Creating Outcomes-based Systems for Quality and Malpractice Reform: Methodology of Accelerated Compensation Events (ACEs)

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THE NUMEROUS SHORTCOMINGS OF THE CONVENtional liability system are easily stated, especially for medical injuries. Solutions that directly address quality enhancement and dispute resolution are harder to come by. We will discuss an innovative alternative for improving judgments about adverse medical outcomes, for both quality and malpractice purposes.

The Need for Malpractice and Quality Reform

The Main Problems

Complaints about the law come from high-ranking legal sources, government task forces, and neutral academics, as well as from the usual parties: defendants and potential defendants (American Medical Association 1984–1985, 1988; Burger 1982; Carlson 1973; Ehrenzweig 1964; Keeton 1973; U.S. Department of Health and Human Services 1977). Indeed, complaints about the law and lawyers are hardly new, as a perusal of *Bartlett's Familiar Quotations* readily shows. The Shakespearean

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line, "The first thing we do, let's kill all the lawyers," of course considerably antedates even the nineteenth-century development of "modern" tort law (Prosser and Keeton 1985). Echoes of such quotations reverberate all the more loudly after the expansion of plaintiffs' remedies in the last generation (Huber 1988; Sansing 1990). What is new today is the scale of the legal enterprise, its widespread economic impact through modern liability insurance, and its influence on access to medical care and the nature of medical practice (Tancredi and Nelkin 1991).

Although some opponents of the system draw as much upon emotion as upon evidence, many problems can be documented (Institute of Medicine 1978; O'Connell 1979; Priest 1987). Objections are particularly intense in the medical arena, where the long litany of criticisms to legal performance can be boiled down to six major failings. Today's system, which includes the liability insurance process that actually pays most bills, can be charged with the following drawbacks:

- failure to detect the great majority of negligent injuries
- failure to compensate deserving victims in a timely and consistent fashion
- seeming haphazardness in assigning liability to medical management
- seeming haphazardness in determining damages
- high operating expenses, such that too little of the liability dollar returns to the injured patient as compensation
- encouragement of acrimonious disputes

Finding so few cases, and appearing to deal with them so haphazardly, undercuts the law's intended deterrent effect, that is, promoting safer, higher-quality care. Rather than carefully improving quality of care, providers too often engage in wasteful "defensive medicine" (Reynolds, Rizzo, and Gonzales 1987; Tancredi and Barondess 1978). Paying few cases, slowly, and at high cost undercuts the law's intended compensation of negligent injuries. Claimants are not rapidly "made whole" as the law intends; rather, the system actually rewards delays in rehabilitation. The system thus fails optimally to achieve the two main goals of tort law: injury deterrence and compensation. At the same time, medical quality assurance is unduly separated from the liability system. Many forms of quality review, too, rely on retrospective case-by-

case review of medical care, which can often lead to disputes (Tancredi and Bovbjerg 1992).

The ACE Set of Solutions

This article sets out the basis for alternative approaches to quality and malpractice control. They are based on categories of medical injuries designated in advance as "accelerated-compensation events," or ACEs. ACEs are predefined classes of medically caused injuries that do not normally occur when patients receive good care. The ACE idea is conceptually appealing. It is based on objectively defined *outcomes*, and outcomes are a key focus for monitoring and improving medical quality. ACEs are created by medical experts who review case scenarios of medical injuries from which they generalize to sets or classes of events.

Not all injuries that occur in the course of medical care would be covered under an ACE, only those for which experts can agree on reasonable medical responsibility. ACEs are defined by three main criteria: First, ACEs are moderately or highly preventable as a class. Second, ACE events are objective—easily specified and distinct from non-ACEs that might appear similar. Finally, including an injury as an ACE does not distort medical decision making. In contrast to the current system, which relies on retrospective, highly idiosyncratic testimony about allegedly faulty processes of care in particular cases, the creation of ACEs relies on generalized expert judgment about statistical outcomes of medical care, applied in advance.

These professionally generated listings of avoidable types of adverse outcomes can be used in a variety of quality and malpractice reforms (Tancredi and Bovbjerg 1991). The ACE lists can be calibrated to be broad or narrow according to the type of care covered and the purposes for which they will be used. Because of this capability, the ACE approach provides for maximum flexibility. It offers the prospect of reforming legal liability by relying on advance determinations and streamlined process rather than on slow, cumbersome, and complicated adversarial processes. For such payment reform, some simplified determination of losses, especially for nonpecuniary claims, is also contemplated. For these reasons, the adoption of ACEs as a payment reform would resolve medical injuries at lower administrative and legal cost

compared with the current system of tort law and liability insurance for medical malpractice.

Most tort reforms merely tinker with the current system to help defendants (Bovbjerg 1989; Robinson 1986). The ACE approach, in contrast, constitutes one of the very few constructive ideas for fundamental malpractice reform. As a malpractice reform it has a distinct advantage of being an outcomes approach that is strongly grounded in scientific understanding of the development of adverse outcomes. This grounding provides it with the consistency and predictability that is an essential component in the design of a viable alternative to pay for medical malpractice. Such a payment reform could be implemented by legislative mandate or adopted voluntarily, either across the board for all medical care, or for selected conditions or occurrences. Alleged harms not covered by ACEs would be resolved either under the current liability system or under an alternative approach, like mandatory arbitration or an administrative system (American Medical Association 1988).

In addition to its use in tort reform, the nature of ACE listings also promises to make them a useful tool for quality assurance, risk management, and improved dispute resolution within an unreformed liability system (Tancredi and Bovbjerg 1992; Wadlington 1991).

We will first describe the history and evolution of ACEs and then will detail the three criteria for ACEs, providing background on how the most recent lists were compiled, and discussing key issues in determining particular ACEs. We will consider the criticisms leveled against ACEs and conclude by reviewing the concept's promise in several areas and suggesting refinements that are required for implementation in a variety of settings.

The Evolution of an Alternative to Malpractice Litigation

The history of ACEs is grounded in tort reform, although their application is not so limited. The idea of shifting to an alternative system for medical injuries, as under ACEs, has existed for some time. Avoiding the lengthy, expensive, individualized demonstration of provider fault has been the subject of scholarly writing for over three decades (Ehrenzweig 1964). Such concepts have become widely known as "no fault," borrowing from automobile insurance (Keeton and O'Connell 1965;

Widiss et al. 1977). Unlike auto no-fault, however, which appropriately pays for every auto injury, no one proposes covering all adverse medical outcomes because most result from the underlying conditions being treated and not from the treatment itself. Some propose that covering most or all medically caused injury would make coverage very expensive (Danzon 1988; Mills 1978). ACEs, in contrast, are quite selective, covering only an appropriate subset of medically avoidable harms. The essence of ACEs is not universal payment (as under broad no-fault), but rather simplified rules of responsibility and payment that reduce disputes and speed resolutions. Indeed, ACEs could be termed "quasi-fault" because of their emphasis on preventability (Bovbjerg, Tancredi, and Gaylin 1991); however, the "no-fault" nomenclature is well established, so we term ACEs a "selective no-fault" approach. Defining ACEs selectively is the key to making the concept work.

Moving to the Third Generation of Reform

The central features of the ACE approach to malpractice and quality reform are the product of two decades of clarification and empirical analysis. The earliest extensive proposal for an alternative system was for a "medical outcome insurance system" (Tancredi 1972). This was improved and renamed "medical adversity insurance" when first published in this journal (Havighurst and Tancredi 1973). In contrast to earlier, less discriminating no-fault approaches, this first-generation proposal set out the basic idea of determining compensation by defining in advance a set of known significant adverse medical outcomes that are usually, although not invariably, avoidable with good quality care. This first publication contained a very general, preliminary listing of 14 avoidable events (Havighurst and Tancredi 1973, 134). The listing was based on cases reaching appellate courts (these cases are cited in Tancredi [1972]) and on expert medical judgment of what constitutes an avoidable adverse event. Subsequently, the method was further detailed in two other articles (Tancredi 1974; Havighurst 1975). This first generation of largely conceptual thinking about a potential alternative showed considerable promise of speeding compensation and yet promoting injury avoidance. However, the work lacked solid empirical grounding, as neither author had access to medical charts, epidemiological literature, legal or insurance files, or evidence at the trial court level.

The second generation sought to move from the drawing board toward the real world. In the late 1970s, the ABA's Commission on Medical Professional Liability (American Bar Association 1979) focused on the key tasks of defining "designated compensable events" (DCEs) in advance and suggesting administrative mechanisms for implementation. The commission sponsored a pilot study to investigate the feasibility of such a system for medical injuries and to examine the problems that would arise out of implementation efforts.

The definitional study covered general and orthopedic surgery (Boyden and Tancredi 1979), listing 18 events for general surgery, and 15 for orthopedic surgery. (Some, like falls from the operating table, were on both lists.) The study used summary information about closed liability claims for those specialties during the period 1975 to 1976 from the national census by the National Association of Insurance Commissioners (NAIC 1977, 1980). This computerized NAIC file of over 24,000 claims was supplemented by a more extensive narrative on the etiology of surgical injuries from a much smaller malpractice claims study by the Department of Health, Education and Welfare.

This project successfully documented that it was possible for medical experts to agree on a finite number of avoidable events (then called DCEs rather than ACEs) that were economically prominent, that is, occurring with high frequency or resulting in high liability payments (Boyden and Tancredi 1979, 14–15). The precise incidence of ACEs and the feasibility of identifying them contemporaneously from medical evidence rather than retrospectively from insurance claims remained unexamined. Thus, both the first and second generations lacked detailed documentation of injuries to which medical expertise could be applied.

Filling that gap became the objective of third-generation development of accelerated compensation events. These most recent improvements in ACE methodology are the primary subject of the rest of this article. Before turning to them, we pause to examine the great potential ACEs have for reform, which motivated the third generation of development.

Advantages of ACE Systems: Reasons for Interest

An ACE-based system has many appealing advantages (Bovbjerg, Tancredi, and Gaylin 1991; Havighurst and Tancredi 1973; Tancredi

1986). The characteristics of ACEs permit them to be used for many valuable purposes.

First, as a payment system to replace much or most of the tort system, the ACE approach would provide widespread and fair compensation of patients whose injuries fall within its scope. Today, compensation goes only to those whose claims survive a process of liability determination that discourages small claims, does not yield consistent results, and is slow and costly (Kakalik and Pace 1986). The name "ACE" itself is now used to highlight the *acceleration* of compensation, one of the most important advantages of using ACEs for an insurance system to replace most litigation (Bovbjerg, Tancredi, and Gaylin 1991; Tancredi 1986).

Second, an ACE system would be more effective in deterring medically caused injuries, thereby improving the quality of care. The tort system relies unduly on stigma and publicity to deter negligence because financial losses are covered by the provider's liability insurance and there is little merit rating of premiums (Sloan, Bovbjerg, and Githens 1991). Moreover, although the legal system purports to hold providers to a high standard of care, it does not send clear signals about what care is substandard. The ACE approach would promote quality by ensuring systematic reporting of avoidable adverse outcomes that can assist quality insurance. Many of these adverse outcomes may not even now be the subject of malpractice actions, but they should be an essential component in a system of monitoring quality of care. Uniform reporting would facilitate statistical analysis and comparison with results across treatment sites and among practitioners. Prompt feedback of such information to practitioners would alert providers to quality problems that otherwise may be missed and would enable them to modify their behavior so as to prevent or ameliorate injuries in their practice. Where the ACEs serve to determine payment responsibility, many also create appropriate financial incentives for preventing injuries. Various forms of experience rating for premiums could provide financial motivation as well (Havighurst and Tancredi 1973).

Third, ACEs, whether used for payment or quality monitoring, would minimize undesirable "defensive medicine." The tort system promotes low-value diagnostic measures in preparation for a possible legal action (Harris 1987; Tancredi and Barondess 1978). These practices can be costly and of little benefit to patients, sometimes even exposing them to unnecessary risk. Fear of an unpredictable legal process may also lead practitioners to omit beneficial high-risk services or to withdraw altogether

from certain types of practice such as obstetrical services to low-income patients (Institute of Medicine 1989). ACEs should not promote unnecessary defensive procedures because they are defined largely by the occurrence of listed outcomes, rather than by whether a provider actually performed certain tests or procedures, and documented doing so.

Fourth, ACEs systematize medical expertise about injuries. ACEs avoid the need for individual case-by-case determination of the type required in a court room or in medical peer review, which considerably streamlines the process. Today each case must have its own expert witnesses and all issues are argued out anew. It is not surprising that the current system's administrative expenses and other transaction costs are very high (Bovbjerg, Sloan, and Blumstein 1989). Expenses for malpractice defense as a percentage of claims payments are more than double those for auto bodily injury coverage, for example, and more than four times those of health insurance (Bovbjerg et al. 1991). An ACE system would save resources that would be better used to compensate injured patients and to educate medical providers about problem areas.

Fifth, in sharp contrast to the tort system, an ACE system offers the opportunity to strengthen the physician-patient relationship and thereby the quality of medical care. The current adversary system pits patients against health care professionals in frequently acrimonious disputes (Bovbjerg 1991; Institute of Medicine 1978). This process discourages physicians from revealing the truth about potential outcomes of their interventions because they fear that such disclosures may trigger a malpractice action. An ACE payment system, by facilitating provider communication of risks before a procedure is undertaken—and prompt payment and rehabilitation after—shores up the values of honesty and trust.

Sixth, the ACE approach provides for the first time a systematic framework for research on specific adverse outcomes and for better assessment of the quality of care. Other work examines outcomes, but judges them through intensive review of the attendant process of care (Harvard 1990; Orlikoff and Vanagunas 1988; Sanazaro and Mills 1991). The ACE categories of "avoidable" injuries provide the basis for broad-scale epidemiological research on the quality of health care outcomes—within hospitals, health maintenance organizations, and other provider facilities. For example, ACE incidence in these facilities can be examined in light of institutional changes such as the adoption or elimination of particular treatment programs, diagnostic measures, or proto-

cols for care. Similarly, ACEs have important educational value to medical professionals and other providers of care.

Finally, ACEs will promote greater confidence in the accuracy and fairness of malpractice and quality determinations. Expert determination in advance of avoidable types of injury will enhance credibility among providers. The system should also curb variability of medical-legal judgments and decisions based on extraneous factors. ACE payment reform closely links compensation with the outcomes of medical intervention. Accomplishing this linkage according to scientific standards creates strong incentives for providers to modify their behavior in order to improve the quality of health care, as does the use of incidence of ACEs for quality surveillance.

Criteria for Development of ACE Lists

To realize all these advantages under various reforms, the ACEs need to be robust. That is, they must comport to strictly defined criteria. In this section, we will explain the theory of ACE development. Most of the theory was set by the first generation of ACE work (e.g., Tancredi 1974). The current, third generation has specified it more fully and has more thoroughly put it into action.

Three principal factors are used to assess the appropriateness of including any specific injury as an ACE (Tancredi 1974): The most fundamental criterion is (1) relative avoidability. The others are (2) detectability and (3) absence of perverse incentive effects. These two additional factors address possible practical difficulties that might arise if a particular injury were classified as an ACE.

"Relative avoidability" is established on a statistical basis before the fact rather than on an individual basis after an injury. That is, it is an epidemiological conclusion about a population of cases, not a legal or clinical judgment about one patient. These judgments can be made scientifically, through dispassionate consensus. In contrast, even after conventional tort reform, the law continues to judge results idiosyncratically, long after the fact, with ultimate authority vested in lay juries operating in an emotion-laden context. Even peer review may be driven by idiosyncratic judgments rather than systematic, statistically based thinking (Boyden and Tancredi 1979, 28). Essentially, in reviewing information to develop lists, the experts ask themselves, based on their clinical expertise

and knowledge of the medical literature, "In what percentage of a large number of similar cases could this outcome be avoided, given good care?"

More specifically, the first criterion of "relative avoidability" itself calls for consideration of three characteristics of a class of injuries:

1. *Preventability* addresses whether a modification in the approach of diagnosing and treating the underlying condition could usually prevent the occurrence of the untoward outcome in a particular class of cases. To assess this, an expert examines the outcome from the perspective of signs and symptoms that may have been evident earlier and that should have alerted the clinician to institute known and available preventive measures.
2. *Iatrogenicity* refers to the probability that a particular injury is caused by medical interventions, including medication, a surgical procedure, or a diagnostic measure, or inaction when action was called for. In any case, the iatrogenicity criterion excludes unavoidable effects of the underlying condition or extraneous factors not related to medical intervention.
3. *Treatability* addresses whether or not early recognition could have resulted in immediate amelioration of the injury so as to prevent or mitigate its long-term consequences. Such consequences include not only temporary or permanent disability or death, but also economic loss for the patient. Even if the basic iatrogenic injury is not highly preventable, its adverse effects may be largely avoidable with prompt intervention.

"Detectability" is the second key attribute of an ACE class. The definition of an adverse outcome should be shaped clearly and precisely to facilitate objective detection by clinicians. The goal is to include all events that fit within the definition of relative avoidability, but no others.

Avoiding "unintended incentive effects" is the third factor to weigh in creating ACEs. Such effects are possibly deleterious side effects of listing a particular injury as an ACE. However avoidable and well defined a class of injury is, the incentive effects of designating it as an ACE must be considered before listing it. Although the purpose of creating an ACE is to induce providers to change their behavior so as to reduce its incidence, it would be undesirable if providers elected to forgo a benefi-

cial procedure in order to avoid a possible ACE, thus causing an undesirable, uncompensable medical outcome to result from the progression of the condition under treatment. Similarly, doctors might substitute an inappropriate and risky course of care because it was not associated with any ACE. An illustration of this might be seen where adverse effects of medication are listed as ACEs. The unintended incentive effect might be the administration of less desirable medications for a medical condition because they are unlikely to produce serious adverse reactions that would be classified as ACEs. On the other hand, the selected medication may be significantly less effective in treating the patient's condition and may involve a prolongation of disability or create even more serious long-term medical difficulties for the patient.

The determination of "avoidability" under the ACE approach relies on a probabilistic association between a type of medical intervention and a class of adverse outcomes (Boyden and Tancredi 1979, 28), not on a detailed examination of a specific clinical incident. The view of causation, therefore, is scientific rather than legal, and the standard is whether there is a high probability of avoiding the specified type of untoward outcome if certain actions along the entire course of the care of a patient are taken or averted. How high is "high" is a matter of judgment on which different implementing organizations or agencies might make different decisions. For listings here, 70 percent avoidable was the standard adopted, a level the expert consultants deemed appropriate.

Improved Methodology for Developing ACE Lists

The Third Generation— Refinement and Application

The study reported in this article marks the third generation of ACE development. This most recent work is characterized by several refinements: First, we have revisited the issue of how to define ACEs. Medical expertise has remained central to the process, but the development of the definitions of avoidable injury also drew upon an extensive empirical data set of malpractice claims (over 15,000 records) closed in Florida over a four-year period (Florida Department of Insurance 1985–1988).

Florida has an unusual requirement that all insurers and self-insurers report closed medical malpractice claims to the state.[1] Recent years' reports used by this project have unusually detailed descriptions of the medical condition and the alleged injury involved in each case. (For a description of the data base, see Sloan et al. [1989].) We examined some 2,350 cases from claims closed in three specialties: general surgery, obstetrics and gynecology, and orthopedic surgery.

We also reviewed a complete set of risk-management and legal files from a large teaching hospital, which we matched to medical records (1979–1986, 330 files). Our "raw material" for considering the avoidability of adverse events was thus considerably richer than what had been previously available.

Second, we actively applied ACE lists to real-world insurance files and medical records. Among other things, we compared information from medical records with legal records to determine the stage at which information about injuries becomes available. Other applications, not presented in this article, empirically assessed surgical ACEs in Medicare hospitalizations and the likely performance of obstetrical ACEs, compared with the current liability system (Bovbjerg, Tancredi, and Gaylin 1991; Bovbjerg et al. 1991). Third, we have more fully explored the uses of ACEs for noncompensation reform—changes in quality monitoring and control, as well as changes in legal or insurance practice without mandatory supplanting of lawsuits by ACEs (Tancredi and Bovbjerg 1991).

In short, the third generation of effort entailed a more methodical and empirical approach than earlier generations.

Steps in Creating ACEs

ACEs were developed through a three-stage, iterative process (table 1). Claims from our two data sources were first subjected to a preliminary sifting process. The lead author, a physician-lawyer, examined all of the individual files. This screening eliminated from consideration only those cases in which the injury was obviously unavoidable and for which information was insufficient to reach any judgment. Working "scenarios" were then derived from the actual cases, each giving the essential clinical information about the case, which was later reviewed by other experts.

[1] Florida Stat. Ann. §627.912.

TABLE 1
The Central Enterprise: Steps in Identifying and Listing Avoidable Adverse Outcomes as ACEs

Initial phase: sifting of data—lead author
- Start: review "raw material" of information from claims and medical records for three specialities: obstetrics/gynecology, general and orthopedic surgery (N = 2,680 total cases)
- Preliminary culling: remove cases with insufficient information; clearly identify unavoidable events
- Output: create preliminary "scenarios," or individualized synopses of possibly avoidable adverse events, based on or inspired by actual cases (N = 470)

Second phase: constructing ACEs—with expert panels
- Ranking of avoidability: rank each scenario as highly or moderately avoidable (≥ 90 percent, ≥ 70 percent, N = 140) versus not avoidable (< 70 percent) or indeterminant[a]
- Abstracting to classes of events: remove case-specific, nonrelevant identifiers from scenarios and consolidate like scenarios
- Reconfirmation of avoidability: revalidate listings as classes of highly and moderately avoidable events
- Broadening event classes: further abstract listings to focus on general clinical action (or inaction) involved
- Delineating event classes: add new specificity about medical processes or causation where necessary to delineate sharp boundaries around each avoidable class of events to be an "ACE"
- Other criteria weighed: consider possible unintended effects of listings on clinical decisions

Final ACE lists—lead author
- Editing: clarify language of ACEs, making it parallel for three different sets of ACEs
- Last refinement: group similar ACEs for three specialties (N = 48 Ob/G, 62 GS, 36 OS) within 11 general parallel categories to facilitate application in research on legal/insurance and medical records

[a] Latter two cases were dropped.

There was a strong tendency in this initial phase of the project to lean toward including scenarios for further consideration by the experts rather than eliminating them. Occasionally, an actual case would suggest a slightly different set of events that could serve as an ACE sce-

nario. Other times, multiple closed claims contributed to a single scenario.

Each scenario included a specifically described adverse outcome and a brief description of how that outcome emerged. For example, a review of one claim produced the following specific scenario (general surgery outcomes case #2305):

> A 59 year old male underwent a reverse of a colostomy. The bowel was connected to the bladder instead of the distal portion of the bowel. Injury: Patient was passing feces while urinating due to the surgical error.

In obstetrics and gynecology, 103 such initial scenarios were constructed. In surgery and orthopedic surgery, the numbers of scenarios were 145 and 212, respectively (University of Texas/Urban Institute 1988).

In the next stage, these first-order scenarios were given an "avoidability evaluation" by other experts. This second phase involved panels of nationally recognized medical experts from each specialty examined. These specialists, who have the greatest expertise for weighing the evidence on avoidability and other criteria, reviewed each scenario and ranked it according to relative level of avoidability as defined by our consultants: highly avoidable (90 percent and above), moderately avoidable (70 to 90 percent), not avoidable, or indeterminate. For example, in obstetrics and gynecology, of the original scenarios, 41 (39 percent) were found to constitute events that, in the specific situations, were highly or moderately avoidable. In surgery and orthopedic surgery, the numbers were 64 (44 percent) and 35 (16 percent), respectively.

The result was a revised listing of the avoidable scenarios in each of the three specialties. These included only events that were ranked as moderately or highly avoidable in the specialists' assessment.

The first listing of potential ACEs was produced from these second-stage scenarios. At this point, the scenarios underwent some abstraction preparatory to developing a true *class* approach to injury. Identifying data such as age, sex, and the specifics surrounding the event were eliminated. This list then was sent to the specialists for confirmation of the degree of avoidability of the more abstract scenarios. For example, in obstetrics the following description of a claim had been perceived as characterizing a highly avoidable event (obstetrics/gynecology outcomes case #2306):

A 26 year old woman entered the hospital with a lump in her right breast. The physician conducting the examination on the woman misdiagnosed the lump and ignored its potential consequences. Subsequently it was learned that the lump was an early malignancy. Because of failure to diagnose it early enough, by the time it was recognized it had metastasized and the patient ultimately died of the malignancy.

This specific scenario was abstracted to the next level so as to develop a more general class of adverse outcome.

Failure to diagnose lump in breast of hospitalized woman early enough to minimize the potential consequences of metastasis and ultimate death.

After confirming the accuracy of these abstract descriptions with the medical experts, the lead author focused on the treating clinician's essential act of commission or omission. Hence, the new listing of this ACE for obstetrics and gynecology further reduced that scenario to the following final ACE (No. Ob/G-37): "consequences of 'misdiagnosis' of breast malignancy."

The individualized scenario of a hospitalized 26-year-old woman who had died of metastasis of the breast had now been abstracted and transformed to a category: all women in the care of obstetricians/gynecologists whose early breast malignancy had been misdiagnosed.

Some difficulties with the ACE abstracted from a failure to diagnose breast cancer are apparent. The minimalist statement of the adverse outcome to be compensated implicates the process that caused that adverse outcome. Although an ACE incorporating the judgment entailed in the term "misdiagnosis" is sufficiently objective for research purposes, an ACE so simply defined could lead in a "real-world" payment system to process-oriented arguments about what constitutes misdiagnosis that would be only somewhat more structured than those occurring in the liability system. Hence, this ACE requires further work to make the determination more outcome oriented and objective. This could be accomplished by referring to existing information on the average rate of growth and spread of breast malignancies. With this information in hand and based on features of the breast lesion at the time of its discovery, it would be possible to extrapolate from the time of its known occurrence the precise consequences of a misdiagnosis. This information

would be important in determining the likelihood of avoiding outcomes like metastasis and the need for extensive surgery or radiation. Furthermore, such information would be crucial to determining the likelihood that the misdiagnosis led to the patient's death. The circumstances that would result in justifiable compensation thus include not only death, but also other adverse consequences, such as disability, involvement of other organs resulting in pain, or further impairment of the patient.

Among the initially developed ACEs for obstetrics and gynecology, some other examples included (No. Ob/G-38) "complications to infant(s) from syphilis during pregnancy, unrecognized during prenatal care," and (No. Ob/G-33) "complications to infant(s) from fetal distress (including brain damage) that was unrecognized or untreated during attended delivery." In the course of our further investigation of the application of ACEs to a different data base for obstetrical and gynecological events, additions were made to our initial listing, such as "complications from intubation or inability to intubate" (No. Ob/G-27) and complications from abandonment of the patient—failure to treat labor (No. Ob/G-21). In all, 48 ACEs for obstetrics and gynecology were developed. In each case the final decisions for inclusion took into consideration the possible "unintended negative effects" that might result from designation. General surgery had 62 ACEs, orthopedic surgery had 36.

The third and final stage of the process involved refinements of editing and reordering. Some minor stylistic editing occurred and some changes to make the three ACE lists parallel in their treatment of similar or overlapping issues. Last, the ACEs were arranged within 11 general categories, such as "puncture or laceration wounds" (IV) and "drug and blood disorders" (VI). (Table 2 gives the major headings, with sample ACEs for each.) Such clustering of the adverse outcomes facilitates the application of the ACE lists to different data sets of events and helps to make the lists applicable across different surgical fields. For example, category I, infections, in obstetrics and gynecology amounts to postoperative wound infections, including peritonitis and abscess formation. Number III, "other complications from procedures," might be "inadvertent removal of ovaries during hysterectomy." (Here "inadvertent" needs documentation from the preoperative plan of the intended surgery.) Once developed, these ACE lists were used for research (Bovbjerg, Tancredi, and Gaylin 1991; Bovbjerg et al. 1991). Additional information on outcomes later led to the addition of a few more ACEs

TABLE 2
Categories of ACEs, with Sample Listings

Category of ACEs	Sample listings
I. Infections	Decubitus ulcer during inpatient care
II. Nerve injuries	Complications (blindness, brain damage) secondary to air embolisms during surgical removal of an acoustic neuroma
III. Other complications of procedures	Infarction of bowel secondary to hernia repair
IV. Puncture or laceration wounds	Complications (including death) from pneumothorax following subclavian venopuncture and closed thoracotomy
V. Device placement and/or malfunction	Postoperative displacement of any internal orthopedic device that was applied during that operative procedure
VI. Drug and blood disorders	Complications (e.g., including hypotension, shock, or death) secondary to anticoagulant treatment in preparation for surgery
VII. Diagnostic issues	Complications from failure to diagnose and treat hypoglycemia in a newborn
VIII. Foreign bodies	Complications (including death) from foreign body unintentionally left in the operative site after any general surgical operation or procedure
IX. Falls	Complications from falls from table during surgical operation or procedure or delivery
X. Vascular events	Complications (severe edema, pulmonary embolism, etc.) secondary to phlebitis and thrombophlebitis (deep vessels of lower extremities) following a surgical procedure
XI. Death	Death during surgical operation (or immediately after) other than with a high-risk patient

Source: ACE listings for obstetrics/gynecology, general surgery, and orthopedic surgery,

in reconsultation with the experts. ACE development is indeed an interactive process.

Specific Issues in Creating ACE Listings

Defining Medically Avoidable Events

Although it is easy to list "relative avoidability" and "detectability" or "boundedness" as separate criteria, in practice, they are interrelated. Similarly, the components of avoidability (preventability, iatrogenicity, and treatability) also tend to merge as applied. The key theme is the concept of medical causation. ACEs, as we noted earlier, are a *class-based* approach to the causative relationship between medical care and adverse events. Ideally, therefore, causation should be considered epidemiologically rather than relying on the clinical or legal approaches, which both require case-by-case determinations. However, epidemiological research on injuries remains almost as rare today as in the past (Boyden and Tancredi 1979). Hence, the ACE definition necessarily relies on expert clinical judgment, but informed by knowledge of the clinical literature and using an epidemiological perspective. In addition to distinguishing between events that are medically avoidable or unavoidable, professional skill must be applied in specifying precisely what complex of circumstances constitutes an ACE. "I know it when I see it" can work for after-the-fact diagnosis or prescription, but considerably more precision is needed to define a class in advance.

In giving effect to epidemiological notions of causation in ACE listings, it is crucial for experts to focus on three links in the causal chain. First, the medical intervention must be statistically associated, affirmatively or negatively, with a bad outcome. An affirmative act refers to a diagnostic or a treatment procedure performed on a patient by a treating clinician, by hospital personnel (e.g., staff nurse), or by another medical practitioner (ABA 1979). Examples would be the administration of a drug or an operative procedure. A negative act would include the omission of an important diagnostic or treatment procedure. As a rule, affirmative acts are more obviously tied to ensuing bad outcomes than are negative ones. Some acts require considerable specification to maintain the appropriate causative link with outcomes (e.g., complications [blindness, brain damage] secondary to air emboli during surgical

removal of an acoustic neuroma); others are more general (e.g., aspiration pneumonia following a surgical procedure).

The second causative link is the physiological mechanism by which that omission or commission causes harm (ABA 1979). If perfect statistical correlation existed, understanding the physiological changes that occur to the patient as a result of a medical decision would be less important. For now, causation is better established biomedically. Consider the administration of a hepatitis-contaminated fluid in a transfusion. The physiological mechanism would be the infection and cellular changes caused by the hepatitis: inflammation of the liver. For some ACEs, it is appropriate to specify this physiological process in delimiting the ACE as a narrow event.

The third element in an ACE's causative chain is the disability or injury that results. Most obviously, an ACE must specify the nature of the abnormality or injury that has occurred. Otherwise, all kinds of patient injuries or dissatisfaction might be raised as part of ACEs, going beyond the clearly avoidable injuries meant to be covered. In the case of hepatitis, the injury would be specific damage to the liver. Moreover, to maintain confidence that an injury actually occurred, and that it resulted from medical care, it is appropriate also to consider the *severity* of the injury. This refers to the extent and intensity of impairment resulting from the medical (non)intervention (ABA 1979). Severity is also important in assessing damages or disability benefits in any system of compensation based on ACEs, but that is not the focus here.

Minimum Threshold of Significance

There is a question of what to do about very minor harm, such as transient pain, short-term emotional distress, or discomfort. If such minor occurrences only slightly lengthen recovery, it will be hard to be confident that any objectively verifiable event occurred, much less that a specific act caused it. Various nonmedical factors may cause one patient to react with more distress than another to the same stimulus. Hence, in establishing ACEs, it may not be possible to list problems that, however real, are minor and hard to detect. The handling of minor injuries has been discussed in terms of a "minimum threshold of significance" (Boyden and Tancredi 1979, 28). This means, in effect, that a cutoff point of severity could determine the extent of disability that warrants consideration as an ACE.

The application of a minimum threshold of significance is somewhat controversial. On the one hand, there may be merit in including even minor injuries as ACEs. First, inclusion may create a more powerful incentive for quality care by alerting practitioners that no avoidable injuries caused by their interventions will go unnoticed and that financial or other responsibilities will be invoked. Second, from an ethical perspective, those patients who have been injured, even minimally, may deserve some recognition of these injuries. Third, counting even minor injuries will increase the scope of the data base created for analyzing quality of care. Systemic problems that cause small injuries today may be detected and corrected before causing larger ones tomorrow.

On the other hand, etiological, administrative, and economic reasons support a decision to omit minimal injuries. First, and most fundamentally, allowing "injury" to include minor occurrences makes causation unclear, as such minimal injuries may be very hard to distinguish from problems inherent in the disease process itself, or from expected inconveniences of medical intervention. This lack of discreteness occurs in large part because the symptoms and signs associated with temporary injury are more general and diffuse, and therefore not easily linked to one clear-cut cause. For example, a temporary injury of the soft tissue surrounding a fracture may be the result of an improperly fitted cast, the initial insult that caused the fracture, or secondary injuries caused by the bone displacement prior to its being set, but not discoverable until later. The first of these, soft-tissue injury related to a tight cast, would easily fit within the ACE criterion of relative avoidability. This would not be the case for the other causes of the condition that are unrelated to medical intervention.

Second, the administrative cost of handling minimal claims can be very high relative to the harm being addressed. As the old legal maxim puts it, "de minimus non curat lex"; trifles are not worth expensive fact finding and potential disputation.

Third, the benefits of early identification and action on ACEs do not exist for marginal, self-limiting injuries. Unlike more serious injuries, which must be treated as ACEs, a minor injury will not be significantly limited by early intervention. This is especially true for transient pain, suffering, or inconvenience, some of which accompany much of medical care.

Fourth, a class of minimal injuries could be extraordinarily large, particularly if it becomes difficult to demarcate truly avoidable minimal in-

juries and discomforts from those relatively unavoidable ones more closely linked with the underlying disease process. Hence, including minimal events in an ACE-based compensation reform could be very costly.

Finally, such subjective matters necessarily also require case-by-case investigation and involve problems of veracity, which the proposed ACE approach seeks to avoid. Objective verification is much easier for more substantial injuries.

On balance, minimal injuries do not seem to belong in a deterrence-oriented system like ACEs. Whether their inclusion makes the system more credible by broadening it statistically, or less credible because of problems of distinguishing iatrogenic injury from normal progression of care, is an empirical question. Perhaps different uses of ACEs call for different standards or possibly the decision may vary according to type of minor injury. The issue calls for further deliberation.

Low-Incidence Events

Another set of adverse outcomes whose causation is uncertain involves those that rarely occur. Arguments for and against including them as ACEs can be illustrated by reviewing the adverse outcomes categorized as "adverse drug reactions," especially allergic reactions, excessive dosage responses, and direct toxic effects, which the expert panels decided to include as ACEs. Consider, for example, the ACE for surgery number GS-36: "Adverse drug reactions—e.g., analgesics, anesthesia, antipyretics, or other medications or combinations thereof: a. allergic response; b. excessive dosage response; and c. direct toxic response."

First, the low-incidence reactions may be associated with nonspecific early signs and symptoms. If an allergy to a particular drug is rare, then it may be reasonable for the clinician to view early symptoms (which can be diffuse and general for a variety of medical problems) as not indicative of an allergic reaction, particularly if other causes for the patient's nonspecific early symptoms are more common and if any reaction, once identified, can be promptly corrected. Therefore, although epidemiological studies may establish that an allergic reaction to a specific drug, no matter how rare, would be highly avoidable if measures were instituted in a timely fashion when the early symptoms emerge, nonetheless, not taking action may be justified because there are so many "false positives"—cases of nonallergic symptoms.

Second, the low-incidence event may be viewed as one of the potential adverse reactions that the clinician knows about and takes into account when recommending a particular treatment. A clinical dilemma may occur when the drug considered for administration has common adverse reactions that may not be avoidable because of clinical exigencies but also other rare adverse reactions representing toxic and allergic reactions that may be avoidable. The early symptoms and signs of a common adverse reaction may be similar to those of a rarely occurring adverse reaction to a low-incidence event. However, the clinician may risk the more idiosyncratic low-incidence event (e.g., toxic damage to the auditory nerve) in favor of the therapeutic benefits of the drug, and the likelihood that the concomitant adverse reactions, if any, will differ significantly in intensity and quality (seriousness and permanence of injury) from the low-incidence event. Accepting this risk would be especially desirable therapeutically if there are no equally effective alternative treatments and the underlying disease condition is likely to lead to very serious disability and possibly death for the afflicted patient.

In most cases, the delay of early intervention to treat adverse reactions will have minimal impact on a patient's care. In a very small number of cases, it might mean that a serious adverse event (one of low incidence) could have been avoided through interventions such as premature discontinuation of the drug or the administration of medications to neutralize or counteract the undesirable effects. However, these interventions themselves may not be without risks, the active drug may become ineffective, thus resulting in worsening of the patient's underlying condition, and/or the additional drugs will have their own accompanying list of potential adverse reactions. The low-incidence event, although avoidable, and therefore a potential candidate for the ACE system, will probably have minimal impact on the clinician's decision making about using a particular therapeutic agent. When balancing the low risk of a serious allergic or toxic drug reaction against the benefits that might be achieved by using the drug and treating common reactions as controllable adverse reactions, the advantage for the patient may seem clearly in the direction of following a policy of early nonintervention.

On the other hand, maintaining adverse drug reactions as an ACE assures that incentives will operate to limit the use of drugs with serious low-incidence events to very necessary and urgent circumstances where suitable alternatives are not available. Therefore, the overall quality-enhancing effects, combined with the low incidence of serious and idio-

syncratic events, more than compensate for the cost of financially covering these adverse events.

Third, a low-incidence event may be theoretically unavoidable where a specific drug is implicated that is essential for treating a particular condition, yet still warrant inclusion within a general ACE category. Drug reactions fall along a continuum, from particular classes of drugs for which serious adverse events may be nearly unavoidable to those for which they may be highly avoidable. The cost associated with identifying the specific drugs with unavoidable adverse reactions under particular circumstances would be high. Because the events are of low incidence in any case, it would be far easier to compensate adverse events of certain categories—such as allergic, excessive dosage, and direct toxic responses—when they occur with *all* drugs rather than attempt to differentiate drugs with unavoidable reactions from those with truly avoidable reactions. A factor that must be considered in support of this decision is that incentives would be created for developing the means to avert even the unavoidable adverse events. These incentives might include the development of less toxic or allergic alternatives.

In sum, therefore, clustering the low-incidence adverse drug reactions into a general category makes economic and administrative good sense. It assures that outcomes information and incentives will be properly aligned for enhancing the quality of medical care on an ongoing basis.

Bounding ACEs with Specification of Medical Process

It is sometimes necessary to specify the cause of an avoidable event or the medical action or inaction involved so as to exclude similar but less avoidable injuries. One reason for conceptualizing the underlying process leading to ACE listings is that it provides the basis for narrowing or further specifying the scope of the injury to be covered under the system. Qualifications based on the nature of the intervention or the physiological mechanism involved allow a broad and overinclusive preliminary description to be tailored to meet the criterion of "high" relative avoidability.

Consider one ACE currently on the list for obstetrics and gynecology (No. Ob/G-7): "kidney damage secondary to inadvertent ureteral laceration and/or ligation." In this example, kidney damage resulting from a specified intervention or event is considered avoidable and thus com-

pensable. An earlier scenario had suggested defining kidney damage secondary to obstetrical procedures as an ACE, but this definition would have included a range of injuries that would not meet the requirement of relative avoidability. One example might be an obstetrical patient with a serious underlying kidney condition, for example, polycystic disease of the kidney. Such a patient would be susceptible to developing serious injury from any surgical procedure simply because the blood flow to the renal area may be temporarily compromised or there may be minor trauma from the surgical intervention itself, especially if it involves entrance into the abdominal cavity. There would not necessarily be a close linkage between the obstetrical procedure, per se, and the event, although the damage to the kidney may occur during the operation. Here, and elsewhere, the broader definition would likely include many circumstances of minimal avoidability. Consider also "drug induced cholestatic jaundice following a surgical procedure" (No. Ob/G-29). By limiting the jaundice or liver condition to a drug-induced situation, the event that is created meets the medical profession's criterion of relative avoidability.

The ACE listings contain many other examples of adding the nature of the intervention or physiological mechanism to the ACE in an effort to create an outcome that scientifically meets the requirements of clearly bounded relative avoidability. One example would be the category within obstetrics and gynecology (No. Ob/G-32) of "complications to infant(s) from postmaturity in the absence of evidence that the fetus is in good condition." Postmaturity is specifically defined as 42 weeks and beyond from accurately dated gestation. This is an excellent example of where the adverse outcome (complications, which include both neurological disturbances and physical handicaps) is narrowed by the definition of "postmaturity." The description of "failure-to-diagnose" ACEs is more extensive than the other categories because of the need to demarcate this category's range of adverse outcomes.

Consideration of the medical intervention, physiological process, and resulting disability is important in creating precise lists of ACEs. They help objectively identify adverse outcomes for which a possible intervention could reduce the risk of occurrence or resulting disability.

These factors contribute to our understanding of where lines are to be drawn in order to assure that the ACE being created reflects existing medical knowledge of avoidability and the other criteria essential to defining ACEs. While adhering to principles of equity and fairness, the

line-drawing dimension of creating ACEs has been the most problematic, yet it is the most important one for the success of the project. When outcomes are described too broadly, linking them with specific interventions allows for refinements of the ACEs. This type of specification may seem paradoxical: having gone from individual scenarios to general classes, we return to the specific. Yet the final ACEs are quite different from the particular scenarios that begin the process. The generalization that occurs must take place in order to create a *class* of avoidable outcomes; it drops *unimportant specifics* like age (in most cases) or location in a hospital. The reintroduced, *relevant specificity* has a different character. It does not identify the specifics of an individual case, but rather creates clear boundaries around each class, ensuring that nonavoidable outcomes are not included. Overall, the focus is on outcomes, conditioned by including descriptions of the intervention or concomitant physiological mechanism.

Minimizing Distortions in Practice, Including the Difficult Case of Fetal Demise

Throughout the process of developing ACEs, we had to remain sensitive to the possibility of unintended consequences of designating a particular outcome as an ACE. This requirement necessitates careful review of the medical decision-making process. Most particularly, we had to consider what alternative diagnostic and treatment measures physicians might resort to in order to avoid care that entails the risk of ACE-linked outcomes. For example, distortions in practice can be seen in decisions involving the use of blood transfusions, where an ACE might include contracting serum hepatitis following a transfusion. The presence of this ACE might induce practitioners to avoid blood transfusions wherever possible and substitute other types of volume expanders like saline solution or dextrose. Here, paradoxically, there might be serious consequences to an injured patient, including death, because blood was a more appropriate and superior fluid replacement.

The case of fetal demise raises different issues about distortion. Such a distortion already exists in the tort system. Today, if a child is born dead, the potential tort loss is far smaller than if the child is born brain damaged. The incentive is in the direction of delivering a stillborn rather than a seriously damaged infant.

Perhaps one way to rectify the distortion might be to include fetal demise as an ACE, under the assumption that it might be better to compensate automatically for all fetal demises rather than segregating the more avoidable ones. There is, of course, a problem with including all fetal demises in ACEs. Many events leading to fetal demise are, in fact, unavoidable. For example, one quarter of abortions are spontaneous, and one study of 250 malpractice claims involving neonatal mortality found that 42 percent were nonpreventable deaths (Cornblath and Clark 1984). However, epidemological studies are rare, and even where they exist, their data are insufficiently disaggregated to assess both the avoidability of events under specific circumstances and what percentage of unavoidable injuries constitutes fetal demise.

In our development of obstetrical ACEs, some of the events already include, at least implicitly, the possibilities of fetal demise, but tie it to a specific intervention. For example, one of the ACEs involves "complications from failure to use fetal monitoring (or other antepartum tests) in high-risk pregnancies according to the guidelines of the American College of Obstetricians and Gynecologists" (No. Ob/G-14). Even more explicit is the example of "complications to infant(s) from unrecognized or untreated fetal distress (including brain damage)" (No. Ob/G-33). Included with this ACE is a detailed definition of fetal distress, which properly restricts the scope of the ACE to avoidable outcomes.

The case of fetal distress does illustrate a dilemma that perhaps can only be resolved with additional information or with mechanisms for setting conditions on the application of an ACE. However, by not including fetal demise as an ACE, we risk the possibility of creating distortions in incentives for practitioners in some of the same ways the current tort system distorts medical practice. There may be several ways to circumvent this problem. One might be to enumerate more precisely the additional instances of fetal demise that would be included as ACEs. This can be done by adding conditions for proper care of the fetus that, if violated and the fetus dies, would be an ACE. For example, fetal demise in the presence of a violation of an established protocol of delivery—and these can be enumerated by a group of obstetricians—would create an ACE. Another illustration might be imposition of the rule that obstetrical intervention is necessary within 12 hours of rupturing of the fetal membranes. Alternatively, a group of obstetricians might agree on those circumstances where fetal demise is relatively un-

avoidable, designate them clearly, and hold fetal demise in the absence of these unavoidable conditions as an ACE.

Other Issues

Two additional points seem important in the final listing of ACEs. First, single-specialty ACEs are insufficient; complementary specialties need joint ACE consideration. Many specialties, especially those connected with surgery—anesthesiology, pathology, and radiology—work together in treating patients. The existing ACEs for complementary specialties need to be integrated so as to maintain consistency among them and cover the range of causes for avoidable adverse outcomes. For example, a complication from a surgical procedure may be avoidable by the surgeon operating on the patient or by the anesthesiologist monitoring that patient's level of consciousness. The two specialists are performing different functions, but specific adverse outcomes may result from the nonintervention of either one. It is also undesirable to have ACEs cover one specialty practitioner in a single episode while others remain governed by traditional malpractice as quality monitoring approaches.

Perhaps the best way to achieve this is to focus not on specialties, but on procedures. As we have seen, the ACEs are not specialty limited; rather, they frequently cross over specialty boundaries. There is thus a need for research into how specialties complement each other and the effects of ACEs in one specialty on the medical decision making in another.

The second concern is clinical substitution. This refers to the use of paramedical or nonphysician health professional involvement that may result in injuries under the ACEs of a particular specialty. A good illustration of this is the nurse/midwife who provides some obstetrical care. If, for example, we create an ACE for a specific complication of cesarean sections, it will be essential to consider its likely impact both on the incidence of normal deliveries (and related injuries) and on the use of midwives.

An additional, yet similar, concern is to achieve consistency among the full range of defendants for adverse outcomes, where ACEs are seen as a payment reform to replace litigation. This would also include the manufacturer of medical devices and drugs where applicable. Everything related to a particular injury should be addressed in one system of compensation, or one does not save on legal costs and the system is not eq-

uitable. For example, a drug company might be involved in a liability matter because an ACE might constitute an adverse outcome secondary to the use of medication. The drug company then might be seen as partially, if not wholly, responsible. An illustration might be the development of agranulocytosis—a marked decrease of granulocytes in the blood, rendering patients very susceptible to infection—from the use of Clozaril. Should such an adverse outcome be considered an ACE for the medical practitioner, the plaintiff might find it to his economic advantage to pursue an additional liability action against a drug company. The theory for such an action might be that the drug company did not provide proper warning to the clinician or should have in fact more thoroughly informed the patient, or perhaps something faulty occurred in the manufacturing of the particular batch of medications that made it more likely to cause a serious condition. It would be critical for the ACE system to subsume necessary litigation against the drug company or other manufacturer. Otherwise, legal strategy would move toward the "deep pocket," thereby defeating the benefits of an automatic compensation for all parties involved.

Criticisms of ACE Approaches

Many observers have expressed reservations about the feasibility and desirability of ACE-based reforms. Most have discussed ACEs as a payment reform, a use emphasized during earlier generations of ACEs. The most basic concern is that it would be virtually impossible in practice to identify and list specific bad outcomes of medical care (Keeton 1973). Some critics have suggested that, even if such outcomes could be identified, it would be virtually impossible to delimit them so as to exclude expected consequences of medical treatment and its unavoidable side effects. Others have suggested that any ACEs would be costly to administer (Calabresi 1978). A variant on this objection is that even if the system were feasible to create, the listing would be impossible to apply in practice because of the idiosyncratic nature of each medical complex of circumstances.

More than a decade ago, however, work by Boyden and Tancredi (1979) showed that medical experts could agree in advance on an appropriate listing of significant problem events, thus answering half of this objection. That study did not address feasibility in application to actual

medical cases, and our current project has done just that. In one phase of our work, nurse-claims investigators applied the ACE listings to data from insurance claims files (Bovbjerg, Tancredi, and Gaylin 1991). They had little difficulty deciding boundary issues; relatively few cases were referred to physician review. In another phase, the lead author applied the listings to descriptions from hospital chart reviews supplied by a team of nurse–physician data abstractors.

Other researchers have also sought to study avoidable medical injuries based on hospital chart review, but using traditional approaches to applying negligence standards on a case-by-case basis. Studies in both California (Mills, Boyden, and Rubsamen 1977) and New York (Harvard Medical Practice Study 1990; Brennan et al. 1991) showed that medical experts could determine which adverse outcomes were caused by medical care. There were substantial disagreements among the New York experts on whether negligence existed in many cases, however, which suggests that improvements can be achieved by a more objective standard, like ACEs.

Concluding Thoughts

In this article we have described the origins of ACEs as scientific categories of avoidable medical injury, the process of listing ACE units, and the strong potential of ACEs to improve the medical and legal process. As in earlier generations of ACE development, the third-generation study described here has once again shown that ACEs are feasible to define. The listings now constructed are broader and more detailed than any previously attempted. We have also documented our criteria and processes for listing adverse outcomes as ACEs, covering both theoretical and practical issues. On the whole, advantages of the concept considerably outweigh disadvantages for various potential uses. Many of the criticisms of ACEs do not hold up under empirical scrutiny; others can only be assessed through field trials of ACEs.

In related work reported elsewhere, we applied the improved ACEs to two types of medical and legal records (see Bovbjerg, Tancredi, and Gaylin 1991). There is still some work to be undertaken in perfecting the methodology for delineating and applying ACEs. The next major task is to assure "interrater reliability," that is, consistency among reviewers in applying ACEs to actual cases in medical records. Because the

creation of ACEs is an ongoing process, updating of the lists will be also necessary.

Our current research has focused not only on listing specific events, but also on the process of developing these events, so that in the future adverse events from new areas, including additional specialties and medical technologies now being developed, can more readily be considered as ACEs. Any practical application of ACEs will also have to specify more precisely the process for implementing them in "the real world," as opposed to the world of disinterested research. This is true for all uses of ACEs, from payment reform, to improving current dispute resolution for insurance settlements, to monitoring quality of care.

Finally, more research remains to be done on the medical record itself. Its value for documenting adverse events must be enhanced. Our preliminary comparisons of medical records with the subsequent risk-management and legal records were somewhat discouraging (Tancredi and Bovbjerg 1991). Most injuries that subsequently attract legal concern are indeed noted somewhere in the underlying medical record. Frequently, they are difficult to locate, however, and the provider's role in the event is hard to establish, as is a categorization of the injury for ACE purposes. The legal records are typically far more helpful in understanding the alleged injury. These records contain information from interviews with health care personnel involved in patient care, giving more complete information on the nature of the alleged adverse event and its relationship to medical care.

Additional work is needed to put ACEs into actual use for quality reviews, for risk management, and to replace inefficient malpractice litigation. Still, work to date has documented the value and feasibility of the ACE approach. Having detailed the methodology for listing ACEs, we are also better poised to expand the reach of ACE lists and to move the concept toward implementation (Wadlington 1991).

References

American Bar Association (ABA) Commission on Medical Professional Liability. 1979. *Designated Compensable Events System: A Feasibility Study*. Chicago: American Bar Association.

American Medical Association (AMA). 1984–1985. *Professional Liability in the '80s*. Reports 1, 2, and 3, prepared by the AMA Special Task

Force on Professional Liability and Insurance. Chicago: American Medical Association.

———. 1988. *A Proposed Alternative to the Civil Justice System for Resolving Medical Liability Disputes: A Fault-Based Administrative System.* Chicago: American Medical Association/Speciality Society Medical Liability Project.

Bovbjerg, R.R. 1989. Legislation on Medical Malpractice: Further Developments and a Preliminary Report Card. *University of California–Davis Law Review* 22:499–556.

———. 1991. Problems and Solutions in Medical Malpractice. In *The Liability Maze: The Impact of Liability Law on Safety and Innovation*, ed. P.W. Huber and R.E. Litan, 274–90. Washington: Brookings Institution.

Bovbjerg, R.R., F.A. Sloan, and J.F. Blumstein. 1989. Valuing Life and Limb in Tort: Scheduling "Pain and Suffering." *Northwestern University Law Review* 83:909–76.

Bovbjerg, R.R., F.A. Sloan, A. Dor, and C.R. Hsieh. 1991. Juries and Justice: Are Malpractice and Other Personal Injuries Created Equal? *Law and Contemporary Problems* 54(1):5–42.

Bovbjerg, R.R., L.R. Tancredi, and D.S. Gaylin. 1991. Obstetrics and Malpractice: Evidence on the Performance of a Selective No-Fault System. *Journal of the American Medical Association* 265:2836–43.

Bovbjerg, R.R., L.R. Tancredi, D.S. Gaylin, and P. Held. 1991. Finding Medical Injuries in Medical Records: Applying Lists of Avoidable Bad Outcomes to Medicare Hospitalizations, paper 3733-02. Washington: Urban Institute. (Unpublished manuscript)

Boyden, J.R., and L.R. Tancredi. 1979. Identification of Designated Compensable Events (DCEs). In *Designated Compensable Event System: A Feasibility Study*, prepared by the ABA Commission on Medical Professional Liability, 11–51. Chicago: American Bar Association.

Brennan, T.A., L.L. Leape, N.N. Laird, et al. 1991. Incidence of Adverse Events and Negligence in Hospitalized Patients, Results of Harvard Medical Practice Study I. *New England Journal of Medicine* 324:370–6.

Burger, W.E. 1982. Isn't There a Better Way? *ABA Journal* 68:274–7.

Calabresi, G. 1978. The Problems of Malpractice: Trying to Round Out the Circle. In *The Economics of Medical Malpractice*, ed. S. Rottenberg, 233–43. Washington: American Enterprise Institute.

Carlson, R.J. 1973. A Conceptualization of a No-Fault Compensation System for Medical Injuries. *Law and Society Review* 7:329–67.

Cornblath, M., and R.J. Clark. 1984. Neonatal Brain Damage, An Analysis of 250 Claims. *Western Journal of Medicine* 140:298–302.

Danzon, P.M. 1985. *Medical Malpractice: Theory, Evidence, and Public Policy*. Cambridge: Harvard University Press.

———. 1988. Medical Malpractice Liability. In *Liability: Perspectives and Policy*, eds. R. Litan and C. Winston. Washington: Brookings Institution.

Ehrenzweig, A. 1964. Compulsory "Hospital-Accident" Insurance: A Needed First Step Toward the Displacement of Liability for "Medical Malpractice." *University of Chicago Law Review* 31:279–91.

Florida Department of Insurance. 1985–1988. Florida Medical Professional Liability Insurance Claims Files. (Unpublished data)

Harris, M. 1987. Defensive Medicine: It Costs, But Does It Work? *Journal of the American Medical Association* 257:2801.

Harvard Medical Practice Study. 1990. *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York*. Report of residents and fellows. Cambridge, Mass.: Harvard University Medical School.

Havighurst, C.C. 1975. "Medical Adversity Insurance"—Has Its Time Come? *Duke Law Journal* 1975:1233–80.

Havighurst, C.C., and L.R. Tancredi. 1973. Medical Adversity Insurance—A No-Fault Approach to Medical Malpractice and Quality Assurance. *Milbank Memorial Fund Quarterly/Health and Society*, 51:125–268. (Reprinted in *Insurance Law Journal* 69:613, 1974.)

Huber, P. 1988. *Liability: The Legal Revolution and its Consequences*. New York: Basic Books.

Institute of Medicine. 1978. *Beyond Malpractice: Compensation for Medical Injury*. Washington: National Academy of Sciences.

———. 1989. Committee to Study Medical Professional Liability and the Delivery of Obstetrical Care. *Medical Professional Liability and the Delivery of Obstetrical Care*, Vol. 1. Washington: National Academy Press.

Kakalik, J., and N. Pace. 1986. *Costs and Compensation Paid in Tort Litigation*, report no. 3391-ICJ. Santa Monica, Calif.: Rand Corporation.

Keeton, R. 1973. Compensation for Medical Accidents. *University of Pennsylvania Law Review* 121:590.

Keeton, R., and J. O'Connell. 1965. *Basic Protection for the Traffic Victim: A Blueprint for Reforming Automobile Insurance*. Boston: Little, Brown.

Mills, D.H. 1978. Medical Insurance Feasibility Study: A Technical Summary. *Western Journal of Medicine* 128:360–5.

Mills, D.H., J.S. Boyden, and D.S. Rubsamen. 1977. *Report on the Medical Insurance Feasibility Study* [sponsored jointly by California

Medical Association and California Hospital Association]. San Francisco: Sutter Publications.

National Association of Insurance Commissioners (NAIC). 1977. *Malpractice Claims.* Milwaukee, Wisc.: NAIC.

———. 1980. *Malpractice Claims, Final Compilation: Medical Malpractice Closed Claims, 1975–1978.* Brookfield, Wisc.: NAIC.

O'Connell, J. 1979. *The Lawsuit Lottery.* New York: Free Press.

Orlikoff, J.E., and A.M. Vanagunas. 1988. *Malpractice Prevention and Liability Control for Hospitals*, 2d ed. Chicago: American Hospital Publishing.

Priest, G. 1987. The Current Insurance Crisis and Modern Tort Law. *Yale Law Journal* 96:1521.

Prosser, W., and J. Keeton. 1985. *Prosser and Keeton on the Law of Torts*, 5th ed. St. Paul, Minn.: West Publishing Company.

Reynolds, R.A., J.A. Rizzo, and M.L. Gonzales. 1987. The Cost of Medical Professional Liability. *Journal of the American Medical Association* 257:2776–81.

Robinson, G.O. 1986. Rethinking the Allocation of Medical Malpractice Risks Between Patients and Providers. *Law and Contemporary Problems* 49:173–99.

Sanazaro, P.J., and D.H. Mills. 1991. A Critique of the use of Generic Screening in Quality Assessment. *Journal of the American Medical Association* 265:1977–81.

Sansing, J. 1990. First, Kill All the Lawyers. *Washingtonian* 26:132–43.

Sloan, F.A., R.R. Bovbjerg, and P. Githens. 1991. *Insuring Medical Malpractice.* New York: Oxford University Press.

Tancredi, L.R. 1972. The Analytics of a No-Fault System for Medical Malpractice: A Medical Outcome Insurance System. New Haven Conn.: Yale Law School. (Unpublished honors thesis)

———. 1974. Identifying Avoidable Adverse Events in Medicine. *Medical Care* 12:935–43.

———. 1986. Designing a No-Fault System. *Law and Contemporary Problems* 49:277–86.

Tancredi, L.R., and J.A. Barondess. 1978. The Problem of Defensive Medicine. *Science* 200:879–82.

Tancredi, L.R., and R.R. Bovbjerg. 1991. Rethinking Responsibility for Patient Injury: Accelerated-Compensation Events, A Malpractice and Quality Reform Ripe for a Test. *Law and Contemporary Problems* 54(2):147–77.

———. 1992. Advancing the Epidemiology of Injury and Methods of Quality Control: "ACEs" as an Outcomes-Based System for Quality Assurance. *Quality Review Bulletin.* In press.

Tancredi, L.R., and D.N. Nelkin. 1991. Malpractice and Its Effect on Innovation. In *The Liability Maze: The Impact of Liability Law on Safety and Innovation*, eds. P.W. Huber and R.E. Litan, 251–73. Washington: Brookings Institution.

University of Texas/Urban Institute. 1988. Adverse Outcomes of Florida Medical Professional Liability Insurance Claims Reports: General Surgery and Ob/Gyn Claims 1985–1986. Houston, Tex.

U.S. Department of Health and Human Services. 1977. *Report of the Task Force on Medical Liability and Malpractice.* Washington.

Wadlington, W. 1991. Medical Injury Compensation, A Time for Testing New Approaches. *Journal of the American Medical Association* 265:2861.

Widiss, A.T., R.R. Bovbjerg, D.F. Cavers, J.W. Little, R.S. Clark, G.E. Waterson, and T.C. Jones. 1977. *No-Fault Automobile Insurance in Action: The Experiences in Massachusetts, Florida, Delaware and Michigan.* Dobbs Ferry, N.Y.: Oceana Publications.

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