CRITICAL CARE ALERT®

A monthly update of developments in critical care and intensive care medicine

Thomson American Health Consultants Home Page—http://www.ahcpub.com

CME for Physicians—http://www.cmeweb.com; CE for Nurses—http://www.ceweb.com

THOMSON
AMERICAN HEALTH CONSULTANTS

INSIDE

Benefits of Ethics Consultation When Life-Sustaining Treatments are Unlikely to be Beneficial

ABSTRACT & COMMENTARY

In this randomized control trial, Schneiderman and associates evaluated the effect of an intervention, namely, an ethics consultation, on several variables associated with the care of patients eventually dying in the ICU. They hypothesized that in critically ill patients, when a conflict arises as to the nature and duration of life-saving therapy, an ethics consultation would reduce the number of days such patients spend in ICU and in the hospital and also the number of days such therapy is continued. They further hypothesized that such intervention would not increase the mortality of the group that received the ethics consultation.

To test their hypothesis, they enrolled 551 patients in 7 diverse ICUs across the country. Nurses routinely rounding in the ICU identified eligible patients. Included were adult patients in whom "value-laden treatment conflicts" were imminent or manifest that could lead to incompatible courses of action. The investigators had established that such conflicts could arise in 6 circumstances:

1. within the health care team as to whether to pursue aggressive care or comfort measures;
2. within the health care team as to whether to pursue aggressive care or comfort measures when a decision maker was unavailable;
3. within the health care team when 1 or more members of the team thought the care was futile;
4. between the health care team and the family as to whether to pursue aggressive care or comfort measures;
5. within the family as to who should be the surrogate decision maker; or,
6. between the family/friends and the health care team when 1 or more of the team members thought the care was futile.

When such patients were identified, an investigator at the local site enrolled the patient. A computer-generated block randomization

VOLUME 11 • NUMBER 9 • DECEMBER 2003 • PAGES 97-108

scheme was used and patients were randomized to receive either an ethics consultation or usual care. The patient or the family members of the usual care group were not informed about the study and did not give informed consent; however, at most institutions, ethics consults were initiated by the health care team, so in general such consultations were not initiated by families. At all centers, any member of the health care team could request an ethics consult for the usual care group.

In the treatment group, the investigator contacted the treating physician to obtain a verbal consent to perform an ethics consultation. If the physician agreed, the ethics consultant followed a general process model of ethics consultation. After consent, an ethical diagnosis was made. Varieties of options were provided to the parties involved. A follow-up meeting was offered and performed if the family agreed. An ethics consultation note was entered in the chart. A follow-up interview was performed after several weeks with the health care team and the patient or surrogate decision maker to assess whether the ethics consult was helpful. The primary outcome measures were hospital days, ICU days, and days of life-saving treatments in those patients who did not survive to hospital discharge. For the purpose of analysis, intent-to-treat basis was used with assignment at the time of randomization as the basis of group allocation.

Out of 551 patients enrolled in the study, 278 were assigned to be offered ethics consultation, of whom 211 received an ethics consult. Of the 273 patients in the usual care group, 77 patients received an ethics consult. The groups were comparable in terms of age, sex, ethnicity, primary diagnosis, and surrogate decision makers. A total of 173 patients in the ethics consultation group (63%) died compared to 156 patients (57.8%) in the usual care group. The mortality rates of the 2 groups were not significantly different.

The ethics consultation group had fewer hospital days (-2.95 days, mean, 8.66 vs 11.62), fewer ICU days (-1.44 days, mean, 6.42 vs 7.86) and fewer days receiving ventilation (-1.7 days, mean, 6.52 vs 8.22), all statistically significant with P values < 0.05. The number of days receiving nutrition/hydration was not statistically different between the 2 groups (-1.03, 7.36 vs 8.38; P = .14). Health care team members and surrogate decision makers were satisfied with the ethics consultation and did not feel coerced to make a decision by the consultant. Schneiderman et al conclude that in those patients who did not survive to discharge from the hospital, ethics consultations were associated with a significant reduction in likely nonbeneficial treatments, without affecting the mortality (Schneiderman LJ, et al. *JAMA*. 2003;290:1166-1172).

COMMENT BY UDAY B. NANAVATY, MD

Addressing end-of-life issues and facilitating discussions regarding the aggressive care or "dying peacefully" during the hospitalization has become an important daily practice for the critical care provider. As the health care costs continue to climb, a variety of approaches are taken to control costs, especially in the areas consuming large amounts of resources. It has been clearly established that a large proportion of overall health care dollars are spent in the care of people during the last 6 months of their lives. A large share of this is in providing critical care to those who are not likely to benefit from it. However, in spite of all the research, it is hard to decide which patient is not likely to benefit from critical care.

It is not clear who should make the decision that critical care is no longer going to be beneficial to the patient. It is not clear what value system or health status should be used to define the group of patients who are not likely to benefit from critical care. Should cost be an issue? Who should decide where the health care dollars

Critical Care Alert, ISSN 1067-9502, is published monthly by Thomson American Health Consultants, 3525 Piedmont Rd., NE, Bldg. 6, Suite 400, Atlanta, GA 30305.

VICE PRESIDENT/GROUP PUBLISHER: Brenda Mooney.

EDITORIAL GROUP HEAD: Glen Harris.

MANAGING EDITOR: Robin Mason.

ASSISTANT MANAGING EDITOR: Robert Kimball.

SENIOR COPY EDITOR: Christie Messina Petrone.

MARKETING PRODUCT MANAGER: Schandale Kornegay.

GST Registration Number: R128870672.

Periodicals postage paid at Atlanta, GA.

POSTMASTER: Send address changes to ***Critical Care Alert,*** P.O. Box 740059, Atlanta, GA 30374.

Back issues: $40.

Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issues date.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. It is not intended for use by the layman.

Subscriber Information

Customer Service: 1-800-688-2421

Customer Service E-Mail Address: customerservice@ahcpub.com

Editorial E-Mail Address: robin.mason@ahcpub.com

World Wide Web: http://www.ahcpub.com

Subscription Prices

United States

1 year *with* free AMA Category 1 credits: $239

(Student/Resident rate: $120)

Multiple Copies

1-9 additional copies: $215 each; 10 or more copies: $191 each.

Canada

Add GST and $30 shipping.

Elsewhere

Add $30 shipping.

Accreditation

Thomson American Health Consultants (AHC) designates this educational activity for a maximum of 28 hours in category 1 credit toward the AMA Physician's Recognition Award. Each physician should claim only those credits that he/she actually spent in the activity.

Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

This CME activity was planned and produced in accordance with the ACCME Essentials.

AHC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

AHC is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California Board of Registered Nursing, Provider Number CEP 10864, for approximately 16 contact hours.

THOMSON™
AMERICAN HEALTH CONSULTANTS

Questions & Comments

Please call **Robin Mason,** Managing Editor, at (404) 262-5517 or e-mail at robin.mason@ahcpub.com between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

Statement of Financial Disclosure

In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Ms. Ball serves as a consultant to Steris Corp, IC Medical, and AMT-Coherent (Canada), is a stockholder of Steris and SLT, and is on the speaker's bureau of AORN. Dr. Pierson is on the speaker's bureau of GlaxoSmithKline, Boehringer-Ingelheim, 3-M, Bayer, and Astra Zeneca. Dr. Rubenfeld is a consultant to Eli Lilly and is involved in research with the National Institutes of Health. Drs. Baigorri, Durbin, Hess, Hoffman, Johnson, and O'Keefe report no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Drs. Crawford, Gladwin, Nanavaty, and Takezawa did not return a 2003 financial disclosure form.

are spent? Who is to decide if the patient's quality of life is such that life-saving treatments should be withheld or withdrawn? When so much of it is unknown yet the decision results in loss of life, ethical conflicts arise.

One way to resolve this dilemma has been to obtain the help of a bioethicist. The benefits of obtaining an ethics consult have largely been studied in case series. Hence the randomized control trial design used in this study is a good step toward starting to resolve the issues. The study also nicely delineates the framework of an ethics consult with all the steps involved in performing one.

This trial has several limitations. One of the foremost in my mind is that mortality was higher in the group of patients who were assigned to the intervention. Although statistically no different, it is possible that the study was not powered enough to detect a difference. A 5% difference may become statistically significant if a larger study group is used and may in fact make one argue that the ethics consultations were "mere subterfuge to pulling the plug"—the very fear of obtaining ethics consultation, as sited by Schneiderman et al. Also, although the study was powered to detect 3 days' difference in ICU stay, the difference was substantially less than hypothesized. Schneiderman et al used intent-to-treat analysis, a rigorous method, to study outcome. However, there was a large crossover population, which may make it difficult to decide whether the effects observed were really due to the intervention.

In spite of these and perhaps other limitations, the study is in the right direction of starting a debate as to the needs to address the cost/resource consumption during seemingly "nonbeneficial" treatments toward the end of life. I believe that rather than counting and saving the ICU days at the very end of life, we need to change the focus toward months and years before that point is reached. As the mother of a dying young woman once said to the patient's husband, "We know she is dying. What is the hurry to withdraw care?" I don't have an answer for that myself. Maybe one of the ethics consultants will answer it one day. ■

Special Feature

Computerized Medical Databases in the ICU

By Gordon D. Rubenfeld, MD, MSc

Measuring the quality of a complex service like critical care that combines the highest technology with the most intimate caring is a challenge. Recently, consumers, clinicians, and payers have requested more formal assessments and comparisons of the quality and costs of medical care.[1] National reports have focused clinicians on the public health effects of medical errors and poor quality care.[2,3] Computerized medical databases offer the opportunity to measure the quality of medical care and, at least theoretically, provide the opportunity to improve that care.

Computerized Medical Databases

There are 2 general types of computerized databases used to assess the quality of medical care: the electronic medical record and an administrative database. Examples of electronic medical records are Eclipsys (Sunrise Critical Care), CareVue Clinical Information System (Philips Medical Systems), MetaVision (iMDsoft), and CareSuite (Picis). There are several types of administrative databases, including state and federal reporting (such as State Inpatient Databases[4]), claims and billing data (such as Medicare Provider and Analysis Review [MedPAR] files), and quality improvement databases (such as Cleveland Health Quality Choice,[5] APACHE Medical Systems,[6] Project IMPACT,[34] and New York CABG Registry).[27]

One type of computerized database is the administrative database collected for purposes other than direct delivery of medical care. These databases are usually collected for billing purposes, but some are collected specifically with the intent of assessing quality of care and reporting outcomes. For example, the State Inpatient Databases were developed as part of the Healthcare Cost and Utilization Project (HCUP), a federal-state-industry partnership sponsored by the Agency for Healthcare Research and Quality to inform decision making at the national, state, and community levels.[4] The State Inpatient Databases cover inpatient care in hospitals in 33 states. This represents about 85% of all US hospital discharges. Elements in this database include diagnoses, procedures, admission and discharge status, patient demographics, expected payment source, total charges, and length of stay. While administrative databases are ideal for evaluating some aspects of quality across groups of hospitals, they have important limitations for studying the quality of critical care. Intensive care-specific diagnoses and procedures are not coded. It can be difficult to distinguish admission diagnoses from comorbidities and complications. Finally, there is limited physiologic severity of illness data. Some administrative databases collected specifically for evaluating the quality of intensive care may address these limitations.[5,6]

More recently, the electronic medical record has become a source of data for assessing and improving the quality of medical care.[7] The electronic medical record is specifically designed to replace all or part of the paper medical chart. It specifically addresses some of the limitations of the administrative databases. It is clinically rich, containing all of the detail of the original medical record including the physiologic and biochemical variables needed for critical care risk adjustment and diagnoses. The data are entered by the actual clinicians caring for the patient and are not coded by lay personnel. While data from an electronic medical record are ideally suited for local quality improvement initiatives, it is difficult to use these data across multiple institutions unless they all use the same electronic medical record. Variations in the electronic medical record formats make data exchange and comparability across systems a challenge.

Garbage In = Garbage Out

This age-old programmer's dictum applies strongly to computerized electronic medical record data. The sheer volume of data collected automatically by many systems does not guarantee its quality, nor does the volume ensure that the data are unbiased. Many of the functions designed to enhance usability—for example, functions that allow users to copy data from one day to the next—can perpetuate these errors rather than reduce them. Some data elements are particularly difficult to analyze. For example, full text fields are more prone to error than pick-lists or check boxes. Diagnostic and clinical data elements are problematic, and the extent to which these fields will be useful will depend on who and how they are entered. For example, the diagnostic and comorbidity elements in the APACHE and MPM are designed to be coded by specific rules. If users try to calculate these scores and do not use the same rules for coding these variables as the developers, then the scores will not be accurate.[8,9]

The electronic medical record is essentially a database and, as with all databases, the most important design step is for users to ask themselves, "What questions will I use this database to answer?" To answer this, users should generate mock tables and reports that will guide the selection of data elements and how they are defined. An important issue to consider is how patients with specific critical care syndromes will be identified. To measure quality of care in patients with acute lung injury, sepsis, or ventilator-associated pneumonia, one must be able to reliably identify patients with these syndromes. Relying on physician identification is one option that would simply have physicians check a box in patients diagnosed with these syndromes. This will only identify patients that physicians recognize with these syndromes. Limiting diagnoses to those recognized by physicians is likely to misrepresent quality of care because it eliminates diagnostic inaccuracy as a factor in poor quality of care. Unfortunately, identifying patients with critical care syndromes independently of physician recognition using electronic medical record data requires fairly sophisticated computer algorithms and some preplanning. For example, a study intended to see if physicians use appropriate low tidal volume ventilation in patients with acute lung injury should evaluate process of care in patients recognized by physicians with ALI and in those who meet the diagnostic criteria but were not diagnosed with the syndrome. To do this using data from an electronic medical record would require that the 3 diagnostic criteria (hypoxemia, chest radiographic opacities, and exclusion of clinical evidence of left atrial hypertension as the primary explanation of respiratory failure) be available independently in the database. Similarly, evaluating process of care in patients with sepsis would require that data are entered in a way to allow them to be screened independently for the diagnostic criteria (systemic inflammatory response, infection, and organ dysfunction).

Measuring ICU Process and Outcome with Computerized Medical Databases

There is an extensive body of literature documenting the inappropriate delivery, both under- and over-provision, of medical care. Despite a mature evidence database and even when conservative criteria for case selection are used, a significant proportion of patients do not receive appropriate aspirin, heparin, thrombolytic therapy, or beta antagonists in the setting of acute coronary syndromes.[3] Similar evidence on implementation of effective practices in critical care is lacking. For example, we have relatively little evidence from large, community-based cohorts on the implementation of noninvasive ventilation for COPD exacerbation, low tidal volume ventilation for acute lung injury, activated protein C for severe sepsis, renal replacement therapy, or the use of daily trials of spontaneous breathing to wean patients from mechanical ventilation.

The use of the word "outcome" in research can be confusing.[1] It can refer to any variable that is the dependent variable in an analysis. For example, in a clinical trial of recombinant human erythropoietin in the ICU, the outcome variable was use of blood transfusions.[10] However, in the context of the Donabedian model of measuring quality and with respect to the field of outcomes research, outcomes refer to a variety

of variables that measure factors that are important to patients including: symptoms, quality of life, duration of life, quality of dying, the effect of their health care on their loved ones, and the cost of medical care. Patient-centered outcomes are distinct from any number of chemical, physiologic, and radiographic variables that may be measured in clinical research. Because of these outcomes' importance to patients, they are referred to as "patient-centered" outcomes. Ideally, clinicians will offer, insurers will pay for, and patients will have the opportunity to use treatments that have been shown to improve patient-centered outcomes. High-quality medical care is more likely to result in improved patient outcomes.

Computerized medical databases can be used to study the process and outcome of critical care as measures of quality. There are several well-described multi-center computerized medical databases of critical care, including the APACHE Medical Systems-linked group of hospitals, Project IMPACT sponsored by the Society of Critical Care Medicine, and the Intensive Care National Audit and Research Centre in the United Kingdom that collect ICU specific data on process and outcome. Whether these databases can be used to actually measure or improve quality of care remains a topic of some debate.

Limits of Using Computerized Medical Databases to Measure and Improve Quality of Care

Perhaps the greatest challenge to using computerized medical databases to measure and improve the quality of intensive care is the enormous challenge of defining what we mean by "quality care." There are 3 major impediments to using process measures from computerized medical databases to audit the quality of intensive care. The first is that even when there is strong evidence of effectiveness in critical care, considerable disagreement about the exact application of treatments in specific cases remains.[11,12] Even in fairly narrow clinical situations with strict review criteria, experts can disagree on the appropriateness of care in individual cases.[13] Identifying appropriate process measures entails identifying conditions where there is consensus that a specific treatment should have been provided. The evidence base for making these recommendations in critical care is only recently evolving. The second impediment to using process measures is that identifying patients with acute lung injury to whom specific therapy should be offered is considerably more difficult than identifying patients with acute myocardial infarction. Finally, ICU process measures are more subtle to capture. For example, surgical and percutaneous interventions for coronary artery disease are captured in administrative databases because they are reimbursed; however, ICU-based interventions like ventilator settings, patient positioning, and medications would require assessment from a specially designed administrative database or an electronic medical record. Other fields in medicine (eg, cardiovascular disease and renal disease) have developed networks to collect disease-specific data on process of care and outcome.[14,15]

The use of risk adjusted outcome, usually mortality, remains a key component in attempts to define, report, and improve quality of care.[16,17] Risk adjustment is designed to address the problem of confounding, that is, centers with sicker patients will have worse outcomes and appear to deliver worse care. By adjusting for severity of illness in a multivariate model, ideally the baseline risk of death is mathematically equalized between institutions. The remaining differences in outcome are attributed to differences in structure and process of care. Unfortunately, there is now an extensive body of literature that demonstrates that risk-adjusted outcome is not a valid technique for identifying high- or poor-quality hospitals because of residual confounding, bias due to referral and upcoding of severity, and chance.[18-22] These limitations are poorly recognized, as evidenced by a recent widely publicized attempt to identify the "100 Top Hospitals" and their ICUs using risk-adjusted outcomes based on administrative (non-physiologic) data from Medicare Provider Analysis and Review database.[23]

On Sept. 22, 1993, President Clinton summarized the 2 goals of auditing risk-adjusted outcomes when he presented his ill-fated health care reform bill to a joint session of the United States Congress: "Our proposal will create report cards on health plans, so that consumers can choose the highest-quality health care providers and reward them with their business. At the same time, our plan will track quality indicators, so that doctors can make better and smarter choices of the kind of care they provide." Computerized medical databases have proven useful in assessing medical technology to inform clinical decisions including the use of blood transfusions and the pulmonary artery catheter.[24,25] However, the promise of using report cards based on risk-adjusted outcomes as a tool to improve health care quality by informing marketplace decisions has not been fully realized. Between 1991 and 1997, all 30 nonfederal hospitals in greater metropolitan Cleveland participated in the Cleveland Health Quality Choice (CHQC) program. Every 6 months, models were used to analyze whether participating hospitals' observed in-hospital mortality rates were greater or less than expected, and these results were distributed in a public report. While

there was a trend over a 7-year period for hospitals with poor risk-adjusted outcomes to lose market share, this effect was not statistically or clinically significant.[26] While there appears to be some benefit to feeding back outcome data to hospitals in terms of improving outcomes, this effect does not seem to be mediated by changes in market share.[27]

Using the Electronic Medical Record to Improve Outcomes in Your ICU

The electronic medical record is much more than a technique to eliminate reams of paper medical records. When used correctly, the electronic medical record has been shown to be one of the few consistently effective tools to change clinician behavior and improve outcomes. There are several ways information from the electronic medical record can improve outcomes in the ICU, including: 1) computer-aided physician order entry; 2) implementing guidelines; and 3) feedback of process and outcome data as part of a quality-improvement initiative. Computer-aided physician order entry reduces medical error by preventing handwriting interpretation errors and by capturing drug dose and drug interaction errors. Guideline implementation can be facilitated by using computer-generated prompts to remind physicians to implement guidelines in appropriate cases. Finally, data from the electronic medical record can be used to track the outcomes of quality-improvement initiatives and to target feedback to individual clinicians where appropriate.

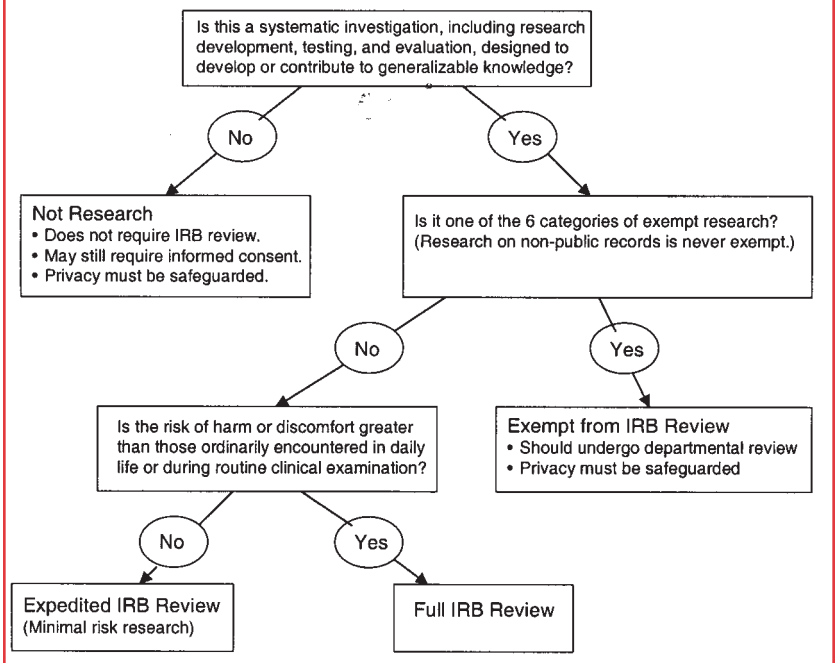
Ethics of Using Data From Computerized Medical Databases

Many uses of computerized medical record data fall under the category of routine clinical care and therefore are not covered by research requirements for institutional review. This might include using the electronic medical record to profile physicians and feedback data regarding antibiotic use; to identify resistance patterns in bacteria in the ICU; or to see whether the purchase of new antibiotic-coated catheters had reduced the incidence of catheter-related bacteremia. Analysis of the electronic medical record for these local quality improvement activities does not require Institutional Review Board approval and may not require informed consent from patients because it is part of ongoing clinical practice review (*see Figure*). However, the line between research and quality improvement is not well established.[28] The investigator's intent on publication is not a useful criterion for distinguishing research from clinical care. The need for informed consent or difficulty in obtaining it should not be used as a criterion for distinguishing research from clinical care; however, these are factors that an Institutional Review Board may take into account in a decision to waive informed consent. In general, any use of nonpublic medical records for research purposes should be reviewed by a research review board. Most of the analyses of computerized medical databases falls into the category of nonresearch or minimal risk research. Institutional Review Boards should have processes in place for the expedited review of minimal risk research covering observation of clinical practice that ensure consistent review.[29]

In 1996, the United States Congress passed the Health Insurance Portability and Accountability Act (HIPAA). HIPAA was created to streamline industry inefficiencies, improve access to health insurance including workers who change jobs, better detect fraud and abuse, and ensure the privacy and confidentiality of health care information. For the most part, HIPAA was designed to enhance patient privacy with respect to payers, employers, and pharmaceutical companies. However, this legislation supplements the Common Rule (the United States Code of Federal

Figure

Categories of Institutional Review Board (IRB) Review



Regulations that guides clinical research) regarding the privacy of clinical data. Health information can be accessed for research in 4 ways: 1) with individual informed consent; 2) with consent waived by an appropriate Institutional Review Board or Privacy Board; 3) under the constraints of a limited data set use agreement which provides investigators with partially anonymous data and requires less-stringent requirements than waived consent; and 4) by providing completely anonymous data. How individual Institutional Review and Privacy Boards will interpret these categories and the requirements they will place on investigators for maintaining records of access to an individual patient's computerized data remains to be seen. An excellent resource for information in this rapidly changing area is at http://privacyruleandresearch.nih.gov. Accessed November 10, 2003.

Conclusions

Perhaps the greatest benefits of computerized medical databases are yet to be realized. As computing power shrinks, standards for wireless computing and data sharing become more robust, and clinical users become accustomed to computer interfaces from early on in their career, the seamless integration of computers into clinical practice will be inevitable. Ample evidence exists that timely computer-generated prompts and decision support can influence clinical practice.[30-32] In considering the electronic medical record as a research and quality improvement tool, investigators should realize that while it will certainly yield an increase in legibility, the content of the information may or may not be improved by conversion to bits. The use of networks of ICUs to test quality-improvement strategies and evaluate trends in outcomes of critical illness syndromes has begun and will be greatly facilitated by computerized medical databases.[33] ■

References

1. Rubenfeld GD, et al. Outcomes research in critical care: Results of the American Thoracic Society Critical Care Assembly Workshop on Outcomes Research. The Members of the Outcomes Research Workshop. *Am J Respir Crit Care Med*. 1999;160(1):358-367.
2. Kohn L, Corrigan J, Donaldson M, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.
3. Institute of Medicine (U.S.). Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C.: National Academy Press; 2001.
4. State Inpatient Databases: Powerful Databases for Analyzing Hospital Care. Available at: http://www.ahcpr.gov/data/hcup/hcupsid.htm. Accessed November 10, 2003.
5. Sirio CA, et al. Cleveland Health Quality Choice (CHQC)—An ongoing collaborative, community-based outcomes assessment program. *New Horiz*. 1994; 2(3):321-325.
6. Knaus W, et al. APACHE III study design: Analytic plan for evaluation of severity and outcome in intensive care unit patients. Introduction. *Crit Care Med*. 1989;17(12 Pt 2):S176-S180.
7. Schriger DL, et al. Implementation of clinical guidelines using a computer charting system. Effect on the initial care of health care workers exposed to body fluids. *JAMA*. 1997;278(19):1585-1590.
8. Polderman KH, et al. Accuracy and reliability of APACHE II scoring in two intensive care units. Problems and pitfalls in the use of APACHE II and suggestions for improvement. *Anaesthesia*. 2001; 56(1):47-50.
9. Polderman KH, et al. Inter-observer variability in APACHE II scoring: Effect of strict guidelines and training. *Intensive Care Med*. 2001;27(8):1365-1369.
10. Corwin HL, et al. Efficacy of recombinant human erythropoietin in critically ill patients: A randomized controlled trial. *JAMA*. 2002;288(22):2827-2835.
11. Eichacker PQ, Natanson C. Recombinant human activated protein C in sepsis: Inconsistent trial results, an unclear mechanism of action, and safety concerns resulted in labeling restrictions and the need for phase IV trials. *Crit Care Med*. 2003;31(1 Suppl):S94-S96.
12. Eichacker PQ, et al. Meta-analysis of acute lung injury and acute respiratory distress syndrome trials testing low tidal volumes. *Am J Respir Crit Care Med*. 2002; 166(11):1510-1514.
13. Shekelle PG, et al. The reproducibility of a method to identify the overuse and underuse of medical procedures. *N Engl J Med*. 1998;338(26):1888-1895.
14. Jencks SF. HCFA's Health Care Quality Improvement Program and the Cooperative Cardiovascular Project. *Ann Thorac Surg*. 1994;58(6):1858-1862.
15. Goldman RS. Continuous quality improvement in ESRD: The role of networks, the United States Renal Data System, and facility-specific reports. *Am J Kidney Dis*. 1998;32(6 Suppl 4):S182-S189.
16. Hadorn D, et al, eds. *Assessing the Performance of Mortality Prediction Models*. Santa Monica, Calif: Rand; 1993.
17. Iezzoni LI. *Risk Adjustment for Measuring Health Care Outcomes*. Ann Arbor, Mich.: Health Administration Press; 1994.
18. Chassin MR, et al. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996;334(6):394-398.

19. Escarce JJ, Kelley MA. Admission source to the medical intensive care unit predicts hospital death independent of APACHE II score. *JAMA*. 1990; 264(18):2389-2394.
20. Park RE, et al. Explaining variations in hospital death rates. Randomness, severity of illness, quality of care. *JAMA*. 1990;264(4):484-490.
21. Hofer TP, Hayward RA. Identifying poor-quality hospitals. Can hospital mortality rates detect quality problems for medical diagnoses? *Med Care*. 1996;34(8): 737-753.
22. Thomas JW, Hofer TP. Research evidence on the validity of risk-adjusted mortality rate as a measure of hospital quality of care. *Med Care Res Rev*. 1998;55(4): 371-404.
23. 100 Top Hospitals : ICU Benchmarks for Success—2000. Available at: http://www.100tophospitals.com/studies/icu00/methodology.asp. Accessed November 10, 2003.
24. Hebert PC, et al. Clinical outcomes following institution of the Canadian universal leukoreduction program for red blood cell transfusions. *JAMA*. 2003; 289(15):1941-1949.
25. Connors AF, Jr., et al. The effectiveness of right heart catheterization in the initial care of critically ill patients. SUPPORT Investigators. *JAMA*. 1996; 276(11):889-897.
26. Baker DW, et al. The effect of publicly reporting hospital performance on market share and risk-adjusted mortality at high-mortality hospitals. *Med Care*. 2003;41(6):729-740.
27. Hannan EL, et al. Improving the outcomes of coronary artery bypass surgery in New York State. *JAMA*. 1994;271(10):761-766.
28. Casarett D, et al. Determining when quality improvement initiatives should be considered research: Proposed criteria and potential implications. *JAMA*. 2000;283(17):2275-2280.
29. Lynn J, et al. The ethical conduct of health services research: A case study of 55 institutions' applications to the SUPPORT project. *Clin Res*. 1994;42(1):3-10.
30. Gardner RM, et al. Computerized continuous quality improvement methods used to optimize blood transfusions. *Proc Annu Symp Comput Appl Med Care*. 1993;[volume not listed]:166-170.
31. Balas EA, et al. Improving preventive care by prompting physicians. *Arch Intern Med*. 2000;160(3):301-308.
32. Bero LA, et al. Closing the gap between research and practice: An overview of systematic reviews of interventions to promote the implementation of research findings. The Cochrane Effective Practice and Organization of Care Review Group. *BMJ*. 1998;317(7156):465-468.
33. Keenan SP, et al. The Critical Care Research Network: A partnership in community- based research and research transfer. *JJ Eval Clin Pract*. 2000;6(1):15-22.
34. Cook SF, et al. Project IMPACT: Results from a pilot validity study of a new observational database. *Crit Care Med*. 2002;30(12):2765-2770.

CME / CE Questions

13. For patients in whom life-sustaining treatment was considered to be nonbeneficial, ethics consultation had which of the following effects?
a. It increased overall time in the ICU.
b. It shortened the time of mechanical ventilation.
c. It increased overall mortality rate.
d. All of the above
e. None of the above

14. A study that poses greater risk of harm or discomfort than those ordinarily encountered in daily life or during routine clinical examination would require which of the following:
a. Departmental review only
b. Expedited review by the Institutional Review Board
c. Full review by the Institutional Review Board
d. No review by any official body

15. Which of the following are diagnostic criteria for acute lung injury?
a. Hypoxemia
b. Chest radiographic opacities
c. The exclusion of clinical evidence of left atrial hypertension
d. All of the above

Answers: 13.(b); 14.(c); 15.(d)

CME / CE Objectives

After reading each issue of *Critical Care Alert*, readers will be able to do the following:

- Identify the particular clinical, legal, or scientific issues related to critical care.
- Describe how those issues affect nurses, health care workers, hospitals, or the health care industry in general.
- Cite solutions to the problems associated with those issues.

In Future Issues:

ICU Delirium Common in Older Patients

CRITICAL CARE Plus

EXPANDING YOUR FOCUS IN INTENSIVE CARE

New Regulations Expected to Affect ICU Population

NEW RULES PUT FORTH BY THE BUSH ADMINISTRATION THAT TOOK EFFECT ON NOV. 10 SIGNIFICANTLY RELAX strictures in the 1986 Emergency Medical Treatment and Labor Act (EMTALA) that required hospitals and some hospital-owned clinics to examine and treat people who need emergency medical care even when those patients can't pay. The law applies to all hospitals that participate in Medicare and offer emergency services.

Because many ICU patients enter hospitals through the emergency room, the new regulation may also improve the ICU staff-to-patient ratio by lowering the number of ICU patients, though by how much will depend on the type of ICU and on a hospital's current admission and staffing policies. The new regulation says that the 1986 law will not apply to emergency patients once a hospital has admitted them. After more than a decade of downsizing, many hospitals throughout the country are experiencing system stress in their emergency departments due to diminished capacity.

Surgical ICUs will Probably Experience Few Effects

According to Eugene Litvak, PhD, a professor of health care and operations management at Boston University School of Management, the proportion of emergent surgeries in surgical ICUs is usually very small. Litvak doubts that relaxed rules will much affect them but says that multidisciplinary ICUs are another story. Reduced demand from EDs will immediately affect these ICUs, Litvak says, but it's hard to speculate what the extent of the effect would be because hospitals differ widely in numbers of available staff and in the proportion of medical and surgical ICU patients they serve.

Litvak has conducted research on the effects of artificial variability on ICU staffing at several major medical centers. His research shows a high correlation between those times when patients can't get into ICU or floor units and times when most surgical patients leave operating rooms and post-operative care unit floor beds, thus turning ED patients into "boarders" who block the patient flow.

Drafted in response to scores of complaints from hospitals and physicians that the old standards exposed them to lawsuits and fines for non-compliance, the new rule states that hospitals will not need not to make specialists available 24/7 and can legally exempt senior medical staff from on-call duty. The preamble to the new regulation says, "The overall effect of this final rule will be to reduce the compliance burden for hospitals and physicians."

The administration drafted the new rule after reviewing complaints from scores of hospitals and doctors who said the old standards were confusing and encouraged people without insurance to look for free care in emergency rooms.

Hospitals and doctors who violate the 1986 law can be fined $50,000 per violation and be excluded from receiving Medicare reimbursement. Since 1998, more than $4 million in fines have been collected by the government from 164 hospitals and physicians accused of violating the 1986 law.

Because courts have frequently ruled for patients and against hospitals, some patients may find that winning lawsuits filed due to injuries that occurred as a violation of federal standards. Patients who are turned away or refused emergency care will still be able to sue, but hospitals will have stronger defenses because the new rule reduces requirements about when and where hospitals must provide emergency services.

At least one ED physician, Robert A. Bitterman, who practices at the Carolinas Medical Center in Charlotte, NC, has commented that the new rule may make it more difficult for ED patients to gain timely access to specialist physicians because specialists are not accepting on-call duties as frequently as they used to. As a result, Bitterman says many EDs are without on-call coverage for such specialties as neurosurgery and orthopedics. (For more information, contact Eugene Litvak at [617] 358-1633 or Robert Bitterman at [704] 355-2000.) ■

Universal Consent Forms Raise Questions of Ethics

USING A UNIVERSAL CONSENT FORM FOR MULTIPLE procedures anticipated for a patient can nearly double the consent rate for most of the invasive procedures performed in an intensive care unit, according to researchers in Chicago. But observers say the tactic may violate the spirit of the informed consent process.

The suggestion for such a consent form arose in one of the first detailed studies of the informed consent process in an ICU. In that study, the researchers found that the rapid, unpredictable pace of critical illness combined with the inability of very sick patients to make decisions took a serious toll on patient autonomy. When caregivers relied on standard practice, patients or their proxies had the opportunity to consent to or refuse invasive procedures recommended by their doctors only 53% of the time.[1] A large fraction of procedures were performed with implied consent because they were deemed necessary by caregivers.

After the authors devised a universal consent form that explained the risks and benefits for the eight most common ICU procedures and presented the options to patients and families as soon as they were admitted to the ICU, they were able to raise the consent rate to 90%, says Jesse Hall, MD, professor of medicine and chief of pulmonary and critical care at the University of Chicago.

"Precise, widely accepted guidelines for obtaining consent in the ICU environment do not exist," Hall says. "Physicians can't even agree on which procedures require consent. Our goal was to begin to standardize the process and to find ways to make it more effective."

The study was performed in a 16-bed ICU at a university hospital. For two months, from Nov. 1 to Dec. 31, 2001, the researchers charted the consent rate for invasive procedures. They found that only 53.1% of the time (155 out of 292 procedures) did patients have the opportunity to consent to or refuse treatment. ICU physicians attributed their inability to get consent to the emergent nature of the procedure and the lack of an available proxy when needed.

Consent Rates Higher With Universal Form

In the intervention period, March 1 to April 30, 2002, a universal consent form that explained the risks and benefits of each procedure was presented to patients and families soon after they came to the unit. For this period, the consent rate increased to 90.5%, with consent secured in advance for 308 out of 340 procedures. "This is a far more acceptable level of patient participation," Hall says. "It enabled us to be more responsive to family wishes and also allowed patients themselves to make more decisions."

Before the universal consent form was introduced, patients made their own decisions in only 28.4% of cases. Proxies made the rest. The comprehensive form allowed the patient to make the call in 34.4% of cases. Comprehension by both patients and proxy decision makers was high and did not differ between the two periods. "We have shown that education of clinicians, patients and proxies regarding the process of informed consent can improve this process in critically ill patients," the authors conclude. ■

Eight Common Procedures

THE UNIVERSAL CONSENT FORM DESCRIBED EIGHT commonly performed procedures: placement of an arterial catheter, a central venous catheter, a pulmonary artery catheter, a peripherally inserted central catheter, lumbar puncture, thoracentesis (surgical puncture through the chest wall with drainage of fluid from the thoracic cavity), paracentesis (surgical puncture through the abdominal wall with drainage or aspiration of fluid from the abdominal cavity), and intubation/mechanical ventilation.

Another researcher who has studied consent forms extensively says the University of Chicago proposal may be well intended, but it seems to violate the spirit of the informed consent process. Melissa Bottrell, MPH, project manager at the National Center for Ethics in Healthcare at the Veterans Administration Puget Sound Health Care System in Seattle, says the universal consent form may solve a practical problem for clinicians but does not benefit the patient.

"It seems like they're trying to put a solution on the problem without realizing what the real problem is," she says. "They're saying they don't get documentation of consent, so that's in essence a legal problem, a lack of consent. So [they are] trying to solve that with this form, but I worry that the real effect is that they get a piece of paper without going through a true process of informed consent."

Bottrell points out that the situation may change significantly after the universal consent form is signed. The patient's condition may worsen or improve, for instance, or relatives may simply change their minds about what should be done for the patient.

The University of Chicago researchers say they urge clinicians to consider such a change in circumstances and repeat the informed consent process if necessary, but Bottrell says she doesn't think that would happen much in a real-world environment. Once the consent is obtained, she says, clinicians are unlikely to consider whether it is still valid. "Informed consent is about

shared decision making," she says, "but having this form signed before there might be a change in the patient's decision-making status, or a change in the patient's condition that would affect that decision, essentially allows the clinician to opt out of that shared decision-making process because they already have documented consent.

"There is coercive power with the clinician in the ICU saying we might need to do these eight procedures and want you to sign off on them now," Bottrell continues. "It puts the patient in a situation in which it seems shared decision making will be less likely to happen rather than more likely, which is not the goal of a consent form in the first place. It solves some of the practical problems with obtaining consent, but it doesn't fulfill the sprit of obtaining informed consent."

Bottrell notes that the proposed universal consent form differs in one important way from consent forms used up front for multiple procedures such as weekly dialysis treatment. In those situations, the patient's condition is unlikely to change significantly during the period covered by the consent form, she says.

Other Consent Forms Also Can Be Faulty

Even the standard consent forms used more commonly in all health care settings might not be as good as you think. Bottrell's previous research suggested that many of them amount to nothing more than a waste of time and may actually create more of a litigation problem than they could ever prevent. She and her colleagues were amazed at how poorly most informed consent forms achieve their goals. Bottrell says most of the forms are "a waste of paper. They're worthless."

Bottrell and her colleagues recommend a wholesale revamping of the informed consent process so that it revolves around a worksheet that the patient and doctor can work through together.

Rather than anything resembling a legal document, the worksheet should be a form that they can use to facilitate a personal discussion about the medical treatment, with plenty of questions prompting the patient to respond. Questions could include phrasing such as "This is a reasonable decision for me because . . . " with the patient filling in the rest as a demonstration that he or she has been adequately informed.

She also suggests that the same list of eight common procedures used in the University of Chicago universal consent form could be used as a checklist to prompt clinicians during the informed consent process in the ICU. That would be a better solution than asking for universal consent up front, she says.

"The problem is they're trying to solve the problem of obtaining consent in emergency situations by just showing proof of documentation," she says. "You could just as easily have the same conversation without necessarily having the form signed. If it's true that the physician does anticipate a number of procedures, you can have that conversation and use the checklist to remember to check them off and talk about them. It can be good to address these issues up front all at once but not obtain consent." ■

References

1. Davis N, et al. Improving the process of informed consent in the critically ill. *JAMA*. 2003;289:1963-1968.
2. Bottrell MM, et al. Hospital informed consent for procedure forms: Facilitating quality patient interaction. *Arch Surg*. 2000;135:26-33.

Checkoffs Play Key Role in SICU Improvement

A PATIENT DAILY GOALS CHECKOFF FORM USED TWICE daily during rounds has helped the surgical intensive care unit (SICU) team at Hartford (CT) Hospital achieve a 25% drop in its mortality rate, while cutting lengths of stay and ventilator days.

The 800-bed hospital, a level one trauma center and urban teaching/tertiary care facility, is a major affiliate of the University of Connecticut School of Medicine and one of the original participants in the "Transformation of the ICU," or TICU Project, sponsored by the Veterans Health Administration to help improve the organization and delivery of care to the ICU.

One of the outgrowths of the project was the concept of a goals form for rounds, first employed at Johns Hopkins in Baltimore under the direction of Peter Pronovost, MD.

"It seemed to work there, and they asked if other teams would try it; we took that challenge," recalls Eric Dobkin, MD, director of the 12-bed surgical ICU at Hartford.

The hospital actually formed two different teams in the surgical and medical ICUs and came up with two different goals forms.

"We [the SICU] clearly had outstanding outcomes, and I think the main reason for that was the way our form was structured," he says.

The form Hartford uses differs not only from the original Pronovost model but from many others Dobkin has seen implemented—including some in his own facility. "The real key is that to some extent, the others miss the point," he asserts. "Their focus is to use this as a to-do list, and I'm sure that is very beneficial.

However, we chose a different path."

One of the key elements of the TICU project, he notes, is improving patient safety. "We felt [with our form] we could improve quality and patient safety," Dobkin says. "That's why some of our questions are attributable to patient safety. They not only reflect the clinical concerns of the patient, but also their safety and psychosocial concerns."

But the key take-home message, he underscores, is that, "We decided to design not just a to-do list, but something modeled after an airplane takeoff checklist." That's why, he says, not only is every item on the list expressed in the form of a question, but each question is designed with a default answer of yes.

The decision on the questions themselves was, like the SICU team, multidisciplinary. The team includes nurses, a physician leader (Dobkin), respiratory therapist, social worker, and midlevel practitioners (nurse practitioner and physician assistant). "We have a multidisciplinary care philosophy in the SICU, and we primarily developed the form by mirroring the way we presented patients on rounds," Dobkin explains.

"We have rounds twice a day, and they had been more or less formalized verbal presentations of the patient, going in systems order—pulmonary, cardiovascular, neurological," he says. "Traditionally, this had been given from the head or from notes. Since we were multidisciplinary, this would include issues around the whole patient. We thought about this and formalized the areas we routinely discussed into questions [for the checkoff]."

Multiple versions of the form were used before the final version was selected. "We asked for input from our nursing staff, so they could incorporate questions they felt were important, too," Dobkin says. His team started with a small "test of change," using one or two patient rooms, then four, then half the unit.

"Each time, the form changed," he notes. The compilation of the questions in their final form was handled by the nurse practitioner, Denise Lawrence.

Communications Improved

Dobkin says that one of the additional benefits of this form has been the elimination of a problem he has seen in every ICU in which he has worked. "Every day on rounds, the residents present the patients the same way, by system," he says. "At the end, the resident inevitably says the plan for the day is 'ABC.' Yet, when you ask the nurses, they inevitably will say there is no plan. I don't know if this is a delivery issue or a reception issue; but since we implemented this, we have had total buy-in from the nursing staff."

Dobkin has the data to back up this assertion. At the outset of this program, nurses were provided with blank goals forms after rounds and were asked to write down the plan for their patients. "We found when we measured that the nurses truly did only know about 50% of the goals planned," he points out. "But after we instituted the [checkoff] procedure, they knew 98-100%. We have tested this for a year and a half, and it has been consistent."

While there is no baseline for the residents, the current data show that 98-100% of them also know their goals every day, Dobkin adds.

It also provides reinforcement for the nurses that this form helps them know the goals for the day, he says. "Nurses feel better organized about their day." And even though it is not the form's primary function, it also does function later on as a to-do list for the nurses.

"Plus, it is a communication form," Dobkin explains. "We print it on fluorescent yellow paper, and we put it in clear plastic sleeves on the breakaway door to the ICU, so everyone involved with the case can see it."

Finally, he says, it serves as a safety and quality "force multiplier."

Of course, it is the change in outcomes that is "truly impressive," Dobkin says. The SICU has decreased its mortality rate from about 11.4% to about 8.3% since the checklist began being used, he reports. "We also decreased [average] length of stay by 1½ days and ventilator days on by one day," he adds.

Scientifically, of course, it is impossible to attribute the entire change to the checklist. "However, we have had no change in patient population, no new technology implemented, nor have we been doing any other studies during this time," he asserts. Could other hospitals duplicate Hartford's results? "Yes and no," he says. "This is very low-tech, simple, and cheap to do. The high cost is the commitment by the staff, including physicians, to use it."

The checklist is done for every patient every morning, then revised in the afternoon. Then at night, the resident and the fellow make sure every goal is being followed. "What's necessary is the absolute devotion and leadership by clinical care physicians," Dobkin says. "How did we do it? We have a great team, and I had the support of the director of the section of surgical critical care and chief of surgery."

The nurse practitioner and the physician's assistant also played a crucial support role. "When I was not there, they reminded the others to adhere to the plan," he adds.

Even so, there was resistance in the beginning, both from nurses and physicians. However, notes Dobkin, "they persisted only until they saw the results." (For more information, contact Eric Dobkin, MD, Director, Intensive Care Unit, Hartford (CT) Hospital. E-mail: edobkin@harthosp.org.) ■