Chapter I

INTRODUCTION

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PURPOSE

In this report, the Office of Technology Assessment (OTA) examines:

- The need for assessing the social impacts of each new medical technology while it is still being developed.
- The kinds of questions that might be asked in such an assessment.
- By whom and at what point in the research and development process assessments could be conducted.

These issues reflect the concern that modest, unexamined investments in biomedical research and development can sometimes lead to large, unexpected costs, both human and financial, in the medical-care system.

The assessment of the potential social impacts of new medical technologies while they are still being developed might serve two important purposes:

- Information obtained from assessments could be used in formulating policies to insure that research-and-development funds are invested wisely. Once the benefits and drawbacks of a particular new technology are considered explicitly, its development might be expedited or constrained, Priority might be given to development of alternative forms of the technology that minimize drawbacks or maximize benefits. One specific issue, for example, concerns whether to invest funds to develop medical technologies that would benefit the greatest number of people, even though such technologies might take many years to develop, or whether to invest those funds in developing technologies in the immediate future that could provide great benefit to (or even save the lives of) relatively few people. Assessment could not, of course, resolve this dilemma, but it might better inform the decisionmaking process that must occur.
- Assessment might provide information that could improve the process of planning for the eventual introduction of new medical technologies into the medical service system. Societal changes that might be required for or result from introduction of a new technology might be anticipated. For example, if programs of medical cost control **are** deemed to be desirable, they could be designed more effectively if information about the nature and potential impacts of new technologies were available before the technologies enter widespread clinical use.

SCOPE OF THE STUDY

This report discusses possibilities for and obstacles to assessing the social impacts of new medical technologies during the stages of research and development that precede their widespread acceptance.

- Technology is defined as "science or knowledge applied to a definite purpose" (86). Thus, medical technology includes all elements of medical practice that are knowledge-based, including hardware (e.g., equipment and facilities) and software (e.g., knowledge and skills) (83, p. 31; 166). Medical technology is defined as the set of techniques, drugs, equipment, and procedures used by health-care professionals in delivering medical care to individuals and the systems within which such care is delivered.
- The social impacts of new technologies can be assessed in a variety of ways. Technology *Assessment* is a form of policy research that purports to provide a systematic and comprehensive format for considering the broad implications of introducing a new technology. Effective assessment may also be accomplished in administrative, public, or academic forums, however, by methods that do not fit the definition of technology assessment.
- The term research and *development* refers to a variety of activities whose purpose is to acquire knowledge and then to apply it to the creation of clinically useful medical technologies. These activities include basic research, applied research, targeted technology development, initial human use, clinical testing, and early stages of experimental clinical practice.

There are five principal boundaries on the scope of this study. The first concerns the types of medical technology. Medical technologies are used for five different purposes: prevention, diagnosis, treatment, support, and administration. Technologies of the latter two classes are not discussed in this report. Similarly, many technologies that may have great impact on health but that do not fit within this definition such as food-producing technology or technology for improving the environment are excluded from consideration in this report.

A second boundary on the scope of this study is in the kinds of concerns addressed. Medical technologies pose both technical and social problems, but only the latter are considered here. Methods for assessing technical factors, such as safety and efficacy, will be examined in a subsequent report from OTA.

A third boundary is that the study focuses on research and development but does not examine ways to assess technologies that are already in use. This is an important limitation because many of the problems posed by the use of medical technology can be addressed only by assessing the system of health-care delivery within which they are used.

A fourth boundary is that the study describes ways to assess the impacts of medical technologies while they are still being developed, but does not consider how one might evaluate the social utility of biomedical research, per se, or of particular programs of research. Research aimed at the generation of new knowledge and unrelated to the development of new technologies could not be assessed by the methods described in this report.

The fifth boundary concerns proposals for implementing technology assessment. Although the report discusses biomedical research and technology development in broad terms, and presents a general framework for assessment, the policy options refer only to Federal agencies.

Note.—Figures in parentheses indicate reference sources in Bibliography.

ORGANIZATION OF THIS REPORT

Chapter II points out both the need for and the difficulty of assessing the social impacts of new medical technologies. Nine short case histories are used to illustrate the diverse nature of medical technologies, the complexity of technology development, and the variety of problems that technologies pose. (A more detailed and systematic description of how medical technologies are developed is presented in app. A.)

Chapter 111 discusses the types of impacts of new medical technologies that need to be assessed. These impacts may result either from the economic burdens imposed by widespread use of a new technology or from indirect benefits and drawbacks of the technology itself. The chapter contains a list of questions that might be used to elicit information about the impacts of new medical technologies on the individual (patient), on families and populations, and on social, medical, economic, legal, and political systems.

Chapter IV describes a method, technology assessment, that can be used to identify and evaluate the potential impacts of introducing a new technology. The strengths and limitations of this method are discussed, and some alternate modes of assessment are presented. This chapter also considers criteria for selecting medical technologies to assess, steps in conducting a medical technology assessment, and ways in which the results of medical technology assessments might be used.

Chapter V summarizes the possibilities for and limitations of social-impact assessment and then presents policy alternatives for implementing programs of technology assessment at Federal agencies such as the National Institutes of Health (NIH) that develop or support the development of new medical technologies.

DEVELOPMENTS IN MEDICAL TECHNOLOGY

This artificial heart kept a calf alive for a record 1451/2 days. The inflow valve of the right heart is removed to show the dark surface of the rubber diaphragm.

Nuclear-powered cardiac pacemaker (left) and heart electrode. The electrode normally is in contact with the left ventricle of the heart.

This renal dialysis machine purifies blood through an artificial kidney.

Photos COURTESY Cleveland Clinic, NIH