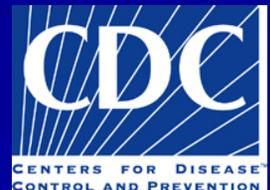


# Future Research Activities

CLIAC Meeting  
February 5, 2009



Devery Howerton, PhD  
Chief, Laboratory Practice Evaluation  
and Genomics Branch  
Division of Laboratory Systems, CDC



# Laboratory Practice Evaluation and Genomics Branch

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Susan Snyder, PhD

Julie Taylor, PhD

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Malaika Washington, MPH

Jonathan Zhong



# Future Focus: Questions to Consider

- What basic information is needed to better understand where quality improvement efforts need to be focused?
- What approaches are most effective in building the needed evidence base for practice standards and guidelines?
- Where can changes/improvements be made with the greatest impact on patient outcomes?
- How can the pre- and post-analytic interface be better evaluated and improved ?
- What are the highest priority policy considerations?
- What impact is new technology having on the field – both complex testing (e.g., genetic testing) and simplified testing (waived testing)?

# Ongoing Studies

- Evidence-based best practices
  - Establishing a laboratory network
  - Implementing the process
  - Evaluating sustainability
- Performance measurement
  - Continuing to develop the evidence base for measurement and improvement
- Clinical decision support for GT
  - Developing reporting tools
- Scope of rapid influenza testing in outpatient settings
  - Evaluating the dissemination of testing, practices and linkages to public health
- Institute for Laboratory Medicine Workgroups

# Current Regulatory Initiatives

## ■ Cytology PT

- Evaluation of PT data
- Final rule regulatory impact analysis (benefits/costs)

## ■ Proficiency testing

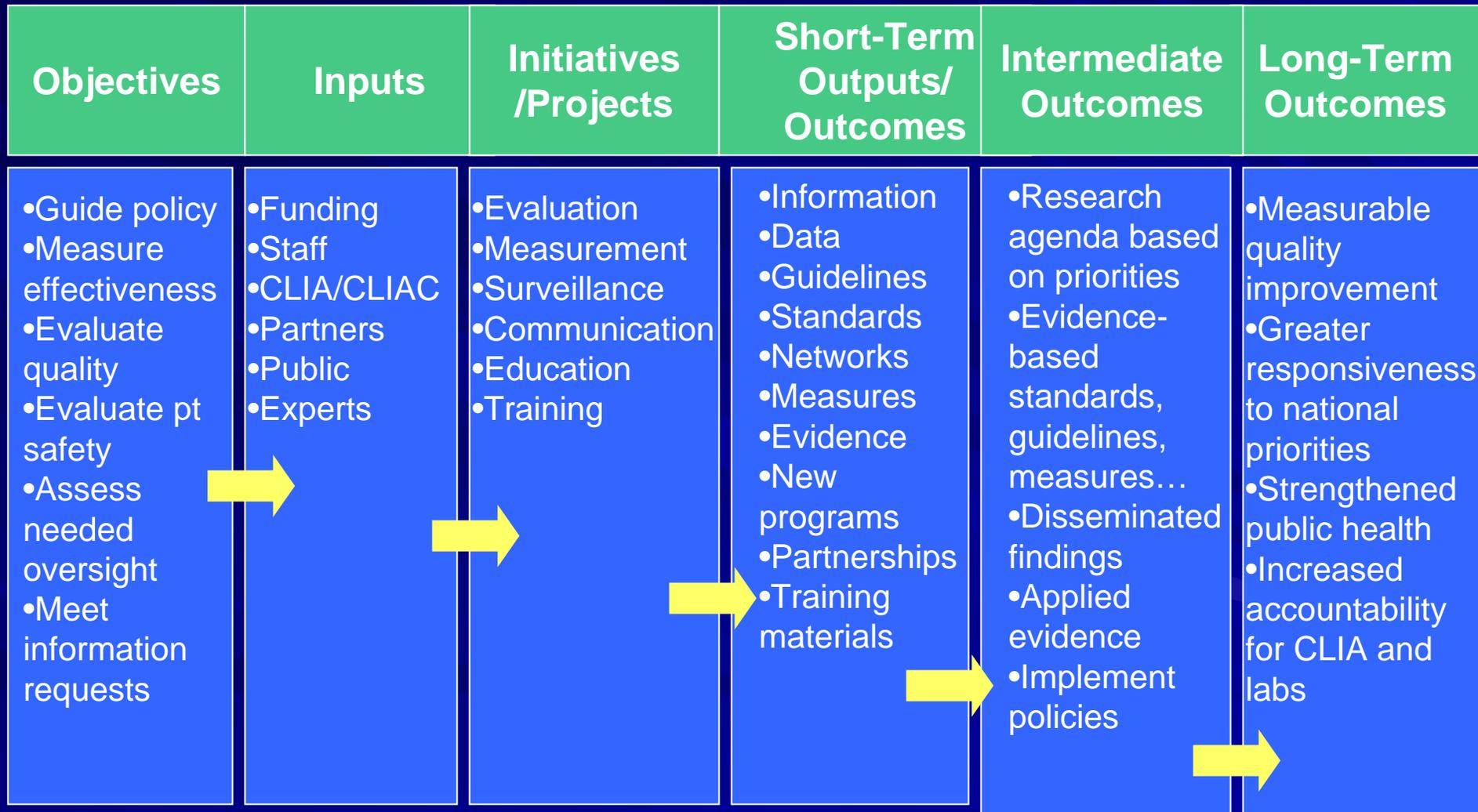
- Evaluation of regulatory approaches
- Proposed rule regulatory impact analysis

# Facilitators and Constraints

## DLS Laboratory Practice Studies

- Availability of funds
- DLS staffing
- Shifting priorities of the CLIA program
- Ability to develop effective study designs and collect data/information
- Stakeholder engagement
- Identifying interested/capable partners

# Research Strategy Logic Model



# Laboratory Systems Research Agenda

**Goal:** Develop a **comprehensive research agenda** that will drive laboratory medicine quality improvement through research and development of evidence-based practices and standards.



# Topics of Interest



- Results from Delphi study
- Growth of waived testing
- Advances/growth in molecular testing
- Building the evidence base for practice standards
- Rapid infectious disease testing
- Enhancing the clinician-laboratory interface
- Laboratory workforce issues

# Waived Testing

## Statutory Descriptive Criteria

Waived test systems include:

- Tests cleared by the FDA for home use; or
- Simple tests with an insignificant risk of an erroneous result, including those that:
  - Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible; or
  - Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

# Growth in Waived Testing

What are the important questions?

- **What is the scope of waived testing: where, which tests, testing volume, personnel, etc.**
- **Are waived testing sites following good laboratory practices? If not, what is the impact on patient outcomes?**
- **What is the impact of inaccurate waived test results on patient outcomes?**
- **Is waived testing cost-effective compared with centralized laboratory testing?**
- **Might exclusion criteria be established that would eliminate tests from waiver consideration?**
- **What study approaches can be considered for collecting data/information about waived testing?**

# Molecular Diagnostics

## Technology, Clinical Utility, Dissemination

- How are changes in technology impacting where molecular testing is performed?
- What data/information is needed to guide policy development to meet changing needs?
- What is the impact of recommending testing in drug labeling (pharmacogenomics)?
- How can the impact of the MMWR on changes in practice be evaluated?

# Committee Discussion: Future Directions



- **What topic areas are of particular interest and why?**
- **What are the high priority policy issues that need to be investigated?**
- **How can we build a more strategic, sustainable research agenda that drives important changes/improvements?**
- **What are the most important outcomes on which to focus?**
- **What measures can be developed to evaluate the research program's success, value?**
- **How can we engage other stakeholders to help us answer these questions?**

Thank you for your feedback!