Patient safety

Part II. Opportunities for improvement in patient safety

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The quality movement in medicine has prompted a shift from a "name, shame, blame" approach to medical errors to one in which each error is regarded as an opportunity to prevent future patient harm. This new culture of patient safety requires the involvement of all members of the health care team and learned skill sets related to quality improvement. A root cause analysis identifies the sources of medical errors, allowing system changes that reduce the risk. In large organizations, sentinel events and signals prompt chart reviews and reduce the reliance on voluntary reporting. Failure mode analysis prompts the development of safety nets in the case of a system failure. The second part of this two-part series on patient safety examines how the culture of patient safety is taught, how medical errors and threats to patient safety can be identified, and how engineering tools can be used to improve patient care. It also examines efforts to measure clinical effectiveness and outcomes in the practice of medicine. (J Am Acad Dermatol 2009;61:193-205.)

Learning objectives: After completing this learning activity, participants should be able to improve patient safety through an understanding of both the beneficial and adverse consequences of quality reporting, apply safety engineering tools to the practice of dermatology, and be able to establish a quality improvement plan for a dermatologic practice.

Key words: medical errors; morbidity; mortality; office-based; patient safety; quality; surgery.

The American Academy of Dermatology (AAD) has implemented a number of projects to help its members ensure top quality in their practices, including preparation of a Patient Safety and Quality (PS&Q) curriculum, a Patient Safety Assessment toolkit for office practices, and a patient safety research/data collection agenda. This article will focus on steps that every physician can take to improve patient safety.

HOW IS THE CULTURE OF PATIENT SAFETY TAUGHT?

Key points
- **A culture of patient safety is based on learned behaviors that can be taught through didactics, patient care, and emergency simulations**
- **Important facets include a systems-based approach to error reduction, communication skills, and root cause analysis**
- **The Accreditation Council for Graduate Medical Education has incorporated patient safety into its requirements for all residency programs**
- **Patient safety has also become an important aspect of continuing medical education**

Education is necessary in order to achieve improvements in patient safety. In response to the Institute of Medicine's mandates on patient safety,[1] the subject is now being taught across the continuum of medical education. This includes foundational instruction within medical schools; experiential learning during residency training; and institutional, departmental, or specialty-specific outcomes focused

patient safety education through continuing medical education (CME).

Medical school and patient safety

The standards for accreditation for US medical schools outlined by the Liaison Committee on Medical Education (LCME) specify no absolute requirement for patient safety education, but exposure to "principles of a quality improvement initiative that maximizes patient safety" is recommended within the curriculum content checklist.[2,3] Curriculum models are emerging in the United States and abroad that teach medical students about medical errors and patient safety.[4-7] Patient safety priorities at the medical student level include basic patient safety knowledge acquisition, teamwork, and communication skill development as primary objectives, and root cause analysis, safe prescribing, and error management as secondary objectives.[8] Education focuses on a systems-based approach to improving patient safety, rather than an approach that emphasizes blame.

Graduate medical education and patient safety

Resident physicians can have a dramatic impact on patient safety,[9] and the Accreditation Council for Graduate Medical Education (ACGME) has incorporated patient safety into its requirements for all residency programs.[10,11] Residency programs in various specialties have developed robust models for patient safety education, including emergency simulations.[12-15] Other key residency-specific ACGME requirements to enhance patient safety include resident supervision and duty hour limitations.

Continuing medical education and patient safety

Maintenance of Certification (MOC) and Maintenance of Licensure (MOL) will require physicians to participate in performance improvement activities and educational activities that qualify for American Medical Association (AMA) Category I CME credits. Dermatologists enrolled in MOC must complete no less than an average of 40 CME credits each year. Patient safety topics have been a growing part of the AAD CME program through live sessions and enduring materials. The first dermatology patient safety symposium at an AAD annual meeting occurred in March 2009. Other live session topics have focused on electronic health records, electronic prescribing, laser safety, improved patient communication, drug-related laboratory monitoring, and drug–drug interactions. The AAD also incorporates patient safety questions into each of the MOC component four modules. Other dermatology organizations also incorporate safety concepts, safety data, and/or safety tips in their CME programming, including topics such as wrong-site Mohs surgery.[16,17]

Innovative opportunities for patient safety education

Unfortunately, evidence suggests that lecture-based learning and articles alone do little to change medical practice, despite good session or speaker ratings.[18,19] Simulation, a technique in use for years in the aviation, defense, maritime, and nuclear energy industries, can be quite useful for patient safety efforts, because the simulation environment allows individuals the opportunity to review and practice procedures or techniques as often as needed to become competent without harming a patient. Nonphysician staff may feel more comfortable calling out potential safety hazards in a simulation setting where hierarchies are more relaxed. Specialties rooted in procedural disciplines (eg, anesthesiology, surgery, emergency medicine, etc) have demonstrably improved the safety of various interventions with the use of procedural simulation.[12]

MEASURING CLINICAL EFFECTIVENESS AND QUALITY
Key points
- **Start by defining the goal of the quality improvement program**
- **Carefully select measures that are both practical and meaningful**
- **Be prepared to "sell" the program to your staff; participation is critical**

CAPSULE SUMMARY

- Patient safety should be a key focus of every dermatologic practice.
- An effective patient safety culture involves all members of the health care team.
- Each dermatologist can adopt engineering tools designed to improve patient safety.
- A root cause analysis identifies the sources of medical errors.
- Failure mode analysis prompts the development of safety nets to prevent patient harm.
- This article examines how the culture of patient safety is taught, how medical errors and threats to patient safety can be identified, and how engineering tools can be used to improve patient care.

- **Only measure what is meaningful and important; be selective**
- **Avoid selection bias through thoughtful risk adjustment**
- **Use multiple measures to ensure safe practice and good outcome**
- **Maintain incentives to encourage innovation; this can lead to increases in performance**

Measurements matter

Measurement promotes transparency; it allows us to benchmark how we are performing relative to others and provides a stimulus to change. At its best, performance measurement is a powerful tool that plays a critical role in improving the effectiveness of care we deliver to patients. At its worst, poorly crafted measures penalize physicians who provide care for more complex diseases and create perverse incentive to abandon the neediest patients. Designing efficient and effective systems of quality measurement is a highly challenging endeavor.

Getting started

Thoughtful selection of what to measure and how to measure it is critical to improving clinical effectiveness. Measures must be matched to worthwhile goals and objectives in order to be meaningful. This might seem self-evident, but programs frequently ask "What can we measure?" before they ask "What do we hope to achieve?"

Performance measures tend to fall into several discrete categories: structural measures, process measures, and outcome measures. The characteristics and relative merits of these measure types are discussed in Table I.

Outcome versus process measures

Outcome measures are often viewed as the gold standard in performance measurement. However, measures also have to be practical in terms of timeline and data collection. Grading physicians on their patient outcomes can also create perverse incentive to abandon sicker patients or take unjustified therapeutic risks.

Physician control over outcome

The AMA's Physician Consortium for Performance Improvement has taken the position that physicians can only be fairly measured on processes over which they have direct control. The counterargument is that the greatest improvements in clinical effectiveness can only be gained by addressing the entire episode of care, including patient compliance and lifestyle changes, and that physicians who successfully promote these behaviors should be rewarded for their efforts.

Figure 1 uses the example of a program that aims to decrease mortality from melanoma through early detection. Tracking whether patients performed skin examinations may correlate more closely with the clinical outcome than tracking whether physicians told patients to conduct these examinations. The former measure evaluates how effective the physician's recommendations were, not simply whether they were delivered. While it is clear that successfully changing a patient's behavior has an impact on that patient's clinical outcome,[20,21] patient-based measures create the perverse incentive to avoid patients who are less likely to be compliant.

Single versus multiple measures

For many skin conditions, there may be a lack of agreement around the most appropriate clinical outcome measures. For example, is it more appropriate to measure a change in Psoriasis Area and Severity Index score or in patient-reported quality of life? In addition, outcomes have to be weighed against issues of safety, such as the level of immunosuppression. In many cases, the use of multiple bundled measures may be more appropriate than any one measure alone. The prevention of ventilator associated pneumonia (VAP) provides a good example of this technique. By creating a ventilator bundle comprised of four evidence-based strategies known to reduce VAP, many centers have significantly reduced or eliminated this issue in their intensive care units.[22] The ventilator bundle is designed as an "all or none" measure. That means that credit is only given when all four strategies are implemented for a patient.

Implementing performance measures

Practical considerations are of great importance in ensuring maximum participation. Performance improvement initiatives typically rely on voluntary reporting, and if the measurement system is too onerous and the reward too small, people will simply opt-out. Many dermatologists in the United States are based in small practices that rely on paper records, so complex reporting requirements will discourage participation.[23]

Performance data can be compiled and shared in a number of different formats. Unlike a clinical trial, there is usually no randomized group of control subjects or centers to act as a comparator. There are a number of ways, however, to benchmark this data using time (Fig 2) or cross-institution comparisons (Fig 3). An example of the use of time would be to conduct a baseline assessment or retrospective review to ascertain the surgical infection rate at an outpatient dermatology clinic. Following the introduction of a formal program to reduce infection

Table I. Characteristics of different types of performance measures*

Type of measure	Description	Examples	Strengths	Weaknesses
Outcome	Measures the end results of care	• 5-year survival rate among patients with melanoma • Surgical infection rate following outpatient procedures • Quality of life in a patient with psoriasis	• Ultimate end product of clinical care • Difficult to manipulate • Promotes innovation around how to get there	• Often not perceived to be under physician control • Multifactorial • Prone to create perverse incentive • Long-term horizon • Can be hard to define or to capture
Process	Measures performance at different steps within the care pathway	• Wait time for clinic appointment for patients with pigmented lesions • Proportion of patients advised to perform monthly skin self-examination	• May directly impact patient experience • Short time course • Closely linked to provider actions • Easy to identify remedial action required	• Open to manipulation • May correlate poorly with clinical outcomes • Can lead to "quick fixes" rather than comprehensive solutions • May become outdated as new technology is introduced
Structural	Measures system-level adjuncts to multiple care processes	• Implementation of an EMR • Staff training in CPR	• May impact multiple care pathways • Can lead to step change improvements in clinical effectiveness • Promotes safe environment for patients	• Often costly as large-ticket items • May require extensive training to ensure efficiency gains

CPR, Cardiopulmonary resuscitation; *EMR*, electronic medical record.
*Adapted in part from Goddard et al.[50]

rates, ongoing measurements can be made to assess the effectiveness of the program. Institutions may be content simply to show improvement, or they may choose a target as the goal of the program (eg, <5%).

## AVOIDING THE NEGATIVE EFFECTS OF MEASUREMENT
Key points
- **Measures should be related to the greatest opportunities to improve patient care, or they simply shift focus away from more worthwhile endeavors**
- **Without proper planning and risk adjustment, measures can create the perverse incentive to abandon needier patients and take unnecessary risks in order to achieve more impressive outcomes**
- **Neglect of unmeasured outcomes**

Once individuals or institutions are truly focused on a measure, their ability to make improvements is often quite remarkable. However, once focus shifts to another measure, performance often slips back to baseline. We need to ensure that any measure selected is relevant, meaningful, and improvable.

Measures should reflect areas where improvements will have a wide-reaching impact on the patient population.

Gaming the system
There are a number of ways in which physicians might react adversely to performance measurement.[24] There may be a tendency to "cherry pick" the patients who are most likely to experience good outcomes and avoid those patients who are at high risk of poor outcomes. This issue was of concern when surgical mortality data began to be publicly reported. Patients with multiple comorbidities became unattractive candidates for surgeons who were working to maintain low mortality rates. In the medical field, similar concerns were raised when performance measures for diabetes were introduced. Some physicians became less inclined to take on patients with brittle diabetes and high levels of hemoglobin A_{1c}. In order to address this issue, performance measurement systems have to be able to risk adjust to account for differences in case mix. The American College of Surgeons has been very proactive about engaging in this issue and has created a program called the National Surgical Quality
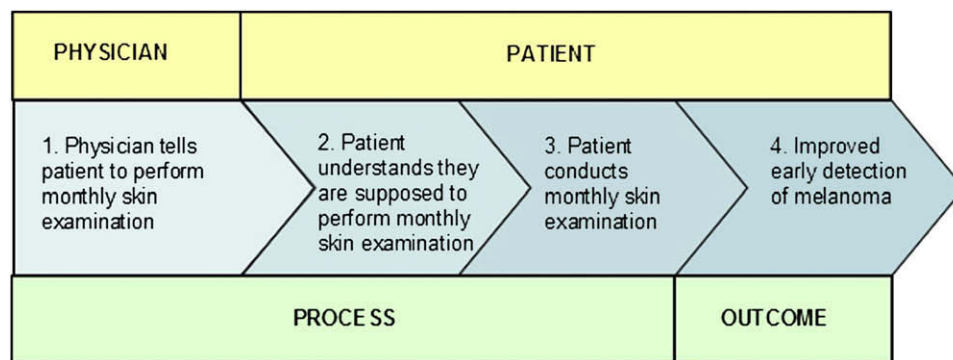
Fig 1. Outline of a series of steps leading from process to outcome. Note that both the physician and the patient contribute process steps.
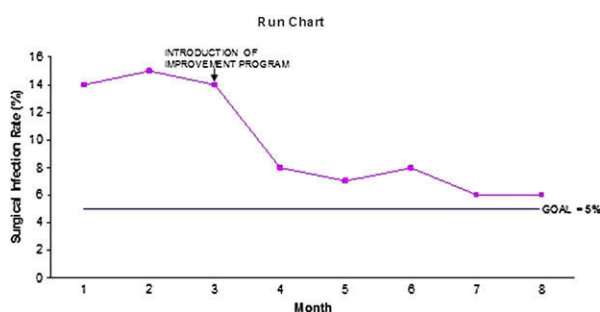
Fig 2. Example of a run chart displaying an improvement in the surgical infection rate after the introduction of an improvement program.
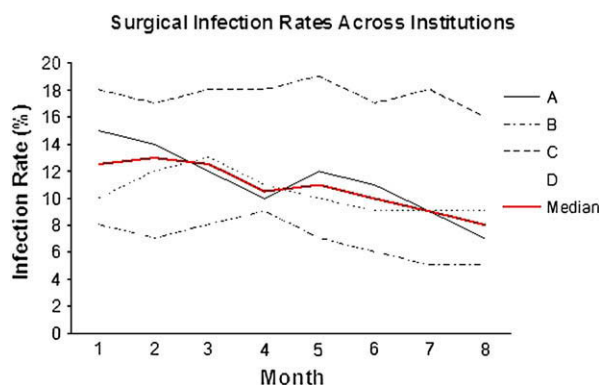
Fig 3. Comparison of surgical infection rates across four institutions.

Improvement Program[25] that is designed to compare risk-adjusted outcome data. Risk adjustment in health care is a complex and sometimes controversial topic, and different techniques of adjustment may produce very different results.[26]

Another potential problem is that physicians might find ways of achieving the measure that do not actually lead to better care. For example, high levels of immunosuppressant therapy might lead to rapid improvements in psoriasis. However, such treatment could also lead to adverse outcomes over the long term.

Losing sight of the big picture

Sometimes the implementation of measurement systems can lead to a narrowing in perspective. Instituting a wait time initiative—stating, for example, that all patients should be able to receive an appointment within 30 days—might lead to inappropriate triage methods. Patients with minor skin conditions who have been waiting 29 days may be prioritized above those referred with an urgent skin condition. Furthermore, once the 30-day period is exceeded for an individual, there is no residual incentive to ensure a timely appointment. This might

lead to some patients facing wait times of many months as the system prioritizes those for whom they can still meet their goal.

ESTABLISHING A QUALITY IMPROVEMENT PLAN FOR YOUR PRACTICE

Key points
- **The most effective quality improvement efforts foster a nonpunitive patient safety culture based on shared goals and mutual respect**
- **All members of the team should be encouraged to identify and report patient safety issues**
- **Larger organizations may benefit from systems that monitor signals of threats to patient safety**
- **Data on adverse events can be used to focus improvement efforts to achieve the greatest gains**
- **Goals should be achievable**
- **Best practices should be identified to help achieve those goals**

Table II. Categories of patient safety risk

Category	Definition
A	A situation with the potential to cause harm
B	An error that occurred but did not reach the patient
C	An error that reached the patient but did not result in harm
D	An error that reached the patient and required an intervention to prevent harm
E	Temporary harm requiring intervention
F	Temporary harm requiring hospitalization or increased length of stay
G	Permanent harm
H	Life-saving intervention required
I	Death

- **These best practices should be scalable and appropriate to the practice**
- **Incentives for office staff should be aligned with measurable and achievable targets**

Keys to ensuring a successful patient safety initiative include establishing a monitoring system for signals of threats to patient safety, gathering data on adverse events (AEs), establishing a culture of patient safety based on fairness and respect for all employees, establishing achievable goals, and identifying best practices that can help achieve those goals. Table II describes commonly accepted categories of AEs.

For many practices, it may be helpful to create a system for assessment and certification of procedural skills for medical personnel, as well as establishing reasonable limits on work hours and volume. Accountability for the success of the program should be clearly established, and incentives should be aligned with measurable quality improvement targets.[27-29] The most effective systems are nonpunitive, with every error viewed as an opportunity to prevent a more serious event.[30,31] Important steps in establishing an effective patient safety program are outlined in Table III.

Performance improvement in both large and small practices

While there is good evidence that the public reporting of performance data encourages quality improvement at a hospital level, the effect of public reporting on patient safety in small practices remains uncertain.[32] Most dermatologists practice in solo or small group practices. Because small practices typically lack the infrastructure and health information technology found in large institutions, this creates unique challenges for performance measurement and the establishment of patient safety programs.[33]

To be practical, performance improvement programs for small practice have to be limited in scope and target issues of sufficient importance to justify the increased burden on a limited number of staff. As performance measurement requirements become more widespread, universally accepted measures are needed to reduce the expense and burden of reporting a variety of measures for different payers. Measures must be risk-adjusted, taking into account the complexity of disease managed by an individual practitioner.

Electronic health records (EHRs) have tremendous potential to create safety checks and facilitate data capture.[34] However, for small practices, the costs of adopting EHRs and e-prescribing systems are significant, and implementation can disrupt the existing workflow. Interoperability issues remain, expensive systems will become obsolete over time, and vendors will go out of business or merge and stop providing support.[35] All of these factors weigh into a practice's decision to invest in information technology systems, especially because the return on investment for a smaller ambulatory practice can take many years.[36] More robust government incentives are needed to offset the cost of implementation and encourage the wider adoption of these systems.

In designing a performance improvement plan suitable for a dermatology practice, it may be helpful to focus on known episodes of patient harm or "near misses." For example, a patient may begin treatment with a high risk medication. Appropriate laboratory monitoring is ordered, but the patient becomes confused and only has the baseline laboratory values drawn. The patient misses several appointments and takes the medication for months without any laboratory monitoring. In this scenario, there is an opportunity to create an infrastructure that alerts the physician when patients who are taking high-risk medications are due for follow-up appointments and when their laboratory results are due. Other medical and surgical topics appropriate for quality improvement efforts in dermatologic practices are listed in Table IV.

Failure mode analysis

Failure mode analysis is an engineering tool used in industry. It is also used by health care organizations to test their patient safety systems. In this setting, failure mode analysis takes a hypothetical patient through a continuum of care with the assumption that something goes wrong at every step and that each safety net fails. For example, a physician who performs testing for a type I allergy may have a policy of maintaining a supply of epinephrine in the office to treat anaphylaxis. Failure mode

Table III. Steps to a successful patient safety program

Gather data on adverse events in the practice or similar practices

Establish a nonpunitive culture of patient safety that encourages error reporting

Identify best practices appropriate to the practice

Establish achievable goals and a timeline

Create a system for the assessment and certification of procedural skills for medical personnel

Establish reasonable limits on work hours and volume

Establish accountability and incentives based on measurable targets

Table IV. Patient safety quality improvement topics appropriate for dermatology

Medication errors

Timely and appropriate reporting of adverse drug reactions

Pathology specimen processing

Wrong-site procedures

Patient identification

Specimen labeling

Timely and accurate communication of biopsy and laboratory results

Supervision and competency assessment of ancillary staff

Surgical infection rate

Management of cardiac arrest and syncopal episodes

Appropriate timing of tuberculosis screening in patients on immunosuppressive therapy

Early osteoporosis risk assessment and intervention for patients on chronic corticosteroid therapy

Responsible use of antibiotics (perioperative, acne, and chronic wounds)

Continuity of care for patients with high-risk tumors

Continuity of care for patients on high-risk medications

Appropriate screening for skin cancer risk, connective tissue disease, and photosensitizing medications before ultraviolet therapy

Appropriate monitoring of the light source and phototherapy visits

Documentation of high-risk tumor attributes in dermatopathology reports to guide management (synoptic reporting)

analysis assumes that the patient does experience anaphylaxis, and that the epinephrine is found to be discolored and brown. The office is located close to a hospital and the policy is to call 911 in the event of cardiac arrest. Failure mode analysis assumes that the telephone lines are down. In short, failure mode analysis prompts the user to create a backup plan for each safety net that is created.

Sentinel event monitoring

Hospitals and health departments use the reporting of sentinel events to focus on interventions and structural engineering that can prevent subsequent patient injury and death. They focus on AEs that actually resulted in harm to a patient. A root cause analysis determines what aspects of the system contributed to the AE. Rather than simply placing blame on individuals, the focus is on creating systems that prevent errors.[37]

Performance improvement programs have traditionally focused on the voluntary reporting of errors. However, because fewer than 20% of errors are reported, and because up to 95% of reported errors caused no patient harm, the focus has now shifted to recording sentinel alerts that indicate potential patient safety risks.[38] The Institute for Healthcare Improvement (IHI) global trigger tool was designed to identify sentinel events or laboratory values without reliance on voluntary reporting and to maximize the benefit of chart audits with small sample sizes.[39] A disadvantage is that the method requires a review of all AEs that meet trigger definitions, whether the events were preventable or not. In large organizations, the system allows continuous real-time monitoring of EHRs to identify potential patient safety issues. Similar systems are scalable for use in dermatologic practices. Safety alert triggers suitable for dermatologic practices are listed in Table V.

Process measures focus on best practices. Bundled process measures focus on multiple best practices that can be grouped to ensure better outcomes. Structural measures are systems put into place to prevent patient harm. Outcomes measures quantify the results of all processes put into place to improve patient safety. Table VI presents examples of how each type of measure could be used in a dermatologic practice. The description of each measure is simplified in the examples. In practice, measure specifications require a high degree of granularity with regard to measurement period, eligible population, numerator, and denominator.

How large organizations and payers capture data

To satisfy quality reporting requirements for federal programs, such as the Physician Quality Reporting Initiative (PQRI), and to qualify for first-tier status for some payers, measures are captured through claims data, such as category II Current Procedural Terminology (CPT) codes. For structural measures, such as the creation of a database, the measure is reported each time a patient is entered into the database. Electronic medical records will allow data to be captured directly from the medical record.

Table V. Safety alert triggers suitable for dermatologic practices

Transfer to a higher level of care (including emergency room visit or hospital admission) related to a medication or surgery

Mislabeling of pathology forms

Discrepant pathologic diagnosis suggesting a mislabeled specimen

Postoperative infection

Prolonged operative time

Falls in the office

Adverse medication reaction or abrupt discontinuation of a medication

Unplanned procedure

Return to operating room

Change in procedure

Change of anesthetic

Inter- or postoperative radiograph

Use of an antihistamine or epinephrine in the office

Cardiac arrest or stroke

Positive *Clostridium difficile* culture

Use of blood products or colony-stimulating factors

Death

The gold standard for any nationally accepted measure is National Quality Forum (NQF) endorsement. The federal government must recognize any measure endorsed by NQF unless a specific exception is made by an act of Congress. NQF endorsement requires that measures be developed through a multistakeholder consensus process, and that they be based on current vetted, evidence-based best practice guidelines. There must be credible evidence of a gap in care and variation in practice. Measures that address overuse must be reviewed for impact on quality. Those that focus on quality must be reviewed for impact on cost.

As MOC, copay tiering, and relicensure requirements become greater challenges for physicians, they will depend on their specialty societies to develop measures they can report that are appropriate to their practices.

Handoff points

While outcomes measures have been considered the "holy grail" of quality measurement, they are the type of measure most prone to create perverse incentives to abandon the sickest patients. Bundled process measures that address the continuum of care represent a great opportunity to improve outcomes and are less prone to create these perverse incentives. Bundled process measures are particularly valuable when they focus on handoff points (each instance when responsibility for a patient or specimen is transferred from one individual to another).[40]

The loss or mislabeling of a biopsy specimen of a pigmented lesion can have catastrophic consequences. Table VII indicates each of the handoff points involved in the biopsy and histologic evaluation of a pigmented lesion. Safety engineering seeks to reduce the number of handoffs and to create electronic interfaces to reduce human error in labeling and transcription during handoffs.

This example demonstrates the complexity of the continuum of care. Even if the dermatologist and dermatopathologist are both pigment lesion experts, an error at any handoff point can result in a catastrophic outcome. Increasingly, quality measurement will focus on the last point on a continuum of care, assuming that if the last step is successfully accomplished, all previous steps were also successfully accomplished. The greatest challenge with such measures is that they require the cooperation of multiple individuals, such as the primary care provider, the dermatologist, and the dermatopathologist. The physician being measured does not have direct control over every step in the process. The greatest strength of such measures is that they capture the entire continuum of care, with the final measure being appropriate care rendered to the patient.

LESSONS FROM CANADA
Key points
- **The Canadian Medical Protective Association (CMPA) is a not-for-profit physician organization whose membership comprises most practicing physicians in Canada**
- **CMPA data on adverse events (harm to patients resulting from health care delivery) specific to dermatology can be used to focus quality improvement efforts**
- **Visual cognitive specialties may have a lower rate of diagnostic errors relative to other specialties, and this can be reduced further through systematic evaluation of the patient**
- **Systems can be engineered to reduce the incidence of patient harm**

The Canadian Medical Protective Association (CMPA) is funded and operated on a not-for-profit basis for physicians, by physicians. CMPA members are eligible to receive a broad range of assistance related to medicolegal difficulties arising from their professional work in Canada.

In 1999, the Institute of Medicine released *To err is human: Building a safer health system*, in which it was claimed that mistakes made in American hospitals accounted for substantial patient morbidity and mortality. Shortly thereafter, similar research was

Table VI. Examples of different types of quality measures applied to the practice of dermatology

Type of measure	Example	Denominator	Numerator
Simple process	Start patients on long-term prednisone on a bisphosphonate to prevent GIOP	All patients on prednisone (>5 mg/day) for >90 days	Those who receive risk assessment and intervention for GIOP within the first 30 days
Bundled process	For patients starting on a biologic therapy; PPD; counseling about signs and symptoms of tuberculosis; influenza vaccine; counseling about live vaccines	All patients started on a biologic therapy	Those for whom all four measures were accomplished
Structural	Database of patients on high-risk medications to ensure timely laboratory monitoring and follow-up	All patients started on azathioprine	Patients entered into the reminder system
Outcomes	Postoperative infection rate	All incisional surgeries performed during the calendar year	Number of surgical wound infections

GIOP, Glucocorticoid-induced osteoporosis; *PPD,* purified protein derivative.

published in Canada indicating that 7.5% of patients admitted to a hospital in 2000 suffered from one or more AEs and that for a third of those patients, the AEs were considered "highly preventable." The study further estimated that between 9250 and 23,750 hospital patients died that year in Canada from a preventable AE.[41]

Following the publication of the Canadian Disclosure Guidelines by the Canadian Patient Safety Institute in 2008, there is now a better national consensus on certain patient safety definitions. Harm is defined as an outcome that negatively affects the patient's health and/or quality of life. An AE is broadly defined as an event that results in unintended harm to the patient, and is related to the care and/or services provided to the patient rather than to the patient's underlying medical condition. A close call (sometimes called a near miss) is an event with the potential for harm that did not result in harm because it did not reach the patient because of either timely intervention or good fortune.

System failures

A system failure is a problem, breakdown, or malfunction in the policies, operational methods, or supporting infrastructure of an institution or clinic. The defensive barriers or safeguards in any health delivery organization may be conceptually described as being like steel plates (Fig 4). Each has some holes, with each hole representing weaknesses or possible failure points, and these are continually opening, closing, or changing location.[42] A single failure is unlikely to result in an AE. AEs usually result

from failures in successive "layers" of protection; the holes or failures line up to allow harm to occur. Safety is improved by minimizing the holes to reduce the likelihood that an AE will occur.

The CMPA helps members with medicolegal matters, including legal actions and complaints by patients or others to the medical licensing regulatory authorities (Colleges) of each province or territory. The medical liability system in Canada is a tort-based legal system that provides compensation to patients proven to have been harmed as a result of negligent health care. The Colleges in each province or territory of Canada are responsible and accountable for regulating the practice of individual physicians. Their mandate includes the responsibility of ensuring that physicians practice competently to meet the standard of practice for their chosen specialty.[43] The CMPA defines a critical incident as any omission or commission in the evaluation or management that led to the problem(s) triggering the legal action or complaint. Each medicolegal case can have more than one critical incident, although some have none.

A review was undertaken of all medicolegal cases between January 1, 2003 and December 31, 2007 involving all members of the CMPA who are dermatologists to determine areas of clinical risk. Within this 5-year period, 175 medicolegal cases were identified.

Canadian dermatologic malpractice cases involving noncosmetic critical incidents

Seventy percent (122/175) of the cases involving dermatologists were considered noncosmetic. Forty-two percent of the medicolegal cases were civil legal

Table VII. Continuum of care for a patient with a presumed malignant melanoma

1. PCP sees patient and places dermatology referral for suspect pigmented lesion*
2. Patient keeps the appointment, is seen by the dermatologist, and a biopsy is performed
3. The specimen is labeled and requisition form is completed*
4. The specimen is placed in a bin for the pathology courier*
5. The courier signs for the specimen and transports it to the laboratory*
6. The dermatopathology laboratory receives the specimen and enters it into their computer system*
7. A technician grosses the specimen and places it into a labeled cassette for processing*
8. The gross dictation is sent to transcription*
9. A histology technician places the cassettes into a tissue processor*
10. After processing, a technician embeds each piece of the tissue in a correctly labeled block*
11. Sections are cut from the paraffin blocks and placed on correctly labeled slides*
12. The labeled slide is stained and a cover slip is applied
13. The slides are reunited with the correct paperwork and delivered to the pathologist*
14. The pathologist reviews the slides and dictates or enters a diagnosis into a computer program*
15. If the report is dictated rather than entered directly into a computer, it must pass to transcription,* then the completed report is returned to the pathologist for review and signature*
16. The report is generated and sent to the dermatologist on paper or electronically*
17. The dermatologist contacts the patient and sends a message to the appointments pool to schedule an appointment for definitive treatment*
18. The diagnosis and treatment plan are communicated to the PCP
19. Treatment is completed*
20. The appropriate interval of follow-up is scheduled*
21. The patient keeps all subsequent follow-up appointments*

PCP, Primary care provider.
*Indicates a handoff point.

actions, and 13% were threats of legal action. Forty-five percent (55/122) of the cases were complaints to the Colleges.

Delay in diagnosis or a misdiagnosis

An allegation of a delay in diagnosis or a misdiagnosis was the central critical issue in 44% of the noncosmetic cases. In 22% of the noncosmetic cases, an allegation of a medication AE was the central issue; 11% involved a critical incident during phototherapy; and 16% involved proven communication

critical incidents. Seven percent involved critical incidents related to administrative failures, such as injuries resulting from inappropriate sharps disposal.

Twenty percent of the cases involving a delay or misdiagnosis of a malignant carcinoma involved other malignancies, such as cutaneous T-cell lymphoma, fibrosarcoma, dermatofibrosarcoma protuberans, or a misdiagnosis of a cutaneous metastasis.

Physician cognitive factors

A great many dermatologic diagnoses are readily made using subconscious "pattern- recognition," a nonanalytical process based on previous knowledge and experience. Misdiagnoses or delays in diagnosis occur even by the very best clinicians. Studies have demonstrated that the "perceptual" specialties—such as pathology and radiology/diagnostic imaging, which rely heavily on visual pattern recognition—have a known diagnostic error rate that is reported to range from 2% to 5% compared with up to 10% to 15% in most other specialties.[44-48] The challenge for dermatologists is to recognize when subtleties in a patient's presentation warrant a more rigorous cognitive approach. In such circumstances, the experienced dermatologist may consider a more analytical approach to the diagnosis. This might include forming a differential diagnosis, considering if the clinical presentation has been altered by preceding therapies, or if a possible "worst-case" diagnosis needs to be ruled out.

Sometimes, if the diagnosis seems immediately obvious, the dermatologist may not revert to developing a differential diagnosis or may fail to consider alternative information from either the history or physical examination that would contradict the original diagnostic impression. Croskerry[49] has called these cognitive pitfalls premature diagnostic closure and confirmation bias.

System factors involved in delay in diagnosis cases

CMPA analysis revealed that failure to follow-up pathology and other investigative reports resulted in a delay in diagnosing dermatologic conditions. Physicians work in complex office and hospital environments with many pressures. Challenges include time and human resource constraints, communicating effectively, access to technology, and using that technology correctly.

Based on this CMPA analysis, the following risk management considerations are suggested:

Cognitive factors

- Have you taken a history and performed a complete physical examination?
- Have you considered a differential diagnosis?

Fig 4. Systems protections. The reason for many adverse events may be thought of conceptually as failures of "layers" of protection. (Courtesy of Mike Murphy, Geisinger Health Systems Biomedical Communications.)

- Have you considered if the clinical presentation has been altered by previous therapy?
- If appropriate, has the worst-case diagnosis been considered and ruled out?
- Have you reassessed the patient and reconsidered the diagnosis if the patient is not improving?
- Would a second opinion be useful?

System factors
- Do you have policies and procedures in place in your office?
- Do you have a system to track pending laboratory tests?
- Do you have a system to ensure the follow up of high risk patients?
- Do you and your employees document relevant patient encounters, including phone advice and no shows, in the medical record?

Medication errors

Allegations of medication AEs were the central issue in 22% of the noncosmetic cases. Prescribing, including telephone prescription repeats and failure to monitor patients, were found to contribute to these alleged AEs. The top medications included isotretinoin, minocycline, topical corticosteroids, and methotrexate.

Dermatologists face an ever-expanding choice of new therapeutic agents. Physicians are encouraged to become sufficiently familiar with the agents they prescribe to enable patients to receive the benefits of the treatment while lessening the likelihood of medication-related difficulties. This can start as soon as one contemplates prescribing and especially as one writes the prescription. Clarity of the dosage and legibility of the script reduce the risk of misinterpretation by the pharmacist of either the drug or the instructions. The off-label use of medications requires a more in depth consent discussion and a careful review of potential alternatives. Resisting requests to prescribe in a novel or unique fashion may also reduce future problems.

Phototherapy

Eleven percent (14) of noncosmetic cases were related to critical incidents during phototherapy. Eighty-six percent of the closed legal cases had an outcome favorable to the plaintiff. This figure is higher than the overall CMPA experience, in which 30% of closed legal outcomes are resolved in favor of the plaintiff. The most frequent clinical complications were patient burns, and the most common critical incident for these complications was equipment failure caused by misprogramming by a technician employee.

The following risk management suggestions are based on this review:
- Has the staff been appropriately trained in the use of equipment?
- Does the staff know when to involve a physician in the care of the patient?
- Is the equipment adequately maintained and are the appropriate alarms functioning?

THE QUESTION OF COST VERSUS QUALITY

As society grapples with the issue of health care funding, some stakeholders will want to focus only on cost containment. Physicians and consumer groups will push for measures of quality rather than merely cost. In addition to the reporting of nationally-endorsed quality measures, practice-based performance improvement projects will become a requirement for maintenance of certification and may become a requirement for MOL in some states. The AAD has a responsibility to its members to

produce toolkits that can be used to help fulfill these requirements. The road ahead will not be easy, but the practice of medicine has never been easy. It is a calling and a noble profession. As always, we will rise to the occasion.

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Answers to CME examination

Identification No. 809-118

August 2009 issue of the Journal of the American Academy of Dermatology.

Questions 1 and 2, Elston EM, Stratman E, Johnson-Jahangir H, et al. J Am Acad Dermatol 2009;61:193-205.

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