Variables, Variability, and Variations Research: Implications for Medical Informatics

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Abstract Variations research is one important strategy in the quality management movement designed to improve the quality of health care and to control costs. Information systems are being utilized in variations research to provide an array of potential variables, to provide measures of the variability inherent in these variables, and to assist with the study of the linkages of patient and provider characteristics with interventions and outcomes. This article presents a systems model of inputs, processes, and outcomes with explication of factors related to client, provider, and setting as a heuristic strategy for variable specification. The implications of variable specification, the design and measurement of variability, and the key issue of control in variations research are linked with a discussion of the implications for medical informatics.

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To understand the design and measurement issues related to variations research, it is helpful to reflect on definitions of variable, variability, and variations that are grounded in measurement theory. These include:

Variable—a property or characteristic of a person, a setting, an event, or a time period that can have different values. Patient demographic variables such as age, ethnicity, and severity of illness are often important in variations research. Provider variables might include location of residency training and years of clinical experience. Characteristics of an intervention might include time to complete task and amount of interpersonal contact with the patient during teaching. One outcome of care might be improved functional status.

Variability—a measure of the extent to which scores on a measure, within a particular sample, differ among themselves. Measures of variability include the range...
(low to high scores), standard deviation, and variance.2 The goal of measurement is to capture the variability that exists in patient, provider, and setting variables.

Variations—the degree of variability of the values or scores on measures of variables in a particular group of participants. Variation in practice refers to providers who implement different therapeutic regimens for patients who have similar demographic characteristics, diagnoses, and severities of illness. Variation may also be the variability in patient outcomes such as functional status or quality of life.

Variables have a degree of predictable or naturally occurring variability. Variations research extends the concept of naturally occurring variability and labels variability as expected or unexpected or as desired or not desired. Variations research begins with the selection of variables hypothesized to be related to outcomes; however, it is often difficult to select which variables to include in the study of variations in health care. This article presents a heuristic outcomes model that can help one to think through many of the variables that might be related to variations of client, provider, and setting characteristics, as well as to interventions and outcomes.

Selecting Variables for Variations Research

The Outcomes Model for Health Care Research provides a framework for examining the complex nature of health-related outcomes (Fig. 1).3 The horizontal axis is a systems axis of inputs, processes, and outcomes based on the work of Donabedian.4 According to Donabedian, structure refers to the resources used in the provision of care, process refers to the activities that constitute care, and outcomes are the consequences to health.5 Holzemer extended these somewhat limited definitions by adding a vertical axis that consists of the three constituents generally involved in a health care encounter: the client, the provider, and the setting.3

| Client/Inputs |
| Client/Processes |
| Client/Outcomes |

The term client is considered to be as inclusive as possible since health care interventions are planned and implemented for both individuals and aggregates of society.6 The client may be an individual, a family, a school, or an entire community. The broader term providers usually refers to traditional health care providers (e.g., physicians, nurses, social workers) yet may include nontraditional healers and other trained community workers. The term setting denotes the formal and informal organizations in which the delivery of health care services takes place. This model extends the work of Donabedian by focusing attention on the interactions and linkages among structure, process, and outcomes at the levels of the client, the provider, and the setting. Variations research captures selected elements of the variability of inputs, processes, and outcomes for the client, the provider, and the setting to make causal statements relating various components of this model.

Client/Inputs

When clients are entered into a health care system, they bring with them a complex constellation of personal characteristics, cultural values and beliefs, social support networks, personal strengths, and concerns and needs. They have varying levels of well-being, functional status, and quality of life. Many of these client characteristics or variables have been linked to variations in health outcomes. The measurements of severity and comorbidity are important in the assessment of the efficacy of health care.7 Small area and regional variation analyses have suggested that sociodemographic factors, e.g., level of education, ethnicity, income per capita, disability rate, and unemployment rate, are statistically significant determinants of the variations in both medical and surgical discharge rates.8 10 Other analyses have documented the importance of considering patient preferences in treatment decisions.11 12

Client/Processes

The relationships between clients’ self-care activities or personal health habits and health outcomes have been the focus of a great deal of research. Research on such topics as diet, weight management, alcohol intake, smoking, preventive health practices, exercise, and patient compliance strongly suggests that there is wide variability of behaviors among individuals and that these behaviors have significant effects on the health of individuals. These self-care practices often explain a large amount of the variation in patient outcomes. Longo used the term “patient practice variation” to refer to domains of health, prevention, and illness and disease in which the variability...
of the patient's practices may directly, as well as indirectly, affect immediate or long-term outcomes, as well as resource consumption.\textsuperscript{12} Variations research is challenged to decide which of these patient practices must be measured to explain variation in outcomes.

**Client/Outcomes**

Maximizing the health of individuals and their communities is considered the primary goal or the outcome of health care services, yet the concept of health is rather vague and thus difficult to measure at a global level of abstraction. Health requires an operational definition that may differ among health care providers and clients.\textsuperscript{11} Patient outcomes have historically been defined as mortality, complications, and measures of utilization such as length of stay and readmission rates. More recently Lohr expanded this conceptualization to include discomfort, disability, and dissatisfaction, in addition to death and disease.\textsuperscript{15} Nursing authors have further expanded and specified patient outcomes to include indicators such as physiologic status, psychosocial status, functional status, behavior (i.e., application of knowledge and skills), knowledge, symptom control, quality of life, home functioning, family strain, goal attainment, safety, and resolution of nursing diagnosis.\textsuperscript{16} There is a growing body of literature describing the development of measures of outcome variables, the natural variability that occurs in these variables in selected populations, and how outcome measures may or may not be sensitive measures appropriate for variations research.

**Provider/Inputs**

Provider inputs include both the technical competence of the provider and the interpersonal skills of the provider. Technical competence involves the knowledge, skills, and judgment of the provider and may be considered the science of care.\textsuperscript{15} The interpersonal dimensions of care are considered the art of care and emphasize the integrity and compassion of the provider in encounters with patients.\textsuperscript{17} Examples of health care provider variables that may have differential effects on client outcomes include level of experience, specialty certification, level of education, and personal characteristics.\textsuperscript{3,18-21} Three additional categories of factors that influence or serve as input to physician practice patterns have been identified: those based on the physician's own benefit, those based on the patient's benefit, and those based on the society at large.\textsuperscript{22}

Since the early 1900s, health care leaders, educators, and administrators have promoted some degree of standardization of practice through the endorsement of educational standards and licensure requirements.\textsuperscript{23} The primary intent of licensure and educational standards is to protect the public from unsafe practitioners.\textsuperscript{24} It is not clear whether the presence or absence of these professional standards can be demonstrated to be related to improved client outcomes; however, it has been established that the higher the percentage of registered nurse (RN) staff in hospitals, the lower the patient mortality rates.\textsuperscript{25,26} It is also clear that these professional standards are related to higher setting operating costs. In addition, standards address only a few of the characteristics that have been linked with provider processes.

**Provider/Processes**

One goal of outcomes assessment is to demonstrate the relationships between processes of care and patient outcomes. When patient outcomes are inadequately linked to specific processes of care, the data offer little guidance for improving the quality of care.\textsuperscript{27} Unexplained regional variations in patterns of medical care practices, such as surgery, hospitalization, length of stay, diagnostic test ordering, and drug prescribing, have been well documented.\textsuperscript{21,28} Variations research on the rates of medical and surgical procedures and comparisons of treatment options have not resulted in consistent explanatory variables. Education, feedback, participation in both clinical and administrative decision making, administrative policies and procedures, financial incentives, and penalties have been effective in changing physician practice patterns.\textsuperscript{22} Critical paths, care maps, standardized care plans, and clinical practice guidelines are recent strategies aimed at the control of variation in the processes of care. Research on the impact of these strategies in changing health care provider practice patterns is under way. For example, in one study the introduction of practice guidelines using opinion leaders resulted in a reduction in the length of stay of patients who had low-risk chest pain without a significant increase in complications, deaths, or readmissions during a two- to four-week follow-up period.\textsuperscript{18}

In nursing, the use of standardized care plans is common within institutions. However, a recent examination of four standardized care plans for patients who have AIDS from four health care institutions with extensive experience in caring for AIDS patients revealed little agreement about the nursing care problems across settings.\textsuperscript{29} The use of standardized care plans for specific patient populations in a variety of settings could enhance the ability to examine the
effectiveness of nursing therapeutics and would allow for comparisons of patient outcomes within and between a variety of health care settings. For example, Henry et al. compared manually generated, computer supported, and standardized care planning systems for patients hospitalized for *Pneumocystis carinii* pneumonia. Although there were significant differences in the numbers of problems reported with the individual systems, no significant difference in patient outcomes was identified.30

**Provider/Outcomes**

Costs of health practitioner services can be considered an outcome at the patient, provider, and setting levels. Provider fees are discussed in this cell because health care providers often bill for and receive different fees based on their professional training. Recent comparisons of the quality and cost of nurse practitioner services versus physician services suggest that nurse practitioners provide comparable quality at reduced costs.31 Other provider outcomes that are of particular interest in systems research include provider satisfaction, provider intent to stay or leave, and level of ongoing continuing education that demonstrates continued competence. The nursing literature has addressed the linkage between practice models and provider outcomes in a number of studies. In one study, the implementation of shared governance resulted in significant improvements in staff nurses’ perceptions of management style and their organizational and professional job satisfaction, and reduced intent to leave.32 In another study, a comparison of a self-management model and a traditional primary nursing model suggested that units adopting a self-management model had increased work satisfaction and retention of staff nurses.33 Physician satisfaction has also been addressed by a number of investigators.34,35

**Setting/Inputs**

Setting input variables include values, attitudes, and beliefs of the organization, as well as available resources including financing, equipment, number and type of providers, size, ownership status, customers, average volume of services, facility type, and environmental and health conditions of communities. Information and documentation systems can also be considered structural characteristics of a setting. Staff mix, staffing levels, professional practice models, and patient acuity levels are setting variables that are often measured in the studies of quality of care and client outcomes. Setting inputs or structural characteristics have been the focus of quality assurance activities for most of the last century.

A recent study of the variation in outcomes of care for nursing home patients demonstrated relationships between structural characteristics and client outcomes. Variations in mortality rates, pressure ulcers, urethral catheterization, and physical restraint were associated with facility characteristics, such as size and for-profit status, and environmental characteristics, such as income per capita and bed supply.36 The relationship between management structures and setting outcomes has also been investigated. Research suggests that hospitals that seek services of contract-management firms are often facing financial difficulties and that given enough time, contract managers appear able to improve the financial conditions of the hospitals they manage.37 Luft posed that the structure and the organization of health maintenance organizations may be responsible for their lower rates of surgery and fewer hospital days.38

Other setting input variables include available medical care resources, number of physicians per capita, percentage of physician specialists, and number of beds per capita. These variables were found to explain between 39% and 56% of the variation in medical and surgical discharge rates.8 An examination of Medicare claims data for 1989 in all U.S. metropolitan statistical areas suggested that areas with high inpatient admission rates tended to have high levels of payment to physicians for inpatient care per admission, and that areas with high payments for inpatient services also tended to have high payments for outpatient services. Expenditures were not related to the number of physicians per capita, but were lower in areas with higher proportions of primary care practitioners.39

**Setting/Processes**

Setting/process variables can include the actual implementation of total quality improvement principles. Setting processes also involve strategic planning, the implementation and evaluation of policies and procedures, governing activities, communication among providers and different departments, evaluation of operational systems, decision making, and organizational interventions. Performance improvement operates on the notion that the ability of an organization to raise the level of its performance and outcomes depends in part on its ability to systematically measure and assess the level at which it carries out the processes of care.40 One interesting measure of setting/processes, communication patterns among nurses and physicians in the intensive care areas, has been demonstrated to be related to reduced mortality rates.41
Setting/Outcomes

Variations in client and provider outcomes by health care setting provide important information of interest to providers, patients, and payers of health care services. Variations in these outcomes by setting are generally measured by evaluating outcomes at the aggregate level. Indicators such as patient satisfaction, provider turnover, morbidity, mortality, malpractice rates, costs of care, and readmission rates are examples of client and provider outcomes that vary by setting. Appropriateness, availability, continuity, effectiveness, efficacy, efficiency, respect and caring, safety, and timeliness are additional dimensions of an organization's performance that are useful in the measurement of processes such as diagnostic tests, procedures, treatments, and services and in the achievement of client health outcomes.40 The significance of these dimensions lies in both their individual impact and their collective impact on patient outcomes and costs and on judgments of quality and value.40 Outcomes assessment can direct an organization's attention to the performance of a process or processes that contribute to the outcome under investigation, permit the setting of priorities for the improvement of processes, and enable an organization to measure the effect of implementing one or more process changes.40 Benchmarking is used as a strategy to report outcomes that vary by setting over time so that an organization can compare its own

Table 1

Key Issues in the Design, Measurement, and Analysis of Variability

<table>
<thead>
<tr>
<th>Study design</th>
<th>Sampling</th>
<th>Selecting a sample for a study of variations has significant impact on the findings. The degree to which the variable varies within the selected sample will determine the results.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Timing and frequency of measurement</td>
<td>Client self-care activities, provider interventions, and health status measures fluctuate with time. The timing and frequency of the measurement may create a false view of reality.</td>
</tr>
<tr>
<td></td>
<td>Data source</td>
<td>Different data sources, e.g., claims data and clinical information systems data, may have differing degrees of errors of coding and missing data. These aspects may reduce the reliability of the data and hence may reduce the ability to draw valid conclusions about variations.</td>
</tr>
<tr>
<td>Measurement</td>
<td>Validity and reliability</td>
<td>Measurement of phenomena with scales that are not standardized, i.e., do not have evidence of validity and reliability, results in drawing conclusions that have low validity or generalizability.</td>
</tr>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Variations research is often interested in capturing change of an outcome measure over time, yet often little evidence is provided of the sensitivity (ability to reflect change over time) of a measure.</td>
</tr>
<tr>
<td></td>
<td>Level of scaling</td>
<td>The level of scaling of a measure (nominal to ratio or discrete/continuous) has a direct effect on one's ability to capture the variability that may exist in it. The level of scaling also impacts on the ability to demonstrate measures of association between interventions and outcomes. Where appropriate, variables ought to be measured with continuous, ratio level scaling. For example, actual age should be captured, not a precoded category system of ages.</td>
</tr>
<tr>
<td>Analyses</td>
<td>Unit of analysis</td>
<td>Variations research struggles with defining the unit of analysis for any one particular study because of the interactions among the cells in the outcomes model presented earlier. There are potential effects of caring for patients on particular units that can affect client outcomes or explain additional variance in the outcome beyond client characteristics and the interventions.</td>
</tr>
<tr>
<td></td>
<td>Missing data</td>
<td>Information systems may choose to leave data elements blank if they are not available when the data are collected; however, data analyses for variations research must make decisions on how to handle missing data (e.g., using mean substitution, if necessary, when there is a great deal of missing data).</td>
</tr>
<tr>
<td></td>
<td>Confounding variables</td>
<td>Most of the literature about risk-adjusted outcomes is attempting to control for the potential relationship between a confounding variable, e.g., severity of illness, and the outcomes of care. The selection and analysis of significant confounding variables is essential in variations research.</td>
</tr>
<tr>
<td></td>
<td>Measuring change</td>
<td>The ability to measure change over time will be linked to the design of the information system and the frequency with which data are collected. For example, if functional status is not measured at hospital admission, will it be a very beneficial outcome measure at discharge?</td>
</tr>
<tr>
<td></td>
<td>Prospective/retrospective</td>
<td>Most variations research analyses data in a retrospective fashion, which limits the ability of the investigator to add important variables, particularly confounding variables. Future variations research will capture data in real time for prospective studies of outcomes.</td>
</tr>
</tbody>
</table>
performances over time and with those of other comparable organizations. This heuristic outcomes model is designed to help planners conceptualize the relevant client, provider, and setting variables important for measurement in variations research. In addition, developers of information systems can use the model in their selection of variables to be captured in their systems so that the variables may be used in studies of variations in outcomes with increased confidence.

**Design, Measurement, and Analysis of Variability**

There are excellent texts about how to measure variability in phenomena, and this brief discussion is not meant to be a review of the psychometric issues related to variability. Rather, several key issues are highlighted to increase our understanding of the relationships among the measurement of variability, variations research, and medical informatics. These issues have been classified into the areas of study design, measurement, and analysis (Table 1).

**Control in Variations Research**

Two basic premises lie at the foundation of research on variation in outcomes: 1) the notion that variation exists in all measured things, and 2) the notion that understanding the underlying causes of variation provides an opportunity to reduce the variation in outcomes. The key concept in variations research is "control for" inputs, processes, and outcomes. In conducting an analysis of outcomes, it is necessary to have only a few variables that are allowed to vary; hence variations research controls for the severity of illness of patients when examining hospital mortality rates, allowing the setting/process variable to vary but controlling for the client/input variable.

Table 2 illustrates the concept of control by providing examples in selected cells of the outcomes model. To date, those working in variations research have limited their work primarily to controlling for patient inputs and provider processes in order to understand variability in client outcomes by setting. Based on the outcomes model described above, it is possible to suggest other variables that may be important to consider because of their relationships to variability in outcomes.

Efforts to reduce variation in health care outcomes play a fundamental role in the agenda of total quality assessment and improvement in health care. Berwick used the terms intended and unintended variation to distinguish between variation based on reason and variation that was not anticipated. Intended variation is planned variation that is introduced for a specific reason and is often the result of guided judgment. Unintended variation results from unplanned friction in the process of delivering health care. Unintended variation erodes quality and reliability in the delivery of health care services, which results in wasted resources. The reduction of unintended variation has become a focus of quality improvement in health care.

**Implications for Medical Informatics**

The need for definitive evidence of the linkages between the processes of care and outcomes is perhaps the most pressing area warranting the attention of health services researchers. Designers and implementers of information systems must be mindful of

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Processes</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus: Clients</td>
<td>Focus: Provider</td>
<td>Focus: Setting</td>
</tr>
<tr>
<td>Client</td>
<td>Attempt to control for impact of variability of inputs on outcomes, e.g., dimensions of risk and severity of illness</td>
<td>Attempt to control for differences in implementation of interventions in order to understand variations in outcomes, e.g., clinical practice guidelines, critical paths, and standardized care plans</td>
</tr>
<tr>
<td>Provider</td>
<td></td>
<td></td>
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<tr>
<td>Setting</td>
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</tbody>
</table>

*Table 2: Key Concepts of Control in Variations Research*
the nature of the underlying variability of certain data needed from existing information systems for outcomes research. Awareness of the nature of the data will provide justification for such modifications as redundant data collection, the need to make explicit links between patient, provider, and organizational data sets, and the requirements for various data types. In this manner, information technology can provide the infrastructure necessary to advance research on variation in health care. Specific implications for medical informatics are in two areas: 1) variable selection and data capture; and 2) delivery of interventions aimed at reducing variation in practice within single or multiple settings.

**Variable Selection and Data Capture**

Whether by design or accident, designers of information systems make decisions about the selection of variables and data capture methods that have a direct impact on the usefulness of the data for variations research. Each of the issues raised in this article is relevant to the development and operations of information systems. The selection of variables that will support the quality assessment and improvement process may be enhanced through the use of the proposed heuristic method so that variables that potentially confound with outcomes will be captured by the system. Certainly the proposed heuristic method is not sufficient for this task, but it can provide an initial framework for clinicians and system planners who are seeking to select with parsimony the variables to be captured by an information system. For example, two categories of variables that may need to be examined in variations research are self-care activities and adherence or compliance to therapeutic regimens. Most information systems do not capture either of these variables.

Selecting variables that have a level of scaling that can capture as much variability as possible increases the utility of the information system for variations research. It would be possible to calculate derived severity scores, e.g., APACHE scores, if the appropriate atomic-level data have been captured by the system. Because variations research has often been conducted using existing administrative databases, this level of data capture has not been available.

The timing and frequency with which variables are captured by point-of-care information systems and stored in secondary databases will have a significant impact on the ability to conduct variations research. Clinicians and researchers must collaborate with information system developers to design strategies for the appropriate frequency and timing of data capture.

**Delivery of Interventions to Reduce Variation in Practice**

Interventions such as standardized care plans, protocols, critical paths, clinical practice guidelines, and benchmarking are aimed at reducing unintended variation in practice for selected groups of patients. Several investigators have recently reported the efficacy and effectiveness of using information technology for the delivery of these types of practice parameters and for concurrent monitoring of compliance with the parameters.

Variations research has been limited by the degree to which existing information systems have captured appropriate variables at the correct level of scaling within logical time frames. Strategies and issues have been raised in this article to assist in enhancing our ability to think about the use of information systems in the area of variations research to facilitate the capture of appropriate data elements for conducting variations research and the delivery of interventions aimed at reducing unintended variation in practice.

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