

Quality Improvement or Research?

July/August 2008

Quality Matters is a newsletter from The Commonwealth Fund. Published bimonthly, the newsletter explores issues of quality and efficiency in health care.

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Welcome to Quality Matters, a bimonthly roundup of news and opinion on quality and efficiency, information technology, performance improvement initiatives, and policy innovations.

In Focus: Pursuing Perfection Safely.....	1
Case Study: Is It Quality Improvement or Research? The Experiences of Intermountain Healthcare and Children's Hospital Boston.....	6
News Briefs.....	11
Recent Publications of Note	13
Editorial Advisory Board and Team.....	17

In Focus: Pursuing Perfection Safely

***Summary:** Health care system performance can only improve with more robust measurement of quality improvement strategies designed to enhance patient safety, quality of care, and health outcomes. But, the federal government's action against a large, multi-site quality improvement project in Michigan last year has left many clinicians pursuing such improvements uncertain as to whether their projects are subject to the regulations for the protection of human research subjects.*

By Vida Foubister

Many health care professionals working to improve the safety and quality of care were astounded last year when the federal Office for Human Research Protections (OHRP) shut down a successful quality improvement project. The Michigan project, which used a five-step checklist to decrease the rate of catheter-related bloodstream infections in 103 intensive care units (ICUs), was halted due to concerns about the protection of human research subjects—in this case, hospital patients being treated in the ICU as well as the providers treating them. OHRP's action also drew the ire of policymakers and patients after the case was highlighted in high-profile articles in *The New York Times* and *The New Yorker*, among others.

Peter Pronovost, M.D., Ph.D., a professor of anesthesiology, critical care medicine, and health policy and management at The Johns Hopkins University, who led the project, submitted it to the Hopkins institutional review board (IRB) prior to initiating the study. The Hopkins IRB determined that it was exempt from the federal regulations, and it was not submitted for further review by the Michigan hospitals implementing the intervention. But, after the study's findings, which showed an up to 66 percent decrease in catheter-related infections, were published in the *New England Journal of Medicine*, a written complaint to OHRP led the agency to take action.

"If the regulations are that vague that a sophisticated IRB could differ from OHRP and [the agency], after the fact, could hold you to their interpretation, it suggests the oversight of these issues need to be reconsidered," says Pronovost. Further, he says, "in a telling example of how confusing the regulations are," two subsequent editorials in the *New England Journal of Medicine*, both written by experts in ethics and human subjects protection, disagreed on whether the Michigan project should have been subject to the federal regulations. (See [here](#) and [here](#).)

While OHRP concluded in a February determination letter that the Michigan hospitals could continue implementing the checklist "without falling under regulations governing human subjects research," the implications of its initial action have been far reaching. "There's been an awful lot of quality improvement that has been stalled or put on hold, trying to understand this IRB issue," says Pronovost. "The chill sent through the quality improvement field has been very, very real."

Quality Improvement, Research, or Both?

Until the federal government halted the Michigan project, the need for oversight of quality improvement (QI) activities was largely under the radar screen of those involved in clinical care. Most physicians and hospital staff members engaged in QI projects are focused on patient care rather than research. As such, many were unaware of OHRP, its mandate to oversee research involving human subjects, and the corresponding requirements for organizations conducting such research. Further complicating matters, many hospitals engaged in QI efforts—including some of those involved in the Pronovost project—are not typically engaged in research and thus do not have local IRBs available to review such activities.

That's not to say that this issue was wholly unrecognized. Experts in both quality improvement and medical ethics, most recently brought together by the Hastings Center, a bioethics research institute in Garrison, N.Y., had begun to explore the policy options for ensuring that quality improvement activities are conducted ethically. A report based on this work, funded through a grant from the Agency for Healthcare Research and Quality, was published in 2006. But, says Mary Ann Baily, Ph.D., associate for ethics and health policy at the Hastings Center and principle investigator of the project, "no one paid too much attention to what we were recommending."

Not surprisingly, this has changed since the facts of the Pronovost case and its potential implications became widely known. As those involved in quality improvement seek clarity on the federal regulations, the [Hastings Center report](#), (registration required) as well as a [shorter version](#) published in the *Annals of Internal Medicine*, have provided a

starting place for thinking through the relevant issues (Exhibit 1). Despite much confusion about the requirements of the regulations, not all quality improvement projects should be submitted for IRB review, says Baily. "There is agreement between the

quality improvement people and the federal regulators that not all QI is research and, if it's not research, there's no reason the federal government should be overseeing it."

Exhibit 1. Ethical Requirements for the Protection of Human Participants in Quality Improvement Activities	
Requirement	Explanation
Social or scientific value	<ul style="list-style-type: none"> The gains from a QI activity should justify the resources spent and the risks imposed on participants.
Scientific validity	<ul style="list-style-type: none"> A QI activity should be methodologically sound (i.e., properly structured to achieve its goals).
Fair participant selection	<ul style="list-style-type: none"> Participants should be selected to achieve a fair distribution of the burdens and benefits of QI.
Favorable risk-benefit ratio	<ul style="list-style-type: none"> A QI activity should be designed to limit risks while maximizing potential benefits and to ensure that risks to an individual human participant are balanced by expected benefits to the participant and to society.
Respect for participants	<ul style="list-style-type: none"> A QI activity should be designed to protect the privacy of participants and the confidentiality of their personal information. Participants in a QI activity should receive information about findings from the activity that are clinically relevant to their own care. All patients and workers in a care delivery setting should receive basic information about the program of QI activities. The QI results should be freely shared with others in the health care system, but participant confidentiality should be protected by putting results into nonidentifiable form or obtaining specific consent to sharing.
Informed consent	<ul style="list-style-type: none"> Consent to inclusion in minimal-risk QI activities is part of the patient's consent to receive treatment. Patients should be asked for informed consent to be included in a specific QI activity if the activity imposes more than minimal risk. The risk to patients should be measured relative to the risk associated with receiving standard health care. Workers (employees or nonemployee professionals who provide care in an organization) should participate in minimal-risk QI activities as part of their job responsibilities. Workers should be asked for their informed consent to be included in a QI activity that imposes more than minimal risk. The risk to workers should be measured relative to the risk associated with the usual work situation. This does not include any risk to economic security (for example, if a QI activity reveals that the worker is incompetent or that the organization can provide quality care without that worker).
Independent review	<ul style="list-style-type: none"> Accountability for the ethical conduct of QI should be integrated into practices that ensure accountability for clinical care. Each QI activity should receive the kind of ethical review and supervision that is appropriate to its level of potential risk and project worth.
<i>QI = quality improvement</i>	

Source: Table 1 from J. Lynn et al., "The Ethics of Using Quality Improvement Methods in Health Care," *Annals of Internal Medicine*, 2007 146:666–673.

What is less clear, however, is how to determine whether a quality improvement project, which seeks to make changes to clinical care, is also research involving human subjects that must be reviewed by an IRB under the requirements of the federal regulations. Although OHRP has developed 11 [decision charts](#) to guide investigators as they seek appropriate review for such projects, these algorithms are complex and leave "a lot of gray," says Don Goldmann, M.D., senior vice president at the Institute for Healthcare Improvement (IHI). "For algorithms to be useful, decision points need to be straightforward."

To fill this void, some institutions that routinely implement quality improvement projects have established their own guidelines (see [Case Study](#)). At Johns Hopkins, QI projects that solely aim to improve patient care go through departmental review. "Those projects that have a more rigorous evaluation or a faculty member who might want to do something scholarly would be submitted to the IRB for review," says Pronovost. Institutions lacking such guidelines can refer to those described in the Hastings Center report on QI oversight, which suggests characteristics to help identify quality improvement activities that also involve research. These characteristics include projects that: aim to test new treatments; randomly assign patients into different intervention groups; delay data feedback to avoid bias in interpreting the data; involve researchers who aren't part of the local care team; and receive funds, sponsorship, or substantial participation from parties outside the clinical setting or organization where the changes are being implemented.

Distinctions between quality improvement and quality improvement research, however, are hard to draw. "This is much more complicated than anybody understood," says

Christine Cassel, M.D., president and CEO of the American Board of Internal Medicine and the ABIM Foundation, which, along with the Institute of Medicine and The Commonwealth Fund, hosted a conference on the issue in May. "There's nothing worse than having regulations that are so unclear that people break them unknowingly. It creates a chilling environment, and that's especially not an environment you want in the quality arena. You want people to measure things—that's the whole point."

Building the Evidence Base for QI

Goldmann, of IHI, likens the current situation in quality improvement oversight—in which few hospitals have the expertise to develop the processes and procedures necessary to determine if proposed QI projects are indeed worthwhile—to that of hospital infection control in the early 1970s. At that time, the Joint Commission came out with a new standard and the health care system had to train enough infection control specialists and hospital epidemiologists to meet the standard. "We have to do this now for quality improvement," he says.

OHRP's action has brought attention to the need for health care organizations engaging in quality improvement activities to develop the local expertise to assess each QI project and determine whether it's well designed, conceptually sound, and appropriately uses limited resources. "It's not justifiable to do any kind of work that will be futile," says Goldmann. "It's not fair to patients; it's not fair to staff."

While accreditation bodies, such as the Joint Commission or the National Committee for Quality Assurance, might be in a position to set standards that guide institutions, such assessments are best done as part of the oversight of clinical quality generally, says Baily of the Hastings Center. "It is important

to have this supervision embedded in the people who understand how the organization works, otherwise you won't understand which projects are dangerous and which aren't," she says. "What looks like an innocuous change could have serious consequences." For example, a clinical process that improves quality at an organization with good nursing care could lead to patient harm when implemented at an understaffed institution.

Looking Forward

The differences between quality improvement activities and biomedical research have led some to question whether the regulations, which were created nearly 30 years ago to stop abuses of human subjects, can and should be applied to QI. At the time the regulations were written, "it was assumed that normal health care was the best it could be and any kind of research put you at risk," says Cassel. "Now we know that's not true; normal everyday health care is not safe for patients."

Further, improving health care quality and safety is increasingly thought to be a critical professional obligation. Patients, who consent to receive care, are also viewed as having an ethical obligation to participate in improvement interventions—as long as their risk of harm is not increased from that of standard treatment. "The challenge is to find oversight that is commensurate with the risk, that doesn't stall things, that allows learning and improvement, and yet protects subjects from undue risk," says Pronovost.

As yet, the federal government has not indicated that it intends to revise the existing regulations. However, Ivor Pritchard, Ph.D., acting director of OHRP, has stated his office's willingness to give guidance to those working on quality improvement projects that have been stalled due to uncertainty

about the level of review needed. Pronovost, who, along with Congressman Henry Waxman (D, Calif.), would like to see the catheter-related bloodstream infection project expanded in 10 additional states, is currently waiting for such guidance.

OHRP's guidance is likely to be specific to the projects that it's queried about, leaving others to extrapolate the agency's comments to their situations. Therefore, Pronovost believes that those working in QI need to develop a structured framework to help institutions evaluate the net risks and benefits of each project that's proposed. This framework should help organizations critically evaluate the methodology of their quality and safety programs and establish the confidence level necessary to support decisions—made at the clinical and managerial levels—that ultimately will change established health care processes. This includes evaluating the published literature for evidence that a QI intervention will work and evaluating any potential harms associated with its implementation.

Once the science of quality improvement is more robust, it should be easier to make appropriate decisions about which projects to pursue. "I don't see us linking the research community with the clinical community and that's sorely needed," Pronovost says. "When I look at the advances in biomedical science in the last decade and the limited advances in quality, it's sobering. ...In part, I think our failure to progress is our lack of viewing [quality improvement] as science."

For More Information

See N. Kass, P. J. Pronovost, J. Sugarman et al., [Controversy and Quality Improvement: Linger- ing Questions About Ethics, Oversight, and Patient Safety Research](#), *Joint Commission Journal on Quality and Patient Safety*, June 2008 34(6): 349–353.

Case Study: Is It Quality Improvement or Research? The Experiences of Intermountain Healthcare and Children's Hospital Boston

By Douglas McCarthy

Summary: Case studies of two leading health care organizations show that they share a common perspective of quality improvement (QI) as integral to excellence in clinical practice and, therefore, subject to the same ethical obligation to deliver the best possible care to patients. Research on human subjects, in contrast, requires independent ethical oversight because of the potential conflicts between researchers' and patients' interests. Both organizations recognize that the decision to publish results or to use a particular analytic method alone does not distinguish QI from research. Moreover, in some cases QI can take on attributes of research, thus eliciting the need for prospective ethical oversight.

Issue

Because health care involves both benefits and risks to patients, health care professionals have long recognized an ethical duty to serve and protect their patients' interests. Research can pose additional risks to participants, both from the unproven nature of interventions being studied and from the potential that the researchers' interests may diverge from those of patients. For this reason, federal regulations require that institutions engaged in federally sponsored research commit to ethical conduct and oversight of research involving human subjects, including review by an institutional review board (IRB) when required. [1]

Health care practitioners and organizations are increasingly engaging in quality improvement (QI) activities to systematically bring routine care into conformance with evidence on best treatments and practices. [2] A recent investigation by the federal Office of Human Research Protections (which enforces the federal research regulations) of a QI initiative in Michigan hospitals has raised concerns about whether and how QI differs from research, as well as what type of ethical oversight should apply to QI activities. [3] The following case studies describe how two leading health care organizations have defined their obligations in this regard.

Case Study #1

Intermountain Healthcare

Organization

Intermountain Healthcare is a not-for-profit, integrated delivery system that provides care and coverage in Utah and southeastern Idaho. The organization employs 28,000 staff, including 700 physicians in a multispecialty group practice, and operates 21 hospitals, 140 clinics and physician offices, 42 pharmacies, and a 500,000-member health

plan. Intermountain has been a pioneer in developing and implementing electronic medical records and in applying the principles of quality measurement and improvement to health care.

Topic Expert

Brent James, M.D., M.Stat., is vice president for medical research and continuing medical education and executive director of the Institute for Health Care Delivery Research, which provides technical support and

education for clinical research and process management within Intermountain.

Date of Implementation

Intermountain began addressing this issue 15 years ago as part of broader discussions about information security issues related to electronic medical records (James chaired the organization's information security committee while also leading its quality improvement work). James' participation on a recent Hastings Center ethics panel on this topic added additional conceptual rigor to the organization's application of these policies to QI. [2]

Definition of QI

Intermountain considers QI to be part of "health care operations," consistent with the federal HIPAA (Health Insurance Portability and Accountability Act) Privacy Rule. Specifically, Intermountain defines QI to mean activities that:

- focus primarily on the performance of local patient-care delivery, rather than the generation of new scientific knowledge;
- attempt to consistently implement established best practices based on existing evidence (including randomized controlled trials, observational studies, and consensus-expert opinion); and
- involve "open-loop systems" in which clinicians are instructed to modify implementation protocols based on patient need (so that QI does not conflict with a clinician's primary ethical commitment to a patient's well-being).

Intermountain *excludes* from QI (and hence considers research) any activity:

- that involves experimental or unproven therapies (not evidence-based treatment);
- in which patients are randomly assigned to competing treatments, potentially conflicting with a clinician's primary ethical commitment to each patient's well-being; [4]
- that imposes additional testing burdens that represent a risk to a patient, while not conveying a countervailing potential benefit to that patient; or
- that is funded by external grants or awards with primary or secondary goals of knowledge generation, such that those managing the endeavor have potential conflicts of interest that could place patients' interests secondary to some other goal.

Oversight of QI

Given the accumulated evidence of gaps in quality of care nationwide, Intermountain views QI as an ethical obligation to close the performance gap and deliver the best possible care to patients consistent with evidence-based standards (insofar as they apply to a particular patient). "Forty years of research has shown that the idea of a physician as a standalone expert, ethically founded, does not guarantee best care to a patient," James says.

Intermountain considers oversight for QI in the broader context of its ethical obligations for every aspect of patient interactions and care delivery. "It is not a question of whether we are going to oversee the ethics of it. . . but how we oversee it," James says. The level of oversight is determined based on the potential for conflicts of interest in comparison to those encountered in everyday clinical practice. When there is a potential that some factor other than the patient's best interest may take primacy in

clinical decision-making, then a more intensive level of oversight is triggered.

- *Detection controls.* All health care operations and research activities are subject to detection-oriented oversight designed to identify violations of policy. This means establishing a standard for ethical behavior (including the reporting of potential unethical behavior), training staff on the standard (such as data confidentiality), obtaining their commitment to the standard (such as through signed access and confidentiality agreements), monitoring for and investigating potential violations of the standard (such as systems for detecting inappropriate access to electronic medical records), and taking appropriate action against violators.
- *Prevention controls.* Lower-volume activities with a higher risk of ethical conflict—such as clinical research activities—are subject to prospective ethical oversight designed to prevent conflicts of interest, such as review by an IRB or privacy board as required by the federal regulations.

Implementing QI so that it does not interfere with (but rather promotes) physicians' ethical duty to patients makes detection-oriented oversight an appropriate strategy for routine QI. Likewise, evaluating QI activities to learn whether they are effective is a function of organizational performance measurement. In circumstances that increase the potential for ethical conflict, QI activities are reviewed by an IRB or privacy board (as appropriate) to ensure patients' interests are protected. Such oversight is geared to the type of risk posed by the activity:

- *Risks to patient privacy:* When someone decides to publish summary QI results outside the organization

(analogous to the situation when a physician publishes a case-series report on his or her patients' clinical experience), ethical review (typically by a privacy board) is applied at that point in time to ensure the protection of patient confidentiality (not to approve the activity itself).

- *Risks to patient health:* If patients will be randomly assigned to different QI interventions to determine which is most effective for providing evidence-based care (as distinguished from a nonrandomized pilot test comparing the experience of different organizational subunits), the project is prospectively reviewed by an IRB (typically one with expertise in QI-related research). In some cases, a project may qualify for "expedited" IRB review or for a waiver of informed consent.

Insights and Lessons Learned

Viewing QI within a framework of risk for conflict of interest is the clearest way to determine appropriate oversight, James says. This approach is more defensible than asking whether results will be published or a particular analytic method will be used. In the simplest analysis, research is trying to understand what is the best treatment, while QI is trying to implement what is known to be best treatment, he says. He acknowledges that there are some gray areas between the two, such as when randomly testing the relative merits of different QI methods ("comparative QI research" as distinct from routine QI practice). Intermountain takes a conservative approach in such cases.

Oversight through rigorous application of detection controls has proven to be an effective approach at Intermountain (although violations are regularly detected in routine clinical areas, none have been

detected in QI activities). Moreover, this type of oversight is widely applied to health care delivery in the U.S.—such as by accreditation agencies and regulators including the OHRP in its oversight of IRBs. James points out that prospective ethical review is not required before obtaining patient consent for treatment, even though physicians have a financial interest in providing care. So requiring prospective

review of routine QI would make little sense considering that it is designed to *decrease* the risk of poor quality.

For More Information

See B. James (2007) [Quality-Improvement Policy at Intermountain Healthcare](#), in B. Jennings et al. (eds.) *Health Care Quality Improvement: Ethical and Regulatory Issues*, Garrison, N.Y.: The Hastings Center.

Case Study #2 Children's Hospital Boston

Organization

Children's Hospital Boston is a 397-bed comprehensive center for pediatric health care. Each year the institution admits more than 22,000 inpatients and serves more than 527,000 patients through specialized clinical programs. Children's is the primary pediatric teaching hospital of Harvard Medical School and is one of the nation's foremost pediatric research institutions, with more than 600 research scientists and \$176 million in current research funding.

Topic Expert

Susan Kornetsky, M.P.H., is director of clinical research compliance at Children's, where she oversees the IRB administrative office, educates investigators on IRB regulations, and establishes policies to ensure institutional compliance with regulatory requirements.

Date of Implementation

Children's policy guidance on the distinction between research and QI activities was developed more than 10 years ago, with some recent refinements based on a recent Hastings Center report on this topic. [2] The

policy was reviewed as part of Children's application for accreditation by the Association for the Accreditation of Human Research Protection Programs.

Definition of QI

Conceptually, the institution views QI as "activities based on existing knowledge about the enduring nature and function of people and their environment, rather than to develop new knowledge." QI includes projects designed to improve clinical care so that it better conforms to established or accepted standards, such as data-guided efforts to ensure the adoption of evidence based on practice guidelines or to introduce procedures to reduce medical errors. The institution is often required to conduct such activities to meet accreditation and regulatory requirements.

In addition, Children's considers surveys that have a primary purpose of gauging the opinion and perceptions of internal and external customers (e.g., trainees, staff, patients, referring physicians) to be an integral component of organizational quality assessment. This includes, for example, surveys to determine users' satisfaction with a service and to gather information on how to improve the service.

Oversight of QI

For the purposes of determining appropriate oversight, Children's distinguishes among pure QI activities that are exempt from IRB review, research that is subject to IRB review under federal regulations, and QI activities that are also research and therefore require ethical review as such. The following examples are indicative of the types of studies that may qualify for IRB review:

- Studies in which subjects or groups of subjects may be randomized to different interventions or treatments (the IRB can consider a waiver or alteration of informed consent requirements when the intervention involves minimal risk to patients and it would be impractical to obtain individual consent).
- Studies in which the anonymity of participants cannot be ensured (participants are defined as individuals who are being asked to provide feedback on a QI initiative, not individuals or services evaluated as part of the QI process).
- Studies involving care practices, interventions, or treatments that are not standard (i.e., neither consensus- nor evidence-based).
- Studies that involve more than minimal risk to patients.

External publication of findings from a QI project does not by itself trigger IRB review at Children's, provided that the project is clearly described as a QI activity and is not represented as research. (The hospital has not experienced any difficulty with journals accepting QI articles for publication under this framework.) QI projects are also subject to the organization's privacy and security policies.

Insights and Lessons Learned

Kornetsky has found that written guidance on this topic educates the institution's staff and helps them frame their projects appropriately as QI or research. "You have to be very clear up front whether you are considering a project research and apply the appropriate criteria" such as obtaining a waiver of informed consent, she says. On the other hand, classifying something as a QI activity "doesn't mean that it can be done sloppily or without attention to ethical issues." To qualify for exemption from IRB review, for example, a satisfaction survey must be completely voluntary and its results completely anonymous.

Before issuing written guidance on this topic, the hospital's IRB was becoming overwhelmed with requests to review surveys and QI projects. The hospital's staff automatically assumed these activities required IRB approval because they used research-like methods or involved the publication of results. According to Kornetsky, "Our IRB would look at these and say, 'this isn't research. This is to help the institution figure out a better way of doing things, so why are we looking at this?'"

Kornetsky finds that the institution's guidance is adequate on its own about half the time. Some projects fall into a gray area, or staff have questions that are not answered by the guidance. For example, randomization may be an indication that a QI project is "beginning to cross the line into research," but it does not definitively classify as research. Kornetsky talks these issues over with staff and encourages them to form a defensible rationale. The final determination about whether to submit the project for IRB review is made by the individual or group responsible for the activity.

Limitations

The organizations described above conduct both QI and clinical research and have established their own IRBs. Their experience may be more relevant to similar types of organizations rather than to community hospitals and other nonacademic

institutions that do not conduct clinical research.

For More Information

Download the hospital's Guidance on [What Quality Improvement and Education/Competency Evaluation Activities Are Considered Research and Subject to Committee on Clinical Investigation Review?](#)

References

- [1] The Federal Policy for the Protection of Human Subjects, as adopted by the Department of Health and Human Services (Code of Federal Regulations, Title 45, Chapter 46), defines research as "a systematic investigation... designed to develop or contribute to generalizable knowledge." See <http://ohsr.od.nih.gov/guidelines/45cfr46.html>.
- [2] J. Lynn et al. (2007) [The Ethics of Using Quality Improvement Methods in Health Care](#), *Annals of Internal Medicine* 146, 666–673. This report defines QI as "systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings."
- [3] B. M. Kuehn (2008) [Update: HHS Reverses Decision to Halt Quality Improvement Study](#), *Journal of the American Medical Association* 299, 1416.
- [4] Intermountain distinguishes between the use of randomization for purposes of experimental research and other circumstances in which randomization is used for purposes of equity to allocate a scarce resource, or when a new treatment or service is pilot tested in a randomly selected organizational subunit to see if claims for its utility (as described in the published literature) hold up in practice.

News Briefs

NCQA Releases Standards for Physician Measurement

The National Committee for Quality Assurance (NCQA) last month released [updated standards](#) for measuring physician and hospital performance. For the first time, the organization recommended using standardized quality measures to ensure the comparability and accuracy of performance reporting.

In particular, the requirements call for the use of standardized measures that have been endorsed by the National Quality Forum (NQF) to measure physician performance. When NQF-endorsed measures are not available, the guidelines call for the use of standardized measures from other nationally recognized entities. NCQA also emphasized that there should be transparency on key methodological issues, including the

assignment of patient results to physicians for measurement purposes, risk adjustment of quality data, and the statistical reliability of comparisons among physicians, practices, or medical groups.

The standards update the voluntary Physician and Hospital Quality (PHQ) certification program, which examines how health plans measure and report on the quality and cost of physicians and hospitals. NCQA launched PHQ in 2006 as a voluntary program to evaluate provider measurement program methods. So far, 64 health plans have received certification.

In an acknowledgement that health care purchasers, regulators, consumer groups, regional collaboratives, and information providers (such as Web sites) use such data to identify high performers, NCQA now

enables these types of organizations to apply for PHQ certification.

New CMS Rules Would Pay for E-Visits; Require Hospice Providers to Improve Quality

The Centers for Medicare and Medicaid Services (CMS) recently proposed adding a new reimbursement code for electronic consultations, or "e-visits." The new code, to go into effect in 2009 after a period of comment, would reimburse providers for electronic visits with hospital patients after an initial, in-person consultation. The code is intended for use by providers who are consulted by a patient's attending physician but are not available for a face-to-face encounter.

If this rule is approved, it would be a major endorsement of electronic consultations and could pave the way for other insurers to follow suit.

Another recently approved CMS rule requires hospice providers to implement quality measurement and improvement programs. The rule comes at a time when a growing number of Americans are using hospice care. In 2007, Medicare spent about \$10 billion on hospice care for Medicare beneficiaries, and costs are expected to increase at an annual rate of 9 percent through 2015, according to an [AARP research report](#).

The new rule, which will take effect in December, mandates that hospices allow patients to help choose their treatment plans and demonstrate improvement in areas where they are found deficient. The performance data on hospices might eventually be available publicly; the federal agency already publishes data on the quality of nursing homes, hospitals, and home health agencies.

CMS Awards \$24.5 Million to High-Performing Hospitals

In June, CMS [announced](#) that it had made \$24.5 million in payments to recognize hospitals that excelled on 30 measures of clinical quality. These payments were made as part of a pay-for-performance demonstration program led by CMS and the Premier hospital consortium.

The three-year project involved 250 hospitals, which together serve 1.1 million patients. Premier officials said that, on average, the hospitals achieved a 15.8 percent increase in quality across the 30 measures. In addition, the variation in quality scores between the highest- and lowest-performing hospitals declined.

In a press release, acting CMS administrator Kerry Weems said, "Given these results, it is time to take the next step and implement hospital Value-Based Purchasing for the Medicare program, so that citizens across the nation can benefit from improved safety and quality [and] get the right care, every time."

2008 Health System Scorecard Finds Little Improvement

In the first health system scorecard it released two years ago, The Commonwealth Fund Commission on a High Performance Health System found that the U.S. fell far short of benchmarks for access, quality, efficiency, and other key measures of health system performance. The [2008 edition of the Scorecard](#) paints an even bleaker picture, with the U.S. scoring an average of 65 out of a possible 100 across 37 indicators—slightly below the overall score in the 2006 report.

One of the primary reasons for the system's poor performance is the worsening access to care. In 2007, more than 75 million adults—42 percent of all adults ages 19 to 64—were

either uninsured or underinsured, up from 35 percent in 2003. The Scorecard also found evidence that the billions of dollars spent on U.S. health care are often squandered on administrative costs, inefficient systems, wasteful care, or treatment of preventable conditions. The U.S. also failed to keep up with advances in health outcomes, falling from 15th to 19th among industrialized nations in terms of the number of premature deaths that could potentially have been prevented by timely access to care.

There have been some gains in quality of care, particularly in areas for which there have been national measurement and improvement efforts.

If the U.S. health system achieved benchmark levels of performance, there would be real benefits in terms of health, patient experiences, and savings, the report concludes. For example:

- An additional 37 million adults would have an accessible primary care provider, and an additional 70 million adults would receive all recommended preventive care.
- 100,000 fewer people would die from causes that could have been prevented by good care.
- The Medicare program could potentially save at least \$12 billion a year by reducing readmissions or reducing hospitalizations for preventable conditions.
- If the U.S. were to lower the administrative costs of health insurance to the level found in Germany, which also has a blended public-private health system, the system could save \$51 billion a year. Reaching administrative cost levels achieved in the best-performing countries would save an estimated \$102 billion per year.

Recent Publications of Note

Selected articles on quality improvement from a number of journals, including the *American Journal of Medicine*, *Annals of Internal Medicine*, *Archives of Pediatric and Adolescent Medicine*, *BMJ*, *Health Affairs*, *Health Services Research*, *International Journal for Quality in Health Care*, *Joint Commission Journal on Quality and Safety*, *Journal of the American Medical Association*, *Journal of General Internal Medicine*, *Journal of Patient Safety*, *Journal of Safety and Quality in Health Care*, *Medical Care*, *The Milbank Quarterly*, *The New England Journal of Medicine*, and *Pediatrics*. The articles are nominated by Editorial Advisory Board members from a preselected list.

Health Care Disparities

Effect of Performance Incentives on Hospital Disparities

This longitudinal study sought to determine whether public reporting and pay-for-performance incentives worsen existing disparities between safety net and non-safety

net hospitals. Specifically, it assessed the relationship between performance and percentage of patients covered by Medicaid from 2004 to 2006 at 3,665 hospitals. The authors found that hospitals with high percentages of Medicaid patients had worse performance in 2004 and significantly smaller improvements in performance over time for acute myocardial infarction, heart failure, and pneumonia than those with low percentages

of Medicaid patients. Further, a simulation model suggested that these low-performing hospitals were more likely to incur financial penalties and less likely to receive bonuses. R. M. Werner et al. (2008) [Comparison of Change in Quality of Care between Safety-Net and Non-Safety-Net Hospitals](#). *Journal of the American Medical Association* 299, 2180–2187.

Health Care System Performance

ACP: National Entity Should Produce Comparative Effectiveness Data

In this article, the American College of Physicians (ACP) argues that cost-effectiveness information is "a necessary complement to comparative clinical effectiveness information for all health care stakeholders." It explores the availability and use of information comparing clinical outcomes and costs, concluding that a national entity needs to be charged with producing comparative effectiveness and cost-effectiveness information. Producing both comparative clinical and cost data is important, according to the ACP, because both factors are critical to making health care resource decisions for all stakeholders. American College of Physicians (2008) [Information on Cost-Effectiveness: An Essential Product of a National Comparative Effectiveness Program](#). *Annals of Internal Medicine* 148, 956–961.

Evaluating Cost and Clinical Effectiveness

In this editorial, Gail R. Wilensky reviews the American College of Physicians recommendations on clinical comparative effectiveness. While she supports the use of cost-effectiveness information as an element in decision making by physicians, patients, and payers, Wilensky argues that "it is vitally important to keep comparative clinical

effectiveness analysis and cost-effectiveness analysis separate from each other." G. R. Wilensky (2008) [Cost-Effectiveness Information: Yes, It's Important, but Keep It Separate, Please!](#) *Annals of Internal Medicine* 148, 967–968.

Quality, Cost, and Coverage

As quality improvement, cost containment, and coverage expansion are intricately interwoven goals, health insurance coverage reforms that fail to address the system's quality and cost problems ultimately will fail, the authors write. They discuss three policy options they believe policymakers should pursue: 1) build the evidence base for better decision making in health care; 2) promote the development of more effective and efficient models of care; and 3) marshal efforts to avert dire health and financial consequences from population health problems, such as obesity. In addition, they discuss steps that Congress and others can take to move in this direction. M. O'Kane et al. (2008) [Crossroads in Quality](#). *Health Affairs* 27, 749–758.

Financial Incentive for Quality

Nonpayment for "Preventable Complications"

This commentary reviews the Centers for Medicare and Medicaid Services' policy, effective October 2008, to withhold additional payments to hospitals when Medicare patients develop one of eight "preventable complications." While the authors believe such policies are likely reasonable and just, they argue that to withhold payments, the complications must be important, measurable, and largely preventable. One complication for which "this is undeniably true" is foreign objects inadvertently left in patients after surgery.

However, they conclude, "[n]onpayment for complications that are truly not preventable may destroy trust in quality improvement programs, reduce access for patients at-risk for these complications (e.g., obese patients at increased risk for decubitus ulcers, deep venous thrombosis, and infections may be shunned), reduce the frequency of diagnosis after admission, and misinform the public when safety and quality results are publicly reported." P. J. Pronovost et al. (2008) [The Wisdom and Justice of Not Paying for "Preventable Complications."](#) *Journal of the American Medical Association* 299, 2197–2199.

Patient Safety

Barcoded Medication Administration Could Reduce Errors

While considerable effort has been directed at reducing prescribing errors, none of the proposed solutions targets medication administration errors, which account for 34 percent of adverse drug events. In this commentary, the authors review barcoded medication administration, which uses barcode labeling of medications and patient wristbands to verify medication and patient identification at bedside. Though this approach requires a significant investment in technology, infrastructure, and training, there is growing consensus on its potential safety benefits. "Nurses have long served as the last line of defense against medication errors," the authors conclude. "The health care system must wait no longer to provide them, and all patients, with the systematic safety net that they deserve." D. W. Cescon and E. Etchells (2008) [Barcoded Medication Administration: A Last Line of Defense.](#) *Journal of the American Medical Association* 299, 2200–2202.

Quality Tools in Practice

Do Collaboratives Improve Quality?

For this study, two reviewers systematically examined 72 articles, identified using Medline, Embase, PsycINFO, CINAHL, and Cochrane databases, to evaluate the effectiveness of quality improvement collaboratives in improving care. The authors found the evidence underlying quality improvement collaboratives suggests that they "may have only modest effects on outcomes at best." Because collaboratives play a key role in strategies to accelerate improvement, "further knowledge of the basic components effectiveness, cost effectiveness, and success factors is crucial to determine the value of quality improvement collaboratives," the authors conclude. L. M. T. Schouten et al. (2008) [Evidence for the Impact of Quality Improvement Collaboratives: Systematic Review.](#) *BMJ* 336, 1491–1494.

Collaboratives' Effects Are Hard to Measure

This editorial reviews the article by Schouten and colleagues, which found limited evidence supporting the effectiveness of quality improvement collaboratives. Yet, collaboratives are one of the most popular methods for organizing improvement efforts at hospitals and ambulatory practices worldwide, and "have improved care and saved many lives at participating hospitals," writes the author. He notes that these positive effects might have been missed, possibly due to the limitations of the studies or the inability of traditional biomedical research methods to sufficiently evaluate quality improvement collaboratives. P. K. Lindenauer (2008) [Effects of Quality Improvement Collaboratives Are Difficult to](#)

Measure Using Traditional Biomedical Research Methods. *BMJ* 336, 1448–1449.

Intervention's Ability to Improve Sepsis Care Limited

This study assessed whether a national educational program improved physician and nursing staff's ability to recognize and treat severe sepsis and septic shock. Staff were trained to complete two treatment bundles: a resuscitation bundle, with six tasks to begin immediately and be completed within six hours, and a management bundle, with four tasks to be completed within 24 hours. The intervention decreased patients' risk of hospital mortality and improved compliance with processes of care for both the sepsis resuscitation and management bundles. Long-term follow-up showed that the improvement in the resuscitation bundle lapsed within one year, though sepsis management and gains in mortality held over time. R. Ferrer et al. (2008) [Improvement in Process of Care and Outcome After a Multicenter Severe Sepsis Educational Program in Spain](#). *Journal of the American Medical Association* 299, 2294–2303.

Increasing Adherence to Practice Guidelines

A demonstration project sought to determine whether a multicomponent intervention could promote the translation of research findings into primary care practice. Conducted from Jan. 1, 2003, to June 30, 2006 at 99 practice sites, this improvement model used performance reports (audit and feedback), site visits for academic detailing and participatory planning, and network meetings for sharing of best practices to enhance adherence to practice guidelines across eight clinical areas. The project resulted in clinically and statistically significant improvements for 29 of 36 quality measures, suggesting that this approach "can have a robust impact in quality of care for

Americans seen in primary care practices," according to the authors. S. Ornstein et al. (2008) [Improving the Translation of Research into Primary Care Practice: Results of a National Quality Improvement Demonstration Project](#). *Joint Commission Journal on Quality and Patient Safety* 34, 379–390.

Engaging Physicians in Decreasing Overuse

The authors describe a project, designed as a proof of concept for their model to reduce overuse of services, that decreased the overuse of fiberoptic laryngoscopy among otorhinolaryngologists. Based on both the project's success and their prior experience with individual practitioner pay-for-performance, they conclude that judgmental programs, such as the use of an efficiency index to measure physician performance, tend to interfere with quality improvement. "They score but do not support physician work and therefore are perceived by physicians as disempowering," the authors write. The approach they tested, in contrast, identified wasteful practices and engaged physicians in changing them. R. A. Greene et al. (2008) [Beyond the Efficiency Index: Finding A Better Way to Reduce Overuse and Increase Efficiency in Physician Care](#). *Health Affairs* Web Exclusive, May 20, 2008 w250–w259.

Study: Hospital Mortality More Likely for Patients Managed by Critical Care Physicians

Patients admitted to ICUs are believed to benefit from the care of specially trained critical care physicians, though evidence of this is scant. A retrospective analysis was used to examine the association between critically ill patients' hospital mortality and their management by critical care or non-critical care physicians. This study assessed the outcomes of 101,832 critically ill adults, treated at 123 ICUs in 100 U.S. hospitals,

and found that patients receiving critical care management (CCM) were generally sicker, underwent more procedures, and had higher hospital mortality rates than those who did not receive this care. Further, "[a]fter adjustment for severity of illness and propensity score, hospital mortality rates were higher for patients who received CCM

than for those who did not," the authors write. They conclude that additional studies are needed to clarify the mechanisms by which these results might occur. M. M. Levy et al. (2008) [Association Between Critical Care Physician Management and Patient Mortality in the Intensive Care Unit](#). *Annals of Internal Medicine* 148, 801–809.

Special thanks to Editorial Advisory Board member Paul Schyve, staff at the ABIM Foundation, and Stu Guterman, assistant vice president for The Commonwealth Fund's Program on Medicare's Future, for their guidance with this issue.

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Citation

Quality Matters: Quality Improvement or Research?, July/August 2008, The Commonwealth Fund, Vol. 30