Outcomes Research:
An Investigator's Journey

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Quality of Medical Care

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Introduction

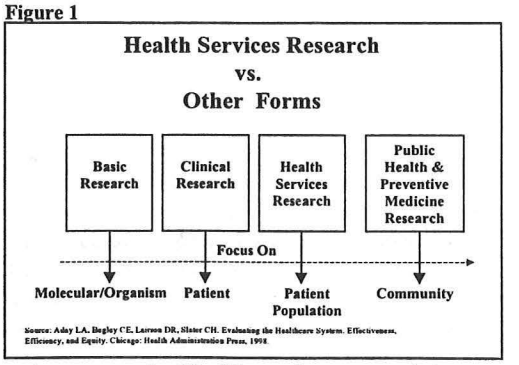
In March of 1998, the Advisory Commission on Consumer Protection and Quality in Health Care Industry released a report in response to U.S. Presidential Executive Order that recommended increasing the funding for basic, clinical, preventive and health services research. This report indicated that outcomes research, which is part of health services research, was critical to the goal of evidenced-based health care in its focus on assessing the effectiveness of treatment and developing new quality improvement approaches.[1]

Current evidence indicates that approximately 80% of commonly used medical treatments have not been shown to be efficacious, because the necessary controlled trials have not been conducted due to methodological problems, the time required for their execution, the expense, or ethical reasons.[2] In addition, because randomized clinical trials are usually performed on highly selected patients at academic health centers, questions have been raised as to the applicability of randomized controlled trials in community practice. As a result, a good deal of uncertainty and disagreement exists among physicians concerning the value of many common clinical practices in all fields of medicine. This uncertainty and disagreement is reflected in the large variations in medical care prescribed for one population or another.[3,4]

One promising approach that has been promoted is the concept of outcomes research. Understanding the link between outcomes and medical care is expected to produce a variety of benefits: providers will distinguish which patients will benefit from specific types of health care; payers will decide which treatments to reimburse; and patients will learn about the consequences of alternative treatments, and thus make more informed treatment decisions.

Outcomes research as used today is a broad term. It involves not only investigations of the link between medical care and outcomes, but also activities aimed at establishing which providers or systems of health care deliver a better quality of care than others. Many authors have advocated that we support and encourage the use of outcomes research to evaluate both the effectiveness and quality of medical care. [5-10] However, despite these recommendations some question whether outcomes research can deliver on its promises.[11] The purpose of this paper is to discuss the development of the outcomes research approach, its limitations, and its potential for fulfilling the expectations of various stakeholders (payers, providers, patients, and the public).

Figure 1



Outcomes research is a part of health services research. Health services research is defined as " a multidisciplinary field of inquiry, both basic and applied, that examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services to increase knowledge and understanding of structure, processes, and effects of health services for individuals and populations."[12] Figure 1 represents health services research in

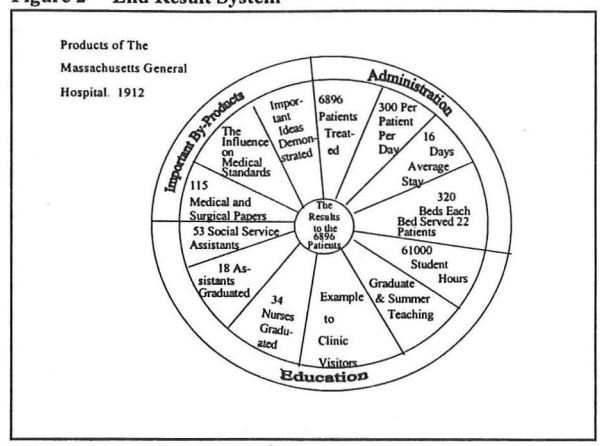
relation to other forms of research. Generally as you move from left to right in this figure, the types of research represent a trend in decreasing experimental control and include larger study groups or populations.

Historical Perspective on Outcomes Research

The foundation of outcomes research is based on the study of naturally occurring events. The importance of using outcomes to assess the value and quality of care has long been recognized by both physicians and the public. The earliest known regulations of the practice of medicine were found in the Code of Hammurabi (c. 1700 B.C.). This code prescribed a series of financial rewards, and financial and physical punishments for physicians based on the outcomes of care accruing to their patients.[13]

The modern history of outcomes research began in 1925, when Ernest Codman, a surgeon at the Massachusetts General Hospital in Boston, created and implemented systematic procedures to evaluate the results of medical care ("end-result system"), even though some of his surgical colleagues viewed his activities as extreme (Figure 2).[13-15] Nonetheless, Codman argued that the "end result system" was essential for improving the quality of care. Codman's basis for the "end result system" was: 1) to find out what the patients' results were, 2) analyze the patients' results, 3) compare the patients' results with those of other hospitals, and 4) publicize the successes as well as the errors.

Figure 2 "End Result System"



Although, Codman's ideas were not adopted during his lifetime, he is now generally recognized as the founder of modern health services research. The argument being that an "end result system" be kept on every patient. Codman suggested that all problems in outcomes be noted and investigated as a way of improving the processes of care. He also developed an elaborate charting system in which cost and a patient's functional status were key variables in measuring a surgeon's performance. Surgeons were to be promoted, based on these evaluations, not just because of seniority.[13-15]

In the 1950s, Lembecke of the University of Rochester, New York calculated per capita surgical rates for the area around Rochester and asked local physicians to review his findings. As a result some high surgical rates were reduced. [16]

In the early 1980s, Wennberg and Gittlesohn at the Dartmouth Medical School began in the field of outcomes research by noting that there was a wide variation in practice between geographic areas, without corresponding differences in health outcomes. They influenced other outcomes research studies.[17]

In the 1980s, the RAND Corporation, led by Brook developed a methodology in which the indications for selected procedures were developed. They then used this methodology to investigate the appropriateness of procedure use in Medicare populations from different geographic locations. They hypothesized that the high use of a procedure in a given area might be explained by a high rate of inappropriateness, and that the low rates might be explained by a low rate of inappropriateness. What they found was that a higher than expected percentage of procedures were clearly inappropriate. They also found that there was little difference in the rate of appropriateness in high-and-low use areas.[18,19]

Together Wennberg and Brook and colleagues contributed the following: 1) Wennberg used hospital discharge data to compare the rates between similar geographical areas and documented widespread variations in the treatment, and 2) Brook and colleagues created a methodology that could be used to rate indications for a wide variety of procedures- a technique that could be useful in developing clinical practice guidelines. These areas of research cast doubt on the high percentage of routine surgeries and procedures being performed and set the stage for the examination of American medicine.[17-19]

Beginning in the early 1980s, the American College of Physicians began developing their own clinical practice guidelines in the Clinical Efficacy Assessment project. The major purpose of these guidelines was to respond to the need for establishing what health care services were associated with the desired patient outcomes at an affordable cost.[20]

In 1988, Ellwood advocated for a national system of "outcomes management." He defined "outcomes management" as a technology of patient experience designed to help patients, payers, and providers make rational medical decisions. "Outcomes Management" was to consist of a national database that would use clinical and financial information to measure the relationships between medical interventions and patient outcomes, and finance. Simply put, he suggested that we find out which efforts receive the best results and at what cost. He proposed that this data would include specific information routinely collected from providers and patients during office visits, before and after surgery and at precise intervals after treatment.[8]

Shortly after Ellwood's article, Relman, who was then the editor of the New England Journal of Medicine, wrote an article entitled "Assessment and Accountability, The Third Revolution in Medical Care." The first revolution being the 1950s-1960s or the era of expansion- a time of strong growth in the supply of hospitals, physicians, and medical specialists, booming clinical and basic science research projects funded by the National Institutes of Health, and widespread access to increasingly sophisticated technologies. The second revolution involved the revolt of payers in the 1980s or the era of cost containment with a sharp growth in total health care spending. Payers began to evolve cost containment mechanisms. The HMO movement, Medicare imposition of DRGs, state imposed price controls, and certificate-of-need laws for hospital construction, were all attempts to address exploding costs. Meanwhile,

the payers frustration was compounded by increasing evidence of variability in treatment and the quality of care. Thus, he cited the third revolution as the era of accountability. The major focus of this era was to examine the costs, safety and the effectiveness of physician's practices, simply because society did not have the money to pay for an infinitely expanding health care delivery system.[10]

The Agency for Health Care Policy and Research (AHCPR) was created in 1989 within the U.S. Public Health Services under the Department of Health and Human Services. The realization that much of today's medical practice is untested led Congress to create AHCPR. Congress was aware that there was a large set of diseases for which current therapy could be expensive and carry risks but would not cure the majority of patients. Its broad mandate included the improvement of clinical practice through outcomes and effectiveness research, the development of clinical practice guidelines, and a program to widely disseminate the results of important clinical research and practice guidelines to clinicians and patients. As stated in Public Law 101-239, AHCPR's research mandate is to "conduct and support research with respect to outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically."[21] The legislation specified, that whenever possible, research should use data that are already available, such as insurance claims data, and emphasize developing new methods for using large databases for outcomes research. The emphasis on using existing data reflected congressional impatience with the time and cost of randomized clinical trials and the hope that more efficient ways could be developed to answer questions of what works and what does not work in treating common medical conditions. In summary, AHCPR has the lead responsibility in the Department of Health and Human Services for influencing clinicians to adopt therapy for which there is strong evidence of effectiveness and to abandon therapy found to be ineffective.[22]

Attributes of Outcomes Research

Outcomes research focuses on the outcomes that are relevant to patients (i.e., symptom relief, survival, adverse side effects of treatment, quality of life, satisfaction with health care, and costs) as well as clinical indicators. This type of research is also performed under the actual conditions of practice.

Outcomes research can be conducted using experimental (efficacy) or non-experimental (effectiveness) research designs. Non-experimental research designs consist of quasi-experimental and observational studies.[23] A quasi-experimental study has an intervention but is not randomized. Whereas, an observational study does not involve investigator implementation of an intervention and is allowed to take its course under natural conditions, with changes in one characteristic being studied in relation to changes in other characteristics. Examples of these types of studies are case-control or cohort study designs.[24]

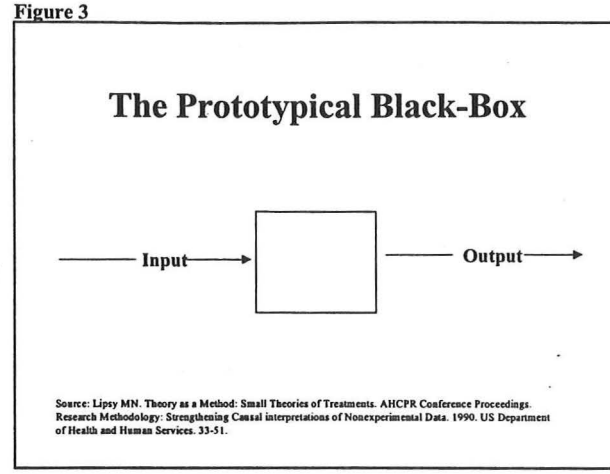
Efficacy refers to the ability of a "particular medical action in altering the natural history of a particular disease for the better," under ideal conditions. Effectiveness refers to the ability of a "particular medical action in altering the natural history of a particular disease for the better", under actual conditions of practice and use.[25] Efficacy studies yield the best information

about the maximum achievable outcome from the intervention. Ideally, these studies are done through randomized clinical trials. Effectiveness studies represent compromises with the efficacy study principles. However, they are often the necessary form of study in the actual practice of medicine. They are sometimes referred to as non-experimental studies. More specifically, effectiveness studies have the following characteristics: 1) no randomization of subjects 2) may or may not have a comparison group with or without treatment, 3) the researcher generally has no control over who gets what treatment, 4) subjects are generally quite heterogeneous, 5) interventions are given by a wide range of clinicians with varying levels of expertise, and 6) patient compliance varies widely. Therefore, even though the randomized clinical trial is the most scientifically rigorous experimental design, it may not be feasible under the actual conditions of practice because: 1) it is unrealistic, 2) it may seem unethical, 3) it is administratively and logistically impossible, 4) it may be too expensive, 5) it make take too long to complete, 6) some interventions may be impossible, 7) there may be a differential loss of conditions, or there may be crossover from one condition to another.[26]

The Use of the Prototypical Black Box in Outcomes Research

Even though non-experimental research does not prove cause and effect related to the interventions or characteristics assessed, a theoretical basis is still required for non-experimental studies to strengthen the interpretation of causal relations. However, in most of the past non-experimental research studies the intervention evaluated has been characterized as a black-box (Figure 3).[27] The black-box provides the minimal specification of variables and relationships necessary for causal research. It is only necessary to identify the black-box of interest (e.g., a target population such as asthmatics), an input to manipulate or observe (e.g., the use of systemic corticosteroids), and an outcome of interest (e.g., objective lung function). Proper observation of the subject's treatment with systemic corticosteroids and a reasonable measure of lung function comprise the basis for the causal proposition that systemic corticosteroids improve lung function in asthmatics. Comparing this research paradigm to reality reveals that it is substantially oversimplified.[28] Unfortunately, most outcomes research is conducted in this minimalist form.

Figure 3



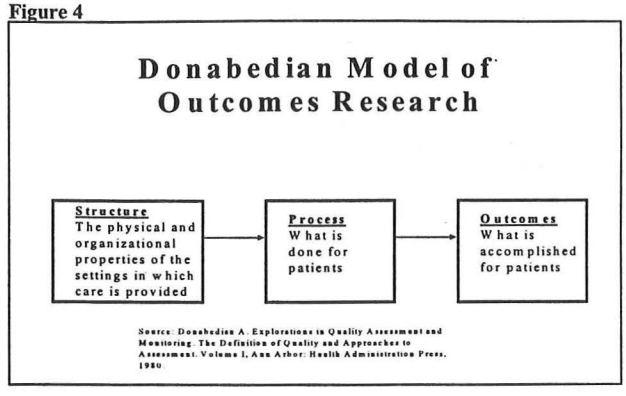
The alternative to black-box research is to create a research paradigm that better represents the underlying complexity of input, treatment, and output, as outlined in Figure 3. This approach results in a research study that more closely represents the details of the causal

process of interest. To obtain a more meaningful representation of input, causal process, and output research one must begin with a theoretical framework.[26-28]

Donabedian Model

Donabedian's structure-process-outcome model, developed over thirty years ago, continues to serve as a unifying conceptual framework for outcomes research (Figure 4) Donabedian's definitions for structure, process and outcome were: 1) structure- the physical and organizational properties of settings in which care is provided, 2) process- what is done for patients, and 3) outcome- what is accomplished for patients.[29]

Figure 4



Outcomes Research Studies and the Use the Donabedian Model

Unfortunately, many outcomes research studies based on this model have not successfully demonstrated a correlation between the processes and outcomes of care (Table 1).[30-39] Although, it is possible that no correlation may exist, certain methodological issues were evident in these studies as summarized below.

- Too small of a sample size to detect a treatment difference between groups
- Inappropriate sampling procedures leading to the omission of patients with poor outcomes
- The use of inappropriate process measures
- The absence of comprehensive outcome measures
- Outcomes inappropriately or insensitively measured
- Absence of data on treatment compliance
- The failure to use the pertinent confounding variables to adjust for pre-existing differences between groups

Of note, is that the conceptual framework for most of these studies failed to take into account the confounding variables to any significant degree. Using more of the pertinent variables that influence the outcomes measured in the conceptual model could have strengthened or weakened the process-outcome relationships generated by the non-experimental studies presented in Table 1.

Summary of Studies of Process-Outcome Correlations in Medical Units

Table 1

Sample	Process Measures	Outcome Measures	Statistical Technique	Reported Results	Evaluation
107 urinary infection, 114 hypertensives, 75 ulcer patients	Implicit; 2 explicit composites	Specific outcomes; death activity, symptoms, physiologic evidence; implicit judgments; composite index	Correlation	All process measures correlated significantly with implicit outcomes; outcome index not related to explicit process; mixed results for implicit process data and specific outcomes	Process validity underestimated; extraneous causes of outcomes uncontrolled; components of outcome index had questionable validity; patient compliance not taken into account in outcome measures (Brook 1973)
I: 50 appendix Operations each from 3 hospitals	I: "Empirical," diagnostic	I: Rate of confirmed appendicitis	I: No statistical measures used	I: Qualitative judgment of no correlation	Results of all 3 studies marred by numerous faults in methods (Fessell and Van Brunt 1972)
II: 50 discharged alive after myocardial infarction	II: % of 44 empirical diagnostic	II: 5 post-hospital outcomes	II: Significance test, between favorable and unfavorable outcome categories	II: No difference in process scores for any favorable vs. unfavorable outcome	
III: 50 alive after myocardial infarction vs. 50 dead	II: 26 empirical	III: Death	III: Significance test, between alive and dead groups for each process criterion	III: No differences for relevant criteria	
137 patients with chest pain who were discharged from emergency room	"Criteria map" on decision to discharge	Death or re-hospitalization at 21 day follow-up	Fisher's Exact Text	Significant correlation (r=0.31, my calculation) between process and outcome	Study's topic narrow, but one ignored by other audits (Greenfield et al 1977)
I:251 acutely ill patients (7 diagnoses)	I: Explicit (5 to 35 criteria depending on diagnosis)	Composite index of death, activity level, subjective symptoms, and physiologic data; good outcome,	I: Compared process scores for good versus bad outcomes	I:Good outcomes in 5 diagnoses had higher average process scores; overall significance was not tested	Controlled for general health status only (Kane et al 1977)
II: 162 acutely ill patients	II: implicit assessment	defined as final health status at least equal to status before illness; patient satisfaction	II: Chi-square	II: Significantly better process scores associated with good outcomes. Patients were	

		with care and outcome		slightly more satisfied with good outcomes but not with good care	
42 cystitis	10 explicit	4 measures of "recurrence"	Chi-square for each process criterion by outcome	No relationship between process and recurrence except "notation of prior infection"	Diagnostic criteria often relevant to only excluded patients; no variation in therapy criterion; "outcomes" could be new illness episodes; acute outcome not studied; inappropriate one-criterion-at-a-time analysis (Lindsay et al 1976)
138 hypertensive	% of 89 explicit criteria (79 diagnostic)	Blood pressure at follow-up	Correlation; multiple regression	Neither correlations nor regressions significant	Failed to control for initial status in correlation; specification error in regression analysis; outcomes irrelevant to diagnostic criteria (Nobrega et al 1977)
122 congestive heart failure	"MD awareness." "communication, "drug error," "management," "satisfaction," "utilization"	Activity levels; subjective symptoms	Correlation; step-wise multiple regression	Correlations mixed: "satisfaction" and "MD awareness" significant regressors for both outcomes	Failed to control for initial status in correlations; regression analysis incorrectly controlled other outcome measures and did not include key process measures in one analysis (Romm et al 1976)
Patients presenting with symptoms of urinary infection (approximately 126)	Weighted composite process	Index including symptoms, satisfaction, understanding, and compliance	Correlation	Significant correlation of 0.38	Outcome index may be too broad; sample selection superior; subjective outcome defined to be relevant to diagnostic process criteria (Rubenstein et al 1977)
46 anemic children	Iron therapy and follow-up	Adequate hemoglobins	Chi-square	Significant correlation (0.33) between combined processes and outcome	Specificity of process-outcome relationship is key feature; No controls for initial severity (Starfield and Scheff 1972)

Source: Adapted from McAuliffe, WE, 1978. Studies of Process-Outcome Correlations in Medical Care Evaluations: A Critique. *Medical Care* 16(11): 907-930

As mentioned previously, an awareness developed within the government and the medical community in the 1980s that outcomes research should be promoted and supported to identify how medical conditions could most economically be treated. Therefore, AHCPR was established in 1989 to conduct and support outcomes and effectiveness research. AHCPR's rationale for performing outcomes and effectiveness research were the following: 1) outcomes for most chronic diseases are difficult to measure, 2) the recognition that patients' have a central role in medical-decision making, 3) the limited generalizability of findings from randomized clinical trials, 4) the interest in reducing clinical practice variation to reduce cost and improve the quality of care, 5) the availability of large databases to learn the effects of medical interventions on patient outcomes in the typical practice setting, and 6) the reduction in health care expenditures that may pose a threat to the quality of care.[40]

Table 2 Summary of Methods of PORT Outcomes Assessment Studies

PORT	Respondents	Patient Age	Patient Gender	Study Design	Sample Source	Collection Sites	Data Collection Procedures	General Patient Outcomes Measures[a]
Acute myocardial infarction	Patient	65-79	M, F	Prospective cohort	Medicare files	In hospital, Patient's home	Telephone, Self-administered, Record abstract	Healthy rating Dis. Days BADL IADL Role function Satis/O
Biliary tract	Patient	18+	M, F	Cross-sectional, Prospective cohort, Clinical trial, Retrospect-ive cohort	Medicare files, Physician list, Hospital list, Procedure rosters	Patient's home	Telephone, Self-administered,	MOS Healthy rating, Dis. Days Satis/C
Cataract	Provider, Patient	50+	M, F	Prospective cohort	Physician list	Physician's office, Patient's home	Self-administered, Telephone	SIP Satis/C,O
Childbirth	Patient (mother)	18-50	F	Cross-sectional	Hospital list	Patient's home	Telephone	MOS
Diabetes	Patient, Provider	30+	M, F	Cross-sectional, Prospective cohort, Clinical trial	Physician list, Hospital list, Medical records	Outpatient clinic, Physician's office, Patient's home	Personal interview, Self-administered, Record abstract	MOS Healthy rating Dis. Days
Hip fracture/ Replacement	Patient, Caregiver	65+	M, F	Prospective cohort	Hospital list	Patient's home, Nursing home In hospital	Personal interview, Self-administered, Record abstract, Observation	MOS Hlth rat. Dis. Days BADL IADL Satis/O
Ischemic heart disease	Patient	30-90	M, F	Prospective cohort	Physician list	In hospital, Outpatient clinic	Personal Interview. Self-administered, Record abstract	MOS Hlth rat.

Low back pain	Provider, Patient	18+	M,F	Prospective cohort	Physician List	Physician's office Patient's home	Personal Interview, Self-administered, Record abstract	MOS SIP Hlth rat. Dis. Days Satis/O
Pediatric gastroenteritis	Caregiver, Physician	0-4	M,F	Prospective cohort	Physician List	Outpatient clinic, Physician's office, Patient/care-giver's home	Personal Interview, Self-administered, Telephone	Dis. Days Satis/O,C Hlth rat.
Pneumonia	Patient, Caregiver, Physician	18+	M,F	Prospective cohort	Physician list, Hospital list	In hospital, Outpatient clinic, Nurs. Home, Physician's office, Patient's home	Personal interview, Self-administered, Record abstract, Telephone	MOS Dis. Days BADL CES-D IADL Satis/C
Prostrate Disease Benign	Patient	50-90	M	Prospective cohort	Physician list	Physician's office, Patient's home	Self-administered	MOS Hlth rat. Satis/O
Cancer	Patient	65+	M	Retrospec-tive Cohort	Medicare files	Patient's home	Telephone, Self-administered	Satis/O,C
Stroke	Patient	40+	M,F	Cross-sectional	Medical records, Population based	Patient's home	Telephone	MOS Dis.days BADL
Total Knee Replacement	Patient	65+	M,F	Cross-sectional	Medical files	Patient's home	Self-administered	MOS Hlth rat. Dis. Days IADL Satis/C,O

MOS-Medical Outcome Study; SIP-some or all of the indices from Sickness Impact Profile; Hlth rat.-Healthy rating, self-rated health, replicates single question from the National Health Interview Survey; Dis. Days-days of disability and/or restricted activity, and/or school and work loss days; BADL-Basic activities of daily living; IADL-Independent activities of daily living; Satis/O-satisfaction with outcome; Satis/C-satisfaction with care; CES-D-Center for Epidemiological Studies Depression Scale.

The work of the Patient Outcomes Research Teams (PORTs) were AHCPR's first major effort to translate research findings into improved patient outcomes. The approach to these projects was to use multi-method, multi-disciplinary teams, multiple study sites, and focus on common medical condition(s) or procedure(s) to try and relate different clinical practice patterns to different patient outcomes. All of the PORTs in Table 2 planned to use nonexperimental study designs.[39]

For the most part, the PORTs projects were organized into five steps.

Step1- Evaluate published evidence and current clinical practice related to expert opinion on common conditions and procedures, and identify hypotheses and understand the controversies concerning these conditions or procedures.

Step 2- Use large claims databases, medical records or provider reports to measure patient outcomes

Step 3 -Conduct interviews with patients and their physicians to assess patient symptoms and health related quality of life

Step 4- Use decision analysis to synthesize the information gathered during steps 1-3. A decision analysis requires information on the actual treatment of patients with the disease or medical condition, the outcomes, and the value of the outcomes to the patient. Information from large databases and other data sources (i.e., patient-report, medical record review) is used to simulate the probabilities of different outcomes from therapy for patients. Patient surveys provide information on patient symptoms as well as their preferences for different outcomes. The advantage of a decision analysis is that it synthesizes a large amount of information related to the effectiveness of the treatment being assessed. The disadvantage is that the necessary information on patient values or preferences are often not available.

Step 5- Disseminate the findings in steps 1-4, and use these findings to conduct outcomes research studies which assess changes in clinical practice patterns and improved patient outcomes.[41]

Although many of the PORTs project studies have made a significant contribution in identifying hypotheses for study, making suggestions for guidelines based on literature review, describing current practice variations, describing and developing methods for assessing patient preferences, and developing outcomes measurement tools, little has been done to translate research findings into improved patient outcomes. For these studies, the lack of progress made in determining the effectiveness of treatments, for the most part, can be attributed to the inadequacy of the administrative databases used.[42] In addition, most of the outcomes research performed over the last decade has had difficulty in linking process with outcome due to inadequate data sources, and the almost total neglect of theory development to guide the research process.[42-44]

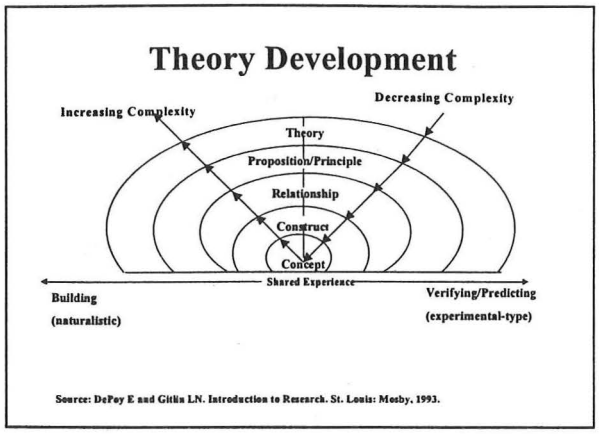
In summary, although the last 10 years has seen a large growth in outcomes research, most of the advances have involved selecting and defining the outcome variable, and developing measures for that variable.[44] This has been a worthwhile activity. However, it seems that it is time to move on to the next step, which is to develop methods for relating these outcome variables that we have defined and know how to measure, to inferences about how processes of care relate to the outcomes that we can control. To take this next step, we need to develop a theoretical basis for outcomes research studies to successfully link the processes of care with the outcomes measured. This emphasizes the need to spend more time defining our independent or predictor variables, thinking about study design, and thinking about the datasets that will allow us to make the link between process and outcome to strengthen the infrastructure for conducting future outcomes research studies. In addition, since many factors that affect the outcomes of care are outside of the health care system, it is likely that the traditional structure, process, outcome theoretical model is too restrictive.

Theory Development

The importance for conducting experimental research using theory goes back to the beginning of experimental medicine. Claude Bernard in his book, entitled "An Introduction to the Study of Experimental Medicine," in 1865, remarked:

> "The true scientist is one whose work includes both experimental theory and experimental practice . 1) He notes a fact; 2) a' propos of this fact, an idea is born in his mind; 3) in the light of his idea, he reasons, devises an experiment, imagines and brings to pass its material conditions; 4) for his experiment, new phenomena result which must be observed, and so and so forth."[45]

Figure 5



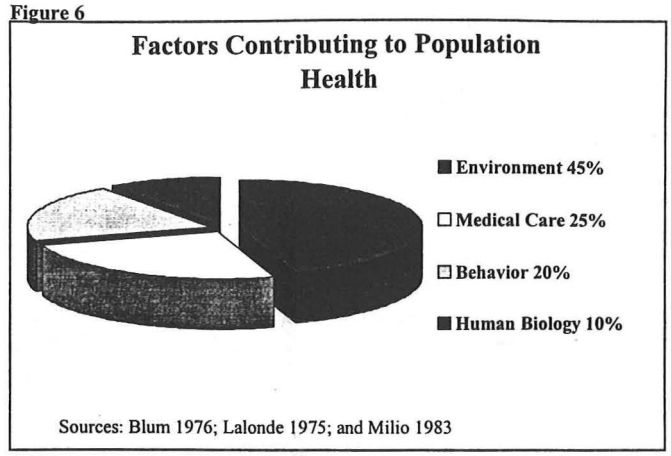
A theory is "a set of interrelated constructs, definitions, and propositions that present a systematic view of phenomenon by specifying relations among variables, with the purpose of explaining or predicting phenomenon" as outlined in Figure 5.[46]

Theory orientation may have its greatest advantage in the area of outcome research, since the black-box theoretical style may be sufficient for conducting efficacy studies. A theory orientation provides a framework within which the researcher can address the fundamental questions of what variables besides treatment affect the outcomes measured (covariates), what samples to use, what measures to take, and what procedures to follow. It can help guide the research designs that have the highest probability of detecting treatment effects, permit stronger causal inference, and produce more meaningful and generalizable results. Furthermore, preliminary studies may be necessary to develop a basis for theory, address the issues of treatment strength, identify the appropriate covariates, explore the use of various measures, and so forth. Obviously, not all outcomes research can be conducted using the highly-differentiated theory-oriented style. More likely, the appropriate effort will lie somewhere between the extremes of the highly-differentiated theoretical style and the overly simplistic black-box style.

The Expanded Outcomes Research Model

Given the importance of including as many of the pertinent variables as possible that affect the outcomes of care, inside and outside of the health care system, others have suggested expanding the Donabedian model for outcomes research to include an individual's pertinent personal characteristics and environmental context.[47-49] This is based on previous studies that have shown that educational attainment, income level, employment status, insurance status, housing status, psychological status, life events, social networking, control over one's work situation, social mobility, occupational and environmental hazards affect health status, to name only a few.[50-55] In fact, past research estimates that medical care only makes a 25 % contribution to the population's health. On the other hand, environmental factors are estimated to make a 45% contribution to population health.[56-58] Behavioral factors also contribute a sizable amount to population health (20%) (Figure 6).

Figure 6

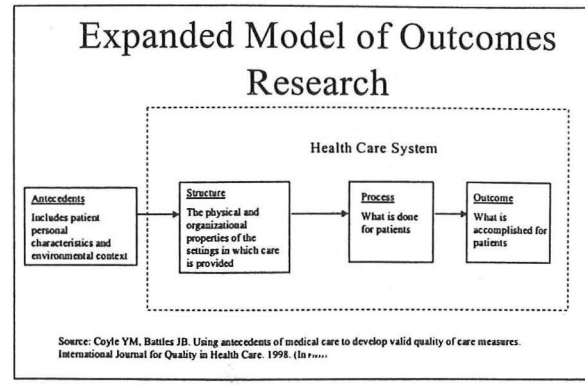


Evans and Stoddard argued that a framework for looking at the relationship between environment and health status is necessary. They stressed that health care decision-makers must have this information to develop comprehensive health policies.[47] Others such as Starfield and later the Institute of Medicine (IOM) also recommended that health services research, which includes outcomes research, recognize the pertinent variables and events outside of the health care system when evaluating the outcomes of medical care.[48,49] The IOM indicated that health services research could be organized into four general levels that include factors affecting patient outcomes: clinical, institutional, systemic or environmental. These levels proceed from the core of clinical practice to relationships between the health care delivery system and the larger social, political and economic environment that affect them.[49]

Since patient personal characteristics and their environmental context (antecedents of medical care) have been shown to significantly influence health status, Coyle and Battles

developed the expanded outcomes research model (Figure 7).[59] The expanded outcomes research model advances outcomes research by using the pertinent antecedents of medical care to adjust for pre-existing differences between groups so one can identify the true linkages between the processes and outcomes of care. Antecedents are factors that affect the structure, process and outcomes of medical care. Therefore, antecedents could have the greatest effect on outcomes. Antecedents involve the environmental context of an individual's personal characteristics (i.e., genetics; sociodemographics; and health habits, beliefs, attitudes, and preferences). Environmental factors may be cultural, social, political, personal, physical, or related to the health professions. Therefore, when applying the expanded outcomes research model, outcomes can be defined as:

Figure 7



Outcomes – f (Baseline- Antecedents of Medical Care, Structure of Medical Care, Medical Care, and Process of Medical Care)

General Applications of Outcome Research

A narrow definition of outcomes research involves linking the type of health care received by a variety of patients in the everyday practice of medicine with a particular medical condition or disease to establish the effectiveness of treatment. A broader definition of outcomes research includes the collection and reporting of data that can be used to compare outcomes across providers to assess the quality of care.[60] The successful application of outcomes research requires statistically risk-adjusting outcomes to link medical care to outcome.

The risk adjustment process attempts to account for all factors, other than the medical care intervention itself or its implementation process that may explain variation in patient outcomes. The variables selected for the risk adjustment model are based on the theoretical basis for the outcomes study. Four major factors account for differences in patient outcomes: 1) differences in the risk factors among patients, 2) differences in how well available data sources represent reality, 3) random variation, and 4) differences in the effectiveness of medical care or the quality of care.[61]

An Example of Theory-Driven Outcomes Research to Assess the Effectiveness of Care

The following study ("Developing and Testing Asthma Quality of Care Measures" funded by The Agency for Health Care Policy and Research) currently being conducted by Coyle, Gruchalla, Khan, Kirk, and Risser demonstrates the importance of using the antecedents of medical care to assess the effectiveness of care (Figure 7). Asthma was chosen as the condition since it is a good example of a medical condition in which one must take into account a patient's personal characteristics and environmental context to effectively evaluate the outcomes of care. Given the measurement error associated with using administrative data, the following project was conducted using clinical and patient-reported data. The predictor variables were collected using medical record reviews and patient interviews or surveys. The outcome measures were all measured and collected during a patient research clinic visit. The process of care data was collected by medical record 2-3 weeks after the medical event of interest (acute asthma exacerbation) occurred.[59] In addition, a preliminary study was undertaken to develop the theoretical basis for the outcomes research study in the project.

The primary purpose of the project is to develop process quality of care measures for acute asthma exacerbation. The quality of care measures will be derived from the processes of care selected for acute asthma exacerbation that produce the desired risk-adjusted asthma outcomes measured.

Table 3

Predictors of Asthma-Related Outcome

	Asthma Recovery (FEV_1 Change)	Medical Facility Visit	Asthma Quality Of Life	Patient Satisfaction With Health Care
Gender (Male)			+	
Age			-	
Race (Minority)				+
Income			+	
Education			+	
Employed			+	
Smoking				-
Current Allergy				-
Co-morbidity			-	-
Asthma Severity	-			
Process of Care				+

Adults with asthma are the target population with the level of analysis being at the provider level. The providers are faculty and physicians in training at UT Southwestern. The conceptual framework for this study considers the pertinent antecedent and structure of medical care variables (environmental-air quality, passive smoking, type of residence, whether the residence is owned, medical facility site staffing achieved; physician- demographics and professional characteristics; and patient- socio-demographics, smoking, recent history of respiratory tract infection, asthma severity, asthma knowledge, asthma medication compliance, current aero-allergen sensitivity, and comorbidity), and processes of care (consistent with the National Asthma Education and Prevention Program guidelines) that could influence the patient outcomes (mortality, health care utilization, meter-dose inhaler technique, pre- and post-bronchodilator FEV_1, patient satisfaction with health care, and asthma quality of life) 2-3 weeks after treatment for an acute asthma exacerbation.

Preliminary results from the first 276 cases (N = 400 cases) have been analyzed to select the predictor variables for risk-adjusting the outcomes measured in the project. Using the Pearson correlation coefficient, gender, age, income, educational level, employment, smoking status, current allergy, comorbidity, asthma severity, and the processes of care assessed related to acute asthma exacerbation correlated with at least one of the outcomes measured (Table 3). It is

generally believed that age, gender, comorbidity, asthma severity, socioeconomic status, and possibly race or ethnicity are the most important measures for risk-adjusting asthma outcomes, when assessing treatment effectiveness.[62-65] However, the preliminary results from this project suggest that other patient risk factors such as current allergy may substantially affect patient outcome following treatment for an acute asthma exacerbation.

An Example of Theory-Driven Outcomes Research to Assess the Quality of Care

The following project proposed by Coyle, Meidell, Peshock, Risser, and Remus illustrates the use of the antecedents of medical care to develop a risk adjustment model for measuring inpatient mortality in patients with acute myocardial infarction (AMI) across hospitals. For this project it was not necessary to include preliminary studies to identify the predictor variables needed to develop the theoretical basis for the project's outcomes studies, since past research had already identified the majority of these variables.[66] However, this project will use condition-specific clinical data, instead of administrative data, collected retrospectively to link AMI processes of care with inpatient mortality.

Past studies indicate that although a number of widely used risk adjustment tools have demonstrated accuracy in predicting risk for adverse outcomes related to common clinical conditions, most of these tools have not been sufficient to say that variations in outcomes are attributable to the differences in the quality of care (attributional validity). As a result, the use of these tools has not helped us identify areas where we need to make improvements in health care. However, the studies that employed a risk adjustment tool based on condition or disease-specific clinical data had greater success in demonstrating attributional validity.[61,67]

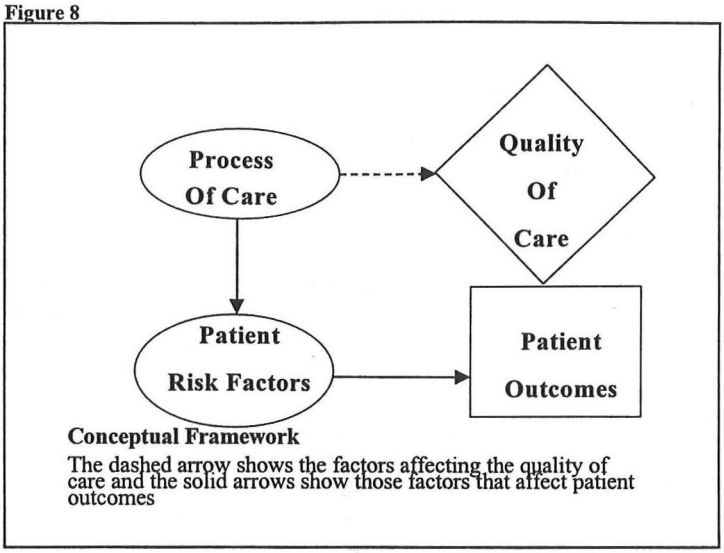
Because of the concern that the available risk adjustment tools had been unable to consistently identify areas for quality improvement, a collaborative effort between investigators at The University of Texas Southwestern Medical Center at Dallas (UT Southwestern) and the Dallas-Fort Worth Hospital Council (DFWHC), which represents the 46 hospitals that are participating in the project, was established to explore the development of a risk adjustment tool based on clinical data. The hypothesis driving the collaborative effort is that by incorporating pertinent condition-specific clinical data describing patient risk before the medical intervention into the risk adjustment model, that we will improve the model's ability to attribute outcome differences to the quality of care (attributional validity).

The conceptual framework for the project (Figure 8) will consider as many of the pertinent patient and clinical risk factors as possible that significantly influence inpatient mortality for patients hospitalized with AMI. This framework recognizes the importance of selecting risk factors from a full range of clinical dimensions that are specific for the medical conditions and outcomes in the population of interest, and are related to the patient's preexisting conditions, excluding those that develop during the hospitalization. The importance of the risk adjustment model being condition-specific is that this should enhance the model's quality of prediction. Timing of the risk adjustment is also crucial depending on the patient and clinical risk factors, specific outcomes, and the clinical practice under study. Therefore, by incorporating the patient and clinical risk factors that are present before the medical intervention, one avoids risk-adjusting the outcomes for the therapeutic or diagnostic errors that can occur related to the process of care. A risk adjustment model developed using this framework should isolate the

patient and clinical factors from the quality of care provided, which makes it possible to attribute variations in outcomes across patients to differences in quality of care (attributional validity). [61]

The project consists of three phases. In phase I, the investigation team will develop the risk adjustment model that accurately predicts AMI inpatient mortality, using 18 condition-specific variables (age; smoking; height; weight; initial systolic blood pressure; initial heart rhythm- sinus tachycardia, atrial fibrillation, atrial flutter; Killip Class I-IV; AMI location-anterior, inferior, other; ST segment elevation AMI; Non-ST segment elevation AMI; Prior myocardial infarction; diabetes mellitus; chronic obstructive pulmonary disease; hypertension; hypercholesterole-mia; prior CABG surgery; transluminal revascularization-, prior PTCA, and prior coronary artery artery stent placement; and prior cerebrovascular accident) collected from the medical record. The project's database will contain 1997 and 1998 hospitalization data from approximately 12,750 AMI patients with an estimated 1,150 AMI related deaths. During phase II, the investigators will test the risk adjustment model's attributional validity by determining whether AMI processes of care, consistent with the American College of Cardiology and American Heart Association clinical practice guidelines, were used or misused at the low and high outlier hospitals for risk-adjusted inpatient mortality related to AMI. During phases I-II, the investigators will compare the validity (predictive and attributional) of the risk adjustment model developed in phase I with that of another risk adjustment model based on administrative data using the same patient database. In phase III, the investigation team will determine whether they can obtain the clinical data necessary to generate the risk adjustment model in phase I efficiently and reliably using electronic medical records at 2 of the 46 participating hospitals. If the project is successful, a prototype for efficiently creating risk adjustment models that attribute outcome differences to the quality of care will be established.

Figure 8



Conceptual Framework

The dashed arrow shows the factors affecting the quality of care and the solid arrows show those factors that affect patient outcomes

This project proposes to develop a strategy that can be used to develop a prototype for creating risk adjustment models that can efficiently attribute outcome differences to the quality of care. As a result, this will not only provide consumers and employers with the information

needed to make the appropriate health care decisions, but more importantly it will provide the health care industry with the information to make the needed improvements in health care.

Value of Theory-Driven Outcomes Research

Although the task of conducting theory-guided outcomes research and using databases that accurately reflect patient risk factors, processes and outcomes of care for this research is challenging, the results from these efforts will be worthwhile. Not only will this approach allow us to establish the effectiveness of treatment and assess the quality of care, but provide results that lead to the generation of specific guidelines for the treatment of a particular type of patient in a specific setting, such as: "Patients less than 75 years old who have ST segment elevation on ECG, present within 6 hours of the onset of symptoms, and have no risk of bleeding contraindications may undergo thrombolytic therapy." However, "Patients 75 years old or older who have ST segment elevation on ECG, present within 6 hours of the onset of symptoms, and have no risk of bleeding contraindications should not receive thrombolytic therapy." Obviously, the more complete our patient risk factor profiles become related to the treatment and outcomes assessed, the closer we will be able to come to developing subgroup or even patient specific clinical practice guidelines. Furthermore, more specific clinical practice guidelines, if used, are more likely to reduce health care costs because they target the population at highest risk for complications from a disease or medical condition.

In addition, we must decide how to handle factors, such as air quality, current allergy, or socioeconomic status, that clearly influence patient outcomes related to asthma treatment. Modifying these factors may require non-medical as well as medical interventions.[68] Therefore, the social system may be better suited to respond to social and environmental problems than the medical care system. This would require that resources be allocated to the social system to create meaningful jobs that result in a higher standard of living or a cleaner environment. The result would be that together the medical and social systems would have a better opportunity to improve the health of the general population. On the other hand, the medical system could target medical interventions to specific patients or subgroups depending on their associated risk factor profiles. An example would be to provide immunotherapy or education on the avoidance of avoidable aeroallergens to those asthma patients that have proven allergy to avoidable aeroallergens, as well provide them with the state-of-the-art treatment for asthma.

Use of the Health Care Research Enterprise to Improve the Quality of Health Care

According to the President's Advisory Commission on Consumer Protection and Quality in Health Care Industry that was published in March of 1998:

> "The purpose of the health care system must be to continuously reduce the impact and burden of illness, injury and disability, and to improve the health and functioning of the people of the United States."[1]

The approach recommended by the commission for improving the health care and enhancing health was to commit to "delivering health care based on sound scientific evidence and continuously innovate new effective health care practices and preventive approaches, using a

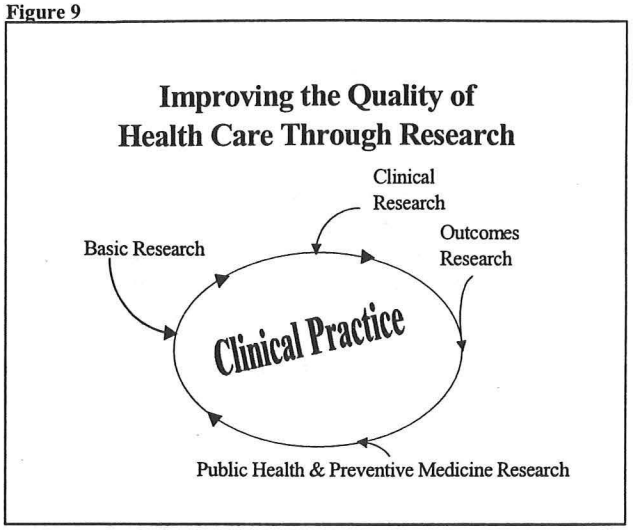
robust research enterprise, including basic, clinical, health services, and prevention research". More importantly this research enterprise would need to dynamically interact as presented in Figure 9.

Uses of Outcomes Research Information

Payers, providers, patients and the public all have a stake in outcomes research. The interest in outcomes research by these groups has escalated in the past decade due to the rapid growth of managed care.

Payers hope that outcomes research will identify ineffective care so that it can be eliminated and thus reduce health care costs. This may or may not occur, since a costly procedure may be under used, and if used appropriately may actually increase costs.

Figure 9



Payers may also use outcomes research results to rank the importance of different types of care, and decide to pay for only those above a certain rank. This approach to providing health care services to Medicaid recipients recently received federal approval in the state of Oregon.[69] Outcomes research results may also be used to determine the regionalization of service or the certificate of need for services. Once effective treatments are identified, some payers may use this information to develop and implement clinical practice guidelines that providers will be expected to follow. A recent example is the expected implementation of the Health Care Financing Administration's Evaluation and Management Guidelines for eight selected diagnoses in 1999.[70] However, despite the interest in establishing guidelines to improve the quality of care, and perhaps lower health care costs, evidence suggests that they have had minimal impact on the behavior of providers.[71-73] Effective methods for their dissemination must be developed so that they bring about the intended changes in clinical practice.

Payers may make reimbursement decisions based on quality assessment. In other words, payers may reward or penalize hospitals on the basis of their health care outcome performance. For example, hospitals are reimbursed based on the expected rate of adverse outcomes. If a hospital does not exceed the expected rate, it makes a profit; if it exceeds the rate, it bears the financial burden (Blue cross/Blue shield of Minnesota Project 1992).[74] This requires that the methods used to predict patient risk are valid, and that the adverse outcomes predicted are primarily subject to medical interventions than to patient characteristics.

It is expected that hospitals and other health care organizations will want to use outcomes research results to: 1) assist in in-house quality improvement programs, 2) to aid strategic planning, 3) to inform negotiations with third party payers, 4) to maintain compliance with regulatory organizations (e.g. the Joint Commission for the Accreditation of Health Care Organizations (JCAHCO)), and 5) to measure outcomes across hospitals or providers as a means to improve their competitive position within the local marketplace. However, the current risk adjustment tools that have demonstrated accuracy in predicting risk for adverse outcomes have not been sufficient to consistently attribute variations in outcomes to differences in the quality of care across hospitals or providers.[61,67] As a result, these tools have frequently not helped identify areas where improvements in health care can be made.

Clinician-providers can provide effectiveness information to patients to help them make treatment decisions. This is particularly helpful in situations where the preferred treatment for an individual is not obvious and the patient is willing to participate in the decision-making process. As more outcomes data is collected, physicians and patients will have a greater opportunity to make decisions based on this information. However, in many cases the available information may not be specific enough to be applied to a given clinical situation.

Patients and the public can use effectiveness data to make treatment and purchasing decisions. As discussed above, this type of information will become more useful when comparable data for more conditions and for more providers and health plans are available.

Future Challenges for Outcomes Research

The previous discussion points out the many benefits that outcomes research is expected to produce, as well as the issues that need to be addressed in the future if outcomes research is to have sustained value. However, even before these issues are addressed, those interested in outcomes research must deal with several other concerns. The first relates to the magnitude and breadth of data needed to conduct outcomes research, especially effectiveness studies. The limitations of readily available sources of information, such as administrative databases and other secondary datasets, mean that to obtain better data there will have to be a major effort to construct databases for prospective use that are not only accurate, but capture important baseline variables (i.e., antecedent and structure of medical care variables), diagnosis, and the appropriate outcome variables.[75] Therefore, the data needed to perform outcomes research for specific diseases or conditions could be incorporated into electronic databases to efficiently improve and monitor the processes and outcomes of care. One could refer to these electronic databases as evidenced-based, in that they would not only include processes of care that have been determined to be effective for specific conditions or diseases, but that they would also include the associated pertinent antecedent, structural, and outcome variables.

Another important issue is that the conceptual framework for the outcomes research studies need to take into account as many of the variables as possible that affect the outcomes being assessed. These factors may be inside as well as outside the health care system.[59,76-78] In addition, depending on the condition or disease studied, there may be many factors that influence outcome that have little to do with the medical care delivered in the health care environment (i.e., smoking, socioeconomic status, patient diet, patient medication compliance, disease or condition knowledge, etc.). Outcomes researchers need to identify these factors to successfully identify the

effectiveness of the treatment under study as well as to risk-adjust outcomes to assess the quality of care. Furthermore, patient risk factor profiles can provide us with the information needed to make guidelines more specific for patient subgroups or perhaps even individuals. Perhaps more important, outcomes researchers can use patient profiles to determine for whom medical interventions work best, or make adjustments in the implementation of these interventions to maximize the benefit for specific subgroups or individuals.

Summary

Outcomes research generates effectiveness and quality assessment information. The potential benefits of effectiveness information are the following.

- May help reduce health care costs
- Provides guidance for rationing health care
- Can be used to develop clinical practice guidelines
- Provides guidance for evidence-based clinical practice
- Provides patient guidance for treatment decisions

The potential benefits of quality assessment information are the following.

- Helps payers make reimbursement decisions
- Helps payers make purchasing decisions
- Health care organizations can use for strategic planning and marketing, regulatory compliance, and for developing quality improvement programs

The directions for outcomes research are the following.

- Adjust outcomes for patient risk
- Identify better data sources
- Develop evidenced-based databases
- Develop new research methods and tools

Conclusion

Outcomes research represents a rational approach to the assessment of medical care at a time when rationality is required. Despite the limitations of outcomes research, it should be supported and encouraged. The current limitations should not be seen as arguments against outcome research, but as challenges for outcomes research, where there is potential for improving the outcomes research approach. Most importantly, if outcomes research is performed using the most complete conceptual framework possible with adequate data sources, these studies will more likely generate the results needed to enhance the medical decision-making abilities of payers, providers, patients, and the public.

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