Using Proficiency Testing to Improve Laboratory Quality

Monday, May 23, 2011, 4:00–5:30 pm
Session 2B
Presenter
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Disclosure

- The speaker for this session has no relevant financial relationships with commercial interests to disclose
**Session Description**

- Proficiency testing can be used as a tool to monitor and improve quality in the clinical laboratory.
- This session will review CLIA and accrediting agency requirements for use of proficiency testing.
- Next there will be an explanation of how to use proficiency testing specimens and aggregate proficiency data as quality tools.
- Finally, participants will work through case studies that will serve as a toolkit to take back and apply in their own laboratory.

**Session Agenda**

1. Background on proficiency testing and improving lab quality
2. CLIA and accreditation guidelines for proficiency testing
3. Use of proficiency testing results in monitoring performance in your laboratory
4. Use of proficiency testing materials for quality and education
5. Use of aggregate proficiency testing data in evaluating test methods
6. What does the future hold/what should you be doing now?
7. References
8. Question and answer
Background on proficiency testing and improving lab quality

The Origins of Proficiency Testing

• 1945: Belk and Sunderman compared results from 59 laboratories in Philadelphia and found performance improved over time

• 1947: the College of American Pathologists (CAP) offered first educational PT program, and found that participating laboratories identified problems and corrected them. CAP embraced PT as a CQI tool

• CLIA’67 requires PT participation for “12,000” labs

• CLIA’88 mandates PT for all laboratories performing regulated analytes with non-waived methodologies
CLIA’88 (1992)  
Required and Regulatory Role for PT

- PT becomes the cornerstone for the government’s assessment of Clinical Laboratory quality
- Reasons
  - Successful history of improvement
  - Could be uniformly applied to 1000s of laboratories
  - Could be provided by non-governmental providers
  - Only practical solution when increasing from 12,000 (CLIA’67) to 200,000+ laboratories

CLIA’88 PT General Requirements

- Format
  - 5 samples per “regulated” analyte (Currently only 83 analytes)
  - 3 shipments (PT events) per year per analyte
  - Each analyte
    - Passing performance is > 4 of 5 correct results (>80%)
    - Failure of analyte in one PT event: 2 or more incorrect results (<80%)
  - All analytes in a specialty/subspecialty – e.g., routine chemistry, hematology
    - Passing performance: >80% correct across analytes in specialty/subspecialty
      - This rule is very difficult to violate except for laboratories performing limited testing
• Acceptable performance criteria specified by CDC before 1992
• Target values (TV) usually PT group mean
• Standard deviation (SD) was PT group SD
• For PT providers to grade, need 80% consensus in the PT group
  o Glucose, Cholesterol: TV + 10%
  o Sodium: TV + 4 mmol/L; Potassium: TV + 0.5 mmol/L; Calcium: TV + 1.0 mg/dL
  o ALT, LD: TV + 20%; AMS, ALP, CK: TV + 30%
  o Cortisol: TV + 25%; T3 uptake, free thyroxine, Triiodothyronine: + 3SD*
  o RBC count, Hct: TV + 6%; WBC count, prothrombin time, PTT: TV + 15%

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CLIA Subpart H--Participation In Proficiency Testing for Laboratories Performing Nonwaived Testing

- Each laboratory must enroll in a proficiency testing (PT) program(s) that meets the criteria and is approved by HHS in each of the specialties and subspecialties for which it seeks certification.
- Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.
- Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS.
- For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with Sec. 493.1236(c)(1).
- For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and
- Authorize the proficiency testing program to release to HHS all data required to determine the laboratory's compliance with this subpart.

Remember that the government has Medicare claims data to compare laboratories filing claims for testing regulated analytes for which they are not reporting PT results.
Treat PT Samples as Patients

- The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

- The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

- The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

- The laboratory must test samples the same number of times that it routinely tests patient samples.

When PT samples can not be treated as Patient samples

Communication and Referral

The following prohibitions take precedence over the requirement that proficiency testing specimens be handled in the same manner as patient specimens:

- Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

- Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

- The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.
When PT samples cannot be treated as Patient samples
Communication and Referral

- Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year.
- Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.
- CLIA surveyors are finding a "plethora of cases," says Judy Yost, MA, MT(ASCP), director of the CMS Division of Laboratory Services. And "even though the regs indicate 'intentional' PT referral," it is not defined, she says. "All of the legal cases we have had thus far pretty much disregard that. So if a lab accidentally sends a PT sample to another lab for testing, basically the lab may still be held accountable for it."
- "When we find a problem like this, the lab either did it or didn't do it." Yost says.

Laboratories seeking Professional Accreditation

- CAP and JC accredited laboratories MUST participate in government-approved PT
  - CLIA PT “rules” of sample handling and grading must be followed
  - Results must be reported to the government
- CAP requires even more
  - CAP mandates that ALL analytes be in PT, when possible (even waived tests)
Responsibilities of the Laboratory Medical Director for Proficiency Testing

- Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-
- The proficiency testing samples are tested as required under subpart H of this part;
- The results are returned within the timeframes established by the proficiency testing program;
- All proficiency testing reports received are reviewed by the appropriate staff (CLIA Director or Designee) to evaluate the laboratory’s performance and to identify any problems that require corrective action;
- An approved corrective action plan is followed when any proficiency testing results is found to be unacceptable or unsatisfactory.

Consequence of PT Failure

- Failing one PT event
  - Get necessary training and assistance
  - Document remedial action and keep records for 2 years
  - Performance in next 2 events is critical
- Failing same analyte in 2 of 3 consecutive PT events
  - Plan of correction created and followed
  - Monetary fines
  - Mandatory suspension of testing failed analyte(s)
- Limitation or revocation of a laboratory’s CLIA certificate for Immediate jeopardy to patients
  - Failure to correct problems
  - Sending PT samples to another laboratory
Tips for the Laboratory

- Policies and procedures must be written and address:
  - Process for enrollment in PT for new or changed test methods
  - Sample handling, testing, timely submission of results, analysis and review of results
  - Investigation and correction of problems that are identified by unacceptable proficiency testing results
  - Investigation of results that, although acceptable, show bias or trends suggesting a problem
  - The prohibition on interlaboratory communication about proficiency testing samples until after the deadline for submission of data to the proficiency testing provider.
  - The prohibition on referral of proficiency testing specimens to another laboratory

Tips for the Laboratory

- Policies and procedures must be written to address:
  - Performance on PT challenges that were intended to be graded, but were not because
    - the laboratory submitted its results after the cut-off date
    - the laboratory did not submit results
    - the laboratory did not complete the result form correctly
    - results were not graded because of lack of consensus
Use of proficiency testing results in monitoring performance in your laboratory

Monitor performance for each event
Investigate failures
Monitor performance over time and evaluate trends

Troubleshooting Guide for Proficiency Testing Data
July 2009

Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition
Monitor Performance for Each Event
Investigate Failures

Troubleshooting Guide

• Analysis of PT results can reveal problems even before there is a failure
• Recognize patterns in the graphical representations that are not likely to be normal variation
We didn’t turn in our results/our results were late

- Many will respond this is random error, no follow-up needed – not so fast
- This type of failure deserves careful attention
- Why were results late/not turned in in this case?
- Has this happened before?
- Carefully examine policy, process and procedures
- Determine the root cause of this event and determine where the failure occurred
- Redesign to make responsibility, accountability, checks and double checks

PT Exception Investigation Checklist
Evaluation of Possible Sources of Error Clerical

- Was the result correctly transcribed from the instrument read-out or report?
- Was the correct instrument/method/reagent reported on the result form?
- Do the units of measure match between the result form and the instrument results?
- Is the decimal place correct?
- Does the result reported on the result form match the result found on the proficiency testing evaluation report?
So I found a random clerical error – am I done?

• Although reporting of proficiency testing results is unlike those for patient results, clerical errors may indicate a need for
  − Additional staff training,
  − Review of instructions provided with the proficiency testing or
  − Investigation of the reporting format provided by the testing device.

PT Exception Investigation Checklist

Evaluation of Possible Sources of Error Procedure

• Was the written procedure followed?
• Were the reagents prepared according to procedure?
• Were the reagents within their open stability acceptable range?
• Were Quality Control results acceptable?
• Were microscopic examinations interpreted correctly?
• Was staining performed and interpreted correctly?

A response of “No” to any of these questions may indicate a procedural error. These errors indicate inappropriate operation of equipment or performance of a method. A review of the instructions provided with the proficiency testing material and/or review of laboratory procedures may be required.
PT Exception Investigation Checklist
Evaluation of Possible Sources of Error

Analytical Error

- Was the most recent calibration acceptable and within established stability limits at the time proficiency testing was performed?
- Does a review of the past proficiency testing results indicate evenly distributed data without bias?
- Was the intended result within the measuring range for the instrument?
- Was instrument maintenance performed on schedule?
- Does a review of records indicate that there were no related instrument/test problems noted prior to or after the proficiency testing was performed?

A response of “No” to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.

Specimen Handling

- Were Survey specimens reconstituted as indicated in the Kit Instructions?
- Were Survey specimens stored as indicated in the Kit Instructions?
- Were any special instructions provided in the Kit Instructions performed as indicated?
- Were the correct tests performed on the correct vial of proficiency testing material?

A response of “No” to any of these questions may indicate an analytical error. These types of errors could indicate a failure to follow recommended instrument maintenance and calibration.
PT Exception Investigation Checklist
Evaluation of Possible Sources of Error
PT Material

- Was proficiency testing material received in the laboratory within an appropriate time after shipment?
- Were your results graded in the appropriate peer group based on the method reported on the result form?

A response of “No” to any of these questions may indicate a problem with the PT material. If a delay in receipt of material in the laboratory is an issue, contact your in-house receivables department to ensure timely receipt of Surveys after arrival in your institution. If you believe your result was compared to an inappropriate peer group, verify the method reported on the result form. Contact your proficiency testing provider for additional information if needed.

Monitor performance over time and evaluate trends
Troubleshooting Guide

Time Trends in PT Evaluation Graphs over Multiple Mailings

<table>
<thead>
<tr>
<th>Rule</th>
<th>Comments</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent results on one side of the target values</td>
<td>Shows persistent bias, even if small; recalibration should have occurred within this time frame</td>
<td>See listing of suggested actions for evidence of systematic error</td>
</tr>
<tr>
<td>Results flip from one side of the target to the other</td>
<td>Shows impact of system and/or process changes; longer bars are of more concern</td>
<td>See listing of suggested actions for evidence of systematic error</td>
</tr>
<tr>
<td>Over time, length of bars increase</td>
<td>A sudden shift may show impact of system and/or process changes; may reveal new source of either systematic or random error</td>
<td>Follow the suggested actions for systematic or random error, as appropriate</td>
</tr>
<tr>
<td>Over time, length of bars decrease</td>
<td>Shows impact of system and/or process changes, particularly as a result of corrective action</td>
<td>Retain as documentation that corrective action has been successful</td>
</tr>
</tbody>
</table>

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Table 3: Examples illustrating various patterns in cumulative PT results

<table>
<thead>
<tr>
<th>Evidence of persistent bias spanning recalibration. Review process of setting QC target values; evaluate performance with assay control material.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-C</td>
</tr>
<tr>
<td>C-D</td>
</tr>
<tr>
<td>C-A</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Results flip from positive to negative bias. Review records to confirm system and/or process change. Follow suggested actions for systematic error.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-C</td>
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<tr>
<td>C-B</td>
</tr>
<tr>
<td>C-A</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Over time, lengths of the bars increase on both sides of 0. For this pattern, follow suggested actions for random error.</th>
</tr>
</thead>
<tbody>
<tr>
<td>C-C</td>
</tr>
<tr>
<td>C-B</td>
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<tr>
<td>C-A</td>
</tr>
</tbody>
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<table>
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<tr>
<th>Over time, lengths of the bars increase primarily on one side. For this pattern, follow suggested actions for large systematic error.</th>
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<tr>
<td>C-C</td>
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<tr>
<td>C-B</td>
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<tr>
<td>C-A</td>
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Troubleshooting Guide

Don’t Forget Non-graded PT and Alternate Assessment

• More than a procedure, an expectation that you will evaluate performance on PT challenges that were not graded because
  o results were not submitted or results were submitted late
  o the result form was not completed correctly
  o there was lack of consensus
• Structured and documented review of alternate assessment events
Use of proficiency testing materials
Can we use Proficiency Testing Materials?  
Yes But…..Watch the timing of use

- Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

- Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 52-12-23
Baltimore, Maryland 21244-1900

Center for Medicaid and State Operations/Survey and Certification Group

November 30, 2007

PT samples, information and results/scores should not be used until the results of the PT samples have been returned to the laboratory from the PT provider. PT samples should not be used for other purposes, for example, training or competency testing, until after the results of the PT event have been returned to the laboratory.
Can we use Proficiency Testing Materials?
Yes But.....Watch out for the Matrix Effect

- Matrix effects due to different PT sample types, components added/removed from sample, and preparation can cause assay interferences
- Routine PT identifies differences between analytical peer groups
  - Matrix effects in PT materials make it difficult to determine whether differences are from assay variations that could affect patient samples
  - Therefore, labs are assessed only in terms of ability to match their peer group
  - Theoretically, all of the results could be wrong, or all of them could be right
- Due to matrix effects, there is not enough information to answer the question of accuracy
CAP’s Accuracy-based Surveys*
(to focus on accuracy)

• Specimens are free from matrix effects
• Target values traceable to certified reference materials
  o Labs compare their results to international reference method results
• Available surveys include:
  o Lipids
  o Creatinine
  o Glycohemoglobin
  o Neonatal Bilirubin
  o Testosterone and Estradiol
  o Vitamin D [April 2011]
  o New analyte added each year

Why would we use PT Materials

• Educational purposes
• PT Samples, if stable, may provide a wider variety of positive or negative, high or low, values than you would ordinarily see in your laboratory
Use of aggregate proficiency testing data in evaluating test methods

- Case Studies to show how to compare methods
- Caveats
What does the future hold/what should you be doing now?

1999 – Government’s Institute of Medicine (IOM) reports
   - 100,000 deaths per year in U.S. hospitals due to medical errors

2004 – Maryland General Hospital
   - Evidence of false HIV and hepatitis results ignored
   - More than 400 people affected; [Over 1000 people were retested]
   - PT and inspections did NOT uncover problems!!

   - Headlines May 19, 2004 - Baltimore (Maryland) Sun Newspaper
     - “…The Maryland General Hospital situation is just the tip of the iceberg that has national implications”
2008 Work Group Recommendations to CDC* (for more effective PT)

- Data Collection and Analysis – a database to:
  - Identify reasons for PT failure
  - Characterize performance and review acceptable limits
  - Identify analytes to add to regulatory PT
  - Collect / summarize complaints to identify correctable trends
  - Publish results in peer-reviewed journals;
  - List national/international PT programs on CDC website

*http://www.aacc.org/publications/cln/2008/june/Pages/cover1_0608.aspx

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2008 Work Group Recommendations to CDC* (for more effective PT)

- Process Improvement
  - Provide samples with minimal artificial matrix effects
  - Have studies, using fresh frozen samples, to identify unrecognized testing problems
  - Identify new/evolving technologies and analytes
  - Assess proficiency in molecular genetic tests
  - Encourage use of internationally recognized standards
  - Assess benefits/costs of PT providers to be audited

- Education – for participant Quality Improvement
  - Teach participants to evaluate, interpret, and use their PT results for CQI

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2010 PT Report to CLIAC (Clinical Laboratory Advisory Committee) on PT Revisions*

- Develop a defined list of required PT analytes
  - List should be separate from regulations for easier update
  - 2-year phase-in period for new additions
  - With additions, consider
    - Availability of PT and materials, volume of testing, clinical relevance, and cost
- Clarify ungraded specimens
  - Too few participants to grade?
  - Sufficient number of participants, but 80% consensus is not reached?
- Distinguish acceptable PT referral from unacceptable PT referral
  - Acceptable PT referral would allow labs to treat PT exactly as patient samples and include referral if in their standard procedure for patients
    - Referral labs would not be penalized
  - http://www.cdc.gov/cliac/cliac0910.aspx#t5_2

Why should we do Proficiency Testing ?

- PT is a regulatory requirement but don’t let PT become just a regulatory exercise
- PT is a component of a quality management program
- PT is an objective evidence of your performance, process performance in addition to analytical performance
- Laboratories that monitor PT improve performance over time
CLSI Document GP27-A2
2007

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Questions?

Thank you for your attention

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