Appendix F.—Model for an Institute for Health Care Evaluation*

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Rationale

Current Federal policy is to reduce the Government's responsibility for health care, substituting wherever possible market mechanisms, and to vest residual control in regional and local authorities. Towards this end, the Reagan administration has recommended to Congress sharp reductions in expenditures for medical technology assessment. This approach is reflected in the failure to fund the National Center for Health Care Technology (NCHCT) and major cutbacks for the National Center of Health Services Research (NCHSR), the National Center for Health Statistics, and the Office of Research and Demonstrations of the Health Care Financing Administration (HCFA).

The budget of the National Institutes of Health (NIH) has been relatively spared, but, with even modest decreases in NIH funding, any cutbacks can be expected to occur primarily in the areas of evaluation and clinical trials (4). This reduction would occur at a time when the pressures for more comprehensive evaluation are increasing, both from academic institutions and from private and governmental insurers. One partial solution to this conflict might be to develop a private Institute for Health Care Evaluation (IHCE), which would operate as a nonprofit corporation (perhaps replacing NCHCT) and extend the Nation's capacity to evaluate medical technologies.

IHCE could be composed of members from several groups concerned with the evaluation of health care: governmental insurers (HCFA); private medical insurers (Blue Cross, Blue Shield, and commercial carriers), health maintenance organizations (HMOs); professional associations (represented, perhaps, by the Council of Medical Specialty Societies and its program for clinical procedure review); and health consumers. Each of the parties could benefit from the data that IHCE generated. Health care professionals could use the data to improve the quality of patient care; health consumers could have increased information on which to base their selection of coverage; and insurers could have access to data allowing them to make more rational and timely coverage and reimbursement decisions.

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Technology assessment is a classic illustration of free-market failure—i.e., market forces will not compel the generation of the optimal amount of performance data essential for the effective and efficient running of the system. Thus, the responsibility for assessing medical technologies cannot be left to the unaided, competitive forces of the marketplace. Because they would receive direct financial benefits, both Federal and private insurers would be expected to provide financial support for IHCE's work. However, because they have vested interests in certain outcomes (e.g., results justifying decreased utilization or advancing lower cost alternatives), these insurers should not have exclusive control of IHCE's operation. In order to maintain its credibility, the organization would have to be governed through a system of checks and balances involving constituent groups.

Goals and Objectives

IHCE's goal would be to generate cost-effectiveness data with a strong emphasis on the measurement of outcomes of therapeutic intervention. These data are needed by medical professionals as a basis for making decisions and informing patients about their choices in medical care; they are needed by health care consumers who are increasingly expected to assume responsibility for their own health and to participate in therapeutic decisions; and they are required by the insurance industry in order to design rational health insurance plans. Adequate technology assessment represents the core of the two major issues facing health care today: 1) how best to employ complex technologies, old as well as new, to meet the public's medical needs; and 2) how to limit the costs of medical care without jeopardizing its quality.

The proposed IHCE would have four major objectives:

- development of a uniform data base;
- systematic identification of agenda issues;
- generation of new data and analyses; and
- dissemination of information to carriers, professionals, and the public.

The achievement of the first objective, development of a uniform data base, is necessary to facilitate the collection of information from diverse sources. At

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present, a modest amount of relevant but often nonuniform data is generated by many health providers. For example, the Kaiser Foundation Health Plan, as part of patient registration, collects detailed information on service utilization at its various hospitals and clinics, then aggregates the information on a regional basis for planning of resource allocations. The proposed IHCE could develop guidelines for an instrument, e.g., a patient registration form, which could serve as both a receipt for billing and method for monitoring utilization and identifying new procedures. Decentralization of data storage at a regional, local, or even health plan level would help address the need for confidentiality of the sources of information. Each plan, locality, etc., might store its own standardized data and make these data available to IHCE-authorized researchers.

The second objective of the proposed IHCE, to serve as a communication clearinghouse that would systematically collect priority issues from its members, is an objective that has not been satisfactorily met in the current system, which relies primarily on signals received from claims data. IHCE would have the authority and capability for routinely surveying professionals to elicit their opinions about the future directions of innovations in their specialities. This model is currently being used by Kaiser-Oakland's Technology Assessment Division. Innovations and medical problem areas could also be identified in a number of other ways, including systematic literature reviews and monitoring of professional meetings. The patient registration forms could act as one "flagging" device. This task might be under the purview of existing and surviving Professional Standards Review Organizations (PSROs). Finally, health plans, private enterprise, and others might directly identify a new procedure and request evaluation by IHCE.

IHCE's third objective would be to participate in the generation of new data, specifically, through the support of clinical trials, retrospective studies, data banks, and possibly surveillance. Currently, a small number of clinical trials are funded primarily by NIH, but it can be anticipated that the NIH investment in this function will diminish in the near future (4), and currently proposed legislation specifically enjoins NCHSR from funding "clinical" studies. Clinical trials, although complex, time consuming, and resource intensive, remain the best method for determining the relative value of alternative medical technologies. Rather than being retreated from, clinical trials should be used more extensively within the limitations of their methodology and the clinical circumstances.

The fourth objective of IHCE could be a second function of its communication clearinghouse: dissemination of results of analysis back to the participants. Such dissemination could be achieved though the provision of access to computerized information, which could include annual reports, strategic objectives, findings of prior assessments, and listings of studies presently in progress. Participants would then be able to incorporate these results as they saw fit into their respective decisions. The proposed IHCE would ***not*** have responsibilities in policymaking. Its responsibilities would rest solely in the areas of data collection and analysis.

Funding

The perception of a need for an IHCE is based on the recognition that health care assessment is a public good. The marginal cost of assessment for any individual or group generally far exceeds the marginal benefit derived for any individual or group. The generation of information as a public good creates a "free-rider" problem. After an individual or group pays to determine that a particular procedure, protocol, device, etc., is more cost effective, the very act of capitalizing on that information makes it public knowledge; the information is freely available to other individuals and groups who did not share the cost of making the determination. The ethics of medical care encourage the early and broad dissemination of information.

The proposed IHCE would be a nonprofit organization funded by a per capita assessment or levy to be received from all qualified health plans. The funding for IHCE could be established on either a mandatory or voluntary basis.

With a mandatory system, health plans (for-profit and nonprofit) would be required to support IHCE as a condition of their receiving recognition as a "qualified" health plan—and therefore becoming eligible to receive tax credits, vouchers, or Medicare payments. To prevent the problem of free-riders (i.e., competing insurance programs which gain access to information without paying for the costs of its generation), a fee would be required to support IHCE. Although there are increasing numbers of industries that self-insure for their employees' medical care, most still carry administrative contracts with private insurers (or claims administrators). Under a mandatory structure, the fee for health care evaluation would be a required component of this administrative contract.

Other service organizations have set up similar models of cooperative research. One model is the Electric Power Research Institute, which assumes responsibility for part of the research agenda of the electric power providers. Participants in the Electric Power Research Institute contribute to the support of the institute without resorting to taxation such as that pro-

posed in the mandatory version of IHCE suggested above, However, their situation differs from that of health care in two significant respects. First, the electric utilities do not compete with one another; they are a regulated monopoly. Second, these utilities all have a cost-based price regulation, allowing them to pass the cost of membership directly on to the consumers.

A second model for cooperative research is the Health Effects Institute, a nonprofit organization established in 1980 to stud, the health effects of automotive emissions. This institute is funded jointly by grants from governmental and charitable services and by additional funds contributed by participating automobile manufacturers according to a formula developed by industry. The Health Effects Institute is an independent organization that has no actual governance link to the Environmental Protection Agency, automotive industry, or public participants. Its health research committee establishes research priorities, develops research programs and protocols, obtains exhaust samples from manufacturers, and contracts with research centers to perform specified tasks.

Yet another example of voluntary cooperative research comes from the insurance industry itself. The Insurance Institute for Highway Safety, founded in 1959, is a nonprofit corporation established to study the contributory factors of drivers, vehicle design, and roadways to highway safety. The Insurance Institute's annual budget is based on contributions from three automotive insurance trade associations and one associated insurance group (whose members do not belong *to any* of the trade associations). These groups, in turn, raise their contributions from individual *com*-panies on the basis of their total premiums. The research protocols are developed by the Insurance Institute and contracted out to academic research centers. These voluntary models might not be feasible in an increasingly competitive health care environment, where some carriers could gain access to the information without paying for it and, thus, offer lower rates to subscribers than could carriers who were contributing members of IHCE.

Nevertheless, it might be possible to fund IHCE through voluntary contributions. Although this would create the free-rider problem described above, it might also alleviate some of the initial resistance to the establishment of such an institute. With voluntary funding, there would still be a membership fee required of all participants, which would cover IHCE's basic administrative costs. IHCE's governing body would develop an agenda of research topic alternatives on which the members of IHCE would vote. Alternatives would be given priorities by the membership, and members would subscribe in advance to cover the costs of conducting specific research studies.

What it would cost to develop the proposed IHCE is of obvious concern to those who would be expected to bear the burden of expenses. Relman has suggested that two-tenths of 1 percent (0.002) of expenditures for medical care might bean appropriate sum to allocate for this purpose **(9).** Since the current expenditures for medical care of private insurance and HCFA are approximately $160 billion **and $85 billion, respectively, this would amount to nearly $500 million. Whether this is more or less than the task will require is by no means clear. If IHCE succeeds in its mission, this will be a small price to have paid. Indeed, as some suggest, the potential savings that could be expected to accrue as a result of better data on cost effectiveness would be many times greater than this amount (3,9).**

IHCE's success, however, cannot be guaranteed. Therefore, rather than making an all-to-nothing commitment to a program of this magnitude, it would be prudent to proceed in modest steps. To test the proposed IHCE's potential, its board or council might begin by identifying those areas of medical care deemed to be in greatest need of evaluation, raising funds by assessment as needed for each subject of inquiry or analysis. Indeed, this would appear to be an appropriate method for the future funding of all projects: funds being generated only as the potential users of information judge necessary and appropriate.

Mechanism and Structure

IHCE could select topics **for evaluation from those generated by its technology** surveys. The topics would be given priority by the appropriate committee (board of directors or council). IHCE would let out contracts for clinical trials, retrospective studies, and technology assessments to carriers, as well as contracts for data analysis to professional organizations. In addition, IHCE would review and fund independently submitted proposals for clinical trials and for technology assessment. For example, investigators planning new procedures might apply directly to IHCE for funding, including the clinical costs of particular innovations. IHCE would coordinate its activities with those of other research organizations such as the disease-specific private foundations and Federal research agencies such as NCHSR, NCHCT (if funded), NIH, and the Food and Drug Administration.

It is anticipated that IHCE would be able to use some already established mechanisms for data collection, including claims data, health systems agencies (HSAs), and PSROs. HSAs and PSROs may succumb to current budget cuts, but the evaluation capabilities

developed by the more successful PSROs could profitably be put to work on contract by IHCE (8).

Although the agenda would be set as a consensus at the national level, most of its implementation would take place under local control and responsibility. Individual institutions, through their institutional review boards, would determine whether proposed new or experimental procedures are used with appropriate standards for patient safety and whether standards for informed consent have been met.

The proposed IHCE would be governed by a board of directors or council composed of representatives from member groups: private insurance carriers, governmental insurers, HMOs, professional associations, and consumers. In addition to topical subgroups, there would be specific departments for legal affairs, communication, and publications.

Concerns With the Model

Legal Problems

Funding Sources.—If funding for IHCE were mandated by a tax, levy, or assessment to be paid by all insurers according to the number of individuals they cover, it would require new legislation. A Federal tax would presumably violate the current position of the insurance industry, which has been exempt from Federal legislation under the McCarran-Ferguson Act. Thus, taxation on private carriers would represent a substantial departure from this position. A tax on nonprofit organizations, including Blue Cross and Blue Shield and HMOs, would present similar problems. However, such a recommendation has a precedent in a recent proposal by David Stockman, Director of the Office of Management and Budget. This proposal, the Gephart-Stockman National Health Care Reform Act, would levy a tax on health insurers to provide funds for insuring subscribers against the financial failure of their selected health plans, The alternative of voluntary funding does not present these legal problems.

Research Authority.—Current insurance trends are generally to avoid involvement in research except under certain explicit circumstances. Therefore, it is uncertain on what legal grounds insurers would participate. Some legal advice indicates that insurers do have a research authority, but this concept is not explicit nor does it appear to have been tested in the courts.

Antitrust. -Various insurers have suggested that the operation of IHCE might be in violation of the Sherman Antitrust Act. However, it should be noted that many commercial carriers, through the Health Insurance Association of America, already jointly use the coverage recommendations of the Council of Medical Specialty Societies based on its program for clinical procedure review. **The program for clinical procedure review identifies clinical procedures that are obsolete, duplicative, or not yet clinically proven.** The Council of Medical Specialty Societies then recommends continuation or withdrawal of reimbursement. The proposed IHCE would differ from the Council of Medical Specialty Societies in that its function would be limited to the development, analysis, and distribution of data and would not include policy recommendations.

Selective Coverage.—The need for selective coverage has been widely recognized by third-party payers. To refuse payment to a hospital on the basis of inadequate experience, equipment, or trained staff, or failure to adhere to published standards, can be expected to lead to litigation—and has already done so. Part of the difficulty results from the wording of current insurance policies and contracts. Future policies should be drawn up explicitly indicating that coverage for specified procedures will be limited to certain providers. (Blue Shield of California is currently exploring the feasibility of contracting with better qualified hospitals and physicians for heart surgery at set prices substantially lower than standard or average fees; this is similar to the arrangement of preferred providers suggested for HMOs by Interstudy (7).) The possible need for legislation to protect third-party payers under such arrangements is deserving of exploration.

Selective coverage for new and experimental medical and surgical procedures might be provided by commercial carriers or by HCFA in conjunction with the proposed IHCE's program, with hospitals and physicians selected for participation in clinical trials on a case-by-case basis. Reimbursement under these ***con***ditions would represent what amounts to a research award and would presumably present less of a threat of litigation by nonparticipating and unapproved hospitals and physicians or their patients.

A serious problem that would remain, however, would be the opportunity for those physicians and/or hospitals not selected for reimbursement for a new (or old) procedure to do it anyway and to submit charges using billing codes for other, standard, procedures. This is one of the difficulties encountered in the current system of reimbursement.

Comprehensive restructuring of the method of reimbursement (e.g., cavitation, prepayment, or payment by voucher) would partially resolve this problem, since a fixed amount of money would be available for all procedures. Additional funds for new procedures would have to be negotiated on a procedure-by-procedure basis. Short of such radical**changes in method of reimbursement, natural forces within the present system may be expected to exert some, perhaps considerable, corrective influence. Malpractice suits**

against physicians who deviate from established standards are occurring with greater frequency. With increasing professional consensus that it is poor practice to perform specified complex procedures on an occasional basis or in facilities not equipped or staffed for such procedures, it can be anticipated that lawsuits will be brought against physicians and institutions that do this. Physicians will be forced to be more circumspect, and hospitals will look more and more to their institutional review boards for guidance in undertaking new and experimental procedures.

Ethical Issues

A fundamental principle of justice that has often been urged is that innovations of established efficacy be available to all of the population. This principle was most dramatically implemented by the Medicare Amendments of 1972, by which entitlement to medical care for end-stage renal disease (hemodialysis, kidney transplant) was conferred on all citizens of the United States. This principle has been repeatedly invoked in policy analyses of the artificial heart program (1), and it underlies current deliberations concerning reimbursement for heart transplants.

Heart transplantation in the United States has been concentrated primarily at Stanford University, where it is now considered an established clinical procedure with survival results comparable to those achieved with cadaver kidney transplants. Funded originally through an NIH research grant, the clinical costs of heart transplantation at Stanford were reimbursed by HCFA from 1979 until early 1981, and many private insurance companies now reimburse for heart transplantation. Relatively few heart transplants have been performed at other institutions, and their combined results have not matched Stanford's. Reimbursement by HCFA has not been made available to these other institutions because of their less satisfactory results. When challenged on this apparent inequity by another institution, HCFA responded by withdrawing reimbursement for heart transplantation at Stanford and announcing plans for a 2-year study of ethical, legal, and economic aspects of heart transplants. This is where the issue now stands.

When a medical or surgical procedure is clearly experimental, there can be no ethical obligation to make such a procedure available to all. An experimental procedure is, by definition, of unknown benefit. It may be better, or worse, or equal to previously available, established therapies or to no treatment at all. It is because of these procedures' unknown efficacy that mechanisms such as informed consent and institutional review committees have been established to advise prospective patients of the risks of such procedures and to reduce the possibilities of harm.

Approval for the performance of experimental procedures must rest on the qualifications of the investigators and on research resources and priorities, not solely on the medical needs of the patients or the availability of reimbursement from the insurers. Local institutional review committees are the appropriate agents to determine whether a proposed research procedure is scientifically and ethically justified and whether the interests of the patient, as experimental subject, are adequately protected. There are clear guidelines for these committees to follow in making these determinations.

The just distribution of efficacious medical care, in accordance with the foregoing general principles, requires better data than the data currently available. It is the exception, rather than the rule, that new therapies are introduced with well-controlled clinical trials leading to definitive evidence of therapeutic worth. In the absence of such data, effective treatments may be withheld or ineffective treatment may be given, Both errors seem likely to occur, in view of the many variations in procedure and hospitalization rates reported by Wennberg and others (12). Both errors, to the extent that they are avoidable, may be considered serious injustices; it is not clear that one is more serious than the other. Neither is it clear which error is the more common. However, there is strong presumptive evidence that when efficacy data are absent, physician-investigators tend to err in the direction of overestimating the potential benefits of therapy (5,6) and that many "unnecessary" procedures are carried out as a result of professional enthusiasm or optimism. The argument that there is widespread overprescribing of therapy has been developed in detail elsewhere (2). Overutilization of unproven medical interventions has immediate and urgent implications for distributive justice. Soon, society will no longer be able or willing to pay for all treatments that might be effective. Purchase of care that is ineffective or of undocumented efficacy for some patients will almost certainly result in the failure to provide effective care to other patients.

Quality of Information

A final and important concern relates to the quality of information to be collected by IHCE. Towery and Perry, at NCHCT, have proposed that "third-party payers, including Medicare . . . make reimbursement to providers contingent on their submitting certain minimal data under a previously agreed on protocol" (11). Sherman, Fineberg, and Frazier, at the Harvard School of Public Health, have made a similar

proposal and have identified a number of contingencies for reimbursement (10), These proposals address the problem from the perspective of an agency whose principal responsibility is to provide reimbursement, and for whom the collection of data is by definition a secondary priority. The mandatory submission of data by medical care providers can also be assumed to be a secondary priority, and the quality of the resulting information may be poor.

The primary responsibility of the proposed IHCE, in contrast, would be to collect reliable information. Grants and contracts would be awarded on the basis of the anticipated quality of that information. Reimbursement for clinical services might be provided in conjunction with the grant or contract, but it would be a secondary consideration.

Discussion and Conclusions

The absence of a consistent and explicit policy of reimbursement for new technologies results in the escalation of charges and at the same time provides incentives to conceal innovations. In addition, there is no single organized and adequately funded program or agency charged with the responsibility for the generation of data with which to evaluate new (and old) technologies. As a result, not only are good outcome data lacking; often it is not even possible to identify when new procedures are performed. Indeed, the current system provides incentives which actively discourage the explicit identification of new and experimental technologies. An additional difficulty is the inability to provide reimbursement for these procedures on a selective basis. This inability makes it impossible to achieve the orderly development and evaluation of new technologies.

Potential remedies for the foregoing difficulties are readily at hand. At the regional and local levels, Medicare contractors, such as Blue Shield of California through its Medical Policy Committee, are already reviewing claims for new therapies. Unproven therapies are currently rejected for coverage, but could, having been identified, be selected for coverage contingent on collection of appropriate evaluation data and/or presentation of an appropriate experimental design.

To justify such a major shift in coverage policy would require major new funding for the evaluative process. There are, at present, instances where funding for clinical procedures and their evaluation is provided on an individual basis, at least in part, by the third-party payer. For example, Blue Shield of Massachusetts has paid the clinical costs of three diagnostic examinations for tumors of the adrenal, kidneys, and pancreas (ultrasound, computed tomography scan, and radionucleotides), the costs of data collection and analysis being funded by a foundation source. Blue Shield of California is funding an analysis of the cost effectiveness of ambulatory surgery. But even such modest efforts severely extend the fiscal capacity of individual insurers—and, at a time of intense competition for subscribers, tend to worsen rather than improve their competitive position. (The individual insurer must charge its subscribers the extra cost, but all insurers can use the information resulting from the investigation.) A resolution of this dilemma might be for the insurers to join in common purpose and to create a joint fund, from which amounts could be awarded by contract for proposals to evaluate specific procedures.

The basic provisions of this option can be summarized as follows: First, an IHCE would be created under the control of: 1) third-party payers, including Blue Shield, Blue Cross, and the commercial health insurance companies; 2) HMOs, represented by the Group Health Association of America and the American Association of Foundations of Medical Care; 3) the Government, represented by HCFA and (if funded) NCHCT; 4) the medical profession, represented by the Council of Medical Specialty Societies and/or the American Medical Association Council on Scientific Affairs; and 5) representatives of the public at large (consumers). Second, IHCE's goals would be: 1) the establishment of a uniform data base; 2) the systematic identification of agenda issues; 3) the generation of new data and analysis; and 4) the dissemination of information to carriers, professionals, and consumers. Third, IHCE would be funded through fees or contributions from public and private insurers (including self-insurers) and/or from HMOs on either a mandatory or voluntary basis. Finally, new and experimental medical and surgical procedures would be selectively covered on the basis of locally approved research protocols and the availability of data for independent analysis.

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