

ERIC Notebook

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Health Care Epidemiology: Health Outcomes

In the previous two notebooks, we have examined how different population perspectives influence research and delivery of health care. This notebook will focus on outcomes.

What is Outcomes Research?

Outcomes research is defined as the study of the end results of health care. Specifically, the Academy for Health Services Research and Health Policy defines outcomes research as “research on measures of changes in patient outcomes, that is, patient health status and satisfaction, resulting from specific medical and health interventions”¹ (p. 20). While some researchers consider satisfaction an end result of care, epidemiology, and hence this issue of the ERIC notebook, focuses on measures of health status.

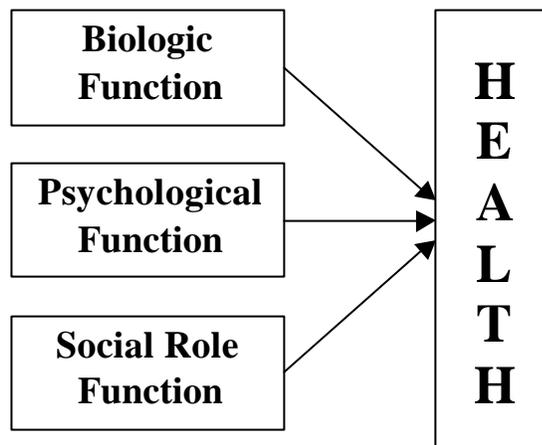
The goal of outcomes research is to determine how closely the end result of interventions approaches the objectives of health care.² The result should be improved clinical, managerial, and public policy decision making related to health. One of the great challenges of outcomes research is separating the impact on outcomes of the intervention under study from the impact of other factors such as clinical condition, patient characteristics, and environmental and social factors.

What are Health Outcomes?

Health outcomes are defined as the effect of care on the health status of patients. Outcomes can encompass traditional measures, such as morbidity, mortality, presence of an infectious agent, or injury and more recent measures, such as quality of life or ability to undertake activities of daily living. In recent years, there has been increased emphasis placed on disease and treatment impacts on patients’ ability to function in their daily lives.

Biopsychosocial Model of Health

The biopsychosocial model of health views health and related conditions as having biologic, psychologic, and social components.^{3,4} Disease involves abnormal biologic functioning resulting from alterations in biochemical function, biomechanical abnormalities, or infection. Psychologic components involve deviation from normal human growth and development resulting in behavioral change indicative of illness. The social component recognizes that individuals relate to the people around them. Illness can affect these relationships. Based on the biopsychosocial model of health, outcomes can encompass measures of biologic function, psychological function, and ability to perform social roles.



Traditional Outcome Measures

Outcome measures have traditionally focused on the biologic functions of the body. While these do not capture all of the components of health status, they are still basic to determining the impact of personal and public health interventions. The two basic measures are mortality and morbidity.

Mortality refers to death. Morbidity is the presence of a disease or illness. Disease or illness can be indicated by the presence of an infectious agent, laboratory values indicating abnormal physical or biochemical functioning (e.g. blood pressure, blood sugar level, cholesterol level), or abnormal

biomechanical function. Morbidity may also be indicated by more subjective symptoms, such as pain.

Domains of Health Related Quality of Life

The broad model for health described above leads to a need to categorize the various outcomes used to describe the end results of care. The ultimate goal of health interventions is to improve people's health-related quality of life (HRQL). Robert Kane (1997) categorizes the outcomes and related measures used to evaluate HRQL into the domains listed below (following list and comments are adapted from Kane (1997)², table 2-1, p. 22).

Physical Function Domain:

- ?? Range of motion (whole body or site specific)
- ?? Physical activity changes (pre and post intervention)

Social Function Domain:

- ?? Network of family and friends
- ?? Social activity (such as frequency or type)

Cognitive Function Domain:

- ?? Memory
- ?? Awareness
- ?? Understanding of abstract concepts

Emotional Function Domain:

- ?? Subjective in nature
- ?? Some validated instruments such as Hamilton-Depression scale

Pain and Discomfort Domain:

- ?? Overall pain index
- ?? Body ache index
- ?? Degree to which it affects other domains

Vitality Domain:

- ?? Not well developed
- ?? Possible inclusions:
 - ?? active participation in community
 - ?? active member of advocacy group

Overall Well-Being Domain:

- ?? Satisfaction with health

Selecting Interventions and/or Conditions to Study

No health care organization can study every condition seen or procedure carried out in its facilities. Generally, it is desirable to study interventions that have great impact on the population of patients served. The following criteria can help select areas of study:

- ?? Common disease or intervention⁵
- ?? Procedures important to patients, physicians, and other providers⁵
- ?? Variation in care provided for a condition⁵
- ?? Treatment affects outcomes⁵
- ?? Knowledge exists about appropriate procedures for treating the condition (i.e. opportunity to use evidence-based practice standards)⁵
- ?? Condition and/or treatment has major impact on organization (e.g. provider time, costs)
- ?? Outcomes information reasonably obtainable

Measurement in Outcomes Research

As for all epidemiology studies, high quality data for outcomes research have the following characteristics:

1. **Validity** - The outcome measure represents what it was intended to measure
 - ?? Internal validity - The degree to which differences in observed outcomes can be attributed only to the intervention under study
 - ?? External validity - The degree to which results can be generalized beyond the target subjects in a study
2. **Reliability** - The degree to which a procedure for measuring outcomes can replicate results under the same conditions

Data for outcomes research come from a wide variety of sources. Decisions about how to compare outcomes depend on issues such as trade-offs between the importance of internal and external validity, cost of obtaining data, whether data currently exist, quality of existing data, completeness of existing data, purpose of previous data collection, and time constraints.

Some sources of data include:

- ?? Results of traditional epidemiologic studies such as clinical trials, cohort studies, and case-control studies that compare specific interventions
- ?? Medical records (paper or computerized)
- ?? Automated administrative records (not the same as clinical medical records)
- ?? Questionnaires administered to patients
- ?? Physical examination of patients

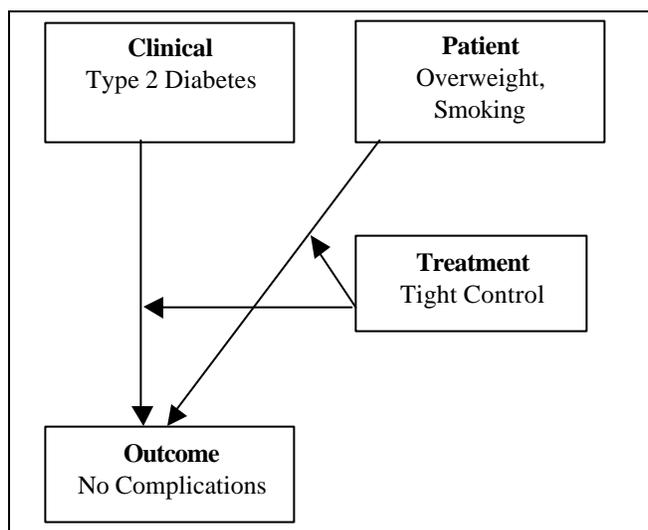
Framework for Outcomes Research

It is helpful to have a framework within which to conduct effective research. Robert Kane (1997) has developed such a framework to consider how treatment interacts with clinical and patient factors to produce outcomes of care.² Treatment factors other than the

intervention under study can also represent potential confounders.

In the Kane framework, there are three main factors that contribute substantially to patient outcomes: clinical, patient, and treatment factors. Clinical factors include diagnosis, severity of disease, prognosis, and co-morbidity. Patient factors include intrinsic characteristics such as age, ethnicity, and gender, as well as extrinsic factors such as socio-economic status and health insurance coverage. Treatment factors include frequency, availability, accessibility, and side effects of care. Outcomes research seeks to determine the impact of specific treatment interventions.

This framework can be applied to a number of diseases and outcomes to evaluate a specific question. The framework can be demonstrated with type 2 diabetes, as the condition of interest, and avoidance of microvascular or macrovascular complications as the outcome of a program aimed at tight control of blood sugar.



Adapted from Kane (1997)², figure 1-1, p. 13

Clinical factors influencing type 2 diabetes are those diabetes-related factors that may affect possibility of experiencing related outcomes. Such factors include blood sugar levels and co-morbid conditions such as hypertension, hypercholesterolemia, and depression that may affect diabetes self-management. Patient factors relate to the individual and could include age, weight, behaviors such as smoking and the patient's social environment. Treatment factors may include pharmaceutical and behavioral activities involved in tight control of diabetes (intervention under study) or treatments for co-morbid conditions. The combination of clinical, patient, and treatment factors can lead to varied complications such as blindness or myocardial infarction. The significant challenge is to measure the impact of the variables (interventions) under study as separate from other factors (confounders).

The following sections of the notebook present some of the pitfalls that are common issues both for those conducting outcomes research and for those using the results to aid decision-making.

Avoiding the *Post Hoc Ergo Propter Hoc* Fallacy

There is great danger in outcomes analysis of assuming causal relationships simply because one event follows another. A current example of such a relationship is concern over the possibility that the measles-mumps-rubella vaccine causes autism. Although most current scientific evidence indicates that such a relationship does not exist⁶, it is understandable that parents of autistic children may believe such a relationship exists. A parent whose child is diagnosed with autism will look for events that may have caused the condition. Because virtually every child in the United States receives immunizations, vaccination will often have preceded the diagnosis. As a result, the parents may believe the condition was caused by the immunization. This is an example of the *post hoc ergo propter hoc* fallacy. A temporal sequence is necessary to infer a causal relationship, but does not by itself establish that one exists. The tendency to infer a causal link based on temporality is especially an issue when examining outcomes of common procedures or activities.

Risk Adjustment

When comparing outcomes across organizations, locations, providers, etc., one must account for the fact that different types of patients may be seen at different sites. Because outcomes are influenced by the attributes that the patient brings to the encounter (e.g. social situation, physiologic reserve, disease characteristics) and health system characteristics not under study, it is necessary to take these characteristics into account so that comparisons represent the impact of the intervention under study, not these other factors.

This process is accomplished by risk adjustment. The goal of risk adjustment "is to control for factors that patients independently bring to health care encounters that can affect their likelihood of experiencing good or bad outcomes"⁷ (p. S8). These potential confounders need to be controlled for in the same way one would control for potential confounders in an etiologic epidemiology study.

Causal Criteria

Because outcomes can be influenced or determined by many factors relating to clinical condition, patient characteristics, environmental and social issues, and the intervention, causality is often difficult to determine. In 1965, Bradford Hill proposed a set of criteria for assessing causality.⁸ Whereas causal

associations may not meet all of these criteria, they provide a framework for evaluating potential causality. The Bradford Hill criteria, with selected commentary from Rothman and Greenland⁹ are presented below.

Bradford Hill Criteria

- ?? **Strength**-A strong relationship can help to rule out the possibility that the association is caused by a weak unmeasured confounder. However, a strong relationship is not necessarily causal, and a weak relationship can be causal.
- ?? **Consistency**-Repeated results are more likely to be causal. However, causal relationships may not always result in consistent results because a factor may contribute to an outcome in only specific situations, research studies vary in methodology, and random error can occur.
- ?? **Specificity**-Hill proposed that the more specific the proposed causal relationship, the more likely it is to be causal. Rothman and Greenland reject this criterion – the fact that one agent contributes to multiple diseases is not evidence against its role in any one disease.
- ?? **Temporality**-It is a sine qua non that a cause must precede its outcome. Of course, precedence in time does not establish causality.
- ?? **Biologic Gradient**-Refers to a monotonic (unidirectional) dose-response relationship. For example, increased smoking increases the risk of lung cancer. However, causal relationships can show a J-shaped or threshold (single jump) dose response curve. At the same time, a monotonic dose-response relationship can result from a confounding factor.
- ?? **Plausibility**-Refers to whether findings are biologically credible. If a result does not accord with prior knowledge of biopsychosocial mechanisms, it may be viewed with skepticism. However, it is possible that the prior knowledge may not be correct. This is why results from different types of studies must be combined to paint a complete picture of a causal relationship.
- ?? **Coherence**-Similar to plausibility, coherence refers to absence of conflict between the association and the totality of what is known about the natural history or biology of the disease. While conflicting information should raise red flags, the conflicting knowledge may be incorrect or misinterpreted.

- ?? **Experimental Evidence**-Properly designed clinical trials (human experiments) are generally considered the gold standard for testing causal associations. However, clinical trials are often not possible. There may also be issues of interpretation or applicability (e.g. lack of generalizability). Clinical trials may also have design issues such as inadvertently testing a change in an exposure other than that under study.
- ?? **Analogy**-Drawing an analogy between the relationship under study and others may aid in considering the plausibility of a causal relationship or developing additional hypotheses. However, the lack of such analogies may be related to deficits in current knowledge or lack of imagination on the part of the scientist.

Guidelines for Using Outcomes Information for Organization Decision Making

In addition to clinical decision making, outcomes research is designed to aid health administrators in reaching organizational decisions. The Veterans Administration primer on using outcomes to improve health care decision-making offers useful guidelines for using outcomes information when making managerial decisions within an organization¹⁰ (guidelines quoted from pp. 5-6). Epidemiologists can assist with decision making through the collection, analysis, and interpretation of related data.

1. Make sure that research results are relevant to your organization before trying to put them to work for you
2. Be careful interpreting research results
3. Work with clinicians [involved in direct patient care]
4. Equip yourself to evaluate the impact of the change
5. Be realistic about what can be accomplished

Helpful Web Sites:

Academy for Health Services Research and Health Policy
<http://www.ahsrhp.org>

Agency for Healthcare Research and Quality
<http://www.ahrq.gov>

Center for the Advancement of Health
<http://www.cfah.org>

Improving Chronic Illness Care
<http://www.improvingchroniccare.org>

Institute for Healthcare Improvement
<http://www.ihl.org>

Joint Commission on the Accreditation of Healthcare Organizations
<http://www.jcaho.org>

National Committee on Quality Assurance
<http://www.ncqa.org>

National Quality Forum
<http://www.qualityforum.org>

Partnership for Prevention
<http://www.prevent.org>

Research Triangle Institute-Health Solutions
<http://www.rtihealthsolutions.org>

University of North Carolina at Chapel Hill-Program on Health Outcomes
<http://www.sph.unc.edu/health-outcomes>

Veterans Administration-Office of Research and Development
<http://www.va.gov/resdev>

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9 Rothman, K. J., & Greenland, S. (1998). Causation and causal inference. In K. J. Rothman & S. Greenland (Eds.) Modern Epidemiology (2nd ed.) (pp. 7-28). Philadelphia: Lippincott-Raven Publishers.

10 Zimmerman, D. L., & Daley, J. (1997, March). Using Outcomes to Improve Health Care Decision Making. Boston: Management Decision and Research Center, VA Medical Center. [available on the Internet at <http://www.va.gov/resdev/ps/pshsrd/outcomes.pdf>].

Other Suggested Readings on the Topic:

Academy for Health Services Research and Health Policy. (2000, July). Health Plan Data, A Rich Resource, Ripe with Challenges. Washington, DC: author. [Available on the Internet at <http://hcfo.net/pdf/healthplan.pdf>].

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Upcoming Topics

- ?? Quality of Care
- ?? Variation in Health Care
- ?? Systematic Review and Meta-Analysis
- ?? Evidence-Based Care

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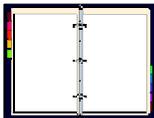
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