Quality in Health Care 1994;3 Supplement:S6–S9

Patient defined outcomes

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In medical care delivery systems the question is being asked: "What works?" Purchasers and payers need to know what value they are getting for dollars spent in benefits, not just their total expenditures; case managers and hospital administrators must decide which services can be substituted or eliminated to control costs while maintaining quality; and clinicians and patients try to select from different treatment options those that will improve health, not just reduce length of stay. Informing such choices and trade offs requires ". . . the improvement of methods for identifying key features of medical care that are associated with favourable *patient outcomes* (my emphasis), so that these features can be preserved despite the constraints imposed by an increasingly cost-conscious healthcare environment."[1]

Outcomes defined

The recent surge of interest in outcomes actually represents a resurgence of attention to the results of medical care. For generations we have used indicators of mortality, morbidity, and expenditure when describing and evaluating the performance of individual clinicians, provider groups, hospitals and other health care organisations, and the health care system in general. We have measured, tracked, reported, and often attempted to alter rates of death, disease, and – in particular – expenditure.

From this previous database of activity various factors combine to move us to an expanded database with which to examine the performance of clinicians, hospitals, managed care plans, and other providers in the health care system. During the past decade the definition of outcomes has expanded to include patients' assessments of their own health and their evaluations of the care and services they receive. This expanded definition recognises a precept stated almost 30 years ago by Donabedian, that "achieving and producing *health and satisfaction* (my emphasis) is the ultimate validator of the quality of care."[2]

For many health care organisations a longer tradition lies behind collecting patients' assessments of care and services than obtaining their assessments of their own health status. The assessments of care and services generally request patients to rate the favourableness or unfavourableness – or quality – of overall care or various features of care and services (for example, access, availability, interpersonal aspects, and continuity)[3–5] or of the insurance or health plan (for example, benefits, information provided, and cost).[6 7] In the past patient "satisfaction" studies were often done by marketing departments or by outside consultants hired to do special purpose surveys. More recently, many health care organisations have begun to collect customers' assessments of care and services routinely – that is assessments by patients, physicians, and employees – with standardised surveys that permit comparison and benchmarking across organisations. When this shift occurs, it often supports a continuous improvement programme[8] that recognises the centrality of the patient's viewpoint in examining quality of care.[4 9]

This paper focuses on patient based health status: it offers a comprehensive model for measuring health status from the patient's viewpoint, summarises the factors that explain increased attention to patients in assessing health, and indicates how the data on outcomes assessment are being used in the United States and world wide.

The three Ms of outcomes

Outcomes assessment comprises three distinct functions: measurement, monitoring, and management. The term "outcomes management," coined by Ellwood[10] in his seminal article on the renewed importance of including patients' assessments of results, is often used to refer to all three functions. Brief descriptions are given here to reduce confusion and to underscore the distinctions and interdependencies among these functions (box).

Three Ms of outcomes: measurement, monitoring, management[11]

- *Outcomes measurement:* the assessment, at a point in time, of one or more of the variables defined as "outcomes" or results of the interaction between a patient and the health care delivery system
- *Outcomes monitoring:* the repeated assessment, over time, of variables defined as "outcomes" or results of interactions between a patient and the health care delivery system, in a manner that permits causal inferences about what (care, services, resources) produced the observed results
- *Outcomes management:* the use of information and knowledge gained from outcomes monitoring activities and related sources (for example, clinical trials) in the processes of clinical decision making, patient care management, and service delivery to achieve optimal patient outcomes

Monitoring differs from point in time measurement in that it repeats the assessments and permits causal inferences about what

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produced changes. Currently, most organisations with outcomes assessment programmes focus on measurement and monitoring; outcomes management, or improvements in clinical and administrative processes for delivering care to produce desired outcomes, is at an early state of development.

Patient based health status assessment

Health status, defined in terms of the patient's functioning and wellbeing, is mistakenly considered to be a relatively recent addition to the outcomes lexicon. In fact, recognition of the importance of health status outcomes – "the extent to which changes in a patient's functioning or wellbeing meets the patient's needs or expectations"[12] – dates back at least to surgical quality assessment approaches advocated by Nightingale during the Crimean war[13] and by Groves in Great Britain[14] and Codman in Boston before the first world war.[15] More recently – but still 40 years ago – Lembcke stated that "the best measure of quality is not how well or how frequently a medical service is given, but how closely the result approaches the fundamental objectives of prolonging life, relieving distress, restoring function and preventing disability."[16]

INTEREST IN PATIENT BASED HEALTH STATUS

Several factors account for the current attention to health status evaluated by patients. Studies showing unexplained variations in practice patterns have led to efforts to determine the relation between different practice styles and patient outcomes.[17–20] Concerns over the high costs of health care have helped to create the need to ensure that services, treatments, procedures, and technologies are truly effective in producing desired outcomes. The marketplace increasingly seeks to obtain and document value in healthcare purchases. As employers and community coalitions seek to evaluate the benefits achieved for patients by their healthcare expenditures, providers attempt to demonstrate and improve the value of their services.[7 21] Plans for health care reform call on purchasers and patients to make choices based on value, and they highlight the role of the consumer in evaluating quality of care in terms of outcomes achieved. Finally, the development of reliable and valid patient based instruments for measuring health status has provided new opportunities for implementing outcomes assessment in clinical settings.[22–24]

The reintroduction of health status outcomes recognises two facts. Firstly, the commonly tracked indicators of physiological or organ specific functioning should be supplemented with data on functional status and wellbeing to capture the *full* impact of health problems and their treatment on patients.[25] Secondly, disease specific clinical indicators do not permit useful and important comparisons of the impact of disease and illness *across* case types.[26] Thus, a comprehensive examination of health care outcomes for today's hospital includes patient based assessments of health status in terms of functioning and wellbeing.

A MODEL OF HEALTH STATUS

By the early 1990s, a comprehensive definition of health included three types of measures: biological, general, and disease specific.[27] Biological measures of health status focus on the physiology and functioning of organs and organ systems (or subsystems), and are commonly used during diagnosis as well as to monitor treatment effects. In many cases a given biological measure is closely associated with a particular disease or condition (for example, glycated haemoglobin and diabetes, blood pressure and hypertension, and serum creatinine concentration and kidney disease).

General measures assess aspects of health status that are relevant regardless of individual characteristics (for example, ages, sex, disease, condition). Being generic rather than specific to diseases, conditions, or procedures, most current general health measures reflect the full range of health states, from limitations and disability to wellbeing.[26] Advanced general health status measures capture at least four concepts: physical function, mental health, social and role function, and general health perceptions. Measures of physical function commonly focus on limitations, disabilities, capacities, and abilities in those bodily behaviours that are common to everyday life – for example, self care, walking, and running. Others reflect bodily pain and physical wellbeing. Measures of mental health focus chiefly on frequency and intensity of psychological distress; increasingly, they also include assessments of psychological wellbeing and cognitive functioning. Social and role functioning measures capture the frequency and nature of social contacts and relationships, and the capacity to engage in activities common to a given role (for example, employment, school). Increasingly, these measures capture the impact of physical and mental health problems on social functioning and role performance. Finally, general health perceptions measures are the most generic of all health status measures, reflecting patients' own beliefs and perceptions about health overall, rather than its distinct physical, mental, social, or role aspects.

Although generic measures of health status provide an important "common denominator" for defining health outcomes across diseases (and in terms particularly relevant to individual patients), they do not always provide enough detail or reflect *all* the aspects of health affected by a given disease or condition. Because most outcomes measurement and monitoring activities focus by design on defined clinical groupings, generic measures are typically supplemented by disease specific or condition specific measures.[28] Like the biological measures, they are commonly specific to a single disease or condition; unlike biological measures, they capture the patient's perspective regarding some aspect of that condition or its effect on general health. For example, disease specific

measures may focus on particular functions affected by the disease (mobility of fingers or pain in arthritic patients) or the experience of symptoms indicative of the disease or its treatment (nausea and vomiting in cancer patients). Others may be measures of the general health concepts identified above, with the attribution of any limitation, problem, or disability reported to the particular disease, condition, or procedure under study (for example, pain due to back problems; limitations in role functioning due to dialysis treatment).

USES OF HEALTH OUTCOMES INFORMATION

Several uses of patient based health status data can be identified, each of which underscores the relevance of this patient defined outcome to assessing the quality of care and services, as follows.

- Managing patient care and services
- Improving care delivery system processes
- Monitoring the health of populations
- Recording the efficacy and effectiveness of clinical therapies and practices
- Evaluating the impact of interventions or policies.

In most hospitals, particularly those that have embraced continuous quality improvement precepts, patient defined outcomes are used to manage and improve care and delivery (T Hammonds, unpublished report).[29-31] As hospitals and physician groups, alone or in networks, serve increasing numbers of managed care patients, population monitoring becomes ever more important. The last two uses of patient defined outcomes characterise clinical and evaluative research of outcomes and effectiveness, whether sponsored by foundations; pharmaceutical companies; or state, regional, or national government agencies. Importantly, the results of this research inform health policy reform agendas at all levels of government.

International approaches to health status assessment

Interestingly, multinational approaches to health status assessment seem to be increasing. Efforts to develop and validate standardised measures of health from the patient's viewpoint reflect the importance of such information to multinational clinical trials of new drugs and procedures. Use of such measures in these trials and in routine monitoring of population health status has been prompted in large part by government demands (at least in Western European countries) for information on health related quality of life when approving and reimbursing new therapies and tracking the impact of social policies.

The World Health Organisation, through its division of mental health, sponsors an ongoing project – WHOQOL – designed to produce a quality of life (QOL) assessment for use in healthcare settings.[32] A multicultural effort, involving countries in developing countries as well as Western Europe and the United States, the pilot phase of this project currently focuses on developing the content and structure of the assessment and testing protocols for its use. The EuroQOL instrument, a multidimensional, generic health status assessment designed for use in monitoring population health status,[33] is being validated in England, the Netherlands, Norway, and Sweden. Also the SF-36 health survey, a multidimensional, generical health status assessment designed for use in population monitoring and health care delivery, is currently being translated and validated in 21 countries world wide in the collaborative international quality of life assessment (IQOLA) project.[34 35] To date, the British SF-36 has been published[36]; the German and Swedish versions will appear later in 1994.[37 38]

While these projects currently emphasise research activities, their empirical results – and the standardised, patient based health status assessments they yield – will directly benefit quality of care assessment activities in health care organisations world wide.

This paper is based on a presentation delivered at the Quality '93 conference, London, England, November 1993, adapted in part from Davies *et al.*[11] The section on the types of health status measures was based largely, with permission, on Bungay and Ware.[27] Preparation of the presentation was partially supported by the Measurement and Monitoring Initiative, New England Medical Center, Boston, Massachusetts, where ARD formerly was senior program advisor.

1 Tarlov AR, Ware JE, Greenfield S, Nelson EC, Perrin E, Zubkoff M. The Medical Outcomes Study: An application of methods for monitoring the results of medical care. *JAMA* 1989;**262**:925–30.
2 Donabedian A. Evaluating the quality of medical care. *Milbank.Q* 1966;**44**:166–203.
3 Ware JE, Davies-Avery A, Stewart AL. The measurement and meaning of patient satisfaction. *Health and Medical Care Services Review* 1978;**1**:1–15.
4 Cleary PD, McNeil BJ. Patient satisfaction as an indicator of quality of care. *Inquiry* 1988;**25**:25–36.
5 Meterko MM, Nelson EC, Rubin HR. Patient judgments of hospital quality: report of a pilot study. *Med Care* 1990;**28**:S1–S57.
6 Davies AR, Ware JE. *GHAA's consumer satisfaction survey and user's manual.* 2nd ed. Washington, DC: Group Health Association of America, 1991.
7 Allen HM. *Consumer assessment of health and health care: the central Iowa pilot study.* Boston: The Health Institute, New England Medical Center, 1994.
8 Nelson EC, *et al.* Gaining customer knowledge: Obtaining and using customer judgments for hospitalwide quality improvement. *Topics in Health Record Management* 1991;**11**:13–26.
9 Davies AR, Ware JE. Involving consumers in quality of care assessment. *Health Affairs* 1988;7:33–48.
10 Ellwood PM. Outcomes management: a technology of patient experience. *N Engl J Med* 1988;**318**:1549–56.
11 Davies AR, Doyle MAT, Lansky DJ, Rutt W, Stevic M, Doyle J. *A guide to establishing programs for assessing outcomes in clinical settings.* Oakbrook Terrace: Joint Commission on the Accreditation of Healthcare Organisations, 1993.
12 Ware JE. Conceptualizing and measuring generic health outcomes. *Cancer* 1991;**67**:774–9.
13 Nightingale F. *Proposal for improved statistics of surgical operations.* London: Savill and Edwards, 1863.
14 Groves EW. A plea for a uniform registration of operation results. *British Journal of Medicine* 1908;**2**:1008–9.
15 Codman EA. The product of a hospital. *Surgery, Gynaecology, and Obstetrics* 1914; April: 491–4.
16 Lembcke PA. Evolution of the medical audit. *JAMA* 1967;**199**:111–8.
17 Wennberg JE. Dealing with medical practice variations: a proposal for action. *Health Affairs* 1984;**3**:6–32.
18 Chassin ME, Kosecoff J, Park RE, Winslow CM, Kahn KL, Merrick NJ, *et al.* Does inappropriate use explain geographic variations in the use of health care services? A study of three procedures. *JAMA* 1987;**258**:2533–7.
19 Wennberg JE, Freeman JL, Culp WJ. Are hospital services rationed in New Haven or overutilized in Boston? *Lancet* 1987;i:1185–9.
20 Greenfield S, Nelson EC, Zubkoff M, Manning W, Rogers W, Kravitz RL, *et al.* Variations in resource utilization among medical specialties and systems of care: results from the medical outcomes study. *JAMA* 1992;**267**: 1624–30.
21 Liberthson D. Outcomes measurement creates a market: the Cincinnati Payor Initiative. *Outcomes Measurement and Management* 1993;**4**:1–2.

22 Wenger NK, *et al. Assessment of quality of life in clinical trials of cardiovascular therapies.* New York: Le Jacq, 1984.
23 Lohr KN, Ware JE, eds. Advances in health assessment conference. *Journal of Chronic Diseases* 1987; **40**(suppl):S1–191.
24 Lohr KN. Advances in health status assessment: conference proceedings. *Med Care* 1989;**27**(suppl):S1–294.
25 Patrick DL, Deyo RA. Generic and disease specific measures in assessing health status and quality of life. *Med Care* 1989;**27**:S217–32.
26 Ware JE. Measures for a new era of health assessment. In: Stewart AL, Ware JE, eds. *Measuring functioning and wellbeing: the Medical Outcomes Study approach.* Durham: Duke University Press, 1993:3–11.
27 Bungay KM, Ware JE. *Measuring and monitoring health-related quality of life. Current Concepts.* Kalamazoo, Michigan: Upjohn Company, 1992. (#8804-37.)
28 Kantz ME, Harris WJ, Levitsky K, Ware JE Jr, Davies AR. Methods for assessing condition specific and generic functional status outcomes after total knee replacement. *Med Care* 1992;**30**:MS240–52.
29 Lansky DJ, Butler JBV, Waller FT. Using health status measures in the hospital setting: from acute care to "outcomes management." *Med Care* 1992;**30**:MS57–73.
30 Meyer KB, Espindle DM, DeGiacomo JM, Jenuleson CS, Kurtin PS, Davies AR. Monitoring dialysis patients' health status. *Am J Kidney Dis* (in press).
31 Greenfield S, Nelson EC. Recent developments and future issues in the use of health status assessment measures in clinical settings. *Med Care* 1992;**30**:MS23–41.
32 World Health Organisation. *WHOQOL focus group work.* Geneva: WHO Division of Mental Health, 1993.
33 EuroQOL Group. EuroQOL – A new facility for the measurement of health-related quality of life. *Health Policy* 1990;**16**:199–208.
34 Ware JE. *SF-36 health survey manual and interpretation guide.* Boston: The Health Institute, New England Medical Center, 1993.
35 Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;**30**:473–83.
36 Brazier JE, Harper R, Jones NM, O'Cathain A, Thomas KJ, Usherwood T, *et al.* Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;**305**:160–4.
37 Bullinger M. German translation and psychometric testing of the SF-36 health survey: preliminary results from the IQOLA project. *Soc Sci Med* (in press).
38 Sullivan M, Karlsson J, Ware JE. The Swedish SF-36 health survey. I. Evaluation of data quality, scaling assumptions, reliability, and construct validity across general populations in Sweden. *Soc Sci Med* (in press).