

Institute for Alternative Futures
Foresight Seminars on Health and Innovation

SUMMARY

TREATMENT PROTOCOLS AND OUTCOME MEASURES:
FUTURE DIRECTIONS
April 22, 1991

The Foresight Seminar explored the following questions:

HOW ARE THESE INFORMATION TOOLS LIKELY TO BE USED TO DETERMINE QUALITY AND DISTINGUISH UNNECESSARY COSTS IN THE 1990s?

- Outcomes research and treatment protocols are establishing the foundation for other tools which will improve quality and eliminate unnecessary costs, such as shared decisionmaking, physician feedback systems, and the use of utilization rates to influence physician behavior.

HOW AND WHEN IS DRUG UTILIZATION REVIEW (DUR) INFORMATION LIKELY TO BE INTEGRATED WITH THESE TOOLS?

- Drug utilization review will employ treatment protocols and outcome measures in the quality assurance process and, as such, will be intimately tied to protocols -- DUR will check protocol use and protocol use will initiate DUR.
- DUR will become increasingly pervasive during the 1990s. Third-party payers will begin to rely on it for reimbursement decisions, and its use by hospitals and HMOs will become more sophisticated.

WHAT IMPACT SHOULD OUTCOME MEASURES AND TREATMENT PROTOCOLS HAVE ON HEALTHCARE FINANCING?

- Outcomes research may be the most appropriate information upon which to base reimbursement decisions. Some third-party payers, such as Blue Cross/Blue Shield, already are using it to justify coverage policy.

WHAT DANGERS OR NEGATIVE CONSEQUENCES SHOULD POLICYMAKERS RECOGNIZE WITH TREATMENT PROTOCOLS AND OUTCOME MEASURES AS THEY APPLY TO PATIENTS, PROVIDERS, AND PAYERS?

- Outcome measures and treatment protocols may stifle innovation unless they are sufficiently flexible.
- Overly rigid outcome measures may hurt certain patient subpopulations.

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**HOW ARE THESE INFORMATION TOOLS LIKELY TO BE USED TO
DETERMINE QUALITY AND DISTINGUISH UNNECESSARY COSTS IN THE
1990s?**

According to **Dr. McGivney**, outcomes research and data will drive both individual clinical decisionmaking and public policymaking by the end of the 1990s, and as such will set the foundation for other tools. These include evolving treatment protocols, shared decisionmaking between patients and health professionals, and feedback to physicians on outcomes. Outcome data also will support implementation of utilization rates which, when shown to a physician, can influence his/her application of specific technologies. They will feed into public policy decisions relating to coverage and the appropriateness and effectiveness of care. Their incorporation into institutional quality assurance mechanisms will have a major influence on individual clinical decisions.

Mr. Angaran asserted that outcome measures are necessary to define quality. In fact, many current definitions of quality health care include the term "desired patient outcomes." A patient with hypertension does not define outcome in terms of lowered diastolic pressure; he or she defines it as not having the disorder interfere with work or sleep patterns. Outcome measures must involve patients and relate to their functional status. Although difficult to construct, once these outcome measures are established, unnecessary costs will be relatively easy to determine because anything that violates the defined protocols will be an unnecessary cost.

Dr. Schoenbaum remarked that the basic cost question is whether or not improved processes will lead to lower costs or just higher quality. Outcomes research has not yet progressed far enough to provide a definitive answer.

Mr. Angaran said that if treatment protocols are designed to detect meaningful patient deviations from the norm, they will serve as explicit criteria for care review. However, no treatment protocol, no matter how detailed, will always be able to predict outcome accurately. To be effective, treatment protocols must be used in conjunction with outcome measures.

Dr. McGivney commented that even though the federal government has funded few outcomes studies, there is a ground swell of support for outcome measures. Insurers, researchers, employers, providers and pharmaceutical firms are gradually getting involved. Further research on outcomes data and applications is critical to shaping the best possible outcome measures. Moreover, such research is a political necessity, because public policy decisions will increasingly be based upon who provides the most direct and cogent data to support their position.

Dr. Schoenbaum asserted that outcomes research is worthwhile, but cautioned that it will be long, difficult and expensive. Much of it is still at an early stage and problems are apparent. For example, a group of large employers and health-care companies jointly involved in a demonstration project on the utility of outcomes management meet in the

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presence of an antitrust lawyer, because health-care companies are still unsure as to what information they can share. Moreover, they do not know what types of information will result from possible comparisons. Such information exchange, however, will eventually help firms determine how to improve their processes.

Dr. Schoenbaum does not see a time line for outcome measures. He envisions an increasing movement toward more management of the processes of care, which will lead to an increased need for the outcomes data that are necessary for determining whether or not processes should be changed.

Mr. Angaran pointed out that protocols have been around for a long time. For example, all major HMOs have detailed guidelines governing the use of all major drugs. Protocols have been shown to have a significant influence on product cost, but their impact on patient health and total costs is less clear. Most organizations say that they will not conduct the studies needed to answer those questions until HCFA and other influential organizations begin to move more vigorously in that direction.

HOW AND WHEN IS DRUG UTILIZATION REVIEW (DUR) INFORMATION LIKELY TO BE INTEGRATED WITH THESE TOOLS?

Dr. McGivney remarked that DUR is basically quality assurance for pharmacotherapy. It may not be necessary to integrate DUR with treatment protocols and outcome measures, but DUR will utilize those systems in the quality assurance process. The outcomes available for a specific drug application will feed into the establishment of treatment protocols, as well as other tools.

During the 1990s, DUR will become much more pervasive. Managed care already has used drug utilization in varying ways; increasingly it will be diffused to other settings as well. There will be an initial focus on the top selling drugs, eventually expanding to encompass all medications. As this occurs, public policy experts will begin to address the use of specific drugs beyond their FDA-approved labeling, and how to provide data to support such use.

Mr. Angaran added that DUR information is already commonly used in many hospitals and HMOs. When they add an expensive drug to their formularies, they already have concurrent criteria that must be met to use those drugs. It is also not unusual for them to use protocol violations to identify drugs for study in terms of overall effectiveness. DUR will be intimately tied to protocols -- checking protocol use and being initiated by protocol.

DUR studies should be done on inexpensive drugs which may be able to reduce total costs significantly by reducing morbidity and mortality (e.g, aspirin therapy for unstable angina).

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From a pharmacy standpoint, the emphasis on product cost, rather than total cost and quality of care, comprises a shortsighted but expedient view. Hospital and HMO administrators have to balance their budgets, and drug expenditures are a definable end point which they can control. What has happened in some institutions is that pharmacists have been forced to act as "cost cops." Pharmacists would prefer to shift their focus to a patient orientation based on "drug optimization" (i.e., ensuring that every patient receives proper drug therapy).

Dr. Schoenbaum said that it is laudable to be interested in total cost, but that is not where the focus is likely to be. Because the public has begun to recognize drug costs as being a major uncontrolled expenditure, increasing attention will be paid to drug utilization in terms of cost rather than outcomes. The public would like to disregard cost but they cannot, which creates an enormous conflict. In general, care providers try to manage the conflict between cost and quality of care by identifying less expensive treatments that have similar results. The greater the flexibility of treatment protocols, the less difficult the conflict between cost and quality will be for health-care professionals.

An audience member noted that OBRA 90 mandates that the states begin Medicaid DUR programs by 1993, and that a key component of these DUR programs will be educational interventions aimed at changing practitioner prescribing behavior.

Dr. McGivney said that the question of how to change physicians' practice patterns is difficult to answer, although relevant research is underway. It should be noted that various forces in the public policy arena, such as patient advocacy groups and third-party payers, are becoming more vocal. This activism is putting increasing pressure on physicians to be more aware of different perspectives concerning practice patterns and to be more receptive to criticism and change.

Dr. Schoenbaum remarked that there have been relatively few strategies for changing physician behavior. Typical ones include educational interventions, reminders, prompts, feedback systems, incentives, and various system supports. Educational interventions have been the least effective because they have been least consistently applied. Practice problems generally occur when physicians are involved in extremely complex care processes and do not receive adequate feedback on treatment outcomes.

WHAT IMPACT SHOULD OUTCOME MEASURES AND TREATMENT PROTOCOLS HAVE ON HEALTHCARE FINANCING?

Dr. McGivney asserted that outcomes data are the most appropriate information upon which to make payment decisions. This already is happening to a limited extent. For example, in its technology evaluation process, Blue Cross/Blue Shield requires that five specific criteria be met before rendering an affirmative coverage recommendation to its constituent plans. Four of those five criteria deal specifically with outcomes. After securing regulatory approval, a technology must: demonstrate sufficient scientific evidence

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to permit conclusions about health outcomes; enhance net health outcome; improve health outcome as well or better than existing technologies, and; produce outcomes under normal use conditions.

Insurers increasingly are looking towards treatment protocols that assess the utility of a particular technology. If information exists from a credible source concerning the status of a treatment for a specific indication, insurers will incorporate that information into their coverage decisions.

Mr. Angaran remarked that DUR has the potential for both increasing and decreasing cost, depending on one's definition of cost. If one looks beyond health care financing to other costs, measurements are difficult, but important nonetheless. For example, if someone is given a drug that makes him drowsy and his drowsiness influences the decisions he makes affecting other people, the total cost of that drug may be much higher than is reflected in its market price. Presently, most examinations of cost are simply inadequate because they do not focus on all effects throughout the system.

Dr. Schoenbaum stated that because outcomes research is going to be slow, it will not have much immediate impact on cost. Treatment protocols could have a significant impact if they were simply to state what treatments would be covered. When that has been done in the past, it has been quite effective. For example, HCFA decided that ambulatory cataract surgery was as effective as inpatient cataract surgery. It set a guideline that was linked to reimbursement, which essentially changed the performance of cataract surgery in the U.S. overnight and saved the U.S. taxpayer a great deal of money. Unfortunately, there are relatively few such examples, because they are politically difficult to devise.

He also asserted that almost everyone conducting outcomes research is focusing on what works, rather than what does not work. Examining what does not work might lead to paring the list of items that currently contribute significantly to cost.

An audience member posed a situation relating to the effect of outcomes measures on coverage decisions. Suppose outcomes research determined that the potential benefits of an expensive treatment would vary greatly for different types of patients. Of those patients, which ones would get the treatment given the cost?

Dr. Schoenbaum stressed that coverage analyses and policy studies do not in and of themselves determine who will receive specific treatments. At some point, someone has to make the difficult choice regarding where to draw the line. There are various rules of distributive justice. However, they do not lead to clear lines. In the future, coverage decisions will have to be made explicitly, rather than implicitly, as is currently the case.

Dr. McGivney said that his organization frequently receives calls from insurance companies trying to make these difficult decisions. Often these questions involve simple case examples that do not take into account important patient-specific characteristics.

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Eventually, some type of organized process will be created to make those decisions. However, no one has yet stepped forward to make these tough choices proactively, leaving the courts -- who typically rule in patients' favor -- to be the final arbiter.

Dr. Schoenbaum said that outcome measures may lead to the stratification of the procedures that are covered. Treatments termed "medically necessary" are likely to be included in standard coverage. For treatments that are termed "medically desirable," patients will be able to purchase supplemental coverage or buy them on their own. This is not a new concept -- it has been done for years with cosmetic surgery. It is simply a matter of applying it to non-cosmetic elective treatments.

In cases involving this type of surgery, **Dr. McGivney** believes that shared decisionmaking involving the patient and physician will enhance the effectiveness of medical care and system efficiency. It will inject subjectivity back into the system, incorporating the fact that patient preferences are scattered across a continuum.

WHAT DANGERS OR NEGATIVE CONSEQUENCES SHOULD POLICY MAKERS RECOGNIZE WITH TREATMENT PROTOCOLS AND OUTCOME MEASURES AS THEY APPLY TO PATIENTS, PROVIDERS, AND PAYERS?

Dr. Schoenbaum commented that because of the time and expense necessary to conduct outcome studies, the people who fund them or who have banked heavily on their success may become impatient for results. Without some short-term, definable impact, there could be a negative backlash that impedes further efforts in this area.

Despite good intentions and sound methodology, all scientific studies are subject to potential errors; this is particularly so with respect to observational studies. And treatment protocols that are based on erroneous data are unlikely to produce good outcomes. Policymakers must be careful not to over-interpret the results of isolated outcome studies as they become available.

Outcome measures and treatment protocols may stifle innovation. However, this is unlikely because treatment protocols will provide innovators with a "gold standard" against which to measure the utility of their innovations.

Mr. Angaran said that the impact on innovation depends on whose guidelines are used. If the guidelines are issued by a large bureaucratic organization that refuses payment if its guidelines are not specifically followed, innovation could be stifled. Since patients typically are seen by several health care professionals, each of these practitioner groups needs to participate in the writing of flexible practice guidelines, if they are to be truly effective.

Dr. McGivney stated that one of the hardest tasks will be preventing the guidelines from becoming too restrictive. Because it is difficult to communicate and meet the needs of individual patient subgroups, overly rigid guidelines based upon outcome measures may

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have a significantly negative impact on some subpopulations of patients.

One of the most difficult questions facing the health care community is the extent to which terminally ill patients should have control over decisions concerning their treatment. With outcome measures, it will be hard to balance patient rights and preferences with cost considerations and the moral dictates of society.

Another major area is technology development, which already has affected medical device companies and will impact drug companies in the 1990s. It is common knowledge that manufacturers must demonstrate to FDA that their products work under ideal conditions. But there is a second approval process, which is becoming more rigorous -- approval by third-party payers. For example, although the FDA approved magnetic resonance imagers in March 1984, Blue Cross/Blue Shield did not agree to cover it until June 1985, and the Health Care Financing Administration withheld its stamp of approval until November of that year. Such delays, which are preventing rapid access to important medical innovations, result from the unwillingness of medical device companies and third-party payers to finance the rigorous studies necessary to ensure a product's medical utility under normal use conditions.