Pharmacy Purchasing & Products: How have implementation expectations for NPSG 3E changed since it was enacted in 2009?

Darryl S. Rich: In 2009 there were two specific changes made to the regulations under NPSG 3E, which is now NPSG.03.05.01. The element of performance (EP) that dealt with the role of pharmacy in patient monitoring was thought to be redundant in light of the requirement that an organization obtain a baseline or current International Normalized Ratio (INR) for patients on warfarin, so it was deleted. The other change was a consolidation of two elements of performance related to patient education: one dealt with staff and patient education on anticoagulation, and the other was a separate EP that outlined what has to be included in the staff/patient education program. So, we reduced the elements of performance from 11 to nine.

However, The Joint Commission (TJC) recently revised the goal for 2010, and the number of elements has been reduced further to eight, with the elimination of old EP 1—the element requiring hospitals to have written descriptions of their anticoagulation management programs. Also deleted was the requirement to notify the dietary department. In addition, the requirement for a baseline INR has been changed to a baseline anticoagulation assessment, which most likely will be based on an INR, but does not have to be. A current INR is still required for patients already on warfarin therapy. Lastly, physicians no longer have to be educated about anticoagulation therapy, just staff and patients.

PP&P: Can you clarify by whom and when these EPs need to be followed?

DR: The elements of performance for this patient safety goal apply to any organization that dispenses, administers, or orders anticoagulation therapy. The actual phrase used in the goal is “provides anticoagulation therapy,” but this is more clearly defined in the FAQ section posted on The Joint Commission’s Web site. Applicable organizations include those where a physician orders or the pharmacy dispenses anticoagulation therapy, or if anticoagulation therapy is administered within the organization.

Organizations that are simply monitoring therapy would not be eligible. For example, a clinic providing diabetic care to a patient may also check the patient’s INR. However, as the clinic did not order, dispense, or administer that product to the patient, they are not responsible for following the elements of performance.

In addition, the requirement applies any time you are providing anticoagulation for therapeutic or prophylactic use with a clinical expectation that the patient’s lab values for coagulation will remain outside the normal values. Thus, prophylactic use where the intent is to keep the lab values within the normal range—with DVT, for example, heparin 5000 units SQ q12h—would generally not be considered within the scope of the national patient safety goal. Many hospitals have been running into problems because their orthopedic surgeons are prescribing warfarin for prophylaxis and are looking for an INR that is not therapeutic, but is still above normal. This instance still meets the requirement for inclusion in the goal. Finally, we did not apply the goal to flushes.

PP&P: Currently NPSG.03.05.01 only applies to three anticoagulants—warfarin, unfractionated heparin, and low molecular weight heparins. Does TJC have plans for adding more in the future?

DR: We started with these three products because they are the most commonly used and have lead to medication errors in the past. In addition, because protocol development requires a significant amount of time, our goal was to avoid overwhelming organizations as they began this task. Eventually other anticoagulants will be added to the list. Certainly an organization can include other anticoagulants in their current management program, as many have already done. We encourage the inclusion of other anticoagulants used in patient care, but do not require it.

PP&P: Why has full compliance with NPSG.03.05.01 been so challenging for many hospitals?

DR: Previously, outside of using pre-mixed products, many hospitals had done little in regard to anticoagulation therapy. Instituting an anticoagulation therapy program is a major undertaking and developing the protocols can be difficult. To create a successful program requires significant input and agreement from the medical staff, and this can take a considerable amount of time to accomplish. Too often, organizations just dump this responsibility on the pharmacy depart-
ment and expect them to implement this goal. In addition, many organizations implementing anticoagulation programs for the first time do not realize the scope and complexity we are looking for in this program. As a result, they develop simple programs that do not sufficiently meet the requirements, such as having a pharmacist call the physician when an INR is out of range.

PP&P: Which EP has been the most challenging to comply with?

DR: The most problematic element of performance is the third one, which states, “The hospital uses written approved protocols for the initiation and maintenance of anticoagulant therapy.” When we say protocol, we want the organization to standardize the care that is being provided for a patient by all prescribers based on best practices that are identified in the literature, unless there is a patient-specific clinical justification for any deviation. We want the implemented protocol to be something that the medical staff has considered and agreed on as a best practice for the dosing and initiation of these medications. Since most protocols vary for the condition being treated, an organization should have a different protocol for atrial fibrillation than they would for DVT, for example. We expect to see that the protocols for anticoagulation therapy use are developed by the appropriate medical staff departments, and then are followed by all physicians. The atrial fibrillation guideline should originate with the cardiology department, and the DVT guideline should come from surgery and/or orthopedics. Also, the guideline should address all initiation and maintenance dosages, including any laboratory monitoring as well as any rescue protocol or use of reversal agents for the treatment of adverse drug events related to these products.

In my experience organizations have the most difficulty with warfarin. Heparin protocols are quite common.
and many organizations had these in place prior to this goal. However, we require protocols for each category of anticoagulants identified in the goal—unfractionated heparin, low molecular weight heparin, and warfarin. We also commonly see the unacceptable practice of a warfarin dose being ordered by a physician and then pharmacy simply monitors the INR and if it is over three, for example, they will sometimes consult with the physician and recommend a different dose, and sometimes not. This does not qualify as a protocol because the physician is not following a protocol in writing the original dose. It is also common to see a physician order for warfarin that states “dosing per pharmacy.” However, a protocol is still required for the pharmacist to follow in dosing the patient. It is not acceptable to state that the organization is using the experience of the pharmacist to make the decision. There has to be a protocol in place that is followed. While some may feel that developing a warfarin protocol is impossible or undesired by the medical staff, the fact is that TJC requires it.

**PP&P: What are the organizations that are successfully complying with this EP doing right?**

**DR:** These organizations determined where anticoagulants are used in their institution and for what indications, gathered the relevant literature, and developed the protocols with the appropriate departments.

While a standing order sheet for warfarin or heparin is not required, I find that organizations taking this approach do a much better job at compliance with TJC requirements. The process of developing the standard order sheets forces the organization to create guidelines. These forms then provide all of the necessary information in one place for the physicians to make the right decision.

**PP&P: What other aspects of NPSG.03.05.01 have hospitals found problematic?**

**DR:** The requirement that states “for patients starting on warfarin a baseline International Normalized Ratio (INR) is available, and for all patients receiving warfarin therapy, a current INR is available and is used to monitor and adjust this therapy” is an issue for many organizations. This was recently changed to require a documented baseline anticoagulation assessment (which may or may not include a baseline INR), and a current INR for patients already on warfarin. We no longer require the pharmacy to hold up dispensing an anticoagulant without the INR value being received and reviewed by a pharmacist. This was problematic at some hospitals in 2009. It needs to be remembered that “baseline” does not mean “on admission”—it means a patient who never received warfarin before or received it so long ago that it is no longer in the body. A patient admitted to the hospital on warfarin must still have a current INR. However, hospital policy decides what is and what is not current.

There also are significant compliance issues with the EP that requires education of staff and patients’ families. While everyone is on board with discharge education, particularly for warfarin, many organizations have not developed educational programs for heparin. Keep in mind that we do require education while patients are in the hospital, not just on discharge.

**PP&P: What are the common struggles pharmacists face with anticoagulation management?**

**DR:** Many organizations are considering pharmacist-run anticoagulation clinics. Some organizations have been successful with this, and others are finding it difficult because of funding and other reasons, such as difficulty developing rescue therapy protocols. There is a dearth of good evidence-based practices out there. For example, when do you use protamine versus fresh frozen plasma for heparin overdoses? There are different guidelines, but there is no real evidence demonstrating the superiority of one over the other and that is causing some people problems. In addition, pharmacists managing anticoagulation therapy may find some of the goals too restrictive—the requirement to have a protocol for instance. They are used to making determinations based on their experience and this approach requires a different mind set.

**PP&P: Regarding compliance, where have you seen successes?**

**DR:** The vast majority of organizations have been able to comply with the EP requiring the use of pre-mixed, pre-filled unit doses.

I also have been very impressed by the compliance with the requirement for notification to the dietary department, and in particular with how dietary has responded to this requirement. A lot of dietary departments that I have spoken with have implemented a program wherein once they are notified that a patient is on heparin, a clinical dietician is assigned to and works with this patient to ensure their diet is proper and that they are more closely monitored. Most of the hospitals I have surveyed have been excellent in this area. However, this is no longer a requirement of the goal.

To put this in perspective, in the first half of 2009, only 5% of organizations were cited for non-compliance with all elements of performance for this goal. Overall, most organizations are doing a good job.

In the first half of 2009, only 5% of organizations were cited for non-compliance with all elements of performance for this goal.

**PP&P: What innovative approaches have you seen during your surveys?**

**DR:** One organization I surveyed uses its TV channel to provide continuous education on anticoagulation to patients. The nurse can refer the patient to the specific TV screen as well as provide the normal written information on discharge. It was good to see an organization going a step beyond the normal practice.

In addition, many organizations are moving toward using smart pumps, either
specifically for anticoagulation products or for general usage. Using this technology definitely adds a level of safety to the process.

At organizations that cannot dedicate a pharmacist to managing their anticoagulation program, I have seen staff pharmacists rotate into the position on a weekly basis, and due to good communication practices, information regarding the patient was not lost in the transition. This is a good approach for organizations that cannot afford to dedicate a pharmacist to anticoagulation management.

Overall, organizations with good anticoagulation management programs in place dedicate significant time to educating their nurses and pharmacists.

PP&P: Do you have any tips to help pharmacy achieve successful compliance with NPSG.03.05.01?

DR: Staying current on this topic is important. Keep in mind, with all of the national patient safety goals there is a learning curve for both the surveyors as well as the organizations being surveyed. For example, we have found that the increase in citations for labeling in the procedural setting is generally a result of the surveyors becoming more comfortable with the requirements of the goal and what to look for. Since the goal came out, TJC has been pretty lenient with its expectations. However as TJC provides more education as to their specific expectations for this goal, surveyors will get tougher and organizations will be found noncompliant more readily.

Also, pharmacy has to understand that this not a program that they have to implement in just their department; rather, pharmacy needs to work with all medical staff involved to ensure a successful program.

PP&P: Why did TJC decide to make changes to NPSG.03.05.01 for 2010?

DR: TJC decided to make changes to all the national patient safety goals—not just NPSG.03.05.01.
In 2008, all of the standards were reviewed individually to reduce duplication and clarify the language of the elements of performance so they would be easier to understand. In January 2009, we released a revised version of all our standards, including a new numbering system. This was called the Standards Improvement Initiative.

However, this was not done for the national patient safety goals, so in 2009 we decided to do the same thing for them. Basically, the goal of the program was the same—to revise the national patient safety goals so the language was clear, eliminating anything that was duplicative or of no value. One of the other goals was to move some of the national patient safety goals to standards. Because there is a limit to the number of goals we can have, transferring some of them into standards makes room for new goals.

PP&P: What are some of the changes for 2010?

DR: The new changes were announced in the October issue of Perspectives—our official newsletter. Pharmacists can get a copy from their hospital’s TJC coordinator. Also the new goals are posted on The Joint Commission Web site (www.jointcommission.org). As I have discussed, TJC has made significant revisions in both the wording and requirements of the anticoagulation management goal that make compliance a bit easier and less prescriptive, and we are not moving it to the standards, as we are with some of the other goals. However, the requirement for a written protocol for warfarin will still give many organizations problems in 2010.

PP&P: What is TJC’s plan for NPSG.03.05.01 in the long term?

DR: We plan to add new drugs to the list down the road. As with all of our national patient safety goals, we look at what issues are coming up at survey and use the feedback we get from organizations to help us make changes and revisions to the goals as we move forward. For example, we are currently completing major revisions to the medication reconciliation goal and we just completed changes to our universal protocol for wrong-site, wrong-patient surgery. The long-term plan for NPSG.03.05.01 is to tweak it to address the most relevant

### Elements of Performance for NPSG.03.05.01*

| 1.  | Use only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available. Note: For pediatric patients, prefilled syringe products should be used only if specifically designed for children. | A |
| 2.  | Use approved protocols for the initiation and maintenance of anticoagulant therapy. | C W |
| 3.  | Before starting a patient on warfarin, assess the patient’s baseline coagulation status; for all patients receiving warfarin therapy, use a current International Normalized Ratio (INR) to adjust this therapy. The baseline status and current INR are documented in the medical record. | A |
| 4.  | Use authoritative resources to manage potential food and drug interactions for patients receiving warfarin. | A |
| 5.  | When heparin is administered intravenously and continuously, use programmable pumps in order to provide consistent and accurate dosing. | A |
| 6.  | A written policy addresses baseline and ongoing laboratory tests that are required for heparin and low molecular weight heparin therapies. | A D |
| 7.  | Provide education regarding anticoagulant therapy to staff, patients, and families. Patient/family education includes the following:  
  1. The importance of follow-up monitoring  
  2. Compliance  
  3. Drug-food interactions  
  4. The potential for adverse drug reactions and interactions | C W |
| 8.  | Evaluate anticoagulation safety practices, take action to improve practices, and measure the effectiveness of those actions in a time frame determined by the organization. | A |

*This is the pre-publication version of this goal for the 2010 National Patient Safety Goals

**Key:**  
- A indicates scoring category A;  
- C indicates scoring category C;  
- Indicates direct impact requirements apply;  
- Indicates Measure of Success if needed;  
- Indicates that documentation is required.
issues and then eventually move it into a standard when compliance is strong.

**PP&I:** If a hospital pharmacy has questions about meeting the goals outlined in NPSG.03.05.01, what should they do?

**DR:** In terms of developing and implementing best practices, peer networking and reviewing what other organizations are doing is the best approach.

For questions about the survey process, the best approach is to contact TJC's Standards Interpretation Group (SIG). You can call 630-792-5900 anytime between 8AM and 5PM central time and have your question answered by a specialist. You also can use the online form on the TJC Web site if you want to receive a response in writing in 10 days or less.

For oft-asked questions, SIG develops written answers and posts them on The Joint Commission Web site as FAQs. Go to http://www.jointcommission.org/Standards/FAQs/ and search under your particular setting—hospital, ambulatory care, and so on.

Darryl S. Rich is a surveyor for The Joint Commission in the hospital, home care, and ambulatory accreditation programs. In addition, he works for the Standards Interpretation Group serving as an internal resource for The Joint Commission on issues related to pharmacy and medication management. He previously served as associate director for surveyor management and development at The Joint Commission for 11 years. Dr. Rich has been with The Joint Commission since January 1993.

Prior to coming to The Joint Commission, Dr. Rich was national director of pharmacy services for Critical Care America, Inc., a national home infusion company. Prior to that, he served as director of pharmacy services at Boston University Medical Center and clinical assistant professor of pharmacy at Northeastern University. Dr. Rich received his doctor of pharmacy degree from the University of California at San Francisco and a master's in business administration in health care management from Bryant University in Rhode Island.