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Palliative care and hospice pain experts provide best practice care guidelines

One hospice reduces pain 100% in 48 hours

Hospices may be the leaders in pain management, but most could improve their efforts by following best practice guidelines and initiating a quality improvement process, several pain experts say.

"It's been well documented over the years that pain is poorly managed for many reasons," says **Frank Forte**, MD, director of medical oncology/hematology and director of palliative medicine at Staten Island (NY) University Hospital.

"Not the least of which is the fear people have of side effects, the fear of becoming addicted, the fear that it will be stigmatized, and a lot of other things that are both patient- and doctor-related," he says. "Many patients who are older think it's good to suffer in silence and think good people don't complain — so, for all of these reasons, chronic pain and cancer pain have been poorly managed."

Forte has been involved with PC Quick, a collaborative quality improvement project, funded by the RAND Corp. of Santa Monica, CA, and the United Hospital Fund of New York City.

"One of the initiatives we did was to see whether or not pain could be better managed at our hospital," he says. "Before that, we had formed a palliative consultation service, so we did a comparison to see whether pain was relieved better with patient consultations or during the usual and customary way of caring for them."

After analyzing outcomes among 29 patients, it became obvious that patients who received care from the consultation service had better and faster pain relief than those who didn't, Forte notes.

"So, our goal was to make this an initiative where everyone would do better," he adds. **(See story about pain management initiative, p. 76.)**

The Hospice of the Western Reserve of Cleveland also has a continuous quality improvement process for pain management that was instituted in 2000, reports **Mary Kay Tyler**, MSN, CNP, pediatric nurse

practitioner/team leader and chair of the pain subcommittee.

"We are constantly reevaluating our practice and making sure we have the most cost-effective tools to assess pain," she explains.

The hospice has always followed pain management basics and maintains a transdisciplinary team approach to pain management, notes **Bridget J. Montana**, MS, APRN, MBA, chief operating officer.

"It's everyone's responsibility to observe and report," she says. "Any time a team member is with a patient, they'll observe the patient's pain and ask the individual to rate the pain."

If the patient's pain level differs from what is usually reported or if the patient reports feeling uncomfortable, then this information is reported to the primary nurse and the rest of the team, Montana adds.

Everyone involved in patient care, including the hospice volunteers, are trained and educated about pain assessment and management, she says. **(See story about Hospice of the Western Reserve's pain management education, p. 78.)**

As a result of the hospice's pain program, a recent chart audit of 109 patient charts showed that of the 64% of patients who experienced pain, 75% had their pain reduced within 24 hours and 100% had their pain reduced within 48 hours, Montana says.

The positive results were achieved partly because of the hospice's adoption of a tool that can be used to assess pain among patients who are unable to verbally indicate their discomfort, Tyler says.

The PAINAD scale, which was developed by nurse researchers through the Department of Veterans Affairs, enables clinicians to use nonverbal cues to determine a patient's level of pain and discomfort, she explains. **(See PAINAD scale, p. 75.)**

"PAINAD was developed for patients with dementia, and we have adapted it to use with any patients who are noncommunicative," Tyler says. "It looks at nonverbal cues, including facial grimacing, crying, things like that."

Caregivers also are educated

Hospice staff educate caregivers to use the tool so they can observe the loved one and report their observations to a nurse, she adds.

"This is particularly important in our elderly

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Administering Procedure for the PAINAD Scale

PAINAD

	0	1	2	Score
Breathing Independent of vocalization	Normal	Occasional labored breathing. Short period of hyperventilation.	Noisy, labored breathing, Long period of hyperventilation Cheyne-Stokes respirations.	
Negative Vocalization	None	Occasional moan or groan. Low-level speech with a negative or disapproving quality.	Repeated, troubled calling out. Loud moaning or groaning. Crying.	
Facial Expression	Smiling or inexpressive	Sad. Frightened. Frowning.	Facial grimacing.	
Body Language	Relaxed	Tense. Distressed pacing. Fidgeting.	Rigid. Fists clenched, knees pulled up. Pulling or pushing away. Striking out.	
Consolability	No need to console	Distracted or reassured by voice or touch.	Unable to console, distract, or reassure.	
Warden, Hurley, Volicer				**Total**

Source: Hospice of the Western Reserve, Cleveland.

and pediatric populations," Tyler says.

Also, the hospice uses pain management protocol cards, which are continuously updated. These are laminated and placed on a ring so nurses can carry them on patient visits, Montana says. **(See Principles of pain management chart, p. 76.)**

"The cards are tied into our drug list, not only for the proper medication for symptoms, but also for looking at pharmacokinetics and the economics of drug prescriptions," she says.

The hospice has a preferred drug list, as many hospices have these days, and this helps solidify the best practices, says **Janice Scheuffler**, PharmD, clinical pharmacist with the Hospice of the Western Reserve.

Staff are audited for compliance

The hospice also uses audits to make certain staff are following pain management best practices and to evaluate why problems have arisen, she says.

"We have an audit committee that looks at outcomes measurements on all kinds of topics, including pain, and we hit charts and outcomes research hard," Scheuffler adds.

Another dimension to the hospice's pain management best practices is the staff's focus on a holistic approach to reducing pain and suffering, Tyler says.

Industry taking notice

While the physical aspect of pain and suffering is the easiest to understand, the hospice and palliative care industry increasingly are recognizing that there are many things that cause people to suffer, she notes.

For example, patients also might suffer from distress caused by spiritual questions of why this is happening to them and the financial stress of wondering how the family will continue financially without them, as well as emotional problems resulting from loneliness and loss, Tyler explains.

The hospice's pain management committee has been working to determine the chief circumstances that cause suffering among the hospice's patient population, she reports.

This type of holistic approach to pain management is important because if a patient is suffering from a spiritual, financial, or emotional

Principles of Pain Management

- Believe the patient. Pain is what the patient says it is.
- Reassess frequently. Monitor regularly to provide ongoing pain control; include nonpharmacological interventions.
- Individualize treatment. Correct dose is the dose that relieves the pain with the fewest side effects.
- Choice of analgesic agent depends on many factors:
  - Renal and hepatic function
  - Past history of regimens, dosages, side effects, or allergies
  - Available routes of administration
  - Quality/type of pain
- Provide preventative therapy. Give analgesics regularly.
- Oral, sublingual, or rectal route is preferred for drug administration.
- Concentrated liquids or finely crushed immediate-release tablets mixed with several drops of water can be placed sublingually. The absorption via the sublingual route is considered equivalent to the oral route for the purposes of equianalgesic dosing.
- Given rectally, MS Contin tablets are equivalent to the same dose orally.
- Subcutaneous or intravenous therapy is reserved for patients with rapidly escalating pain and/or after failed therapy with alternative routes.
- Provide an immediate-release/short-acting agent for breakthrough pain.
- Breakthrough dosing should be roughly 10%-15% of the 24-hour dose.
- Maintenance dose usually is increased if three or more breakthrough doses are used in a 24-hour period:

$$\frac{\text{Old Maintenance}}{\text{24 Hours}} + \frac{\text{Breakthrough Dose}}{\text{24 Hours}} = \frac{\text{New Maintenance Dose}}{\text{24 Hours}}$$

- Remember the bowels. Patients will not develop tolerance to constipation.
- Manage side effects for optimal opioid clinical response. Typical opioid side effects include sedation, constipation, nausea/vomiting, pruritus, sweating, myoclonus, urinary retention, and mental status changes (confusion, delirium, hallucinations).

Source: Hospice of the Western Reserve, Cleveland.

problem, then it may be difficult to manage the patient's physical pain unless this other problem is addressed, Tyler says.

"The health care community throws pain and suffering together, but they're very different," she notes.

Research has shown that patients view pain and suffering as separate entities and, even patients who report no pain frequently will report experiencing some suffering.[1]

"We're very conscious that suffering is such an all-encompassing emotion that we don't want people to go in with a checklist, asking, 'Are you suffering? Is this bothering you?'" Tyler says. "We want to integrate assessing suffering into our practice and educate staff about how to identify when someone might be suffering."

Reference

1. Baines BK, Norlander L. The relationship of pain and suffering in a hospice population. *Am J Hospice Palliat Care* 2000; 17(5):319-327. ■

Pain management project includes hospital pathway

Pain expert describes how it works

A quality improvement team that focused on ways clinicians could better manage patients' pain developed a one-page clinical pathway that clearly shows what needs to be done.

"Our job now is to promulgate that pathway throughout our hospital, and to share it with anyone who wants to use it," says **Frank Forte**, MD, director of medical oncology/hematology and director of palliative medicine at Staten Island (NY) University Hospital.

One side of the pathway includes written guidelines, including general principles. **(See pathway, p. 77.)**

One of the general principles is for clinicians to be familiar with the analgesic ladder, which is part of the World Health Organization's (WHO's)

Staten Island University Hospital
Sample Pain Management Quick Reference Card

General Principles
- Avoid agonist/antagonists or meperidine
- Be familiar with the analgesic ladder
- Assess quality and quantity of pain
- Use a drug to its ceiling dose, relief, or intolerable side effects

Initial Opioid Treatment
- Never PRN for routine dosing
- Use short acting opioids to "dose find"
- Anticipate constipation — start with stimulant laxative and stool softener
- Renal or severe hepatic dysfunction: consider increased interval or decreased dose
- Remember breakthrough dose (10%-20% of 24-hour dose q C_{max}* prn)
- Use T½** to evaluate for steady state and dosing interval
- T½ of most opioids at steady state is 3-4 hours
- Use C_{max} to evaluate for breakthrough interval
- C_{max} depends on the route of administration

— p.o. ~ 1 hour
— sub-q ~ 30 minutes
— i.v. ~ 6-15 minutes

* = peak plasma concentration
** = time to 50% plasma concentration

Reassessment
- Reassess frequently, change dose at steady state if necessary (sooner if severe pain without improvement)

Adequate pain control
- Consider conversion to long-acting preparation
- Continue short-acting preparation for breakthrough
- Consider cost
- Consider consult if no significant relief in 48-72 hours

Partial Intolerance
- Tolerance may develop to the opioid in use — this may not be as marked when switching to a new opioid
- Therefore, start with 50%-75% of published equianalgesic dose, when switching to a new opioid

Source: Staten Island (NY) University Hospital.

recommendations for palliative care.[1]

The idea behind the analgesic ladder is there are three levels of pain and three types of medications and ways for treating it, including assessing the pain, using a drug appropriately, and not managing it continuously, Forte says.

The guidelines also address what should be done with initial opioid treatment, reassessment, adequate pain control, and partial intolerance.

"For some reason, when someone goes into the hospital they're immediately put on IVs, and it makes no sense," Forte says. "So, one of our comments is to use IVs only when necessary and to use the appropriate dose for breakthrough pain."

The pathway has two main categories of opioid-naïve and nonopioid-naïve. Under the opioid-naïve flowchart section, there are two choices to be made, depending on whether a patient is able to take medication by mouth. Only if the patient is not able to do so, does the algorithm direct the clinician to the box for choosing an opioid that would be given intravenously.

"We looked at those who could take medication orally, and then the algorithm says if they can take it orally, they should choose an opioid, such as morphine and have a breakthrough dose," Forte says. "The breakthrough dose is provided at 10%-15% of the total daily dose."

The next major step in the algorithm is to reassess the patient in 18-24 hours, unless the patient's pain requires an assessment before then, he notes.

"If the patient's pain is controlled, we keep the patient on dose and consider changing to a long-acting medication, and if the pain is not controlled, then we go over the cycle again," Forte says.

For nonopioid-naïve patients, the only difference is that the dose might be different, so the clinician works with a bigger dose at baseline and makes adjustments as needed, he says.

"For example, we took care of a lady several months ago who was on a methadone maintenance program, so we had to start her on much bigger doses than someone who wasn't on opioids before," Forte says.

"Physicians in general are very hesitant about making changes in opioids because of a fear of side effects and addiction, but addiction in patients with chronic pain due to ultimately progressive terminal diseases is not a great problem," he notes. "They're also afraid of respiratory depression, but if you watch someone closely, that's a very unusual occurrence."

Finally, when the patient has reached the algorithm step where the pain is controlled, then it's time to switch to a long-lasting medication and have the patient stay on that dose as long as is needed," Forte says.

Reference

1. The World Health Organization. Palliative Care: Symptom management and end-of-life care. World Health Organization's interim guidelines for first-level facility health workers. December 2003; pp. 1-52. Available on WHO web site: www.who.org. ■

Making pain management education top priority

Hospice offers tips for stellar program

The Hospice of the Western Reserve of Cleveland makes pain management education a top priority, and the efforts have resulted in faster and more effective pain control for patients, officials say.

"We can't stress enough how important it is to make sure the staff is totally confident and totally on top of their assessment skills," says **Janice Scheuffler**, PharmD, clinical pharmacist.

"At all times, they are comfortable with what they're assessing in the patient, and we get the best information on how the patient is experiencing pain, describing pain, and feeling pain," she explains. "That drives the plan of care from pharmacological or nonpharmacological aspects."

Education is crucial because a hospice has to be 100% confident in its staff's assessment skills when it comes to pain management, she notes.

For this reason, the hospice has a supportive educational program that emphasizes learning and clinical programs, inservices, and competencies for training and supporting staff, Scheuffler says.

Each new employee attends a pain management class, with nurses attending eight hours of pain treatment training that brings them to a baseline understanding of all aspects of pain management, including methadone use, she says.

Also, there are clinicians who have greater training, including nurse practitioners, best practice nurses, pharmacists, and physicians who do home visits, Scheuffler adds.

All other hospice disciplines and hospice volunteers receive four hours of training in pain management, and this training includes information on documentation, team involvement, and assessment, Scheuffler says.

The hospice also has a core practice committee consisting of all members of a hospice team, including social workers, counselors, and others, and the pain subcommittee is part of that committee, says **Bridget J. Montana**, MS, APRN, MBA, chief operating officer.

Each month, the hospice holds education sessions at the team leader meetings about hot topics or new medications or controversial areas, reports Scheuffler.

"The team leaders take that information, and it floats down to the team," she notes. "We're constantly looking at how you can get all the information out to such a large agency, and we feel this is a good way to do that."

The hospice also sends educational information to ancillary providers, including pharmacies under contract with the hospice, Scheuffler adds.

"We ask them to be part of our team; and if they are working with our nurses, then they should have the same information," she explains.

Hospice nurses also are taught how to use their math skills to make the appropriate conversions between opioids and analgesics, Scheuffler says.

"We often rotate and switch medicines for a variety of reasons, and we are strong in our feeling that nurses must have skills available to rotate patients from one drug to another, and that means math conversions to make sure the patient is handled appropriately," Scheuffler says.

The pain management training is repeated on a regular basis for hospice nurses, says **Mary Kay Tyler**, MSN, CNP, pediatric nurse practitioner/team leader, and chair of the pain subcommittee.

Nurses are given a critical thinking test with five or six scenarios of pain and symptom management, and they're asked questions about these scenarios, such as what medications to use under certain conditions and how to do the conversions from one form to another, she reports.

"We require an 80% pass rate on those tests," Tyler says. "Anyone having difficulty with that needs to go back through the pain management class or have a one-on-one training session with a team leader or advance practice nurse."

Now the hospice requires staff who have not taken the full day training course within the past two years to take it and the critical thinking test again, she says.

"I think the staff really feel supported by these classes," Tyler notes. "It might be anxiety-provoking to do yearly competencies, but I do think it's evidence, at least for myself from being in an acute care setting, that they are being supported by the agency."

This focus on education is part of the hospice's culture of investing resources to promote certification and education of its staff, Montana notes.

"A lot of times organizations focus on the new employee, and we're very committed to evolving those clinicians," she says. "But, we have an environment where the training takes staff to the next level, and it's easier to do this because of our culture." ■

Use the four-box method to enhance decision making

Certified medical ethicist offers this case study

Whether or not hospices have an ethics committee, it is a good idea to review and improve policies regarding ethical decision making, an expert says.

One way to do this is to train staff in the use of the four-box method for making ethical decisions, an expert suggests.

"Once you learn this method, it can be applied to any situation where ethical issues arise," said **Michael Frederich**, MD, FAAHPM, regional medical director of Trinitycare Hospice in Torrance, CA. Frederich is the chairman of the ethics committee at Trinitycare and is a certified medical ethicist, who completed ethics training coursework at the University of Washington in Seattle. He spoke about the four-box method at the National Hospice and Palliative Care Organization's (NHPCO) Sixth Clinical Team Conference, held April 21-23, 2005, in Atlanta.

"Using the four-box method is very practical," Frederich said. "It allows you to sort out salient issues and focus on what's really important, and it's a tool that makes sure you have all the information you need in order to make a decision."

The first step is to gather information and divide it according to each of the four boxes, he explained.

The boxes are as follows:

• **First box — Medical indications:** This box pertains to the disease process, the patient's prognosis, and any medical problems the patient is having, Frederich said.

• **Second box — Patient's preferences:** This area highlights what the patient wants, including his or her goals and desires and whether the patient is able to speak for him or herself. If the patient's interests must be represented by a relative, then that is noted in this box, he said.

• **Third box — Quality of life:** This involves the patient's capacity to enjoy him or herself, and it highlights the quality of life the person currently is experiencing and what sort of quality of life the person would like to have it possible, Frederich says.

• **Fourth box — Contextual features:** "This is the garbage bag where everything else fits in," he explained. "These are the cultural and religious aspects and living arrangements, family features, etc."

By organizing the information into these four boxes, the hospice ethics committee obtains a more complete picture of what is going on, Frederich noted.

"You then apply the ethical principles to reach a conclusion and ethical decision," he pointed out. "These are the things we do on every case we look at."

For hospice work, the five ethical principles are as follows:

• "Relief of suffering is our No. 1 job ethically in end-of-life care," Frederich said.

• Beneficence — doing something for someone's good;

• Nonmalfeasance — do no harm;

• Autonomy — letting the patient do what he or she wants;

• Justice — making sure it's fair and equitable for the public.

Trinitycare's ethics committee meets every

other month and is on call for ethics consults, Frederich reported.

"It works in three steps," he explained. "One step is using me as a medical ethicist to look at a case and render a decision, if it's a simple case."

If a case is complicated, then Frederich, the chaplain, a nurse, and a social worker will do a four-box method on the case and come out with recommendations and, then if it's a very complex case, the entire committee of 15 people, including a lawyer and members of the community, would be called to convene and look at the case from all angles, Frederich reported.

The entire committee has never had to meet to discuss a case because most of the ethical dilemmas are resolved at the level of the hands-on hospice providers, and what is left has not been so complex that it has required the entire committee, he noted.

"At committee meetings, we write policy and procedures over controversial issues like artificial hydration and nutrition," Frederich said. "We want a policy written on each of these controversial issues so the staff have a clear direction of where to go."

Real-life example

At the recent NHPCO meeting, one attendee described to Frederich an ethical dilemma that arose for a hospice, and he used that case as an example of how to apply the four-box method.

"It was a case of a relatively young woman — if I remember right — and that was part of the dilemma; she was fairly comfortable with letting nature take its course and not fighting too hard to survive," Frederich recalled.

"She was having trouble swallowing and didn't want a tube inserted," he said. "But the family was not as comfortable with her decision and, they were making statements about how as soon as she couldn't talk, they'd demand an IV and tube to be put in."

Particularly one sister, who was the patient's nearest kin, was very uncomfortable with the patient's decision to let go, Frederich added.

The patient had not signed an advance directive, but she had made her desires known verbally to her family and health care providers.

Putting the facts of the woman's case into the four boxes, this is how it worked:

- **Box 1:** The woman had metastatic cancer, which had spread to her bones and liver. She had lost a significant amount of weight and, while she was tall, weighed only 110 pounds because she wasn't eating well, Frederich explained.

"She could express herself, but was getting sleepier and didn't have much appetite," he added. "Her pain was well controlled, so she was pretty comfortable."

- **Box 2:** The patient's preference was clear: She did not want to be artificially maintained. Medical staff had heard the woman specify her desire, so even though she did not have an advanced directive, this would be the instruction they would follow even after she could no longer speak for herself, Frederich recalled.

"Part of palliative care is to help the family understand," he said. "She was clear in her wishes, and this is her decision, but we appreciate how difficult it is for family members to accept it."

- **Box 3:** The patient's quality of life was as well as could be hoped because she wasn't suffering and her pain was well managed, Frederich noted.

"She was weak and not able to do as much as she would like to do, so the prospect of increasing her quality of life was poor," he added. "The long-range outlook for her quality of life was poor and consistent with her decision to not extend her life."

- **Box 4:** While the patient espoused no specific religious philosophy, her sister was a born-again Christian, who held all life to be sacrosanct, and believed her sister's life should be sustained at all costs, Frederich said.

That was where the ethical conflict arose, he added.

The next step is to take those four boxes together and apply to them the five ethical principles.

In following this step, the ethical discussion reveals that medical knowledge of what happens when nutrition and hydration are withdrawn demonstrates that this does not cause a patient suffering, Frederich said.

"It's very peaceful and comfortable, and we make sure the mouth doesn't get too dry with a little ice chip or something," he explained.

So the answer to principle one, the relief of suffering, is that withholding artificial maintenance would not contribute to the patient's suffering.

Likewise, since the patient had requested that medical professionals do not prolong her life artificially, beneficence is served because that is what she desires, Frederich said.

There was no issue of malfeasance since withholding feeding and hydration tubes were not harmful in this situation and the woman's

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autonomy is maintained if her wishes are honored, he explained.

Finally, there would be justice in the course to withhold artificial treatment because this type of treatment would not affect society or be inequitable in society, since it has been public policy since 1982 to honor patient's wishes in providing artificial life support, Frederich concluded.

So, the ethical decision would be to honor the patient's verbal wishes and withhold artificial treatment when the time came, Frederich said.

However, there were other suggestions an ethical committee might make in this case, including advising the hospice to have the woman review and sign an advance directive while she was able to do so, he said.

Also, if it were appropriate in this case, there is a strategy hospices might use called the time-limited trial, in which, if there's a specific goal, then a patient could be provided the life support treatment for a limited time, Frederich noted.

This would apply in the case where the dying patient has a specific family member who has unfinished business with the patient and who is hoping the patient will improve for a brief period of time so the family member could speak with him or her, he explained.

"We might consider intravenous fluid for a few days in this case," Frederich said.

Another recommendation would be for the hospice to work closely with the sister to help her see how important and medically ethical it is to honor the dying woman's wishes.

"In this case, the hospice had a responsibility to continue to work with the sister and support her through the bereavement process, but also to open the sister's eyes and continue to show her how much the patient is declining," Frederich said. "No amount of food or water would reverse the cancer and save her life."

Hospice staff also could contact the sister's pastor and have the minister and other members of the church visit with the sister to help her with the process of letting go of her sister, he said.

"Hospice staff could say, 'She's having a hard time accepting the fact her sister doesn't want artificial hydration and nutrition, and we'd like to have you help her work through this,'" Frederich said. "Anything you can do to get through to the family is important because the patient and family are the unit of care."

While the legally and medically correct answer in a situation such as this might be readily apparent, the family conflict over that decision makes it difficult for hospice staff, which is one reason why the four-box method is so important, he noted.

"The beauty of the ethics consultation is it's done by an interdisciplinary team of people, using the four-box method and five principles, and we make a good decision," Frederich said. "Then, we communicate that decision back to the team, and they'll see that due process has been followed and it's the right decision." ■

Don't be fooled by the illusion of patient safety

Judge effectiveness with actual data, observations

As a part of their overall patient safety program, many health care organizations require that managers submit corrective action reports for every significant incident in their department. Those corrective action reports may give senior leaders the feeling they are doing something about every identified problem. However, such reports may represent more of an illusion of patient safety rather than reality.

In some cases, when an incident reveals an obvious equipment problem that can be remedied through repairs, such corrective actions may genuinely contribute to improved patient safety. In other incidents, there may either be no obvious fix that would eliminate the problem that was observed in the incident, or the needed changes may simply be too expensive to implement.

In those instances, the requirement to identify a corrective action for each incident tends to result in corrective action reports that are long on promises — such as reducing staff distractions or implementing better maintenance procedures. Such "mother-and-apple-pie" pledges of corrective action do not ensure a reduced risk to patients.

Action plans such as those often are hard to enforce, and broken promises may become evident only when similar types of incidents reoccur.

Corrective actions that involve staff counseling or training are equally problematic. Even if the promised counseling is done, it is unclear whether this intervention actually will reduce the risk of similar incidents.

When the corrective action report simply says that the particular employee involved in the incident was "counseled," it presumably means the employee was instructed not to make the same mistake in the future. Another similar example of a motherhood-and-apple-pie corrective action is staff training. If the person involved in the incident is particularly ill trained, then retraining actually might be helpful. However, most likely, future instances of the same type of error will not involve the same employee.

Finding the root cause

If the problem is important, it should be brought to the attention of *all* staff members who could potentially end up in similar situations, not just the particular person involved in the most recent incident. Without doing a definitive root-cause analysis for each incident, it often is difficult to determine whether the promised corrective action is even relevant to the problem at hand. For example, a frequent type of human error is failure to use equipment properly, e.g., not programming an IV pump correctly. If this is done purely as a result of inattention, then counseling employees to pay closer attention could conceivably be effective.

However, if the instructions are vague or if the equipment is used only occasionally, it is unclear whether most employees would be able to reliably use the equipment properly. In this situation, providing better labeling and easily accessible instructions are likely to be much more effective than counseling the employees to pay closer attention to their work.

Even when a definitive root-cause analysis is done, this also can give the illusion of patient safety instead of the reality if the root causes are not actually found and corrected.

Incident investigation teams often stop their analysis before the root causes are uncovered. Thus, actions are directed at the significant contributing causes, not the root causes. Take for example incidents involving misadministration of medications in the operating room.

The apparent root cause of many of those events is the lack of an identifying label on the containers used to store drugs on a sterile field (syringes, basins, or other vessels).

The corrective action: All containers *must* be labeled with the name of the medication in the container. So, why do hospitals continue to have similar types of medication errors in the operating room if the root cause has been accurately identified and the proper corrective action implemented?

The most likely reason for continued problems is that the underlying latent system failures have not been found and corrected. In a 2004 survey of approximately 1,600 hospitals by the Huntingdon Valley, PA-based Institute of Safe Medication Practices, more than 42% reported inconsistencies in their labeling of medications and solutions on the sterile field.[1] It is the latent system failures that allow for these inconsistencies, not the lack of a defined procedure. For example, is there inadequate supervision? Are staff members not held accountable for complying with procedures? Are there insufficient resources (e.g., not enough labels)? Do senior leaders have a laissez-faire attitude toward patient safety? Is there a culture of complacency? Will the same problem reoccur?

Those are the types of latent system failures that often are overlooked during a root-cause analysis. Yet these failures must be identified and addressed; otherwise, they will trigger more patient incidents of all types.

If an incident investigation stops when contributing causes have been identified, the underlying system problems are never addressed. To get to the root-cause level, the investigation team must ask, "Why was this situation allowed to exist?" Answers to this question will help uncover the latent system failures that represent the true root causes.

The purpose of this example is not to argue that root-cause analysis is undesirable or counterproductive, but simply to point out that the act of performing a root-cause analysis does not ensure that the root causes actually are found. Leaders can observe that the investigation did indeed take place, but the effectiveness of the root-cause analysis only can be judged in retrospect by the absence of similar incidents in the future.

The existence of a root-cause analysis creates an illusion of patient safety; only the absence of future events confirms the reality of safety.

It may well be appropriate to require a root-cause analysis for each significant patient incident that occurs just to ensure such events are treated with appropriate seriousness. However, resources may be wasted if there is pressure to find a so-called "root cause" in each incident

investigation and implement a corrective action for each identified root cause. More importantly, this may contribute to the illusion of safety by creating a pretense that the root cause of every significant incident has been found and fixed.

Organizational initiatives intended to ensure patient safety are beneficial in many instances. The intent is not to discourage root-cause analyses, corrective actions, and other worthwhile processes changes, but rather to point out that the goal of maximizing patient safety is very elusive.

Requiring incident investigations and corrective action reports can give management the false security that something is being done about all identified problems. However, if only contributing causes are being identified or if corrective actions are mostly motherhood-and-apple-pie interventions, the impression of patient safety may in fact be deceptive. To keep from being fooled by this illusion, organizations must judge the effectiveness of patient safety programs and improvements based on actual data and observations, not solely on the number of incident investigations completed or corrective actions implemented.

Reference

1. Institute for Safe Medication Practices. *ISMP Medication Safety Alert*. Dec. 2, 2004. ■

Aspirin prevents strokes in middle-aged women

Study reveals gender differences

Results from a new major study show middle-aged women who take aspirin lowered their risk of having a stroke, but their risk of myocardial infarction (MI) or death from cardiovascular causes was not affected. The therapy, however, did significantly affect the risk of both heart attacks and ischemic strokes in women ages 65 or older. In addition, the study found that taking a vitamin E supplement (600 IU every other day) had no benefit nor added risk for the women.

The Women's Health Study is the first major trial that focused on the effects of aspirin therapy on women. Previous research had shown that aspirin therapy for men has been associated with a significant reduction in the risk of MI and a nonsignificant increase in the risk of stroke.

The results of the women's study were published on the web site of the *New England Journal of Medicine* on March 7 and appeared in the March 31 issue of the journal. The findings also were reported in March at the meeting of the American College of Cardiology in Orlando, FL. The National Institutes of Health's National Heart, Lung, and Blood Institute and the National Cancer Institute supported the research.

Details of the study

To look at the risk and benefits of low-dose aspirin and vitamin E for women in the "primary prevention of cardiovascular disease and cancer," researchers in the Women's Health Study followed almost 40,000 initially healthy women 45 or older. The women received either 100 mg aspirin every other day or placebo. The researchers then monitored the women for 10 years for a first major cardiovascular event.

During follow-up, researchers confirmed 477 major cardiovascular events in the aspirin group and 522 in the placebo, for a nonsignificant risk

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reduction. There also was a 17% reduction in the risk of stroke in the aspirin group compared to the placebo group. The risk reduction of ischemic stroke was 24%, but the increase in the risk of hemorrhagic stroke was nonsignificant. The aspirin therapy had no significant effect on the risk of fatal or nonfatal MI or death from cardiovascular causes.

Women age 65 or older seemed to benefit most from the aspirin therapy. That subgroup had a 26% risk reduction of major cardiovascular events for those who took aspirin as compared to those who took placebo as well as a 30% risk reduction of ischemic stroke. The subgroup was also the only one in which the women taking aspirin showed a significant reduction in the risk of MI.

The researchers found a greater benefit of aspirin therapy on women who had never smoked or who had quit smoking. The women's menopausal status, the question of whether the women had used hormone-replacement therapy, or their global cardiovascular-risk status did not change the affect of the aspirin. The women who took the aspirin therapy, however, did experience more side effects related to bleeding and ulcers.

Women in the aspirin group reported 910 instances of gastrointestinal (GI) bleeding, as compared with 751 in the placebo group. Forty percent more women in the aspirin group (127) required transfusions for the bleeding as the placebo group (91).

The benefits of aspirin therapy, even in healthy women age 65 and older, definitely should be weighed against the risks of serious GI bleeding and the potential for increasing hemorrhagic strokes, says **Lori Mosca**, MD, in a media advisory issued by the American Heart Association (AHA) in Dallas. Mosca is the chair of the association's writing group for AHA's evidence-based guidelines for cardiovascular disease prevention in women.

"Many women over the age of 65 have uncontrolled blood pressure, which may increase their risk of hemorrhagic stroke, and this should be taken into consideration," she explains. "This, along with the GI bleeding risk, may tip the scales against using aspirin therapy in these women. That's why the decision must be an individual one."

Mosca also reiterated the steps that women — and men — should follow for reducing their risk of cardiovascular disease: not smoking, eating a healthy diet and being physically active, maintaining a healthy weight, and being sure that their cholesterol and blood pressure levels are controlled optimally. "In diabetics, preventive measures are especially important," she says.

Why the gender difference?

The differences in the efficacy of aspirin for primary prevention in men and women are not clear and require further study, the researchers say. The finding that aspirin therapy helps reduce the risk of stroke is particularly relevant because women experience a greater proportion of strokes than men. "From a policy perspective, our findings clearly demonstrate the importance of studying women as well as men in major cardiovascular clinical trials," the researchers say.

The AHA also wants to emphasize that among women with known cardiovascular disease, aspirin therapy is known to be beneficial in reducing heart attacks and strokes. Unless it is contraindicated, those women should receive aspirin therapy, says **Alice Jacobs**, MD, AHA president. "We want to be sure that these women realize that this study does not apply to them. If they and their doctor have decided that they should be on aspirin, they should continue to take aspirin so they receive the best protection," she adds. ■