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Anticoagulation Management

Address TJC Guidelines Now for a Successful Survey in 2009

Widely used for multiple clinical indications, anticoagulation therapies require close dose monitoring and optimization to achieve its full benefit. This therapy is prone to overdosing and bleeding complications, but can also be at risk for under-dosing and the resulting loss of therapeutic benefit. Many hospitals have established innovative anticoagulation management programs in their ambulatory care clinics, utilizing the skills of their pharmacists and advanced practice nurses. However, these excellent pilot programs do not often reach across the entire organization or into the inpatient sector at all. Using its national patient safety goal program, the Joint Commission (TJC) has created the impetus to stimulate the expansion of these programs.

While health care literature describes many innovative patient safety practices and TJC describes many important risk issues and potential solutions in its publications, hospitals have to prioritize and decide which innovations can be of greatest value to their patient population. In addition, in 2007, the Joint Commission's Sentinel Event Advisory Group proposed, and the TJC board approved, a national patient safety goal for January 1, 2008, to "reduce the likelihood of patient harm associated with anticoagulation therapy".

Learning from the Medication Reconciliation Experience

The Joint Commission introduced its safety goal for medication reconciliation with a phase for 2005. Unfortunately, many organizations allowed 2005 to slip by, and only began to focus on implementation in 2006, when frequent reports of surveyors scoring this issue began to appear. In 2005, all TJC surveys were announced and conducted only in the year anticipated, but in 2006, TJC began to conduct its surveys in an unannounced fashion. TJC will be more aggressively pushing and pulling survey dates in 2008, so it is possible that a hospital that had a full survey in 2006 could have another full survey in 2008. This will continue in 2009, making it possible for hospitals surveyed in either 2006 or 2007 to have another full survey in 2009. This unpredictability is particularly important to those interested in success with the anticoagulation management safety goal, because, even though organizations surveyed in 2006 knew to expect TJC, medication reconciliation was one of the most frequently scored issues in that year.

Milestones for 2008

Presumably to encourage organizations to make greater use of the planning year, TJC has established four milestones for 2008 in the anticoagulation safety goal. By April 1, hospitals have to identify and assign an "in charge" person for implementing the safety goal. By July 1, they have to create a formal work plan for organization-wide implementation. By October 1, they have to do pilot testing on at least one unit. Lastly, by January 1, 2009, the program has to be fully implemented throughout the entire organization. The first three milestones are easily accomplished, whereas the leap between the October 1 pilot and the January 1 house-wide implementation is significant. It is likely that systems that work well in the pilot location may not work as well elsewhere. Because you have to fully implement your anticoagulation management program by January 1, 2009, it is advisable to advance the implementation timeline. Leaving the expansion entirely to the fourth quarter of 2008 could create delays in house-wide implementation and lead to unneeded requirements for improvement in 2009.

EP2 requires absolute performance in the use of unit dose oral anticoagulation products and pre-mixed infusion solutions, if they are available.

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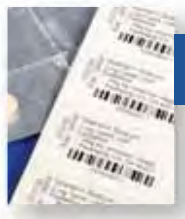
2009 Elements of Performance

EP1: Begin focusing immediately on the requirements of the 2009 safety goal as you design your anticoagulation management programs. The first element of performance (EP) is an A element, meaning that surveyors will look for a defined policy and absolute implementation, and requires that there be a "defined anticoagulation management program" that is written down in detail and up and running throughout your organization. Failing to have a written program description or implement a program organization-wide may lead to citations on this EP.

EP2: Another A element, the second EP requires absolute performance in the use of unit dose oral anticoagulation products and pre-mixed infusion solutions, if they are available. It is quite likely that hospitals are already using oral unit dose products, but some hospitals may still be performing in-house compounding or, worse yet, on-unit admixing. Examine the concentrations of infusions that you routinely use and try to identify vendors that can supply you with manufacturer-prepared infusions. The safety goal for standardizing drug concentrations has been eliminated, but the expectation has not gone away. It has been moved to the medication management chapter under MM.2.20, EP 10. Thus, if the concentrations of anticoagulants used in your hospital are proving difficult to obtain from manufacturers, re-examine your compliance with the standardization



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requirement and develop a purchasing solution to improve compliance.

As one last piece of advice on this issue, make sure you are distributing oral unit dose products to all inpatient sectors of the organization. Many hospitals have a small extended-care-type unit that TJC reviews as part of the hospital, and you will want to ensure you are distributing oral unit dose anticoagulants to this unit in order to achieve compliance. At press time, TJC had not yet published its "Frequently Asked Questions" for this safety goal, but it is assumed that oral unit dose anticoagulants are not required in outpatient settings. However, check the Joint Commission's website for this information going forward.

EP3 and EP 4: Both EP3 and EP4 are C elements of performance, meaning they are rate-based evaluations that require 90% compliance or better. TJC's first expectation is that you "dispense warfarin in accordance with established monitoring procedures." In other words, establish structured protocols for INR monitoring and structured response processes to those INR values. Most importantly, EP4 requires that you follow your established monitoring procedures in at least 90% of cases. EP4 requires that you use "approved protocols, for both initiation and maintenance" that take the disease being treated and the risk of drug interactions into consideration. Again, this expectation is rate-based, so if your protocol says you will perform INR testing every third day, you must make sure this is accomplished. To reduce the potential for omission, many hospitals will develop preprinted order sheets that outline detailed drug and monitoring requirements.

EP5: Also an A element of performance, EP5 requires that you obtain a baseline INR for patients started on warfarin, and that you use INR for all patients receiving warfarin. When you meet with your medical staff to spell out how you will accomplish EP3 and EP4, also determine how you will meet EP5. Bear in mind, however, that this element is not rate-based; it requires a written policy and carries an absolute performance expectation. One area of ambiguity in this EP is the term "started on warfarin." At the TJC summer 2007 Executive Briefings, we heard this expectation for a baseline INR applied to all patients being started on warfarin at your organization, including those admitted on a stable warfarin regimen, as opposed to just those patients beginning warfarin therapy in the hospital. This issue will likely be detailed in the Joint Commission's FAQs for this safety goal.

EP6: This C element of performance requires your dietary department to be notified and respond accordingly when patients are taking warfarin. Build and refine your business process for EP6 as early as possible in 2008, so you are sure it works effectively before 2009. There are already standards and routine processes for nutrition screening upon admission, followed by evaluations when warranted. For this goal, you will need to establish a notification process to keep dietary informed. For example, if your physician order entry system or pharmacy information system can automatically send a notification, that system will probably be more reliable than asking unit clerks to send requisitions or consult paperwork. Bear in mind that this EP will be evaluated by tracer; the surveyor will see patients on warfarin and look for the documentation that dietary was notified and involved. If your established policy requires that dietary respond to consult requests within 24 or 48 hours, the surveyor will also be in a position to evaluate if this internal expectation, which counts just as heavily in the accreditation process, was achieved.

EP7: This A element of performance requires the use of infusion pumps for heparin delivery, which many hospitals are already doing. While, as of yet, there is no requirement for the use of smart pumps to deliver heparin, verify this information against the Joint Commission's FAQs for this goal, once they are published.

EP8: While it is a C element of performance and, as such, a rate-based evaluation, EP8 requires a policy addressing baseline and ongoing laboratory monitoring for all patients receiving either heparin or low molecular weight heparin. It is safe to assume that surveyors will also look for implementation of that monitoring policy.

EP9 and EP10: Both EP9 and EP10 are C elements. EP 9 establishes a requirement to conduct training for four target populations: staff, prescribers, patients, and families. EP10 establishes a content expectation requiring training about monitoring, dietary restrictions, interactions, and potential adverse effects. During tracers, the surveyors may encounter staff, physicians, patients, or families who know or recall nothing about this kind of training, and this may lead them to drill down to find out if training was provided, but forgotten. Organizations should establish a goal to provide training that leads to demonstrated comprehension. Too often, we hand brochures to patients so that we can check a box that information was provided, but our true goal needs to be comprehension in our audience. For 2009, train the staff that will conduct patient education and document their competency in providing education. In addition, when patient education is provided, document its completion, as well as a statement of the patient's comprehension level. If the patient did not seem to understand, follow-up sessions may be needed. Our goal is successful inpatient treatment, as well as a successful discharge and outpatient treatment. A patient who acquired knowledge about their anticoagulation treatment and the potential for drug or food interactions is more likely to be successful after discharge.

EP11: This last EP for 2009 is an A element and thereby requires documentation of completion. Under EP11, you must perform a self-evaluation of your anticoagulation management program. Hospitals may want to tie this activity to their self-evaluation of MM.8.10 or their the overall medication-use process. You may also time your self-evaluation to feed the TJC requirement for a periodic performance review (PPR). Be sure to document your evaluation activities and present your findings and your plans to improve your program to the appropriate clinical review committee at your hospital. It is important to remember that these are not just paperwork requirements, but are meaningful steps in a performance-improvement process. Whatever vulnerabilities you uncover and whatever improvements you propose in 2008 should be formally reevaluated in 2009 to determine if you are achieving the desired results.

Conclusion

Pharmacists will likely welcome the new anticoagulation safety goal because of its potential for immediate patient safety benefits. In comparison to the medication reconciliation goal, the 2008 requirements for anticoagulation management established by TJC are easy to achieve organization-wide. The requirements for 2009 are more detailed and not as easily adopted, so prepare in advance for the TJC's milestones in order to have time to make program changes prior to January 2009. n

Now the owner of Patton Healthcare Consulting, LLC, Kurt A. Patton, MS, RPh, served as executive director of accreditation services at the Joint Commission for over seven years, until his retirement in December 2005. Before joining the Joint Commission, Patton was the deputy director for the Division of Strategic Initiatives and Managed Care in the New York State Office of Mental Health. Previously, he served as the administrator for a state-operated behavioral health managed care program and as the director of the Bureau of Health Services. Patton earned his bachelor's degree in pharmacy and his master's degree in institutional administration from St. John's University.