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An Analysis of Quality Assessment Efforts in Health Care

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AN ANALYSIS OF QUALITY ASSESSMENT EFFORTS IN HEALTH CARE

by

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The purpose of this research was to determine whether consensus could be reached by experts in the field of quality assurance on the most important indicators of health care quality and to determine whether cause and effect relationship could be attributed to the process and outcome indicators suggested in our survey. We invited participation by a representative sample of experts in a Delphi Panel to address these issues. There were 49 respondants to our Round One Questionnaire and they evaluated the relative importance of 50 process and 50 outcome indicators. Panelists were asked to establish cause and effect relationships between the process and outcome indicators where possible on Round Two. The coefficient of correlation was utilized to test the null hypothesis that the relationship between the process:outcome mean score ratios and the process:

outcome cause and effect ratios was not statistically significant at the .01 level. The null hypothesis was rejected and the researchers determined that the relationship between the indicator mean ratios and the cause and effect ratios was statistically significant. It was concluded that indicators high in context and specificity are more useful and important in the measurement of health care quality.

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CHAPTER ONE

INTRODUCTION

Implementation in 1965 of the Medicare national health care program in the United States was followed by immediate pressures to assess the quality and cost-effectiveness of the care provided at taxpayer expense. For the past 25 years providers of health care have been challenged to prove that they are giving care that is both cost-effective and of acceptable quality.

External regulators of health care providers, which have included the Health Care Financing Agency (HCFA), Medicare's Professional Review Organization (PRO), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), various state agencies, and private insurance companies have each developed methodologies for assessing the quality and cost-effectiveness of care provided. In addition, it has been necessary for health care providers to develop their own unique quality assurance and cost control programs in order to satisfy the external regulators. The result is a proliferation of indicators of quality of care as used by the various external agencies and health care providers with little consistency among the indicators now in use by these organizations.

In the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), the United States Congress took a giant leap

toward the development of national criteria by authorizing expenditures of $568 million over the next five years for a new entity to be called the Agency for Policy and Research. That agency will concentrate most of its efforts on establishing guidelines, standards, performance measures, and review criteria for use by review organizations, consumers, providers, and educators. The Agency is charged with developing practice guidelines and studying medical effectiveness through outcomes research (Ellison, 1990).

Recent literature has focused largely on the measurement of outcomes. Outcome standards have considerable intuitive appeal, since presumably the effect of medical care interventions on patients is the true "bottom line" for the health care enterprise and they fit quite nicely in an era which glorifies market behavior. Outcomes are presumed to be what consumers can most readily comprehend and what they care most about. External control agencies by contrast cannot deal very well with outcomes. The reasons for this inability poses questions about the utility of outcome measures altogether. The problem with use of outcome measures by external control agencies is that they do not link cause and effect sufficiently to support control mechanisms that fit in the due process environment. To invoke any kind of sanction on the producer of a bad

outcome, it is necessary to demonstrate that the provider did or failed to do that which caused or contributed to that outcome. Those things that providers do or fail to do are what we usually call "process." To effectively operate any kind of quality assurance process, whether external or internal, one has to be able to associate outcomes with behaviors. If not, adverse outcomes become random events or otherwise inexplicable phenomena that one may deplore but about which it is impossible to do anything. Outcome data tend to be used either in an attempt to employ a crude measure of quality or as a screen or flag to identify instances on which review of the processes of care should be focused. The question thus becomes whether the processes of high quality health care can be sufficiently specified to make external controls effective and worthwhile (Vladeck, 1988).

If, as suggested by previous research, there is insufficient evidence of the relationship between the processes of care and observed patient outcomes, how shall we depend upon either of these elements as reliable indicators of the quality of care provided? The various external agencies involved in assessing the quality (or disquality) of care utilize different outcome and process indicators which circumstance further confounds our ability to draw sound conclusions

from the information gathered. Given the multiciplicity of indicators currently in use by the external regulators of health care, can there be any question why a particular health care institution would have difficulty in deciding which external agency's model to follow?

STATEMENT OF THE PROBLEM

The use of outcome data to measure quality of care provided is limited by the lack of linkages between cause and effect and by insufficient evidence of the relationship between the processes of care and observed patient outcomes. Moreover, there is a lack of consensus among external regulators of health care providers and among the health care providers about the most reliable indicators of both outcomes and processes of care.

PURPOSE OF THE STUDY

The purpose of this study was to assess the presence or absence of consensus among experts as to the most reliable indicators of process and outcome and to establish relationship between the indicators of process and outcome.

ASSUMPTIONS

The following assumptions apply in the study:

1. Patient outcome and process indicators referenced in the research project were applicable to the acute care hospital setting.
2. Some of the outcome and process indicators referenced in this project are currently in use by one or more external control agencies. Other indicators have been developed by health care consultants and by acute care hospitals. The source of the outcome and process indicators which appear in the project was identified where possible.
3. The individuals invited to participate in this study had no bias toward any of the organizations credited for introduction of the outcome and process indicators referenced.
4. The individuals invited to participate in this study have expert knowledge in the field of quality measurement and quality assurance. Participants included quality assurance, risk management, nursing and utilization management professionals.

DELIMITATIONS

The following delimitations apply in the study:

1. The research project invited participation by a representative sample of the 500 expert consultants who are board certified by the National Association of Quality Assurance Professionals (NAQAP), which professional organization maintains active dialogue with the JCAHO and PRO organizations.
2. The research project participants comprised the Delphi Panel.
3. The project format was open-ended and requested creative input from participants.
4. The project required the mailing of two questionnaires. The Round One Questionnaire was mailed to 150 Certified Professionals in Quality Assurance (CPQAs) selected at random from the 500 CPQAs listed in the NAQAP Membership Roster. The Round Two Questionnaire was mailed to only those individuals who responded to the Round One Questionnaire. There were 49 respondants.
5. The Round One Questionnaire was mailed on June 15, 1990, and stipulated that responses must be received by July 15, 1990. The Round Two Questionnaire was mailed on October 10, 1990,

and required that responses be submitted by October 31, 1990. There were 14 respondants.

LIMITATIONS

The following limitations were applied in the study:

1. The study did not address the element of structure in terms of relationship to process or outcome.
2. The outcome and process indicators which received the lowest scores as determined by the experts were deleted from the Round Two Questionnaire. Thus, the ten least reliable process and the ten least reliable outcome indicators did not appear on the Round Two Questionnaire.

DEFINITIONS

1. Quality Assurance is usually defined as consisting of two elements; quality assessment and quality improvement and control, which represent respectively measurement and action (Wyszewianski, 1988).
2. Outcomes are the end results of medical care and represent what happened to the patient in terms of palliation, control of illness, cure or rehabilitation (Brook, Williams & Avery, 1976).
3. Processes of care embody both the technical competence of the provider and the interpersonal or humanistic aspects of the patient-provider relationship. Technical competence involves knowledge, skills, and judgement. The humanistic dimension of care emphasizes integrity and compassion on the part of the care giver as well as mutual respect between physician and patient for the dignity of both parties (Arnold, Povar & Howell, 1987).
4. Quality of care can be summarized by the statement, "Care is of good quality insofar as it contributes to the patient's health and well-being" (Ginsburg & Hammons, 1988, p. 109).

CHAPTER TWO

REVIEW OF THE LITERATURE

HISTORICAL OVERVIEW OF QUALITY ASSURANCE EFFORTS

"The evolution of the health care industry in Western society shares similar patterns of development with industry throughout history. These similarities, when examined against the common background of the ever changing demands and expectations of society, clarify the uncertainties and difficulties that health care professionals and hospitals are facing today; accountability, external regulation and liability. Beginning with the industrial revolution, continuing through the Sherman Anti-trust legislation and the birth of the consumer movement in the 1960s, and culminating in the 1980 landmark legal action against Ford Motor Company for reckless homicide, it is clear that the free market infancy of industry has adapted to the constraints of societal expectations, government regulations and ensuing internal control mechanisms. So, too, has the health care industry evolved to the stage where concerns about the accountability, liability, external regulation and the assured provision of quality patient care are of transcendent importance. This is attested to by the new

professions of quality assurance and risk management, and by the rapidly increasing numbers of hospital based professionals and consultants involved in those areas on a full time basis" (Orlikoff & Lanham, 1987, pp. 11-12).

CONCEPTS OF QUALITY ASSURANCE

"Health care professionals have always had an interest in examining and evaluating the quality of care they provide toward the goal of continually improving the quality of that care. Quality assurance is the term that has come to describe this concept and those activities through which it is expressed" (Orlikoff & Lanham, 1987, p. 13).

The Joint Commission on Accreditation of Health-care Organizations defined quality of patient care as "the degree to which patient care services increase the probability of desired patient outcomes and reduce the probability of undesired outcomes, given the current state of knowledge" (Joint Commission on Accreditation of Healthcare Organizations, 1990, p. 310).

Care is of good quality insofar as it contributes to the patient's health and well-being. The principal dimensions or aspects of quality are "technical" or "interpersonal." Technical quality depends upon how well the science and technology of medicine are

applied to diagnosing and treating the patient's problems. It is largely determined in the context of whether the appropriate services are provided to meet the patient's needs and whether these services are performed competently. Interpersonal quality is dependent upon how well the patient's personal needs are accommodated. Interpersonal quality often depends upon whether the physician communicates well with the patient and will allow the patient to participate in decisions about his or her care (Ginsburg & Hammons, 1988).

Steele (1987) stated that quality assurance in medicine is hard to define because it has been used in so many contexts when applied to other fields, including industry and government. "For the medical application, quality assurance can be divided into three areas; quality control, quality of services and quality of diagnosis/treatment" (Steele, 1987, p. 70).

The American Medical Association has conceptually defined care of high quality as that which consistently contributes to improvement or maintenance of the quality and/or duration of life. This definition essentially characterizes such care as that which is consistently related to favorable patient outcomes. It follows that care of high quality should produce the optimal improve-

ment in the patient's physiological status, physical function, emotional and intellectual performance and comfort at the earliest time possible consistent with the best interests of the patient. It should also emphasize the promotion of health, the prevention of disease or disability, and the early detection and treatment of such conditions. It should be provided in a timely manner. It should seek to achieve the informed cooperation and participation of the patient in the care process and in decisions concerning that process. It should be based on accepted principles of medical science and the proficient use of appropriate technological and professional resources. The care should be provided with sensitivity to the stress and anxiety that illness can generate and with concern for the patient's overall welfare. It should make efficient use of the technology and other health system resources needed to achieve the desired treatment goal. It should be sufficiently documented in the patient's medical record to enable continuity of care and peer evaluation (Council on Medical Service, American Medical Association, 1986).

IMPACT OF COST CONTROL EFFORTS ON QUALITY OF CARE

The medical profession as an industry has been relatively free of both market controls and government

regulations, and has existed as a virtual monopoly in the American economy. Escalating costs have stemmed from the general inflation of prices in this previously uncontrolled sector of the economy (Green & Anderson, 1986).

With the passage of the Hill-Burton Act in the late 1940s, hospitals proceeded under the doctrine of "the bigger, the better" with size, comprehensiveness of services, research and technology contributing to the image of quality of care. Costs, duplication of services, excess capacity and efficient performance were not major issues for survival (Rosenstein, 1986).

The Medicare and Medicaid programs were started in 1966, with the goal of increasing access to medical care for the elderly and medically indigent. Under Medicare, investor-owned hospitals were paid costs plus two percent. Physicians were paid on a fee-for-service basis. Private health insurance was generally paid by employers as part of the work force's benefit package. Individual concern about the health care costs incurred diminished along with out-of-pocket expenses, as the insurance companies and government picked up the bills. The use of hospital and physician services increased (Feldstein, 1986).

The United States Congress balanced many political, structural and policy interests in the enactment of

the Medicare Program in 1965. In the area of payment for inpatient hospital care, the choice was between paying hospital charges or the "reasonable costs" associated with care for beneficiaries. Congress selected the latter approach because it was considered fair to hospitals and ensured access to hospital services for beneficiaries. Extensive administrative regulations and operating instructions defined reasonable costs and methods for determining them. Despite the complexity of the methodologies, the system responded to hospital cost increases simply by providing increased reimbursement; the greater a hospital's costs, the greater was its Medicare reimbursement. The 1978-1979 Congressional debate over hospital cost containment brought increased understanding of the problems associated with hospital payment and fostered a consensus that retrospective cost reimbursement should be replaced. The Congress required the Department of Health and Human Services (DHHS) to develop a full prospective payment proposal for Congressional consideration by the end of 1982. The resulting proposal became the current prospective payment system (Prospective Payment Assessment Commission [ProPAC], 1985).

Implementation in 1983 of Medicare's Prospective Payment System (PPS) for inpatient hospital care

increased pressure for substantial change in the nation's health care system. Because Medicare accounts for about 40 percent of all inpatient hospital expenditures, changes in reimbursement policy significantly affect hospitals in particular and health care in general. In its Report to the Congress of February 1986, ProPAC reported that between 1980 and 1982 alone, health care spending had risen 30%. The Commission attributed the disturbingly rapid growth in national health care spending to higher prices due to general inflation and the more rapid rise in medical care prices, greater use of services per patient, increased intensity of services and growth in the Medicare population. The Report noted in particular that changing medical practice patterns had shifted the site of service away from inpatient hospital settings to those outside the hospital. With its altered financial incentives for hospitals, the PPS created the challenge of maintaining quality health care while restraining costs. PPS has encouraged a reduction of hospital services to include tests, special procedures, supplies, equipment and personnel time devoted to patients. The reduction in hospital services provided to patients was thought to be the natural consequence of the need for hospitals to lower their costs, which could be accomplished only

by controlling resources devoted to inpatient stays (Prospective Payment Assessment Commission [ProPAC], 1986).

ProPAC's June 1988 Report to the Congress presented a far less optimistic view of the results achieved under PPS. It stated that PPS had had mixed effects on health care in America. It claimed that the rate of increase in Medicare inpatient hospital expenditures was down, but that total inflation-adjusted Medicare expenditures continued to increase at rates similar to those of the past ten years. While PPS had encouraged reductions in lengths of stay and other efficiency gains during the early years of the system, recent increases in inpatient expenses per case had been significantly greater than the rate of inflation. Decreased inpatient hospital use had been accompanied by substantial acceleration of expenditures in outpatient, ambulatory and alternative care sites. Thus, there had been a significant shift in the way health dollars had been spent during the 1980's without an apparent change in the overall spending trend. Despite efforts by the health care industry, government and private sector payors toward containment of health care spending, the growth in aggregate expenditures had not changed. The Report stated that in many significant areas, needs were going unmet.

These needs included payment for long-term care services and health services for the millions of Americans who lack financial protection against the costs of illness. ProPAC reported that national health expenditures continued to grow faster than general inflation in the economy. As a result, the proportion of gross national product devoted to health services continues to rise. The proportion grew to 11.2 percent in 1987. During the five year period spanning 1978 to 1983, Medicare spending more than doubled, growing from $26 billion to $58 billion (Prospective Payment Assessment Commission [ProPAC], 1988).

Dr. Sidney Wolfe, co-founder with Ralph Nader of the Public Citizen Health Research Group (PCHRG) in Washington, D.C., stated that high costs to a large extent have resulted from widespread unnecessary and inappropriate health care. PCHRG estimated that as much as one-third of the $540 billion spent on health care in the United States in 1987 was wasted on unnecessary surgery, hospitalizations and other services. Dr. Wolfe stated that too many people are making too much money from health care, a condition resulting from inadequate regulatory restraints. Dr. Wolfe offered his expectation that by the early 1990's there will be an explosion of health-related information

which will revolutionize medicine in that consumers will have the ability to make informed choices about doctors and hospitals (Waldholtz, 1988).

QUALITY IMPROVEMENT AS THE PRIMARY SOURCE OF COST REDUCTION

Peters' investigations have revealed that when quality goes up, costs go down. The elementary force at work is simplification. Since almost all quality improvement comes through simplification of design, layout, processes and procedures, there is an interesting asymmetry which has profound consequences. Cost reduction campaigns do not often lead to improved quality and except for those involving large reductions in personnel, they do not usually result in long-term lower costs. On the other hand, effective quality programs yield not only improved quality, but offer lasting cost reductions and increased revenues as well (Peters, 1987).

Crosby has observed that the cost of quality is the expense of doing things wrong. During a 10 year period at ITT, the cost of quality was reduced by an amount equivalent to 5% of sales. The savings attributable to the quality improvement program were $30 million in 1968, $157 million in 1971, $328 million in 1973 and $530 million in 1976. The

company had eliminated through defect prevention costs amounting to those dollar figures. Crosby advised that the best single way to eliminate or reduce costs is through defect prevention (Crosby, 1979).

"Cost control, productivity, technology and certain other causes can be meaningful for a while. However, the most enduring motivating causes focus on quality, service and the customer and in making the work people do seem worth the effort. Quality service and people quality (making people believe in their individual worth) are motivating because they relate equally to people and the organization. In all of the other causes, the organization comes first and the individual is secondary" (Waterman, 1987, pp. 288-289).

Management does not know the price of non-conformance, according to Crosby (1984). Product companies spend 20% or more of their sales dollars doing things wrong and doing them over. Service companies spend 35% or more of their sales dollars doing things wrong and doing them over. These expenses are very real and very high. A prevention-oriented quality management system can replace all that cost with the modest expense of an educational and

monitoring process (Crosby, 1984).

Minnesota Mining and Manufacturing Company (3M) was a pioneer in the audio tape cassette market but today enjoys only a small market share. The Company almost lost its dominant market share position in video tape cassettes for the same reason; the organization lost its quality leadership. Facing the hard realities of life, the Company rolled up their sleeves and went about the pursuit of quality leadership. Today Minnesota Mining and Manufacturing is rated in the top position in the video tape cassette market in both quality and sales volume. William Coyne, Group Vice President for the Company's Health Care Group, stated that the Company discovered through its Total Quality Management Program that as quality went up, the per unit cost of production went down. Total Quality Management at Minnesota Mining and Manufacturing means doing things right the first time. He offered an interesting parallel for hospitals. He commented that hospitals have been known for quality since the very beginning, but quality is a moving target. Coyne noted that a 1987 Gallop survey found that the most important component of quality hospital care as perceived by the public is simply good treatment by the staff. Good clinical care is important, but

also important is the question of whether the care is delivered in a good and compassionate manner (Coyne, 1988).

Richard Palermo, Vice President for Quality and Customer Satisfaction at Xerox Corporation, stated that when Xerox observed a downward trend in profits and revenues, this was found to be attributable to decreases in quality and cost increases. This combination set the stage for Japanese entry into the copier market. In a short time the Japanese had captured 40% of the copier market. He commented that one of the key Japanese business success elements is the requirement for continual improvement every day. He stated that when an organization adopts a quality policy to provide internal and external customers with solutions which will satisfy their requirements, then that organization will experience a huge cultural change. That organization will move from incomplete or ambiguous understanding of customer requirements to understanding specifically what they want and need. The organization will move from tolerance of a margin of error to zero defects and error prevention. The organization will move from unstructured, individual problem-solving to participative problem-solving and decision-making. Mr. Palermo noted that 20 to 25% of revenue is spent in redoing tasks. He stated

that there are five factors critical to successful implementation of a Total Quality Management Program: (1) top-down development; (2) visible and consistent leadership involvement; (3) participative problem-solving; (4) assessment and coaching on how to use the process; and (5) patience and discipline. He reported that every employee at Xerox is given performance evaluations based on the individual's quality management behavior. Between 1982 and 1986, following implementation of their quality program, Xerox lowered manufacturing costs by 20% and has enjoyed increased market share. Xerox currently has 2500 problem-solving teams who are completely trained on Total Quality Management. Xerox has received the British Quality Award, the Dutch Quality Award, the Deming Prize for its Fuji Division, and has won a record number of customer decisions in favor of Xerox. Mr. Palermo concluded his presentation by stating his belief that use of the quality process to focus on internal and external customers is totally sufficient for business success (Palermo, 1988).

Hospital Corporation of America's Thomas F. Frist, Jr. has stated that a hospital's management must be willing to devote sufficient resources to quality. He has described the quality management process as

that there are five factors critical to successful implementation of a Total Quality Management Program. These factors are top-down development; visible and consistent leadership involvement; participative problem-solving; assessment and coaching on how to use the process; and patience and discipline. He reported that every employee at Xerox is given performance evaluations based on the individual's quality management behavior. Between 1982 and 1986, following implementation of their quality program, Xerox lowered manufacturing costs by 20 percent and has enjoyed increased market share. Xerox currently has 2500 problem-solving teams who are completely trained on Total Quality Management. Xerox has received the British Quality Award, the Dutch Quality Award, the Deming Prize for its Fuji Division, and has won a record number of customer decisions in favor of Xerox. Mr. Palermo concluded his presentation by stating his belief that use of the quality process to focus on internal and external customers is totally sufficient for business success (Palermo, 1988).

Health Corporation of America's Thomas F. Frist, Jr. has stated that a hospital's management must be willing to devote sufficient resources to quality. He has described the quality management process as

"all encompassing" because it involves every employee and every procedure (Perry, 1988).

Deming (1982) claimed that improvement of quality transforms wasted man-hours into better service. The result is a chain reaction which produces lower costs, a better competitive position, happier people on the job, and creation of more jobs. He observed that productivity increases as quality improves because there is less rework and less waste (Deming, 1982).

"It is possible by becoming more efficient to obtain higher levels of quality with the money we now spend or to maintain the present level of quality at lower cost. First, through efficiencies of management and production, we can offer at lower cost the goods and services to be used in health care. Secondly, we can improve clinical efficiency by not using these goods and services in ways that make no contribution to health or which actually bring harm to the patient. Although evidence is sometimes lacking, large savings can be realized from improvements in managerial and clinical efficiency. Since these savings occur without any lowering of the expectation for improvements in health, we should pursue them vigorously and without reservation" (Donabedian, 1986, p. 6).

Glanddier and Segade (1986) presented three conclusions relative to the cost-quality controversy:

(1) medical efficiency and affordable cost are two equal objectives of management; (2) hospital management must view the evaluation of quality as an operational instrument; (3) analysis of hospital care must focus on both administrative and medical questions (Glanddier and Segade, 1986).

The Total Quality Management Program which was introduced at Rush-Presbyterian-St. Luke's Medical Center in Chicago has prompted development of a database to define the costs of quality (staffing, systems, processes) and the benefits realized through improved quality and reduced costs. The hospital expects to be able to measure the reduction in costs and improved financial performance attributable to quality improvement. Additionally, Rush-Presbyterian-St. Luke's anticipates improved employee morale and commitment will occur as a result of their quality program. The hospital expects to undergo a corporate culture change and will build into its performance reward system merit increases which are dependent upon individuals' contributions to quality (Sinioris, 1988).

Brewster and Francis (1988), Corporate Directors of Quality Management and Planning/Marketing for Evangelical Health Systems, have witnessed the favorable impact of improved quality on market share. The organization

believes that quality is the key to growth and survival. Through their Total Quality Management Program the organization expects to add value which is sustainable over a long period of time and which will positively affect the corporation's infrastructure (Brewster & Francis, 1988).

Jeanne Fitzgerald, Vice President for Planning and Marketing, and Dan Willis, Director of Marketing Services for Intermountain Health Care, Inc., Salt Lake City, have stated that in the long term the quality of clinical and personal services will be the major basis for differentiation and will offer the major competitive advantage for most hospitals. They have noted that consumers still rely on physicians' advice when selecting a hospital, but that is shifting to reflect the consumer's increasing role in selection. They advocate a consumer-driven strategy and have completed a detailed survey of the factors contributing to a consumer's perception of hospital quality (Fitzgerald & Willis, 1988).

CALCULATING COST SAVINGS ATTAINED THROUGH IMPROVED QUALITY

If we accept the notion that the cost of quality is the expense of doing things wrong or over again, we are required to focus our attention on specific

undesired outcomes of care which can occur. These outcomes identify possible problems for which potential human, physical and financial loss can be reduced or eliminated through investigation, analysis and corrective action.

The American Hospital Association's Ad Hoc Advisory Committee on Hospital-wide Quality Outcome Indicators identified 24 undesired outcomes. They are as follows:

- Unplanned admissions after outpatient treatment;
- Unplanned readmissions within 15 or 30 days;
- Deaths;
- Cardiac/respiratory arrest;
- Neurological complications not present on admission;
- Low Apgar scores;
- Failure to recognize abnormal laboratory or x-ray results;
- Operative procedure performed during admission for a medical problem;
- Removal of normal tissue during surgery;
- Unplanned removal of or injury to an organ during surgery;
- Unexpected, excessive or multiple transfusions;
- Transfusion reactions;
- Myocardial infarctions occurring within 24 hours after surgery;
- Unplanned return to surgery;

- Unplanned transfers from general care units to special care units;
- Transfers to other facilities;
- Discrepancies on operative consent forms;
- Hospital-incurred trauma;
- Nosocomial infections;
- Significant adverse drug reactions;
- Medication errors;
- Equipment failures;
- Patient/family complaints;
- Returns to the Emergency Room within 15 days

(Schreiber, 1985).

It would be possible to estimate the cost of a hospital-acquired infection through analysis of the billing data and the medical record from the time the patient was diagnosed with the infection until discharge. It would be possible to estimate the cost of an adverse drug reaction by analysis of the billing data and the medical record from the time the reaction occurred until discharge. Similarly, it would be possible to calculate the cost of an unplanned return to surgery, a hospital-incurred trauma, etc.

The cost of repeat x-rays and repeat laboratory studies can be easily estimated. The cost of billing errors and the cost of equipment downtime can be estimated. It would be appropriate to determine the

causative factors surrounding these occurrences which represent the cost of doing things wrong or doing them over.

QUALITY ASSURANCE AS PROGRAM EVALUATION

"It could reasonably be questioned whether quality assurance has been sufficiently identified as an integral part of the program evaluation framework. Quality assurance and program evaluation developed from different roots and have emphasized both the use of different sources of information and the taking of different types of action" (Clemenhagen & Champagne, 1986, p. 383).

More recently a trend has developed to view quality assurance and program evaluation as overlapping and converging. While program evaluation has been defined as any approach used in making a value judgement about a program, quality assurance has traditionally been perceived as a clinical concern, usually delegated to the hospital's medical advisory committee and its subcommittees. The demarcation between clinical and managerial evaluation concerns is no longer as clear as it once was, since the scope of quality assurance has expanded to include concerns previously confined to program evaluation. Today there seems to be little substantive difference between program evaluation and quality assurance as they are now defined, except for

differences in types of analysis used and in ways of organizing information. Evaluation is but one sub-component in the hospital-wide process of management control (Clemenhagen & Champagne, 1986).

The logical blending of quality assurance and program evaluation in a continuing effort to achieve more effective and efficient delivery of services seems inevitable (Woy, Lund & Attkisson, 1986).

EXTERNAL CONTROLS AND LIMITATIONS OF CURRENT METHODOLOGIES USED IN THE MEASUREMENT OF HEALTH CARE QUALITY

"Providers of health services in the United States are subjected to more external controls than their counterparts anywhere else in the world. There are two primary reasons for this. First, there are more external controls in the American system precisely because it is so decentralized, pluralistic and fragmented. Providers in the United States derive their incomes from literally dozens of different sources, each seeking to develop unique external controls on utilization and minimum quality of services or acquiescing in or supporting the collective delegation of that role to government bodies. Secondly, the extent and nature of external controls on providers of health services in this country arise in a way largely not well understood by those providers themselves. In

the American legal context, the critical question, in terms of external controls on the quality of health services, is what constitutes evidence. Subjective clinical judgement which lies at the heart of actual medical practice rarely generates the kind of objective, documentable, testable evidence that becomes necessary whenever quality is called into question. To impose sanctions or provide an official stamp of approval or acceptance, public agencies must extend due process of law to providers, which means observing certain evidentiary standards. The surrounding legal environment pushes external control processes in the direction of that which is objectifiable, measurable, quantifiable. The result, however, is that external control may focus on relatively secondary or tangential aspects of service quality, not because anyone really believes that these aspects constitute high quality service, but because that is what they are capable of focusing on" (Vladeck, 1988, pp. 102-103).

The basic process of external control on health care services can be described in three separate steps: (1) the adoption of formal standards; (2) surveillance of providers to assess the degree of compliance with those standards; and (3) imposition of whatever sanctions or incentives the external control agency may employ in response to deviations from standards. The real problem in the use of external controls to assure quality is

the difficulty specifying the components of quality in a way that can be effectively employed in control processes, either internal or external. In those few instances in which a causal relationship between structural attributes of health care providers and quality of care are well understood, external controls have contributed importantly to quality improvements. The question is what to do about the far more numerous instances in which such causal relationships are not so well understood. To address that question and to more fully explore the relationship between quality and external controls, it is necessary to complete the classic trilogy and consider the outcome and process dimensions of quality (Vladeck, 1988).

Vladeck (1988) commented that the current literature focuses largely on the measure of outcomes. Outcome standards have considerable intuitive appeal and they fit quite nicely in an era that glorifies market behavior, since outcomes are presumably what consumers can most readily comprehend and what they care most about. Vladeck stated that external control processes cannot deal very well with outcomes. The reasons they cannot raises questions about the utility of outcome measures altogether. The problem with use of outcome measures for external control processes is that they do not link cause and effect closely enough to support control

processes that fit in the due process environment. To invoke any kind of sanction on the producer of a bad outcome, it is necessary to be able to demonstrate something that the provider did or failed to do which caused or contributed to that outcome. But those things that providers do or fail to do are what we usually call "process." To effectively operate any kind of quality assurance process, whether internal or external, one must be able to associate outcomes with behaviors. If the association is not established, adverse outcomes become random events, acts of nature, or otherwise inexplicable phenomena about which it is impossible to do anything. If one looks at instances in which outcome data have actually been put to use, they tend to serve one of two purposes. Outcome data are used either as an attempt to employ a crude measure of quality or as a screen or a flag to identify instances on which review of the processes of care should be focused. Thus, such measurement has only an indirect and secondary relationship to assuring quality. The question becomes whether the processes of high quality health care are or can be sufficiently specified to make external control both effective and worthwhile. Vladeck concluded that if we are truly concerned about not merely measuring the outcomes of health services, but assuring that they

are as good as possible, we should probably be devoting less time and energy to the measurement of outcomes themselves and more to the substantially more irksome and frustrating tasks of developing and maintaining internal and external controls on quality assurance processes in health care (Vladeck, 1988).

"Outcome measurement - a central concept of quality of care - has both conceptual appeal and limitations as a practical assessment tool. The degree to which outcomes can be directly related to processes of care continues to be especially problematic. I view the continued debate about whether processes or outcomes are the preferable measure of quality as fundamentally unproductive, because both are needed. To strengthen our understanding of both measures in ascertaining quality of care, I suggest that work in four areas is needed: more definitive evidence of process and outcome linkages; stronger relationships between technology assessment and quality assessment; improved reliability and validity of outcome measures as screening tools; and continued development of health status measures" (Lohr, 1988, p. 37).

CHAPTER THREE

METHODS

This chapter provides a discussion of the methodologies used in this study. The topics include research questions, selection of sample, description of instrumentation and procedures for communicating with the sample population.

RESEARCH QUESTIONS

The purpose of the study was to establish the presence or absence of consensus among experts as to the most reliable indicators of process and outcome in the acute care hospital setting and to attempt to establish relationship between the indicators of process and outcome.

The questionnaire mailed to each participant in the study contained 50 outcome indicators which represent adverse patient occurrences and 50 process of care indicators which can potentially result in a favorable or unfavorable patient outcome. Participants were requested to contribute their ideas for important outcome and process indicators which were not included in the questionnaire. The indicators selected for inclusion in the questionnaire are currently in use by one or more external health care agency(ies) and/or

individual hospitals. Participants were asked to rank the relative reliability of each of the indicators on the Round One Questionnaire.

The Round Two Questionnaire mailed to each of the 49 individuals who responded in Round One required the participants to link each of the top 40 outcome indicators with one of the top 40 process indicators. Where a direct relationship between process and outcome could not be established, participants were asked to state that fact or to furnish their own unique indicators.

SELECTION OF SAMPLE

The individuals invited to participate in this study have expert knowledge in the field of quality measurement and quality assurance. The research project invited participation by a representative sample of the 500 experts who are board certified by the National Association of Quality Assurance Professionals (NAQAP), a professional organization which maintains active dialogue with the JCAHO and the Medicare program administration. The research participants comprised the Delphi Panel. The 1990 NAQAP membership roster was consulted and every fourth board certified individual was identified and invited to participate by responding to the Round One Questionnaire. The NAQAP membership roster begins with the state of Alabama and lists each

board certified member alphabetically within each state category. We also included board certified members who reside in the British Isles.

The Round One Questionnaire was mailed to 150 CPQAs and there were 49 respondants (32.7% response rate). The Round Two Questionnaire was mailed to each of the 49 Round One respondants. There were 14 participants in Round Two (28.6% response rate).

INSTRUMENTATION AND PROCEDURES

The 50 outcome indicators and 50 process of care indicators included in the study are currently in use by one or more external agency (ies) or by individual acute care hospitals. The purpose of the survey was noted on the instructions for completing the instrument (Appendix A). The survey instrument was presented in the matrix question format and was divided into two parts. Part One consisted of 50 suggested patient outcome indicators. Part Two consisted of 50 suggested process of care indicators. Participants were asked to score these indicators in terms of their relative importance. The 49 participating Delphi Panelists identified the 40 most important outcome and the 40 most important process indicators by their assessments on Round One. The panelists established relationship between each suggested outcome and process indicator

where possible on Round Two. Where no relationship could be determined, this was stated by the participants. Panelists were invited to enter their unique indicators when they could not establish a cause and effect relationship between outcome and process. Where relationship between outcome and process could not be provided, we inferred that cause and effect were lacking (Appendix B).

THE COEFFICIENT OF CORRELATION

The correlation coefficient is a widely used measure of the correlation (relationship, association, or dependence) between two variables. The coefficient of correlation is generally denoted by the letter "r." When "r" equals zero, we say that there is no correlation, which means that none of the variations can be attributed to relationship. It is sometimes overlooked that when "r" is calculated on the basis of sample data, we may get a fairly strong correlation by chance (Freund, 1976). Therefore, it was necessary for the researchers to determine whether valid relationships existed between the process and outcome mean scores and the cause-effect ratios of the indicators, or whether these relationships should have been attributed to chance.

RANK CORRELATION COEFFICIENT (SPEARMAN RHO)

Since the calculation of "r" for large sets of paired data can be fairly tedious, it is sometimes appropriate to base "r" on the ranks of the observations instead of their actual numerical values. We utilized the rank correlation coefficient formula and applied it to the process/outcome mean score ratios and the cause and effect ratios for the eleven pairs of process and outcome indicators determined by our panelists to have relationship.

NULL HYPOTHESIS AND ALTERNATIVE HYPOTHESIS

We formulated our hypothesis to be tested in such a way that the probability of erroneously rejecting it could be calculated. Thus, we offered the null hypothesis that the relationship between the process/outcome mean scores and the process/outcome cause and effect ratios would not be significant at the .01 level of significance.

SUMMARY

This chapter discussed research questions and the survey instruments as well as the process of selection of our sample population of experts invited to participate in our Delphi Panel assignments. Our survey instrument for Round One was presented in the

matrix question format. Our panelists are board certified quality assurance experts. Our panelists identified the relative importance of indicators of patient outcome and processes of care. They also identified eleven process/outcome indicator pairs to which cause and effect relationship could be attributed. We defined the coefficient of correlation, the Spearman rho rank correlation coefficient, and the testing of our null hypothesis.

CHAPTER FOUR

ANALYSIS OF RESULTS

The purpose of this study was to determine the most important and useful indicators of patient outcome and processes of care and to determine if a cause and effect relationship existed between the process and outcome indicators. This chapter presents an analysis of the procedures utilized toward this end. The chapter is divided into the following sections:

1. Demographics
2. Discussion of the Relative Importance of The Indicators and Their Cause and Effect Relationships
3. Discussion of The Mean Score and Process/ Outcome Ratio Analysis
4. Discussion of the Results of Correlation Analysis
5. Addressment of Research Questions

DEMOGRAPHICS

Of the 150 board certified professionals in quality assurance who were selected at random from the membership directory of the National Association of Quality Assurance Professionals to participate in our

Delphi Panel, there were 49 who participated in Round One, with 30 of the panelists being registered nurses and 36 employed in hospitals with bed size ranging from 50 to 550 beds. Ten of the panelists hold Master's degrees. Twenty report directly to a Vice President, 9 report to the Chief Executive Officer, and 10 report to other Administrators. The demographics are presented in Tables 1 through 4.

RELATIVE IMPORTANCE OF THE INDICATORS AND THEIR CAUSE AND EFFECT RELATIONSHIPS

Our panelists rated all of the 50 outcome and 50 process indicators suggested on Round One as "somewhat important" to "very important." Mean scores for each of the indicators were computed. 30 of the process indicators received mean scores rated as "very important," while 33 of the suggested outcome indicators had mean scores rated as "very important" by our panelists. The panelists also determined which of the indicators had a cause and effect relationship. Eleven of the 40 pairs of process/outcome indicators presented on the Round Two Questionnaire were found to have cause-effect relationships.

The researchers determined the relative importance of the process and outcome indicators by mean

score computations and comparisons. The researchers also computed cause-effect ratios for each of the eleven pairs determined to have relationship. The researchers found that indicators high in specificity and context offered a greater opportunity for establishing cause and effect relationship.

MEAN SCORE AND PROCESS/OUTCOME RATIO ANALYSIS

We computed mean scores for each of the 50 process and outcome indicators. The indicators were scored in terms of relative importance by each of the 49 Delphi panelists. These are presented in Table 5.

Of the 50 outcome indicators, all received mean scores between 3.0, "somewhat important," and 5.0, "very important." The outcome indicator receiving the highest mean score was Outcome 09 (O-09), with a mean of 4.980. The outcome mean scores are presented in Table 6.

The indicator, "Death related to malfunctioning equipment," was found by our panelists to have a cause and effect relationship with Process 11 (P-11), "Preventive maintenance for critical equipment." Where the relationship between outcome and process could not be provided, we eliminated the indicators from further evaluation.

Of the 50 process indicators presented on Round One, all received mean scores ranging from 3.0, "somewhat important," to 5.0, "very important." Forty of the process indicators were scored between 4.0 and 5.0. The process indicator receiving the highest mean score was Process 37 (P-37), "Surgery not clinically indicated." However, since panelists could not establish a cause and effect relationship for this indicator, it was omitted from further analysis. Thus, the process indicator with the highest mean score which could be linked with an outcome indicator to attribute cause and effect was Process 01 (P-01), with a mean score of 4.61. P-01, "Carrying out Doctor's orders," was linked with Outcome 06, (O-06), "Death related to failure to carry out orders." The mean scores for process indicators are presented on Table 7.

We determined which of the outcome and process indicators had attribution to cause and effect. The researchers concluded that insufficient cause and effect relationship existed when half or more of the 14 panelists in Round Two were unable to attribute an outcome (effect) to a specific process (cause).

There were 11 process/outcome relationships to which cause and effect could be attributed. The relationships are evidenced in Table 8.

Of the 11 process/outcome relationships accepted as valid for cause and effect, the highest cause-effect ratio was found between Process 21 (P-21), "Observing protocols for turning of patient," and Outcome 11 (O-11), "Hospital-acquired decubitus." It is possible that our panelists scored this relationship high because of the emphasis placed on these indicators by the Medicare Program. Hospitals whose patients acquire decubiti after admission receive close scrutiny for quality of care by the Medicare reviewers. Hence, we believe there is a high degree of familiarity with these indicators. Their cause-effect ratio was calculated to be .929, since 13 of 14 panelists linked the two indicators for cause and effect. The cause and effect linkages are presented in Table 9 and Appendix C.

We observed that where context was lacking, panelists experienced difficulty in establishing a cause and effect relationship between process and outcome. For example, on the Round One Questionnaire, Outcome 01 (O-01), was "Death." This indicator

received a low mean score on Round One (3.57) in relation to other outcome indicators which were more specific. For example, Outcome 06 (O-06), "Death related to failure to carry out orders," received a mean score of 4.98.

We established a process/outcome indicator mean score ratio for each of the eleven pairs determined to have a cause and effect relationship.

RESULTS OF CORRELATION ANALYSIS

The coefficient of correlation was used to establish the presence or absence of true relationship between the process/outcome indicator mean score ratios and the cause and effect ratios. The researchers utilized the results of the coefficient of correlation to test their null hypothesis that no relationship existed between the mean score ratios and the cause and effect ratios of the eleven pairs of indicators thought by our panelists to have relationship. The null hypothesis was rejected and the researchers concluded that the relationships between the mean score ratios and the cause and effect ratios were statistically significant at the .01 level of significance. The relationships are presented in Table 10.

ADDRESSMENT OF RESEARCH QUESTIONS

The 49 participants in Round One were able to rank the outcome and process indicators in terms of their relative usefulness and importance. None of the process and outcome indicators presented in the survey instrument received mean scores of less than 3.0, "somewhat important." The researchers concluded that the high mean scores assigned to the indicators by our panelists were reflective of appropriate selection of indicators to be presented in the Round One survey. Participation by one-third of the 150 experts invited also lends credibility to the project. We identified the 10 outcome and 10 process indicators with the lowest mean scores on Round One and excluded them from the Round Two instrument. This required renumbering of the indicators on the Round Two survey.

The Round Two Questionnaire required panelists to establish cause and effect relationships between the suggested outcome and process indicators. Our panelists were able to attribute a cause and effect relationship to 11 pairs of indicators of the 40 presented on the Round Two survey. The researchers concluded that indicators high in context and

specificity possessed greater potential for usefulness. Therefore, the particular wording of each indicator is critical to its usefulness.

TABLE 1

DEMOGRAPHICS

Professional Designation

RN	=	30
LPN	=	01
RRA	=	01
ART	=	07
Unknown	=	10

TABLE 2

DEMOGRAPHICS

Hospital Bed Size

050-100 = 09
101-250 = 13
252-400 = 10
401-550 = 04
551-700 = 07
701-950 = 02
951+ = 01
Unknown = 03

TABLE 3

DEMOGRAPHICS

Reporting Relationship

VP	=	20
CEO	=	09
ADM	=	10
ND	=	04
CMS	=	01
MRD	=	01
QAC	=	01
Unknown	=	03

TABLE 4

DEMOGRAPHICS

Education

MA	=	01
MHSA	=	01
MS	=	03
MPA	=	01
MHA	=	03
MPH	=	01
BS	=	15
BA	=	04
BMT	=	01
BHS	=	01
Other	=	02
Unknown	=	16

TABLE 5

INDICATOR MEAN SCORES
AS NUMBERED ON ROUND TWO

Outcome Indicator Number	Outcome Indicator Mean Score	Process Indicator Number	Process Indicator Mean Score
O-09	4.98	P-37	4.84
O-08	4.96	P-03	4.71
O-03	4.92	P-25	4.67
O-06	4.92	P-04	4.63
O-05	4.88	P-01	4.61
O-04	4.84	P-27	4.57
O-15	4.84	P-33	4.53
O-31	4.79	P-29	4.51
O-07	4.73	P-05	4.49
O-36	4.36	P-34	4.49
O-22	4.59	P-11	4.49
O-20	4.55	P-08	4.47
O-23	4.53	P-13	4.45
O-40	4.49	P-15	4.43
O-25	4.47	P-30	4.43
O-35	4.45	P-40	4.42
O-12	4.33	P-17	4.41
O-24	4.27	P-14	4.41
O-26	4.24	P-16	4.39

TABLE 6

OUTCOME INDICATORS
MEAN SCORE ANALYSIS

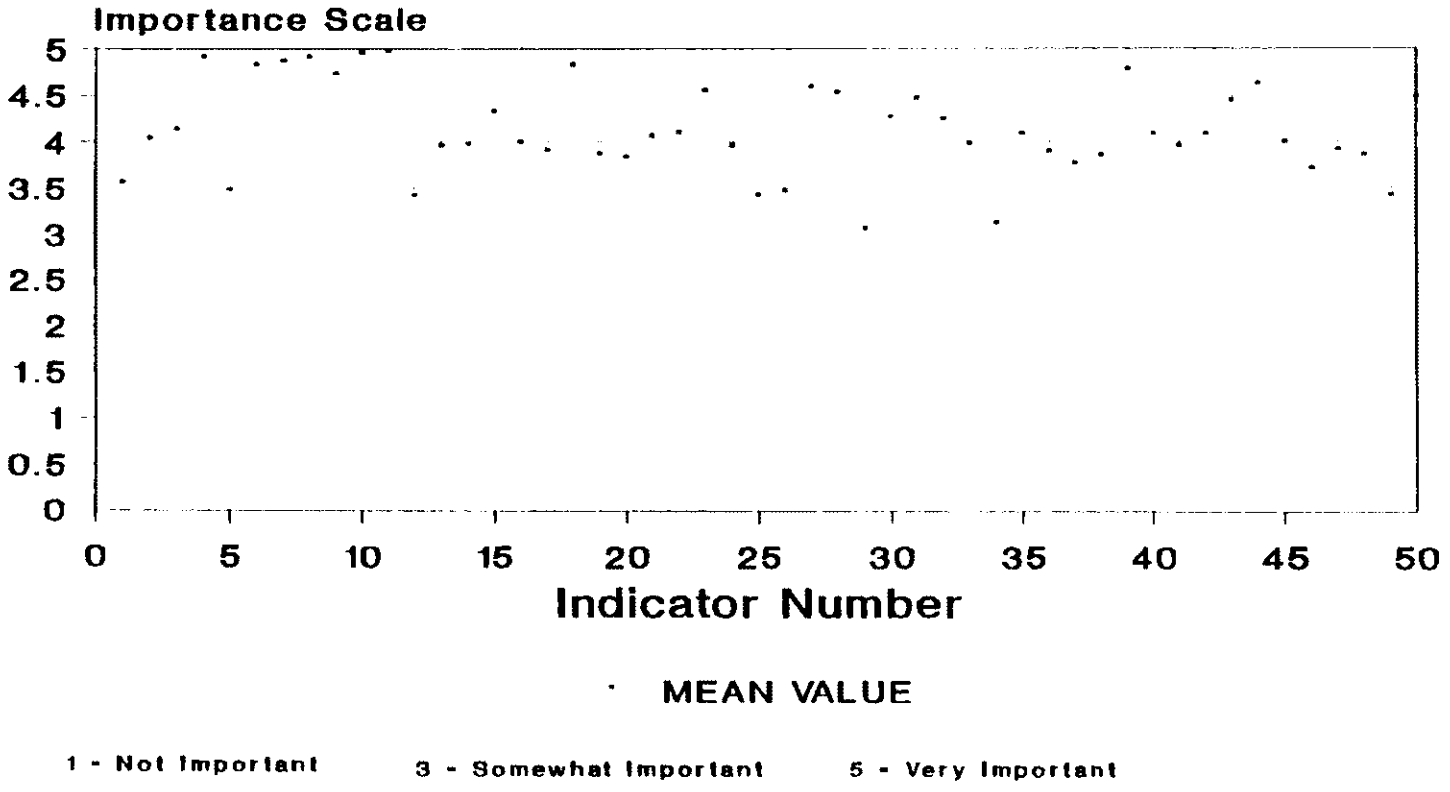

TABLE 7

PROCESS INDICATORS
MEAN SCORE ANALYSIS

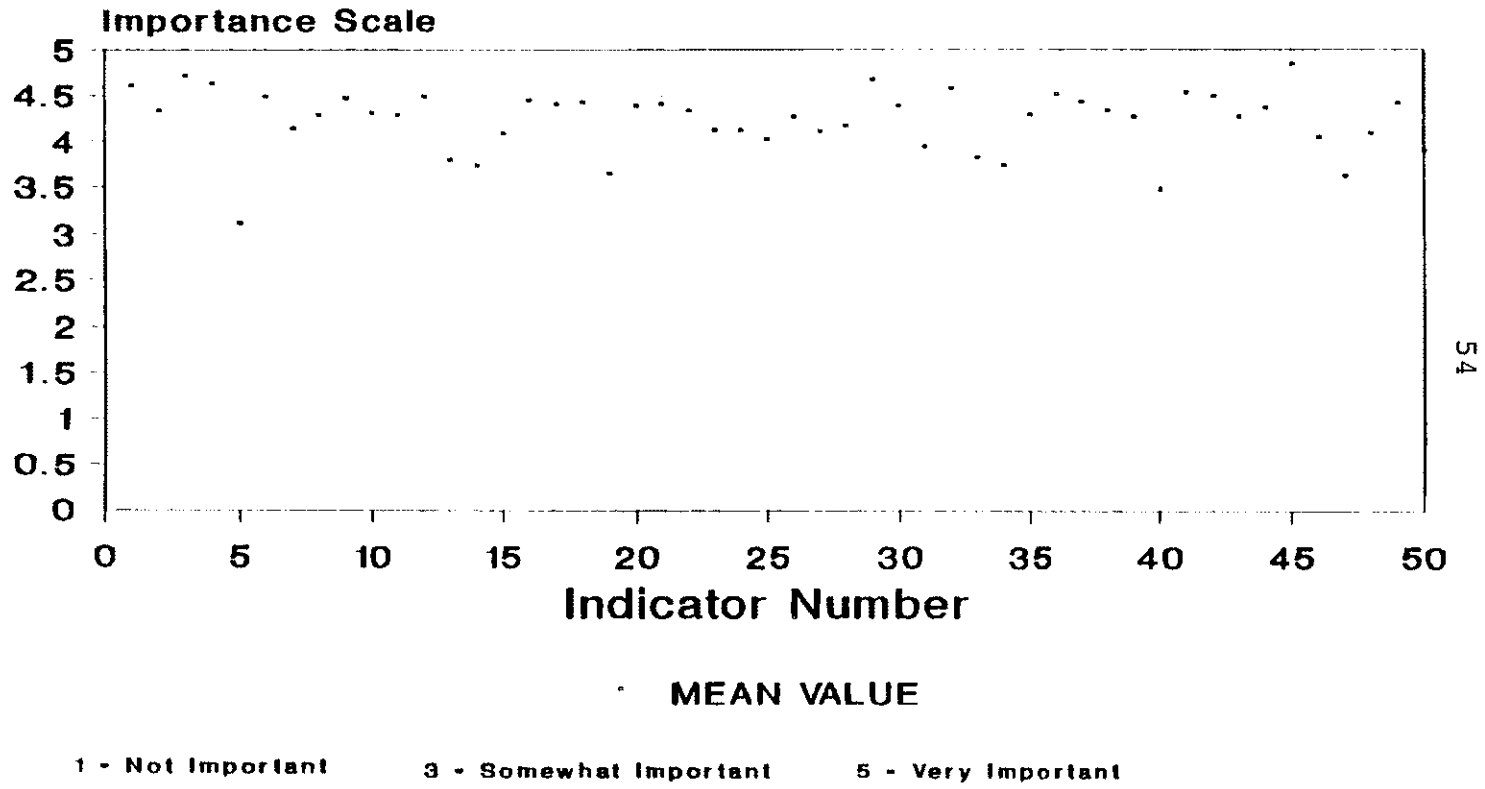

TABLE 8

ROUND TWO DELPHI PANEL RESPONSES

Indicator Cause and Effect Relationships

Process 21/Outcome 11	=	13 votes	from 14 panelists
Process 08/Outcome 15	=	12 votes	from 14 panelists
Process 05/Outcome 14	=	12 votes	from 14 panelists
Process 01/Outcome 06	=	10 votes	from 14 panelists
Process 05/Outcome 08	=	10 votes	from 14 panelists
Process 13/Outcome 10	=	10 votes	from 14 panelists
Process 22/Outcome 20	=	10 votes	from 14 panelists
Process 15/Outcome 40	=	10 votes	from 14 panelists
Process 01/Outcome 06	=	10 votes	from 14 panelists
Process 18/Outcome 24	=	09 votes	from 14 panelists
Process 11/Outcome 09	=	08 votes	from 14 panelists

TABLE 9

ROUND TWO DELPHI PANEL RESULTS

Process:Outcome Cause-Effect Ratio*	Outcome Indicator Number	Outcome Indicator Mean Score	Process Indicator Number	Process Indicator Mean Score	Ratio Process:Outcome Mean Scores
.929	O-11	3.98	P-21	4.02	1:0.990
.857	O-15	4.84	P-08	4.47	1:1.082
.857	O-14	3.92	P-05	4.49	1:0.873
.714	O-08	4.96	P-05	4.49	1:1.105
.714	O-06	4.92	P-01	4.61	1:1.067
.714	O-20	4.55	P-22	4.27	1:1.066
.714	O-40	4.49	P-15	4.43	1:1.014
.714	O-10	3.96	P-13	4.45	1:0.890
.643	O-24	4.27	P-18	4.33	1:0.986
.571	O-34	4.08	P-26	4.39	1:0.929
.571	O-09	4.98	P-11	4.49	1:1.109

* Based on number of votes by participants attributing outcome to corresponding process indicator.

TABLE 10

COMPUTATION OF THE COEFFICIENT OF CORRELATION

Process:Outcome Mean Score Ratio O	Process:Outcome Cause-Effect Ratio E	Indicator Number	Difference D	Difference Squared D^2
1:1.109	.929	O-11:P-21	.180	.0324
1:1.105	.857	O-15:P-08	.248	.0615
1:1.082	.857	O-14:P-05	.225	.0506
1:1.067	.714	O-08:P-05	.353	.1246
1:1.066	.714	O-06:P-01	.352	.1239
1:1.014	.714	O-20:P-22	.300	.0900
1:0.990	.714	O-40:P-15	.276	.0762
1:0.986	.714	O-10:P-13	.272	.0740
1:0.929	.643	O-24:P-18	.286	.0818
1:0.890	.571	O-34:P-26	.319	.1018
1:0.873	.571	O-09:P-11	.302	.0912
				.9080

$$rho = 1 - \frac{6(D^2)}{N(N^2 - 1)} \; ; \; rho = 1 - \frac{6(.908)}{11\ (121-1)} \; ; \; rho = 1 - .0041$$

rho = .9959 = Statistically significant at .01 level for 9 degrees of freedom.

CHAPTER FIVE

SUMMARY, RECOMMENDATIONS AND CONCLUSIONS

SUMMARY

The researchers have followed with interest the development of health care quality assessment and management during the past decade. The continuing quest for accountability to the consumers of health care services as well as to the payors for these services provides the impetus for this development. The need for accountability has been particularly important to the Medicare Program which must oversee the provision of health care services in a cost and quality effective manner. Providers of health care services have turned to the voluntary regulatory bodies (primarily the Joint Commission on Accreditation of Healthcare Organizations) in an effort to maintain some degree of control over their operations. The alternative appears to be federally-mandated provision and control of health care services. We see the U.S. Department of Health and Human Services and the Joint Commission as the dominant forces guiding the requirement for cost and quality effectiveness in health care.

The issue of how best to measure the quality of

health care continues to confound the providers, consumers and regulators of health care services. The Department of Health and Human Services has activated the Agency for Policy and Research which agency has been charged with the responsibility for developing indicators which can be agreed upon as reliable and appropriate measures of quality.

The researchers have been especially interested in Vladeck's (1988) comments in which he stated that external control processes cannot deal very well with outcomes, particularly when causal relationships are not well understood. Vladeck further stated that outcome measures generally do not link cause and effect closely enough to support control processes that fit in the due process environment. Therefore, if outcomes cannot be associated with behaviors, they become random events or otherwise inexplicable phenomena about which it is impossible to do anything. Vladeck argued that health care providers should probably be devoting more time to the tasks of developing and maintaining internal and external controls on processes in health care (Vladeck, 1988). This view would support the current wisdom at the Joint Commission which challenges health care providers to explore improvements in the quality

of the services they provide. The Joint Commission has become increasingly supportive of the Deming management methodology which primarily utilizes scientific approaches to identify defects and rework, focusing on their sources of causation (Deming, 1982).

INTERPRETATION AND CONCLUSIONS

Our Delphi Panelists have confirmed the researchers' expectations that the identification of cause and effect through linkage of process and outcome indicators would be a frustrating and difficult task for participants. The concept of cause and effect has not been widely emphasized in health care quality management. The researchers join those who believe that the health care industry is on the threshold of an exciting new age of possibility through the study of cause (process) and effect (outcome). The Delphi Panelists were able to attribute a cause and effect relationship to 11 process/outcome indicator pairs through their completion of our Round Two Questionnaire. The panelists' thoughtful evaluation and the difficulty of the task is noted. We were also able to conclude that a statistically significant relationship exists between the mean scores of the indicators and their cause and effect ratios.

The researchers eagerly await the findings of the Agency for Policy and Research on health care quality indicators.

RECOMMENDATIONS

1. More work needs to be done on the development of health care indicators which consider the cause and effect relationship.
2. Once process (cause) and outcome (effect) indicators have been developed which are applicable to health care providers, these will need to be tested for reliability and validity.
3. The real need and challenge for health care providers is to become educated on process (cause) and outcome (effect) relationships and to follow this knowledge with an absolute commitment to improving their services.
4. Health care quality management professionals must arm themselves with knowledge shared by their colleagues in industry and the health care arena. There is a compelling need to apply this knowledge toward the goal of achieving improved health care at lower cost.

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Ms. Jane Doe, CPQA
Director of Quality Assurance
City Hospital
Anytown, USA 00010

Dear Ms. Doe:

As a board certified practitioner in the field of Quality Assurance, you are invited to participate in a project concerning the use of outcome and process indicators of quality of care in the health care field.

The study will utilize the Delphi Panel methodology whereby we will collect information from experts on the most valuable outcome and process indicators. The Round One questionnaire will require approimately 30 minutes of your time. If you agree to participate we will furnish you with a summary of the indicators selected as most valuable by approximately 150 (depending on the number of individuals who agree to participate) of your colleagues. In Round Two, we will establish linkages between outcome and process indicators. These results will also be furnished to you upon request. Please make no identifying marks on the instrument.

The end results of this project can only be as valuable as the participants make them. Therefore, we appreciate very much your support and contribution. Please return the completed questionnaire in the enclosed envelope by July 15, 1990.

Sincerely,

Margaret Curran

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INSTRUCTIONS FOR COMPLETING THE PATIENT CARE OUTCOME/PROCESS INDICATORS QUESTIONNAIRE

A. The purpose of the survey is to identify those patient care outcome indicators and processes of care indicators which best represent reliable measures of the quality of care provided in the acute hospital setting.

B. The survey instrument is divided into two parts:

Part 1: Suggested patient outcome indicators which could consistently and accurately reveal the quality of health services provided in the hospital setting.

Part 2: Suggested process of care indicators which could be relied upon to reveal the quality of health services provided in the hospital setting.

C. The rating scale for completing both parts of the survey is as follows:

5 = very important
4 = important
3 = somewhat important
2 = not very important
1 = not at all important

Please circle the number on the scale which most nearly reflects your perception of the importance of each of the patient outcomes (Part 1) and processes of care (Part 2) as illustrated below:

	Very Important		Somewhat Important		Not At All
01. Death	5	4	3	2	1

D. Next, please add additional patient care outcome indicators and process of care indicators that come to mind as you complete the questionnaire.

E. Please return the questionnaire in the enclosed envelope by the date indicated on the cover letter. Thank you.

Part 1: Suggested patient outcome indicators which could consistently and accurately reveal the quality of health services provided in the hospital setting.

Please indicate your opinion on the relative importance of each item as a significant patient outcome indicator using the scale below. Please circle the number which most nearly reflects your perception of the importance of each outcome.

5 = very important
4 = important
3 = somewhat important
2 = not very important
1 = not at all important

Patient Outcome Indicator	Very Important		Somewhat Important		Not At All
01. Death	5	4	3	2	1
02. Death within 24 hrs. of admission	5	4	3	2	1
03. Death within 72 hrs. of transfer from a Special Care Unit	5	4	3	2	1
04. Unexpected death	5	4	3	2	1
05. Death in ICU or CCU	5	4	3	2	1
06. Death within 72 hrs. of elective surgery	5	4	3	2	1
07. Death related to complication of elective surgery	5	4	3	2	1
08. Death related to failure to carry out orders	5	4	3	2	1
09. Death related to complication of treatment	5	4	3	2	1
10. Death related to medication errors	5	4	3	2	1
11. Death related to malfunctioning equipment	5	4	3	2	1
12. Fall	5	4	3	2	1
13. Nosocomial Infection	5	4	3	2	1
14. Hospital acquired decubitus	5	4	3	2	1
15. Return to surgery within 24 hours of procedure	5	4	3	2	1
16. Unplanned admission following outpatient surgery	5	4	3	2	1
17. Medication error	5	4	3	2	1
18. Life-threatening complication of anesthesia	5	4	3	2	1
19. Transfusion reaction	5	4	3	2	1
20. Adverse drug reation	5	4	3	2	1
21. Unexplained reaction to anesthesia	5	4	3	2	1
22. Malnutrition during hospital stay	5	4	3	2	1
23. Hospital incurred trauma	5	4	3	2	1
24. Cardiac/respiratory arrest (exclude "no code" patients)	5	4	3	2	1
25. Readmission within 30 days after discharge from hospital	5	4	3	2	1

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Patient Outcome Indicator	Very Important		Somewhat Important		Not At All
26. In-hospital transfer to ICU/CCU	5	4	3	2	1
27. Injury during invasive procedure	5	4	3	2	1
28. Neurologic deficit not present on admission but present at discharge	5	4	3	2	1
29. Walkout (AMA, AWOL)	5	4	3	2	1
30. Incorrect radionuclide	5	4	3	2	1
31. Foreign body retained	5	4	3	2	1
32. Altered neurological function not present on admission	5	4	3	2	1
33. Postsurgical bleeding	5	4	3	2	1
34. Radiology film rejects/repeats	5	4	3	2	1
35. Apgar less than 3 at 1 minute or less than 6 at 5 minutes	5	4	3	2	1
36. Prolonged labor (over 24 hours)	5	4	3	2	1
37. Induction without progress (over 6 hrs)	5	4	3	2	1
38. OB laceration, 4th degree	5	4	3	2	1
39. Birth injury	5	4	3	2	1
40. Stillbirth/fetal demise	5	4	3	2	1
41. Myocardial infarction or stroke occurring during hospitalization	5	4	3	2	1
42. Patient/family dissatisfaction	5	4	3	2	1
43. Admission for adverse results of outpatient management	5	4	3	2	1
44. Readmission for complications of previous hospitalization	5	4	3	2	1
45. Postoperative pulmonary embolus	5	4	3	2	1
46. Postoperative atelectasis	5	4	3	2	1
47. Postoperative fistula formation	5	4	3	2	1
48. Hypoxia not evident on admission	5	4	3	2	1
49. Postoperative fluid retention	5	4	3	2	1
50. Anaphylactic reaction where patient's allergies not documented	5	4	3	2	1

Please list your suggestions here

51. _____	5	4	3	2	1
52. _____	5	4	3	2	1
53. _____	5	4	3	2	1

Part 2: Suggested process of care indicators which could be relied upon to reveal the quality of health services provided in the hospital setting.

Please indicate your opinion on the relative importance of each item as a significant care process using the scale below. Please circle the number which most nearly reflects your perception of the importance of each care process.

5 = very important
4 = important
3 = somewhat important
2 = not very important
1 = not at all important

	Patient Care Process Indicator	Very Important		Somewhat Important		Not At All
01.	Carrying out Doctor's orders	5	4	3	2	1
02.	Timely diagnosis	5	4	3	2	1
03.	Accurate diagnosis	5	4	3	2	1
04.	Prompt initiation of treatment	5	4	3	2	1
05.	Autopsy request	5	4	3	2	1
06.	Medications given on time, in correct dosages and via correct route	5	4	3	2	1
07.	Obtaining appropriate consultations	5	4	3	2	1
08.	Obtaining prompt results from diagnostic tests	5	4	3	2	1
09.	Performing complete preoperative/ postoperative anesthesia assessments	5	4	3	2	1
10.	Obtaining sensory levels on spinal anesthesia cases	5	4	3	2	1
11.	Replacing fluids adequately	5	4	3	2	1
12.	Preventive maintenance for critical equipment	5	4	3	2	1
13.	Performing nutritional assessments	5	4	3	2	1
14.	Instructing patients on modified diets	5	4	3	2	1
15.	Obtaining vital signs assessments	5	4	3	2	1
16.	Observing sterile technique protocols	5	4	3	2	1
17.	Observing isolation protocols	5	4	3	2	1
18.	Performing assessment of patient at admission	5	4	3	2	1
19.	Assigning patient to proper nursing care unit	5	4	3	2	1
20.	Regular checks to determine proper calibration of radio-nuclide equipment	5	4	3	2	1
21.	Regular checks to determine proper calibration of surgical equipment	5	4	3	2	1
22.	Observing proper radiopharmaco-logical technique	5	4	3	2	1

Continued on reverse side

Patient Care Process Indicator	Very Important		Somewhat Important		Not At All
23. Observing protocols for changing of IV site and dressings	5	4	3	2	1
24. Observing protocols for changing of surgical dressings	5	4	3	2	1
25. Observing protocols for turning of patient	5	4	3	2	1
26. Performing falls/risk assessment at admission	5	4	3	2	1
27. Observing protocols for raising of bed side rails	5	4	3	2	1
28. Observing protocols for use of restraints (active & passive)	5	4	3	2	1
29. Maintaining adequate communication among physician staff, nursing staff and other members of the health care team	5	4	3	2	1
30. Patient education	5	4	3	2	1
31. Maintaining clean patient rooms	5	4	3	2	1
32. Maintaining clean surgical suites and diagnostic rooms	5	4	3	2	1
33. Maintaining clean public areas within hospital	5	4	3	2	1
34. Performing periodic health checks for direct care providers and others in contact with patients	5	4	3	2	1
35. Checking for safety of patient transport equipment	5	4	3	2	1
36. Monitoring of kidney function when aminoglycoside is used	5	4	3	2	1
37. Regular checking of emergency carts, boxes and equipment	5	4	3	2	1
38. Pharmacy assessments of drug orders (including stop orders)	5	4	3	2	1
39. Carrying out doctor's orders for respiratory treatment	5	4	3	2	1
40. Preventive medicine workups performed by physicians who treat patients in Ambulatory Care setting	5	4	3	2	1
41. Failure of M.D. to respond to call	5	4	3	2	1
42. Nephrotic antibiotic ordered without peak/trough serum levels or without renal function studies	5	4	3	2	1
43. Failure to check vital signs after blood transfusion	5	4	3	2	1
44. Transfusion not clinically indicated	5	4	3	2	1
45. Surgery not clinically indicated	5	4	3	2	1
46. Patient given 3 or more antibiotics concurrently	5	4	3	2	1
47. Transfer from general to special care unit	5	4	3	2	1

	Patient Care Process Indicator	Very Important		Somewhat Important		Not At All
48.	Respiratory therapy not given as per orders	5	4	3	2	1
49.	Trauma alert response time	5	4	3	2	1
50.	Continuous compliance with pre-operative checklist requirements	5	4	3	2	1

Please list your suggestions here

51.	_____	5	4	3	2	1
52.	_____	5	4	3	2	1
53.	_____	5	4	3	2	1

OLD DOMINION UNIVERSITY

College of Health Sciences
School of Community Health Professions and Physical Therapy
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Dear Colleague:

Thank you for serving on our Delphi Panel via your completion of the Round One Questionnaire.

We have computed the mean, median and standard deviation scores for each of the fifty outcome and fifty process indicators which were submitted for your consideration. The Round Two Questionnaire contains the mean scores for the highest ranking outcome and process indicators. The ten outcome and ten process indicators with the lowest mean scores on Round One have been eliminated from the Round Two Questionnaire.

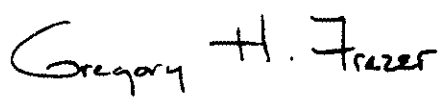
You are requested to indicate on the Round Two Questionnaire which of the process indicators are best related to each of the outcome indicators in terms of cause and effect linkages. If, in your opinion, there is no appropriate process indicator available to relate to a particular outcome indicator, please either write "none" in the space provided or write in a suggested process indicator. Please note that the outcome indicators are phrased in the context of adverse outcomes and that the process indicators are phrased in the context of appropriate processes of care. Therefore, you will need to view the processes of care as those which if not carried out properly could cause the adverse outcomes.

Please return the Questionnaire in the enclosed envelope by October 28, 1990. We will be glad to mail you a copy of the Round Two Questionnaire results if you will designate that you wish us to do so in the space provided at the bottom of this page.

We appreciate your continued participation.

Sincerely,

Margaret Curran, CPQA, RRA
Master's Degree Candidate
School of Community Health Professions
Old Dominion University
Norfolk, Virginia 23529



Gregory H. Frazer, Ph.D.
Graduate Program Director
School of Community Health Professions
Old Dominion University
Norfolk, Virginia 23529

If you wish a copy of the Round Two Questionnaire results, please write "Yes" in the following space:_____.

ROUND TWO

INSTRUCTIONS FOR COMPLETING
THE PATIENT CARE OUTCOME/PROCESS INDICATORS RELATIONSHIPS
QUESTIONNAIRE

A. The purpose of the survey is to identify those outcome indicators which can be attributed specifically to process of care indicators.

B. The survey instrument is designed to allow you to select the process indicator which is best related to each outcome indicator.

C. The outcome indicators are phrased in the context of adverse outcomes while the process of care indicators are phrased in the context of appropriate processes of care. Therefore, you will need to view the processes of care as those which if not carried out properly could cause the adverse outcomes.

Examples:

Outcome Indicator	#	Process Indicator
09. Death related to malfunctioning equipment	17.	Regular checks to determine proper calibration of surgical equipment
11. Hospital acquired decubitus	21.	Observing protocols for turning of patient
01. Death within 24 hrs. of admission	None	

D. If you cannot select from the Questionnaire listing a process indicator to link with an outcome indicator, please write "none" in the corresponding process indicator blank space or write in the blank space your suggested process of care which if not properly observed could result in the adverse outcome.

E. Please return the Questionnaire in the enclosed envelope by the date indicated on the cover letter. Thank you.

MEAN SCORES FOR INDICATORS: ROUND ONE

The mean scores of each of the 40 outcome and process indicators as ranked from 5 (very important) to 1 (not at all important) by the 49 participants in the Round One survey are provided.

ROUND TWO INSTRUCTIONS

Please place in the blank space following each outcome indicator the number representing the process of care indicator which in your opinion is most likely to have caused the outcome. If you cannot select a process indicator from the list to link with the outcome indicator, please write "none" in the corresponding process indicator blank space provided or write in the space your suggested process of care.

Mean Score		Outcome Indicator	#	Process Indicator
4.04	01.	Death within 24 hrs. of admission	____	_____
4.16	02.	Death within 72 hrs. of transfer from a Special Care Unit	____	_____
4.92	03.	Unexpected death	____	_____
4.84	04.	Death within 72 hrs. of elective surgery	____	_____
4.88	05.	Death related to complication of elective surgery	____	_____
4.92	06.	Death related to failure to carry out orders	____	_____
4.73	07.	Death related to complication of of treatment	____	_____
4.96	08.	Death related to medication error	____	_____
4.98	09.	Death related to malfunctioning equipment	____	_____
3.96	10.	Nosocomial infection	____	_____
3.98	11.	Hospital acquired decubitus	____	_____
4.33	12.	Return to surgery within 24 hours of procedure	____	_____
4.00	13.	Unplanned admission following outpatient surgery	____	_____
3.92	14.	Medication error	____	_____
4.84	15.	Life-threatening complication of anesthesia	____	_____
3.88	16.	Transfusion reaction	____	_____
3.84	17.	Adverse drug reaction	____	_____
4.06	18.	Unexplained reaction to anesthesia	____	_____
4.10	19.	Malnutrition during hospital stay	____	_____
4.55	20.	Hospital incurred trauma	____	_____
3.96	21.	Cardiac/respiratory arrest (exclude "no code" patients)	____	_____

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4.59	22.	Injury during invasive procedure	____	_____
4.53	23.	Neurologic deficit not present on admission but present at discharge	____	_____
4.27	24.	Incorrect radionuclide	____	_____
4.47	25.	Foreign body retained	____	_____
4.24	26.	Altered neurological function not present on admission	____	_____
3.98	27.	Postsurgical bleeding	____	_____
4.09	28.	Apgar less than 3 at one minute or less than 6 at five minutes	____	_____
3.89	29.	Prolonged labor (over 24 hours)	____	_____
3.85	30.	Obstetrical laceration, 4th degree	____	_____
4.79	31.	Birth injury	____	_____
4.09	32.	Stillbirth/fetal demise	____	_____
3.96	33.	Myocardial infarction or stroke occurring during hospitalization	____	_____
4.08	34.	Patient/family dissatisfaction	____	_____
4.45	35.	Admission for adverse results of outpatient management	____	_____
4.63	36.	Readmission for complications of previous hospitalization	____	_____
4.00	37.	Postoperative pulmonary embolus	____	_____
3.92	38.	Postoperative fistula formation	____	_____
3.86	39.	Hypoxia not present on admission	____	_____
4.49	40.	Anaphylactic reaction where patient's allergies not documented	____	_____

PROCESS OF CARE INDICATORS

Mean Score		Process Indicator
4.61	01.	Carrying out Doctor's orders
4.33	02.	Timely diagnosis
4.71	03.	Accurate diagnosis
4.63	04.	Prompt initiation of treatments
4.49	05.	Medications given on time, in correct dosages and via correct route
4.14	06.	Obtaining appropriate consultations
4.29	07.	Obtaining prompt results from diagnostic tests

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4.59	22.	Injury during invasive procedure	____	_____
4.53	23.	Neurologic deficit not present on admission but present at discharge	____	_____
4.27	24.	Incorrect radionuclide	____	_____
4.47	25.	Foreign body retained	____	_____
4.24	26.	Altered neurological function not present on admission	____	_____
3.98	27.	Postsurgical bleeding	____	_____
4.09	28.	Apgar less than 3 at one minute or less than 6 at five minutes	____	_____
3.89	29.	Prolonged labor (over 24 hours)	____	_____
3.85	30.	Obstetrical laceration, 4th degree	____	_____
4.79	31.	Birth injury	____	_____
4.09	32.	Stillbirth/fetal demise	____	_____
3.96	33.	Myocardial infarction or stroke occurring during hospitalization	____	_____
4.08	34.	Patient/family dissatisfaction	____	_____
4.45	35.	Admission for adverse results of outpatient management	____	_____
4.63	36.	Readmission for complications of previous hospitalization	____	_____
4.00	37.	Postoperative pulmonary embolus	____	_____
3.92	38.	Postoperative fistula formation	____	_____
3.86	39.	Hypoxia not present on admission	____	_____
4.49	40.	Anaphylactic reaction where patient's allergies not documented	____	_____

PROCESS OF CARE INDICATORS

Mean Score		Process Indicator
4.61	01.	Carrying out Doctor's orders
4.33	02.	Timely diagnosis
4.71	03.	Accurate diagnosis
4.63	04.	Prompt initiation of treatments
4.49	05.	Medications given on time, in correct dosages and via correct route
4.14	06.	Obtaining appropriate consultations
4.29	07.	Obtaining prompt results from diagnostic tests

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Process  2 predicts outcome  1:    1 votes.
Process  3 predicts outcome  1:    1 votes.
Process  4 predicts outcome  1:    2 votes.
Process  6 predicts outcome  1:    1 votes.
Process 15 predicts outcome  1:    1 votes.
Process 33 predicts outcome  1:    1 votes.
Process 40 predicts outcome  1:    1 votes.

Process  3 predicts outcome  2:    1 votes.
Process  6 predicts outcome  2:    1 votes.
Process 12 predicts outcome  2:    1 votes.
Process 15 predicts outcome  2:    1 votes.
Process 25 predicts outcome  2:    4 votes.

Process  2 predicts outcome  3:    1 votes.
Process  3 predicts outcome  3:    3 votes.
Process 25 predicts outcome  3:    2 votes.

Process  8 predicts outcome  4:    5 votes.
Process 37 predicts outcome  4:    1 votes.

Process  1 predicts outcome  5:    1 votes.
Process  2 predicts outcome  5:    1 votes.
Process  3 predicts outcome  5:    1 votes.
Process  4 predicts outcome  5:    3 votes.
Process  8 predicts outcome  5:    1 votes.
Process 15 predicts outcome  5:    1 votes.
Process 37 predicts outcome  5:    2 votes.

Process  1 predicts outcome  6:   10 votes.
Process  4 predicts outcome  6:    1 votes.
Process 25 predicts outcome  6:    2 votes.
Process 32 predicts outcome  6:    1 votes.

Process  2 predicts outcome  7:    1 votes.
Process  4 predicts outcome  7:    2 votes.
Process  7 predicts outcome  7:    2 votes.
Process 25 predicts outcome  7:    3 votes.
Process 34 predicts outcome  7:    2 votes.

Process  3 predicts outcome  8:   10 votes.
Process 29 predicts outcome  8:    1 votes.
Process 31 predicts outcome  8:    1 votes.

Process 11 predicts outcome  9:    8 votes.
Process 17 predicts outcome  9:    5 votes.
Process 30 predicts outcome  9:    1 votes.

Process 13 predicts outcome 10:   10 votes.
Process 14 predicts outcome 10:    1 votes.
Process 27 predicts outcome 10:    1 votes.
Process 38 predicts outcome 10:    1 votes.
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Process 15 predicts outcome 11:    1 votes.
Process 21 predicts outcome 11:   13 votes.

Process  3 predicts outcome 12:    1 votes.
Process  6 predicts outcome 12:    1 votes.
Process  8 predicts outcome 12:    3 votes.

Process  3 predicts outcome 13:    3 votes.
Process  4 predicts outcome 13:    1 votes.
Process  6 predicts outcome 13:    1 votes.
Process  7 predicts outcome 13:    1 votes.
Process  8 predicts outcome 13:    1 votes.

Process  5 predicts outcome 14:   12 votes.
Process 31 predicts outcome 14:    2 votes.

Process  8 predicts outcome 15:   12 votes.
Process  9 predicts outcome 15:    1 votes.

Process 12 predicts outcome 16:    1 votes.
Process 35 predicts outcome 16:    5 votes.
Process 36 predicts outcome 16:    4 votes.

Process  3 predicts outcome 17:    1 votes.
Process 15 predicts outcome 17:    3 votes.
Process 31 predicts outcome 17:    5 votes.
Process 34 predicts outcome 17:    1 votes.
Process 38 predicts outcome 17:    1 votes.

Process  8 predicts outcome 18:    7 votes.
Process  9 predicts outcome 18:    1 votes.
Process 17 predicts outcome 18:    2 votes.

Process  6 predicts outcome 19:    2 votes.
Process 10 predicts outcome 19:    5 votes.
Process 15 predicts outcome 19:    2 votes.
Process 25 predicts outcome 19:    3 votes.

Process 22 predicts outcome 20:   10 votes.
Process 40 predicts outcome 20:    1 votes.

Process  3 predicts outcome 21:    1 votes.
Process  7 predicts outcome 21:    1 votes.
Process 11 predicts outcome 21:    2 votes.
Process 30 predicts outcome 21:    3 votes.
Process 33 predicts outcome 21:    1 votes.
Process 40 predicts outcome 21:    2 votes.
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VITA

Name: Margaret Anne Morris Curran, CPQA

Program: Community Health Professions

Education:

Old Dominion University
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1988-1991
M.S. Community Health Professions

Emory University
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1978-1980
Bachelor of Medical Science

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Bachelor of Science

Thesis Title: An Analysis of Quality Assessment Efforts in Health Care
January 1990 - May 1991

Thesis Advisors: Dr. Gregory H. Frazer
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Employment:

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Director, Quality Improvement and Utilization Review
August 1990 - Present

Sentara Norfolk General Hospital
October 1986 - July 1990

Richmond Memorial Hospital
May 1983 - September 1986

Colonial Virginia Foundation for Medical Care (PRO)
April 1982 - April 1983

Lake Taylor City Hospital
March 1981 - March 1982