

## **Research: How Health Care Advances**

### **Introduction**

People are depending more on the statistical probability from accurate studies to make advances in medical research. This is a big change from depending on the clinical impressions of individual physicians and other health care practitioners. Currently, published findings are based on research studies that have been rigorously designed and conducted to yield statistically credible results. However, the growing amount of reports on medical developments that appear in the popular media are often premature and may be cause for skepticism.

### **Different Types of Research**

#### *Research in Health and Disease*

Basic science research is the work of biochemists, physiologists, biologists, pharmacologists, and others concerned with sciences that are fundamental to understanding the growth, development, structure, and function of the human body and its responses to external stimuli. Much of basic science research is at the cellular level and takes place in highly sophisticated laboratories. Other basic research may involve animal or human studies. Basic science is the essential antecedent in clinical medicine.

Clinical research focuses primarily on the various steps in the process of medical care – 1. the early detection, diagnosis, and treatment of disease or injury; 2. the maintenance of optimal physical, mental, and social functioning; 3. the limitation and rehabilitation of disability ; 4. the palliative care if those who are irreversibly ill. Much of clinical research is experimental, involving carefully controlled clinical trials of diagnostics or therapeutic procedures, new drugs, or technological developments. Clinical trials test a new treatment or drug against a prevailing standard of care. If no standard exists or if it is too easily identified, a control group will receive a placebo or mock drug to minimize subject bias. These research studies have a number of safeguards to protect safety and rights of volunteer subjects.

#### *Epidemiology*

**Epidemiology** or population research is concerned with the distribution and determinants of health, disease, and injuries in human populations. Much of that research is observational. Observational studies may be descriptive or analytical. Descriptive studies use patient records, interview surveys, various databases, and other information sources to identify those factors and conditions that determine the distribution of health and disease among specific populations. These studies are normally followed by analytical studies, which try to explain biological phenomena by seeking statistical associations between factors that may contribute to a subsequent occurrence and the occurrence itself.

Some analytical studies attempt, under naturally occurring circumstances, to observe the difference between two or more populations with different characteristics or behaviors. Observational studies usually are followed by another major type of research: experimental studies. In experimental studies, the investigator actively intervenes by manipulating one variable to see what happens with another. Although they are the best test of cause and effect, they are technically difficult to carry out and often raise ethical issues.

Advances in statistical theory and the epidemiology of medical care make it possible to analyze and interpret performance data obtained from the large Medicare and other insurance databases.

### *Health Services Research*

Until the last two decades, most research addressed the need to broaden understanding of health and disease, to find new and more effective means of diagnosis and treatment, and in effect, to improve the quality and length of life. Medicare and Medicaid were politically crafted solutions rather than research-based strategies. Nevertheless, those major health care subsidy programs were the driving forces behind the rise of health services research. Health services research was born of the need to improve the efficiency and effectiveness of the health care system and to determine which of the health care treatment options for each condition produces the best outcomes.

The **Agency for Health Care Policy and Research (AHCPR)** was established in 1989 as the successor to the National Center for Health Services Research and Health Care Technology. It is one of the eight agencies of the Public Health Service within the Department of Health and Human Services. AHCPR was responsible for updating and promoting the development and review of clinically relevant guidelines to assist health care practitioners in the prevention, diagnosis, treatment, and management of clinical conditions.

The agency's priority activities included extramural research through the **Medical Treatment Effectiveness Program (MEDTEP)**. MEDTEP funded two types of research projects: **patient outcome research teams (PORTs)** and literature synthesis projects or meta-analyses. Both the PORT groups and the smaller literature synthesis projects identified and analyzed patient outcomes associated with alternative practice patterns and recommended changes where appropriate.

The **Healthcare Research and Quality Act of 1999** was passed, which retitled the Agency for Health Care Policy and Research (AHCPR) to the Agency for Healthcare Research and Quality (AHRQ) and changed the title of the administrator to director. The mission of AHRQ is to: (1) improve the outcomes and quality of health care services, (2) reduce its costs, (3) address patient safety, and (4) broaden effective services through establishment of a broad base of scientific research that promotes improvements in clinical and health systems practices. A top priority of AHRQ is getting its sponsored research results and new health information into the hands of consumers. Building on concerns about medical errors and the quality of care, Congress and the president have

increased support of the AHRQ. If that support continues during the next decade, the agency's greatest contribution to health care may be in the increases in patient care quality and reductions in costs.

Health services research combines the perspectives and methods of epidemiology, sociology, economics, and clinical medicine. Therefore, its curriculum is broader than the research courses taught in most medical schools.

Until the last few years, health care's impressive accomplishments made it difficult for health care researchers, policy makers, and organizational leaders to publicly acknowledge that poor quality health care is a major problem within the dynamic and productive biomedical enterprise in the United States. For decades, practitioners assumed that quality was immeasurable except in cases of obvious violation of generally accepted standards. Only physicians could judge the work of other physicians. Peer review medical care is based on factual knowledge. A substantial component of medical decision making is based on clinical judgment. Clinical judgment means combining consideration of the potential risks and benefits of each physician's internal list of diagnostic and treatment alternatives with his or her medical intuition regarding the likelihood of success based on the condition of each patient.

Specifying and striving for excellent care are very recent quality assurance phenomena in the health care arena. Health services researchers had known for decades that health care quality was measurable, and that excellent, as well as poor, care could be identified and quantified. In 1966, Donabedian characterized the concept of health care as divided into the components of structure, process, and outcomes. Donabedian suggested that the number, kinds, and skills of the providers should in the aggregate, influence the quality of the subsequent outcomes. For many years, the Joint Commission on the Accreditation of Hospitals made judgments about the quality of hospitals on the basis of structural standards, ratios of professionals to patients, and the qualifications of various personnel. Later it added process components to its structural standards. Only recently did the JCAHO include outcomes in its accreditation assessments.

In November 1999, the **Institute of Medicine (IOM)** issued a report on the quality of medical care. Focused on medical errors, the report described mistakes occurring during the course of hospital care as one of the nation's leading causes of death and disability. The report contained a series of recommendations for improving patient safety in the admitted high-risk environments of modern hospitals. Among the recommendations was a proposal for establishing a center for patient safety within the AHRQ. Congress responded by designating part of the increase in the budget for the AHRQ for that purpose.

### *Evidence Based Medicine*

**Evidence-based medicine** is defined as the systematic application of the best available evidence to the evaluation of options and decisions in clinical practice, management and policy-making. Although it is generally assumed that physicians are reasonably confident that the treatments they give are beneficial, the reality is that medical practice is

fraught with uncertainty. Articles on evidence-based medicine are appearing with increasing frequency in the medical literature. Cost-control pressures that encourage to ensure that therapies have documented patient benefit, growing interest in the quality of patient care, and increasing sophistication on the part of the patients concerning the care that they receive have stimulated acceptance of the concepts of evidence-based medical practice.

### *Outcomes Research*

Insurance companies, state and federal governments, employers, and consumers are looking to outcomes research for information that will help them make better decisions about what kinds of health care should be reimbursed. Outcomes research evaluates results of health processes in the real world of physicians' offices, hospitals, clinics, and homes. The research in usual service settings differs from controlled trials, or "efficacy research," in the nature of the outcome measured. To more adequately capture health status, outcomes research measures a patient's functional status and well-being. Functional status includes three components that assess patients' abilities to function in their own environment:

- 1. Physical Functioning**
- 2. Role Functioning**
- 3. Social Functioning**

Outcomes research also uses meta-analysis, a technique to summarize comparable findings from multiple studies. Outcomes research goes beyond determining what works in ideal circumstances to assessing which treatments for specific clinical problems work best in different circumstances. The endpoint of outcomes research, the clinical practice guidelines intended to assist practitioners and patients in choosing appropriate health care for specific conditions, must be disseminated in acceptable and motivational ways.

Patient satisfaction has become an important component of the quality of care. A number of instruments have been devised to measure patient satisfaction with health care, and most managed care plans, hospitals, and other health service facilities and agencies have adopted one or more to regularly assess patient satisfaction. Some, like the Patient Satisfaction Questioner (PSQ) developed at Southern Illinois University School of Medicine, are short, self-administered survey forms.

### **Research Ethics**

The growth of medical knowledge is unparalleled, and the United States can take pride in its research accomplishments. However, many of the sophisticated new technologies address the need to ameliorate the problems of patients who already have the condition or disease under treatment. Both the priorities and the profits intrinsic to the US healthcare system focus on remedial rather than preventative care.

**Key Words**

*Epidemiology* – Population research concerned with the distribution and determinants of health, disease, and injuries in human populations

*AHCPR* – Agency for Health Care Policy and Research

*MEDTEP* – Medical Treatment Effectiveness Program

*PORTs* – Patient Outcome Research Teams

*Healthcare Research and Quality Act of 1999* - retitled the Agency for Health Care Policy and Research (AHCPR) to the Agency for Healthcare Research and Quality (AHRQ)

*IOM* – Institute of Medicine

*Evidence-based Medicine* - systematic application of the best available evidence to the evaluation of options and decisions in clinical practice, management and policy-making

*Outcomes Research* - evaluates results of health processes in the real world of physicians' offices, hospitals, clinics, and homes