Current Status of Proficiency Testing (PT) in the US: Summary Report from a PT Working Group

Robert Rej, PhD
Wadsworth Center
New York State Department of Health

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Working Group Objectives

- Evaluate US PT programs to determine extent they met quality improvement , educational, and regulatory roles
- Assess need to improve use of PT programs
- Evaluate ways to enhance educational value of PT programs
- Determine how well PT programs provide challenges to keep up with advances in laboratory testing technology
- Determine whether accreditation of PT programs to international standards would increase quality or uniformity of those programs

Methods

Work done through a CDC task order with Battelle:

- Formation of a 15-member proficiency testing working group (PTWG)
- Representation by PT users, PT providers and accrediting organizations
- Members selected based on expertise in PT and laboratory medicine
- Input from laboratory community in response to an invitation sent to various stakeholders

Methods (Contd.)

- Comments/Relevant data provided by stakeholders before PTWG's initial face-to-face meeting in January 2007
- Summary of PTWG's discussions/comments for final report sent to stakeholders, inviting them to provide additional comments, suggestions or relevant data
- Comments received, reviewed and integrated into a report narrative
- Final PTWG's face-to-face meeting in April 2007 to develop a final report ("consensus")

PT Working Group (PTWG) Members

Barbara Burmeister, MT (ASCP)	Wisconsin State Laboratory of Hygiene
George S Cembrowski, MD, PhD	Univ of Alberta
Kandace Cendejas, BS	Bio-Rad Laboratories
Greg Cooper, CLS, MHA	Bio-Rad Laboratories
Daniel Edson, PhD	American Proficiency Institute
George K Fiedler	CAP
Judith Gabriel	JCAHO
Verlin K Jansen, MD, FAAFP	Univ of Kansas, Wichita and Hutchinson (KS) Clinic, PA

PTWG Members (Contd.)

Margaret Peck, MS, MT (ASCP)	JCAHO
Joseph B Perrone, ScD	American Type Culture Collection
Robert Rej, PhD (Chair)	New York State Dept of Health
Karen A Rupke, MT (ASCP), MPA	Quest Diagnostics
Nicolas T Serafy, Jr	Am Assoc of Bioanalysts
Max Williams	COLA
James Winkelman, MD	Harvard Medical School

PTWG Ex-Officio Members

- Sousan S Altaie, PhD; FDA
- D Joe Boone, PhD; CDC
- Devery Howerton, PhD; CDC
- Adam Manasterski, PhD; CDC
- Raelene M Perfetto; CMS
- Shahram Shahangian, PhD; CDC
- Kathleen J Todd; CMS
- Julie R Taylor, PhD; CDC
- Dan Tholen, MS; CDC

Battelle Team

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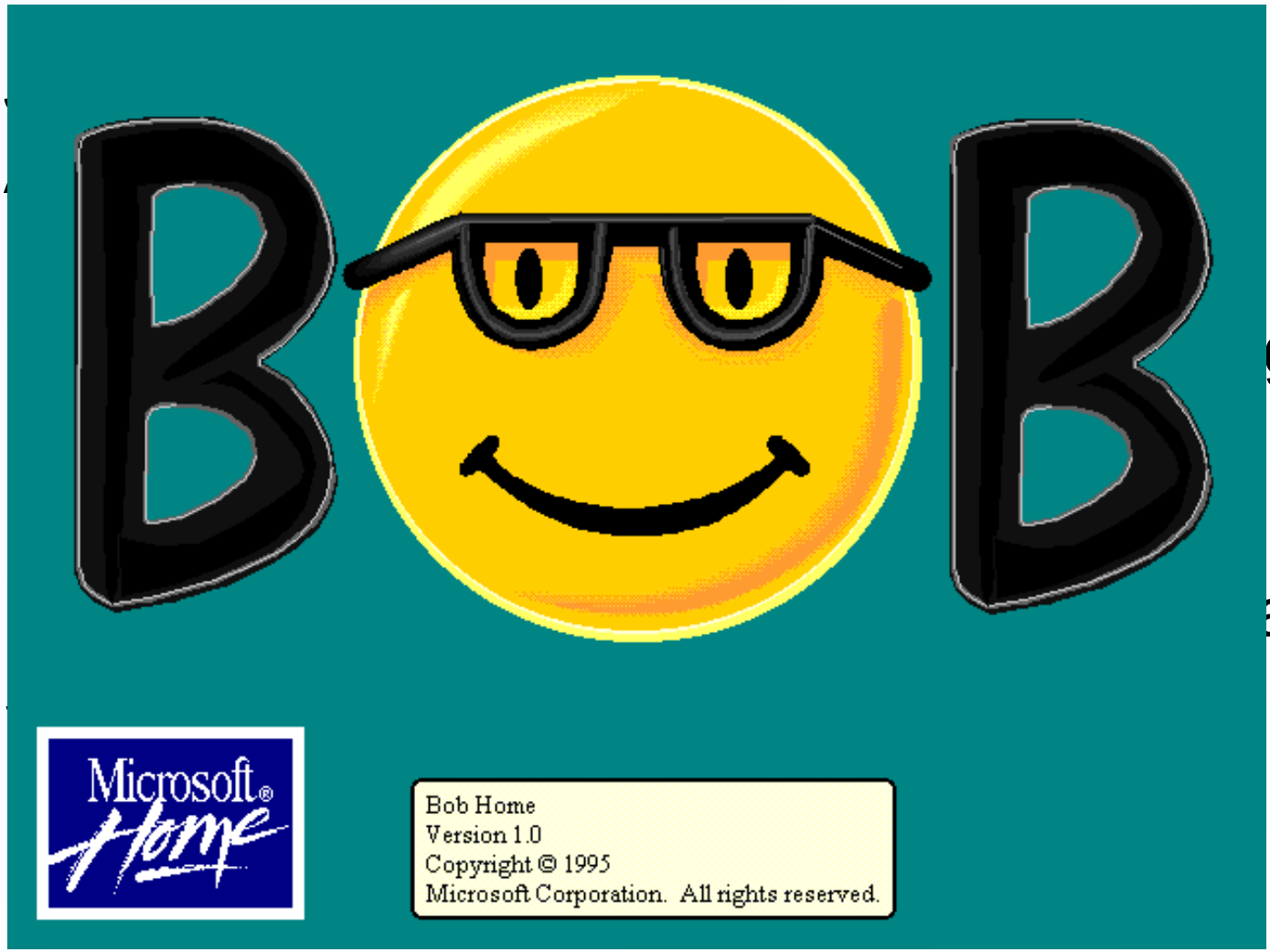
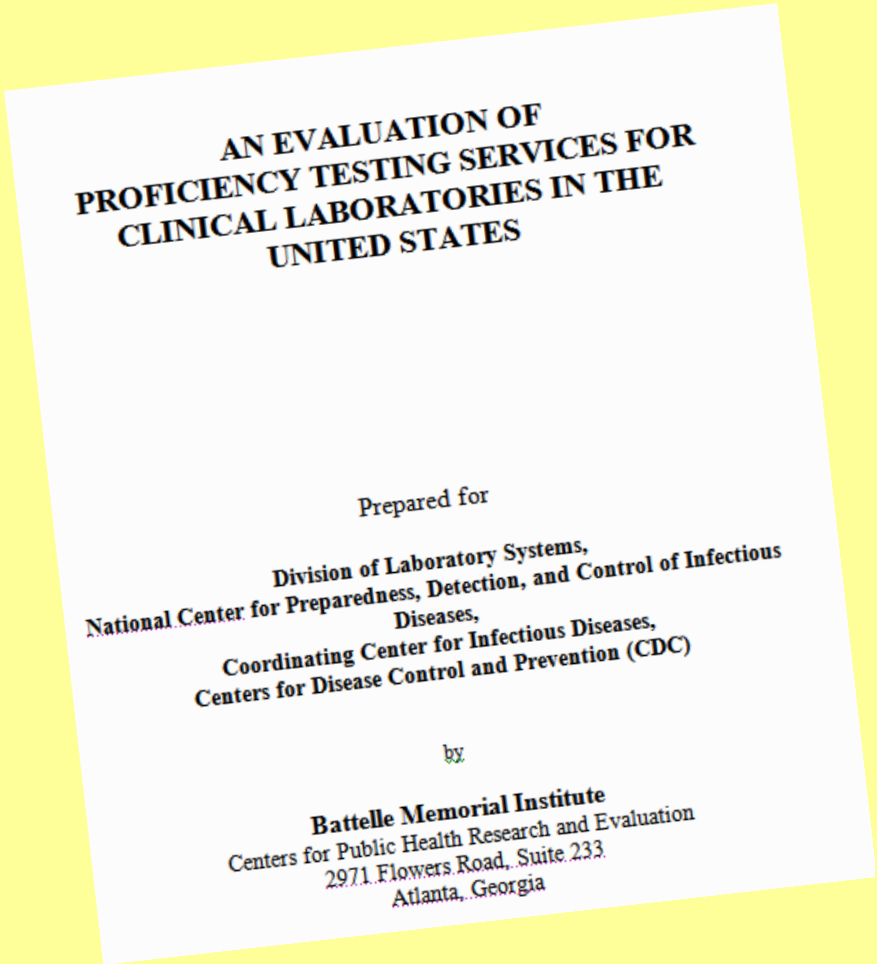


PTWG Members (Contd.)

WG Report



AN EVALUATION OF
PROFICIENCY TESTING SERVICES FOR
CLINICAL LABORATORIES IN THE
UNITED STATES

Prepared for

Division of Laboratory Systems,
National Center for Preparedness, Detection, and Control of Infectious Diseases,
Coordinating Center for Infectious Diseases,
Centers for Disease Control and Prevention (CDC)

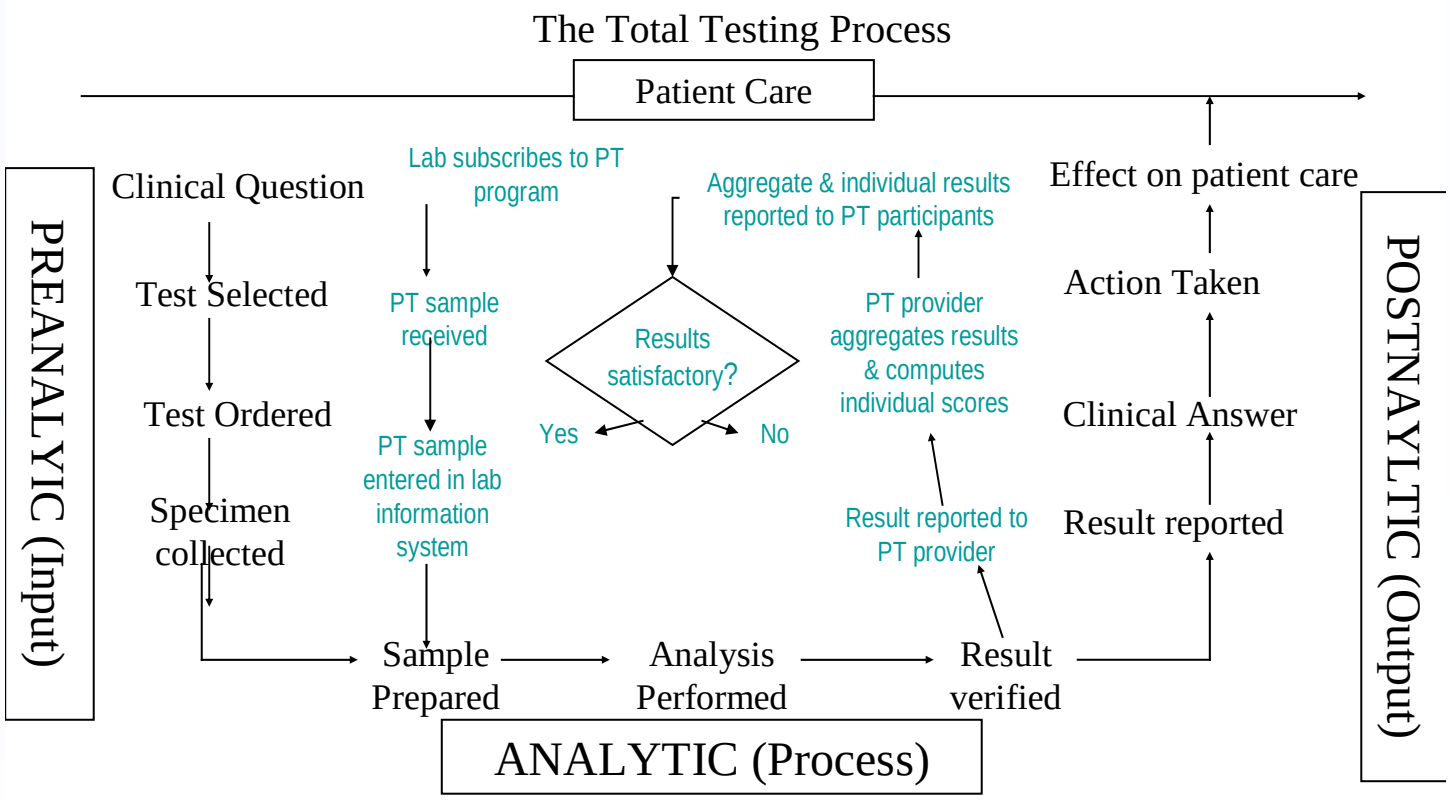
by

Battelle Memorial Institute
Centers for Public Health Research and Evaluation
2971 Flowers Road, Suite 233
Atlanta, Georgia

- 61 page report: review, findings, discussions, recommendations
- WG Draft – not final
- Now out for WG comments and suggestions

Proficiency Testing in the Total Testing Process for Clinical Laboratories

PT in Relation to the Total Testing Process



Some Findings

- Experience with PT unquestionably reduces PT failure rates.

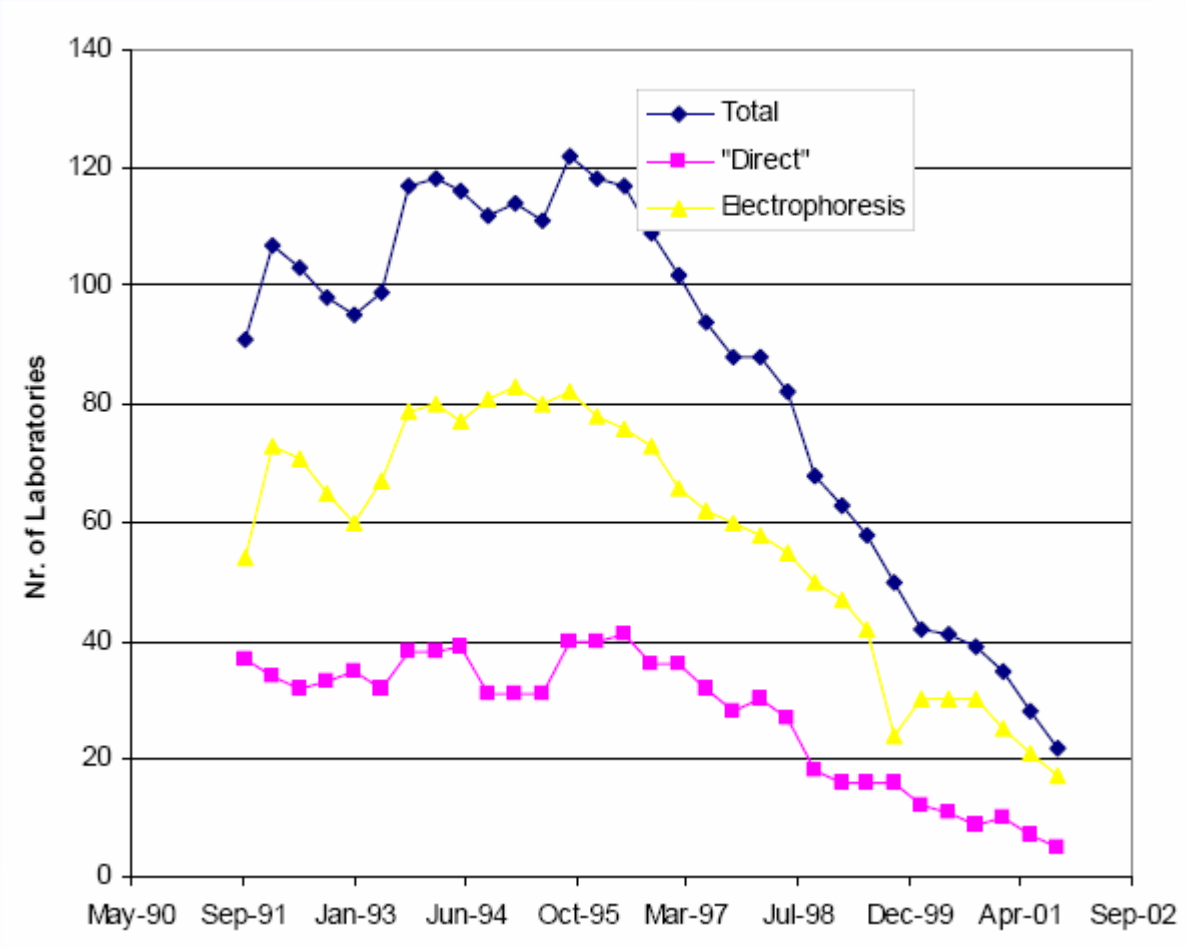
- There is no single study – much less a body of published evidence – which unequivocally demonstrates that participating in PT reduces the rate of errors in routine testing of patient specimens

Some Findings (Contd.)

- List of regulated analytes not revised since implementation of CLIA. Laboratories not required to participate in PT for many tests that are currently performed.

- PT performance may not reflect results obtained using clinical (patient) specimens.

LD-Isoenzymes



Some Findings (Contd.)

- List of regulated analytes not revised since implementation of CLIA. Laboratories not required to participate in PT for many tests that are currently performed.

- PT performance may not reflect results obtained using clinical (patient) specimens.

Some Findings (Contd.)

- Slow turnaround time is a major factor limiting usefulness of PT program data both for a QA and educational perspectives.
- A PT program that tests a laboratory's ability to perform a generic method does not satisfy the CLIA requirement that analytes be subject to PT or some other form of quality assessment – not methods.

Recommendations

- Undertake a systematic assessment of the relationship of laboratory performance on PT challenges and laboratory error rates in routine testing of patient specimens and measures of patient outcomes and quality of care.

- Conduct a study of existing information in scientific literature and in current databases regarding reasons for unsatisfactory PT results to identify areas most in need of improvement.

Recommendations (Contd.)

- Develop a process to collect and consolidate all complaints received about PT. Identify trends that may be subject to corrective action; and promote the complaint process for widespread use by all stakeholders.

- Make available a database to collect PT data for characterizing performance of all laboratories, identifying reasons for unsatisfactory PT results, reviewing acceptance criteria used and identifying analytes that should be regulated.

Recommendations (Contd.)

- Assure that all clinical laboratories, including those that perform waived tests, engage in an external QA program that may include PT.

- Develop a process to periodically review, update and publish requirements of the CLIA PT program including list of regulated analytes and allowable limits. Alternatives to current CLIA PT scoring schemes should be evaluated.

Recommendations (Contd.)

PT providers should

- periodically publish PT results in appropriate, independent peer-reviewed journals.
- allow for reporting of results in different units of measure and be able to convert all measurement units to a common unit when reporting results.
- develop a system for electronic submission and reporting of PT results.

Recommendations (Contd.)

PT providers should

- present information back to PT end users graphically in a manner that is easy to read and understand.
- seek ways to provide a faster turnaround time and more detailed feedback on test results.
- provide samples that mimic patient samples as much as possible with a minimum of artificial matrix effects. Goal = reduction of peer group evaluations.

Recommendations (Contd.)

- Studies using fresh frozen specimens from a single patient should be conducted in conjunction with routine PT to identify and characterize testing problems that would otherwise go undetected.
- PT sample frequencies different from current CLIA frequency should be evaluated.
- An educational program that teaches laboratory testing personnel to evaluate PT results and increase PT benefits should be developed.

Recommendations (Contd.)

- PT providers should provide training materials that help PT users interpret and use their PT results for quality improvement.
- PT providers should provide more ungraded challenges whose sole purpose is educational.
- Before releasing official results, PT providers should provide immediate feedback to laboratories when results indicate that PT failure is likely; and they should also institute a system that gives warning to laboratories that trends of cumulative results are moving toward PT failure.

Recommendations (Contd.)

- An independent advisory board should be established to identify new/evolving technologies and analytes in laboratory medicine, to develop innovative approaches in PT programs and to alert PT providers of new opportunities for PT offerings.

- Develop a PT program for genomic testing based on testing process so that it can be used generically for many molecular genetic tests.

Recommendations (Contd.)

- Maintain and update listing of national and international PT programs on a Web site.
- PT providers should assess use of internationally recognized PT standards.
- Benefits and costs of adopting a standard that requires PT providers be audited by a qualified 3rd party should be assessed.

Questions to Consider

- How should recommendations be prioritized (e.g., health impact, probability for successful implementation, etc.) and what recommendations should be targeted first?
- What are major barriers for adoption and successful implementation of these recommendations and the best ways to circumvent them? WG Report notes *"Statute change" / "Change in regulations"* where appropriate
- What are the best ways to promote and implement the highest priorities?

Acknowledgements

- The Working Group members
- Battelle participants
- Federal partners
- Joe Boone
- Shahram Shahangian

Thank you
Questions/Comments

- PT providers will eventually need to reconsider developing generic technical schemes to meet quality demands of clinical laboratory science being transformed by molecular genetic technologies.