Optimizing Laboratory Testing Services for Improved Patient Care

Julie R. Taylor, Ph.D.

COLA Spring 2011 Symposium
27-30 April 2011
Nearly Everybody’s Had a Laboratory Test
Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

- History
- Team Members
- Goals and Objectives
- Key Projects
CLIHC™ History

- CDC’s Division of Laboratory Systems hosted 6 Institutes
  - latest in 2007
- Integration Workgroup initiated in 2008 to address some recommendations from institutes
- Focus on optimizing the utilization of laboratory services for better patient care
- Renamed in 2010 –

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™
CLIHC™ Workgroup

- **Co-Lead**: John Hickner, MD, MSc  
  Cleveland Clinic

- **Co-Lead**: Michael Laposata, MD, PhD  
  Vanderbilt University Hospital

- **Scott Endsley MD, MSc**  
  Cleveland Clinic

- **Paul Epner, MEd, MBA**  
  Paul Epner, LLC

- **Marisa B. Marques, MD**  
  University of Alabama at Birmingham

- **Jim L. Meisel, MD, FACP**  
  Boston Medical Center

- **Elissa Passiment, EdM**  
  American Society for Clinical Laboratory Science

- **Brian Smith, MD**  
  Yale School of Medicine
CLIHC™ Workgroup Meeting
January 26 and 27, 2011
Atlanta, GA

Left to Right: Mike Laposata, Elissa Passiment, Paul Epner, Marisa Marques, Bob Hoffman, John Hickner, Brian Jackson, Brian Smith
Not Photographed: Scott Endsley and Jim Meisel
# CLIHC™ Workgroup Support

## Altarum:
- Kim Bellis
- Beth Costello
- Brian Jackson (ARUP)
- Jim Lee
- Dana Loughrey
- Megan Shaheen
- Tom Wilkinson

## CDC:
- Diane Bosse
- MariBeth Gagnon
- James Peterson
- Anne Pollock
- Julie Taylor
- Pam Thompson
Others Participating in CLIHC™ Projects

Samir Aleryani, PhD  
Vanderbilt University Medical Center

Julian Barth, MD  
University of Leeds, United Kingdom

Allison Floyd, MD  
Vanderbilt University Medical Center

John Fontanesi, PhD  
University of California at San Diego

George A. Fritsma, MS MT (ASCP)  
University of Alabama at Birmingham

John A. Gerlach, PhD  
Michigan State University

Robert D. Hoffman, MD, PhD  
Vanderbilt University Medical Center

Katherine Kahn, MD  
Rand Corporation and UCLA

Mario Plebani, MD  
University of Padua, Italy

Mitch Scott, PhD  
Washington University

Oxana Tcherniantchouk, MD  
Cedars-Sinai Medical Center
Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

- Programs and training courses
- Systems
- Models
- Test Selection
- Result Interpretation
CLIHC™

- **Key Projects**
  - Clinician Test Selection & Result Interpretation
    - Diagnostic Algorithms
    - Nomenclature
    - Survey of Clinicians’ Challenges
    - Improvement in Test Selection and Result Interpretation (ITSRI)
  - Medical Student Education
    - Survey of US Medical Schools
    - Clinical Pathology Residency Education
  - Develop Organizational Collaborations
Clinician Test Selection and Result Interpretation
An increasing number of reports showing that errors in test selection and result interpretation jeopardize patient safety.

Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data
Articles on Test Selection Errors

<table>
<thead>
<tr>
<th></th>
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<td>7</td>
<td>16</td>
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- Errors in Test Selection
- Decreasing Errors in Test Selection

Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data
Articles on Result Interpretation Errors

Number of Articles

Decade

Errors in Result Interpretation
Decreasing Errors in Result Interpretation

Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data
Articles on Adverse Outcomes

<table>
<thead>
<tr>
<th>Decade</th>
<th>Number of Articles</th>
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<tr>
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<td>2</td>
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<td>2000-2009</td>
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</table>

Adverse Outcomes from Incorrect Test Selection or Results Interpretation

Allison Floyd, MD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center, unpublished data
Clinical Laboratory Testing - 1970

30-50 lab tests

Michael Laposata, AACC 2010
### Clinical Laboratory Testing - Today

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>Intro of automated instruments</td>
</tr>
<tr>
<td>1980</td>
<td>RIAs for hormones</td>
</tr>
<tr>
<td>1990</td>
<td>Immunoassay automation</td>
</tr>
<tr>
<td>2000</td>
<td>Intro of molecular testing</td>
</tr>
<tr>
<td>2010</td>
<td>Major expansion of molecular testing</td>
</tr>
<tr>
<td></td>
<td>&gt;5000 lab tests</td>
</tr>
</tbody>
</table>

30-50 lab tests

Michael Laposata, AACC 2010
Diagnostic Algorithms
Project Leads – Michael Laposata, MD, PhD and Marisa B. Marques, MD

Goal:
• Demonstrate complexity of selecting the appropriate laboratory test
• Understand the most effective testing strategies
Methods:

• Three clinical pathologists with expertise in coagulation created diagnostic laboratory test algorithms to guide evaluation of patients with a prolonged Partial Thromboplastin Time (PTT) and a normal Prothrombin Time (PT).

• The 6 algorithms addressed:
  – age (adult versus newborn)
  – patient location (inpatient or outpatient)
  – symptoms (none, bleeding or thrombosis)
  – timing of the abnormal PTT result (recent versus extended period of time)
Evaluation of a Prolonged PTT

Degrade heparin in sample and repeat PTT - if the PTT normalizes, heparin is the cause

PTT mixing study (50:50 mix of patient & normal plasma)

PTT Normalizes

Factor deficiency - measure factors VIII, IX, XI, and XII

PTT remains prolonged

Inhibitor, most often a Lupus anti-coagulant; may be a Factor VIII inhibitor if PTT mixing study first normalizes and then becomes prolonged

Perform tests for specific inhibitor suggested by results of PTT mixing study
Diagnostic Algorithms
Project Leads – Michael Laposata, MD, PhD and Marisa B. Marques, MD

Status:
• Finalizing the paper to submit to peer reviewed journal

Next Steps:
• Implement the algorithms in other institutions for validation and improvement
Nomenclature
Project Leads – Elissa Passiment, EdM and Jim Meisel, MD, FACP

Goal:
• Demonstrate the complexity of test selection
  – Multiplicity - Hepatitis B surface antibody
    • HBs Antibody, Hepatitis Bs Ab, HBG, Anti-HBs
  – Complexity - rheumatoid factor- not for rheumatoid arthritis

Methods:
• Develop flow chart and tables demonstrating:
  – Complexity – Vitamin D
  – Breadth – Commonly ordered tests
  – Depth – Coagulation
Methods, cont.

• Test name variation based on:
  – Disease association
  – Methods used to perform the test
  – Name of developer
  – Inappropriate names (i.e. no link between name and what is being tested)

• Multiple test name abbreviations
  – Many evolved from implementing Laboratory Information Systems
<table>
<thead>
<tr>
<th>Nomenclature Options for Vitamin D</th>
<th>Nomenclature Options for Vitamin D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin D2</td>
<td>1,25 (OH)2 vitamin D</td>
</tr>
<tr>
<td>Vitamin D3</td>
<td>1,25 dihydroxy vitamin D2</td>
</tr>
<tr>
<td>25-0H vitamin D2</td>
<td>1,25 dihydroxy vitamin D3</td>
</tr>
<tr>
<td>25-0H vitamin D3</td>
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<tr>
<td>25-0H vitamin D</td>
<td>Vitamin D 25 Hydroxy D2</td>
</tr>
<tr>
<td>25 hydroxy vitamin D2</td>
<td>Vitamin D 25 Hydroxy D3</td>
</tr>
<tr>
<td>25 hydroxy vitamin D3</td>
<td>Vitamin D 1,25 Dihydroxy</td>
</tr>
<tr>
<td>25 hydroxy vitamin D</td>
<td>Cholecalciferol</td>
</tr>
<tr>
<td>1,25 (OH)2 vitamin D2</td>
<td>Ergosterol</td>
</tr>
<tr>
<td>1,25 (OH)2 vitamin D3</td>
<td></td>
</tr>
</tbody>
</table>

CLIHC™ Nomenclature Team, 2011
<table>
<thead>
<tr>
<th>Key Name</th>
<th>Synonyms/Confounders</th>
<th>Abbreviation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkaline Phosphatase</td>
<td>Alkaline Phos blood</td>
<td>ALP, Alk Phos, AP, AKP</td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphomonoesterase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline phosphohydrolase</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alkaline phenyl phosphatase</td>
<td></td>
</tr>
<tr>
<td>Beta HCG</td>
<td>BHCG (serum qualitative)</td>
<td>BHCG, HCGB, Beta-HCG</td>
</tr>
<tr>
<td></td>
<td>Beta-Chorionic Gonadotropin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Blood vs urine</td>
<td></td>
</tr>
<tr>
<td>Complete blood count with differential</td>
<td>Hematology profile; blood count; hemogram</td>
<td>CBC</td>
</tr>
<tr>
<td></td>
<td>CBC with diff</td>
<td>CBC d/p</td>
</tr>
<tr>
<td></td>
<td>CBC with differential</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC with differential and platelets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC w/diff &amp; PLT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CBC diff plts</td>
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CLIHC™ Nomenclature Team, 2011
<table>
<thead>
<tr>
<th>Nomenclature Options for Coagulation Tests</th>
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<tbody>
<tr>
<td><strong>Anticardiolipin antibody</strong></td>
</tr>
<tr>
<td>Anti-cardiolipin antibody</td>
</tr>
<tr>
<td>Antiphospholipid antibody</td>
</tr>
<tr>
<td>Anti-phospholipid antibody</td>
</tr>
<tr>
<td><strong>Factor XII activity assay</strong></td>
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<tr>
<td>Factor XII assay</td>
</tr>
<tr>
<td>Factor XII functional assay</td>
</tr>
<tr>
<td>Hageman Factor assay</td>
</tr>
<tr>
<td><strong>Lupus anticoagulant assay</strong></td>
</tr>
<tr>
<td>Lupus anticoagulant</td>
</tr>
<tr>
<td>Lupus antibody</td>
</tr>
<tr>
<td>Anti-phospholipid antibody</td>
</tr>
<tr>
<td>Lupus inhibitor</td>
</tr>
<tr>
<td>Dilute Russell viper venom time</td>
</tr>
<tr>
<td>Tissue thromboplastin inhibitor</td>
</tr>
<tr>
<td>Dilute prothrombin time</td>
</tr>
<tr>
<td>Kaolin clotting time</td>
</tr>
<tr>
<td>Non-specific inhibitor</td>
</tr>
<tr>
<td><strong>ACCA</strong></td>
</tr>
<tr>
<td><strong>ACL</strong></td>
</tr>
<tr>
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<tr>
<td><strong>DRVVT</strong></td>
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<tr>
<td><strong>dRVVT</strong></td>
</tr>
<tr>
<td><strong>TTI</strong></td>
</tr>
<tr>
<td><strong>KCT</strong></td>
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<td><strong>DPT</strong></td>
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</table>
Nomenclature
Project Leads – Elissa Passiment, EdM and Jim Meisel, MD, FACP

Status:
• Finalizing the paper to submit to peer reviewed journal

Next Steps:
• Investigate IT strategies and systems to assist the clinician in selecting the correct test - search support technology
There is substantial regional variability in test ordering practices that cannot be explained by case mix


www.nejm.org May 12, 2010

10.1056/nejmsa0910881 nejm.org
Clinicians’ Challenges in Test Ordering and Interpretation of Test Results
Project Lead – John Hickner, MD, MSc

Goal:
• Raise awareness of the challenges clinicians face in test ordering and result interpretation

Methods:
• Phase 1 - Conduct three focus groups targeting internal, family, and general medicine practitioners
• Phase 2 - Using information from focus groups in Phase 1, conduct a national survey of clinicians
Focus Group Methods

• Sample frame
  – Family Practice & Internal Medicine Practitioners
  – Mailing lists of local clinicians from several insurance companies databases

• Sites
  – Pilot test at Cleveland Clinic, Cleveland, OH
  – March 17, 2010, Atlanta, GA
  – April 12, 2010, San Antonio, NM
  – May 20, 2010, Ann Arbor, MI
Clinician Demographics

AGE

<table>
<thead>
<tr>
<th>Participant Age</th>
<th>N</th>
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<tr>
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<td>71-75</td>
<td>1</td>
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<td>76-80</td>
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N=27

CLIHC™ Clinicians’ Challenges in Test Ordering and Interpretation of Test Results Team, 2011
Years in Practice

![Bar chart showing the distribution of years in practice with N=27.](chart.png)

N=27

CLIHC™ Clinicians’ Challenges in Test Ordering and Interpretation of Test Results Team, 2011
Clinician Demographics, cont.

N=25 (2 did not specify)

CLIHC™ Clinicians’ Challenges in Test Ordering and Interpretation of Test Results Team, 2011
Clinic Demographics, cont.

N=26 (1 did not specify)

CLIHC™ Clinicians’ Challenges in Test Ordering and Interpretation of Test Results Team, 2011
Challenges/ Barriers
Test Ordering

• Insurance and cost limitations
• Issues with accessing and communicating with laboratories
• Variations in test names
• Variable and nebulous practice guidelines
Enablers
Test Ordering

• Electronic resources
• Access to peers and colleagues
• Access and relationships with laboratory professionals
• Availability of practice guidelines
Challenges/ Barriers

Result Interpretation

• Insurance and cost limitations
• Varying practice guidelines and methodologies
• Difficulties in accessing and communicating with laboratory professionals
• Inconsistency of laboratory test results with clinical presentation
• Inadequate laboratory reporting and documentation
Enablers
Result Interpretation

• Access to electronic results and resources
• Access to peers and colleagues
• Access to laboratory professionals
• Follow-up testing information and reflex testing, when appropriate
Focus Group Summary

• Physicians are comfortable with selecting from a small working repertoire of common tests
• When results did not fit their suspected diagnosis, physicians relied on combination of patient presentation and own diagnostic instincts more than the laboratory results
• Laboratory consultation was a useful resource when the physician had effective and consistent access to laboratory services and were comfortable with laboratory professionals
• Electronic resources are becoming more important, with level of utilization dependent on ease of availability and a culture that encourages their use
Phase 2 - Clinicians’ Survey

Methods:

– National sample of Family Practice and Internal Medicine physicians drawn from AMA Master File
– Target sample size of 1600
– Survey delivered via Web

Status:

– 60 Day Federal Register Notice submitted
– Survey developed
  • Cognitive testing completed
  • Expert review by national authorities
– Expect results – late Fall, 2011
Questionnaire Section Headings

– Ordering Uncertainty
– Ordering Influences
– Ordering Challenges
– Interpretation Uncertainty
– Interpretation Challenges
– Test Utilization Enablers
– Laboratory Consultation Practices
– New Test Awareness
– Diagnostic Evaluation Practices
– Demographic and Practice Characteristics

CLIHC™ Clinicians’ Survey Team, 2011
Q02. When uncertain what clinical laboratory tests to order for diagnostic (NOT for screening or monitoring) purposes, how often do you do the following?

<table>
<thead>
<tr>
<th>Please select one best answer for each of the below →</th>
<th>Daily</th>
<th>At least once per week</th>
<th>At least once per month</th>
<th>At least six times per year</th>
<th>At least once per year</th>
<th>Less than once per year</th>
<th>Never</th>
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<tr>
<td>Ask another primary care physician for advice</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Ask a laboratory professional (e.g., pathologist, laboratory technologist, etc.) for advice</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>Refer the patient to a specialist</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
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<tr>
<td>Review electronic reference(s): professional articles, journals, newsletters</td>
<td>□</td>
<td>□</td>
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CLIHC™ Clinicians’ Survey Team, 2011
Key Projects

- Clinician Test Selection & Result Interpretation
  - Diagnostic Algorithms
  - Nomenclature
  - Survey of Clinicians’ Challenges Education
  - Improvement in Test Selection and Result Interpretation (ITSRI)

- Medical Student Education
  - Survey of US Medical Schools
  - Clinical Pathology Residency Education

- Develop Organizational Collaborations
Severity of 583 Physician-Reported Diagnostic Errors

Schiff, G. D. et al. (2009). Diagnostic error in medicine: analysis of 583 physician-reported errors. Archives of internal medicine, 169(20)
Schiff, G. D. et al. (2009). Diagnostic error in medicine: analysis of 583 physician-reported errors. *Archives of internal medicine, 169*(20)
Interventions that Reduce Test Order and Result Interpretation Errors

• Guideline/ clinical pathways
  – National and locally developed
  – With or without electronic decision support
• Structured requisitions
• Reflex testing
• Consultations
• Interpretive comments

Published studies summarized by Paul Epner, Diagnostic Errors in Medicine, October 25, 2010
What we don’t know

• What is the prevalence of diagnostic errors impacted by the testing process?
  – Failure to order necessary tests
  – Ordering of unnecessary tests
  – Inappropriate utilization of test results

• What are effective interventions that reduce diagnostic errors and could be initiated by laboratory professionals?
  – What settings are appropriate for these interventions?
  – What limitations exist in the use of these interventions?
  – What new sources of errors are created by the interventions?

Paul Epner, Diagnostic Errors in Medicine, October 25, 2010
Improvements in Clinicians’ Test Selection and Result Interpretation (ITSRI)
Lead – Paul Epner, MEd, MBA

Goal:
• Demonstrate the effect of improvements in laboratory test selection and result interpretation on diagnostic errors

Methods:
• Develop methods to measure the effect of laboratory test selection and result interpretation on diagnostic errors
• Conduct pilot studies to determine the effect of improvements in laboratory test selection and result interpretation on diagnostic errors
Reviewed one week of consultation requests

53 cases total
- 29 cases had appropriate test orders (55%)
- 19 cases had incomplete test orders (36%)
- 5 cases had inappropriate test orders (9%)

Of 24 cases where tests were added or deleted following consultation, the diagnosis was impacted in 2 cases.

The timing of the diagnosis in the other cases was not impacted only because of the near real-time addition of tests.

*Information and analysis provided by Jennifer M. Giltnane, MD, PhD and Michael Laposata, MD, PhD, Vanderbilt University Medical Center*
Next Steps

• Continue pilot studies to develop measures
• Continue to identify pilot study partners and sites
• Fall strategic planning meeting
  – Review goals for project
  – Review pilot study data
  – Develop strategic plan
Medical Student Education
Laboratory Medicine Education in US Medical Schools

- Required courses in 57% (68/120) of schools
- Few schools report no training at all (2-4%)

An ad hoc committee of The Academy of Clinical Laboratory Physicians and Scientists
- Proposed medical student laboratory medicine curriculum
- Developed:
  - Goals and objectives for training
  - Guidelines for instructional methods
  - Examples of how outcomes can be assessed

Smith, Brian R, et. al.; Educating Medical Students in Laboratory Medicine A Proposed Curriculum; AJCP; 2010: 133: 533-542
Survey of U.S. Medical Schools
Project Leads – Brian Smith, MD and John Hickner, MD, MSc

Goal:
• Raise awareness to the gaps in US medical school curricula and laboratory medicine training

Methods:
• Survey all 133 allopathic and 26 osteopathic U.S medical schools
• Recruit one medical student (via AMSA) per school to help complete the survey
Survey of U.S. Medical Schools
Project Leads – Brian Smith, MD and John Hickner, MD, MSc

Sample Questions:
• Does your school periodically have a formal review of the overall laboratory medicine curriculum by a Laboratory Medicine / Pathology physician?  Yes/No
• Is competency in Clinical Laboratory Medicine formally evaluated as a distinct curriculum component?  Yes/No

Status:
• Expect survey results in Fall, 2011

CLIHC™ Medical Survey Team, 2011
Next Steps

Depending on results, consider:

• Establishing a national resource for instruction
  • Refine the ACLPS curriculum in conjunction with primary care and specialty physician-educators
• Establishing a national assessment that schools can use (e.g., an on-line examination)
• Extending the survey to other health professionals
  • Physician Assistants
  • Advanced Practice Registered Nurse
Clinical Pathology Residency Education
Project Leads – Robert Hoffman, MD, PhD & Michael Laposata, MD, PhD

Goal:
• Establish the nature and amount of clinical consultation education provided to clinical pathology residents
• Raise awareness to the gaps in, and solutions to improve clinical pathology residency education

Method:
• Conduct observational study of academic institutions assessing clinical pathology resident training activities
Clinical Pathology Residency Education
Project Leads – Robert Hoffman, MD, PhD & Michael Laposata, MD, PhD

Results:

• 14 Accredited programs contacted – invited to visit 3
• “You would be surprised to see how little consultation there is”
• Some training programs have focal areas of consult activity
• Many programs not prepared to develop meaningful consultative roles for residents in laboratory medicine
• Obstacle- Limited # of doctoral level laboratory directors to teach residents

Next Steps:

• Obtain more data to substantiate the results
• Identify model programs to share nationally

Robert D. Hoffman, MD, PhD, Vanderbilt University Medical Center
Developing Organizational Collaborations

Project Lead – Scott Endsley, MD

Goal:
• Develop partnerships and collaborations that support and sustain CLIHC™ initiatives

Methods:
• Utilize a webinar to:
  • Increase the awareness of CLIHC™ work among key stakeholders
  • Solicit partnerships for current and future projects

Next Steps:
• Expand list of CLIHC™ collaborators
• Plan webinar for fall
“Knowing is not enough; we must apply. Willing is not enough; we must do”

Goethe

For more information please contact:
Julie Taylor at Jtaylor1@cdc.gov