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POLICY ISSUES AND ALTERNATIVES

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A broad range of impacts accompanies the introduction of medical information systems into medical care institutions. Improved quality, coordination, and timeliness of data about patients have been documented. Some institutions have experienced cost savings, particularly in labor expenses. Other anticipated benefits, as well as possible disadvantages, of medical information systems have not yet been carefully studied. Two reasons are primarily responsible for this lack of evaluation. First, those medical information systems in use are, for the most part, prototypes. Second, those applications of medical information systems that may have the broadest impact on the medical care system are least developed. For example, few systems incorporate applications that support clinical decisionmaking and are capable of influencing the quality of medical care. None have been used to produce data on the cost and efficacy of medical care.

Careful consideration of Federal policy on medical information systems is nonetheless worthwhile at this stage of their development. The Federal Government supports basic research on such systems, but has few policy mechanisms to promote or guide the demonstration and diffusion of the technology. The issue of when and how the Federal Government should become involved in the development and use of medical information systems is important for several reasons.

- Existing systems vary in scope, cost, and impact on the medical care system. Consensus has not been reached about the defining characteristics of a medical information system.
- It is unlikely that a strong constituency will form in medical care institutions either supporting or opposing medical information systems. Unlike new diagnostic or therapeutic technologies that impact on special groups, medical information systems improve the use of medical services and affect all providers and patients in a medical care institution.
- Medical information systems are a costly technology. Initial costs for implementation may amount to millions of dollars; and operating expenses in a medium-sized hospital may exceed a million dollars annually.
- Medical information systems are currently installed in few institutions. Recent advances in computer technology, which will lower costs, could lead to rapid acquisition of a variety of systems. Unless the Federal Government formulates a policy toward medical information systems now, development and diffusion could proceed indiscriminately, making standardization impossible.

The range of policy alternatives that follows addresses how development of medical information systems can be directed for maximum benefit to the medical care system. The alternatives discussed are neither exhaustive nor mutually exclusive.

DEVELOPMENT AND DISSEMINATION

Presently, development of medical information systems is conducted by many investigators pursuing different approaches. The commercial computer industry is conducting limited marketing of medical information systems and continuing some research, Grants and contracts from the National Center for Health Services Research support research for some projects. Other Federal agencies (Veterans Administration, Indian Health Service of HEW, Department of Defense) are funding projects for Government-supported medical care facilities. A number of medical care facilities are using internal funding or funds from local government or foundations to develop systems for inhouse needs.

Alternative 1: Continue current research and development policies and allow dissemination of medical information systems to be determined by the open marketplace.

The first alternative available to the Federal Government is to allow the evolution of systems without direct intervention. The Federal Government could continue current levels of funding for research without attempting to influence the kinds of computer systems used in various medical care settings. This policy continues the pluralistic approach that now characterizes the delivery of medical care in the United States. Further, one school of economic thought presumes that in the open marketplace those computer systems benefiting the medical care institution will be adopted, while those that do not will compete unsuccessfully.

Continuation of present policy, however, could have several disadvantages. Because medical information systems support the organization of medical services, administrators of medical care facilities have been their primary consumers. The capabilities of medical information systems for improving institutional efficiency and supporting administrative functions are thus most marketable, as well as best developed, and systems limited to these functions could predominate.

A further risk is that industry will elect to market the technology without additional investments in research and development (R&D). Capabilities of medical information systems to improve and monitor the quality of medical care and to facilitate research and planning primarily benefit the patient and the medical care system as a whole, rather than the institution. Without further development, these potential benefits to the medical care system may be lost, although taxpayers would continue to support a large portion of institutional costs for computer systems through Medicare and Medicaid payments.

Continuation of present policy could also maintain a slow rate of dissemination for medical information systems. Except for the few institutions with the technical personnel, financial resources, and motivation to develop their own computer systems, medical care facilities would have the option of choosing only from among those systems available commercially. Because industry must recover R&D costs

through market prices, institutions without large capital resources (primarily smaller facilities) might be unable to acquire a medical information system.

If Federal action influencing development and eventual use of medical information systems were considered desirable, several strategies could be pursued.

Alternative 2: Establish a central clearinghouse to coordinate developmental projects and provide information to the public about medical information systems.

Conferences, or other forums, could ensure that technical innovations are shared and ideas exchanged. Various medical information systems could be classified and ranked by their capabilities. Guidelines could be developed for use by hospitals and other medical care facilities in selecting, implementing, and evaluating medical information systems.

Because diverse groups are developing medical information systems, representation by all sectors, including public, private nonprofit, and commercial, would be appropriate at these forums. Although the coordinating group need not be a governmental agency, several Federal agencies could perform this function. Since its establishment in 1969, the National Center for Health Services Research has had primary responsibility for medical information systems technology. It has convened a conference for investigators working on automated ambulatory medical records. The Bureau of Health Planning and Resource Development (BHPRD) provides technical assistance to areawide health systems agencies (HSAs), which have regulatory authority over capital investments by medical care facilities. BHPRD currently is funding a study comparing automated hospital information systems that are available commercially. Other offices in the Department of Health, Education, and Welfare might also perform the clearinghouse function. For example in the National Institutes of Health, the Lister Hill National Center for Biomedical Communications has a mandate to develop networks and information systems for improving health education, medical research, and the delivery of medical services.

Having a central organization coordinate information about medical information systems would demonstrate the Federal Government's interest in these computer systems. By increasing public awareness, it might promote adoption of medical information systems. If systems were carefully classified by capability and relative value, administrators would be more able to act as prudent buyers. Furthermore, an approach based on public information would not violate current policy of removing the Federal Government from the direct dissemination of new technologies. This approach, however, holds no incentives for developers to expand the capabilities of systems or for medical care facilities to purchase such systems.

Alternative 3: Provide funding for evaluation of medical information systems in a number of different medical care facilities and locations to determine their effectiveness in terms of relative benefits and costs.

A number of questions regarding medical information systems remain unanswered. Because a medical information system in a medium-sized community hospital is the only one that has been evaluated in depth, * studies of costs and impacts in

● The Technicon Medical Information System at El Camino Hospital was evaluated in an in-house study and by an independent contractor, the Battelle Laboratories.

other kinds of medical care delivery settings are needed. For example, smaller institutions would not necessarily realize the same economies from medical information systems as large facilities. Existing systems have differing capabilities, but it is not known which systems would have the greatest impact in different kinds of settings. The cost effectiveness of systems designed for use in small groups or even solo practices has not been carefully studied.

Priorities on the kinds of medical care facilities that might use medical information systems have not been established. On one hand, priority might be given to teaching hospitals so that detailed data about less common conditions can be made available for research. If, on the other hand, priority went to small hospitals, community physicians could benefit from the capabilities of medical information systems for continuing education and quality assurance.

Funding the evaluation of a sufficient number of medical information systems would provide the necessary information on which policy makers could base decisions. In addition, placement of medical information systems in various kinds of facilities and in different parts of the country would enhance their visibility. Having a number of systems operational could itself spur further adoption.

The National Center for Health Services Research has authority to fund such evaluation projects through grants and contracts to investigators in the field. Medical information systems in institutions operated by the Government could be funded directly by the responsible Federal agencies. No new legislation would be required to implement this approach, although additional funding may be needed.

Alternative 4: Ensure the availability of medical information systems with specified capabilities and applications by contracting for their development.

Additional development of medical information systems is necessary to achieve the full range of anticipated benefits described in this report. To speed development of systems with desired characteristics, the Federal Government could conduct a targeted research and development program. Government could contract directly for the development of medical information systems with specified capabilities and applications.

Under this approach, Government would absorb the larger portion of R&D costs, while private industry would be encouraged to invest its money in marketing the systems and reducing their costs. Targeted development would eliminate duplication of efforts and would ensure the availability of broad-based systems with full capabilities. Without more extensive information than is presently available, however, specifications for such development would be difficult to formulate. Supporting research by grant funds tends to encourage new ideas and approaches. Grants may still be the most appropriate mechanism for developing medical information systems.

Contracting with industry for the development of needed technologies is a common procedure for Federal agencies such as the Department of Defense and the National Aeronautics and Space Administration. The National Center for Health Services Research, however, does not currently have the authority to contract for the development of new medical technologies. Contracts can be used only to obtain specifications for the operation of an existing technology. Enabling legislation limited NCHSR to support of research, evaluation, and demonstration projects. Modifi-

cation of NCHSR Legislation would therefore be required to implement this alternative.

Alternative 5: Provide incentives for medical care facilities to adopt medical information systems that improve the quality of patient care and support research and planning.

Even after medical information systems with full capabilities have been developed and tested in the field, several factors could discourage their purchase. Medical information systems must compete with other technologies for the financial resources of medical care facilities. They compete directly with computer systems designed solely for administrative and billing purposes. The functions of these subsystems would be subsumed by medical information systems, but management and financial systems are well established, have proven capabilities, and can usually be purchased at lower cost than medical information systems.

Current payment methods encourage the adoption of technologies that produce revenues for the institution. Thus, facilities might invest in new diagnostic and therapeutic technologies instead of medical information systems. Hospitals can itemize patients' bills for tests and procedures, but not for the services of medical information systems, which are included as a part of a daily inpatient rate. Furthermore, the practice of public programs paying on the basis of "reasonable costs" does not create a strong incentive for institutions to adopt cost-saving technologies, although medical information systems can reduce some institutional expenses.

The Federal Government could promote the dissemination of medical information systems through appropriate incentives and sanctions for medical care institutions. Two possible mechanisms could be employed: regulatory authority over capital expenditures and direct subsidy.

Under section 1122 authority of the 1972 Amendments of the Social Security Act and, in many States, under certificate-of-need legislative authority, local health systems agencies (HSAs) review and either approve or deny hospital applications for capital expenditures over **$100,000.** Under Federal guidelines, these HSAs could deny applications for computer systems that do not meet specified capabilities. The Bureau of Health Planning and Resource Development (BHPRD), which supplies HSAs with technical advice, could issue guidelines to define acceptable computer applications.

The Federal Government could also directly subsidize the purchase of medical information systems. Grants, loans, loan guarantees, or interest subsidies could be given to institutions purchasing approved computer systems. Such financial assistance could be a strong incentive for implementation of computer systems by medical care facilities otherwise lacking sufficient capital.

Existing legislative authority allows NCHSR to make grants available to nonprofit institutions for the demonstration of medical **care technologies.** Health systems agencies could also give grants from their area health services development funds. State health planning and development agencies could make loans, loan guarantees, and interest subsidies available from health resources development funds. This latter alternative would require amending legislation by Congress. Health resources development funds are now restricted to modernization projects of facilities and exclude the purchase of new equipment such as medical information systems.

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CONTROL AND STANDARDIZATION

Beyond the development and dissemination of medical information systems, initiatives by the Federal Government could ensure uniform impact of the computer systems. Controls on medical knowledge incorporated into medical information systems would maintain the quality and credibility of the computer systems. Standardized patient data bases would permit PSROs, planners, and researchers to use medical information systems. Issuance of standards could protect the confidentiality of computerized patient records. In each case, the professional groups affected should be consulted. The following alternatives address these issues of standardization.

Alternative 6: Charge a central organization with authority for developing, validating, and maintaining the content of medical knowledge within medical information systems.

Without controls on the entry of medical knowledge into medical information systems, therapies, drugs, or tests of unproven efficacy could be incorporated as guidelines for physicians in computer programs. A central organization could control and accredit the content and distribution of medical knowledge frames, All systems would thus contain carefully researched medical information of uniform quality. Having a central organization distribute medical content frames would also ensure the dissemination of new medical knowledge as it becomes available.

The National Library of Medicine in the National Institutes of Health has recognized expertise in the area of medical information. It, or a newly established organization, could be funded and staffed to perform this function.

Alternative 7: Develop standardized medical data bases, including nomenclature, terms, definitions, classifications, and codes, for use in medical information systems.

A standardized data base would permit the coordination of medical information systems with health data systems. If standardized, data from different medical care settings and geographic areas would be comparable and could be used for research and planning. More uniform specifications of data base content would expedite the transfer of the technology by enabling the production of multiple copies of systems and fewer "custom-built" applications, Similar research and development in the standardization of programing languages also would be required so that software could readily be exchanged among systems.

The National Center for Health Statistics (NCHS) is the Federal agency charged with providing general-purpose health statistics on the Nation's population. Many activities of NCHS bear upon comparability and definitions of medical data. The U.S. National Committee on Vital and Health Statistics is an independent panel of experts who serve in an advisory capacity to the Secretary of DHEW. The National Committee has recommended minimum uniform data sets for different medical care settings and is now conducting a review of the classification of diseases. These groups, or others, could direct development of standardized medical data bases.

Alternative 8: Establish guidelines for precise standards to protect confidentiality of patient data within an institution and release of identified data to third parties.

Unauthorized access to patient data within an institution is a potential danger of medical information systems. Standardized security precautions and careful delineation of staff responsibilities would minimize this risk. Computerized patient files also make detailed data available to outside organizations. Laws and policies that define limits on data sharing could be developed as well as mechanisms to police these boundaries. The National Bureau of Standards in the Department of Commerce, which has recently supported a detailed study on computers and health records, is one agency that could develop standards and recommendations to protect the confidentiality of patient data.