



News

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Preparing for Accreditation: What's the Process?

Clarifying the Process Approach to Laboratory Management and Assessment

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The purpose of this article is to clarify what is meant by the term “process approach” and describe how it can be used to manage a laboratory. In addition, it will clarify how Ontario Laboratory Accreditation (OLA) assessors will use the process approach to assess laboratories.

QMP-LS encourages laboratory management teams to adopt a process approach to the design, implementation and maintenance of their quality management system and its assessors will use a process approach to conduct assessments for accreditation.

Definitions

Process approach

A desired result is achieved more efficiently when activities and related resources are managed as a process.¹

Process

A series of inter-related steps involved in an activity or examination that uses resources and is managed to transform inputs into outputs.

Quality management system

A program developed to support efficient and effective, high quality and appropriate laboratory services.

Comprehensive and coordinated efforts (policies, processes and procedures) designed to meet quality objectives, to direct and control an organization with regard to quality.

Using Processes to Mistake-proof

The concept of managing processes as opposed to procedures has been used in business and industry for over 40 years. In 1961, a mistake-proofing system called poke-yoke was established by the creator of the Toyota production system. The basis for the poke-yoke system is to create a process in which a worker cannot create an error.

It is important to recognize that most mistakes are not made by people, but are caused by process failures. To prevent mistakes, the root cause (usually a process error) must be determined, and the process redefined for safety. Focusing on procedures and individuals as a way of preventing mistakes will not eliminate the root cause of a problem, the mistakes may reoccur and there will not be any improvement in quality.

The Status of Health Care

Traditionally, health care asserts that systems are safe for patients because medical professionals are highly trained experts. We depend on excellent individual performance to achieve quality and safety. We preach that excellent people make the difference, not the systems in which they work.

Despite the efforts of our professionals, a report released by the Institute of Medicine



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in 1999 titled “To Err is Human” estimated that more people die from medical errors than from motor vehicle accidents, breast cancer, or AIDS. The report asserts that “the problem is not bad people in health care—it is that good people are working in bad systems that need to be made safer. Errors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing.”² Clearly it is time to look beyond quality control and quality assurance of individual procedures and look for ways to improve processes to ensure quality.

Applying the Process Approach to Laboratory Medicine

Recent data from the College of American Pathologists show that only 7% of laboratory errors on proficiency testing surveys can be attributed to analytical error. The remaining 93% of errors are in the pre- and post-analytical phases not managed by traditional quality control practices.

A study conducted by Callum et al in 2001 revealed that 7.4% of transfusions are “near-misses” that were potentially life-threatening or could have led to permanent injury. The study concluded that “innovative mechanisms must be designed to prevent these errors, instead of relying on faulty informal checks to capture errors after they occur.”³

We in laboratory medicine are ahead of many of the medical fields in that quality control and quality assurance routines are part of our culture, but it is time to take quality measures beyond the analytical phase and into the entire path of workflow (pre-analytical, analytical and post-analytical phases). We have yet to embrace the concept of using a process approach to reduce errors.

How to Develop and Implement Processes

Your goal in managing processes is to create a system that is failure resistant.

The first step is to map out the laboratory’s processes, but committing your processes to paper will not in itself result in any improvement. Staff must be trained to consistently follow the processes as defined. Even experienced employees may need to be trained. The next steps are to measure the effectiveness of your processes, develop strategies for change, then measure again to show that the change resulted in improvement. These steps are summarized below:

1. Identify and map the primary processes in your facility. Begin at the highest level possible, likely a simple flow chart that traces a laboratory examination from physician order to the reported result.
2. Map the processes down to greater detail and determine the sequence and interaction of the processes. Usually the output from one process will form the input to the next, but the relationship may be far more complex in some cases. Clarify the start and stop of each process to avoid creeping beyond the boundaries of the process being defined. Identify the personnel position responsible for each step of a process and be sure to involve these individuals when mapping.
3. Define the criteria for determining that the process is effective.
4. Ensure that there are adequate resources available to implement the process.
5. Train staff and implement the process.
6. Monitor and measure the effectiveness of the process through the use of indicators, internal audits and evaluation of feedback. Identify high-risk processes or steps within some processes for improvement.
7. Formulate action plans for improvement and implement them. Follow-up to ensure that the corrective action(s) was effective.

OLA Assessment by the Process Approach

OLA assessors will conduct a process-based assessment, as opposed to a procedural-based inspection. In other words, OLA assessors will concentrate on laboratory policies and processes. Each laboratory should provide evidence that its processes are effective in meeting the goals defined in its policies. The laboratory defines what records and documentation are necessary to provide this supporting evidence. OLA assessors will observe whether policies, processes and procedures are implemented, that staff follow them as written, and that appropriate “checks and balances” are in place to ensure quality and allow for continual improvement.

How Will This Work?

For example: One OLA program requirement (VIII.7) states that laboratory management, in consultation with the requesters, shall establish clinically appropriate turnaround times (TAT) for each of its examinations. A procedural-based approach would likely lead assessors to look at the actual TAT of each examination and make a judgment on whether or not the TAT is acceptable. OLA’s process-based assessment will direct assessors not to judge individual TATs but to review the process by which the laboratory determined that its TATs are clinically appropriate. Thus, the specific “What to Look for” instructions for this requirement are:

- A) Did the laboratory determine clinically relevant TATs for each examination in consultation with their clients?
- B) Does the laboratory monitor the established TATs to ensure that they remain clinically relevant?

Further examples from the OLA checklist are presented in Table 1.

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Table 1: Comparison of Procedural-based Inspection to Process-based Assessment

Requirement	WHAT TO LOOK FOR	
	Procedural-based	Process-based
VII.7: Laboratory management, in consultation with the requesters, shall establish clinically appropriate turnaround times (TAT) for each of its examinations.	Are actual TATs for each examination in the laboratory acceptable?	Did the laboratory determine clinically relevant TATs for each examination in consultation with their clients? Does the laboratory monitor the established TATs to ensure that they remain clinically relevant?
I.B.5: There shall be adequate staff resources to undertake the work required and to carry out the other functions of the quality management system.	Are staff resources adequate?	Is there evidence that the laboratory management assessed their staff resources? Did the assessment of staff resources include consideration of quality assurance and the maintenance and improvement of the quality management system?
I.B.7.1: Staff shall be assessed for competence to perform assigned tasks following training and periodically thereafter.	Are staff members competent?	Is there evidence (e.g. records) that the facility performs competency assessments of all staff? Are competency assessments performed with regular frequency, as defined by the laboratory?
II.G.4: The laboratory shall ensure that the referral laboratory or referral consultant can demonstrate competency to perform the requested examinations.	Are all referral laboratories and consultants competent?	Does the laboratory ensure that each referral laboratory and consultant can demonstrate competency to perform the requested examinations?
III.4: The laboratory shall monitor and record environmental conditions (as appropriate) to ensure they do not adversely affect the quality of examination results (e.g. dust, electromagnetic interference, humidity, temperature, sound levels, vibration levels, ventilation).	Are the appropriate environmental conditions monitored?	Has the laboratory management determined its criteria for the monitoring of environmental conditions, and ensured that the criteria are met?
III.7: Laboratory storage space and conditions, whether within the facility or off site, shall be adequate to ensure the integrity of samples, slides, histology blocks, retained microorganisms, documents, files, manuals, equipment, reagents, supplies, records and results.	Are all storage spaces adequate?	Has the laboratory management determined its criteria for laboratory storage space and conditions, and ensured that the criteria are met?
V.B.2: Specimens shall be transported to the laboratory within an appropriate time frame according to the nature of the requested examinations and the laboratory discipline concerned.	Are the time frames for the transport of specimens appropriate in the opinion of the assessor?	Is there a policy that describes the acceptable transit times?

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Conclusion

The goal of establishing a quality management system that hinges on the process approach is to be consistent in what we do. We should not rely solely on the judgment of our excellent professionals to provide safe and error-free care. The system itself must provide a failure-resistant environment. Documented policies, processes and detailed procedures should clearly define every aspect of the operation. Once the system is in place, regular monitoring will help identify opportunities for improvement and allow laboratory management to prioritize its continual improvement plans for high-risk processes.

OLA's assessment of each laboratory will be based on the laboratory's unique circumstances and patient population served. OLA assessors will ask to see evidence that the laboratory's defined processes are followed by staff and are effective. The assessment will be as objective as possible, using a checklist developed with emphasis on a process approach.

References

1. ISO Document ISO/TC 176/SC 2/N 544R. ISO 9000 Introduction and Support Package: Guidance on the Process Approach to quality management systems. May 2001.
2. Kohn LT, Corrigan JM, Donaldson MS, editors. Committee on Quality of Health Care in America, Institute of Medicine. To Err is Human: building a safer health system. Washington: National Academy Press, 1999.
3. Callum JL, Kaplan HS, Merkley LL, Pinkerton PH, Rabin Fastman B, Romans RA, Coovadia AS, Reis MD. Reporting of near-miss events for transfusion medicine: improving transfusion safety. *Transfusion* 2001;41:1204-1211.

Additional Reading: NCCLS. A Quality System Model for Health Care; Approved Guideline. NCCLS document GP26-A October 1999.



Staphylococcus aureus Resistant to Vancomycin—United States, 2002

The Centers for Disease Control and Prevention (CDC), Morbidity and Mortality Weekly Report, recently released a report on *Staphylococcus aureus* resistant to vancomycin. The report describes the first documented case of infection caused by vancomycin-resistant *Staphylococcus aureus* (VRSA) (vancomycin MIC >32 µg/mL) in a patient in the United States. The MIC results for vancomycin, teicoplanin, and oxacillin were >128 µg/mL, 32 µg/mL, and >16 µg/mL, respectively, by the broth microdilution method. The isolate contained the vanA vancomycin resistance gene from enterococci, which is consistent with the glycopeptide MIC profiles. It also contained the oxacillin-resistance gene mecA.

The emergence of VRSA underscores the need for programs to prevent the spread of antimicrobial-resistant microorganisms and control the use of antimicrobial drugs in healthcare settings.

The complete report is available at the CDC Web site <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5126a1.htm>.

QMP-LS MAILINGS SENT July 8, 2002 - JULY 19, 2002

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|----------------------|---|
| ● C-0104-PP | Chemistry Committee Comments (Patterns-of-Practice Survey-HbA _{1c} Testing) |
| ● CHEM-0207-AE,-HB | Chemistry Analysis Worksheet & Testing Material (Albumin Excretion Rate, Hemoglobin A _{1c}) |
| ● DRUG-0207, -CY,-DA | Drug Monitoring Analysis Worksheet & Testing Material (Routine, Cyclosporine, Drugs of Abuse) |
| ● ENZY-0206 | Enzymes Survey Report |
| ● LIPS-0206 | Lipids Survey Report |

Provisional reports recently released to QMP-LS Web site:

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|-------------|--------------|
| ● BACT-0206 | Bacteriology |
| ● ENZY-0206 | Enzymes |
| ● LIPS-0206 | Lipids |

Items may be shipped separately during the period shown above. Each laboratory will receive items related to disciplines it participates in. If you consider that you should have received an item and have not done so, please contact QMP-LS.