alternative means of organizing and delivering these services. As grant requests in this area are reviewed studies that have broad applicability are given priority, provided that they meet the standards of scientific merit set by the study sections. Too often proposals are submitted that are really local service demonstrations; the characteristics of hospitals or other institutions involved as well as the communities are sufficiently unique to make the results of little value outside of the particular community. In its program solicitation for emergency medical services research, the NCHSR had stressed four areas:

(1) measures of effectiveness;

(2) system descriptions and relationships;

(3) policy issues; and

(4) techniques and devices.

The benefits of this research will be not only in terms of better policy decisions and money saved, but also in terms of better services for people who desperately need it. Two areas are particularly important -- emergency care for the seriously injured and emergency care for those with acute medical emergencies, such as heart attack, gastrointestinal hemorrhage, and drug overdose.

There are a number of other areas in which the work carried out or supported by the NCHSR has been of critical importance in health policy deliberations, in the enactment of important pieces of health legislation, in the operation of federal programs, and in the improvement of health services in a broad sense.

Since the NCHSR was established in 1968, it has been the principal supporter of health services research. It has been, and remains, a unique institution because it is not constrained by the needs or the defined policies of a specific program, such as Medicare. It is possible for the NCHSR to support studies that question existing policies, explore new areas, and generate research that will contribute to future policy decisions.

A critical shift in federal health policy began with enactment of the Health Information and Health Promotion Act of 1976 (P.L. 94-317). Although a number of people contributed to the deliberation and evaluation of this legislation, an important contribution was made by Dr. Lester Breslow and his associates at the Human Population Laboratory in Alameda County, California. The work of this group demonstrated very clearly the role of specific behaviors associated with good health and longevity. For almost a decade this work was supported by the NCHSR. As a result of this work and that of a few others the vital importance of behavior and social support networks to health is beginning to be recognized.

The Health Information and Health Promotion Act of 1976 (P.L. 94-317) was to provide the statutory authority for Secretary of Health, Education, and Welfare Califano to launch his campaign to better inform young people, pregnant women, and the general public of the hazards to health associated with cigarette smoking. It has also provided the impetus for an expanded approach to disease prevention. In the years to come P.L. 94-317 may be viewed as the real beginning of a shift in national health policy from an excessive reliance on medical care to a more balanced approach including health promotion and health protection.

A shift in policy of lesser potential magnitude, but probably of more immediate fiscal impact, was represented by the Medicare and Medicaid Amendment regarding Rural Health Clinics Services (P.L. 95-210), which permits payment of nurse practitioners and physicians assistants under Medicare and Medicaid. The report prepared for the Congress by the Congressional Research Service, "Issues in Physician Extender Reimbursement," pointed out that services by physician extenders were cost effective, did not compromise quality, and were acceptable to consumers. The analysis was drawn largely from research supported by the NCHSR.

Two areas that will be of vital concern to policy makers in the future -- health outcomes of medical care and health information systems -- are in different stages of development. Health outcome studies have been pioneered by John Williamson at Johns Hopkins and Robert Brook at the University of California, Los Angeles. Rather than analyzing the process of care or the structure of the health care system, they are designing measures of the quality of care. These studies, and others like them, will be of increasing importance in future decisions about cost/quality trade-offs.

Health information systems represent another area of great promise. Although developmental costs seem high in the short run, these systems have the potential for great savings in the future. For example, the Technicon System in use at El Camino Hospital in California could result in savings in excess of one billion dollars per year if it were used in hospitals throughout the United States. That will give you some idea of the potential value of these systems. This system is now being tested in a half dozen hospitals, but present reimbursement methods provide little incentive for hospitals to install such systems. A system with far-reaching potential for medical care is the PROMIS system under study at the University of Vermont Medical Center in Burlington, Vermont. The development of these innovative systems has been made possible by support from the NCHSR.

The work of the Center for Health Administration Studies, University of Chicago, deserves special comment because it has provided a model for the development of multidisciplinary health services research center. Under the direction of Dr. Odin Anderson, the Center has conducted basic studies on the utilization of medical care services, medical care expenditures, and access to care. In their book Two Decades of Health Services: Social Survey Trends in Uses and Expenditures, Anderson, Lion, Andersen summarize the results of their 1956, 1963, 1967 and 1970 surveys. In an appendix, they list six pages of places, including books, papers, hearings, in which the 1970 survey data has been used. We have recently used their expenditure data to estimate expenditures for prescription drugs by age and income group in our analysis of options for the coverage of prescription drugs under national health insurance. That analysis, by Milton Silverman and Mia Lydecker,incidentally, was recently published by the NCHSR.

Soon to be published by the Center for Health Administration Studies are the results of their recent national survey of access to medical care. This survey was supported by the NCHSR and the Robert Wood Johnson Foundation. I would like to submit for the record a brief summary of the preliminary analysis recently published by the Robert Wood Johnson Foundation (Attachment).

I would cite a number of other areas in which important contributions have been made by health services research: economic determinants of medical care, including incentives for hospitals and physicians; performance of health maintenance organizations; improved methodologies to assess outcomes of patient care; hospital cost accounting systems; and computer assisted electrocardiograms, but I think that a detailed account of these contributions is not necessary at this time.

WHY A NATIONAL INSTITUTE FOR HEALTH CARE RESEARCH?

Why, if the NCHSR is doing so well and health services research is making important contributions to health policy and health care, do I support the National Institutes of Health Care Research Act of 1978, which would significantly alter present administrative arrangements, expand the authority of the National Center for Health Statistics, and add a new National Center for Evaluation of Medical Technology? Why add the proposed superstructure when the Center Directors already report to an outstanding Deputy Assistant Secretary, who has already proven that she is committed to the idea of protecting the integrity of both Centers from political interference?

I did not reach my conclusions quickly. Initially, I was not in favor of another change in organizational arrangement. I felt that the existing authorities should be maintained, that a technology assessment function should be added to the NCHSR, and that both Centers should be given increased authorizations.

The action of the Carter Administration on the budgets for health services research in the NCHSR and in the Health Care Financing Administration convinced me that at the highest policy levels in the Department of Health, Education, and Welfare and in the Office of Management and Budget there is little, if any, understanding of the need for health services research and technology assessment and only limited support for the work of the National Center for Health Statistics.

Mr. Chairman, I know that this is not the appropriations committee, but the budget of the NCHSR does reveal a great deal about the Carter Administration's understanding of health services research. While estimating a $4.4 billion increase in Medicare expenditures and a more than $1.1 billion increase in Medicaid expenditures, they propose to cut the funds allocated to the NCHSR by $2 million. Since FY 1973 there has been a steady drop in the funds allocated to the NCHSR:

FY 1973 $58 million

FY 1974 $37.9 million

FY 1975 $35.9 million ($8 million was reprogrammed by DHEW)

FY 1976 $26 million

FY 1977 $24 million

FY 1978 $26 million

FY 1979 $23.8 million

In the past three years the Department of Health, Education, and Welfare budget has included personnel and other administrative costs as part of the NCHSR budget. Thus in FY 1979 the Administration lists a figure of $31 million for the NCHSR, but $7.2 million of this amount represents overhead. As the appropriation for research shrinks, the overhead relative to total expenditure rises. Since 1973, the NCHSR has requested $100 million more than has been approved by OMB. Even the NCHSR requests were modest in view of the needs and opportunities.

The figure of $23.8 million in FY 1979 must be contrasted with the $20 million proposed by President Johnson for the FY 1968 budget. You will recall that total national health care expenditures in 1968 were $43 billion; in FY 1977 federal health expenditures exceeded that figure by $6.6 billion and national health expenditures had risen to $160.6 billion. In FY 1979 total federal health expenditures will exceed $63 billion, Mr. Chairman. The NCHSR appropriation request by the Carter Administration would be a joke if it were not such a serious mistake in judgment. The Congress must take dramatic steps to reverse this decision and give health statistics, health services research, health policy research, and the evaluation of medical technologies the priority that they deserve, rather than allow them to be relegated to a state of malignant neglect.

Does the proposal to establish the National Institutes of Health Care Research solve the problem? First, does it make sense conceptually? Are health services research and health policy research really linked? If so, what is the connection?

WHAT IS HEALTH SERVICES AND HEALTH POLICY RESEARCH?

Research at the most basic end of the spectrum is usually described as "discipline" or "conclusion oriented" research. The aim is to test hypotheses and arrive at certain conclusions about what is, descriptively, the state of affairs. This type of research is designed to contribute to knowledge in a substantive area and to contribute to theory as well. This research typically lacks a problem focus and usually employs the skills, methodology, and approach of one discipline. Although the findings from this type of discipline research can contribute to the identification and eventual solution of problems, this application is not contemplated by the investigator.

Health services research might be described as the next step along the continuum. Health services research has an applied focus, it is usually problem oriented, and almost always involves the skills of more than one discipline. The scope of health services research spans anthropology, epidemiology, economics, sociology, bioengineering, systems analysis, psychology, medicine, and management sciences. It is primarily concerned with problems in the organization, financing, staffing, utilization, regulation, and outcome of health services. It can be distinguished from biomedical research, which is related directly to normal biological or behavorial processes or disease processes.

The problem orientation of health services research brings it one step beyond discipline research in the research spectrum. Although health services research may contribute to the disciplines involved and it may be useful in solving some specific problems related to health services, it is usually of very little aid in health policy formation because the research questions are usually formulated without specific policy questions in mind.

Health services research can be policy relevant if the research is designed to investigate factors amenable to policy manipulation, if the quality of the research is such that it may increase the likelihood of better policy outcomes, and if the information is available in time to contribute to policy decisions.

Health policy research deals with a wide range of biological, behavioral, environmental, and sociocultural factors, including health care, that affect the health status of individuals and populations. Unlike health services research, it involves primarily a synthesis and analysis of information relevant to specific policy problems. Policy research attempts to synthesize and interpret findings that are relevant to a policy problem, draw out implications, and make recommendations for policy consideration. Policy analysis brings the process one step closer to the decision making process. The aim of policy analysis is to permit improvements in decision making and policy making by permitting careful consideration of a broad set of alternatives.

Policy researchers must have a more refined appreciation of the policy process than investigators undertaking policy-relevant health services research. The ability of policy researchers to synthesize and interpret findings in light of policy problems must be matched with an ability to translate information into a form that is understandable and useful in the world in which policy makers operate.

CONCLUSION

The proposed National Institutes of Health Care Research Act (S.2466) forges a strong connection between health services research and health policy research. Some might prefer that you not change the names of the National Center for Health Statistics and the National Center for Health Services Research, but make clear in both the language of the bill and in the Committee Report what is the intent of the Congress. Personally, I am not fearful that the changes you are proposing will result in a neglect of health services research or the training of health services researchers.

The proposal to establish a National Center for Evaluation of Medical Technology separate from the NCHSR, but within the framework of the National Institutes of Health Care Research, also makes a great deal of sense. The need for evaluation far exceeds our present methodologies or capacities, but we must undertake a major effort in the field or the problems will loom even larger and more complex. There are two promising signs that progress can and will be made with the right leadership and organization: the work in the health field by the Office of Technology Assessment and the studies undertaken by the Center for the Analysis of Health Practices, School of Public Health, Harvard University. A beginning has been made in studies of expensive technologies and coronary care units, but much more must be done. To do it right, however, requires careful planning and step-by-step development.

How can the goals defined in the proposed National Institutes of Health Care Research Act (S.2466) best be accomplished? I fully support the proposal and view it as an important, indeed, a critical step by the Congress in firmly establishing health services research, health policy research, health statistics, and technology assessment as areas of high priority.

The goals and plans for reorganization set forth in the Act cannot, however, be achieved overnight. As one who played an important role in a major overhaul of the health programs in the Department of Health, Education, and Welfare in the late 1960's, I am fully cognizant of the difficulties; the disadvantages, and the loss of program momentum that often occur during the process of organizational change. We have first-class leadership in the Department, particularly in the health field. Dr. Julius Richmond is one of our most able and most sensitive health leaders. He has recently brought both the NCHSR and the National Center for Health Statistics into a direct relationship with his office. The Directors of both Centers report to Ms. Ruth Hanft, his superb and extraordinarily able Deputy for Health Policy, Research, and Statistics. She has already instituted measures to improve the analytic capacity of the National Center for Health Statistics and to strengthen the planning and performance of the NCHSR. I am very much impressed with what she is doing to gain support for these activities within the Department of Health, Education, and Welfare, the Congress, and OMB. What Dr. Richmond has done and what Ms. Hanft is doing are steps toward the creation of the National Institutes of Health Care Research.

As part of the legislation perhaps you can include a timetable to achieve the proposed organizational changes. I would suggest 18-24 months from the date of enactment of the Act to the full development of the National Institutues for Health Care Research. This would provide the time for adequate funds and new positions to be provided for the Director's office as well as for the staffing and development of the National Center for Evaluation of Medical Technology, under the guidance of the proposed National Institutes.

In summary, Mr. Chairman, I am impressed by the quality of the work supported by the NCHSR and the National Center for Health Statistics and by the importance of some of this work in improving health care and health policy. I fully support the proposal embodied in the National Institutes of Health Care Research Act of 1978 (S.2466). I have suggested that a phased, carefully planned transition over an 18-24 month period would be the best means to establish the National Institutes of Health Care Research.

The
Robert Wood Johnson
Foundation

Special Report

Number One/1978

Foreword

Americans of all ages, of all races, at all income levels have greater access to health care services than ever before. And by and large, individually, they are pleased with the care they receive.

That is the simple and encouraging message contained in a report of a national survey now being completed. At the same time, a significant majority of Americans also say they believe there is a health care crisis in this country.

Why this seeming paradox?

Politicians, health care professionals, and policy analysts will have this and other riddles to dissect when the findings of a national survey of access to medical care are published late in 1978. The study is more than a compilation of statistics; it seeks to pinpoint and measure significant factors that determine whether or not people obtain the medical care they need.

The Robert Wood Johnson Foundation has supported this study in the belief that a clear and comprehensive understanding of these factors is essential for a large national philanthropy conducting a highly targeted program to assist those seeking ways to improve America's health care system. Obviously, other institutions and groups—both public and private—share an interest in this aspect of the $140-billion a year health enterprise.

When published, this study will present a comprehensive portrait of the nation's health system from the perspective of those it serves. One of its principal uses will be to identify areas that need attention. It also can serve as a benchmark so that future changes in the system's performance can be observed and measured. At the same time, it reveals much about today's world as well.

America's Health Care System: A Comprehensive Portrait

How the nation's 220,000,000 people obtain their medical care (and what they think about it) is probed in a new survey. It reveals that barriers are tumbling, most patients are satisfied, but cost remains an overriding concern.

In the world of business, a variety of indicators reflect the ups and downs of economic activity. Selected separate indicators, for example, comprise the Consumer Price Index, Department of Labor employment statistics, Dow Jones stock averages, and others.

Magazines such as *Business Week* and *U.S. News and World Report* each have identified certain indicators which they believe reflect the state of the nation's economy. *Business Weeks*'s includes net tons of steel, kilowatt hours of electricity, freight car loadings, board feet of lumber, wheat prices in Kansas City, gold prices in London, the prime interest rate, the Federal Reserve money supply, housing starts, and many others.

For businessmen, government officials, economists, bankers, and investors, such indicators are considered essential to decision making. They tell where the economy of the nation is going, and they guide and influence those who have a hand on the tiller.

In the business of health, too, a variety of specialized statistics show how some parts of the system are performing currently:

- the infant mortality rate has decreased in the last five years by 19 percent
- more than 230 million days of care are rendered to 29 million patients admitted to hospitals each year
- health expenditures total 8.6 percent of the gross national product—$140 billion annually
- federal Medicaid payments to states total almost three-quarters of a billion dollars each month
- the ratio of doctors to population has increased from 139 per 100,000 in 1960 to 162 in 1976.

Analysis of these statistics, however, only skirts the fringes of a central question: is health care available to those who need it, and what kind of barriers must be overcome to obtain care? In the jargon of health policy analysts, this crucial issue goes by the phrase access to care.

In "people terms," however, access translates into a multitude of factors which together determine whether or not persons obtain the medical care they need. Is a doctor available? How far away is the doctor's office? How long is the trip? How long does it take to get an appointment? How much time does the doctor spend with the patient? How much does the visit cost? How will the bill be paid? Was the patient satisfied with what the doctor did?

There is about to be completed a study which identifies these and other important factors—indicators—bearing on access. One of its purposes is the development of standard means for consistent measurement of these indicators.

The national survey of access to medical care was carried out by the Center for Health Administration Studies of the University of Chicago.[1] The field work was conducted by the University's National Opinion Research

1. **Principals in the study are:** Lu Ann Aday, study director; Ronald Andersen, principal investigator, and Gretchen Voorhis Fleming and Grace Chiu, assistant study directors, all of the Center for Health Administration Studies, University of Chicago, 5720 Woodlawn Avenue, Chicago, Illinois 60637. Support included grants from The Robert Wood Johnson Foundation totaling $1,229,143, and a $250,000 grant from the National Center for Health Services Research for secondary and special analyses.

Center between September 1975, and February 1976. It is based on a sample of 7,787 persons and is statistically representative of the U. S. population.

The study focuses on many factors believed to affect access for the entire population. Moreover, data for each indicator can be examined for sub-groups of the total population—sub-groups defined by a number of important variables, including age; sex; race; income; region of the country; suburban, urban, and rural residence; and education levels. (For a graphic representation, see chart on pp. 8-9.) As a bonus, certain parts of the survey are comparable with other projects carried out in 1963 and 1970, so some trends can be seen.

The survey generated large amounts of data and the analytic task facing the investigators has been formidable. The challenge: out of all the information available, identify those particular indicators which appear to be most significant in determining access for the total population and for sub-groups as well.

In a number-oriented society, nothing makes a problem come alive so much as the measurement of it. Walter Lippman, a half century ago, said: "The printing of comparative statistics of infant mortality is often followed by a reduction of the death rate of babies . . . the statistics make them visible, as visible as if the babies had elected an alderman to air their grievances."[2]

Grievances, indeed, have been aired about America's health system: its cost, and its accessibility to such groups as minorities, rural and inner city residents, and the aged. Attempts have been made to fix deficiencies. Medicare and Medicaid are examples.

The new University of Chicago study promises to provide abundant information enabling an assessment of the impact of these and newer health initiatives. This information will give new currency to the debates which shape changes in the nation's health laws—ranging from recommendations of seeming minor consequence to the sweeping changes implicit in proposals for national health insurance.

Professional organizations, Congress, state legislatures, and other groups will be able to evaluate the relative needs of population groups believed to have particular problems obtaining medical care. Similarly, over time, these data may define the nature of the so-called crisis in American health care.

The study's principal strength derives from its attempt to go beyond the raw numbers and to interpret and analyze what they mean.

This process is now underway by principal investigator Ronald Andersen, 38-year-old sociologist, and his colleagues at Chicago. Ahead lie many more computer runs and much more analysis. Nevertheless, Andersen declares flatly that the work " . . . provides a comprehensive and timely baseline for informing the current debates over national health policy options intended to impact—directly or indirectly—on access to medical care in the United States."

Traditional Health Indicators in Perspective

Much past analysis of the subject of access has focused on counting doctors (with suggested remedies concentrating on increasing the supply of physicians) and has emphasized mortality and morbidity statistics.

But the first approach is akin to analyzing the energy shortage only by counting corner gas stations. And the latter falls short because traditional mortality and morbidity statistics fail to reflect adequately much that the health system does.

A health care system provides useful outcomes other than prevention and cure—reassurance and encouragement, for example. As Walsh McDermott puts it: "Medicine is . . . not a science but a learned profession that attempts to blend affairs of the spirit and the cold objectivity of science. Everything the physician does, therefore, is a blend of technology and samaritanism. By samaritanism is meant that collection of acts, big and little, that lends reassurance or at least gives support to someone troubled by disease or illness."[3]

To illustrate, the clinical capability of pinning broken hips among the injured elderly has not changed the nation's gross mortality statistics, but it has increased the utilization of medical services and it contributes substantially to improving the quality of these patients' lives.

Similarly, take the case of a woman visiting a physician because of a lump in her breast. A diagnosis which reveals the lump is benign does not show up in morbidity statistics, but that diagnosis represents a major benefit to the patient.

It is statistical intangibles such as these—

Publication of the final report is expected late in 1978. For details about the survey, how it was carried out, many of its statistical aspects, and a bibliography, see Technical Specifications on page 15.

2. **Lippman, Walter.** *Public Opinion.* New York: The Free Press (paperback edition), 1965. p. 239.

3. **From: McDermott, Walsh.** "Medicine: The Public's Good and One's Own." *Cornell University Medical College Alumni Quarterly.* 40 (1) Winter 1977. pp. 15-24. McDermott is Emeritus Professor of Public Health and Medicine at Cornell and special advisor to the president, The Robert Wood Johnson Foundation.

quality of life, samaritanism, and reassurance—that separate mortality and morbidity statistics from the real world.

The Study:
Who Gets What Care

The national survey investigates five principal dimensions impinging on access to care: *source* of care, *convenience* of care, actual *utilization* of care, the *need* for care, and the patient's *satisfaction* with care received. It examines all in considerable detail.

In the 1976 survey year, 76 percent of the population—160,000,000—saw a doctor. The percentage of infants and small children seeing a physician was highest: 87 percent. The percentage declines sharply in the middle and late years of childhood, then climbs slowly through the adult years to a level of 79 percent for those 65 or older.

The report's most significant findings show that the population at large—and every subpopulation group studied—has better access to medical services today than in 1970 or 1963.

There are some instances of dramatic change. Chart 1 shows the improvement experienced by blacks since 1963 in one important measure: percentage seeing a physician at least once in the previous year. And Chart 2 shows how the gaps between persons of different income levels have narrowed, though discrepancies continue.

"These trends," says Andersen, "correspond to those which might be expected as a result of the implementation of Medicaid and Medicare in 1966. Medicaid and most health center programs begun since 1963 were designed to serve the low income population of all ages."

The removal of financial barriers appears to have major impact on whether or not various groups have access to care. Whereas physician utilization by low and medium income groups has moved closer to that for the upper income group (Chart 2), the same narrowing of utilization has not occurred for dentist visits (Chart 3). Andersen concludes: ". . . dental services are least apt to be covered by existing financing mechanisms and it is this service for which the greatest inequities in use by family income and race . . . continue to persist."

The study places special emphasis on whether or not persons surveyed indicated they had a regular physician or regular source of care. Previous studies have shown a strong correlation between having a physician and seeking medical service when illness occurs. More than 78 percent of the population claim to have a physician they see regularly; another 9 plus percent report a regular source of care (e.g., a clinic), but without identifying a particular physician.

That leaves almost 12 percent who have neither a physician nor a regular source of care. Andersen speaks frankly of this group: "Though this may appear to represent a small proportion overall, it means that there are actually an estimated 24 million people who can identify no particular place or provider as their regular point of entry to the health care system."

The survey data reveal that low income groups, urban blacks and Spanish heritage persons in the Southwest were less apt than whites to have their own doctor. And for all races, persons below the poverty level were less likely to have a regular source of care than those above.

Other findings include:

- 11 percent of the population spent at least one day in the hospital in the survey year
- 52 percent had a physical exam
- 49 percent saw a dentist
- rural farm dwellers were less likely than city residents to see a physician
- low income Spanish heritage persons were least likely of all ethnic groups to see a physician
- most persons can reach their regular source of care within 30 minutes
- blacks, when in their doctor's office, wait longer to see a physician than whites
- city residents use specialists more frequently than other groups
- rural residents and farmers make greatest use of general/family practitioners
- 64 percent of the population can obtain a doctor's appointment within two days; 8 per cent have to wait more than 2 weeks.

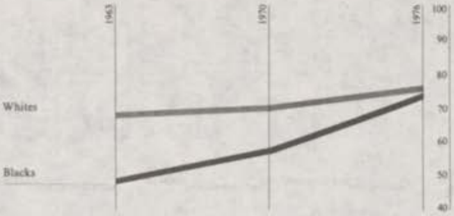
Moving Toward A Measure
of Medical Need

Although the survey's findings clarify the picture of access to health care for different population groups, a central and intriguing question remains: are people really getting the medical care they need?

One of Andersen's colleagues, study direc-

Chart 1

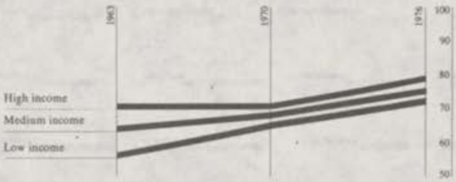
Percentage of Whites and Blacks Seeing a Physician in a 12-Month Period



The percentage of the black population seeing a physician has increased substantially since 1963. While a small gap in physician utilization remains between blacks and whites, it has closed dramatically since 1970. The Chicago researchers report that the largest gains were made in areas of the central city.

Chart 2

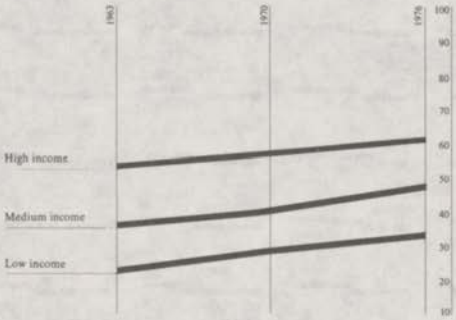
Percentage of High, Medium, and Low Income Groups Seeing a Physician in a 12-Month Period



A comparison by income shows how low income groups have increased their use of physician services. Between 1963 and 1970, both low and middle income groups moved toward the high income group. During the next period, all three groups moved upward together in utilization.

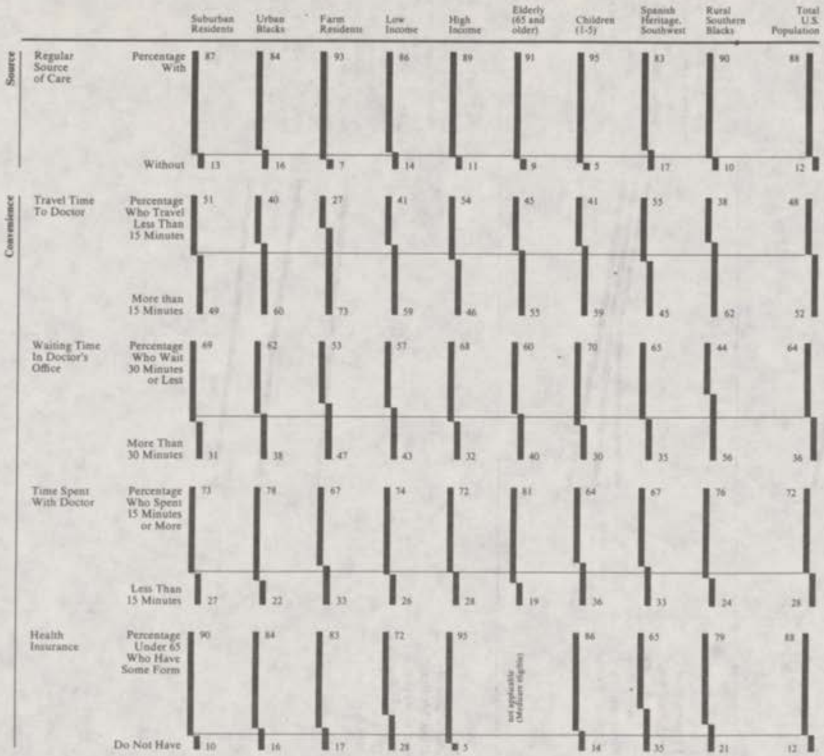
Chart 3

Percentage of High, Medium, and Low Income Groups Seeing a Dentist in a 12-Month Period



The impact of insurance is revealed in this chart showing the percentage of the population seeing a dentist. For all income levels, the utilization of dentists is lower than for physicians. And the gaps between high, medium, and low income groups in 1976 are not significantly different from 1963. One reason: 88 per cent of the population have some form of medical insurance; only 18 per cent have dental insurance.

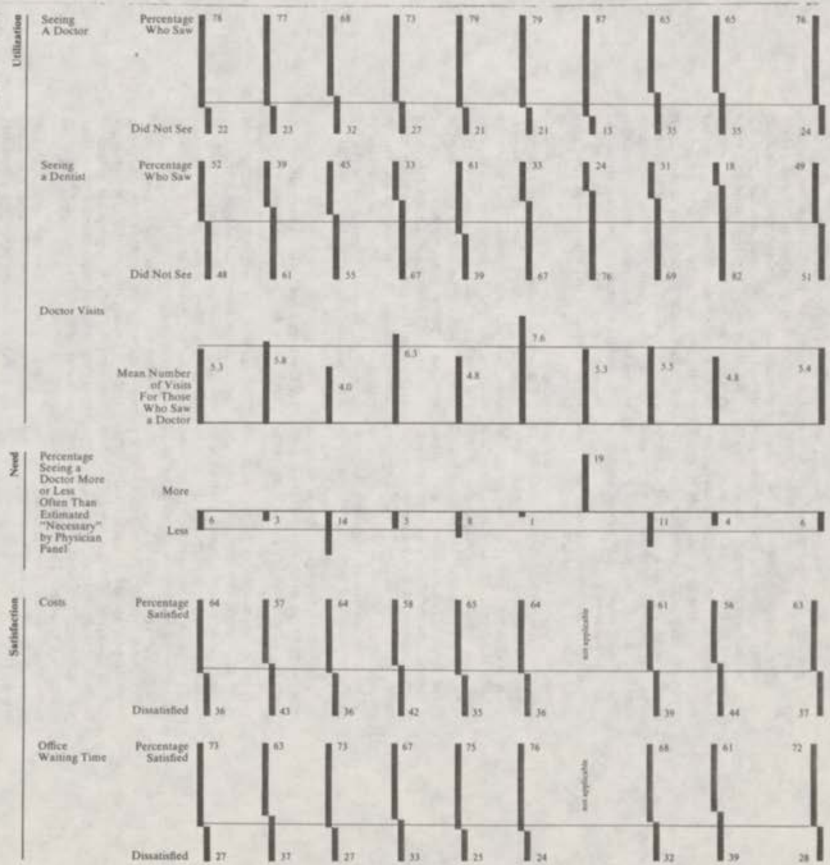
Leading Indicators of Access to Medical Care—A Panoramic View



The conceptual framework developed by the authors emphasizes five principal dimensions which determine access:

- *Source: do people have a regular source of medical care?*
- *Convenience: what are the problems in obtaining care?*
- *Utilization: what services were actually used?*
- *Need: did people get the medical care they needed?*
- *Satisfaction: was the patient pleased with the experience?*

Despite the temptation to seize upon only one or two dramatic indicators, Andersen and his colleagues stress a multi-dimensional approach. "In examining access," he says, "it is necessary to take into account all relevant factors. If a policy maker were to focus on a single indicator of access, a misleading conclusion could be reached about a particular group. That would be unwarranted—and unwise." In the accompanying chart, selected indicators from the Chicago survey are arranged in a matrix format to permit comparisons among various population groups across a range of factors. An expanded version of this chart is available from the Center for Health Administration Studies, University of Chicago, 5720 Woodlawn Avenue, Chicago, Illinois 60637.


Utilization
Seeing A Doctor
Percentage Who Saw
78 77 68 73 79 79 87 65 65 76
Did Not See
22 23 32 27 21 21 13 35 35 24
Seeing a Dentist
Percentage Who Saw
52 39 45 33 61 33 24 31 18 49
Did Not See
48 61 55 67 39 67 76 69 82 51
Doctor Visits
Mean Number of Visits For Those Who Saw a Doctor
5.3 5.8 4.0 6.3 4.8 7.6 5.3 5.5 4.8 5.4
Need
Percentage Seeing a Doctor More or Less Often Than Estimated "Necessary" by Physician Panel
More
19
Less
6 3 14 5 8 1 11 4 6
Satisfaction
Costs
Percentage Satisfied
64 57 64 58 65 64 61 56 63
Dissatisfied
36 43 36 42 35 36 39 44 37
not applicable
Office Waiting Time
Percentage Satisfied
73 63 73 67 75 76 68 61 72
Dissatisfied
27 37 27 33 25 24 32 39 28
not applicable

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tor Lu Ann Aday, puts it this way: "Is the level of access to the system medically appropriate or not?"

To probe this important area, the Chicago researchers have taken their methodology a step beyond some methods already in widespread use and have pursued a new experimental approach which utilizes what is called the symptoms-response ratio. This approach, they say, "reflects the difference between the number of people with a given mix of symptoms who contact a physician at least once for the symptoms and the number that a panel of medical professionals say should contact a doctor for the symptoms."

To develop this measure, the research team asked a panel of medical school physicians to determine for a variety of symptoms an appropriate level of medical care that could be considered standard. They did it this way. Each doctor participating in the panel was asked "to estimate, based on his training and experience, how many people out of 100 manifesting a certain symptom should see a doctor for it." For example, frequent headaches are considered to be a symptom requiring the attention of a physician in nearly all cases for young children, less frequently among adults.

The study group then compared this standard with the actual experiences reported by the total population and specific sub-sets of the population. The result: based on 1976 data, virtually all groups saw doctors more often than the panel of doctors estimated should be the case.

To refine the technique further, a second group of doctors was impaneled consisting this time of community-based, primary care physicians from throughout the nation ". . . since a non-academic group was thought to be more representative overall of U.S. primary care physicians."[4]

This panel provided the criteria necessary to develop a second symptom index. The doctors analyzed 22 symptoms, including headaches, rash, diarrhea, heart pain, weight loss, and "tired mornings," and, as before, estimated a standard. The community-based panel of physicians recommended that patients see physicians more frequently than the original panel.

Armed with this second index, the research team compared it once again with the actual experiences reported by the population and several sub-groups. By this measure, the total population sees physicians 6 percent less frequently than recommended. (Results of the second panel are incorporated in the chart showing leading indicators of access, pp. 8-9.)[5]

Andersen is the first to caution that these data must be interpreted with care, so as to avoid incorrect conclusions. He points out that the physician panels provided judgments only at a general level, not at an individual, patient-specific level. Further, the experiment covers only a segment of an individual's overall medical care needs. Patients undoubtedly visit their doctors at times simply for the reassurance provided. Andersen believes that a special value of this index lies in being able to compare use to need for various population categories.

This phase of the study—still in its early stages of development and refinement—is important and has already proved to be controversial. But Andersen strongly believes that the study of access demands a way to measure need and he and his team intend to continue to pursue this approach.

If, in fact, differences do exist between what patients do and what some doctors think they should do, it perhaps should not be considered surprising. Medicine is an inexact science and wide variations exist in the beliefs, opinions, and perceptions of doctors, as well as patients.

Are People Satisfied? What Americans Think About the Care They Obtain

Whether or not people are satisfied with their medical care, the Chicago researchers believe, is an important dimension of access and one part of the survey measures satisfaction: how patients feel about their encounters with the system.

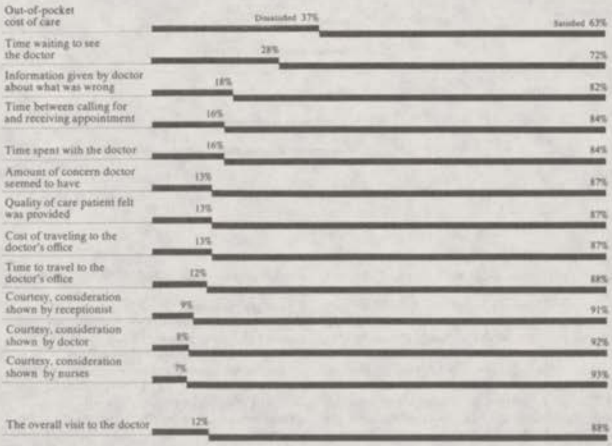
Studies on consumer satisfaction in many areas, including health, have been increasing in recent years. Critics of this approach argue that patients are not appropriate judges of their health experiences because they lack sufficient technical knowledge to make an informed judgment.

The study team does not agree with that contention. Gretchen Fleming, assistant study director, notes: "Querying consumers derives from the very notions on which democracy itself is defended—that it is appropriate for the public to be invited and even

4. **The primary care physician panel** consisted of 36 physicians from the following specialities: internal medicine, 18; family/general practice, 10; and pediatrics, 8. Physicians from ob-gyn are to be included in future work on this measure. The original panel of physicians included 40 University of Chicago medical faculty from these specialities: internal medicine, 13; surgery, 9; pediatrics, 7; obstetrics-gynecology, 6; psychiatry, 5.

5. **Among population sub-groups analyzed** thus far, children represent an exception: their utilization pattern is 19 percent above the panel's estimate of need. This finding is for the total population of children, and its interpretation will have to await further data analysis for groups of children described by family income levels and other potentially significant characteristics.

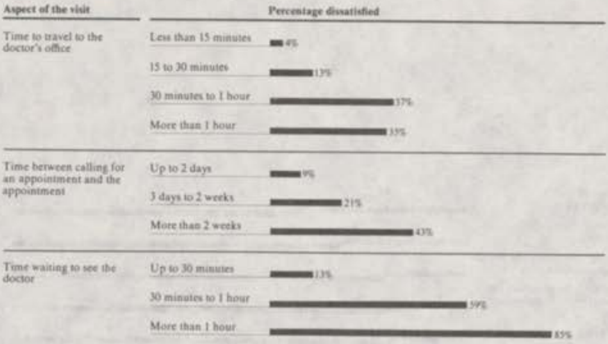
Chart 4 **Among Those Who Saw a Physician in a 12-Month Period, Percentage Dissatisfied/Satisfied with Various Aspects of the Visit**



To determine whether people are satisfied or dissatisfied with their medical care, the research group asked questions of all persons who had visited a doctor during the past year. The questions probed impressions of specific aspects of the visit. "Responses were very skewed toward the positive end of the scale," the group reports. For the total population, cost is the greatest cause of dissatisfaction. Overall, the chart reveals the U.S. population is generally satisfied.

Chart 5

Among Those Who Saw a Physician in a 12-Month Period, Percentage Dissatisfied with Various Aspects of the Visit Classified by the Nature of the Experience



While people generally express satisfaction with most aspects of their medical experiences, there comes a time for most when they cross a threshold of tolerance. At that point, satisfaction turns to dissatisfaction. Each variable—travel time, cost, amount of time spent with the doctor, appointment waiting time—has its special threshold. This chart matches a range of experiences with a set of variables and shows levels of dissatisfaction. Overall, it captures some sense of the dynamics of the doctor-patient relationship.

urged to voice judgments, and that such opinions should be taken seriously. Should consumers' views appear ill-informed to policy makers or those who possess more technical information on the subject, it is their (the policy makers) prerogative in turn to try to convince the consumers otherwise by making further information available to them."

The study probes in some depth whether patients are satisfied or dissatisfied with the care they receive. Chart 4 summarizes how the U.S. population feels about various aspects of its most recent doctor visit.

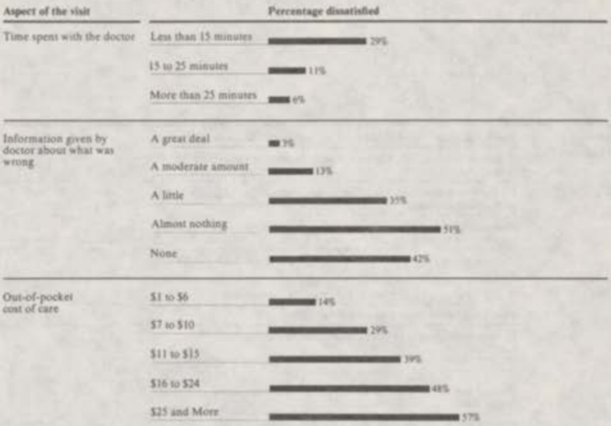
Time spent waiting to see a doctor and the amount of information given to the patient by the doctor are major areas of dissatisfaction. But no factor rivals cost as a cause of dissatisfaction.[6]

As with all aspects of the study, each factor has been analyzed by income, age, race, region, sex and other variables, and the following generalizations can be made:

- satisfaction with care received increases with age
- persons in the South are least satisfied
- persons with higher income and more education are the most satisfied
- blacks are less satisfied than whites
- persons who see their own doctor regularly are more satisfied than persons who see different doctors in a series of visits
- rural blacks in the South are least satisfied of all groups
- people of Spanish origin in the Southwest are less satisfied than other whites.

The study team has carried its analysis of satisfaction and dissatisfaction an important step further. Chart 5 illustrates how they analyze different variables. The chart shows a range of actual experiences reported by patients, together with the percentage of patients who are dissatisfied with various aspects of that experience. For example, dissatisfaction with the amount of time it takes to get to the

6. **Cost and utilization both are being probed** in a new study being conducted by the federal government's National Center for Health Statistics (NCHS) which carries out extensive research on many aspects of the nation's health system. The study, which is collecting 1977 data from a national sample of 11,500 households, is being jointly conducted with the National Center for Health Services Research.



doctor's office ranges from a low percentage of 4 percent for those who required less than 15 minutes to a high of 37 percent dissatisfied if the trip took over 30 minutes.

"It is very clear that the kinds of events that surround delivery of care strongly affect people's levels of satisfaction," the study team concludes. "Consumers in general are not inclined to be highly critical of their medical care."

The Paradox of Personal Satisfaction and Perceived Crisis

But then comes a paradox. Despite the survey data which show, generally, a high level of satisfaction, as well as increased access to the health system for Americans of all ages and races, the study also shows that 61 percent of the population—125,000,000 people—believe there is a crisis in health care in the U.S. And another 26 percent are so uncertain they cannot deny it.[7]

Why this paradox exists is a mystery still to be probed—not only by the Chicago team, but by other investigators as well.

It could be a product of the human propensity to seek reassurance and support when in need. When people contemplate their own medical care (i.e., "Were you satisfied with what your doctor did for you?"), the response is from the perspective of a patient—each individual is then a statistic of only one and answers are shaped accordingly.

It is quite another matter to respond to questions about health in the abstract, simply as a part of the aggregate (i.e., "Is there a crisis in health care?").

In spite of these mixed perceptions about what goes on in America's health care system, the national survey of access to medical care provides important new insight into the how and why of the system and is a study of importance likely to be analyzed for years.

7. **The issue of a crisis in health care** was measured in the 1970 survey as well and has been quoted at 76 per cent. However, the test question was altered slightly in the 1976 survey, so direct comparison is impossible.

Health Opinions of the U.S. Population[8]

Some things people say about health care, doctors, and hospitals.		Agree	Uncertain	Disagree
	There is a crisis in health care today in the United States.	61%	26%	13%
	A person understands his own health better than most doctors do.	29%	15%	56%
	If I have a medical question, I can reach someone for help without any problem.	70%	13%	17%
	Without proof that you can pay, it's almost impossible to get admitted to the hospital.	56%	25%	19%
	Doctors always do their best to keep the patient from worrying.	60%	24%	16%
	In an emergency, it's very hard to get medical care quickly.	38%	15%	47%
	More hospitals are needed in this area.	39%	26%	35%
	Sometimes doctors take unnecessary risks in treating their patients.	22%	41%	36%
	Doctors always treat their patients with respect.	67%	16%	17%
	Medical insurance coverage should pay for more expenses than it does.	63%	24%	13%
	Doctors cause people to worry a lot because they don't explain medical problems to patients.	40%	20%	40%
	Most people receive medical care that could be better.	48%	35%	17%
	Doctors ask what foods patients eat and explain why certain foods are best.	40%	26%	34%
	If more than one family member needs medical care, we have to go to different doctors.	35%	11%	54%
	There is a big shortage of family doctors around here.	51%	26%	23%

Opinions about nurse practitioners and physician's assistants doing some of the tasks traditionally performed by doctors.		Yes	No	Uncertain
	Do the preliminaries of a medical examination before the doctor comes in, including medical history taking, blood pressure, and so on?	84%	10%	6%
	Decide whether or not you need a doctor when you go to a clinic or a doctor's office when you are not feeling well?	31%	58%	11%
	Provide follow-up care and treatment after a physician has diagnosed your condition and prescribed treatment?	58%	31%	11%
	See pregnant women and babies on their regular visits when nothing seems to be wrong?	46%	36%	18%

8. **A Health Opinions questionnaire** was an integral part of the national survey. Emphasizing to the respondents that there were no "right" or "wrong" answers, it probed their views on a wide variety of health and personal issues. Much of the data collected in the national survey have been incorporated into various indices and scales, but in this particular section the raw responses themselves reveal interesting information about what the U.S. population thinks about health in the broadest sense. Some examples are presented here. All percentages have been rounded to equal 100 percent across each item.

Technical Specifications

The 1976 survey is the fifth in a series of national household surveys of health care utilization and expenditures conducted by the Center for Health Administration Studies. The previous four—1953, 1958, 1963, and 1970—emphasized estimates of families' total health care experiences and costs. The 1976 survey focuses on access issues. While the emphasis of the 1976 survey differs from earlier ones, some questions were designed for comparability.

The Study: Between September 1975 and February 1976 interviews were conducted with 7,787 persons in 5,432 households representing the non-institutionalized population of the United States (among the exclusions: groups in prisons, long term care institutions, religious institutions, military installations). The sample was representative of a population estimated at 209,065,000. All population calculations in this report are computed on this base. Overall response rate was 85 percent.

Oversampling: There was supplementary sampling of persons experiencing episodes of illness, non-SMSA (Standard Metropolitan Statistical Areas) Southern blacks, and Spanish heritage persons living in the Southwest. Oversampling was done to insure that a sufficient number of cases would be available for analysis. All computations are weighted distributions to correct for the oversampling and to allow estimates to be made for the total non-institutionalized U.S. population.

Regions: Standard U.S. Bureau of the Census regions were used in the study: Northeast, South, North Central, West.

Blacks: Because of the particular variable definitions employed, the category of *blacks* includes a small proportion of other non-white persons.

Urban Blacks: The *urban black* category includes a small proportion of non-urban residents.

Rural Southern Blacks: This category is defined as blacks who reside in areas outside SMSA's in the states of Arkansas, Alabama, Delaware, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North and South Carolina, Oklahoma, Tennessee, Texas, Virginia, West Virginia and the District of Columbia.

Spanish Heritage, Southwest: This category includes persons who had Spanish surnames, or who were from families in which the head or spouse spoke Spanish as a child. The sample was drawn from Arizona, California, Colorado, New Mexico, and Texas.

Suburban Residents: This category includes persons living in SMSA's, but not in the central city.

Income: Family income levels used in the 1976 study are as follows: Low (below $7,999 annual income), Medium ($8,000-$14,999), High ($15,000 and above). Income categories in the three studies—1963, 1970, and 1976—were different to reflect differences in inflation for the respective time periods. For all studies, approximately one-third of all families fell into each of the income categories.
Determination of poverty level cutoffs conforms to a Social Security Administration index.

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U. S. Health Resources Administration. *Health of the Disadvantaged (Chartbook)*. Hyattsville, MD, 1977. DHEW Publication No. (HRA) 77-628

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Senator KENNEDY. Thank you. Initially, you had health services research in your department, did you not?

Dr. LEE. When I was Assistant Secretary, we established the National Center for Health Services Research, and we established that within the Health Services and Mental Health Administration—at that time thinking it was important to insulate it from the day-to-day demands of policy. But it proved to be too disconnected from policy in the first 5 to 6 years.

Now that Dr. Rosenthal is the Director, he has moved it very much into a much more policy oriented, but still strong research base, which we very much need.

Senator KENNEDY. Isn't that an additional reason to spin this off into the kind of organizational structure that we have outlined here——

Dr. LEE. I think so, absolutely.

Senator KENNEDY [continuing]. Based on your own experience?

Dr. LEE. The years of experience we have had first of all in the Health Services and Mental Health Administration, and then in the Health Resources Administration convinces me it should be done. In the past the Center did not get the support it needed in HRA. The people in the Administrator's Office did not give the positions needed, and they did not support the appropriations requests. In the kind of a setting we have proposed, the center will be out there where it can be viewed on its own merits in relation to other health services research priorities.

Senator KENNEDY. OK.

Dr. Remington?

Dr. REMINGTON. Thank you, Senator Kennedy.

I have a brief statement that I would like to make in opening. It has been my privilege to serve as a consultant to most of the individual institutes of the National Institutes of Health, to the U.S. Veterans' Administration, to the National Center for Health Services Research and the National Center for Health Statistics.

I am presently chairman of the council on epidemiology of the American Heart Association, and as you noted in your introduction, immediate past president of the Association of Schools of Public Health.

Today, as a member of its executive committee, I represent the latter association and will venture, I guess, to speak for them—an organization composed of the 19 accredited U.S. schools of public health.

These schoals are located within some of our country's leading public and private universities, and each school has a major interest in the National Institutes of Health Care Research Act of 1978.

This act is in the best interest of the Nation's health, and it is a privilege for me to endorse it with appropriate modifications as outlined later in the statement and to urge, after due deliberation, its enactment into law.

The present system for providing personal and public health services to the American people is seriously fragmented. Unfortunately, that fragmentation, I think, extends to the Federal health bureaucracy and interferes with optimal allocation of scarce resources toward discovery of solutions to problems of health promotion and disease prevention and treatment.

The present legislation would bring together several of these fragments to form a better coordinated and more productive unit, the National Institutes of Health Care Research.

The proposal to create a National Center for the Evaluation of Medical Technology is an idea whose time has surely come. My own research has been mainly devoted to statistical and epidemiological evaluation of drugs, surgical procedures, medical devices, and preventive strategies, utilizing randomized controlled clinical trials, comparative studies, follow-up investigations, and surveys.

There is presently no unit of the Federal Government devoted primarily to the total evaluation of new modalities for the prevention and treatment of disease. The Food and Drug Administration has major regulatory responsibility for new drugs prior to marketing, but until now has shown little systematic interest—here, the operative word is "systematic," I think—in agents after their release for general use.

Senator KENNEDY. Let me ask, What is your view—and then maybe Dr. Lee would comment on this—Should we have a more forceful regulatory process, in terms of medical practices, like FDA does with drugs?

Dr. REMINGTON. I think that makes good sense. In the drug field itself, we seem to lose interest in drugs once they have come on the market. And I know that you have held hearings on this matter several times in the past.

I think there needs to be a much more systematic evaluation of drugs that have been around a while, some of which have effects that are not visible in the first three phases of testing.

Senator KENNEDY. We are moving on that very closely with the administration. I am just wondering in terms of the totality of procedures, though, if we should not get sort of a measure of inputs and outputs, just in terms of information, perhaps as a starter—maybe later it gets into something else—just in the area of technology, obviously, and try to do health evaluations and other factors.

I do not know what sense either of you have about the importance of that process.

Dr. REMINGTON. We might take surgical intervention as an example. At present, there really is no system for applying the clinical trial methodology to surgical intervention that we have had in the pharmacologic intervention field for some time. And I think that is an oversight. These are important interventive strategies, and I think they really need to be systematically evaluated.

Dr. LEE. I think in the drug area that the phase 4 notion of testing, where the drug is used in a fairly large population group, but with careful surveillance and a limited number of physicians and pharmacists and involved in the prescribing and dispensing is a good idea. It would be difficult, when drugs are approved for more general use, to further restrict their use. I have been an advocate, as you probably know, for years of restricting chloramphenocol to hospital-based physicians.

We know that in hospitals, we can and we do restrict the use of drugs. I think we should have much more careful restriction of particularly antibiotics within the hospital. And I think that is the setting in which that can be accomplished.

I am not sure that the best way to accomplish this is with Federal regulation. I think we can do a much better job, and I think the FDA should be involved much more aggressively in education. I think we need things like a compendium of drugs for physicians. The FDA drug bulletin could be used much more effectively——

Senator KENNEDY. I suppose if you knew the amounts that were being used——

Dr. REMINGTON. We wish we knew.

Senator KENNEDY [continuing]. And the procedures and the outputs, without getting into saying who is going to do what to whom—but just in terms of information, I think you clearly have to start off with that in mind on it. But it seems to me we have not got those measuring devices at the present time. We do not have that kind of information that is generally available.

Dr. LEE. It is interesting to note that the Center for Health Services Research is supporting a project at Stanford to develop a hospital-based drug information system. Once that system is well developed, we will have a methodology that can be applied very widely in hospitals to have a surveillance on prescribing, and it could have I think a significant impact, for example, on drug—drug interactions and the prevention of adverse drug reactions in that area alone. In addition, such a system could make sure that if an unauthorized drug was prescribed that an automatic consultation could take place.

We absolutely have to have the information systems. Without that, we really could not do the job.

Senator KENNEDY. Let me ask Dr. Remington, what about an Institute on Prevention? Where do you come out on that? Should we be adding that?

Dr. REMINGTON. Well, in my statement, I rather strongly recommend that as one of the possibilities. Frankly, the area that I find to criticize in the legislation, and it takes some hard looking, because I do favor the legislation as you have proposed it, is in that area of prevention.

I see a National Institute for Prevention as an important addition to the National Institutes for Health Care Research.

I have also proposed, changing the title of the Institutes, to broaden it somewhat.

Senator KENNEDY. What about NIH for such an institute; what are your thoughts about that?

Dr. REMINGTON. Well, that would be interesting. I would fear myself, within the NIH umbrella, that if prevention is isolated as a separate institute, it would be a place to put activities that really are not all that important.

It would be in an identifiable location, and the rest of the Institutes can get on about the "really important" business of stomping out disease at the individual patient level by direct intervention.

Now, that is a rather cynical point of view. I do not mean to be accusatory in this. I think NIH is a marvelous organization with important activities within each of the institutes.

I would worry that if an Institute for Prevention is formed, for example, the very excellent Epidemiologic Unit within the National Heart, Lung, and Blood Institute might be pulled away and removed from the focus on cardiovascular disease that I think is appropriate.

I think it is a delicate balance, but I would favor bringing prevention into an aggregate of the sort you have proposed in the new National Institutes structure.

Senator KENNEDY. What about the environmental health sciences? Currently, NIH does most of the work in this area. Should this be over in the National Institutes of Health Care Research?

Dr. REMINGTON. It is certainly appropriate that an emphasis on environmental science would belong in an institute devoted to public health research; there is no question about that.

On the other hand, there are important environmental health-related research thrusts now in NIOSH, in the National Institute of Environmental Health Sciences, and in EPA. And it seems to me that should be the subject of another reorganization discussion.

I get confused when I look at the Federal environmental health research structure. It is difficult to know which agency has what responsibility.

[The prepared statement of Dr. Remington follows:]

TESTIMONY OF RICHARD D. REMINGTON, PH.D., DEAN,
UNIVERSITY OF MICHIGAN SCHOOL OF PUBLIC HEALTH
BEFORE U.S. SENATE SUBCOMMITTEE ON HEALTH
AND SCIENTIFIC RESEARCH
FEBRUARY 7, 1978

MR. CHAIRMAN, MEMBERS OF THE COMMITTEE. I AM RICHARD D. REMINGTON, DEAN OF THE UNIVERSITY OF MICHIGAN SCHOOL OF PUBLIC HEALTH. IT HAS BEEN MY PRIVILEGE TO SERVE AS CONSULTANT TO MOST OF THE INDIVIDUAL INSTITUTES OF THE NATIONAL INSTITUTES OF HEALTH, THE U.S. VETERANS ADMINISTRATION, THE NATIONAL CENTER FOR HEALTH SERVICES RESEARCH, AND THE NATIONAL CENTER FOR HEALTH STATISTICS. I AM PRESENTLY CHAIRMAN OF THE COUNCIL ON EPIDEMIOLOGY OF THE AMERICAN HEART ASSOCIATION AND IMMEDIATE PAST PRESIDENT OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH. TODAY, AS A MEMBER OF ITS EXECUTIVE COMMITTEE, I REPRESENT THE LATTER ASSOCIATION, AN ORGANIZATION COMPOSED OF THE NINETEEN ACCREDITED U.S. SCHOOLS OF PUBLIC HEALTH. THESE SCHOOLS ARE LOCATED WITHIN SOME OF OUR COUNTRY'S LEADING PUBLIC AND PRIVATE UNIVERSITIES, AND EACH SCHOOL HAS A MAJOR INTEREST IN THE NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978.

THIS ACT IS IN THE BEST INTEREST OF THE NATION'S HEALTH, AND IT IS A PRIVILEGE TO ENDORSE IT WITH APPROPRIATE MODIFICATIONS AS OUTLINED LATER IN THIS STATEMENT AND TO URGE, AFTER DUE DELIBERATION, ITS ENACTMENT INTO LAW. THE PRESENT SYSTEM FOR PROVIDING PERSONAL AND PUBLIC HEALTH SERVICES TO THE AMERICAN PEOPLE IS SERIOUSLY FRAGMENTED. UNFORTUNATELY, THAT FRAGMENTATION EXTENDS TO THE FEDERAL HEALTH BUREAUCRACY AND INTERFERES WITH OPTIMAL ALLOCATION OF SCARCE NATIONAL RESOURCES TOWARD DISCOVERY OF SOLUTIONS TO PROBLEMS OF HEALTH PROMOTION AND DISEASE PREVENTION AND TREATMENT. THE PRESENT LEGISLATION WOULD BRING TOGETHER

SEVERAL OF THESE FRAGMENTS TO FORM A BETTER COORDINATED AND MORE PRODUCTIVE UNIT, THE NATIONAL INSTITUTES OF HEALTH CARE RESEARCH.

THE PROPOSAL TO CREATE A NATIONAL CENTER FOR THE EVALUATION OF MEDICAL TECHNOLOGY IS AN IDEA WHOSE TIME HAS SURELY COME. MY OWN RESEARCH HAS BEEN MAINLY DEVOTED TO STATISTICAL AND EPIDEMIOLOGICAL EVALUATION OF DRUGS, SURGICAL PROCEDURES, MEDICAL DEVICES, AND PREVENTIVE STRATEGIES, UTILIZING RANDOMIZED CONTROLLED CLINICAL TRIALS, COMPARATIVE STUDIES, FOLLOW-UP INVESTIGATIONS, AND SURVEYS. THERE IS PRESENTLY NO UNIT OF THE FEDERAL GOVERNMENT DEVOTED PRIMARILY TO THE TOTAL EVALUATION OF NEW MODALITIES FOR THE PREVENTION AND TREATMENT OF DISEASE. THE FOOD AND DRUG ADMINISTRATION HAS MAJOR REGULATORY RESPONSIBILITY FOR NEW DRUGS PRIOR TO MARKETING, BUT UNTIL NOW HAS SHOWN LITTLE SYSTEMATIC INTEREST IN AGENTS AFTER THEIR RELEASE FOR GENERAL USE. FURTHERMORE, EVALUATION OF SURGICAL PROCEDURES, PREVENTIVE STRATEGIES, AND COST-EFFECTIVENESS OF NEW TREATMENTS ARE NOT ADDRESSED IN AN ORGANIZED MANNER BY ANY AGENCY. THE PROPOSED CENTER IS URGENTLY NEEDED. WHILE IT IS NOT INTENDED TO REPLACE THE IMPORTANT WORK OF FDA, NIH, CDC, AND OTHER AGENCIES ENGAGED IN THE ASSESSMENT OF MEDICAL TECHNOLOGY, THE CENTER WILL PLAY A KEY ROLE IN COORDINATING, EVALUATING AND SETTING PRIORITIES FOR THE FULL RANGE OF PREVENTIVE AND THERAPEUTIC INTERVENTIONS.

THE NATIONAL CENTER FOR HEALTH STATISTICS IS AN EXCELLENT AGENCY CHARGED WITH THE RESPONSIBILITY OF KEEPING TRACK OF BIRTHS, DEATHS, MARRIAGES, DIVORCES, AND CASES OF ILLNESS. IN ADDITION, IT COORDINATES HEALTH STATISTICS COLLECTION AND ANALYSIS AT THE FEDERAL, STATE AND LOCAL LEVELS.

YET OUR INABILITY TO TRACE PATTERNS OF HEALTH AND DISEASE THROUGH THE POPULATION IS A NATIONAL SCANDAL. STRONG WORDS WHICH SURELY REQUIRE SOME DEFENSE. THE NATIONAL HEART LUNG AND BLOOD INSTITUTE AND THE AMERICAN HEART ASSOCIATION ARE THIS WEEK SIMULTANEOUSLY CELEBRATING THEIR THIRTIETH ANNIVERSARIES. THERE IS A REAL REASON TO CELEBRATE. MORTALITY DATA FROM NCHS SHOW A RECENT SUBSTANTIAL DOWNTURN IN TOTAL CARDIOVASCULAR DISEASE MORTALITY, IN CORONARY HEART DISEASE MORTALITY AND, BECAUSE HEART DISEASE IS OUR LEADING CAUSE OF DEATH, IN ALL CAUSE MORTALITY. ALL OF US ARE INTERESTED IN EXPLAINING AND UNDERSTANDING THIS DECLINE. IS THE REDUCTION IN DEATHS FROM CORONARY HEART DISEASE DUE TO A DECREASE IN NEW CASES OF DISEASE, OR IS IT DUE TO IMPROVED SURVIVAL OF EXISTING CASES? WE DON'T KNOW, AND OUR HEALTH STATISTICS SYSTEM CAN'T TELL US. IN SUMMARY, OUR MORBIDITY MEASUREMENT SYSTEMS ARE PITIFULLY INADEQUATE IN SCALE AND SCOPE. I HOPE AND BELIEVE THAT BY IMPROVING THE LEVEL OF FUNDING FOR THE NATIONAL CENTER FOR HEALTH STATISTICS AND BY ADDING A MAJOR EMPHASIS ON EPIDEMIOLOGY THE PROPOSED LEGISLATION WILL CONSTITUTE AN IMPORTANT FIRST STEP TOWARD IMPROVING THIS SORRY SITUATION.

THE NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH, REPLACING THE CURRENT NATIONAL CENTER FOR HEALTH SERVICES RESEARCH HAS SEVERAL IMPORTANT FEATURES. ITS NAME SEEMS TO IMPLY THAT THERE SHOULD BE A NATIONAL HEALTH POLICY AND THAT THIS POLICY SHOULD BE BASED ON RESEARCH. THE INSTITUTE STRUCTURE IMPLIES RELATIVE PERMANENCE, TAKING APPROPRIATE ACCOUNT OF THE FACT THAT, CONTRARY TO OPINIONS EXPRESSED ONLY A FEW YEARS AGO, QUICK, CHEAP, AND SUPERFICIAL INTERVENTIONS WILL NOT BE ADEQUATE TO TREAT OUR

PRESENT AILING SYSTEM OF ORGANIZING, FINANCING, AND DELIVERING PERSONAL HEALTH SERVICES. EXTENSIVE RESEARCH IS NEEDED. WE ARE A COMPLEX, PLURALISTIC SOCIETY, AND WHEN OUR HEALTH SERVICE SYSTEM IS STIMULATED, IT OFTEN RESPONDS IN UNFORESEEN AND UNFORESEEABLE WAYS. THIS BILL ALSO RECOGNIZES THE NEED TO IMPROVE THE FLOW OF TRAINED HEALTH SERVICES RESEARCH WORKERS. INASMUCH AS OUR SCHOOLS OF PUBLIC HEALTH ARE A PRIMARY SOURCE OF SUCH WORKERS AND SCIENTISTS, WE PARTICULARLY APPLAUD THIS INITIATIVE.

FINALLY, A FEW RESERVATIONS ABOUT THE LEGISLATION AS PRESENTLY WRITTEN. THE BILL PLACES ITS MAJOR EMPHASIS ON TREATMENT OF DISEASE RATHER THAN ON PREVENTION. IT EMPHASIZES PERSONAL RATHER THAN PUBLIC OR COMMUNITY HEALTH SERVICES. I DO NOT ARGUE, MR. CHAIRMAN, THAT WE SHOULD DEEMPHASIZE IMPROVED UNDERSTANDING OF DISEASE TREATMENT OR DELIVERY OF PERSONAL HEALTH SERVICES. I DO ARGUE, HOWEVER, THAT THERE SHOULD BE SUBSTANTIALLY GREATER EMPHASIS ON PREVENTION.

THE HISTORY OF CONTROL OF MASS DISEASE SHOWS THAT PREVENTION HAS BEEN BOTH MORE EFFECTIVE AND LESS COSTLY THAN INDIVIDUAL MEDICAL TREATMENT. WHETHER WE ARE TALKING ABOUT IMMUNIZATION, SANITATION, BETTER HOUSING, CLEANER DRINKING WATER OR IMPROVED NUTRITION, THE RESULT IS THE SAME. THESE ARE THE METHODS THAT HAVE RESULTED IN REDUCED INFANT AND MATERNAL MORTALITY AND INCREASED LONGEVITY. THESE ARE THE METHODS THAT IMPROVE THE HEALTH OF THE PUBLIC. TO BRING THE MATTER UP TO THE MINUTE, STUDIES OF FACTORS MOST LIKELY RESPONSIBLE FOR THE RECENT REDUCTION OF HEART DISEASE MORTALITY CONVINCE ME THAT, ONCE AGAIN, PREVENTION HAS BEEN THE KEY. CHANGES IN CIGARETTE SMOKING PATTERNS, IN THE EXTENT OF PUBLIC PARTICIPATION IN HIGH BLOOD PRESSURE

DETECTION PROGRAMS AND IN DIETARY HABITS ARE PROBABLY RESPONSIBLE FOR THE MAJORITY OF THE REDUCTION. THIS IS NOT TO DENY THAT CORONARY CARE UNITS, CORONARY ARTERY BYPASS SURGERY AND OTHER TERTIARY CARE INTERVENTION MAY HAVE BEEN HELPFUL IN SOME CASES, BUT SUCH METHODS COULD HARDLY HAVE PLAYED A MAJOR ROLE IN THE MASS POPULATION IMPACT THAT HAS BEEN DUE, ALMOST CERTAINLY TO PUBLIC RATHER THAN INDIVIDUAL INTERVENTION.

I ARGUE ONLY FOR BALANCE. WE SPEND A POUND FOR CURE, BUT ONLY A FARTHING FOR PREVENTION. ON BEHALF OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH, I WOULD RECOMMEND THAT YOU FIND, MR. CHAIRMAN, MULTIPLE OPPORTUNITIES IN LEGISLATIVE LANGUAGE TO ADD AN EMPHASIS ON PREVENTION. POSSIBILITIES MIGHT INCLUDE ESTABLISHMENT OF A NATIONAL INSTITUTE OF PREVENTION, AND ON A DIFFERENT LEVEL A CHANGE IN THE TITLE OF THE PROPOSED NATIONAL INSTITUTES OF HEALTH CARE RESEARCH TO THE NATIONAL INSTITUTES OF PUBLIC HEALTH OR NATIONAL INSTITUTES OF COMMUNITY HEALTH. THESE CHANGES WOULD RECOGNIZE AND ENHANCE THE EMPHASIS ON DISEASE PREVENTION AND HEALTH PROMOTION.

ONCE AGAIN, ON BEHALF OF THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH I APPRECIATE THE OPPORTUNITY TO REVIEW AND COMMENT ON THIS IMPORTANT LEGISLATION. I WILL BE PLEASED TO TRY TO ANSWER ANY QUESTIONS.

THANK YOU, MR. CHAIRMAN.

Senator KENNEDY. Senator Schweiker is, of course, a cosponsor. We have had very strong support for this proposal from both Drs. Lee and Remington, Senator Schweiker. I think they have given us good indication of their continued interest and help for it, and I think they have made a very strong case for the organizational structure, and I think what is most important, the functions of those particular agencies. And I think that this is reassuring to us.

I think their statements are very clear and crisp, and they have been very responsive.

Senator SCHWEIKER. I have just one or two minor questions. Do you have a better name for this new agency than the one we have come up with? I am not so sure that the name in the bill is as clear and crisp as your testimony.

I do not know if you have made any suggestions or have any thoughts about that or not.

Dr. REMINGTON. I ventured a couple of them, Senator Schweiker, in my testimony. I am a little worried about the title, National Institutes of Health Care Research. To me, that implies too much emphasis on treatment of disease at the individual provider/client level. "Care" and "Health Care" even more seem to imply exclusively a personal health services orientation.

I find missing the emphasis on prevention that we are beginning to see from the administration in the President's budget message, in Secretary Richmond's testimony today, and in programs of several of the National Institutes of Health.

I think most of us agree that when we look at the great gains in public health in the past, the majority of those gains have not been through the treatment of disease, but through the prevention of disease in the first place—in absolute or in relative terms, and in terms of cost containment.

The name, National Institutes of Public Health is an option that I understand has been discussed; National Institutes of Community Health might be another option.

I would argue for any kind of a crisp term that suggested something more than personal health services as the exclusive focus of this agency.

When we put the National Center for Health Statistics into an agency like this, for example, we get a polyglot group, because their concern is broader than personal health services—as important as that is. It is difficult for me to state this position without seeming to diminish the appropriate emphasis on personal health services research, and I do not mean to do that either.

Senator SCHWEIKER. Well, I share your concern. I think that was my reaction in seeing the label first off. I am not quite sure where we should come down to be clear and crisp, but I think the present name is subject to an awful lot of misinterpretation about the focus of resources and the emphasis that the bill intends this organization to have.

So I can certainly assure you we will give it some further thought and take your suggestions into account.

Dr. LEE. I think it is important, Senator Schweiker——

Senator SCHWEIKER. Yes; I was going to ask you, Dr. Lee: What are your thoughts on the name?

Dr. LEE. I think the term, "National Institutes," is very important in this regard, and I think the use of the term "Research" is very important, because the institutes have been associated with research.

What you are doing in this set of institutions—whether you call them centers or not—is research, basically research—health services research, policy research, the gathering of statistical information that is useful in health services research, useful in health policy.

It is that emphasis, that is implied by the title—I have a broad view of health care, and I think the title actually is quite a good title. I do not have the same concern that it emphasizes too exclusively personal health care, because you are talking about an institute within that for health policy. That is a broad concept and one that must be based on the statistics that you are going to gather out of the National Center for Health Statistics, basic health services research, epidemiological studies, social and behavioral sciences studies of the kind Dr. Hamburg described this morning.

I do not see those as at all incompatible. As a matter of fact, I was very impressed with the manner in which you were able to come up with what to me was a very good set of titles——

Senator SCHWEIKER. Well, we changed our minds three times——

Dr. LEE. Well, I thought that as it went along, it improved. But I think it is important, in terms of the use of the term, "National Institutes."

Senator SCHWEIKER. Well, there is no argument with that. I think that is a very valid point. It is putting the word "Care" in there. It seems to me that the word "Care" conjures up medicaid and medicare, which I think is completely off-target of what we mean in the bill and ought to be saying in the name.

I agree with you about keeping "National Institutes," and possibly even "Research," although I think "National Institutes" already connotes research.

Dr. LEE. But I think also, the point Dr. Hamburg made this morning was very important. The present NIH is not the right place for these kinds of activities, including the technology assessment activities.

They have got a very good management structure, but they have got more than enough to do. If this is going to get the kind of attention and priority and quality that it must have, I think it must be in this kind of separate agency such as you have proposed in this legislation.

Senator SCHWEIKER. Well, we certainly agree with that. I do not want to prolong the hearing. I know you have gone over the issues with Senator Kennedy.

Senator KENNEDY. I think the strong support of what we are attempting to do is very reassuring. The former Assistant Secretary of Health, who has been very much involved in the whole areas of research program, reminded us in his testimony about the gradual decline—on page 11, in 1973, from $58 million, and how it has just continued to go down and how this really is such an important element in terms of trying to get a real handle on cost. We are talking about everything in this. We are talking about cost, we are talking about quality, we are talking about equity, and so many of these elements.

Dr. LEE. And you might ask Julie Richmond or, perhaps, Gerry Rosenthal, how many supergrade positions Dr. Rosenthal has been given since 1974 when he was made Director of that Center; how many additional new positions has he been given to staff up to do the job that has to be done.

Dr. Richmond indicated they are taking even more money away from the center to carry out this technology assessment activity in his office, further limiting what they are able to do. I think you raised some very pertinent questions on that this morning.

Senator KENNEDY. Well, if you have some more questions we ought to be raising, we welcome those, too. I think it is helpful to the people in the Department to understand this, as well as those of us outside who are trying to move this issue forward to be able to dramatize it.

We talked about it, but I would like to just get your sense on the prevention institute. I think Dr. Remington indicated that NIH is not the place to do it—I think I asked this before, but maybe you can just hammer it. How do you think we ought to deal with the function of prevention?

Dr. REMINGTON. I think if you are going to have a National Institutes structure, with the kind of breadth that I think we are all discussing here, I think it needs more of a focus on prevention than I see in the present language of the bill.

Senator SCHWEIKER. You want to see that accomplished through this National Institutes of Health Care Research concept? In other words, you are saying we should put prevention into that structure, provided for in this bill, in a bigger way?

Dr. REMINGTON. Yes; or community health—whatever umbrella concept you want. Health care seems to me, as I have stated already, not to be an appropriately broad umbrella.

But in public health or community health, which I think are appropriately broad, supporting Dr. Lee's statement that national institutes is very appropriate, I would like to see a much greater emphasis on prevention.

For one thing, as you did epidemiology to the National Center for Health Statistics, you will inevitably, then, have people who are doing work that closely relates to prevention. Perhaps epidemiology may be thought of as the basic science of prevention.

And one worry I would want to articulate there is that I would not want to see an emphasis on epidemiology in this group draw epidemiologic strength away from CDC or from the individual Institutes in the Institutes of Health.

That would be very unfortunate. And I do not think it is the intent of the cosponsors of this legislation to do that. As I read Senator Kennedy's flood statement introducing the legislation, that is quite clear. But I would like to stress it again. I think our colleagues at CDC in epidemiology, particularly in such units as the Epidemic Intelligence Service—which by the way, is doing as much to produce new epidemiologists as any unit we have—will be worried about the addition of epidemiology to a unit like this, if they believe that their budget will be affected or that their program will be diminished. I do not think we want that.

Senator KENNEDY. Well, wouldn't that also be true, say, for the Cancer Institute, where they have got about $75 million for prevention, and the Heart as well.

Dr. REMINGTON. Yes; indeed.

Senator KENNEDY. So how do we do that? They do not want to lose that. The institutes feel that that is an important dimension, and I think it is. So how do we deal with that? I suppose the NIH would say they are doing 20 percent of their budget——

Dr. REMINGTON. Well, they are doing more and more. I think prevention and epidemiology are a couple of words that have come to town and are really beginning to move, as we all appreciate what they really can do.

And I think Les Breslow and Nedra Belloc and their work, as Dr. Lee has pointed out, suggest to us the gains we can make.

As I look at the downturns in cardiovascular disease mortality, particularly coronary heart disease mortality, and begin to try to explain that latter downturn, it seems to me that most of it simply has to be due to changes in the way of life, changes in personal health habits. And that is an analysis that needs to go forward.

Now, I have just recently learned—very recently, in fact—of a Committee on Epidemiology at the Director's level within NIH that is providing a forum for all of the epidemiologists within the individual Institutes, within NCHS, within CDC, to get together to share ideas and to begin to think of ways of capitalizing on their limited—numerically limited—strength. And I think that should be encouraged.

Dr. LEE. I would agree, Senator, that the idea of an institute ought to be very carefully explored within this context, that it is more appropriate in this setting than within NIH, that NIH, certainly in the Cancer Institute and other institutes, should have a component of prevention, just as the Health Care Financing Administration must have a programmatically related health services research component.

But it is not going to support the fundamental health services research that needs to be supported or the policy of the research that is going to question the policies of medicare and medicaid. They simply do not support that kind of research.

Nutrition is a critically important area that has a very low priority in the last decade in HEW. We have seen in the Agriculture Department a significant turnaround, I think, with this current administration that is very encouraging.

The Office of Science and Technology Policy has almost directed HEW to do an assessment of dietary goals. I do not see that that has been carried out yet.

That is the kind of thing that an institute like this could do. It might include nutrition, environmental and social-cultural components, including social and behavioral sciences and epidemiology. Studies of social networks, the impact of widowhood on health, various other social factors that impact on health might be examined. If we had better research in these problems the kinds of blaming-the-victim statements that we now see made repeatedly by some very prominent health professionals would be heard less often. It might also help to deal with the social and environmental problems that contribute to poor health, the problems of poverty and other things.

I think that it is an excellent idea. I am sure you can get the people in DHEW to put the pieces together. They could identify the various activities in prevention that might logically go into an institute that has this kind of community population focus as opposed to a disease-specific focus.

Senator SCHWEIKER. Would you put "epidemiology" into the title, or is that drawing too much away from CDC and some other efforts?

I mean, you said that is a word whose time has come, and it probably has. Should "epidemiology" be part of the title?

Dr. LEE. Certainly you would want to have training grants as part of it, and training grants in epidemiology. Perhaps the Director of that institute would be an epidemiologist. That is such a basic discipline for the development of policies in prevention and for individuals to make decisions about what they should do in prevention.

Senator SCHWEIKER. What I am getting at is that maybe we ought to use that word in the title, because it does explain many of the things we are talking about.

Dr. REMINGTON. It is possible. Of course, you are talking to somebody who is biased. I think public health is a very appropriate umbrella, and public health does not have quite the same narrower connotation that it once had. It is a field that has been changing and adapting.

There would be those, I suspect—perhaps not Dr. Lee or myself—who might find "epidemiology" a bit confining in the title, just as some of us would find "health care."

Senator KENNEDY. Can I ask how you relate this to our health information and promotion kind of agency?

Dr. LEE. The authority that is there, as a matter of fact, would permit you now, or would permit HEW to create such an institute. The major initiatives that Secretary Califano has taken in the field of prevention—his whole antismoking program—is based on the authorities in that legislation.

Senator KENNEDY. That is exactly right. So we have got a good deal of flexibility to move.

Dr. LEE. That authority is there already, in terms of moving it if the Department wished to.

Senator KENNEDY. We ought to press on that, obviously, for the reasons you have outlined.

Thank you very much.

[The following information was subsequently supplied for the record:]

AMERICAN PUBLIC HEALTH ASSOCIATION
1015 Eighteenth Street, N.W., Washington, D.C. 20036 • (202) 467-5000

WILLIAM H. McBEATH, M.D., M.P.H., *Executive Director*

February 22, 1978

The Honorable Edward M. Kennedy
Chairperson, Subcommittee on Health
and Scientific Research
4220 Dirksen Senate Office Building
Washington, D. C. 20510

Dear Senator Kennedy:

The American Public Health Association is pleased to have the opportunity to present its views on S.2466, National Institutes of Health Care Research. APHA is supportive of efforts to develop capabilities in public health and health services research, and wishes to offer testimony designed to assist in making S.2466 achieve these goals.

Very truly yours,

Frank Ellis

E. Frank Ellis, M.D., M.P.H.
President

cc: David Blumenthal

S.2466 - National Institutes of Health Care Research
comments of the
AMERICAN PUBLIC HEALTH ASSOCIATION
to the
Subcommittee on Health and Scientific Research
of the
Senate Committee on Human Resources
February 1978

The American Public Health Association has long been aware of the need for research, evaluation, and demonstrations related to the area of community and preventive health services. We are supportive of attempts to develop capabilities in public health and health services research comparable to our current highly developed biomedical capabilities. The goals of S.2466 encompass these endeavors and are worthy of support.

APHA is anxious to assist in making the legislation achieve these goals and wishes to offer comments designed to strengthen the bill.

While the purposes of S.2466, as we have indicated, are broad and far-reaching goals, we are concerned that the title and specific aspects of the bill limit the scope. We feel strongly that the title of the bill, National Institutes of Health Care Research, with its emphasis on traditional health care is not reflective of the stated goals of the bill. We would suggest that the title be amended to National Institutes of Public Health. Changing the title would serve the purpose of emphasizing areas of community health services and prevention research, demonstration, and training.

Because the area of prevention is so critical to investigations of health services, an additional purpose of the bill should be added to Sec. 304(b) (2)a-f to read,

(g) the prevention of illness, disability, and premature deaths in the United States.

As currently drafted, S.2466 addresses two of the six goals in Section 304(b) (2). These deal with:

(c) the collection, analysis and dissemination of health related statistics, and

(e) the safety efficacy, effectiveness, cost effectiveness, and social, economic and ethical impacts of medical technologies.

Legislative initiatives related to the four other goals are incompletely addressed in the bill. These are:

(a) the accessibility, acceptability, planning, organization, distribution, utilization, and financing of systems for delivery of health care,

(b) alternative methods for measuring and evaluating the quality of systems for the delivery of health care,

(d) alternative methods to improve and promote health statistical and epidemiological activities, and

(f) alternative methods for disseminating knowledge concerning health and health related activities.

SECTION 102

Section 102 changes the name of the National Center for Health Services Research to the National Institute for Health Policy Research but does not add additional responsibilities or functions. Language should be added to incorporate the research described in Sec. 304(b)(2)(a)related to the accessibility, acceptability, planning, organization, distribution, utilization and financing of systems for the delivery of health care. It would also be useful to include in the bill report some indication of the congressional intent leading to a change from the word "services" to the word "policy".

We note that in his remarks on the bill, Senator Kennedy makes reference to a new mandate to conduct training programs for health services researchers. We are unable to find specific language to this effect, but hope that some could be added to provide an expanded and continuing supply of persons qualified to perform needed research, evaluation and demonstration projects.

SECTION 103

Section 103 renames the National Center for Health Statistics and adds epidemiology to the title. It appears as if the National Center for Health Statistics (NCHS) would be expected to carry out new epidemiological investigations anticipated by this legislation. Epidemiological expertise currently rests in the Center for Disease Control, but the relationship of CDC to this Institute is unclear.

NCHS currently operates a statistical service which relates very well to operating health agencies. APHA is concerned that the move to a research orientated organization might result in a loss of focus on the cooperative federal-state health statistics system. It is important that statistical work for ongoing programs be continued.

SECTION 104

Section 104 establishes a National Center for the Evaluation of Medical Technology. As outlined in S.2466, this Center would provide useful information concerning the safety, efficacy, effectiveness, cost effectiveness and social, economic and ethical impacts of medical technologies. This kind of research, while difficult to accomplish, will yield extremely helpful data. In keeping with the spirit of Section 104, it might be appropriate to retitle the institute, National Institute for Health Technology Assessment, since it would deal with investigations related to health services delivery and medical practice as well as biomedical technology.

NATIONAL PREVENTION INSTITUTE

APHA urges the establishment of a fourth Institute to be titled National Prevention Institute. This Institute would be devoted to the investigation and evaluation of individual services and community activities of a preventive nature. The Institute should be concerned with the demonstration and testing of new preventive models for community and environmental health programs and with measuring the effectiveness and efficacy of existing models. Specific examples of areas of inquiry might include evaluation of the cost effectiveness of programs to change individual behaviors. It might undertake quantitative assessments of the effect of educational efforts to motivate healthy life styles. It may also attempt to gain a more definitive understanding of the potential for early identification of disease through screening.

In summary, although we have indicated areas where S.2466 needs clarification and expansion, APHA would support the concept of Institutes which would give new focus and definition to public health policy.

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Written Statement

of

EUGENE W. FOWINKLE, M.D.

Commissioner, Tennessee Department of Public Health

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The Association of State and

Territorial Health Officials

for the

Subcommittee on Health and Scientific Research

Committee on Human Resources

U. S. Senate

February 27, 1978

I appreciate the opportunity to offer written testimony on S. 2466, the National Institutes of Public Health Act of 1978, and in particular that portion concerning the National Institute for Health Statistics and Epidemiology. As Commissioner of the Tennessee Department of Health, as Past President of the Association of State and Territorial Health Officials, and especially as a former member of the Advisory Committee to the Cooperative Health Statistics System (CHSS) of the National Center for Health Statistics (NCHS), I have become familiar with the programs of the Center and with some of its problems.

I am pleased with the current enabling legislation for the Center and the broad authorities it provides for collecting, analyzing, and disseminating health data which is so critically needed for planning and evaluating the nation's health services and health research programs. There is, however, a modification to the legislation which I feel would significantly aid the Center in continuing to develop and implement a cooperative data collection system. I would suggest that appropriations for the new National Institute for Health Statistics and Epidemiology be divided into two separate authorizations - one for the Cooperative Health Statistics System mandated under Subsection 306(e) of the Public Health Service Act and one for all other statistical activities of the Institute which are conducted under Sections 304 and 306 of the Act. A separate appropriation can also go a long way in helping the Institute instill confidence in, and develop permanent relationships with state and local governments which are essential for the successful implementation of the CHSS. This is particularly true since the Cooperative Health Statistics System is designed to establish a coalition among the various levels of government and the private health sector to gather health data in a manner which permits the collection of any particular data element(s) by the organizational level best equipped to collect it and then to share it with the other levels.

For the past several years, the NCHS has been restricted in its budget to mandatory increases for such items as salaries or special projects. I strongly recommend that the total appropriation be increased to a level which could adequately support the activities of the Institute. To accomplish this, a total appropriation of at least $60,000,000 would be needed for FY79. Of this $60,000,000 total $35,000,000 should be designated for the CHSS with $25,000,000 to be used for operational data activities and $10,000,000 to be used for the development of "core" staffs in State Centers for Health Statistics in all 50 states. Therefore, I would suggest that more appropriate total amounts would be as follows:

Fiscal Year	Total	For NCHS National Activities	For CHSS Operational Activities	For State Center "Core" Staffs
1979	$ 60,000,000	$ 25,000,000	$ 25,000,000	$ 10,000,000
1980	90,000,000	30,000,000	40,000,000	20,000,000
1981	115,000,000	35,000,000	50,000,000	30,000,000

It should also be pointed out that additional appropriations should be authorized if any substantial epidemiological activities are planned.

In addition to the appropriation issue, there is a need for a special Advisory Committee to the Institute which would assure adequate representation of state and local interests in policy development and decision making. Our experience has shown that state-local participation in the decision-making process concerning the development and operation of data systems is a necessity. I would suggest that three-fourths of this committee be composed of state and local representatives who are actively involved with CHSS activities, including representatives of Health Service Agencies (HSAs) and State Health Planning and Development Authorities. This type of representation appears to be essential to assure long-term viability and effectiveness.

A final point for consideration is the need to clarify and strengthen the role of the Institute/CHSS as the coordinator of uniformly defined standard health care information for all Department of Health, Education, and Welfare (DHEW) agencies. Coordination of data activities is of utmost importance in avoiding costly and inefficient duplication in data systems. Section 304 (d) of the Act provides for coordination of statistical activities by the Secretary of DHEW. This coordination could be strengthened by providing clear authority and jurisdiction for the Director of the new National Institute of Health Statistics and Epidemiology to coordinate all of DHEW's health statistics activities, especially those of the Health Care Financing Administration and other Public Health Service agencies. To further strengthen coordination, this legislation should provide for an internal Health Data Policy Committee chaired by the Director of the Institute. This committee would replace the present ad hoc committee of the same name but would have the capacity to make decisions and implement changes.

In summary, I feel that the legislation currently under consideration would significantly strengthen national, state, and local efforts in collecting, processing, and disseminating quality health data by incorporating the modifications outlined in this testimony, ie: 1) a separate appropriation for CHSS which would include funding for development of "core" staffs in all states as well as operational funding, 2) an increase in the total appropriation, 3) establishment of an Advisory Committee to the Institute with more state representation, and 4) a stronger coordinative role for Institute/CHSS.

aamc association of american medical colleges

JOHN A. D. COOPER, M.D., PH.D.
PRESIDENT

202: 466-5175

February 28, 1978

Honorable Edward M. Kennedy
Chairman
Subcommittee on Health and
Scientific Research
Committee on Human Resources
United States Senate
Washington, D.C. 20510

Dear Senator Kennedy:

The Association of American Medical Colleges is pleased to have been asked on your behalf by Dr. David Blumenthal for an evaluation of and a position on S. 2466, "The National Institutes of Health Care Research Act of 1978."

The proposal has been discussed at length within our staff. On February 18, all but one member of the Association's Executive Committee reviewed a staff analysis of the proposal. The unanimous opinion of those present was that with some comparatively minor modifications, described later in this letter, the Association should urge support of this piece of legislation. While persuasive reasons were cited for advocating your approach, the real possibility that it could create overexpectation was recognized. The complexities and difficulties of research in health services have been amply demonstrated. Furthermore, the extreme shortage of well-trained individuals in the many facets of research encompassed by this proposal would be a severe deterrent to major accomplishments in the immediate future, regardless of the organizational setting and the provision of adequate financial resources. Should the legislation pass, particular care must be taken to provide first-rate leadership for these new programs and proper criteria in the establishment and evaluation of the programs to avoid serious waste of resources as well as failure to accomplish the desirable objectives of the act. Additionally, whether or not this new organization is established, there will be a requirement for vigorous and continuing coordination at the level of the Assistant Secretary for Health of these functions as well as related activities in existing Public Health Service agencies.

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AAMC support is based on the following considerations:

- As you pointed out in your floor statement, the need for initiatives in the areas assigned to the proposed National Institutes of Health Care Research is of the utmost importance. While elements of these activities are presently undertaken in both the public and private sectors, there is presently no overall concept of how these functions should be related to one another and no overreaching managerial strategy for their support and conduct.

- The proposal is a very timely one. Examination of the various studies conducted in this area in recent years and the evidence developed in various Congressional hearings, suggest that now is an auspicious moment to modify the programmatic nature, the organizational location and the magnitude of effort for the National Centers for Health Statistics and for Health Services Research as well as related efforts. In fact, if the opportunity is not grasped now, an unusual advantage will have been wasted.

- S. 2466 enumerates for the first time in understandable, reasonable and badly needed fashion some of the specific components which comprise the important but amorphous and poorly understood series of activities encompassed by the inadequate term, "technology transfer."

- The bill offers a potentially effective and appropriate counterpart in the health care area to the National Institutes of Health, with the latter's important and productive programs in biomedical research and related areas.

- The designation of separate authorizations for these activities should provide a necessary identifiable focus for assuring that each can gain at least minimal allocation of the essential financial resources for expanded programs in each area.

- The inclusion of an overarching organization, similar to the Office of the Director, NIH, provides the basis for one level of intra- and interagency cooperation and coordination required for its success.

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February 28, 1978

- While advancing health care research and technology transfer through separately identified functions, there is also assurance in your floor speech that the NIH and other agencies can conduct or support, within reasonable limitations, epidemiological research and clinical trials which are especially pertinent to their categorical missions. The AAMC believes that this important point should be explicitly reaffirmed in Report language.

- The programs of the NIHCR will complement the programs of the NIH and should increase the total funding of research in the areas of biomedical, behavioral and health care research. The attractiveness of the categorical foci of the NIH will remain a potent magnet for funds as in the past.

In conveying its endorsement of this legislation, however, the Association recommends thorough consideration of several modifications which would even further improve the present bill:

- An Advisory Council should be mandated for each of the three components, rather than just for the National Center for Evaluation of Medical Technology as presently proposed. The Association is convinced that the activities subtended by each component are sufficiently different as to justify separate senior level advisory panels. Furthermore, we suggest that in Report language an Advisory Committee to the Director of the entire organization be recommended similar to the administratively established Director's Advisory Committee at NIH.

- The Advisory Councils, like their counterparts at NIH, should have public representatives and should otherwise be appropriately constituted so as to reflect the specific responsibilities of each component. For example, eminent statisticians, epidemiologists and clinicians should definitely be members of the Advisory Council for the National Institute for Health Statistics and Epidemiology. On the Advisory Council for the National Institute for Health Policy Research there should be prominent clinicians and other provider representatives, economists, and behavioral and social scientists.

- Peer review of grants and contracts should be mandated for each component so as to assure the highest possible quality in the awards and the subsequent research.

- The authorization ceilings for the three components should total at least 0.5 percent of Federal health care expenditures. This would represent at the present time approximately $200 million. There are two reasons behind this proposal. First, this provision would provide a reasonable and definite level of financial underpinning for these activities. Second, in very explicit fashion it would tie support for these types of research to the health care function and the Federal component of its funding. It seems only proper to set out in highly visible fashion the necessity of an investment for the future through research so as to assure continued improvements in the quality, quantity and cost effectiveness associated with the health care delivery system.

Once again, we appreciate the opportunity to comment on the proposed legislation. We stand ready to assist you and your colleagues in any way possible to assist in its success.

Sincerely,

John

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February 10, 1978

Honorable Edward M. Kennedy
United States Senate
Room 431
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Dear Senator Kennedy:

On behalf of the Association of Schools of Public Health, we wish to thank you for the opportunity of presenting testimony in support of S. 2466, the National Institutes of Health Care Act of 1978 before the Senate Subcommittee on Health and Scientific Research on February 7. At the hearings you and Senator Schweiker discussed with Dean Remington the title for the new National Institutes. There seemed a general concern that the proposed title could be misunderstood to limit the jurisdiction of the agency to the administration of personal health services on a one to one basis, whereas the intent of the legislation appears to include a major emphasis on prevention and an improved federal posture in public health research.

The undersigned Deans wish to urge that you carefully reconsider changing the title of the proposed new organization to <u>The National Institutes of Public Health</u>. This change would, we believe, recognize that health statistics, epidemiology, evaluation of preventive strategies, and personal health services as now included in the language of S. 2466 are part of Public Health. In fact, statistics, epidemiology and health services administration are, in addition to environmental health, major components of every School of Public Health, mandated by our accrediting agency.

In addition, the Schools of Public Health are among the most research intensive units within their respective Universities. At the University of Michigan, for example, the School of Public Health generates per capita more research activity in terms of external federal, state, and private funding than any other school or college including the Medical School. Yet there is within the federal government no umbrella agency responsible for supporting public health research. That is why the Association of Schools of Public Health so strongly supports S. 2466 with an increased emphasis on prevention, promotion of positive health, and more appropriate title.

Public health is a field with a distinguished record of research leading to major advances in the conquest of disease, improved delivery of personal, environmental, preventive, and therapeutic health services out of all proportion to the past and current investment in its research efforts. The National Institutes of Health, an excellent agency with a critical national mission is in reality devoted almost entirely to biomedical research, an emphasis which should continue.

We believe that the proper and intended concern of S. 2466 is not exclusively with health care but with public health, and therefore, urge that you amend the Act to retitle the proposed Institutes, the National Institutes of Public Health.

Thank you for your consideration.

Sincerely,

Richard D. Remington

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With the endorsement of the following individuals:

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HAND DELIVERED

AMERICAN NURSES' ASSOCIATION

Statement

S. 2466

National Institutes of Health Care Research Act of 1978

February 21, 1978

Submitted To

Subcommittee on Health and Scientific Research

Committee on Human Resources

United States Senate

The American Nurses' Association supports the thrust of S. 2466, "The National Institutes of Health Care Research Act of 1978." We regret that the subcommittee's public hearings were restricted to one day and that witnesses were by invitation only as we consider this a most important piece of legislation deserving thorough public discussion and debate.

Groups such as ours, with keen interest in improving the delivery of health services, need time to fully assess the impact of each of the bill's suggested major changes in structure.

We commend the sponsors for taking such a careful look at the existing programs and their problems and for developing the bill being considered.

We agree with the views expressed by Senator Kennedy in his speech at APHA in November 1977 that health services research and health statistics programs must be insulated from politicalization which is a real future possibility within the recently revised structure of HEW.

The National Center for Health Services Research has had a difficult time since its inception. Internal administrative problems, lack of adequate financing and organizational upheavals all are factors. Location in administrative charts is an important aspect for any program attempting to break new ground.

Health services research is certainly a field needing new breakthroughs. To make such breakthroughs requires coordinated research efforts on a number of fronts concurrently so that a cohesive plan for change can be developed rather than a bit by bit approach to such change.

Congressional expectation of quick research results from the Center has at times seemed unrealistic.

Low appropriations also have restricted its progress. Some of us have also felt that certain of the research carried out was not in fact scientifically evaluated prior to recommending changes in policy (i.e. evaluation of effectiveness of nurse practitioners and physicians assistants in practice using time per encounter and numbers of encounters only, rather than measuring the quality of care provided by those groups).

The four purposes of the bill (S. 2466) do address areas of major importance to the future effectiveness of our health care system.

The umbrella agency approach would provide the coordinating mechanism essential to sound planning for health services and would provide access of the Institutes' director to top policymakers in DHEW and in Congress.

The National Center for the Evaluation of Medical Technologies would provide leadership and coordination of efforts to assure both safety and necessity of new technological advances. We think it wise to point out, as was done by Senator Javits when S. 2466 was introduced, that this Institute will not "inhibit innovation and research in the development of new medical technology." Inadequate evaluation of apparent breakthroughs in the past are now causing skepticism on the part of the public. The large scale development of coronary care centers has been questioned in the past year or so by researchers who claim mortality rates are not significantly affected by the spending of those hundreds of millions of dollars. The cost and value of neonatology intensive care centers are currently being questioned in the public press. Solid evaluation by the proposed Institute, to be done in controlled settings, would provide more effective public policy guidance. It will be important to assure that cost factors alone are never allowed to be the overriding factor in decision making in relation to the use of technology in health delivery.

We feel that nursing research is an element that needs to be included in such studies. ANA's research priorities speak to this as one of our key areas of interest. These priorities include;

Studies to improve the outlook for high risk parents and high risk infants.

Studies to improve the health care of the elderly.

Studies of life threatening situations, anxiety, pain and stress.

Studies of adaptation to chronic illness and the development of self-care systems and group care systems.

Studies to facilitate the successful utilization of new technological developments in patient care.

ANA supports the third focus of the bill, the creation of a stronger Center for Health Statistics. We agree with the chairman that adequate data is essential to plan and evaluate national programs. Morbidity and mortality studies, for example, are essential and must be of the highest caliber to guide policy.

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Short term political goals should not interfere with such data development. We have concerns currently about the exclusion of certain types of expertise from the health statistics expert committees. We therefore urge the legislative requirement that the National Committee on Health Statistics include persons specifically distinguished in the fields of health manpower and health facilities statistics. The nursing field, for one, has several such experts, and quality manpower studies have been done on nursing needs and resources for many, many years. To exclude experts from these fields will continue to result in duplication of studies, unnecessary errors in developing the studies' methodologies, and extra cost to the taxpayer.

The fourth purpose of S. 2466 is to create a more comprehensive program for health services research to be named the National Institute for Health Policy Research. The name can be misleading but our understanding is that research demonstrations and evaluation of new or different methods of delivering care will be its focus leading to policy development through research. Hospice care, currently receiving public attention, might be an example of one type of care to be so demonstrated in a variety of situations and evaluated prior to implementation of a national program.

We heartily agree that health services research needs to be a more prominent and aggressive program. Long term support needs to be assured so that subsidized large scale (costly) demonstration studies can be conducted on many issues.

Nursing has long sought demonstration funds to try new patterns of delivering nursing care. Nursing research needs to be tested in controlled settings. Then when proven effective, those findings must be more quickly put into general nursing practice.

In 1968, the HEW Program Review Committee evaluating the effectiveness of the 1964 Nurse Training Act recommended a stronger Federal focus for nursing to tie research services and education together. It specifically recommended that federal funds be substantially increased for all mechanisms of support to accelerate and advance:

- research into all aspects of nursing practice, the organization and delivery of nursing services to the patient, nursing as an occupation, and ways of communicating research findings;
- research training, as a necessary adjunct to prepare nurses to do independent research, to collaborate in interdisciplinary research, and to stimulate and guide research important to nursing.

Demonstration grants are still one of the missing links. In fact, there has been real interest on the part of nurse researchers to have an Institute of Nursing Research. However, administration support has not been evident for such an Institute, Center or Bureau. It seems extremely short sighted when the health care system employs close to one million registered nurses, almost one half million licensed practical nurses and many thousands of nursing assistants to have so little attention paid to research that could significantly improve the utilization of those groups, possibly saving millions of dollars in federally funded health programs alone. Yet for fiscal year 1979 the administration requested 0 funding for nursing research! We have had to work hard to get research project funding up to $5 million for this year. Congressional recognition of the potential impact of such research on the health delivery system has saved that program repeatedly. Only one million dollars a year is being spent to prepare nursing researchers. Again a short sighted view it seems.

It now is timely to suggest the inclusion in S 2466 of a Center for Nursing Research. This would not detract at all from the essential participation of nurse researchers in the Institute's other interdisciplinary health services research. In fact that element is essential. We do think it is appropriate that, in addition, nursing research should have a line item in the budget of such an institute and an administrative structure allowing it to participate effectively in policy making. Such a Center would assure that and would make it possible to do demonstration studies and get significant results into practice settings fairly quickly.

We urge your committee to add a specific amendment to S 2466 to include a Center for Nursing Research within the proposed Institute for Health Services Research. Coordinating linkages could be built in to promote effective cooperative relationships with other units of government which fund nursing education and/or pertinent studies of importance to the delivery of nursing care. We suggest that the director of the Center for Nursing Research be given that coordinating responsibility.

Finally we want to comment on the opposition of HEW to S 2466. The reasons for opposing and the problems addressed by Dr. Richmond in his testimony of February 7 are real. We know how hard it is for programs to move ahead when too frequent restructuring and reorganization occur. Staff energies are dissipated and pressures to produce needed administrative documents distract from programs moving forward. A major change has just been implemented within HEW. We think the changes proposed in S 2466 are appropriate at this time. If however, you should decide to delay action for two years as HEW requested we urge that you suggest the department include nurse researchers in all of its deliberations and its internal studies.

In closing, we do support the several thrusts of S 2466. Important areas of health research essential to sound planning for the health system of the future need more attention and more support and soon.

We want to work with the Congress and with the Administration as the best methods of implementing such changes are worked out. We think S 2466 offers a very good start for the necessary movement to improve the existing programs.

We ask that this statement be made a part of the hearing record.

2-21-78

AMERICAN NURSES' ASSOCIATION

Preparation of Nurses for Participation in Research

Commission on Nursing Research

In meeting its obligation to the profession of nursing and to society, the Commission on Nursing Research of the American Nurses' Association presents guidelines for the preparation of nurses for participation in and utilization of research. These guidelines are designed to establish the broad context within which nurses can learn to fulfill their research roles. They also provide members of other disciplines and the public with information upon which to base their expectations of the nurse investigator. The guidelines are also an approach to implementation of the research aspects of the *Standards for Nursing Education.*[1]

New knowledge concerning human health and response to illness is accruing at an exponential rate. For nursing as for other disciplines such tremendously rapid accretion of knowledge demands continued systematic investigation of both content and process. Explicit emphasis on preparation for such research has become an increasing concern of the profession.

The Commission on Nursing Research of the American Nurses' Association recognizes the essential nature of research in the continuing effort to improve nursing practice. As reported by the National Commission for the Study of Nursing and Nursing Education,[2] very little research has been done on the actual effects of nursing intervention and care. This points to the need for greater emphasis on education for research for the improvement of practice. If education for nursing research is to be useful and effective it should include both the development and testing of theory and the application of findings.

An attitude of inquiry and an introduction to research should be initiated in the early phases of undergraduate education. A climate should be fostered in which the findings of research are sought and utilized in the provision of patient care. In addition to providing the nurse with a fund of usable scientific knowledge, undergraduate education should include both an introduction to and a beginning experience in the research process.

On the undergraduate level, education for research should prepare the nurse to read research critically and to determine its value to practice. It should also provide an understanding of the rights and responsibilities of participants in research as well as of the rights of subjects.

The preparation of nurse researchers involves supervised activities in an investigative program including observation of and participation in all phases of research, from the definition of a researchable problem through the dissemination and utilization of findings. This preparation must include participation in theory building and conceptualization, acquisition of investigative skills, experience in data reduction and analysis, practice in interpretation of results, competence in writing of research findings, and consideration of all aspects of the research experience.

As more nurses are prepared for participation in research through undergraduate, graduate, and continuing education, new knowledge resulting from research should increasingly pertain to the effects of nursing intervention and care, and an observable impact on practice can be expected.

The following components are considered important examples of the elements essential to the development of sound researchers and practitioners. Although these areas of study have been divided into undergraduate, graduate, and continuing education categories, the elements of competence in research should be integrated throughout the educational process.

PREPARATION FOR RESEARCH WITHIN UNDERGRADUATE EDUCATION

A. The nature of inquiry
   1. Logic and the reasoning process
   2. Development of knowledge
   3. Significance of the research question
   4. Importance of theories in science

B. Introduction to research ethics
   1. Ethical issues in research
   2. Protection of human and animal subjects
   3. Place of boards of review
   4. Behaviors of researchers

C. Introduction to the research process
   1. Establishment of the knowledge base
   2. Identification of scientific methodology
   3. Identification and appropriate utilization of related resources
   4. Elements of critique

D. Introduction to research methodology
   1. Evolving and/or formulating a conceptual framework including statement of rationale
   2. Developing a problem statement
   3. Defining and operationalizing variables
   4. Development of methods or tools
   5. Development of a disciplined approach to data collection and processing
   6. Understanding of reliability and validity
   7. Interpretation of findings
   8. Interrelationship of design, analysis, and interpretation
   9. Dissemination of new knowledge

E. Utilization of research findings
   1. Necessary or sufficient conditions for generalization
   2. Recognition of other conditions where findings are not applicable
   3. Communication of results of utilization

PREPARATION FOR RESEARCH WITHIN GRADUATE EDUCATION

Research education for the graduate student builds upon a previously gained background of knowledge, assumes development of an advanced knowledge base, and includes advanced study of methods in research. Graduate education emphasizes experience in the conduct of research under direction of an experienced precepter. It promotes an acceptance of the obligation to conduct, disseminate and apply research.

A. Philosophy of research
   1. Philosophy of science
   2. Utilization of inductive and deductive logic
   3. Human rights and ethics
   4. Ethics of collaboration
   5. Theory development and relation to research

B. Conduct of research
   1. Development of an advanced knolwedge base and use of information retrieval systems
   2. Design and implementation of research
   3. Importance of replication
   4. Entre into research settings
   5. Development of methods or tools
   6. Reduction, analysis, and presentation of data
   7. Intrepretation and significance of findings

C. Advanced research methodology
   1. Development and critique of design models appropriate to the question
   2. Sampling techniques
   3. Measurement and advanced statistics
   4. Use of the computer in analysis
   5. Depth in the art of critique

D. Dissemination of findings
   1. Professional writing/speaking
   2. Application of findings

PREPARATION FOR RESEARCH WITHIN CONTINUING EDUCATION

Continuing education toward the advancement of research in nursing is important in view of the rapidly changing knowledge base and the continued development of new methodology. Continuing education relevant to research must take several forms. Offerings of subject matter analogous to those listed above for undergraduate and graduate education should provide the opportunity for nurses to update their skills in research and to be introduced to the research process. Programs should be developed for nurse educators, nursing service administrators, and nurse practitioners, which will encourage improved climates supportive of open inquiry by nurse researchers and the furtherance of research in patient care.

Through sound programs of continuing education—including symposia, colloquia, and seminars as well as formal education—active nurse researchers will be able to extend their knowlege, improve their understanding of the substantive base of research, and incorporate new concepts and methods in research. The practitioner will be better prepared to function as a participant in and implementor of nursing research and its findings and to assess nursing interventions and patient outcomes within a research framework. The administrator will have an expanded information base for decision making related to the support and implementation of research studies and findings.

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1. American Nurses' Association Commission on Nursing Education. *Standards for Nursing Education.* Kansas City, Missouri: American Nurses' A Association, 1975.

2. National Commission for the Study of Nursing and Nursing Education. *An Abstract for Action.* New York: McGraw Hill Book Company, 1970.

AMERICAN HOSPITAL ASSOCIATION
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STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION
TO THE SUBCOMMITTEE ON HEALTH AND SCIENTIFIC RESEARCH
OF THE SENATE COMMITTEE ON HUMAN RESOURCES
ON S.2466
THE NATIONAL INSTITUTES OF HEALTH CARE RESEARCH ACT OF 1978

March 3, 1978

The American Hospital Association, which represents some 6,400 member hospitals and other health care institutions across the country, as well as more than 27,000 personal members, appreciates this opportunity to present its views on S.2466, the National Institutes of Health Care Research Act of 1978.

S.2466 would create a National Institutes of Health Care Research (NIHCR), which would be composed of three agencies. Two of these agencies currently exist and one would be established under this legislation: the National Institute for Health Policy Research (NIHPR), to be principally patterned on the former National Center for Health Services Research; the National Institute for Health Statistics and Epidemiology (NIHSE), based on the former National Center for Health Statistics including some of the epidemiological activities carried out within certain Public Health Service programs; and finally the National Center for the Evaluation of Medical Technology (NCEMT), an essentially new activity.

The AHA supports the overall goals of this legislation, which are to bring together organizationally some of the existing elements of health services research, health statistics and epidemiology, and to develop a greater capability for the evaluation of medical technology, for the purposes of improving both the delivery of health care and the systems through which such care is provided. In the past, we have given strong support and cooperation to the activities that have been conducted in these areas, particularly those of the National Center for Health Services Research and the National Center for Health Statistics. Further, we have clearly recognized the need for improved methods in the evaluation of advances in medical technology. Nonetheless, while these goals are commendable, we further recognize that there is no existing, specific model for the development of an NIHCR. The lack of such a model necessitates careful study and evaluation, and subsequent phasing and testing, of a variety of approaches in the development and implementation of such an endeavor.

In many of its aspects, S.2466's development of research approaches and methodologies for the health care service area can take into consideration the pattern utilized in biomedical research under the National Institutes of Health. These national approaches recognize an important role of the federal government, as well as nonfederal activities, in health care research. It is our belief that, in exercising its role, the federal government must develop a coordinating and a supporting mechanism for carrying out this vast task through extramural, as well as intramural, activities.

We therefore recognize the basic need for a federal organizational structure--a focus--which brings together under its direction many of the governmental contributors to such efforts and, where such direction is inappropriate, coordinates the activities carried out beyond its direct administrative purview. Such a federal structure also requires the development of an effective, broad-scale extramural program to encourage and assist existing, and develop additional, nonfederal resources--resources which are essential to the achievement of the legislation's goals.

National Institute for Health Policy and Research

Section 102 of S.2466 would amend Section 305 of the Public Health Service Act by establishing within the NIHCR a National Institute for Health Policy Research. In our review of the amendments proposed to Section 305 of the Act, we have identified limited changes in the basic authority of the existing National Center for Health Services Research.

One change, that of undertaking and supporting research evaluation and demonstration projects in "the uses of computer science in health services delivery and medical information systems," appears to be substantial. In this connection, we certainly support the development of computer science for health services delivery and medical information systems, and the identification of this area as a responsibility of the NIHPR. However, we believe that, in the categorization of responsibilities, it will be necessary to make a distinction between those that are appropriately a function of NIHPR, and the application and evaluation of computer science, as utilized in computer-assisted technologies, such as CT Scanners, cardiac catheterization systems, and microcomputer and microprocessor controls. These latter applications and evaluations in the clinical setting would probably be more appropriately a function of the National Center for the Evaluation of Medical Technology.

Our review also indicates that the legislation proposes no advisory council or committee for the NIHPR. Because the present and future activities of the NIHPR, as well as such activities of the NIHSE and the NCEMT, will involve a close, cooperative effort between federal and nonfederal activities, we believe that an advisory council or committee should be established. We further recommend that such a council or committee be composed of individuals from both the private and public sectors, who would bring competence to this body from the fields of law, economics, science in its broadest definition, physicians, hospital administrators, health insurers, and consumers. We think that such a council is essential to provide advice and expertise in the entire area of policy setting and program development.

<u>National Institute for Health Statistics and Epidemiology</u>

Section 103 of S.2466 would amend Section 306 of the Public Health Service Act to rename the National Center for Health Statistics, the National Institute for Health Statistics and Epidemiology, and incorporate it under the NIHCR. The NIHSE would be expanded not only to conduct health surveys, but also to coordinate health data collection in the Department of HEW and to undertake an expanded program of epidemiology and data analysis. The AHA supports the expansion of the existing health survey function as outlined above and recognizes the importance of coordinating and supporting not only the health data collection efforts within the Department but also data collection and analysis activities which are carried out in many nonfederal areas.

With regard to the National Committee on Vital and Health Statistics, we recommend that it include appropriate representation from the hospital industry, third-party payers, and parties concerned with issues of confidentiality of data.

<u>National Center for the Evaluation of Medical Technology</u>

Section 104 of S.2466 would amend Section 306 of the Public Health Service Act by establishing a new unit, the National Center for the Evaluation of Medical Technology. The AHA commends the authors of this bill for their efforts in addressing this important area. We clearly recognize not only the importance but also the complexity of medical technology evaluation.

In our review of the responsibilities that are assigned to this center, we note that they range from those which consider the safety, efficacy, effectiveness, cost effectiveness, and social, ethical, and economic impact of particular technologies, to those which involve the evaluation of methods for measuring the quality of health services and the effectiveness of administration and enforcement of quality assurance programs. These latter responsibilities in many ways include subject matters that might well be assigned to the NIHPR. Such categorization difficulties highlight the fact that no pattern has been established for such efforts, and that considerable study of the appropriate structure for managing this task is needed before any rigid boundaries are established.

In the activities of this center, as in those of the other institutes included in the NIHCR, we believe that it is important there be recognition of a very significant responsibility which will have to be carried out in the nonfederal sector. While supporting the legislation's provision for establishment of an advisory council for the NCEMT, we suggest that, because of the overlap of activities among the NIHPR, NIHSE, and NCEMT--all of which will have impact on evaluations of medical technology that will be conducted, as well as, "to the extent practicable, the development of exemplary standards, norms, and criteria concerning the utilization of particular technologies"--consideration be given to the development of an overall council. The overall council's responsibilities would encompass those of the NIHCR, with other advisory committees or councils responsible for the specific activities, respectively, of the NIHPR, NIHSE, and NCEMT.

With particular reference to the proposed Council for the Evaluation of Medical Technology, and in recognition of the far-reaching effects of the recommendations which the council will provide, we believe that it should include specific representation from major health care constituencies. These constituencies will be affected by the recommended codes, criteria, and standards and therefore should have the opportunity for input. The bill provides that the council membership include 16 persons (seven from the fields of medicine or science, two from economics, and two from law, as well as five whose areas of expertise are not delineated), and certain specified ex officio members from departments of the federal government. We urge that there be a definition of members from medicine, as well as from the broader area of science, and that there be representation from hospital administration.

We are concerned about the application of recommendations that result from the evaluation of medical technology. The drafters of S.2466 seem to recognize this problem. The bill states that "after consultation with appropriate public and private entities," the council should "develop, <u>when appropriate and to the extent practicable</u> [emphasis added], exemplary standards, norms, and criteria concerning the utilization of particular medical technologies." It is important to recognize that there are many examples in medicine, and in other areas, of early development of technologies which, on first review, appeared to provide little clinical promise, and from a cost benefit aspect seemed inefficient. However, after further development, they became both promising and cost effective, resulting in technologies of benefit both for clinical and/or administrative purposes. It is therefore exceedingly important that, in the development and implementation of this legislation, those exemplary standards, norms, and criteria which are developed encourage, rather than stifle, initiative, creativity, experimentation, and flexibility.

Authorizations

The AHA believes that the authorizations as identified for each of the activities within the NIHCR reflect the important element that such funding will play in the assistance and development of nonfederal activity. We believe, as we have indicated before, that there is need for federal intramural activity in this area. We are strongly convinced, on the other hand, that the vast majority of this activity will have to be conducted in the nonfederal arena, as is done in the National Institutes of Health. It is our understanding that approximately 83 percent of National Institutes of Health expenditures are in the nonfederal setting, and we would recommend that authorizations for funding the NIHCR recognize this long-established research pattern.

Conclusion

We wish to express the Association's appreciation for this opportunity to present our comments and recommendations on S.2466 and to offer our assistance and technical support in the strengthening of this legislation.

Senator KENNEDY. The subcommittee stands in recess.
[Whereupon, at 3:23 p.m., the subcommittee was adjourned.]

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