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Enhance pursuit of excellence by integrating ISO 9000, Baldrige

National Baldrige winners often use ISO as platform

Health care quality professionals have, of late, modeled outstanding companies in other industries in their ongoing pursuit of excellence, adopting vehicles such as Six Sigma and ISO 9000. The next step, some observers say, is to integrate ISO standards with the Malcolm Baldrige Award criteria. The Malcolm Baldrige National Quality Award is administered by the National Institute of Standards and Technology in Gaithersburg, MD. (For more information, go to: www.nist.gov.)

"Essentially, what we see is that ISO is definitely the platform with the essential fundamentals for a business model," says **Denise Bertin-Epp,** COO at Pinnacle Enterprise Group Medical Division, in West Bloomfield, MI. Pinnacle is a medical process improvement consulting firm that uses the ISO platform to improve medical processes.

Pain management standards: Find out if your facility is up to speed

Don't run the risk of losing your accreditation

The first obstacle to overcome in developing a pain management strategy is the misconception that effective pain management is not a problem within your facility or does not need to be a high priority. Health care organizations constantly face pain management challenges, not only in treatment, but also in meeting Joint Commission on Accreditation of Healthcare Organization (JCAHO) standards for the assessment and management of pain. Do you know how your facility measures up?

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Key Points

- Integration links strategic approach to customer-oriented philosophy.
- ISO provides essential fundamentals for a business model.
- Breaking down silo effect key to performance improvement.

"ISO looks at breaking down the historical silo effect in health care, encouraging the sharing of information and model inspiration. ISO looks at reducing redundancies, limiting inefficiencies, reducing costs wherever possible, and increasing quality. It also looks at the lack of standardization of processes and improves upon that situation."

"I would say ISO is the platform through which your organization can make sure the fundamental pieces are in place," says **Judy Homa-Lowry,** RN, MS, CPHQ, director of patient care services at Brighton (MI) Hospital.

"With Baldrige, when you evaluate your facility, you try to look for a strategic plan and for the integration of all the pieces. ISO also makes you focus on what you want to do as an organization, but with the customer as No. 1, so you look at all these issues in terms of how they apply to the customer. When you apply Baldrige criteria, it really gives you a global perspective in terms of your ability to evaluate how well your clinical and business practices are functioning," she says.

Perhaps most telling is the fact that a number of recent national Baldrige winners from industry have integrated Baldrige criteria with ISO standards; no health care organization has ever won a national Baldrige award. **(See box, p. 27.)**

The integration 'pyramid'

To more readily understand this integration model, Bertin-Epp says, envision a pyramid divided into three sections (not unlike the Food and Drug Administration's food pyramid).

"The bottom of the pyramid would be ISO 9000; the next rung would be the Joint Commission [on Accreditation of Healthcare Organizations]/IWA [International Workshop Agreement] — an integration of Joint Commission standards and the ISO 9004 standards; the top of the triangle is Baldrige," she explains. "You have a progression of strength, beginning with ISO. As you move up the pyramid, through continuous quality improvement and the strength of your business model, you progress to incorporate them all."

The ISO 9004 standards are more progressive, represent a higher standard, and require a stronger business model to support them, Bertin-Epp adds. "They are 'out there,' but not publicly accepted yet. But if you want to attain a Baldrige award, these other elements earn you significant points from a Baldrige perspective."

Joint Commission standards are an important part of this triangle, Homa-Lowry emphasizes. "ISO and Baldrige, as well as the Joint Commission standards, would point you in the direction of winning a national award," she notes. "Baldrige wants to make sure you have the right systems and processes, and the Joint Commission standards make sure everything is in place for optimal patient care."

"From a Baldrige perspective, it is a high-performance business model," Bertin-Epp says. "I truly see Baldrige as the point of real excellence — exceeding customer's expectations. When you have the systems and processes to meet their needs, you will exceed their expectations. Whereas in ISO 9000, you will meet the requirements you have defined for them — the basics."

This might even be the first time your organization has ever defined those basics, she notes. "In many health care organizations around the country there are *no* basic customer requirements; ISO would absolutely mandate that you have them in place," Bertin-Epp explains. "As part of that, you would ask your clients what they are seeking. If Joint Commission standards are part of the mix, it would be a minimum qualification to become ISO-certified."

With this pyramid approach, there is a much

COMING IN FUTURE MONTHS

- 'Learning organizations': What they are, and why you should care
- Just how 'wired' does your institution need to be?
- Physician-assisted suicide: An issue of ethics, quality, or both?
- Collaborative groups: how to get the most from your benchmarking efforts
- New state quality institute links health care, insurance, business, government

National Baldrige winners use integrated tools

To date, not one health care organization has earned the coveted Malcolm Baldrige National Quality Award. (The Malcolm Baldrige National Quality Award is administered by the National Institute of Standards and Technology in Gaithersburg, MD.) A look at several businesses that have may prove instructive; many have integrated ISO 9000, and sometimes Six Sigma as well, into their performance improvement efforts.

The following summaries are excerpted from the Summer 2002 Baldrige National Quality Program *CEO Issue Sheet:*

- **STMicroelectronics Inc. – Region Americas**, was a 1999 recipient in manufacturing. "As we at ST see it, the Baldrige criteria lay the foundation for the entire organizational process by encouraging review of its approach," said **Richard Pieranunzi,** president and CEO of ST Americas Region. "ISO addresses systems that have direct influence in product quality and customer satisfaction, without suggesting tools for analysis, prioritization, and evaluation."
- **Eastment Chemical Co.**, a 1993 recipient in manufacturing, has operated using the principles of the Baldrige criteria and ISO 9000 for more than 10 years. "The company's quality management system is underpinned by the Baldrige principles, though expressed in a manner specific to the Eastman culture," said **Joe Wilson**, director of corporate quality. "ISO lays a foundation for necessary procedural standardization, and we benefited most from ISO implementation in the creation of maintainable systems for process documentation and training."
- **Leadership at Ames Rubber Corp.**, a 1993 recipient in small business, view the Baldrige criteria, ISO 9000, and Six Sigma as tools that all fit in the toolbox for continuous improvement. According to president and CEO **Tim Marvil**, "Baldrige gives Ames an overarching set of criteria questions to determine where we are, ISO helps us document what we're doing, and Six Sigma helps us to implement the processes to correct the problems . . . each of them has played a critical role in meeting the needs of both our customers and our businesses through their use in our organizational processes."

(For more information, go to the web site: www.nist.gov.) ■

greater emphasis on keeping the patient as your focal point, Homa-Lowry says. "Traditionally, a lot of systems and processes have been created more for the benefit of the hospital," she notes.

"When you look at standards of patient care or outcomes, ISO with the Joint Commission incorporate the minimum standards for processes you need to have in place to create the patient outcome you are looking for," Bertin-Epp adds.

"For example: removing the wrong limb; *no* system in health care makes sure errors like that are not there. People needed the IOM [Institute of Medicine] report on errors [*To Err is Human: Building a Safer Health Care System*, 2002, the IOM and the Committee on Quality of Health Care in America] for organizations to wake up and smell the coffee. This is the kind of core processes you can address," she explains.

In addition, Homa-Lowry says, when you begin to look at the patient moving through the system and breaking through silos, "you really begin to see a reduction of duplication of policies and procedures that are in conflict with each other," she notes. "It is extremely costly to organizations to maintain a multiple approach to things instead of identifying a single best method."

Homa-Lowry says she has decided to put this Baldrige/ISO integration model into practice at her facility, and has contracted with Bertin-Epp to assist her in this process.

"Our first phase will be to map out all existing systems and processes, or the lack thereof," she notes. "There will be one ground rule: no problem-solving can go on when we are doing evaluation."

In other words, this first phase will be limited to discussing processes and defining issues and opportunities.

"Sitting around the table are the people responsible for each area of patient care, our regulatory payers, and our customers," Homa-Lowry says. "Then, we will go back to build the processes so that they function in the right way and train our staff. We have already made a commitment to our CEO that we will save costs, so we will monitor what we do."

"Judy will be using [total quality management] skills to define the process with line staff," Bertin-Epp notes. "In the past, staff were not even part of the decision process. She's taken down the silos."

Without frontline involvement, she adds, you often have a disconnect between what management thinks is occurring and what really *is* occurring. "The typical management systems that are put in place are dysfunctional," she notes.

Need More Information?

For more information, contact:

- **Judy Homa-Lowry**, RN, MS, CPHQ, Director of Patient Care Services, Brighton (MI) Hospital. Telephone: (734) 459-9333.
- **Denise Bertin-Epp**, COO, Pinnacle Enterprise Group Medical Division, West Bloomfield, MI. Telephone: (248) 706-1740.
- **Patrice L. Spath**, RHIT, Brown-Spath & Associates, Forest Grove, OR. Telephone: (503) 357-9185.

"Throughout this process, the admission-to-discharge continuum, we will try to define what the key processes are, what they need to be to have the outcomes you want, while meeting the ISO platform. We will have one admission process, standard criteria for patients, and shared information," Bertin-Epp says.

The process also incorporates a significant amount of benchmarking. "We will begin to use the literature to compare ourselves with best practices in all areas," Homa-Lowry says. "We have talked to other organizations, and we have visited another health care organization [that has integrated Baldrige and ISO] to make sure we are integrating the best of the clinical knowledge available to us as we design our processes."

A word of caution

Despite the promise of integrating ISO, Six Sigma, or other processes with the Baldrige Criteria, quality managers should proceed with caution, advises **Patrice L. Spath**, of Brown-Spath & Associates, a health care consulting firm in Forest Grove, OR.

"Consultants who are very much into ISO or Six Sigma generally think that their product is all-encompassing and will fix every problem that you have," she warns.

"The problem I have with them is that I view ISO and Six Sigma as just a process-management technique or tool, with Baldrige really being a comprehensive framework that deals with the culture or the strategic objectives of an organization," Spath says.

The good news, she says, is that both ISO and Six Sigma are beginning to add those pieces to their models. "What's wrong with them for health care is that they are very prescriptive; they tend to appear to be the magic bullet we are looking for and want to hang our hat on."

"They could fail because things that Baldrige values — like human resources, aligning your mission, vision, and values throughout organization — if those pieces are not there and you don't have the support of top management to achieve the vision the organization wants to achieve, then no prescriptive methodology to improve process will work successfully in your organization," she observes.

The reasons that ISO and Six Sigma could fail in health care "are the same reasons why CQI [continuous quality improvement] failed and, I fear, the same reason patient safety will fail," Spath says.

"They are tools, techniques, methodologies. Jack Welch [former G.E. CEO who helped make Six Sigma a household word] had a vision — he probably could have used any tools or techniques," she adds. "It's not the graphics you use; it's the vision of the leaders and how you align and excite organizations about achieving that vision."

Nevertheless, she says, ISO *is* integratable into the Baldrige criteria. "There are several categories — one is process management — where ISO and Baldrige can be merged together," she asserts.

"But I think Baldrige has to be the umbrella; it informs how the ideal organization should look. If an organization decides to use ISO, it's just one piece of the many different strategies. You could use Six Sigma, too. It's just one of the many different methodologies you can use to achieve performance excellence," Spath adds. ■

ED diversions reduced by tight monitoring

Borrowed processes allow real-time reaction

Using a combination of techniques that benchmark best practices from other industries, **Roger Resar**, MD, pulmonologist and change agent at the Luther Midelfort-Mayo Health System in Eau Claire, WI, has gained tighter control on monitoring patient flow and, based on preliminary results:

- Reduced emergency department (ED) diversion hours from 12% to less than 2%.
- Slashed the cost of diversions from about

Key Points

- Hospital had no good system for measuring flow through the organization.
- Mechanism to ensure action is a key element in program's success.
- Giving nurses greater control drops staff vacancy rates and boosts satisfaction.

$250,000 a month to less than $30,000.

• Increased from 23% to 40% the percentage of patients who were put to bed within one hour.

In addition, since nurses were given greater control over processes, staff vacancy rates dropped significantly and satisfaction rose, Resar says.

IHI sparks interest

Resar says that a trip to Boston in January 2001 helped set things in motion. At that time, he and his CEO participated in an IHI-sponsored session about hospital flow.

"They set up a group of experts to talk about what we might start to do to improve the problem," he recalls. "Our problem was not as acute as the one they had in Boston, but there were still times when the ER shut down, operations were cancelled, and so on."

Resar and his CEO eventually met Eugene Litvak, MD, professor of health care and operations management at Boston University, an expert in the field, and also involved one of their senior vice presidents in charge of nursing in the process.

"What we heard from that group of experts tweaked our interest, and we felt we could probably use some of their ideas," Resar notes. "So we came back and tested some of these ideas."

No system for measuring flow

One realization that emerged very early on was that the hospital had no good system for measuring flow through the organization. "We measured bodies that went through in a month or a year, but we had no real-time measurement of flow," Resar explains. "Every industry, every airport, any kind of large organization that deals with production measures flow at various points; they know where their bottlenecks are and what to do in contingencies. In hospitals, we don't do that at all."

Benchmarking these other industries really opened Resar's eyes. "My CEO, myself, and several vice presidents went to a local power company that serves a large area of the Midwest," he recalls. "Their office has a huge control board with a panel that runs all around a huge room. They can tell at any time almost down to a single telephone pole how much power is going through, how much is needed, and how much should be changed if there is an increase in demand. It struck me that at any given time in a given hospital, you can't tell what's going on; nobody knows."

Another instructive visit was made at the Minneapolis airport's hub for Northwest Airlines. "They really need to understand flow," Resar notes. "If you notice, airplanes very seldom circle airports anymore before landing. That's because you can't take off from Boston, for example, until you have a landing slot in Minneapolis. In hospitals, we just take patients without knowing where they will 'land.'"

Setting up the system

The first thing Resar and his frontline staff did was set up a measuring system that involves all patient floors of the hospital. "We started out very small, using a pilot area, and did it all on paper before we moved to an electronic [computerized] system," he explains.

The system is based on the 'stoplight' concept, designating red, orange, yellow, or green states of patient flow. "We set it up so that each unit would report on a regular basis, or if something changes drastically, what their color was," says Resar. "If you tell someone you're having a 'red' day, you really don't have to go into a long description for other departments to understand you."

A given unit's color is determined by using a measurement tool — a paper assessment anchored in several objective measures, the end result being the reporting of a color. This is done by the frontline staff.

By April 2001, Resar says, everybody in the hospital was using the system, which was accessed through its intranet.

Ensuring action

One of the unique aspects of the changes instituted at Luther Midelfort, and a key to its success, was a mechanism to ensure action. "You can't have a measurement system if people can't act on it," Resar explains. "The first action we put into place was that when a unit reached a point,

Practical Tips for Improved Flow Monitoring/Control

1. Institute a frontline staff-designed and staff-run rapid assessment tool.
2. Utilize an assessment tool to "smooth" demand from hour to hour.
3. Utilize management tools to plan resource use on a quarterly or yearly basis.
4. Institute a "Capping Trust Policy."
5. Study upstream recognition of downstream resource use for natural and random variation.
6. All hospital bed use coordinated through one person or team.
7. Critical downstream units need to be identified and pull systems developed.

Source: Roger Resar, MD, Luther Midelfort-Mayo Health System, Eau Claire, WI.

usually red, which in the frontline staff's estimation meant they could not accept another patient, they capped the unit." This policy, he says, was called the Capping Trust Policy.

"If you were a frontline staffer and assessed your unit as completely saturated, you were allowed to cap your unit for safety reasons," Resar observes. "This was what Litvak was talking about; the limitation of elective procedures so that you could end up smoothing the artificial variability," he says.

A lot of admissions to hospitals are artificial variations, Resar asserts. "What if I get a call from a doctor at another hospital who says he'd like to send a patient over? In my former life, I would have sent him over. Now, I think about the airport. If I said yes without knowing there was a bed available, the patient ends up in the [emergency department] with no landing spot [and] waits for a bed."

Now, when a patient can't go on a unit, the only way for physicians to have him admitted is to go through an admissions coordinator, who functions very much like an air-traffic controller. "We are a level 2 trauma center; we will bring in a patient if it is an emergency," Resar notes.

"But if the patient is 100 miles away, has pneumonia, and needs tests done, they can wait to come in in a couple of hours, not right away," he explains.

The measurement initiative, Resar notes, "allowed the Capping Trust Policy, allowed us to shut down, and forced us to think about how to handle people coming in."

Another key element of the new system is what Resar refers to as upstream evaluation for downstream resource use. It addresses certain facts you must have in hand before scheduling an elective procedure.

"If I'm a surgeon doing a procedure that requires an ICU [intensive care unit] bed and a ventilator after surgery, and if I have four operations on Monday and all will require a breathing machine for at least two days, those four will totally plug up the ICU," he observes.

"Instead, I might want to schedule just two procedures for Monday and two for Wednesday, and fill in the operating time with patients who don't need breathing machines. We never did that until now. You can't schedule procedures willy-nilly without realizing what the downstream effects will be," Resar says.

A big plus for morale

The new system has had a profound effect on nursing morale, he says. "In 2001, we had a nurse vacancy rate running somewhere around 8% to 10%," he recalls. "About six months after we started the Capping Trust Policy, it went down to 1% to 2%, and each unit shows the same dramatic change."

Resar has no doubt there is a connection.

"When frontline nurses get empowered to have a say-so in their work, it improves morale considerably," he asserts.

He also notes that despite the new system, admissions did not drop. "We were able to hire more nurses, but the other thing is this: We found out these nurses and other folks who work in our hospital are dedicated people. We don't see them slacking. Yes, when it gets to the point where they just can't take any more patients, they shut down for a few hours. But they are not taking advantage of the policy." ■

Need More Information?

For more information, contact:

- **Roger Resar,** MD, Pulmonologist and Change Agent, Luther Midelfort-Mayo Health System, P.O. Box 1510, Eau Claire, WI 54702-1510. Telephone: (715) 838-3566.

Consortium approach gets results in prostate cancer

Peer review, patient advocates highlight program

An innovative approach to treating prostate cancer in Buffalo, NY, has not only won national recognition but also benefited patients through peer reviews of diagnoses, enhanced entrée into clinical studies, improved odds of survival, and achieved a reduction of unnecessary procedures.

The Buffalo Niagara Prostate Cancer Consortium (BNPCC), located at Roswell Park Cancer Institute (RPCI), includes community urologists, academic institutions, patient support groups, insurance carriers, and RPCI. Men with newly diagnosed prostate cancer are offered a number of treatment options, including surgery, observation, three-dimensional conformal radiation therapy, brachytherapy (radiation implant), hormone therapy, chemotherapy, biological therapies, or a combination of those therapies.

The BNPCC, founded in January 2001, has been recognized as a national model by the National Comprehensive Cancer Network (NCCN), a nationwide group of experts that reviews clinical trials and makes evidence-based recommendations on diagnosis, work-up, treatment, and follow-up, and the Oncology Roundtable of the Washington, DC-based Advisory Board Company, a 2,000-member group of health systems and medical centers that identifies best and worst practices.

One of the aspects that make the BNPCC approach unique is its peer review process, says **Susan Walsh,** RN, clinical data manager/program development, for the consortium. Walsh manages the consortium, including the design and management of its clinical database.

"Normally, if you have prostate cancer, you will see a urologist," she says. "According to the literature, 93% of them will tell you that you need surgery. A radiation oncologist will say you need radiation. With our peer review process, we bring all the disciplines to one table."

The peer review group meets on the first and third Tuesday of every month, Walsh says. All clinical information is presented anonymously, protecting the identities of physicians and patients. The group includes community urologists, radiation oncologists from RPCI, specialized support staff, and protocol managers, to heighten the odds that if the patient were presented, he or she would qualify for a protocol.

Every consortium meeting also includes one or more patient advocates — another critical component of the process, Walsh says.

"In peer review, they act as clinical police, helping to ensure that no physicians' biases come out," she explains. The advocates make sure all options are considered. The consortium follows NCCN guidelines, which have both patient and physician sections.

During the first patient consult, which is done prior to peer review, the patients also are informed about support groups that are available. "The

Key Points

- Benchmarking national centers for excellence hones diagnoses.
- Patient advocates help achieve balanced approach to treatment.
- Nearly 80% of eligible patients go on to national clinical trials.

BNPCC Goals

- Standardize prostate cancer screening, diagnosis, and treatment.
- Follow National Comprehensive Cancer Network guidelines for patient work-up, treatment recommendations, and follow-up testing.
- Offer eligible patients the choice to enter clinical trials.
- Track and publish patient outcomes.
- Work with local insurance carriers to improve quality while containing costs.

Source: Buffalo Niagara Prostate Cancer Consortium, Buffalo, NY.

The Need for Clinical Trials

- Contribute knowledge to improve the various treatment options available to patients.
- If a new treatment proves effective in a trial, it may become a new standard (generally approved and accepted) treatment that can help many patients.
- Many of today's standard treatments for pro-state cancer and many other types of cancers are based on the successes of previous clinical trials.

Source: Buffalo Niagara Prostate Cancer Consortium, Buffalo, NY.

Need More Information?

For more information, contact:

- **Susan Walsh**, RN, Buffalo Niagara Prostate Cancer Consortium, Elm & Carlton Streets, Buffalo, NY 14263. Telephone: (716) 845-3173. Fax: (716) 845-7616. E-mail: bnpcc@roswellpark.org.

patient advocates also accompany us to outside events and insurance meetings," Walsh adds.

The BNPCC's pathology review is also noteworthy, says Walsh. "According to the literature, up to 47% of patients are being underscored in terms of their Gleason scores [a grade given cancer cells, in which a higher number is a more severe rating]," she notes. "That is clinically significant, because theoretically [with a lower score] you get less treatment."

BNPCC has all pathology reviewed by local and national experts in urologic pathology. "We send out a certain percentage to centers of excellence around the country, and they peer review us," says Walsh. "We've found that about 11% of the patients' scores change, and the majority are understaged."

Data gathering extensive

Detailed collection and sharing of data help ensure an ongoing high quality of treatment at BNPCC. "When a patient first comes in for a consult, we try to collect as much previous data as possible, as well as data from the consult itself," Walsh says.

This information is combined, entered onto a template created by the consortium for consults, and then put directly into the database.

"There are several other areas of data we track," she says. "There's pathology — both the original, and reviewed pathology from other centers; treatment; and follow-up information, which is ongoing." Also tracked is dosimetry, which involves how radiation is dosed and delivered, as well as the scans used to make such determinations.

BNPCC regularly compares its data with similar data at other prostate cancer Centers for Excellence, including M.D. Anderson in Houston and Washington University Medical Center in St. Louis.

Much of the data also are sent to the National Institutes of Health and National Cancer Institute government clinical trials.

"About 80% of our eligible patients go on to the trials, while the national average is anywhere from 3% to 5%," Walsh says. "This reflects extremely well on us because national clinical trials are really what drive clinical data."

BNPCC and its patients already are reaping the benefits of the consortium/peer review model. For example, unnecessary procedures are being reduced drastically.

"According to NCCN, CTN bone scans are not required for all prostate cancer patients," she notes. "Because we monitor closely and teach our physicians that they do not need them for low-risk patients, we have cut 'unnecessary' bone scans from 15% to single digits; the national average is 40%."

This, in turn, has impressed insurance companies and enhanced reimbursements for BNPCC physicians. "We have case rates with the insurance companies and collaborate with them," Walsh says. "We present our clinical data on outcomes twice a year. When we show them how through the consortium we are reducing unnecessary procedures, they see us as providing higher value and we can negotiate higher reimbursement rates." ■

Study links nursing shortage, poor quality

Harvard study shows direct health impact

In the most comprehensive look at the subject to date, a study by the Harvard School of Public Health in Boston, and Vanderbilt University's School of Nursing in Nashville, TN, has shown that the size and mix of nurse staffing at U.S. hospitals has a direct impact on patient health outcomes.

The import of these findings was underscored by the recent release of a major report, *Health Care at the Crossroads: Strategies for Addressing the Evolving Nursing Crisis*, by the Joint Commission

(Continued on page 34)

Key Points

- Associated complications include pneumonia, upper gastrointestinal bleeding, shock, and cardiac arrest.
- Large sample helps bolster validity of findings.
- Quality managers should look beyond charts for issues to address.

Highlights of Study on Nursing Shortage, Outcomes

Summary of association of lower nurse staffing and patient outcomes

Patient Pool	Outcome	Higher rate for outcome is associated with: Lower proportion of RNs	Higher rate for outcome is associated with: Fewer RN hours per day	Difference in rate between low and high RN hospitals
Medical Patients	Length of stay	**X**	**X**	3.5%-5.2%
	Urinary tract infection	**X**	**X**	3.6%-9%
	Upper gastrointestinal bleeding	**X**	**X**	5.1%-5.2%
	Pneumonia	**X**		6.4%
	Shock or cardiac arrest	**X**		9.4%
	Failure to rescue	**X**		2.5%
Surgical	Urinary tract infection	**X**		4.9%

How important are these complications affecting patients for which an association with RN staffing was found?

- Longer lengths of stay increase costs to patients and hospitals.
- Urinary tract infections are common complications, affecting about 6% of medical patients and 3% of surgical patients; they can add to patient cost, discomfort, and prolong a patient's stay in the hospital.
- Pneumonia, shock and cardiac arrest, and upper gastrointestinal bleeding are all associated with an increased risk of death, can increase patient costs and discomfort, and prolong a patient's stay in the hospital.
- Failure to rescue. As used in this study, "failure to rescue" is the death of a patient with one of five serious complications — pneumonia, shock or cardiac arrest, upper gastrointestinal bleeding, sepsis, and deep vein thrombosis (a blood clot in a vein which can break off and cause a heart attack, stroke, or pulmonary embolism) — for which early identification by nurses and medical and nursing interventions can influence the risk of death. In this study, nearly 20% of the patients with these five complications died. We reasoned that in hospitals where staffing is short, there is a greater chance that nurses will not detect one of these five complications early enough, or intervene quickly enough to prevent the complication from worsening and eventually causing death vs. hospitals where there is more nurses on staff.

Because of data limitations, our measures do not capture all of nursing's impact on quality of patient care. We view the results from these outcomes as lower bound estimates of the impact of registered nurses.

How big a difference does care from registered nurses make?

- We estimate that hospitals with high registered nurse staffing have lengths of stay 3% to 5% shorter and rates of complications 2% to 9% lower than hospitals with low registered nurse staffing, controlling for other factors. **(The difference varies by complication. See table above.)**
- High registered nurse staffing refers to a hospital whose staffing is at the upper quarter (75th percentile) of the 799 hospitals included in this study.
- Low registered nurse staffing refers to a hospital whose staffing is at the lower quarter (25th percentile) of the hospitals studied.

Source: Jack Needleman, PhD, Harvard School of Public Health, Boston.

(Continued from cover)

To help you meet these challenges, American Health Consultants offers the **Complying with JCAHO Pain Management Standards: Is Your Facility at Risk?** audio conference, scheduled for Oct. 8, from 2:30-3:30 p.m., Eastern time. The facility fee is just $299, which includes free CE for your entire staff.

The conference package also includes, handouts, additional reading, 48-hour replay of the live conference, and a CD recording of the program.

Conference speakers **Patrice L. Spath**, BA, RHIT, and **Michelle H. Pelling**, MBA, RN, will teach participants how to:

- ❒ Comply with the new JCAHO standards relating to pain medication range orders and titration.
- ❒ Integrate JCAHO 's "Speak Up" campaign into patient education initiatives. The groundbreaking program encourages patients to become active, involved, and informed participants on the health care team.
- ❒ Develop a performance measurement system to evaluate the effectiveness of pain management and continually monitor and improve outcomes.
- ❒ Avoid documentation deficiencies and staff complacency that can derail a pain management program.

"Hospitals must have a systemwide standard of care for pain management that will reduce patient suffering from preventable pain," Spath says.

"Failure to meet this standard of care can result in a Type I recommendation from JCAHO. But more important, inadequate pain management will undermine patients' confidence in the quality of care provided by your health care facility," she says.

A Type I recommendation would require your health care organization to resolve insufficient or unsatisfactory pain management standards compliance in a specified amount of time to maintain your accreditation.

This audio conference is a must for hospital nursing directors and staff nurses, pharmacists, pain management team members, quality directors, risk mangers, accreditation/compliance directors, patient educators, case managers, ED managers/nurses, same-day surgery managers, and home health managers.

Educational programs for hospital staff at all levels can ensure that sound pain management standards are understood and put into practice throughout your facility.

To register for this audio conference, call customer service at (800) 688-2421 and reference effort code: **62751**. ■

on Accreditation of Healthcare Organizations (JCAHO), based in Oakbrook Terrace, IL. In it, JCAHO warned that the nursing shortage is "putting patient lives in danger and requires immediate attention."

The Harvard/Vanderbilt study, published in the May 30, 2002, issue of the *New England Journal of Medicine,* represents a re-examination and refinement of the co-authors' previous analysis released last year by the Health Resources and Services Administration (HRSA) in cooperation with the Department of Health and Human Services, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicare Services, and the National Institute for Nursing Research.

"In some subtle ways, this article is different, but the fundamental conclusions hold up," says **Jack Needleman,** PhD, assistant professor at the Harvard School of Public Health, a co-author of the article with Peter Buerhaus, PhD, RN, FAAN, of Vanderbilt.

The main difference, says Needleman, is that in the original HRSA presentation "we were somewhat equivocal — there was no consistent evidence of an association between LPNs and aide staffing and these outcomes, but some evidence of a total effect. When looked more and harder, we determined that all we really see on these data is a registered nurse effect."

Specifically, the researchers confirmed their initial findings that low levels of RNs among a hospital's nurses were associated with rates of serious complications such as pneumonia, upper gastrointestinal bleeding, shock, and cardiac arrest, including deaths among patients with these three complications, as well as sepsis or deep vein thrombosis. These complications occurred 3% to 9% more often than in hospitals with higher RN staffing.[1] **(For a more complete summary of the findings, see the chart, p. 33.)**

Studies such as these, Needleman says, face a number of challenges, which accounts at least in part for the fact that much of the earlier research on this subject has been inconclusive and perhaps even contradictory.

"Several things account for difficulties when one does research," he says. "Sample size makes a difference in the power of your ability to detect associations that really exist. (His own study used data from 799 hospitals in 11 states and 6 million patients discharged, clearly a large sample.)

"You're also dealing with some data that has a lot of 'noise' in it. Take staffing, for example: I'd really like to know how many nurses you have relative to the number of nurses that are *needed*. But what we deal with in most research are measures of staff in units that don't take into effect as much as a researcher would like in the differences in patient acuity, plant layout that tells you how many nurses you need, and so on. So when you compare staffing across different hospitals, [you could take into account] other things that influence one hospital in a given eight hours that may not affect another in the same eight hours."

Needleman notes that his team worked very hard to develop a model of risk for anticipating the likelihood of a patient having the complications to be studied, and took the best available adjustments for nurse staffing that were available. "This made our data cleaner," he asserts.

The bottom line, he says, is that "I feel pretty good about what we found; if anything, we were likely to be conservative in the way we drew inferences. He thinks the door "may still be open" on mortality, although he notes that a recent JCAHO *Sentinel Event* analysis found an association. "I would be shocked to know that, given the work nurses do, being short-staffed has no impact," Needleman says.

Despite problems with data noise and idiosyncrasies at specific institutions, Needleman is unwavering in his belief in the linkage between a shortage of RNs and a drop in quality. "The data at this point, and not just in our study, are very clear; there are some hospitals that have low levels of RN staffing, and patients are being injured by that — some seriously," he asserts.

Solving the problem may be a lot more difficult than identifying it, he concedes. "Fixing that problem is going to require bringing more nurses into the hospital," he says. "There may be ways to restructure work, but efforts in the '90s [to do that] do not seem to have been very successful."

To some degree, he says, the idea that using fewer nurses will save a hospital money can be misleading. "There is some reason to believe that the cost of bringing in more nurses will be associated with *savings,* in terms of shorter lengths of stay, a reduction in the need to treat complications, and so forth," he notes. "I can't tell you whether there will be a full offset; but to the extent it isn't in this climate, it seems to me that the patient may not be prepared to play roulette with his health. Given that, patients will be willing to pay some of the increased costs through higher premiums and Medicare."

His study has a special take-home message for quality managers, Needleman says. "A lot of work on QI in hospitals has focused on very clear events — often those that can be found in a chart — such as a patient not getting a prophylactic antibiotic before surgery and then getting an infection," he observes. "But a lot of the work

Need More Information?

For more information, contact:

- **Jack Needleman,** PhD, assistant professor, The Harvard School of Public Health, 677 Huntington Ave., Boston, MA 02115. Telephone: (617) 432-1318.

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Editor: **Steve Lewis**, (770) 442-9805, (wrdmanpr@bellsouth.net).
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Coles McKagen**, (404) 262-5420, (coles.mckagen@ahcpub.com).
Managing Editor: **Russell Underwood**, (404) 262-5521, (russ.underwood@ahcpub.com).
Senior Production Editor: **Ann Duncan**.

Editorial Questions

For questions or comments, call **Steve Lewis** at (770) 442-9805.

Clinical trials harmed by lack of informed consent

The mention of clinical trials often triggers a silence between physician and patient, usually because neither one knows much about the subject. Nearly 80% of physicians admit they would like to know more about clinical trials, so they can help their patients make an informed decision before volunteering to participate.

"Most subjects enrolled in clinical studies have a meager understanding of what they have gotten into," says **Alan Sugar**, MD, chairman, New England Institutional Review Board and professor of medicine at Boston University School of Medicine. "Informed consent has largely focused around the signed form and has not practically become the continuous process that it needs to be. As a result, a subject's misunderstandings largely go unchallenged."

Properly informing patients is not only ethically necessary, say clinical trials experts, but it also ensures better trials and data. Last year, more than 17 million people thought seriously about participating, but only a few million actually completed their trials. And even among them, many gave their consent without a thorough knowledge of the facts. Indeed, patients can be so daunted by questions and lack of information that they simply decide not to volunteer.

"There's a simple ethical mandate that you don't ordinarily do dangerous things to people without their knowledge and consent," says **Dale E. Hammerschmidt**, MD, FACP, associate professor of medicine and director of Education in Human Subjects' Protection for the University of Minnesota Medical School in Minneapolis. "From a more pragmatic perspective, a well-informed subject is likely to cooperate better with the trial and is more likely to report potential problems. The quality of the data and the safety of the trial are both enhanced when the subjects really know what's going on."

A new resource, written for doctors and clinical trial participants, can help answer some of these tough questions. Boston-based CenterWatch, the leading publisher of clinical trial news and information, now offers *Informed Consent,* a guide to the risks and benefits of volunteering for clinical trials.

Informed Consent, a step-by-step guide with a history of the clinical trials industry, explores the drug development process and how a new drug makes its way to the marketplace. It also details why people decide to participate, how to find clinical trials, how to research clinical trials and evaluate their risks, how to ensure proper informed consent, what the vulnerable populations are, and what to do when things go wrong. Cost is $16.95, and can be ordered from CenterWatch at (800) 765-9647, or by faxing (617) 856-5901. It also can be ordered through www.centerwatch.com; www.amazon.com; and www.barnesandnoble.com. ■

nurses do, and the lapses they may have, are not well-documented in charts, but these are clearly important issues. The quality managers need to find ways to build QI activities around solving the problems of nursing systems where they may not have the clearest indicators in charts as to what went wrong."

Reference

1. Needleman J, Buerhaus P, Mattke S, et al. Nurse-staffing levels and the quality of care in hospitals. *N Eng J Med* 2002; 346:1715-22. ■