Quality assessment in the medical intensive care unit: evolution of a data model

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■ Quality assessment and assurance in the intensive care unit require systematic monitoring and evaluation of patient care and its outcome. For analysis of these activities, data must be organized to reflect changes in such factors as patient types, ages, and lengths of stay. A model was developed to group data from the Cleveland Clinic Hospital medical intensive care unit into structural, process, and outcome categories. Development and application of the model are described.

□ INDEX TERMS: INTENSIVE CARE UNITS, QUALITY ASSURANCE □ CLEVE CLIN J MED 1990; 57:273–279

QUALITY ASSESSMENT and quality assurance are separate activities (although the term quality assurance is often used to represent both). *Quality assessment* uses some method to compare systematically monitored data with standards of quality. *Quality assurance* is the confirmation of quality or its lack by individuals or governing bodies both internal and external to the activity.[1]

Consumers and health care providers are increasingly concerned about the quality of health care. More and more, quality assessment data are needed to provide consumers with facts upon which to base health care decisions, as well as to alert providers to areas that need improvement and to harmful or useless technologies that should be abandoned.[2]

Quality assessment and assurance in intensive care units (ICUs) have been the focus of many scientific studies.[3–5] Most of these studies are outcome analyses.[6–11] In this analysis, we examine the relationship between structure, process, and outcome of care.[12]

A systematic approach to quality assessment and assurance in ICUs will probably become mandatory.[13] In anticipation of such a requirement, we reviewed the quality assurance activities in the medical intensive care unit (MICU) of the Cleveland Clinic Hospital. We found only traditional quality assessments of nursing activities, procedures, infection control, and audits of complications and practice patterns. There was little emphasis on physicians' analyses of quality of care and on the appropriate use of resources. Without additional methods to assess and assure quality, it seemed obvious that the nature of the patient population treated in the MICU required definition.

To accomplish this we developed a data model to be tested over 1 year. The data collected were reported to The Cleveland Clinic Foundation's Quantification of Quality Committee for analysis and recommendations.

In this review we discuss the logic of our data model, its limitations, and the results of the data collection. We include some preliminary demographic data to demonstrate a reporting format and to outline deficiencies in certain areas of data collection. In addition, we speculate on the evolution of the model and its future use in

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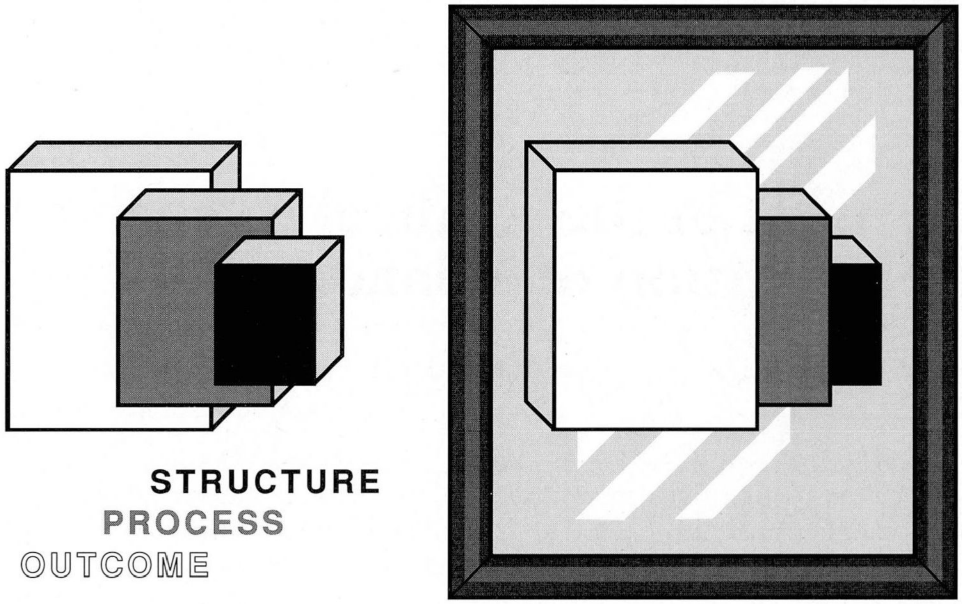

FIGURE 1. One problem with quality assessment has been the natural tendency to focus on the outcome, rather than on the structure and process that lead to the outcome. We use the above "mirror image" model to demonstrate the need to place structure and process in the forefront when assessing quality. For example, the outcome of a patient's ICU course may be death. If we examine the process, which involved the judicious application of technology without unnecessarily prolonging life, we may find that the outcome was satisfactory. Further analysis may show that the structure, or rules that governed the process, is responsible for the outcome.

quality assessment activities. For example, using this patient population data, we can address the following quality assurance questions.

1. How does the patient population of the MICU relate to the hospital population in general? For example, what is the percentage of total number of hospital admissions and total number of patient days?

2. How does length of stay in the MICU compare with that in other ICUs?

3. Which admitting services (physician specialties) admit the most patients to the MICU?

4. How do mortalities in the various ICUs compare with each other and with total hospital mortality?

5. How does length of stay in the hospital before ICU admission and after discharge compare among services? Is there any relationship between this time and mortality?

6. Were orders for mechanical ventilation, hemodynamic monitoring, or dialysis always appropriate?

7. Do certain patients have long periods of hospitalization following unit discharge? Is this length of stay due to rehabilitation requirements?

8. How do hospital admission diagnoses compare with ICU admission diagnoses? Are there unexpected new diagnoses?

THE DATA MODEL

Every data model has a certain logic that depicts the situation to be modeled. The model most frequently applied to quality assurance divides activities into structure, process, and outcome—divisions commonly used for quality assurance in industry.[12] Each division affects the other two.

To understand the nature of the outcome, one must determine the quality of the process behind the outcome and the structure or rules used to apply the process. *Figure 1* illustrates the logic of our data model, which we call the "mirror image" model. Data can be grouped within each division of the activity. For example, death or survival is an outcome. Length of stay is a process element. Requirement for mechanical ventilation is a process element. A diagnosis of respiratory failure dictates the application of this process and is, therefore, a structural element (*Table 1*).

Structure

Ordinarily, structural data are facilities, personnel, and equipment required to deliver patient care. With clinical activities, the question of what is required is less important than why it is required. Therefore, data in this portion of the model describe the patient population and reasons for the application of technology. The data are quantified by dividing hospital days prior to ICU admission by total hospital days.

Process

Care of critically ill patients is labor- and technology-

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TABLE 1
DATA COLLECTION

Structure (pre-ICU phase)	Process (ICU phase)	Outcome (post-ICU phase)
Name	ICU admission diagnosis	ICU discharge status
Identification number	Severity of illness on admission	Condition on discharge
Age	Technologies used in patient care (dates started and discontinued)	Custodial care
Sex	Mechanical ventilation	Rehabilitation care
Hospital admission date	Hemodynamic monitoring	Ventilator-dependent
Hospital admission service	Pressor agents	Hospital discharge date
Severity of illness on admission	Inotropic agents	*Post-ICU hospital days
Pre-ICU diagnoses	Vasodilator agents	Hospital discharge status
Pre-ICU procedures	Antibiotics	Home
*Pre-ICU days (number)	Parenteral nutrition	Nursing home
ICU admission day	Plasmapheresis	Ventilator-dependent (home, nursing home)
ICU admission diagnosis	Cardiopulmonary resuscitation	Follow-up (1, 3, 6, 12 months post-discharge); survived, died, quality of life
	If appropriate, date DNR order writtren	
	ICU discharge date	
	*ICU days (number)	
	Discharge Status (died, survived, ventilator dependent)	

*Quantitation is obtained by dividing the number of days in each category by the total number of hospital days.

intensive. One method for quantifying process-of-care data is the Therapeutic Intervention Scoring System (TISS).[14] Application of this without computers is labor-intensive, so we included only key technologies used in the process of care in our data model (*Table 1*). The process of care is quantified by dividing the number of ICU days by total hospital days; technologies are quantified by dividing the number of days of their application by the total ICU days.

Outcome

Outcome data include short-term (unit discharge status), intermediate-term (hospital discharge status), and long-term (survival at 3, 6, and 12 months after hospital discharge) results. In each category, the status is survival, death, or discharge from the unit. A separate category is included for those who are ventilator-dependent on discharge. Outcome is quantified further with length of hospital stay after discharge from the MICU.

The organization of data into quality assessment information met with some limitations as the model and the monitoring evolved. Structure and outcome data proved to be relatively easy to collect because the information was collected on a one-time basis.

METHODS

The MICU has 10 beds. The Cleveland Clinic Hospital, a large tertiary health care center, also has surgical (14 beds), neurosurgical (8 beds), cardiovascular (45 beds), and coronary (15 beds) ICUs. During the year 1987, there were 962 active beds in the hospital, of which approximately 10% were ICU beds.

Beginning January 1, 1987, and ending December 31, 1987, a portion of data pertaining to the model structure shown in *Table 1* was collected on each patient within 24 hours of admission to the MICU. Outcome data were verified when the patient was discharged from the unit. Hospital discharge status was obtained from the Foundation's Division of Finance in March 1988, when the financial database was upgraded to include all data from 1987.

From these data, total length of hospitalization and time in the hospital after ICU discharge were calculated. When data collection started, it became apparent that there would be limitations to collection of process-of-care data (*Table 1*). The development of the data model was a demonstration project for which no data collectors or funding were requested. Hence, early in the project, it was decided to focus on issues related to structure and outcome in the data model.

A log book is maintained in the MICU to document each patient's admission, Clinic identification number, age, hospital admitting physician, date and time of admission, date and time of discharge, and unit discharge status. Periodically, because the authors were absent, data on some patients could not be captured. The log book was reviewed quarterly and data gathered retro-

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TABLE 2
COMPARISON OF PATIENT DEMOGRAPHICS BY KEY SERVICES

						Median stay (days)			Mortality (%)		
Service	Number of admissions	M	F	Age range	(Median)	Pre-ICU	ICU	Post-ICU	ICU	Post-ICU	Total hospital
Cardiology	38	25	13	(S) 38– 81	64.7	0	1.0	8.0	10.8	21.2	29.7
				(NS) 47– 85	79.5	9.0	3.5				
Gastroenterology	59	33	26	(S) 22– 92	66.0	0	1.0	7.5	32.2	20.6	44.0
				(NS) 30– 78	51.0	0	4.0				
Hematology/ oncology	82	47	35	(S) 19– 72	59.5	7.0	3.0	11.0	65.8	34.6	77.5
				(NS) 20– 75	42.0	13.0	3.0				
Hypertension/ nephrology	59	28	31	(S) 30– 78	62.0	0	2.0	11.5	15.8	18.8	32.1
				(NS) 47– 78	58.5	5.0	1.0				
Internal medicine	64	25	39	(S) 21– 83	65.0	0	1.0	8.0	36.2	19.0	40.7
				(NS) 38–104	74.5	3.5	2.0				
Pulmonary disease	83	44	39	(S) 19– 87	59.0	0	2.0	8.0	21.7	18.6	36.7
				(NS) 23– 87	66.0	0	3.0				
Thoracic cardio-vascular surgery	31	18	13	(S) 15– 78	66.0	11.0	3.5	5.0	9.7	23.1	29.0
				(NS) 59– 69	67.0	1.0	7.0				

S = survivors; *NS* = nonsurvivors of ICU hospitalization.

spectively to describe the patient population as completely as possible. For data organization and analysis we used Lotus 123 version 2.0 spreadsheet software (Lotus Development Corporation, Cambridge, Massachusetts).

To characterize our patient population in relation to the entire hospital population, data on total admissions and total patient days as well as patient unit days were requested from the hospital admitting office.

RESULTS

All patients were admitted to the MICU of the Cleveland Clinic Hospital. Those admitted through the emergency room were either previously scheduled as transfers from other hospitals or had previously received health care at The Cleveland Clinic Foundation.

In 1987, there were 31,964 admissions to the hospital; of these, 552 (1.73%) were MICU admissions. The basis for our calculations was the analysis of 530 admissions involving 508 patients, of whom 53.3% were male (median age, 60.2 years) and 46.7% were female (median age, 57.8 years. Of the males, 46% were age 65 or older and 40% of the females were age 65 or older. The mean pre-ICU hospital stay was 8.2 days, ranging from 0 to 105 days; the mean ICU length of stay was 5.6 days, ranging from 0 to 83 days; and the mean hospital stay after ICU discharge was 15.3 days, ranging from 0 to 96 days.

The ICU mortality for 508 patients was 29%. Of a subgroup of 22 patients admitted to the MICU more than once during the same hospitalization, the mortality was 68.2%. If patients who were discharged from the ICU on mechanical ventilation are included in the ICU mortality, then the mortality for the combined groups is 31.3%. Hospital mortality for all patients admitted to the medical intensive care unit was 43.1%.

We organized patient data by the physician service (specialty) that admitted the patient to the hospital. Admissions from 7 of the 25 services represented 78% of admissions to the intensive care unit (*Table 2*). These services included cardiology, gastroenterology, hypertension/nephrology, hematology/oncology, internal medicine, pulmonary disease, and cardiovascular thoracic surgery.

We further analyzed the reasons for admission to the MICU. Twenty-eight categories emerged and are listed in *Table 3*, along with number of admissions and mortality rates for each category. According to the logic of the data model, these constitute structural data.

Links to outcome were made by listing mortality data for each category. We attempted to compare the hospital admitting diagnoses with the diagnoses or reasons for MICU admission. However, no uniform coding could be defined for analysis of MICU data, and analysis of the hospital ICD-9 codes and DRG diagnoses proved beyond the scope of this review. Such efforts would have required extensive data collection from our financial database and would have further delayed reporting of observations.

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TABLE 3
ICU MORTALITY BY ADMISSION DIAGNOSIS IN 1987

Diagnosis or reason for admission	Number of admissions	Mortality (%)
Respiratory failure	138	65.9
Upper GI bleeding	79	30.8
Respiratory insufficiency	58	34.6
Hypotension	32	40.0
Sepsis	28	57.7
Altered mental status	21	55.0
Cardiac arrest	20	80.0
Postoperative ventilator dependency	20	40.0
Pulmonary edema	19	16.7
Postoperative observation	19	5.3
Seizure	14	21.4
Unstable angina	10	10.0
R/O myocardial infarction	6	16.7
Drug overdose	5	0.0
Hypertension	5	20.0
Lower GI bleeding	5	0.0
Hyperkalemia	4	25.0
Metabolic acidosis	4	50.0
Myocardial infarction	4	50.0
Miscellaneous	3	33.0
Cardiac arrhythmias	2	50.0
Electrolyte imbalance	2	0.0
Constrictive pericarditis	1	100
Cardiogenic shock	1	100
Inappropriate admission	1	0.0
Neuroleptic malignant syndrome	1	0.0
Pneumonia	1	0.0

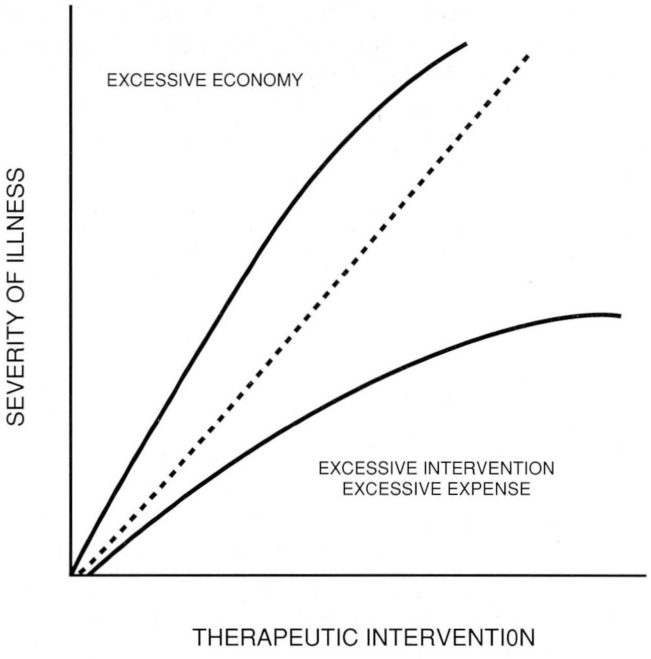

FIGURE 2. The dotted diagonal line represents a balance between severity of illness and the appropriate application of technology. The X axis could be calibrated with the Therapeutic Intervention Scoring System (TISS).[14,22] and the Y axis, or severity of illness, with APACHE II.[8] The balance between these two variables can be determined only over time and through comparison with other institutions. Excessive intervention (or higher TISS) with low or moderate severity of illness could be associated with excessive cost or with iatrogenic problems related to excessive intervention. Thus, quality is compromised. On the other hand, high severity of illness with a low TISS could result in high mortality, prolonged ICU stay, or compromised quality of life after discharge.

DISCUSSION

The data collected are a reasonable starting point for quality assessment activity and identification of areas where process and outcome of care may need improvement. Quality assessment cannot be instituted until the nature of the patient population is understood. This project demonstrated that most of the MICU population was derived from about one third of all possible admission services. Further analysis revealed that mortality was higher in gastroenterology and hematology/oncology patient groups. A review of outcome and age revealed that the median age of survivors in the hematology/oncology group was greater than that of nonsurvivors (*Table 2*). This suggests that, for these patients, mortality was disease-specific rather than age-specific. In the gastroenterology group, a large percentage of the mortality was due to end-stage liver disease. This indicates that a need for better definition of requirements for admission or limitations for therapeutic intervention in these groups.

Our objective was to describe the nature of patient activity in our MICU. We expected the model to identify some areas where further analysis is indicated. This information has been given to various Foundation committees for review and recommendations for further study. In addition, we sought to identify areas of the model that need refining. The model serves as a baseline description of our patient population and can be used for trend analysis.

One deficiency in our analysis is the absence of a severity of illness index for each patient and a summary of these indices. Knaus and associates reported increasing probability of death as severity of illness worsens, as demonstrated by APACHE II (Acute Physiology and Chronic Health Evaluation) scoring.[8,15] We have mortality data, but did not quantify the severity of illness. In

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each of the key service groups, mortalities may have been excessive, but our total hospital mortality of 43.1% may be comparable to that of other tertiary care centers. Kruse et al reported a 40% mortality in 366 MICU patients for a 5-month period in 1986.[15] Since mortality is an indicator of outcome, future reports must include adjustments in mortality for severity of illness. This will allow objective comparisons to other intensive care units in various hospitals.[16-20] Data collection for such activities, however, remains labor-intensive and expensive.

Additional emphasis should be placed upon monitoring of severity of illness. Simple indices are available that require standard vital signs and hospital laboratory data. From these data, the clinician is able to state objectively what "sicker patients" really means (APACHE, Simplified Acute Physiology Score [SAPS]).[8,15,21] By adding a diagnostic category to the severity of illness, the clinician can develop patient databases to help predict mortality based on physiologic derangement. Quality of care can be assessed by comparing the actual with the predicted outcome. Substantial differences between the two would suggest further investigation into the process of care. Exclusive of severity of illness, the Mortality Prediction Model developed by Lemeshow and Teres may also be used to compare actual to predicted mortality.[9]

When we quantify the process of patient care, the importance of severity of illness and prediction of outcome is even clearer. For example, assignment of points to various types of interventions results in a TISS score[22] that may correlate with severity of illness. When severity of illness is combined with quantification of therapy, issues of over- or underintervention are brought to light (*Figure 2*). Such analysis makes quality assessment more objective.

Information on the process of care remains deficient because of the time and labor required to extract data. At best, our information describes length of stay with no further definition of the process of care. The 1988 database model contains patient days on mechanical ventilation, days of monitoring with flow-directed catheters, and use of dialysis. In 1990 we expect to include patterns for antibiotic use in patients who receive mechanical ventilation. This information should be sufficient to address some of the important aspects of care in special units as suggested by the Joint Commission on Accreditation of Health Care Organizations, and the effort may link some process data to outcome and structure.[23]

Structural data need further enhancement to better define the relationship between hospital admitting diagnosis and MICU admitting diagnosis.

SUMMARY

We present our experience with the development of a data model and its application to a population of patients in a medical ICU. There were deficiencies in the collection of process data and severity of illness data because of limited resources for data collectors, abstractors, and computing power. The deficiencies in our efforts should not discourage others from similar endeavors.

The fact that all data collected was a reflexive byproduct of the delivery of patient care will lead to a trend in computerization of intensive care units.[24] Data modeling is a step in that direction. The activity of data collection, regardless of its deficiencies, will enhance our understanding of the tasks involved in patient care and the data derived from patient care. Definition of reporting requirements and data organization will result in commercially available computer systems; these will not only facilitate the process of patient care, but also make administrative data for quality assessment and assurance a reflexive byproduct of patient care.

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Commentary

The development of medical technology in recent years has been explosive. Unfortunately, better technology does not necessarily equal better care; as a result, medicine has entered a new era of quality assessment and assurance.

Health care consumers and providers, third party payers, and society are asking: Is the care appropriate and, if so, is it delivered correctly? This question has particular relevance and importance in the intensive care unit (ICU). Standards of care are difficult to determine here, given the complexity of medical problems in this patient population, and the varied expectations of families struggling to cope with a loved one's critical illness.

In the ICU, perhaps more than in any other area of medicine, families are involved in the medical decision-making process. Should higher levels of technology be employed? Should the patient be resuscitated in the event of a cardiopulmonary arrest? Should support be withdrawn from the critically ill patient? Outcome data such as that presented by Sivak and Perez-Trepichio will permit health care consumers and providers to make better informed decisions when struggling with these questions.

On a societal level, health care spending cannot continue to increase indefinitely. The high cost of ICU care will ultimately restrict its use. ICU care will not be available to every patient with a life-threatening illness, nor will we be able to afford the indiscriminate use of high technology. A side benefit of ongoing quality assessment data collection should be the development of guidelines for the use of the ICU and its associated technology.

Sivak and Perez-Trepichio report their experience with a three-component data collection model consisting of structure, process, and outcome elements. Personnel and financial restraints limited their collection to structural elements (eg, admitting diagnosis) and outcome data (eg, mortality). The absence of a severity of illness assessment is a significant drawback and precludes comparison of their data with that from other institutions.

The model as outlined is a useful construct from which to develop an ongoing quality assessment program. Data from the process element (ie, what happens to the patient between his presentation to the ICU with an admitting diagnosis and his ultimate outcome) is awaited with interest. Does the use of varying levels of technology significantly alter the outcome in comparably ill patients?

In a setting where a randomized control trial may be difficult to perform, quality assessment data collection should provide critical insights into our use of the ICU and its technology. Only through careful analysis of data generated by such a model will we resolve the definition of "appropriate care" from the standpoint of the provider, the consumer, and society.

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