

Chapter 5

Adverse Events

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Adverse Events

INTRODUCTION

The idea that problem medical care can be identified through poor patient outcomes that are unexpected is behind the “occurrence screening” and “incident reporting” systems that have been implemented in almost all U.S. hospitals. Touted as early warning systems for hospital administrators, occurrence screening and incident reporting systems grew out of the malpractice crisis of the mid-1970s, when institutions desperately began to seek ways to limit their liability. Exactly what constitutes an occurrence or an incident varies widely among institutions. Although most reporting systems use patient outcomes as criteria to screen for occurrences or to define incidents, some also use criteria related to the process of care. The single thing that all the reporting systems have in common is that they are used by hospitals only as a first step for finding poor-quality medical care. In many cases, the occurrence of adverse events may result from factors other than poor quality. Thus, to establish a link between the quality of hospital care and adverse events, hospital cases identified by the reporting systems must be followed up with more thorough investigation and interpretation by medical advisers.

In the early 1970s, Rutstein and his colleagues proposed counting “sentinel health events,” or cases of unnecessary diseases, disabilities, and untimely deaths, to monitor the quality of medical care (546). Working with numerous specialists, these researchers developed a list of specific conditions for which adverse outcomes—whether caused by commission or omission—should never occur, such as death from tuberculosis.

Specific criteria for reporting adverse incidents across all conditions were first developed in 1976 in the California Medical Insurance Feasibility Study (432). That study, sponsored by the California Medical Association and the California Hospital Association, used general outcome criteria to screen more than 20,000 patient charts from 23 hospitals for adverse events that might result in litigation for malpractice compensation.

The 20 “potentially compensable events” developed by physicians and medical audit experts in the 1976 California study later became the basis for “occurrence screens,” adapted and modified for use by individual institutions. An adaptation of the general outcome criteria that was developed by Medical Management Analysis is shown in table 5-1 (154). The outcome criteria in the table, now used in more than **200** U.S. hospitals, cover all aspects of hospitalization and are generally used to screen every patient record during the patients’ hospital stay (**290**).

Among the common adverse events used as criteria in most occurrence screens are deaths, nosocomial (hospital-acquired) infections, unusually long lengths of stay, and unscheduled procedures, readmissions, or transfers. The use of deaths as a criterion maybe limited to cases where death is a statistically rare outcome for the procedure, condition, or diagnosis-related group or is in some other way unexpected. In most hospitals, cases with adverse events identified by an occurrence screen are subsequently reviewed in depth for possible problems related to the quality of care. Almost all hospitals adapt occurrence screens for their own particular needs, for example, adding suitable clinical indicators developed at the departmental or service level. The use of occurrence screens in a hospital is usually part of the hospital’s quality assurance program and therefore directly linked with existing peer review endeavors.

It is not known how many U.S. hospitals currently use occurrence criteria to screen their patient populations for adverse events. Increasingly, insurance companies are requiring hospitals to use occurrence screens as a condition for underwriting the medical malpractice insurance of affiliated physicians (420). The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) encourages the use of specific criteria to select cases for review in hospitals’ quality assurance programs, yet it gives ample leeway in

Table 5.1.—General Outcome Screening Criteria for Hospitals

Criterion 1: Admission for adverse results of outpatient management.	Exceptions: Specific instructions may be developed by the clinical departments concerning expected admissions for chronic conditions managed in the outpatient setting.
<p>Criterion 2: Readmission for complications or incomplete management of problems on previous hospitalization.</p> <ul style="list-style-type: none"> a. Pre-existing complication with deterioration. b. New complication. c. Recurrent disease state. d. Unresolved disease state. 	<p>Exceptions:</p> <ul style="list-style-type: none"> . Complication or incomplete management occurred at another hospital not associated with this hospital or involved a practitioner who is not on this medical staff. • Planned admissions for secondary procedures needed to complete treatment.
<p>Criterion 3: Operative/invasive procedure consent.</p> <ul style="list-style-type: none"> a. Incomplete. b. Missing prior to procedure. c. Different procedure done from procedure on permit. d. Different surgeon performed procedure than name on permit. e. Not signed by patient or legal guardian. f. No informed consent note. g. Other. 	<p>Exceptions:</p> <ul style="list-style-type: none"> . Emergency procedures where the patient was unable and the family or legal guardian unavailable to sign the consent. • Life-threatening problems found and addressed during surgery.
Criterion 4: Unplanned removal, injury, or repair of organ structure during surgery or other invasive procedure, or vaginal delivery.	Exceptions: None.
Criterion 5: Unplanned return to operating room, delivery room, or other special procedures room on this admission.	Exceptions: Planned second procedure or second stage of a procedure planned prior to first procedure.
<p>Criterion 6: Surgical and other invasive procedures which do not meet criteria for necessity and appropriateness.</p> <ul style="list-style-type: none"> a. Diagnostic tissue—pathology report does not match preoperative diagnosis. b. Nondiagnostic or normal tissue removed and medical staff criteria for necessity or appropriateness not met. c. No tissue removed and medical staff criteria for necessity and appropriateness not met. d. Other 	Exceptions: As developed by the medical staff.
<p>Criterion 7: Blood loss excessive or blood/blood component utilization which is unjustified, excessive, results in patient injury, or is otherwise at variance with professional staff criteria.</p> <ul style="list-style-type: none"> a. Excessive blood loss occasioned by iatrogenic bleeding or anemia with or without transfusion. b. Transfusion of blood or blood components not clinically indicated. c. Transfusion reaction. d. Other. 	Exceptions: As developed by the professional staff.
Criterion 8: Nosocomial infection (hospital-acquired infection),	Exceptions: Infection acquired outside this hospital, clinic, or home health care setting and did not involve any member of this medical staff.
<p>Criterion 9: Drug/antibiotic utilization which is unjustified, excessive, inaccurate, results in patient injury, or is otherwise at variance with professional staff criterion.</p> <ul style="list-style-type: none"> a. Does not meet professional staff criterion for appropriateness. b. Inadequate/excessive/inappropriate/inaccurate dosage or timing. c. Drug or contrast material reaction/interaction. d. Other. 	Exceptions: As developed by the professional staff.
Criterion 10: Cardiac or respiratory arrest/low Apgar score.	Exceptions: None.
Criterion 11: Transfer from general care to special unit.	Exceptions: Transfer scheduled prior to surgery or other special procedure.
Criterion 12: Other patient complications.	Exceptions: None.
<p>Criterion 13: Hospital-incurred patient incident.</p> <ul style="list-style-type: none"> a. Falls, slips, patient accident. b. Intravenous problems, such as calculation errors, overloads, or infiltrations. c. Skin problems, such as rash, threatened or new decubitus ulcer. d. Equipment failures/malfunctions. e. Other incidents, such as procedural errors, electrical shock or burn, actual or attempted suicide, and lost or damaged property. 	Exceptions: None.

Table 5-1.—General Outcome Screening Criteria for Hospitals—Continued

Criterion 14: Abnormal laboratory, X-ray, other test results, or physical findings not addressed by physician.	Exceptions: As developed by the professional staff.
Criterion 15: Development of neurological deficit which was not present on admission.	Exceptions: As developed by the medical staff for expected outcomes, such as deficits following intracranial surgery.
Criterion 16: Transfer to/from another acute care facility.	Exceptions: Mandatory transfer for administrative reasons, or transfer for tests not available at this hospital,
a. Financial reasons,	
b. Management/procedures not available at this Institution.	
c. Patient option.	
d. Other.	
Criterion 17: Death	Exceptions: None.
a. Unexpected with surgery.	
b. Unexpected without surgery.	
c. Expected, disease related.	
d. Other.	
Criterion 18: Subsequent visit to emergency department or outpatient department for complications or adverse results from a previous encounter.	Exceptions: Planned returns for wound checks or suture removal.

SOURCE: J. W. Craddock, *Medical Management Analysis Series: Vol. II, Improving Quality and Resource Management Through Medical Management Analysis* (Rockville, MD: Medical Management Analysis International, Inc., 1987).

the degree of specificity. There are certainly wide disparities in the occurrence screens used by hospitals. All or samples of patient populations can be screened for occurrences either during the patients' hospital stay or retrospectively after discharge. Hospitalwide, "generic" screens can be applied equally across all patients, or detailed service-specific criteria devised for similar sets of patients. Screens can be computerized too, but the level of patient information detailed in the screens usually requires the review of patients' medical records by specially trained personnel in all but a few highly computerized hospitals.

Incident reporting systems, though often overlapping with occurrence screens and also growing out of concerns about rising malpractice liability, tend to be organized and operated somewhat differently from occurrence screens. Incident reporting systems are organized directly by the hospital administration (rather than being part of a hospital's quality assurance program) and tend to be operated independently of the medical record or other existing information systems. Typically, as part of risk-management programs, hospital personnel (most frequently nurses) complete forms when they observe an adverse event, and the forms are reviewed centrally by a hospital administrator/risk manager. The definition of an "incident" is often left to the discretion of the frontline health professionals who deal with patients. Most commonly, adverse events such as

patient falls, medication errors, equipment failures, and commission of procedure or treatment errors are considered incidents. Reliance is placed on educating nurses, physicians, and other health care workers to recognize problems and report them.

Because health care personnel use their judgment in reporting incidents, it is more likely that incidents reflect quality-of-care problems than do the adverse events that are initially identified by occurrence screens; screening systems are expected to identify substantial numbers of false positives. Although reported incidents might therefore be viewed as being one step closer to identifying poor-quality care than are occurrences picked up in screens, further investigation of incidents is also necessary. First, an incident may not have been caused by negligent medical care; for example, a patient fall may have resulted from the patient's own carelessness. Second, an incident may not have had an important impact on the patient; for example, even though a medication has been administered incorrectly, a patient may suffer no ill effects.

Almost all hospitals have incident reporting systems, but the quality and reliability of reporting in these systems was enormously across institutions. Currently, eight States¹ and the Veterans

¹The eight States are Alaska, Florida, Kansas, Maryland, Massachusetts, New York, Rhode Island, and Washington (290).

Box 5-A.—Mandatory incident Reporting in Massachusetts

Since July 1, 1987, all hospitals, clinics, and health maintenance organizations in Massachusetts have been required to submit detailed quality assessment plans—which must include reporting systems for both incidents and occurrences—to the Massachusetts Board of Registration in Medicine (the Medicine Board). State regulations, which grew out of the Malpractice Tort Reform Act of 1986, empower the Medicine Board (which also has responsibility for licensing and disciplining physicians) to approve or disapprove these quality assessment plans.

Health care institutions are required to submit copies of their occurrence screens and information on how the screens are to be used in their quality assurance programs to the Medicine Board, but they are not required to report the numbers or kinds of occurrences. (All the underwriters of physicians' malpractice insurance also require that hospitals use occurrence screens.) Likewise, all health care facilities must submit their plans for incident reporting systems to the Medicine Board. Summary reports of incidents must be reported to the Medicine Board at least quarterly.

Four major incidents have been defined in the Massachusetts regulations, and their reporting is mandatory for all providers: 1) maternal deaths related to delivery; 2) fetal deaths (excluding abortions); 3) chronic vegetative state resulting from medical intervention (the Medicine Board is refining this definition further at the complaint of the medical profession); and 4) death in the course of or resulting from ambulatory surgical care. Major impairments or deaths that are unexpected are also supposed to be reported, although their definition is left to the providers (243 CMR 3.08 (1987)). Reports on these incidents must include identification of the provider, a brief description of the incident, and patient data. Health care organizations also must define further criteria for incidents, but the ongoing reporting of other incidents is required only in summary form.

Because the system is so new, the Medicine Board has not as yet started to audit hospitals and other providers based on the incident reports (420). Although the right of the Medicine Board to collect and act upon the information was upheld in a recent court case, the court ruled that the Medicine Board must give notice to a hospital or clinic when it plans to enter and review records. Moreover, peer review records can be obtained only upon subpoena.

The Medicine Board is required to report its findings to the Massachusetts legislature. Consideration is now being given to how the data should be displayed and how adjustments should be calculated so that providers are represented fairly. In turn, the information prepared by the Medicine Board will be directly available to consumers. Organizationally, the Medicine Board is located under the Massachusetts Office of Consumer Affairs.

Administration require hospitals to have risk-management programs. Massachusetts and New York require that hospitals submit incident reports directly to State authorities (see boxes 5-A and 5-B). The Veterans Administration requires that summaries of incidents be collected centrally.

At present, incident reporting and occurrence screens are in widespread use only in hospitals, but conceptually, there is nothing to preclude their use in other health care settings. Massachusetts already requires that certain kinds of incidents be reported by physicians in office practice to the State Medicine Board (243 CN'IR 3.11 (1987)).² To

be of use in ambulatory settings, the screening criteria used in hospital inpatient systems would have to be redefined to identify the adverse events that occur in ambulatory settings. The Public Citizen Health Research Group has suggested screening in ambulatory settings, for example, for the misprescribing of antibiotics such as chloramphenicol, which is rarely medically indicated for ambulatory patients and can cause severe adverse reactions (712). The Health Care Financing Administration (HCFA) has developed criteria for

²Incidents that must be reported by physicians include: 1) "unplanned transfer to a hospital precipitated by an invasive procedure

performed in the office"; and 2) "major or permanent impairments of bodily functions or death that are not ordinarily expected as foreseeable results of the patient's condition or of appropriately initiated and administered treatment" (243 CMR 3.11 (1987)).

Box 5-B.—Mandatory Incident Reporting in New York

Since October 1985, first under the general authority of the Commissioner of Health and later in 1986 under statutory authority of the New York Public Health Law, hospitals in New York have been required to report incidents to the State Department of Health within 24 hours of the incidents' occurrence. Hospitals are further required to investigate the incidents and file copies of their reports with the State. The Public Health Law exempts hospital incident reports from disclosure under the Freedom of Information Law and from civil litigation disclosure proceedings. However, the State Department of Health can release summary statistics, as well as statements of deficiencies generated as a result of departmental investigations (592).

Incidents that must be reported in New York include the following:

- patients' deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease, or proper treatment in accordance with generally accepted medical standards;
- fires in the facility that disrupt the provision of patient care services or cause harm to patients or staff;
- equipment malfunction during treatment or diagnosis of a patient that did or could have adversely affected a patient or health facility personnel;
- poisoning occurring within the facility;
- strikes by facility staff;
- c disasters or other emergency situations external to the hospital environment that affect health facility operations; and
- termination of any services vital to the continued safe operation of the health facility or to the health and safety of its patients and personnel (591).

Guidelines provide examples of incidents that would fit into the first category, but hospitals still have considerable leeway in interpreting the regulations. Statewide, there were 19 reported incidents per 100,000 patient days in 1986, but with wide variations in reported incidents among hospitals. The Department of Health suspects that this is largely a function of underreporting.

In March 1987, the State Department of Health released the first annual report on the hospital incident reporting system (593). Patient falls accounted for the greatest number of reported incidents (3s percent), but the second highest category of incidents was those related to a treatment or procedure (21 percent including 109 patient deaths). Summary statistics are reported on a statewide, area, and hospital-specific (but not hospital-identified) basis. A stated goal of reporting these statistics is to increase public awareness and knowledge about hospital care.

screening patients' records for quality problems in hospital outpatient departments, home health agencies, and skilled nursing facilities (652); however, these will not be used for reviewing the ambulatory care received by Medicare beneficiaries until 1989. For occurrence screens, as for some of the other potential indicators of quality of care examined in this report, considerable further research is needed if the intention is to use them in nonhospital settings.

Identifying the occurrence of adverse events/incidents is really a problem-oriented approach to quality assessment. Most reporting systems are the inhouse creations of hospitals designed for their own internal needs. Some reporting systems rely on the review of patients' medical records,

while others are independent of existing information systems. With such variability in systems for identifying adverse events/incidents and no standardization of the elements/criteria used in the systems (much less of how data should be collected), how can the reliability and validity of the systems as indicators of the quality of care be investigated?

Some of the specific criteria used in existing reporting systems may prove to be reliable and valid indicators of the quality of medical care. Researchers are currently investigating the usefulness in assessing the quality of care of specific patient outcome measures, including rehospitalization and targeted mortality rates (170,193, 594). To demonstrate the strengths and weaknesses of using specific criteria to assess quality,

this chapter examines intensively one criterion that is frequently found in occurrence screens—namely, nosocomial infections. (Another common element in almost all screens—hospital deaths, or some subset of deaths—is analyzed as a potential indicator of quality in ch. 4 of this report.)

A shortcoming of the use of nosocomial infection rates as a quality indicator is that a single indicator may effectively identify quality problems in a specific type of patient or clinical service but not address problems in other areas of medical care; very poor-quality care may go unregistered. A major strength of existing hospital screening systems may well be the use of multiple criteria to identify problems. On the other

hand, multiple variables complicate analysis, even under ideal research conditions. Where relevant research related to occurrence screens has been done, this chapter notes it.

The remainder of the chapter is organized as follows. First, occurrence screens that might be considered standardized because they have been developed at the State or national level are described. Then, the reliability, validity, and feasibility of using either nosocomial infections or “standard” occurrence screens as indicators of the quality of care are examined. Finally, conclusions are stated, and the policy implications of using adverse events as indicators of the quality of care in hospitals are explored.

STATE= AND NATIONAL-LEVEL OCCURRENCE SCREENS

In the vast majority of cases, hospitals design and implement their own screening systems for adverse events. Under development or already in place, however, are a number of national and State-level activities that use the same general methods and approach. In the private sector, for example, the Maryland Hospital Association has undertaken a project to find a limited number of data elements (clinical indicators) that could be commonly defined and would permit meaningful comparisons among hospitals for the purpose of assessing quality. Nine indicators were tested in pilot Maryland hospitals beginning in 1985, and today, following deletions, additions, and revisions of various indicators, the study is being conducted in more than 40 voluntarily participating hospitals. The indicators being studied include nosocomial infections, surgical wound infections, autopsy rates, newborn deaths, perioperative deaths, cesarean sections, hospital readmissions, unplanned admissions following ambulatory surgery, intensive care unit readmissions, and unscheduled returns to the operating room (607).

The State of Pennsylvania’s Health Care Cost Containment Council collects data on two elements that are usually considered occurrences, nosocomial infections and hospital readmissions (484). Because the data are collected on every hospital patient discharged, adverse events can be

linked to specific physicians and services. Moreover, for every hospitalized patient, Pennsylvania hospitals are required to submit to the State Council an indicator of the severity of illness (Medis-Groups methodology) along with other more standard discharge abstract information. The Pennsylvania reporting system is currently being implemented, and published statistics that include patient severity of illness adjustments are not expected before 1990. Other States have demonstrated interest in similar reporting systems. Colorado, for example, has issued regulations effective January 1989 that require reporting patient severity of illness levels as part of required hospital discharge abstracting systems (140).

JCAHO expects to expand its accreditation activities to include the use of clinical indicators to screen hospital cases for quality problems (324). Three JCAHO task forces, working on obstetrical, anesthesia-related, and hospitalwide clinical indicators, have identified structure, process, and outcome clinical criteria that are currently being tested as screens for quality problems in pilot hospitals. The hospitalwide indicators being evaluated are shown in table 5-2. Also shown in that table are the most important patient risk factors or covariates that might also influence outcomes. JCAHO is continuing to develop indicators for a variety of clinical areas, but use of the clinical

Table 5.2.—JCAHO Hospitalwide Clinical Indicators Being Evaluated as Screens for Hospital Quality Problems**HOSPITALWIDE CLINICAL INDICATORS BEING EVALUATED**

1. Unplanned readmission to a hospital shortly after inpatient surgery
2. Unplanned admissions to a hospital shortly after outpatient surgery or specified procedures
3. Development or worsening of pressure ulcers (decubiti)
4. Development of wound infections after clean or clean-contaminated surgical procedures
5. Development of pneumonia in patients treated in special care units
6. Development of infections related to the use of intravascular devices in special care units
7. Proper timing of antibiotic prophylaxis for specified surgical procedures
8. Appropriate use of blood culture sensitivities in the treatment of bacterial sepsis
9. Development of complications associated with suboptimal methods of administration and monitoring of specified medications
10. Commission of important medication errors resulting in death or major morbidity
11. Mortality of patients with specified medical conditions either during hospitalization or within 30 days of admission if death occurs at another institution to which the patient was transferred
12. Mortality of patients after specified surgical procedures either during hospitalization or within 30 days of admission if death occurs at another institution to which the patient was transferred
13. Mortality among patients treated in the hospital for injuries sustained immediately prior to treatment when death occurs within 30 days of injury or during a hospitalization that was precipitated by the occurrence of the injury

Supplemental information collected

Patient risk factors (covariates) that might influence outcomes

Age

Sex

Height and weight

Braden Risk Scale on admission to hospital and special care units

Glasgow Coma Score on admission to hospital and special care units

Trauma Score of patients prior to treatment for injuries

Diagnoses on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units (6 digit ICD-9-CM)

Types of surgical or other specified procedures, if any (4 digit ICD-9-CM)

Nature of surgical or other specified procedures, if any (scheduled, urgent, or unscheduled)

Type and site of intravascular devices used in special care unit

Selected chronic medications on admission to hospital

Selected laboratory values on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units

Temperature, pulse, respiration, and systolic and diastolic blood pressure on admission to hospital, immediately prior to operation or specified procedure, and on admission to special care units

Other information

For patient admitted after outpatient procedure: stated reason for admission

Insertion of drains during clean and clean-contaminated surgery

Patient with endotracheal tube or tracheotomy in special care unit

Use of nasogastric tube in special care unit

SOURCE: Joint Commission on the Accreditation of Healthcare Organizations, *National Invitational Forum on Clinical Indicators* (Chicago, IL: November 1987).

indicators as part of the accreditation process is not expected to be fully implemented until 1990 at the earliest.

The U.S. Department of Defense screens about 10 percent of all discharges from its 167 hospitals using exhaustive process and outcome clinical criteria that were developed by consensus panels of experts (447). This screening takes place under the Department of Defense Civilian External Peer Review Program. All cases involving 1 of 34 specific diagnoses or 14 problems are sampled, and the patients' medical records specially abstracted by medical record technicians. The abstracted information is computerized, and the

screen of clinical criteria then applied. Cases failing the computer screen (about 10 to 20 percent fail) are reviewed by physicians.

The adverse event screening program that has had the most far-reaching impact to date is HCFA'S "generic quality screen," which is used to screen hospitalized Medicare patients for quality problems (see table 5-3). Since July 1986, utilization and quality control peer review organizations (PROS) have been required to apply the generic screens to every case they review (about one-fourth of all Medicare discharges). Nurse reviewers examine patients' medical records, and if a screen is failed, the medical record is referred

Table 5-3.—HCFA'S Generic Quality Screens^a

● 1. Adequacy of discharge planning

No documented plan for appropriate followup care or discharge planning as necessary, with consideration of physical, emotional, and mental status/needs at the time of discharge.

2. Medical stability of the patient at discharge

- a. Blood pressure on day before or day of discharge
systolic—less than 85 or greater than 180
diastolic—less than 50 or greater than 110
- b. Temperature on day before or day of discharge greater than 101.0 F oral (rectal 102° F)
- c. Pulse less than 50 (or 45 if the patient is on a beta blocker), or greater than 120 within 24 hours of discharge
- d. Abnormal results of diagnostic services which are not addressed or explained in the medical record
- e. Intravenous fluids or drugs on the day of discharge (excludes KVOs, antibiotics, chemotherapy, or total parenteral nutrition)
- f. Purulent or bloody drainage of postoperative wound within 24 hours prior to discharge

3. Deaths

- a. During or following elective surgery
- b. Following return to intensive care unit, coronary care or special care unit within 24 hours of being transferred out
- c. Other unexpected death

● 4. Nosocomial infections

- a. Temperature increase of more than 2° F more than 72 hours from admission
- b. Indication of an infection following an invasive procedure (e.g., suctioning, catheter insertion, tube feeding, surgery)

5. Unscheduled return to surgery within same admission for same condition as previous surgery or to correct operative problem (exclude "staged" procedures)

6. Trauma suffered in the hospital

- a. Unplanned removal or repair of a normal organ (i.e., removal or repair not addressed in operative consent)
- b. Fall with injury or untoward effect (including but not limited to fracture, dislocation, concussion, laceration, etc.)
- c. Life-threatening complications of anesthesia
- d. Life-threatening transfusion error or reaction
- e. Hospital acquired decubitus ulcer
- f. Care resulting in serious or life-threatening complications, not related to admitting signs and symptoms, including but not limited to the neurological, endocrine, cardiovascular, renal or respiratory body systems (e.g., resulting in dialysis, unplanned transfer to special care unit, lengthened hospital stay)
- g. Major adverse drug reaction or medication error with serious potential for harm or resulting in special measures to correct (e.g., incubation, cardiopulmonary resuscitation, gastric lavage) including but not limited to the following:
 - i. Incorrect antibiotic ordered by the physician (e.g., inconsistent with diagnostic studies or the patient's history of drug allergy)
 - ii. No diagnostic studies to confirm which drug is correct to administer
 - iii. Serum drug levels not performed as needed
 - iv. Diagnostic studies or other measures for side effects not performed as needed (e.g., BUN, creatinine, intake and output)

^aFO entries marked with an asterisk in this table, the PRO reviewer is to record the failure of the screen, but need not refer to physician reviewer

SOURCE: U.S. Department of Health and Human Services. Health Care Financing Administration, Health Standards and Quality Bureau. 1986-1988 PRO Scope of Work. Baltimore, MD, Nov. 4, 1985.

to a physician advisor for further review. Only the physician advisor can declare a case a "quality problem." On the basis of this information, the PROS build provider profiles for their own internal use; they also take corrective actions

ranging from education to intensified review, and ultimately to sanctions (see ch. 6). Appendix D provides a full description of the PROS' review procedures and responsibilities.

RELIABILITY OF THE INDICATOR

Nosocomial (Hospital-Acquired) Infections

As noted earlier in this chapter, OTA chose an adverse outcome used in almost all existing occurrence and generic screens for indepth review—

namely, nosocomial infections. One reason for selecting nosocomial, or hospital-acquired, infections is that such infections are quite prevalent. Six percent of all U.S. hospitalizations are complicated by nosocomial infections, amounting to more than four million nosocomial infections per

year (269). of course, infections may also be acquired in the community prior to admission to the hospital. Nosocomial infections are defined as infections that are not known to be present or incubating at the time of admission. The most common nosocomial infections are urinary tract infections (42 percent), followed by surgical wound infections (24 percent), pneumonia (10 percent), and infections of the bloodstream (bacteremia) (5 percent). These four types of infections account for about 80 percent of all nosocomial infections. Almost three-quarters of nosocomial infections occur among patients undergoing surgery (273).

The most difficult obstacle to the reliable measurement of nosocomial infections is the lack of standardized case finding. Reliable measurement of infections requires that trained surveillance personnel search actively for cases using standardized clinical definitions of infections (269). No system of routine data collection is completely sensitive in identifying nosocomial infections, and the surveillance techniques that are used in case finding in various hospitals differ fundamentally (616). The likelihood that nosocomial infections will be clearly recorded in a patient's medical record and/or coded on a hospital discharge abstract varies widely by hospital, but relying on written diagnoses is generally an inaccurate method of determining infection rates (232). One study in a university hospital found, for example, that 43 percent of nosocomial infections were not coded in the hospital discharge abstract (409).

A study sponsored by the Centers for Disease Control (CDC) showed that reliable measurement of, and changes in, nosocomial infection rates at various sites are possible in a large-scale data collection effort that relies on medical record review (275). The Study on the Efficacy of Nosocomial Infection Control (SENIC) Project evaluated the efficacy of the infection surveillance and control programs established between 1970 and 1975-76 in a representative sample of U.S. hospitals. Incidence rates of nosocomial infections in four sites (urinary tract, surgical wound, lower respiratory tract, and bloodstream) were determined from a random sample of medical records in each of the 2 years in 338 hospitals stratified by size, teaching status, and infection control activity. To meas-

ure nosocomial infection rates reliably, CDC devised a standardized method of making diagnoses via retrospective review of patients' medical records, and it validated the method's accuracy through a series of pilot studies. Nonphysician CDC reviewers, who underwent careful training and infield monitoring, abstracted relevant data, recorded them on standardized forms, and applied a set of standardized algorithms to arrive at the infection diagnoses.

The retrospective chart review method used in the SENIC Project (by nonphysicians following a standardized procedure) compared favorably (average sensitivity of 0.74) with the "gold standard" method of physician-epidemiologists supervising intensive prospective data collection teams (230,275). As measured against this standard, physician self-reporting forms were least sensitive (0.14 to 0.34) in finding cases of nosocomial infection, and clinical surveillance for evidence of fever, antibiotic use, or both were only moderately sensitive (0.47 to 0.59) (230).

Because the recognition of infections depends in part on physicians' propensity for ordering the cultures and chest X-rays that confirm the presence of infection, the SENIC Project also analyzed the use of these diagnostic tests in the sample hospitals (270). Generally, the researchers found an increase over time in the use of diagnostic tests, and the increased use of these tests was associated with increased recognition of infectious diseases. More importantly, despite clinical agreement on the efficacy of these diagnostic tests, hospitals differed significantly in diagnostic medical practices. Hospitals with high rates of culturing, working up fevers, and obtaining chest X-rays showed higher observed rates of nosocomial infections.

This finding presents an additional measurement problem that cannot be resolved through better or standardized data collection efforts (270). If nosocomial infection rates were used as indicators of quality in cross-hospital comparisons, those hospitals that were effectively identifying nosocomial infections through appropriate testing could be penalized. Because no diagnostic testing is necessary to confirm the presence of surgical wound infections, a possible solution would

be to compare infection rates only for this subset of nosocomial infections (270,305).

HCFA'S Generic Quality Screens

As shown in table s-3, HCFA'S generic quality screens apply two criteria related to nosocomial infections (item 4): "a) temperature increase of more than 2 degrees more than 72 hours from admission; and b) indication of an infection following an invasive procedure." Depending on how individual PROS interpret and use the nosocomial infection screens, results could vary greatly. Nurse reviewers searching for "indications of an infection," for example, could either rigorously review all laboratory records, progress notes, and nursing notes or simply look for documentation of antibiotic use or specific laboratory test results. According to an initial report from HCFA on the use of the generic quality screen by PROS, more of the discharges reviewed failed the nosocomial infection screen (5 percent) than any other (except medical stability at discharge), but fewer than 15 percent of these cases upon further review by a physician advisor actually had a significant medical problem (653).

The physician advisor must decide which of the discharges that have failed the nosocomial infection screen constitute actual "quality problems." There are no guidelines on how clinically to ascertain a quality problem; the judgment is primarily subjective. Thus, at present, the same case that is considered a problem in one PRO (or by one physician advisor) might be discounted by another PRO. In some PROS, for example, the physician advisors were not counting nosocomial infections as quality problems if the infections were treated appropriately (487). Recently revised guidelines on the application of the generic quality screens clarify that nosocomial infections should be counted regardless of therapy (652). Nonetheless, there is obviously a severe reliability problem with HCFA'S generic quality screen that results from the subjective nature of the physician advisor's audit.

Only summary data on the generic quality screens (neither hospitals nor physicians are identified) are forwarded by the PROS to HCFA. Data reported to HCFA for the first year during which

the generic screens were used showed wide variation in the incidence of screen failures and of confirmed quality problems across PROS (660). In several PROS, fewer than percent of cases failed any screen; in other PROS, more than 40 percent failed. In cases of screen failures, the percentage of confirmed quality problems ranged from zero to 100 percent.

To ameliorate substantial reliability problems, the so-called SuperPRO, an independent contractor, is charged to re-review a sample of each PRO'S cases to validate the determinations of nurse reviewers and physician advisors. In its first review of the application of the generic quality screens in 45 PROS, the SuperPRO found 8.9 percent of sample cases with quality problems v. only 3.8 percent reported by the PROS (654).

In response to critiques, HCFA has revised the generic quality screens for the PROS' third round of contracts, which will probably begin in early 1989 (652). The revised generic quality screens have several changes (see app. D). In the future, for example, nurse reviewers will flag a case as a nosocomial infection only if two or more indications listed in new HCFA guidelines are present in a patient's chart.³ In addition, all PROS have

³Indicators of a nosocomial infection include: temperature elevation of 101 degrees Fahrenheit or greater; elevated white blood count and/or left shift; isolation of organism from body fluids or specimens; appropriate radiographic imaging abnormalities; purulent drainage; heat, redness, focal tenderness and/or pain; pyuria, dysuria; and productive cough (652).



Photo credit: George Washington Medical Center

Rates of surgical wound infections are potentially valid indicators of the quality of care in hospitals.

been issued the CDC guidelines for the surveillance of nosocomial infections.

These steps are likely to improve the reliability of HCFA'S generic quality screens over the next several years. Unlike the CDC personnel in the SENIC Project, however, PRO reviewers do not receive intensive training in the use of the guidelines, nor do they use diagnostic algorithms.

VALIDITY OF THE INDICATOR

Nosocomial (Hospital-Acquired) Infections

Numerous studies link nosocomial infections to lengthened hospitalization, morbidity, and/or mortality (160,233,251,261,263,493,536,587,698). A prospective study of patients with indwelling bladder catheters in a teaching hospital, for example, found the development of urinary tract infections among these patients to be associated with a threefold increase in mortality (493). One analyst estimates that more than \$2.8 billion in excess hospital charges are generated each year because of nosocomial infections (182). Because of the empirical association of nosocomial infections with adverse outcomes for patients, nosocomial infections have high face validity as an indicator of the quality of medical care.

Although the relationship between nosocomial infections and poor patient outcomes is well established, the link between inadequate/poor hospital care and the onset of infection is less clear. The fact that an infection is acquired in the hospital does not mean that it is *caused* by the hospital or by the poor quality of its practitioners. No available studies have examined or compared nosocomial infection rates in hospitals explicitly to examine the quality of providers. Numerous studies have published institutional nosocomial infection rates, however, as part of investigations of effective interventions, changes in rates over time, or the health and cost implications of hospital-acquired infections.

A review of the literature through 1975 identified 24 studies that published survey data on nosocomial infections in hospital populations

Moreover, the audit by physician advisors of cases that fail the screens is largely subjective. The SuperPRO has now started to analyze the reliability of PRO results for individual generic screen criteria. Depending on the findings of these analyses, further revisions of HCFA'S generic quality screens may be necessary in the future.

(230). The prevalence of nosocomial infections in the hospital populations in these data ranged from 4.5 to 15.5 percent, and the incidence of such infections (infections per 100 discharges) varied from 3.1 to 14.1 percent. Community hospitals had lower reported nosocomial infection rates than referral, municipal, or chronic disease hospitals.

Comparisons of data from these studies tell little about the quality of care in the hospitals surveyed because, aside from measurement problems, the data are not adjusted for the hospitals' case mix or patients' severity of illness. Although most of the studies report nosocomial infections by site of infection, by service, and by procedure, the samples are too small to allow adequate stratification of the patient populations. Researchers attempting to calculate the impact of nosocomial infections on morbidity and costs usually compensate for confounding variables by matching infected patients with comparison subjects on as many attributes as possible. Although the results may be valid for the institution studied, it is very difficult to compare study results across institutions, even for seemingly similar subgroups of patients (e.g., all surgical patients or all patients with the same primary diagnosis). The authors of the literature review just mentioned attempted to compare the results of their matched subject study at Boston City Hospital with three other epidemiologic reports. Inconsistencies in results were attributed to possible further confounding variables among the patient populations (231).

The risk of acquiring a nosocomial infection is related to a number of factors in addition to the quality of providers. The likelihood of an infec-

tion's occurring and its outcome depends more on patient susceptibilities than on the presence of the organism (49). Patients' underlying diseases, medical procedures, severity of illness at admission, hospital service, age, sex, race, and urgency of admission have all been found to be significant risk factors for nosocomial infection (96,232).

Understanding and adequately adjusting for such risk factors are critical to the use of nosocomial infections as a valid indicator of the quality of care. Moreover, the necessary adjustment factors for nosocomial infections may be different from those used to compare mortality statistics or other quality indicators. For example, one study, which compared urinary tract infections in small hospitals (under 75 beds) with infections in a large, teaching hospital, observed that the higher prevalence rate in the teaching hospital was due to the increased use of indwelling bladder catheters (5s). With even a rudimentary understanding of case mix, it is not surprising that community hospitals have lower rates of nosocomial infections than teaching and municipal hospitals.

The SENIC Project provides valuable information, because the researchers attempted to control for patient risk and other intervening factors in their investigation of the efficacy of infection-control programs. Using the large SENIC data base, the researchers determined estimates of the frequency of nosocomial infection by selected characteristics of patients (273).⁴ Hospital-related characteristics were controlled by using American Hospital Association survey data as proxies for changes in hospitals that could not be measured (272). And finally, differences in physicians' diagnostic practices (their propensities for ordering tests) were controlled by defining hospital-specific measures for use in analyses (272).

Because of confidentiality provisions, the SENIC Project data cannot be analyzed by hospital. Nevertheless, the research helps to validate nosocomial infection rates as quality indicators in several ways. First, the SENIC Project research-

ers have measured and quantified the patient risks and other variables that contribute to the outcome of hospital-acquired infection. This information could be used in further research to allow comparisons among hospital populations. The large, statistically valid data base developed in the SENIC Project could permit "norms" for nosocomial infection rates to be established by patient risk category.⁵

Second, in concluding that one-third of all nosocomial infections could be prevented through surveillance and control programs, the SENIC Project demonstrates the potential of nosocomial infection rates to serve as an indicator of the quality of care across hospitals (272). One infection-control program shown to be efficacious was the systematic feedback of surgical wound infection rates to the practicing surgeons. (In combination with an ongoing surveillance and control program, this program led to a 19-percent decrease in surgical wound infections.) Thus, changes in physicians' behavior, or the process of care, are associated with changes in nosocomial infection rates. Moreover, the extent to which hospitals establish and maintain effective infection control programs is an aspect of their quality of care.

There is no evidence that nosocomial infection rates are correlated to the general quality of health care institutions (external validity). In fact, there are well-defined inpatient groups who have very little risk of acquiring nosocomial infections, for example, pediatric, psychiatric, and rehabilitation patients (274). Nosocomial infections would not be valid indicators of the quality of care received by such patients.

Occurrence Screens

Most occurrence screens are based on the criteria established in the California Medical Insurance Feasibility Study, which reviewed a large sample of 1974 California hospital records. The study sought to identify potentially compensable events or medically caused patient disabilities. For

⁴Risks were significantly related to age, sex, service, duration of total and of preoperative hospitalization, presence of previous infection, types of underlying illnesses and operations, duration of surgery, and treatment with urinary catheters, continuous ventilatory support, or immunosuppressive medications (273).

⁵CDC has another ongoing data collection system, the National Nosocomial Infections Surveillance System, that collects nosocomial infection rates from 85 volunteer hospitals. CDC is using these more recent data to develop risk indices by diagnosis-related groups and for surgical, critical care, and neonatal intensive care patients (305).

the purposes of this OTA assessment, the potentially compensable events identified in the study are synonymous with adverse events caused by poor-quality care. Investigators in the California study sampled hospital charts by service from a group of 23 hospitals stratified by size, ownership, and teaching status. Of the more than 20,000 charts reviewed by medical record auditors, approximately 50 percent failed the screens. The study investigators (all physicians) reviewed these records and concluded that 11 percent of those failing the screens constituted potentially compensable events (or 5.5 percent of all records reviewed) (432).

The California Medical Insurance Feasibility Study validated its 20 screening criteria as part of a controlled two-step screening and audit process for determining the incidence of potentially compensable events. It usefully identified potentially compensable events by medical specialty, location (e.g., 72 percent of the potentially compensable events occurred in the operating room), diagnosis and procedure, and by selected characteristics of patients. However, the study did not validate the screening criteria (by themselves) as quality indicators. In fact, on the basis of the published data, it is not possible to calculate the sensitivity or the specificity of the screening criteria in identifying either potentially compensable events or adverse events (potentially compensable events are a subset of adverse events that are medically caused). There is insufficient information about the patients' medical charts that passed the screens to determine these values. Moreover, of the records in the study that failed the screens, 81 percent were eliminated by the investigators because no medically or patient-caused disabilities were found upon further examination of the records. This high percentage indicates a substantial false-positive problem, whether the goal of the screens is identification of adverse events or identification of potentially compensable events. The two-step screening and audit process may be a valid and effective, yet very inefficient, method of identifying poor-quality care.

The California study did not examine the effectiveness of individual criteria in screening for potentially compensable events. Moreover, the determination by the physician investigators of

whether a potentially compensable event occurred was largely subjective (as is also true in the PRO program). The subjectivity of such assessments is a critical factor in the reliability of audit when more than just a few investigators are involved.

Research commissioned by New York State under recent medical malpractice reform legislation will update the results of the California study and help to ascertain the validity of occurrence screens. As part of a comprehensive study to find which patients suffered injuries in the course of their hospital treatment and which of these injuries were produced as a result of substandard treatment, the Harvard Medical Practice Study Group is reviewing the medical records of 30,000 patients hospitalized in New York in 1984. These records are being reviewed by medical record administrators using 17 screens derived from the 1974 California Medical Insurance Feasibility Study.⁶ The medical records that fail the screens are then subjected to further review by physicians to confirm the adverse event, to estimate the probability of causation, and finally to estimate the probability of negligence (283).

The results of the Harvard study commissioned by New York State could validate the relationship of the screening criteria (outcome measures) to poor-quality care (the process of medical management) if the data are directed to that purpose. The Harvard study may reaffirm the finding of the California study that occurrence screening as part of a two-step process involving screening and subsequent audit is a valid approach to quality assessment. The relationship of the screening criteria to the universe of adverse events or poor-quality care in hospitals, however, will not be resolved adequately by the Harvard study. Because the medical records that do not fail the screens are not examined in depth, the true denominator number of adverse events remains unknown. The full-scale study began in mid-1987, and results are expected in early 1989.

⁶The California screens have been modified by the deletion of four criteria ("unplanned removal of an organ or part of an organ during an operative procedure," "wound infection on last full day prior to or day of discharge," "discharge with indwelling urinary catheter," and "parental analgesics last full day prior to discharge") and the addition of one criterion ("obstetric mishap or complication of abortion, labor, or delivery") (283).

The SuperPRO has evaluated the accuracy of HCFA'S generic quality screens in finding quality problems. In a special study, the SuperPRO reviewed a sample of medical records from nine PROS for the period August 1986 through January 1987 (444). Just as the PROS do, the SuperPRO'S nurse reviewers applied HCFA'S generic screens and referred cases that failed to physician reviewers for determination of quality problems. In addition, the SuperPRO calculated how many false negatives the screening process yielded by sampling the records that had passed the generic screens. These records were re-reviewed by a physician to determine if there were quality problems.

The SuperPRO concluded that HCFA'S generic screening process had a sensitivity (i.e., ability to identify cases with quality problems) of 49 percent and a specificity (i.e., ability to exclude cases without quality problems) of 73 percent (444). A sensitivity of less than 50 percent means the screening process was no better at detecting quality problems than chance. Because a small sample size (100 records) was used by the SuperPRO to determine the false negatives, the sensitivity finding may have some degree of error and may actually range between 37 and 70 percent. In any event, the SuperPRO researchers concluded the quality problems that were found through HCFA'S generic screening process were more serious than the quality problems missed by the process.

The SuperPRO also evaluated individual screening criteria used in HCFA'S generic screen, especially those criteria thought to be responsible for substantial numbers of false positives. The study recommended dropping several screening criteria (including one related to nosocomial infections) and modifying several others. HCFA'S revisions of the generic quality screen for the 1988-

90 PRO contract cycle were a response to these recommendations {see app. D}.

The SuperPRO study is useful insofar as it relates to the validity and effectiveness of individual criteria, but it also has several shortcomings. The study's sample of Medicare cases, for example, is not a random sample; it is probably weighted toward problem cases. In addition to reviewing a mandatory random 3-percent sample of hospital discharges, PROS review cases based on a number of negotiated objectives. In selecting its re-review sample, the SuperPRO did not distinguish among the types of cases reviewed by the PROS. Moreover, the small sample size used in the special SuperPRO study does not permit reliable estimates of the validity of the screening process. The SuperPRO may undertake a larger analysis in the future.

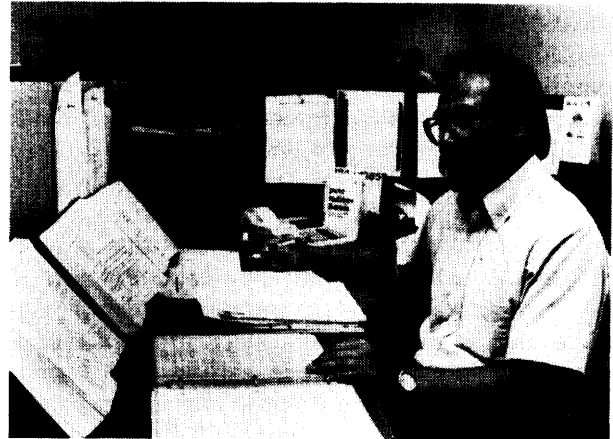


Photo credit: California Medical Review, Inc.,
Chindy Charles, Photographer

HCFA's generic quality screens, which PRO reviewers apply to all Medicare cases, have not been validated empirically.

FEASIBILITY OF USING THE INDICATOR

Nosocomial (Hospital-Acquired) Infections

The feasibility of obtaining nosocomial infection rates by standardizing data collection methods in all hospitals and maintaining reliability

over time is questionable (269,305). Relying on coded diagnoses from hospital discharge abstract systems would be an unreliable method of establishing infection rates across hospitals. At a minimum, thorough medical record review by trained personnel is essential for finding cases of

nosocomial infections. The PRO audit process involves such thorough chart review by nurse reviewers with followup by physician advisors.

An alternative to medical record review would be to establish new channels to obtain more reliable data. Currently, for example, all hospitals are required to have designated infection-control personnel and infection-control committees in order to be JCAHO accredited and to be eligible for Medicare and Medicaid reimbursement (424). Infection-control officers, usually nurse and sometimes physician epidemiologists, use ongoing surveillance techniques to find cases of nosocomial infections. If infection-control officers were required to use the standard definitions and guidelines provided by CDC, the data obtained by these personnel and utilized by the infection control committees could be channeled outside the institution for quality assessment purposes. CDC currently collects such data from approximately 85 volunteer hospitals in its National Nosocomial Infections Surveillance System (305).

Using rates only for selected sites of nosocomial infections, such as the bloodstream and surgical wounds, rather than combined rates of nosocomial infections at all sites, would minimize the measurement problem created by differing physician diagnostic practices. Bloodstream infections, which require only one verifying laboratory culture, have been suggested as one type of nosocomial infection for which reliable statistics could be gathered (305,699). Surgical wound infections do not require laboratory verification, although an impartial view of the wound in the operating room is necessary to determine the degree of contamination before and during the operation. Moreover, research has progressed furthest in understanding confounding patient risks for surgical wound infections. Data from the SENIC Project were analyzed using multiple logistic regression techniques (271). The researchers concluded that four risk factors predict a patient's probability of getting a surgical wound infection twice as well as the traditional classification of wound contamination alone: abdominal operation, operation lasting more than 2 hours, contaminated or dirty-infected operation, and three or more underlying diagnoses.

Occurrence Screens and Incident Reporting

The use of occurrence screens and incident reporting by hospitals is widespread. The general availability of such systems was a primary reason for OTA'S decision to study adverse events as a potential indicator of the quality of care. To the extent that occurrence screen and incident reporting systems are already in place, the additional costs of supplying information on adverse events to consumers could be minor as compared with costs of supplying information on other quality indicators. Moreover, poor patient outcomes are readily understandable by consumers and associated in the public mind with the quality of care.

Regulators are increasingly turning to occurrence screen and incident reporting systems to accomplish their goals in quality assurance. New York, and more recently Massachusetts, are collecting incident reports and, in turn, making selected information publicly available. Pennsylvania is implementing a statewide hospital discharge abstract system that includes information on the patient's severity of illness at admission and on several data elements normally considered occurrences or adverse outcomes. A primary purpose of Pennsylvania's data system is to inform the public about health care costs and quality. Several other States, including Colorado and Iowa, are pursuing approaches similar to Pennsylvanians. Thus, a number of State-level systems either already are, or soon will be, using statistics on adverse outcomes to inform consumers about the quality of hospitals.

On the national level, hospital-specific data generated by the PROS through the application of HCFA'S generic quality screens are available to the public upon request to a PRO, subject only to hospital notification at least 30 days before disclosure (42 CFR 476.120,476.105 (1987)). Consumers can request information by hospital on screen failures, on quality problems identified during audit, or on both. As far as HCFA is aware, no such requests of PROS have been made to date (487). The Public Citizen Health Research Group contends that at least one PRO has refused to make similar types of outcome data available to

public requesters even though it is legally required to do so (713).

To the extent that incidents and occurrences are reported through inhouse systems (without independent audit by outside quality assessors), hospitals have plentiful opportunities to underreport or to “game” the results. The congressional General Accounting Office investigated the Veterans Administration’s incident reporting system and found that 86 percent of the incidents occurring in a sample of cases were unreported (624). The disincentives for hospitals to report adverse events

are obvious: possible malpractice litigation or other disciplinary action and recognition as a poor-quality provider. New York State relies on several other systems it has in place, including State accreditation surveys, patient complaints, and special studies, to verify the accuracy of incident reporting by hospitals. Nonetheless, despite such possible cross-checks on hospitals, the reliance of most occurrence and incident reporting systems on self-reporting is a major shortcoming with regard to their use as quality indicators.

CONCLUSIONS AND POLICY IMPLICATIONS

As this chapter has shown, a number of systems for reporting adverse events in hospitals are in place and either are, or could be, used to inform consumers about the quality of care in these institutions. Unfortunately, however, none of these systems have been adequately validated. Data on the number of screens failed or the overall number of self-reported incidents alone are clearly not valid quality indicators and would be meaningless and misleading if used to compare hospitals. The screens in place were not designed to measure quality directly, and substantial proportions of cases that fail the screens, variably across institutions, turn out on further review to be false positives. Moreover, incident or occurrence reporting systems that rely solely on self-reports are unreliable sources of information.

On the other hand, several systems that employ a two-stage process of screening and intensive auditing have been partially validated for quality assessment. Access by consumers to the end results of these assessments has great potential. Two primary unresolved problems that need to be addressed through further research are the extent to which these systems do not identify quality problems that actually exist and the subjective nature of professional audits.

Some of this research is already underway or could be easily undertaken. New York State, in its Harvard study, is investigating a screening and audit method of identifying problem care. JCAHO is studying clinical indicators that will operate at

the hospital service level and can be analyzed using covariates of patient risk. Various other efforts, for example, by the Maryland Hospital Association and the Pennsylvania Health Care Cost Containment Council, are underway to verify, define, and/or standardize useful adverse outcome measures for quality assessment.

Further research on the validity of HCFA’S generic quality screens for quality assessment is also merited. The screens were developed primarily by professional consensus, and the screen elements have not been validated in empirical studies. HCFA could provide leadership on such research. HCFA’S generic quality screens are applied to more hospitalization reviews than any other standardized occurrence screen, and potentially, the results of these reviews could be made easily accessible to the public.

Because all the systems described in this chapter are very new (virtually all have been started during the past several years or are still being implemented), many independent research initiatives are probably useful and appropriate. Pursuing many similar approaches has the potential benefit of developing a wholly new, more effective and efficient system. The rush of State officials and others to implement some kind of quality assessment system means the results of research need to be shared in as timely a fashion as possible. For those systems where new data collection systems are required, a major concern is that different measures or definitions will be used in vari-

ous systems and the ability to link systems in the future will be lost. Thought should be given now to such long-term needs of uniform reporting and linkage among various State systems.

Another concern is that, because some occurrence screen and incident reporting systems are in operation and the data can be accessed, statistics about adverse events might be released prematurely and misinform the public. None of the sys-

tems now in place is specifically designed to provide comparative information about the quality of hospitals. Regulatory agencies employ the systems to target their review or investigations. The potential misuse of information about adverse events in hospitals gives added impetus to the need for research on the validity and reliability of this indicator.