AMERICAN HEALTH CONSULTANTS
HOSPITAL PEER REVIEW®
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28

IN THIS ISSUE

FEBRUARY 2003

VOL. 28, NO. 2 (pages 17-28)

JCAHO: Serious nosocomial infections are sentinel events, RCA necessary

Emphasis on infection control part of JCAHO's patient safety focus

Serious nosocomial infections should be considered sentinel events and thoroughly investigated, according to new information from the Joint Commission on Accreditation of Healthcare Organizations. This interpretation could lead to a significant increase in the number of sentinel events for any health care provider, though it may not be possible to reach the same conclusions with a nosocomial infection as with other sentinel events.

The new interpretation on nosocomial infections comes as the Joint Commission is raising the profile of infection control, part of its continuing emphasis on patient safety. The Centers for Disease Control and Prevention (CDC) also has put more focus on hospital-acquired infections, a departure from its longstanding position that infection rates within a given benchmark range were more or less acceptable. Instead, the CDC — under the direction of veteran health care epidemiologist Julie Gerberding, MD — now is emphasizing the importance of striving for zero infections.[1] The Joint Commission is in the process of making a similar paradigm shift, particularly in its view of serious hospital-acquired infections, says **Paul Schyve**, MD, Joint Commission senior vice president.

"We have specifically begun discussing exactly that issue," Schyve says. "If a patient dies in a hospital or has a permanent disability as a result of a nosocomial infection, the hospital really should think about that as a sentinel event and treat it and evaluate as such. When the outcome is that serious, it is not the same as saying, 'Let's add these [infections] up and look for trends and patterns.' It is, in fact, a sentinel event. Everybody understands that there are nosocomial infections that occur, [but] it seems that people haven't perhaps thought of them in quite those terms. We will be urging people to think of it that way."

As part of that emphasis, the Joint Commission plans to advise accredited organizations in the near future that nosocomial infections resulting in death or serious injury also should be reported to the Joint Commission's database.

Quality improvement professionals may find Schyve's advice difficult to implement, says **Patrice Spath**, RHIT, a consultant with Brown-Spath & Associates in Forest Grove, OR. Spath says she supports the basic idea of paying more attention to nosocomial infections in hopes of preventing future problems and expects that other quality improvement professionals would be willing to analyze serious nosocomial infections as well. But she wonders how many hospitals will report nosocomial infections as sentinel events to the voluntary database when many already opt out of reporting more clear-cut situations. Adding serious nosocomial infections to the list won't change anything for those organizations, she says.

Hospital Peer Review® (ISSN# 0149-2632) is published monthly, and **Discharge Planning Advisor**™ and **Patient Satisfaction Planner**™ are published quarterly, by American Health Consultants®, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals postage paid at Atlanta, GA 30304. POSTMASTER: Send address changes to **Hospital Peer Review**®, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information

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Subscription rates: U.S.A., one year (12 issues), $429. Outside U.S., add $30 per year, total prepaid in U.S. funds. Two to nine additional copies, $343 per year; 10 to 20 additional copies, $257 per year. For more than 20 copies, contact customer service for special handling. Missing issues will be fulfilled by customer service free of charge when contacted within 1 month of the missing issue date. **Back issues**, when available, are $72 each. (GST registration number R128870672.)

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Spath also is concerned that nosocomial infections, by their nature, are difficult to trace back to a root cause. That might mean that even the most well-intentioned organizations won't be able to investigate them as thoroughly as with other sentinel events, and they won't come up with conclusions that are as practical and usable.

"One challenge with nosocomial infections is that these tend to be patients with a host of illnesses anyway, usually very compromised patients. So it would be very difficult to say this patient had congestive heart failure, diabetes, and a host of other things, but then he got pneumonia and that's why he died," she says. "And it's difficult to say that this patient died because a specific nurse on the night shift didn't wash her hands. You usually can't pin it down that much."

That doesn't mean that a nosocomial infection shouldn't be thoroughly investigated when it leads to patient harm, Spath says, but putting the "sentinel event" label on it may be counterproductive.

"The sentinel event label makes it sound like something that was preventable, and a nosocomial infection may or may not be preventable," she says. "And too often, when we put a label on something, people end up arguing about the label and they miss the point. They forget the goal of why you put the label on it."

Spath notes that the National Quality Forum eliminated nosocomial pneumonia from its proposed list of quality measures because there was insufficient evidence of predictability, meaning it was difficult or impossible to determine the root cause in many cases. Adjusting for the patient's risk also made investigating pneumonia difficult, the group said.

The best approach may be to broaden your organization's parameters for what adverse incidents are considered for root-cause analysis, Spath says. Most hospitals have a system in which significant events are reviewed by a committee or ad hoc group that determines whether a root-cause analysis is in order, so Spath says nosocomial infections should be referred to them.

"Broaden your thinking about which events go to that group for consideration for a root-cause analysis," she says. "Let the sorting out happen at that level. If you have a perfectly healthy 35-year-old in for routine surgery and he dies from septicemia, I might consider that a sentinel event that needs investigation. If it's an immunosuppressed cancer patient who dies from an infection, what would be the value of a root-cause analysis in that case?"

Spath suggests including an infection control practitioner (ICP) in that preliminary review, or including one even earlier to help decide which infection cases should go to the committee for review.

"There are so many factors involved in whether they get the initial infection and how it affects them that it would be impossible to say all patients who die from a nosocomial infection should get a root-cause analysis," she says.

Screening also can occur in physician mortality reviews, she says. You might want to ask physicians to include another question on their mortality review forms — asking if the case would benefit from a root-cause analysis to determine how future nosocomial infections of this type could be prevented. In many cases, the physicians will note that there is nothing to be learned from the infection, she says, but the cases they recommend might be especially meaningful. It might be necessary to educate the physicians more about root-cause analysis.

"If physicians don't see the root-cause analysis as a punitive activity but as a positive, then they might be the best screeners to determine which cases might benefit from a closer look," she says.

The Joint Commission convened the first meeting of a special task force on infection control recently, after ICPs protested a proposal to consolidate and reduce the number of infection control standards in 2004, when the commission plans to implement its ambitious Shared Vision/New Pathways accreditation program.

The Shared Vision program represents one of the most comprehensive revisions of the accreditation process the Joint Commission has ever attempted. The changes are nothing less than "revolutionary," says **Dennis O'Leary**, MD, Joint Commission chairman. "The net effect of these changes will be to substantially increase the relevancy of the accreditation process to health care organizations and to direct even greater attention to improving patient safety and health care quality," he says. "We [have] operated, in part, out of a black box. I mean, the organizations knew what the standards were. They knew what the intent was, but they weren't sure exactly what the surveyors were looking at and how they were being scored for their compliance on the standards. Now, it's all transparent."

The infection control aspect of the new approach will be added after the considerations of the newly formed task force, a panel of about 20 members that will include ICPs, epidemiologists, other clinicians, and administrators, Schyve says. But what began as a flap over standards has now opened up into a much wider discussion about infection control and what many believe is its key for survival — accreditation requirements by the Joint Commission.

Reference

1. Gerberding JL. Hospital-onset infections: A patient safety issue. *Ann Intern Med* 2002; 137:665-670. ■

Six Sigma boosts quality with ongoing analysis

QI strategy promises to improve quality, finances

Quality managers in health care are hearing more about Six Sigma, the quality improvement strategy that has been taking hold in other industries for years now, and the statistics-focused techniques promise great improvements for hospitals and other providers.

One of the greatest benefits, proponents say, is that you can improve quality while improving your employer's bottom line.

Chances are good you've heard of Six Sigma, but unless you've actually employed it already, you might not know much about what it can do in a health care setting. The basic concept won't be foreign to peer review professionals who have used quality improvement/total quality management (QI/TQM), but Six Sigma is different in some significant ways. In a nutshell, Six Sigma is a quality initiative that tries to reduce variation in a system or process, says **Mary Williams**, vice president of AON Management Consulting in East Hartford, CT, which takes the Six Sigma process to health care clients. Six Sigma started out in more nuts-and-bolts industries, so some health care leaders balk at using a process designed to reduce variations, she says.

"They say health care isn't the same as manufacturing widgets, so you can't standardize the process to eliminate variation," she says. "But in fact, with Six Sigma, we're trying to reduce the unnecessary variation so you get a more standardized procedure that reduces costs and time while improving quality."

The whole Six Sigma strategy is aimed at reducing errors, and the name actually is an analytic

term that means having 3.4 defects per million opportunities, the ultimate for most processes.

"So you're talking about a very low defect rate," Williams says. "That is definitely a goal that health care providers are striving for already, and Six Sigma is proving to be an effective way to reach that goal."

Though the concept is based on that ultimate goal of 3.4 defects per million, not every Six Sigma project has to strive for that level of near-perfection. Depending on the particular process, it might be sufficient to work toward four sigma or five sigma — in which each lower level represents a tenfold increase in the error rate.

Heavy on statistics

The process is focused on statistical analysis, more so than QI/TQM or other quality improvement efforts, says **Andy Mayfield**, managing director with North Highland, a business performance and technology consulting company, in the Atlanta office.

"Six Sigma is a very disciplined tool that puts a much higher degree of emphasis on both measurement of processes and the improvements being made on those processes," Mayfield says. "Two things are unique about Six Sigma. The first is the emphasis on the customer and how processes impact the customer. The second is the high degree of rigor around how we design measurement systems for processes. Those measurement systems are geared around identification of defects that inhibit both the customer experience and the process performance."

Six Sigma is based on the idea that if you measure how many "defects" you have in a process, you can systematically determine how to eliminate them and get as close to "zero defects" as possible. Six Sigma training levels are similar to those in karate, with a "black belt" and "master black belt" being the two highest levels of training and the green belt level being the starter level.

Most Six Sigma projects are either process improvement or process redesign. Mayfield explains that for process improvement — used when a product or service is not meeting customer expectations or performing adequately — the major steps are:

- **Define the project**. Clarify the project's purpose and scope and get background on the process and customer.
- **Measure the current situation**. Focus the improvement effort by gathering information on the current situation.
- **Analyze to identify causes**. Identify root causes and confirm them with data.
- **Improve**. Implement solutions and evaluate results. Develop, try out, and implement solutions that address root causes. Use data to evaluate both the solutions and the plans used to carry them out.
- **Control**. Standardize and make future plans. Maintain the gains by standardizing work methods or processes. Anticipate future improvements and preserve the lessons from this effort.

For process redesign — used to design a new process or redesign a process that cannot meet customer requirements through improvement — the steps are define, measure, analyze, define, and verify. Those steps are similar to the steps for improving a process, but they include developing alternative concepts and transitioning the new process into the organization.

Data are everything for Six Sigma. As Williams says, "If it doesn't get measured, it doesn't get managed." She offers this example of how Six Sigma can be used in health care: The first step in any project is defining the problem. In this case, the organization determines that the cost of hip replacement procedures is too high. The "customers" — clinicians are the internal customers, and patients are the external customers — don't want to sacrifice any quality when you cut costs. So the next step in the Six Sigma process is to measure what you're doing so far. The Six Sigma team, made up of either your internal Six Sigma experts or the consultants who will work with your quality professionals, start by measuring what you currently do with hip replacements.

"We'll look at costs and outcomes over the past year and ask why costs are so high," she says. "We'll look for the major drivers and brainstorm, saying we *think* these are the primary reasons for the high cost. But then we'll go and collect data to see if the data support what we think."

In this example, the team finds that room costs and operating costs are the major drivers. Then the team asks how it can get the cost to where it should be. Creative solutions are found and implemented, and analyzed to see if they worked. Then the final step, control, comes into play. Unlike some other quality initiatives, Six Sigma emphasizes ongoing analysis after the implementation, after it seems that the problem has been solved.

"We want to keep the gains," Williams says. "We may have reduced the costs and kept quality high, but we don't want to come back a year later

Six Sigma boosts revenue, reduces outpatient wait time

Results achieved without adding new equipment

Six Sigma proved useful for the Department of Radiology at California's Stanford University Medical Center, which recently announced that it has been able to substantially boost revenue and reduce outpatient wait time without adding new equipment. **Marcia Maihack**, director of radiology, says Stanford not only increased projected department gross billings by $8 million, it also increased computerized tomography (CT) and magnetic resonance imaging (MRI) revenue by more than $2.6 million and reduced CT outpatient appointment wait time from six to eight weeks to one to two days.

Stanford worked with Six Sigma consultants from GE Medical Systems Healthcare Services in Los Angeles.

The results are part of a broader and ambitious three-year digitization and improvement initiative launched in May 2000. Using Six Sigma quality methodology, the goal was to move Stanford's 594-bed adult hospital, a children's medical center, and an outpatient facility to an all-digital or filmless imaging environment.

"Stanford prides itself on delivering high-quality patient services through the use of state-of-the-art technology and innovative techniques. Our MRI and CT departments are renowned for innovation, but we are always seeking to improve," Maihack says.

"With GE's Six Sigma process, we found opportunities to reduce our backlog and increase throughput both in CT and MRI. Since implementing the changes, patients no longer wait weeks for an appointment," she explains.

Gary Glazer, MD, professor and chairman of the department of radiology, says the rigor of Six Sigma and the expertise of the combined Stanford and GE teams enabled Stanford to complete several customized projects that led to impressive results, including faster report turnaround time and better throughput in the MRI, CT, and computed radiography/orthopedics imaging areas.

"In an environment where our scarcest asset is people, due to a shortage of technologists and radiologists, I am delighted we were able to increase productivity and reap satisfaction from delivering better patient care," Glazer says. "Stanford's goal is to seek additional opportunities for major improvement as the digital transformation of the department is completed this year." ■

and see higher costs. So we determine what needs to measured on an ongoing basis." **(For an example of how Stanford University used Six Sigma in a quality improvement project, see box, above.)**

One key difference from other quality improvement efforts is that using Six Sigma can be a major undertaking. Unless you have special training yourself, you almost certainly will have to bring in consultants who specialize in the kind of sophisticated statistical analysis that makes up the bulk of Six Sigma work.

To really make Six Sigma work, senior leadership in the health care organization should support the effort, Williams says. Six Sigma can take a good deal of time, effort, and money, so it helps if senior leadership staff are involved in designating projects and assigning resources, she says.

"This can be a fairly major undertaking, so you want to be sure that you're using the resources wisely," she says. "We like to see senior leadership involved so that we're addressing the problems that will really have an impact on the organization. You don't need to use Six Sigma to clean the back stairs."

Six Sigma is a quality improvement tool, but Mayfield says it can have a significant impact on the organization's financial health. The key, he says, is to link the quality improvement goals to the organization's strategic goals.

"The Six Sigma measurement tools give you a clear path so you can begin to link the strategic direction of the overall organization, and the goals associated with that, to the process improvement activities of the project you're working on today," he says. "The tools help you determine whether your process improvement is aligned with that larger strategy, misaligned, or not affecting the overall strategy at all."

Mayfield says financial savings should be a significant component of every Six Sigma project in health care, even though that may not be the goal initially. The statistical analyses help you find a way to achieve your initial, immediate goal while also positively impacting the organization's overall financial health, he says.

"When you can bring that component along with the other goals, it's easier to get the leadership support you need, because finance is such a big component of their responsibilities," Mayfield says. "They can see patient satisfaction increasing all the time, but if it doesn't have a connection to the financial, it loses some of its value. You can satisfy customers all the way to bankruptcy."

For those who have never used Six Sigma before, Mayfield says how you start will depend on your situation. In the first scenario, the Six Sigma idea is highly supported by the leadership team, and the quality improvement leaders are willing to drive the Six Sigma process. The organization's culture is ready for a significant change. "That's what you find when an organization is facing significant financial difficulty, or a problem in the industry," he says. "Everyone has their attention focused on survival. The leadership is willing to drive this, rather than just support it."

In that situation, Six Sigma can be implemented on a wide scale, training a large number of organization leaders and tackling large problems right away. On the other hand, your organization might not be too eager to embrace Six Sigma. If you think it's a good tool but not sure Six Sigma can really take hold in your organization, Mayfield says the best approach is to be very focused. Start with a highly critical process, one that you know can be improved with the right focus and one that will have a material impact on customers and on process performance.

"Focus on people within that business who are the known quantities, the ones you know you can rely on and who know the process, people who are willing to support the effort," he says. "Do those projects one at a time, build people's skills in Six Sigma, and move on to the next one. Build credibility with each project."

Mayfield says the biggest mistake he sees with Six Sigma is trying to bite off more than you can chew. "Beginners sometimes try to tackle something far too big, something with multiple root causes that they're not prepared to address," he says. "Without some experience in Six Sigma, it's difficult to take those apart and address them in small enough chunks to manage them through completion. You end up doing the work without really solving the problems."

Another common mistake is attacking symptoms without finding the root causes. "You never get done because you treat the symptoms and then something else pops up because you haven't addressed the root cause," Mayfield says.

Six Sigma consultants specialize in the statistical tools that are key to the strategy, but many will train you in those analytical skills so that you can carry on after they leave.

"What we do typically is go in and train the people in a hospital who need to work on these projects," Williams says. "It's usually four weeks of training, working with whoever is involved with the process at hand, people from all levels of the organization. Part of the Six Sigma culture is that you become skilled in using these statistical tools, and you progress through levels."

Williams and Mayfield both say that Six Sigma is not something you can tackle on your own if you have no experience with it, but it certainly is something you can learn with help from experts. You may have to hire consultants at first, but eventually any quality improvement professional can become the in-house expert on Six Sigma and direct projects without outside help.

"Our goal is to transfer the technology," says Williams. "You can't just go and read a book and do this, but we train others to become the in-house expert. Ideally, that should be someone considered for senior leadership, with good leadership skills and able to persuade people to do things differently. Six Sigma black belts are usually in the top 10% of their organizations, either because they started out there or because Six Sigma helped them get there."

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Reader Question

Think how records might be used before discarding

Accreditation, legal concerns factor into decision

Question: How long do we need to keep quality improvement (QI) and peer review documents before tossing them out? I'm thinking of department or team QI reports, minutes from QI meetings, peer review worksheets with no adverse findings, and similar documents. We're trying to implement a policy of discarding these materials after two years to free up storage space.

Answer: As with most questions about document retention, there is no easy, absolute answer to when you can discard those materials. Many

experts advise holding on to the records as long as you can, just to be safe, but the best advice is to consider carefully how each of the documents might be used in the future and let that guide your retention policies, says **Matthew Rosenblum**, chief operations officer for privacy, quality management, and regulatory affairs at CPI Directions, health care consultants in New York City.

He suggests you consider three areas in which you might possibly need those documents in the future: clinical, legal, and accreditation.

From a clinical standpoint, peer review requires providing the reviewer with enough longitudinal information to track a physician's performance over time. "So you really don't want to be throwing this information out every two years," he says. "If that information is going to be valuable to the peer review process, you have to keep it for some length of time, certainly longer than two years."

For legal concerns, Rosenblum says you must consider how long the records could be useful in a malpractice case. "If an infant is discharged tomorrow, that infant has 21 years to come back to the hospital with a lawsuit," Rosenblum says. "So the hospital must keep some records that long, but I'm not suggesting you keep all your peer review records that long. Some will be helpful, however, in the context of substantiating why treatment occurred as it did. If the prosecuting attorney wants to know how the hospital determined that the doctor was providing good care, you might want to show the peer review records."

How much of that information you keep around "just in case" depends a lot on the type of care you provide. Long-term care facilities or others considered at low risk for lawsuits can be more liberal in what they discard, he says. An acute-care provider should be more cautious.

Accreditation concerns also will guide how long you keep some peer review and QI documents. The Joint Commission on Accreditation of Healthcare Organizations and other accreditors will expect to see a longitudinal analysis of physician practices, so documents must be kept for some time. Rosenblum notes, however, that you don't necessarily have to keep all the original documents or entire documents. In many cases, the records or the pertinent information from individual records can be recorded in computer files or otherwise summarized. Information can be integrated into an intermediate trend analysis that will preserve the data for long-term study.

He makes these other recommendations:

- **Consider the experience level of your physicians.** A teaching facility or a provider with generally less experienced physicians may need to keep peer review documents longer than other providers. The chance of a future lawsuit is increased, and you need the trend data to measure quality.
- **High-risk or unusual medical procedures could require longer retention.** Questions are more likely to arise about high-risk or unusual procedures. Even routine but potentially risky activities, like medication administration, should be considered for longer record retention.
- **Avoid inflexible rules about when to discard records.** Life would be easier in some ways if you could just say "keep everything for five years and then throw it out." But simple is rarely the best way to go. Some records must be kept longer than others.
- **Look for duplication of records.** Even for important information that must be retained, you don't need multiple copies. For instance, you might have QI reports or trend information attached to monthly meeting minutes, but the same reports are in an individual's file. "In that case you could throw out the meeting minutes three or four years down the road, but maybe not the original report if it has to do with a physician's performance."

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Public to get inside scoop on quality of providers

Information to be posted on CMS web site

Before long, the public will gain access to information on the quality of health care that previously was available only to those on the inside. The federal government will begin publishing data this summer.

Launched by the American Hospital Association (AHA), the Federation of American Hospitals (FAH), and the Association of American Medical Colleges (AAMC), the plan is voluntary, but health care quality leaders are encouraging hospitals to participate. The U.S. Department of Health and

Human Services will collect and post data on how hospitals treat patients with acute myocardial infarction, heart failure, and pneumonia. Rather than focusing on survival rates, the reports will indicate how well hospitals comply with 10 performance measures for the three conditions. For instance, the reports will indicate whether hospitals consistently treat patients with aspirin after heart attacks, and whether pneumonia patients receive antibiotics in a timely fashion.

The information will be posted on the web site of the Centers for Medicare & Medicaid Services. Hospitals already collect the data and report it to the Joint Commission on Accreditation of Healthcare Organizations, and they must give permission for the information to be reported publicly. A 1986 effort was met with considerable resistance, but many organizations are urging hospitals to participate in the new effort.

Kenneth W. Kizer, MD, MPH, president and CEO of the National Quality Forum (NQF), endorses the effort. In October 2002, the NQF board of directors endorsed 31 hospital care performance measures, and a second group of measures currently is under consideration by NQF, he says. The endorsed measures constitute the first-ever set of national voluntary consensus standards for hospital care quality.

The consensus standards in the first group of measures cover six care areas: cardiac-related (acute coronary syndrome and heart failure), pneumonia, pregnancy / childbirth / neonatal-related, pediatric-related, surgical complications, and smoking cessation. The second group of proposed measures will expand the measures in these six areas and also cover hospital-acquired infections, Kizer says. "The NQF is strongly committed to making health care performance information available to the public. This initiative is a good first step toward making standardized and comparable performance information available to patients, patients' families, and other stakeholders."

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NCQA releases draft standards for research

Program seeks to promote self-evaluation

The National Committee for Quality Assurance (NCQA) recently released draft standards for its Human Research Protection Accreditation Program (HRPAP) for public comment. The new program is designed to ensure that rigorous processes are in place to protect and inform volunteers in clinical trials and other research.

Margaret E. O'Kane, NCQA president, says an explosion in the volume of medical research, drug trials, and other studies involving human subjects over the past 10 years has increasingly overwhelmed existing programs' capacity to ensure that studies' risks and benefits are thoroughly weighed, that volunteers are adequately informed, and that adverse events are disclosed.

"We all benefit from advances in research," she says. "But we need to ensure that the good intentions of researchers are translated into robust processes for protecting the volunteers who make progress possible. Accreditation will help ensure that protecting volunteers is paramount."

NCQA developed the nation's first HRPAP in 2001 for the Department of Veterans Affairs (VA). The draft standards are based on the VA standards and NCQA's experience in accrediting research efforts conducted at VA Medical Centers.

The new program is designed to address other governmental and nongovernmental entities where research takes place, such as hospitals, medical schools, and pharmaceutical firms, and for independent institutional review boards (IRBs) that review, but do not conduct, research. The standards are organized into four domains: organizational responsibilities; IRB structure and operations; consideration of risks and benefits; and informed consent. NCQA's program is designed to promote self-evaluation and continuous quality improvement (QI) and is equally applicable to research organizations and IRBs.

Calls for more formal research oversight processes also have come from within the research community itself. "Progress in medical and other research is contingent on people's confidence in the systems we have established to protect them," says **Mary Faith Marshall**, PhD, professor of medicine and bioethics at the University of Kansas Medical Center in Kansas City. "NCQA's HRP Accreditation Program will help restore people's confidence and ensure that our protections are strong."

The bulk of an accreditation review will be conducted via the Standards, Guidelines and Assessment Tool (SGAT), a web-based application. The SGAT for human research protection will provide

organizations with the means to assess their readiness for an accreditation review, and to identify areas where improvement is needed. Once an organization has committed to a review, the SGAT is used to transfer and store documents on-line, minimizing an organization's preparation efforts and resulting in rapid turnaround time for accreditation decisions. Also, upon completion of the on-site portion of the review, the SGAT will allow organizations to receive detailed performance reports, which they can use to advance future QI activities. The draft HRPAP standards and instructions for submitting comments are available at NCQA's web site, www.ncqa.org.

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How's your outpatient 'continuity of care'?

By **Patrice Spath**, RHIT
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Evaluating the continuity of patient care in ambulatory health care services is challenging. Continuity of care implies the progression of a predetermined plan for health care services without disruption of the plan. However, the ambulatory care client, unlike the hospitalized patient, is not as easily controlled, monitored, or guided through health care processes. For this reason, the client of ambulatory care must be a more active player in the health care process if it is to be successful. Traditional continuity measures have included counts of the number of:

- missed appointments that are not further reviewed or evaluated for trends;
- scheduled laboratory tests or imaging procedures that never occur;
- results of testing services that never find their way into the medical record or at least are not posted in a timely manner;
- lack of documentation of clinical findings in the medical record, including not signing and dating the entry by the physician or other clinicians.

Three other quality monitors also may effectively evaluate continuity of care in the ambulatory care program, depending on the nature of the care required or offered and the setting of the program. These are monitors of:

- referral for consultation by a specialist without adequate documentation of clinical findings and test results;
- referral for surgery or hospitalization without the aforementioned documentation;
- inadequate medical record documentation where there is a multiphysician staff rotation or where medical residents rotate through the ambulatory care program every several weeks.

As health care networks expand to encompass a variety of settings, the concept of continuity of care also should expand. In integrated delivery systems, evaluating continuity requires quality management systems that extend from outpatient services to the inpatient environment, if necessary.

Departments that provide outpatient care must constantly monitor the flow of the patient and communications about that patient's care in an effort to avoid interruptions in the care process. Many ambulatory units telephone patients the day before their scheduled appointment to remind them of the appointment and then contact them again the day after the treatment to inquire about the outcomes of treatment. Staff should contact patients who miss scheduled appointments to determine why the appointment was missed and arrange for rescheduling. Ambulatory care units also can evaluate wait times between the arrival of the client and the initiation of treatment intervention or the start of therapy. Such data can be used to identify and eliminate events that cause clients to leave prior to treatment.

Appropriateness reviews of prescribed treatments, tests, or referrals can be used to identify quality of care concerns as well as continuity of care problems. High on the quality evaluation list should be the measurement of client satisfaction as an important aspect of continuity of care. If clients are not satisfied, they are likely to seek care from another provider or discontinue treatment entirely.

Many measures of continuity are applicable to any setting or service; however, departments also should focus evaluations on issues of particular importance to their unit and the clients served. For example, the durable medical equipment (DME) service provides in-home care and services including IV infusion therapy, oxygen therapy, and all types of medical equipment support (wheelchairs, walkers, hospital beds, etc). To evaluate continuity of care, the DME service can measure client satisfaction with continuity of care issues, e.g., Was the equipment timely in arriving? Were instructions adequate? Was service unnecessarily interrupted for any reason? If questions arose after the initial installation, did the client receive timely and appropriate responses? Was there adequate medical intervention when the DME service needs of the client changed? Were equipment vendors responsive to the medical and emotional needs of the client? Early identification of quality problems in these potentially problematic areas can reduce or eliminate continuity of care concerns.

Ambulatory care departments such as outpatient physical and occupational therapy can monitor clients' utilization of services as a measure of continuity of care. By evaluating such issues as client/therapist ratios, rehabilitative services can identify potential overcrowding problems that may cause clients to seek services elsewhere. Home care services also can evaluate over- and underutilization as a measure of continuity of care. Clients should be accepted for home care only if needed services are available. If the services needed for appropriate continuity of care are not available through the home care department, then an alternative care program must be found to assure that care is not interrupted. Home care personnel should visit clients within 24 hours of receiving a referral. Evaluating compliance with this standard is a measure of continuity of care.

The outpatient oncology service can evaluate patient care continuity by monitoring patient treatment plans and goals, e.g., Is the care plan complete and up-to-date? Is goal accomplishment realistic? To ensure continuity, the oncology staff constantly must evaluate the efficiency of communication between inpatient providers and their outpatient counterparts. There are times when interruptions in the treatment process are unavoidable. However, each case should be reviewed independently with the department's performance standards in mind. Staff in oncology services also must be sensitive to the patient's clinical and emotional needs. Through early identification of treatment interference problems, staff can encourage the patient to keep returning for care until the designated plan of treatment is completed. An important measure of quality is patient/staff communication. Patients and families must know what their responsibilities are in the treatment process. Is the treatment active or passive? Do they need constant supervision, or can they continue the treatment with minimal help, once instructed? If these matters are not addressed proactively, continuity of care and health care problem resolution can be adversely affected.

Outpatient labs play a vital role in preserving continuity of care. For example, patients receiving chemotherapy or radiation can be adversely affected by poor quality lab services. The length of time between blood draws and reporting of the test results to the respective physician are important performance measures for the laboratory. Tests results must be available quickly to assure that

CE *questions*

5. Six Sigma is an analytic term that means what?
   A. eliminating all human error
   B. automating systems whenever possible
   A. having 3.4 defects per million opportunities
   D. instituting continuous quality improvement
6. Which of the following is not a major step for process improvement under Six Sigma, according to Andy Mayfield, managing director with North Highland in Atlanta?
   A. define the project
   B. revise original estimates
   C. analyze to identify causes
   D. measure the current situation
7. Using Six Sigma, the Department of Radiology at California's Stanford University Medical Center was able to increase projected department gross billings by $8 million.
   A. true
   B. false
8. List the region of the United States represented with the highest number of benchmark hospitals in Solucient's 100 Top Hospitals National Benchmarks for Success study.
   A. North Central region
   B. Northeast
   C. West
   D. Southern region

Answers: 5. C; 6. B; 7. A; 8. D

doses of chemotherapy or radiation are accurate to the patient's needs. The outpatient labs can evaluate the quality of the specimen collection process through periodic assessments of the behavior of collection personnel, compliance with patient identification procedures, appropriateness of specimen choice in relation to the test ordered, and specimen rejection rates. These performance measures provide important data about the quality of laboratory services and help to identify issues that can affect continuity of care.

Continuity of patient care is an important component of effective performance in ambulatory services. Outpatient providers should measure important aspects of care to identify issues that can create undesirable lapses in health care services. Managers of departments that provide care to outpatients should ensure that mechanisms are established to maintain continuity of care as patients enter or leave the department. Patients must be provided with pertinent information as they move through the health care delivery system. Care must be coordinated among health care professionals through effective sharing of important information as the patient receives services in different levels of care. ■

Meeting top performance levels could save lives

Solucient releases 100 Top Hospitals study

If overall performance in all acute-care U.S. hospitals were the same as the nation's top hospitals, close to 57,000 more patients could survive each year and nearly $9.5 billion in annual expenses could be saved, according to a new study.

Solucient's 100 Top Hospitals National Benchmarks for Success, a study released recently, recognizes 100 hospitals for setting national performance benchmarks across four critical areas: quality of care, operational efficiency, financial performance, and adaptation to the environment. The study found that the number of medical complications could decrease by more than 18% for patients in nonwinning or "peer" hospitals, affecting more than 150,000 patients annually, if those hospitals improved to the winning or "benchmark" performance level. If all hospitals operated at the benchmark level, a patient's average length of stay could show a marked decrease, says **Jean Chenoweth**, executive director of Solucient's 100 Top Hospitals program.

"Winners of the 100 Top award have demonstrated superior performance across their hospital as a whole by successfully balancing quality of care with operational and financial performance to better meet community needs and assure improvement of outcomes for patients, while adapting to external constraints and pressures," she says. "In short, these hospitals are able to bring increasingly better services to their patients and provide great value to their communities, despite the growing pressures of an aging population and tighter reimbursements."

Winning hospitals treat more and sicker patients than nonwinning hospitals, admitting an average of almost 16% more patients and maintaining higher patient-case mix than peer hospitals. The 100 Top Hospitals provided more successful outcomes, helping patients survive life-threatening illness 10% more often than their peers. Winning hospitals employ fewer staff, but offer nearly $2,000 more per employee in annual salary and benefits than do peer hospitals. A recent related Solucient study indicated that benchmark hospitals tend to maintain higher ratios of registered nurses to inpatient days. Total profit margins for winning hospitals are twice that of their peers. However, benchmark hospital revenue tied to outpatient services is lower than at peer hospitals.

The Southern region represents the highest number of benchmark hospitals (31), followed by North Central region (29), Northeast (26), and West (15). "Our results indicate that winning hospitals are achieving success through routine measurement of key performance indicators and collection of accurate internal and comparative information," Chenoweth says. "These hospitals appear to understand that a focus on daily organizational and clinical processes in combination with sound strategic decision making assures better patient outcomes and greater organizational efficiency." ■

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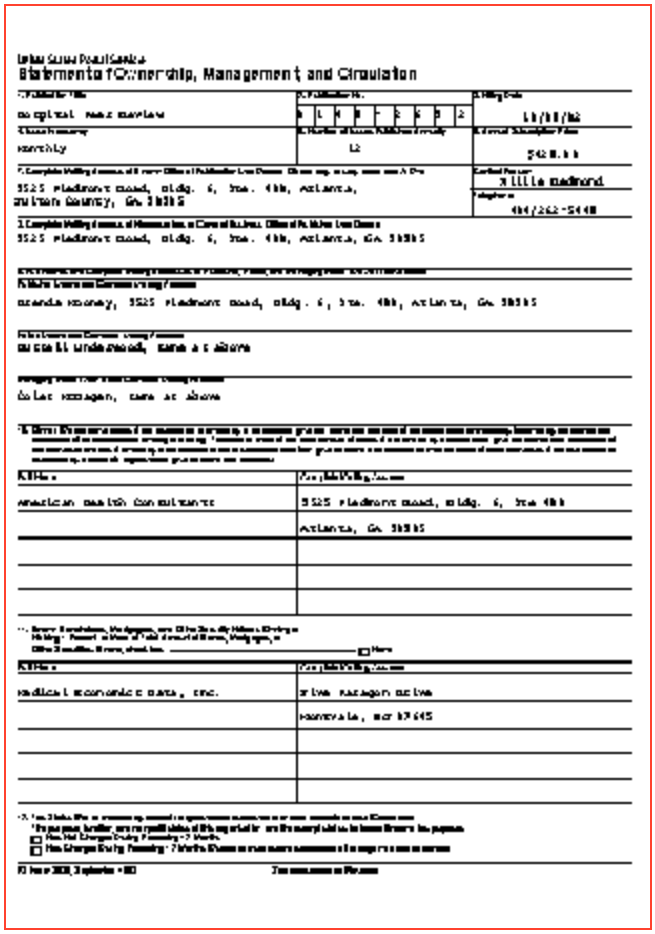

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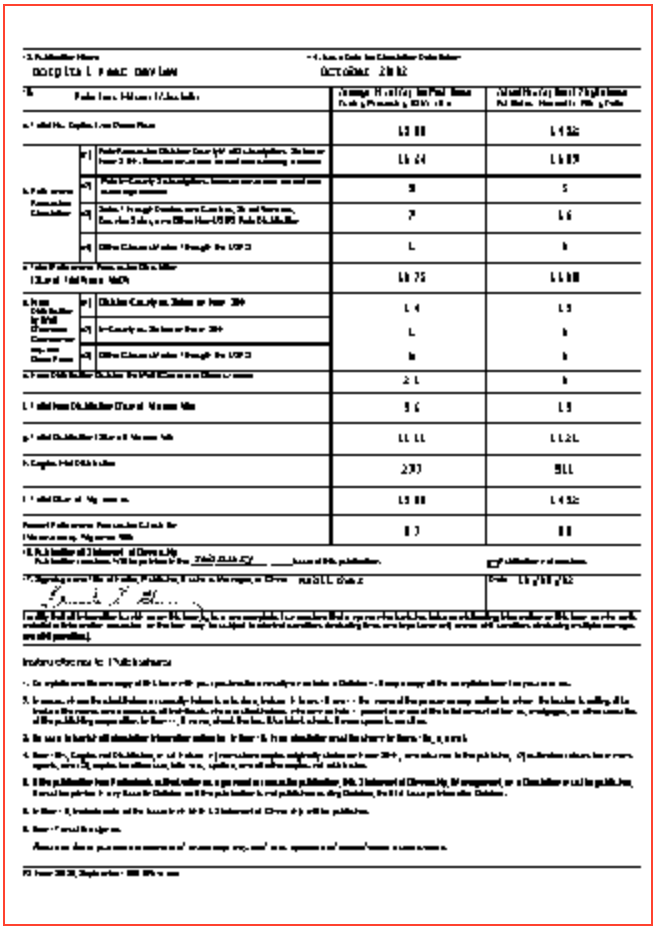

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