

CDC CLIA-Related Initiatives to Improve Laboratory Practice A Key Component of Quality Health Care

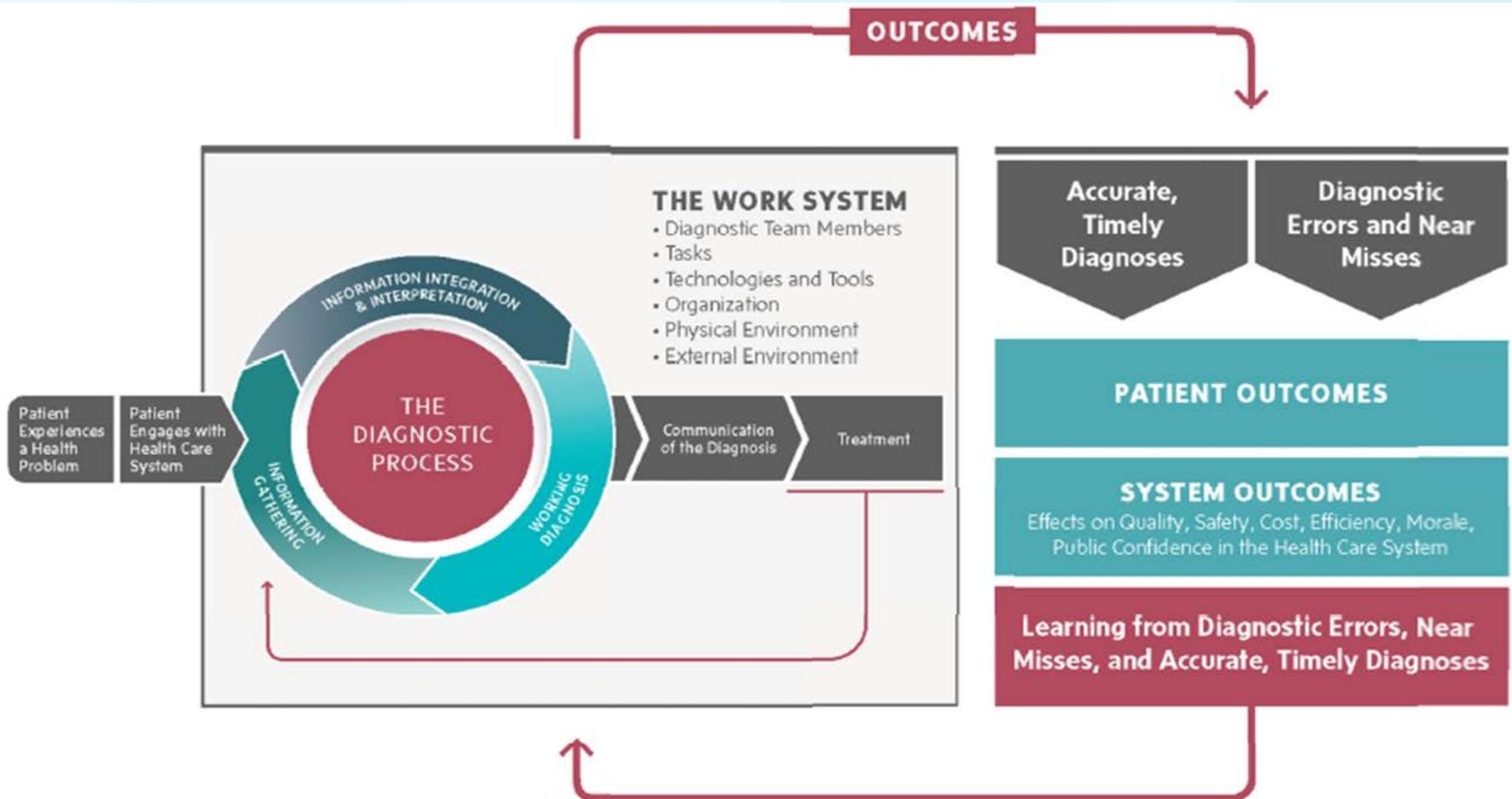
**Ira M. Lubin, PhD, FACMG
Branch Chief (acting)**

**Clinical Laboratory Improvement Advisory
Committee**

Thursday, November 19, 2015

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

The IOM Diagnostic Model



National Academies of Sciences, Engineering, and Medicine. 2015. *Improving diagnosis in health care*. Washington, DC: The National Academies Press.

IOM Goals for Improving Diagnosis and Reducing Diagnostic Error

- Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families
- Enhance health care professional education and training in the diagnostic process
- Ensure that health information technologies support patients and health care professionals in the diagnostic process
- Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice
- Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance
- Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses
- Design a payment and care delivery environment that supports the diagnostic process
- Provide dedicated funding for research on the diagnostic process and diagnostic errors

National Academies of Sciences, Engineering, and Medicine. 2015. *Improving diagnosis in health care*. Washington, DC: The National Academies Press.

Intersections of the Division of Laboratory Systems CLIA Initiatives with the IOM Recommendations

- **Provides support for the CLIA program**
- **Enhance integration of laboratory and clinical professionals**
- **Development, implementation, and evaluation of practice guidelines**
- **Provide and support education and training**
- **Improve Health information technology**
- **Advance New/evolving technologies and practices**

Interface Between Laboratory and Clinical Professionals

Challenges to Physicians in Practice and Training

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

ORIGINAL RESEARCH

Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results

*John Hickner, MD, MSc, Pamela J. Thompson, MS, Tom Wilkinson, MPH,
Paul Epner, MBA, MEd, Meghan Sheehan, MPH, Anne M. Pollock, BA,
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JABFM 2014;27:268-274

Research Report

Laboratory Medicine Education at U.S. Medical Schools: A 2014 Status Report

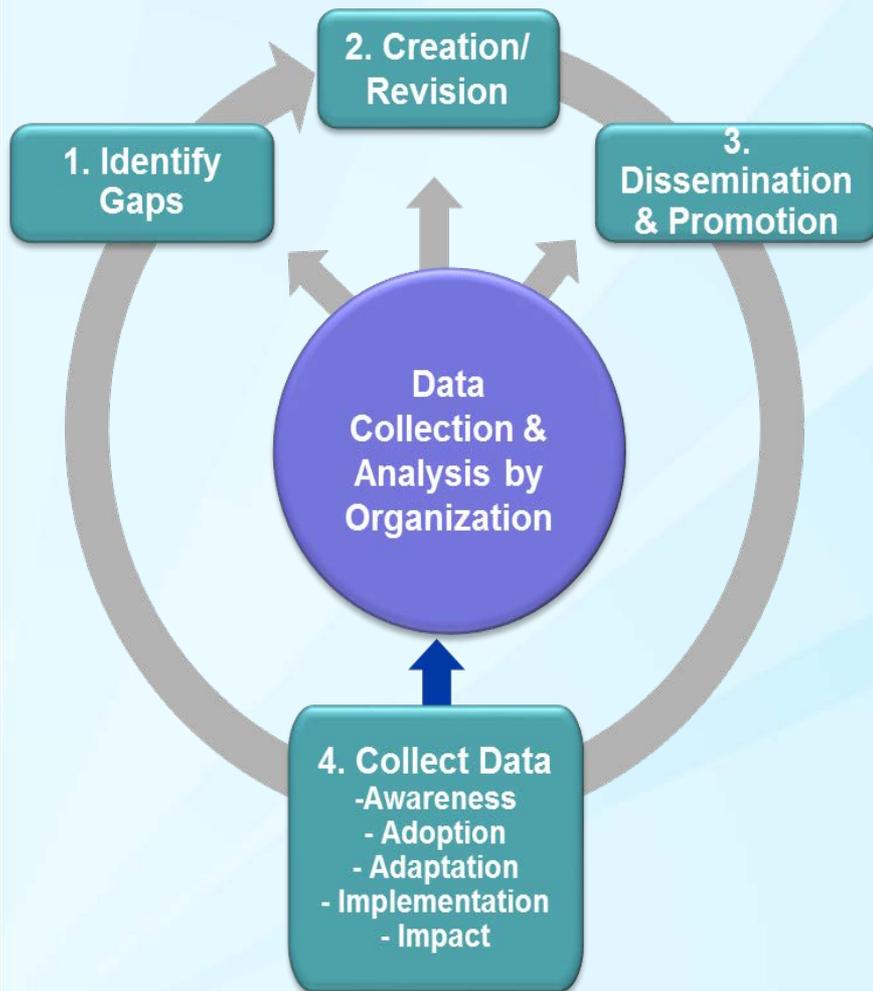
Brian R. Smith, MD, Malek Kamoun, MD, PhD, and John Hickner, MD, MSc

Acad Med. 2015 Jul21 [Epub ahead of print]



Development, Implementation, and Evaluation of Practice Guidelines

Laboratory Practice Guidelines (LPG) Metrics Projects



Project Goals

- Improve uptake and use of LPGs
- Identify gaps in awareness/use
- Partners develop metrics to better understand gaps and strategies to address them
- Self-assess their guideline SOPs and use AGREE II tool to assess quality of representative LPGs to learn how to improve them

LPG Metrics Projects

- **Clinical and Laboratory Standards Institute**

- Glucose blood monitoring at sites with and without laboratory support

- **College of American Pathologists**

- Immunohistochemistry (IHC) Assay Validation
- Acute Leukemia Algorithm

- **American Society of Microbiology**

Based on LMBP A6 Systematic Review Process

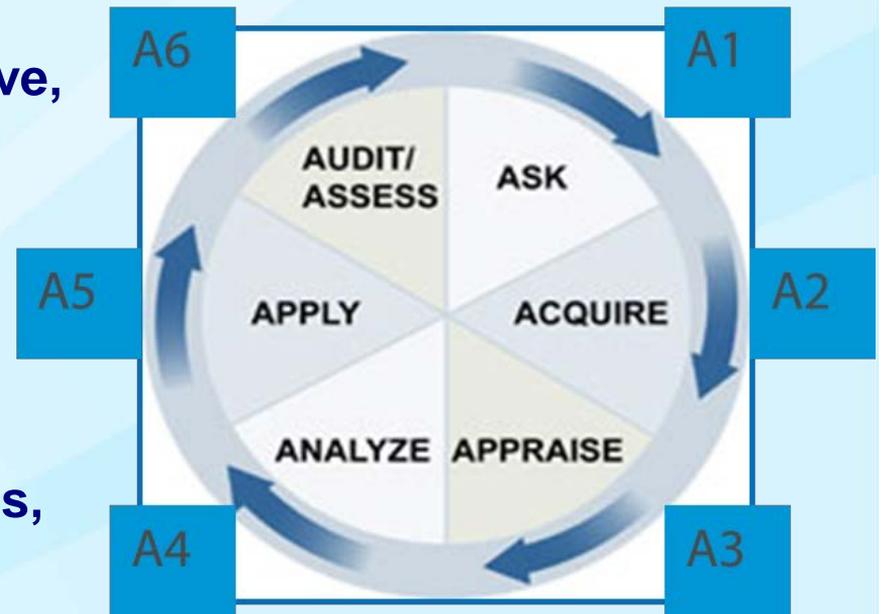
- Reduction of Blood Culture Contamination
- Rapid ID of Blood Stream Infection
- Proper Handling of Urine Specimen
- Laboratory diagnosis of *C. difficile* colitis

Laboratory Medicine Best Practices (LMBP™)

What is LMBP™?

LMBP™ Initiative is to

- Apply a systematic, comprehensive, and transparent approach (A-6 Method) to conduct evidence reviews
- Develop evidence-based recommendations
- Evaluate implementation
- Disseminate findings (publications, (e.g., National Guideline Clearinghouse)
- Disseminate method through partnerships with others



LMBP™ Review Summaries and Recommendations at the National Guideline Clearinghouse

 U.S. Department of Health & Human Services

 Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

 National Guideline
Clearinghouse

Guideline Summary NGC-10709

Guideline Title

Effectiveness of practices to reduce blood culture contamination: a Laboratory Medicine Best Practices systematic review and meta-analysis.

Guideline Summary NGC-10710

Guideline Title

Effectiveness of automated notification and customer service call centers for timely and accurate reporting of critical values: a Laboratory Medicine Best Practices systematic review and meta-analysis.

Guideline Summary NGC-10711

Guideline Title

Effectiveness of practices to reduce blood sample hemolysis in EDs: a Laboratory Medicine Best Practices systematic review and meta-analysis.

Guideline Summary NGC-10712

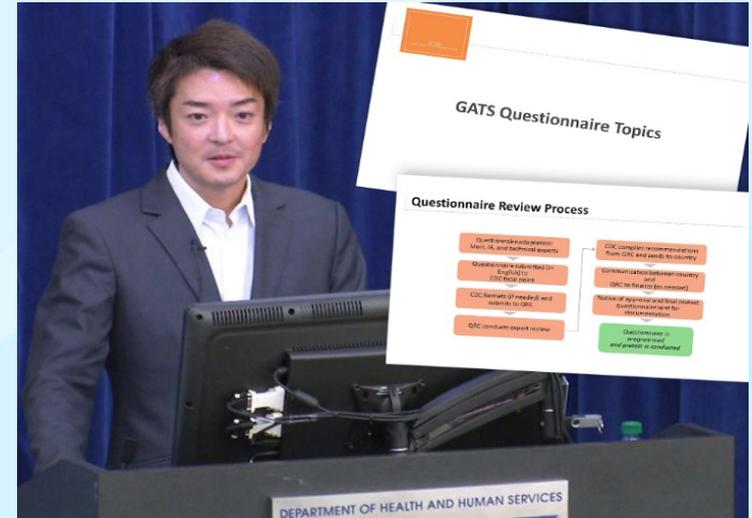
Guideline Title

Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: a Laboratory Medicine Best Practices systematic review and meta-analysis.

Education and Training

CDC Laboratory Training

- ❑ Assists CDC laboratories in communicating technical program information to public health, clinical, and federal laboratories.
- ❑ Communication examples:
 - Raise awareness of new tests, techniques, technologies or emerging threats
 - Provide updates on issues of public health importance
 - Provide instruction on new laboratory tests, techniques, technology or requirements
 - Provide instruction on core lab skills
 - Emergency communication during incident response



The image is a screenshot of a video player interface. At the top, it says "BASIC MOLECULAR BIOLOGY CURRICULUM" and "Basic Science". There are navigation tabs for "Molecular Diagnostics", "Molecular Diagnostic Workflow", "DNA Structure and Replication", and "RNA Structure and Transcription". The video content is titled "DNA Structure" and shows a diagram of a nucleotide. The diagram includes a "NUCLEOSIDE" (a phosphate group, a pentose sugar, and a nitrogenous base) and a "NUCLEOTIDE" (the nucleoside plus a phosphate group). The nitrogenous bases shown are Adenine (A), Thymine (T), Guanine (G), and Cytosine (C). A play button is visible in the center of the diagram. At the bottom, there is a progress bar showing 01:15 / 02:55 and a "Click the play arrow above to play video" instruction.

New CDC Laboratory Training Website

<http://www.cdc.gov/labtraining/>

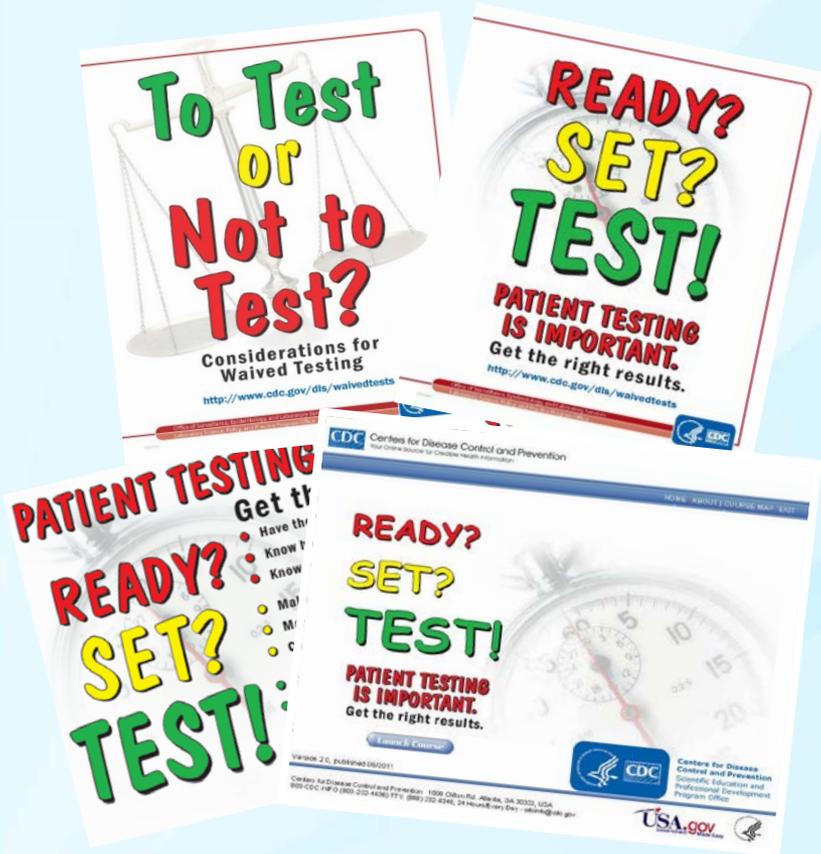
New website designed to more easily connect you to live and online laboratory training options offered by DLS.

Don't see what you need? External Training Links will connect you with other laboratory training providers.

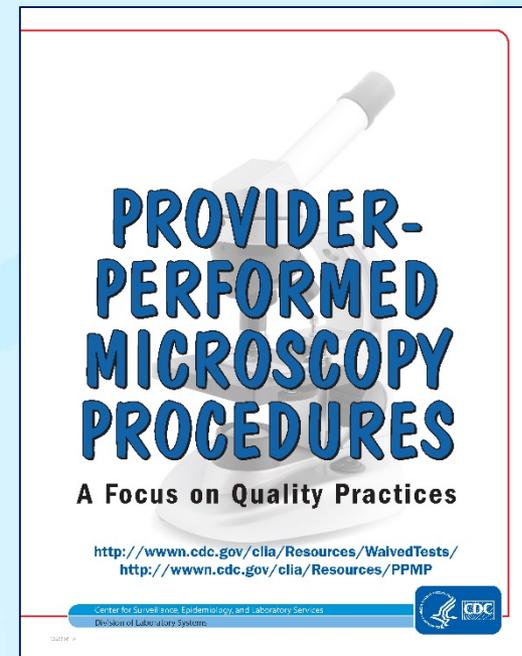
The screenshot shows the CDC Laboratory Training website homepage. At the top left is the CDC logo and the text "Centers for Disease Control and Prevention" and "CDC 24/7: Saving Lives. Protecting People™". To the right is a search bar with the word "SEARCH" and a magnifying glass icon. Below the search bar is a "CDC A-Z INDEX" dropdown menu. The main header area features a large banner with the text "CDC Laboratory Training" and "CDC Laboratory Training" in a large font, followed by "Live and archived laboratory training online and in-person for FREE!". The banner includes illustrations of a DNA helix, a certificate, a laptop, a microscope, and a globe. Below the banner are social media icons for Facebook, Twitter, and a plus sign. The main content area is divided into four columns: "Register for Live Training" with a timer showing 00:00:00:00 and a "Registration" button; "24/7 Online Training" with a photo of a person at a computer and a link to "Click here for a current schedule of eLearning courses, educational videos, and webinars."; "External Training Links" with a globe icon and a link to "View a list of additional online training provided by our external partners."; and "Help/FAQs" with a "connecting worldwide" logo and a link to "Have a question about how CDC Train works? Need help with a course, or just have a question?". Each column has a corresponding "All Live Events", "All Online Training", "All External Training", or "All Help/FAQs" button.

Educational Tools to Assure Accurate Testing in Non-Traditional Settings

Waived Testing



Provider-Performed Microscopy Procedures (available soon)



<http://wwwn.cdc.gov/clia/Resources/WaivedTests/>

Translation of a CDC Guideline to an Online Course

http://www.cdc.gov/labtraining/course_listing/1043113.html



CDC Lab Training

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Continuing Education
External Training
Help and Information
LabTraining Train Portal Login

[CDC Lab Training Home > Courses](#)
[Recommend](#) [Tweet](#) [Share](#)

Good Laboratory Practices for Molecular Genetics Testing

 *eLearning Course*

Course Title: Good Laboratory Practices for Molecular Genetics Testing
Course Duration: 90 minutes (estimated)
Course Description: This on-line learning module is presented in first person. This means the learner is actually depicted as getting an assignment and doing the work throughout the course.
This training is not meant to be prescriptive. There are several different ways to obtain information and perform the tasks described in the training. Examples are provided as potential options.

Quick Links
A Quick Introduction to TRAIN. How to use it and how to register for free.
[PDF \(1 page\)](#)
[Video \(3:38\)](#)
Add CDC Lab Training to an Existing TRAIN

Good Laboratory Practices for Molecular Genetics Testing

[fact sheets](#) [course folders](#) [exit](#)

HOME

- INTRODUCTION 1
- NEEDS AND REQUIREMENTS 2
- PERSONNEL AND TEST METHODS 3
- TEST PERFORMANCE VERIFICATION 4
- QC AND SOP 5
- TEST DIRECTORY, REQUEST & REPORT 6
- RETENTION AND ASSESSMENT 7
- SUMMARY 8

Good Laboratory Practices for Molecular Genetics Testing

[Start the course](#)

 Division of Laboratory Quality Management, Office of Laboratory Operations, Center for Disease Control and Prevention

QUALITY LABORATORIES, HEALTHIER PEOPLE

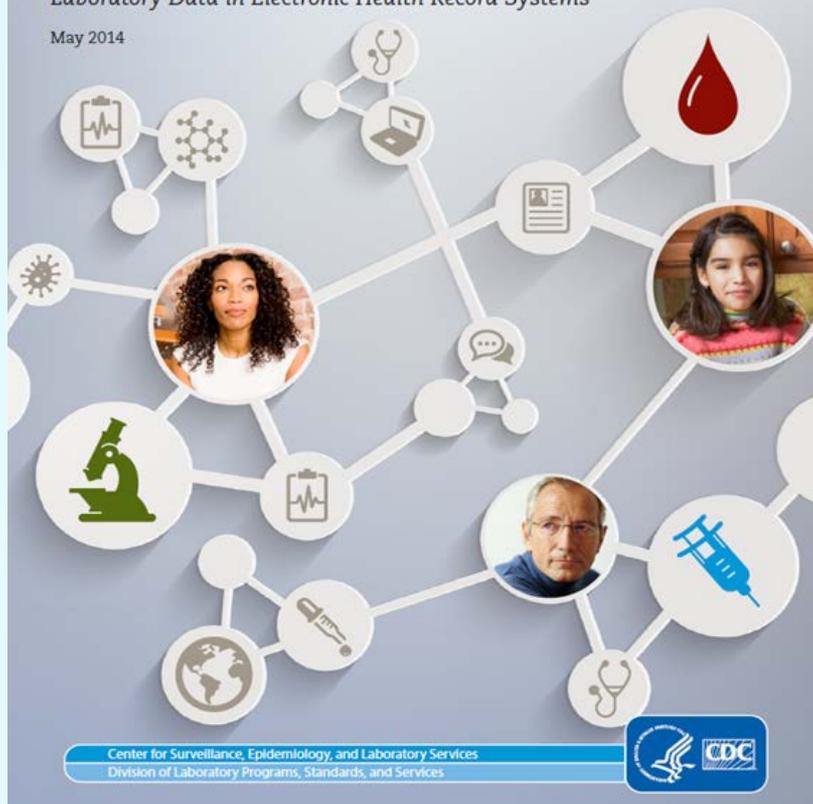
Health Information Technology

Intersection of Laboratory Practice and Health Information Technology

The Essential Role of Laboratory Professionals

Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems

May 2014



- **Nomenclature / Coding (LOINC)**
- **Interoperability**
- **Work with ONC, FDA and others in developing standards**
- **Connecting laboratory professionals to standards development**

Published on website 2014

<http://www.cdc.gov/labhit/index.html>

New and Evolving Technologies and Practices

Next-Generation Sequencing: Standardization of Clinical Testing Workgroups

Assuring the quality of next-generation sequencing in clinical laboratory practice

To the Editor:

We direct your readers' attention to the principles and guidelines (Supplementary Guidelines) developed by the Next-generation Sequencing: Standardization of Clinical Testing (Nex-StoCT) workgroup. These guidelines represent initial steps to ensure that results from tests based on next-generation sequencing (NGS) are reliable and useful for clinical decision making. The US Centers for Disease Control and Prevention (CDC) convened this national workgroup, which collaborated to define platform-independent approaches for establishing technical process elements of a quality management system (QMS) to assure the analytical validity and compliance of NGS tests with existing regulatory

The workgroup recommendations are summarized in Table 1. Although the workgroup focused on detection of DNA sequence variations associated with heritable human disorders, many of the principles and recommendations described are also relevant to the application of NGS to other areas of laboratory medicine, including the diagnosis, pro

treatment of cancer and infectious-disease testing.

Validation is the process of establishing analytical performance specifications for a clinical test system developed in house to confirm that the system is suitable for its intended use¹. During the validation process, the laboratory must demonstrate that the

Table 1 Selected workgroup clinical use

Requirements for test establishment	Objective
Validation	Document reliability of the platform, test and informatics

Good laboratory practice for clinical next-generation sequencing informatics pipelines

Nat Biotech 2012;30:1033 + Supplemental

To the Editor:

We report principles and guidelines (Supplementary Note) that were developed by the Next-Generation Sequencing: Standardization of Clinical Testing II (Nex-StoCT II) informatics workgroup, which was first convened on October 11–12, 2012, in Atlanta, Georgia, by the US Centers for Disease Control and Prevention (CDC; Atlanta, GA). We present

recommendations are summarized in Table 1, and detailed in the guidelines presented in the Supplementary Note.

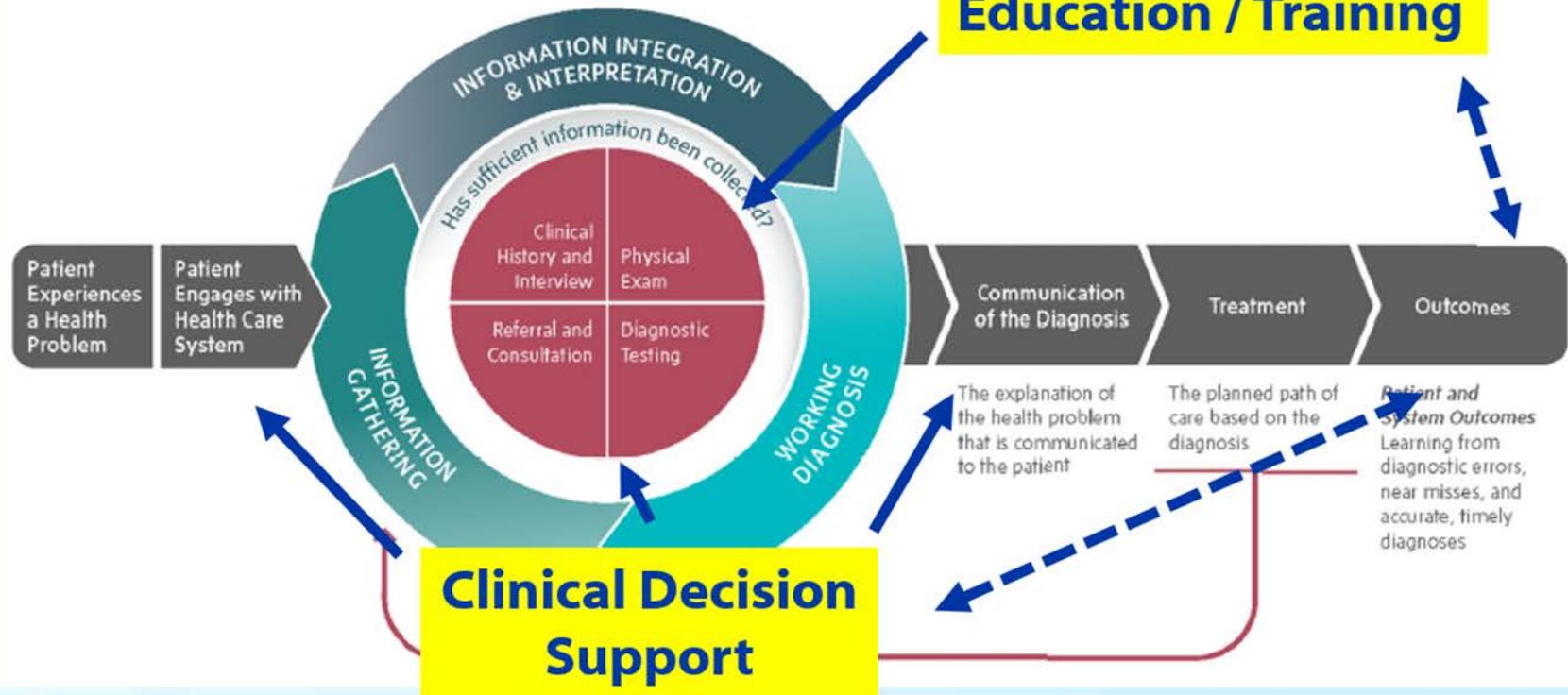
Currently, most clinical NGS tests are offered as laboratory-developed tests (LDTs), which are tests designed, manufactured and used within a single laboratory. These tests use commercially available sequencing platforms to generate raw sequence data that are subsequently

Nat Biotech 2015;33:689 + Supplemental

Summary: Efforts to Enhance the Laboratory's Role for Improving Diagnosis

Overarching: Assessment, Practice Standards and Guidelines, Health IT Initiatives

Education / Training





For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems

