EDITORIAL

CONSENSUS DEVELOPMENT

An Historical Note

Seymour Perry
Georgetown University Medical Center

The National Institutes of Health (NIH) has always carefully limited its responsibilities to biomedical research and knowledge development, including clinical trials, dissemination of results of research, and training. Ten years ago, NIH undertook to examine its possible role in the evaluation of medical technologies.

In 1976, the U.S. Congress became alarmed over the increase in health care costs: in particular, that a number of expensive technologies, such as coronary artery bypass surgery and electronic fetal monitoring, had entered the delivery system without adequate study of their safety, efficacy, cost, or other implications. At the time, there was no formal structure or forum in either the executive branch of the government or in the private sector for seeking a consensus that a medical innovation was actually safe, beneficial, and ready to be transferred into the health care delivery system. Similarly, there was no structured process through which the parties who comprise the delivery system could meet with representatives of the research community to examine the medical-scientific issues surrounding a given innovation along with cost and cost-effectiveness, ethics, and other societal issues of importance to the system.

It was recognized that clinical trials, academic medical centers, textbooks, and review articles all provide, in one way or another, a sort of consensus, but in the absence of any formal structure, such consensus is achieved in a limited, incomplete, and erratic way.

In March 1976, Senator Jacob K. Javits of New York (1) wrote to Donald Fredrickson, the then new director of the NIH that

> I am deeply concerned with respect to the value and cost of the diffusion of medical technology . . . certain technologies are raising concern. The medical profession, acting from [an] understandable desire to help sick people as far as possible, has often accepted innovations in practice only to have them later prove to be of limited value or dangerous.
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> Society is faced more and more, I believe, with difficult choices when technologies of limited value are exceptionally expensive, unsafe, or raise other serious societal and ethical problems.
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> We must assure that medical practice is on as firm a scientific footing as possible. We must assure that the cost-benefit equation, in both monetary and

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human terms is positive. And we must assure that other impacts on the general society will, if not always positive, at least not be overly burdensome or deleterious.

In a December 1976 speech, Senator Edward Kennedy of Massachusetts (2) asked,

> Can we in some way aim our biomedical research capacity at evaluating and improving the scientific base for ongoing clinical practice? Shouldn't some institution in our society have an ongoing function of reviewing not just new knowledge that might be transferred into clinical practice but also old knowledge that underpins current procedures involving risks, high costs, or simply great inconvenience to millions of patients in order to determine what needs to be changed, updated, or further researched?

In response to such congressional concerns, the director of NIH commissioned a study to define the role of NIH and the biomedical research community at the interface between research and the delivery of health care. It was my good fortune to head that study, which, in February 1977, resulted in a "white paper" entitled "The Responsibilities of NIH at the Health Research/Health Care Interface" (4).

The cardinal principle enunciated in that document was that NIH — playing the role of a catalyst while involving appropriate members of the research community as well as professional and other relevant organizations — would seek "a technical consensus" on "the clinical significance of new findings; whether validation for efficacy and safety has been adequate, and if not, what more needs to be done; what cost, ethical or other social impacts need to be identified for caution when formal recommendations are made" (4).

The NIH insisted that this concept had to be complemented by another mechanism, "interface consensus," where the broader health care delivery issues could be addressed before recommendations for entry of an innovation into the delivery system were implemented. Interface consensus would deal not only with safety and efficacy, but also with cost, cost-effectiveness, and legal, ethical, and other societal issues.

The Office of Medical Applications of Research (OMAR) was then established and the first consensus development conference dealing with breast cancer detection, particularly mammography, was held in September 1977. In November 1978, a mechanism for interface consensus was created when the National Center for Health Care Technology was established by law.

What is "consensus"? There are three definitions: (a) group solidarity in sentiment and belief; (b) general agreement, unanimity, accord; or (c) collective opinion, the judgment arrived at by most of those concerned.

NIH adopted the third definition for the consensus development program; the "collective opinion" or the opinion of *most* of those concerned.

But others have viewed "consensus" somewhat differently. For example, Mark Twain (6) wrote:

> Then there was consensus about it. It was the very first one. It sat six days and nights. It was then delivered of the verdict that a world could not be made out of nothing; that such small things as sun and moon and starts might, maybe, but it would take years and years, if there was considerable many of them. Then the consensus got up and looked out of the window, and there was the whole outfit spinning and sparkling in space: You never saw such a disappointed lot.

In this era of sophisticated technology, a computer program was even developed to expedite consensus development. This was "The Consensor" which was billed as a "new tool for decision makers" (5). In essence, this system provided a terminal for each participant in a consensus development exercise. Participants could then cast a "secret ballot" and the different degrees of agreement would be determined.

On September 29, 1980, a humorous piece by Eugene McCarthy and James J. Kilpatrick (3) in the *Washington Star* (Washington, DC) concluded that consensus "has no before. It has no after. It is a coming together not unlike an aardvark, which did not evolve from any other animal and is not evolving into any other. It follows that it is no easy job to generate a Consensus."

As the NIH Consensus Program evolved and after a few consensus development conferences had been conducted, there were objections raised in parts of the medical profession. One heard statements such as:

1. "Consensus recommendations will become regulations."
2. "Consensus statements create the danger of being forced to perform 'cookbook therapy'."
3. "Individual physicians may not be permitted to make diagnostic or therapeutic decisions."
4. "Physicians may be coerced into practicing medicine dictated by government-appointed committees."
5. "Medicine will increasingly become a matter of legislation."

The head of the American College of Surgeons suggested that surgeons boycott consensus development conferences. A medical professional society threatened to sue NIH and the participants in one conference.

In 1982, consensus development took on an international dimension when a conference on hip replacement was convened by SPRI in Sweden about two months after an NIH conference on the same topic. Subsequently, other countries have engaged in consensus development including Britain, Canada, the Netherlands, Denmark, Norway, Finland, and Israel, although in most instances the process has been modified from the original design.

Determining the impact of the recommendations emanating from these conferences has been difficult, but it seems clear that in certain instances, physicians' behavior has been affected, yet in other instances, there apparently has been no effect.

Although the concerns expressed over the potential consequences of consensus development have not come to pass, there has been criticism of the process both in the United States and in other countries. There have been charges that the data provided to some panels have been incomplete, that they have been over-interpreted or misrepresented, that recommendations have been made in the absence of supporting evidence, and that there has been bias in the composition of panels and speakers.

Nevertheless, it seems clear that in the United States, at least, the program has achieved a certain prominence and importance, and I believe that it has had an overall influence on medical practice and in stimulating awareness of the importance of careful scrutiny of available evidence for safety and effectiveness of the technologies used in delivering health care.

Simply stated, consensus development is the careful examination of the state of the art of a technology in a more formal and structured manner than hitherto. The

traditional approach of a review by one or two experts no longer suffices in the modern era of medicine since the technologies which are now available are often remarkably complex and sophisticated.

In the United States and in many other countries, there is a great deal of preoccupation with containing or reducing health care expenditures, but at the same time there is relatively little attention to quality of care. In my opinion, it is the responsibility of all those concerned with or having an interest in health care delivery to insist that society is afforded the best quality of care within the limits imposed by available resources. In turn, that objective is attainable only if medical technologies are subjected to careful evaluation through consensus development or some other formal and structured mechanism.

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