Advance and contingency preparations meet changed inspection system

By David R. Jadwin, DO, FCAP

On one of my vacation mornings in January 2006, I received the call from the hospital. The College of American Pathologist’s (CAP’s) inspection team had just arrived, unannounced, to perform our biennial laboratory inspection — without me present! Several weeks earlier, I had been invited by CAP to voluntarily enroll our laboratory to become the first laboratory inspected under a trial program. Their goal for the trial was to assess problems that might arise from operating unannounced inspections. Planning and thorough preparation in our 220-bed teaching hospital for this inspection would make the difference between our laboratory’s success or failure.

All CAP had told me was that the inspection would take place after the first of the year, so the laboratory had to be fully prepared by January 3 — just a few weeks away and likely months ahead of what would have been a routinely scheduled inspection. Although our county hospital struggles with extreme California clinical laboratory scientist shortages and chronic budgetary restrictions that permit only the most basic of needs, we reasonably manage to keep current with policies, documentation, and compliance standards. Of course, laboratories always struggle with the typical last-minute rush to get final details in place. Are all of the policies up-to-date and signed? Are all of the reagents dated? Are expired supplies off the shelves? Was the last fire drill required by standards performed and documented? Pleasantly enough, that sense of last-minute urgency was largely missing because we had recently been doing what we should have been doing all along — continuous preparedness.

Many months earlier CAP’s Washington staff was abuzz with scandalous articles pumping from The Baltimore Sun following its exposé article in 2004. Maryland General Hospital, immediately post-satisfactory CAP inspection, was being inspected by the Maryland Department of Health for fraudulent laboratory practices involving HIV and hepatitis testing. Congress was launching hearings into accreditation by Centers for Medicare and Medicaid Services-deemed organizations that had been launching hearings into accreditation by Centers for Medicare and Medicaid Services-deemed organizations that had been launched unexpected inspections. The time-honored CAP inspection process was also to change, from the collegial-peer improvement process to a critical review and scrutiny of actual laboratory practices. Inspectors and inspections were about to get much tougher. But how could laboratories possibly prepare for unannounced inspections? It was not possible to have all key staff present all the time for a possible inspection that could occur any unscheduled day. This was impractical and absurd, declared many senior pathologists.

Preventing for the unknown

This is how our laboratory successfully prepared for this eventuality: advanced preparedness and contingency scheduling. Foremost, laboratories must now do what they should always have done — keep current on all administrative functions. Directors must develop and maintain a rigorous system of administrative control and update. Gone are the days of sitting back 22 months between servicing deficiencies during the month following the last inspection and preparing for inspection one month before the next inspection. Directors and managers need to maintain a disciplined approach to laboratory management that ensures continuous compliance with accreditation standards and governmental regulations.

Contingency scheduling is the key to a smooth inspection process when the day of the unannounced inspection occurs. During the tentative inspection period — the period within which an inspection team could show up any day — contingency arrangements must be made for coverage in the event of a key staff absence. This means having a contingency schedule for administration, nursing, medical-staff leadership, laboratory director, and lab supervisors. This is not as onerous as it may...
first appear. Directors must identify scheduled absences, assign alternates, ensure that alternates are fully knowledgeable about policies and procedures, and make sure that an alert system is developed to inform and activate key staff and alternates when the inspection does occur.

You may avoid anxiety altogether if you are as fortunate as I was to be on vacation when the unannounced inspection occurs!

Another good practice includes attaching flags referencing standards to actual policies, procedures, and performance documents in the event that a key member is absent when the inspection occurs. The benefit of this measure is well worth the effort. Rapid and organized laboratory response to surveys questions about standards conveys confidence that the laboratory is orderly and well managed, and will greatly shorten the inspection process. Cross-referencing laboratory documents with laboratory standards also facilitates staff practice and preparedness for the inspection process.

Learn the ‘tracer’ methodology

Finally, be aware of CAP’s use of tracer methodology during the inspection process. The tracer methodology is patterned after The Joint Commission’s Continuum of Care focus, which was implemented during January 2006. Continuum of Care is a focus method to better assess the patient’s hospital course, as documented in the medical record, looking for appropriateness and timeliness of patient care in relation to hospital accreditation standards. CAP tracer methodology was similarly adopted during the same time as The Joint Commission’s Continuum of Care. Tracer methodology is designed to assess the appropriateness and timeliness of laboratory-specimen handling by tracking the movement of one or more samples in real-time through pre-analytic, analytic, and post-analytic phases of the testing process. In this process, an inspector will ask persons handling the specimen to recite their knowledge of standards and practices in an effort to evaluate how adequately staff functions.

Such preparedness will go a long way in eliminating the anxiety that often accompanies the laboratory inspection process. And who knows? You may avoid anxiety altogether if you are as fortunate as I was to be on vacation when the unannounced inspection occurs! To receive other useful preparatory suggestions for meeting the challenge of an unannounced accreditation inspection, contact the CAP laboratory-accreditation program. I

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A perfect score
By Julie Bos

For most clinical laboratories, biennial The Joint Commission surveys can be a time of trepidation. After all, there is much riding on these on-site evaluations — including the ability to operate as well as eligibility for reimbursement by Medicare. The Joint Commission surveys, intricate endeavors on their own, became further complicated in 2006, when they started being conducted on an unannounced basis — evolving from regularly scheduled evaluations into “surprise” checks. The laboratory at John T. Mather Memorial Hospital (JTMMH) in Port Jefferson, NY, recently completed its Joint Commission survey, and proudly reported a perfect evaluation — thanks in large part to the lab’s streamlined processes, LEAN best practices, and a comprehensive automation solution.

Laboratory survey background
The Joint Commission, the national accrediting body for hospitals, laboratories, and other healthcare-delivery organizations, began conducting laboratory evaluations in 1979. Its goal has been to encourage safe, high-quality healthcare through a regular accreditation process that supports and evaluates the organization’s quality and safety goals. The Joint Commission’s National Patient Safety Goals reinforce that mission by providing a guide to reducing the accidents, miscommunications, and preventable medical errors that can compromise patient safety. According to CLIA’88 regulations, laboratory surveys must be conducted every two years. For labs within hospitals, this biennial survey is separate from the hospital’s triennial survey.

Since the John T. Mather Memorial Hospital laboratory was last surveyed in July 2004, the lab knew it was due for another visit in the summer of 2006. The lab’s anticipated survey became reality a year ago on July 18, 2006, when the lab learned that the surveyor was not only on her way, but that the two-day survey process was to begin in less than an hour.

JTMMH is a not-for-profit hospital situated on the north shore of Long Island in Suffolk County (population 1.4 million). Since its establishment in 1929 as the first community hospital in its area, Mather has continued to meet the changing healthcare needs of the community by pioneering programs unique to a community hospital. Mather gained another first in February 2001 when it became the only hospital on Long Island, and the only community hospital in the entire northeast region, to be equipped with a state-of-the-art, fully automated, in-house laboratory robotics system.

Tracer methodology at work
As is now typical for The Joint Commission, the majority of the surveyor’s time is spent conducting the survey using a tracer method of evaluation, looking at how care is being delivered, rather than on policies. This process involves “tracing” the patient’s stay — from point of entry to post-discharge and all points in between. Surveyors examine how the patient-care

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the JTMMH lab meet its The Joint Commission patient-safety goals by automating patient identification, speeding up TAT, and increasing results accuracy.

Stellar results

At the end of the two-day process, The Joint Commission surveyor conducted an exit interview with hospital’s senior management team and provided the survey results and his findings, which often include recommendations for meeting National Patient Safety Goals — specifically, proper patient identification, increased and effective communication between caregivers, as well as efforts to prevent medication errors. In the case of JTMMH, however, the surveyor informed the laboratory it had received a perfect evaluation, with no specific recommendations for improvement, no follow-up issues, and no supplemental items requiring attention.

“In the past, The Joint Commission assigned numeric scores to its surveys, but in 2004, the Joint Commission eliminated performance scores — shifting the focus from passing the exam to continuous operational improvement,” says Geiger. “So even though we did not get a numeric score, the fact that The Joint Commission did not list any recommendations says that they found our lab’s systems of safety and quality of care to be in full compliance with their standards and elements of performance.”

Meeting more rigorous standards

“Today’s regulatory environment is more complex than it used to be — and requires more stringent patient safety goals than ever before,” says Geiger. “For me, this Joint Commission survey score was one additional affirmation of our recent transacted changes — the most important being our adoption of laboratory automation in 2001.”

After installing a total automation system, the lab increased total testing volume by 82.6%, while maintaining the same number of lab employees. It also witnessed a 152% increase in revenue, a 17% decrease in cost per test, and a 79% reduction in drugs-of-abuse turnaround time.

“As part of our LEAN process-improvement efforts, we viewed the adoption of automation as a cost-effective way to improve our processes, increase productivity, and lower overall costs,” says Geiger. “The automation system we selected offered the most comprehensive solution to our ongoing efforts, which are validated every day by keeping us inspection-ready at all times. We are very pleased with our latest The Joint Commission results, and attribute much of our success to our best practices and our automated processes.”

Julie Bos is a freelance writer for Beckman Coulter. The instrumentation mentioned in this article includes the company’s Power Processor (pre-analytic processing), its UniCel DxC 800 chemistry analyzers, and its DataLink DL2000 data-management software.

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