

Review ■

Capturing and Using Clinical Outcome Data: Implications for Information Systems Design

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Abstract There is an urgent need to capture and record data related to clinical outcomes, but there are many barriers. The range of problems includes lack of agreement on conceptualization of the term "outcome," inadequate measures of outcomes, and inadequate information systems to capture and manipulate data that would reflect outcomes. This article focuses on information system requirements to capture, store, and utilize clinical outcome data. For greatest accuracy, outcome data should be captured as close to the source as possible, including direct data capture from patients themselves and from their families. To make maximum use of outcome data, systems must be designed to 1) store data in multipurpose databases; 2) share data across different platforms; 3) link outcome data to other data that might influence or explain outcomes; 4) allow querying of the data by authorized personnel; and 5) protect patient confidentiality.

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The need for capturing measures of client outcomes has been recognized for decades by researchers, policy makers, administrators, payors, and practitioners. A variety of forces have made this need more urgent than ever. From a political perspective, policy- and law-making bodies are responding to consumers' demands for accountability from health care professionals for the results of their treatment plans.^{1,2} Health care professionals themselves, through their professional organizations, have spent a great deal of energy developing guidelines that incorporate outcome standards.³⁻⁵ The U.S. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has made outcome measurement a central focus of its "Agenda for Change."^{6,7} Economic forces around the world are forcing the health care industry to move from its quality-at-any-cost paradigm to models that provide acceptable outcomes within limited costs.^{8,9}

The demand for data to support examination of outcomes of health care has far exceeded our current capacity to respond.¹⁰ The range of problems includes lack of agreement on conceptualization of the term outcome,¹¹ inadequate measures of outcomes,¹² and inadequate information systems to capture and manipulate data that would reflect outcomes.¹³ This article focuses on one of those problems: inadequate information systems to capture and manipulate data that would reflect clinical outcomes. In so doing, it works within the current state of the art of outcome measurement. That is, while acknowledging that many conceptual and methodologic issues do exist, it also recognizes that acceptable, valid, reliable measures of *some* clinical outcomes are currently available, and that more will be developed. Furthermore, it asserts that linkages among outcome indicators and other essential related data (such as patient sociodemographic data, patient clinical data, and provider and site information) are required elements.

Background: Clinical Outcomes in Nursing

Because of the forces described earlier, a great deal has been written recently about nursing-sensitive clinical outcomes. Lang and Marek have provided comprehensive reviews of the literature related to outcomes of nursing care, which amount to a summary of the state of the art.¹⁴⁻¹⁷ Hinshaw,¹⁸ Strick-

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land,¹² Hegyvary,¹⁹ Ozbolt,²⁰ Higgins et al.,²¹ and Johnson and Maas,²² as well as others, have provided analyses of conceptual and methodologic issues related to outcome measurement in nursing. On a more concrete level, there are many examples of clinical articles that report specific interventions and their effects on patient outcomes.^{23,24} After surveying this literature, one is struck by a few overarching observations.

The first is that there appear to be at least two very broad classes of outcomes: those that could be considered *generic*, i.e., pertinent to all consumers of health care services; and those that could be considered *condition-related*, i.e., pertinent to subpopulations of patients who have specific diagnoses or procedures. For example, outcomes related to general physical functioning, such as mobility, may be considered generic outcomes, applicable to all clients. But an outcome such as reduced dyspnea following administration of oxygen in patients who have pneumonia is more pertinent to that subpopulation.

The second observation is that there appears to be a time dimension that must be taken into account in measuring and evaluating clinical outcomes. For example, degree of pain is an outcome that can often be influenced in minutes with appropriate intervention; however, degree of mobility may take days, weeks, or months to reach desired levels, depending on the patient's clinical condition, procedures, therapies, etc. Therefore, repeated measures over time may be required, and expectations of results will be different depending on the point in time at which the outcome is measured.

The third observation is that outcome-related data can come from several sources: from the patient, from biomedical instruments, from families and caregivers, and from health care professionals. Many outcomes are best judged by patients themselves: degree of pain, ability to carry out activities of daily living, mood, satisfaction with care, and quality of life.²⁵ Some outcome measures, such as vital signs and other physiologic parameters, can be obtained from biomedical instruments attached to the patient or from instruments that analyze blood and other biologic products. Some outcome measures, such as affect, behavior, condition of the skin, and social functioning, can be observed by families and lay caregivers. Some outcomes, such as wound healing, respiratory status, and family dynamics, are observed by the patient's health care providers.

The fourth observation is one that has probably occurred to the reader from the examples listed in the previous paragraphs. The single term outcome can

be used at widely varying levels of abstraction, from very broad outcomes such as "health status" or "quality of life" to very specific outcomes such as "blood glucose" or "ability to bathe self." From an informatics perspective, this has implications for linkage and computation. For example, the dimensions of health status are often listed as physical, psychological, emotional, and social functioning.¹² But are these *measures* of health status? Each of these dimensions has subdimensions. One aspect of physical function is the ability to perform activities of daily living. In turn, the subdimension "activities of daily living" is made up of its own set of sub-subdimensions, including eating, walking, bathing, and dressing. Each of these sub-subdimensions can be measured on a scale that ranges, for example, from "independent" to "unable." Thus the atomic-level data element is "ability to bathe self" with a value such as "requires assistance." Ability to bathe self is but one of many measures that can be computed for a total score that reflects the broad outcome "health status." Ware and Sherbourne²⁶ have developed highly structured health status surveys as part of the work of the Medical Outcomes Study.

Of course, it is possible to simply ask patients whether they think their overall health status is "good," "fair," or "poor." However, the crudeness of the measure, the meaning and reliability of the information, and the questionable comparability among large populations of patients would seriously hamper any effort at relating outcomes to practice.

Implications for Systems Design

Each of these observations about outcomes has implications for systems design:

Generic vs. condition-specific. Automated documentation systems can cue the clinician to make pertinent observations related to outcomes. Logic must be specified so that cues for generic outcomes are provided for all patients, and cues for condition-specific outcomes are provided depending on the patient's diagnosis or procedure. Whenever possible, responses to the cues should be structured, with definitions easily available to promote maximum objectivity and reliability.

Time dimension. Immediate outcomes, such as pain relief after administration of analgesic, should be documented immediately, and appropriate technology should be provided to support that. Otherwise, the information becomes "old news," and may never be recorded, or may not be recorded in time to influence further decision making. If a specific medication in

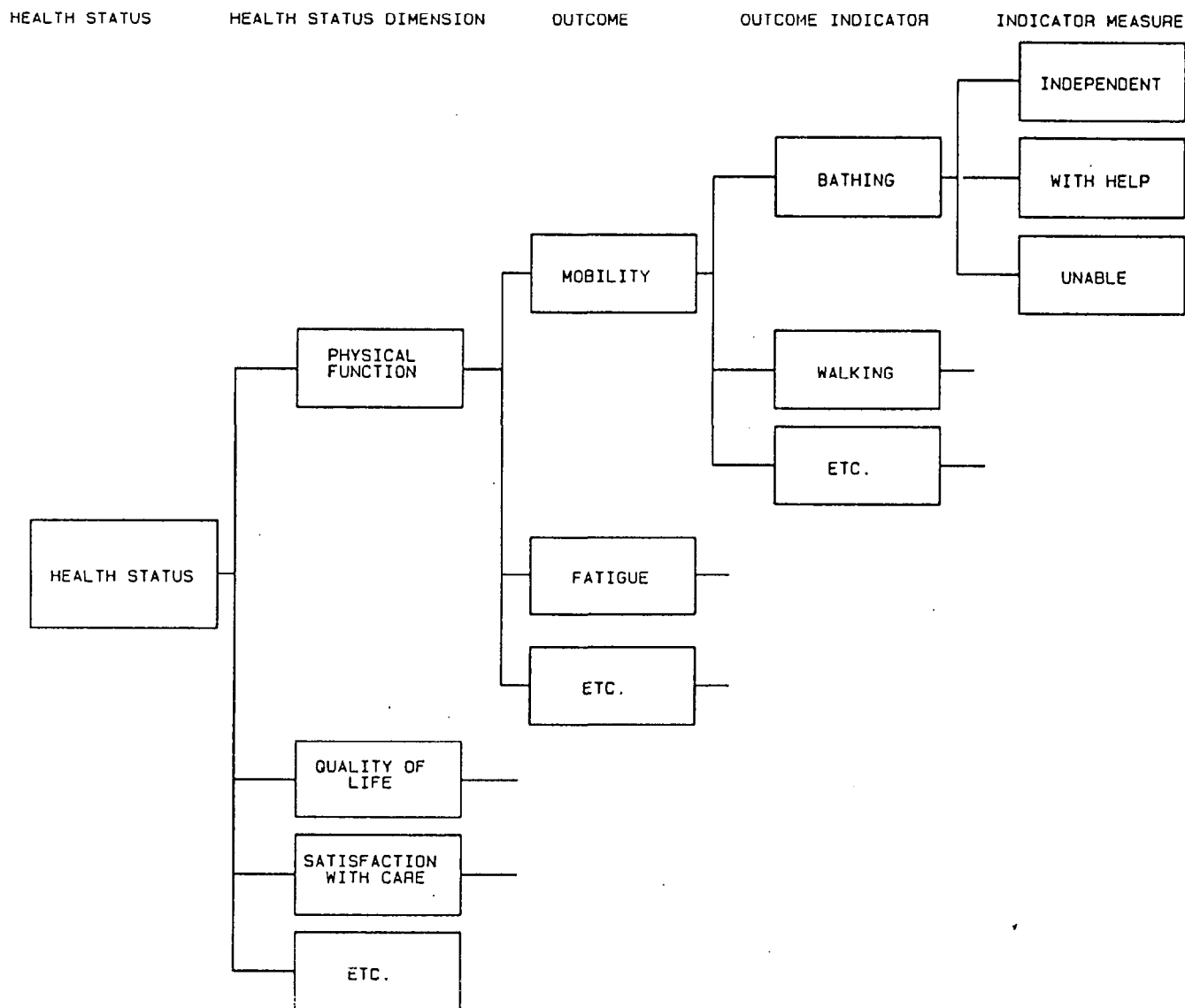


Figure 1 Levels of abstraction that can occur for patient outcomes.

a specific dose is not providing pain relief, then that information must be recorded and acted upon before the time that the next dose is due. For maximum efficiency, this requires point-of-care technology. In some cases, computer-generated alerts may be appropriate when recorded outcomes fall outside the range of the expected or desired.

In contrast, it is probably acceptable for visiting nurses to record functional assessments for their patients through the course of the day, and to hold transmission of these data to the central system until it is convenient, up to several hours later.

For outcomes that are measured repeatedly over time, the system should provide the ability to trend outcome data to support decision making. When patients are seen by multiple providers over extended

periods of time, trended data can contribute to continuity of care and improved decision making. Another major implication of recording outcome measures over time is the necessity for a longitudinal record, one that begins with the patient's entry into the health system and continues throughout the entire health care episode or, more preferably, for life. Appropriate portions of the record must be made available to all authorized providers of care over time, no matter where they are or where the data originated.

Multiple sources of outcome data. Outcome measures should be captured as close to the time and source of their creation as possible. This follows a basic principle of information science that maintains that the less distance there is between the source of a signal

and its receiving point, the less interference there will be with the signal, and the less distortion there will be in the information provided. This means that for outcomes that are best reported by the patient, the patient should have access to technologies that allow him or her to report these outcomes *directly*. In some instances, e.g., reporting functional status, this may be as simple as giving the patient a mark-sense form to complete that is subsequently fed into a mark-sense reader for automatic interpretation and storage. Summaries could then be generated automatically for the clinician to review and to follow up on points that require further clarification. In other instances this may be as sophisticated as a patient's using a computer terminal directly to record blood sugar, using an automated telephone assistant to record blood pressure,²⁷ or wearing a monitor that transmits its measurements directly to a central receiving computer that interprets and stores the data for clinician review.²⁸

When laypeople are expected to provide information related to outcome measures, it may be necessary to provide for their special needs in order to get the most reliable information. For example, native language, cultural background, amount of education, and deficits in hearing, vision, or cognition all require special consideration in developing instruments and tools that elicit outcome-related data from patients and/or their families and lay caregivers. These factors are sources of "interference" that can distort the true outcome data, unless they are appropriately managed.

New technologies are on the horizon that will greatly assist with direct communication between the patient at home and the provider in a remote location. For example, home-based camcorders with links to the "information superhighway" could permit videoconferencing between patients and their health care providers and could allow observation of patients without the necessity for them to leave home. The patient's family could use the camcorder to record the patient's walking, or exercising, or could take pictures of the patient's wound. They could then transmit this information to the health center, where it could be viewed directly by providers or analyzed automatically and summarized for the provider and the patient's record. Multimedia patient records that incorporate video and audio clips are already being described in the literature.²⁹ Telemedicine is an infant technology, with many hurdles yet to be overcome.³⁰ But it holds great promise for following patients directly throughout the course of care, and for directly capturing outcome data without the distortions of memory and perception. Perhaps in the future

"telehealthcare" will be a routine aspect of follow-up care of patients.

Multiple levels of abstraction in outcomes. For maximum utility, each outcome must be reduced to its atomic-level indicators, and each indicator must have a quantifying measure. Figure 1 illustrates the levels of abstraction that can occur, starting with the very high level "health status," down to an atomic-level indicator "bathing," with its measures. Not all outcomes will have as many levels of abstraction. Johnson and Maas, in their research at the University of Iowa on classification of nursing-sensitive outcomes, have specified three levels: outcomes (the conceptual level), outcome indicators (the measurable concepts), and outcome measures (quantification of specific indicators).²² To the extent that the measures are reliable and valid and can be treated as interval data, or at the very least as ordinal data, they will be more useful for aggregation and statistical manipulation.

Using Clinical Outcome Data

The previous paragraphs have focused on capturing clinical outcome data. However sophisticated the means of capturing data is and however reliable and valid the measures are, this will not be sufficient unless systems are designed to allow maximum use of the data. There are at least five critical requirements related to this:

1. The data must be stored in retrievable format, i.e., embedded not in the programs that capture the data, but in multipurpose databases.³¹⁻³³
2. The data must be stored according to standards that allow for data sharing across multiple hardware and software platforms.³⁴
3. There must be a way to link the outcome data to all of the factors that might influence outcomes: morbidities, comorbidities, procedures, treatments, interventions, patient sociodemographic data, provider characteristics, organizational characteristics at the site of care, etc.¹¹ Since it is unlikely that any one information system will contain all this information, the ability to retrieve pertinent information from different systems is a necessity.
4. There must be some way to allow querying of the data, either directly or by downloading to standard data analysis packages.^{31,33}
5. There must be mechanisms in place to protect patient privacy and confidentiality.^{10,35} For individual longitudinal records, data should be provided only to those who have authorized access.

For pooled data, individual patient identifiers should be either stripped or encrypted.

If these requirements were met, computer-stored clinical records would be not just a passive record of events and observations, but a vital resource for managing individual clients, for evaluating quality and costs of care, for research, and for policy making.^{13,20,33,34}

Conclusion

Most U.S. information systems of the past few decades have not been designed with a clinical focus. However, this picture is changing rapidly. Capture and utilization of clinical data are currently very "hot" items in clinical system development, as market forces demand an ability to assess both quality and costs of care. The advent of clinical pathways,³⁶ with their multidisciplinary focus on day-to-day accounting of designated tasks and expected patient outcomes, and the necessity to be able to analyze "variances" from the expected pathway are creating a demand for systems that handle data in a highly structured way. These forces are mandating new system designs that rely heavily on structured, retrievable databases. If care were taken in structuring these databases according to accepted standards, this development could well lead to the ability to create large pools of patient data that could be used for many purposes. Although many conceptual and methodologic issues must be resolved with respect to outcome measurement and evaluation, the technology for capturing, storing, retrieving, and analyzing outcome data is well within reach.

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