APHL CLIA Training Projects

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Project Background

- RFP first released in fall of 2011
 - o Funded through CDC/APHL Cooperative Agreement
 - Modeled after the APHL Innovations in Quality Public Health Practice program
 - Awards were up to \$15,000 each
 - Proposals accepted from APHL member laboratory staff
 - Partnering with other entities was encouraged
 - Quarterly milestones to be reported
 - Training materials developed to be shared with others
 - <u>http://www.aphl.org/mrc</u>
 - All training components must have an evaluation
 - Final report must contain evaluation results
 - Selection team from APHL, CDC and PHLs



Training Topics

- Proposed training projects should be targeted for clinical or physician office laboratories and address one or more of the topics below:
 - $\circ~$ Developing and delivering waived testing training for POLs
 - Developing and delivering training on a CLIA related topic such as proficiency testing, competency training, validation studies, etc.
 - Delivering training using tools already available, such as CDC's "Ready? Set? Test?" materials or APHL's Bench aids
 - **o** Developing tools for preparing for a CLIA inspection

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 Developing and delivering training for quality management systems (QMS)



Proposals

- Round 1 for project completion June 2012
 o 16 applications, 13 accepted, 2 withdrawn, 1 requested extension
- Round 2 for project completion June 2013
 o 8 applications, 8 accepted, 1 on hold
- Round 3 for project completion June 2014
 o 4 applications, 4 accepted, 1 on hold
- Total of 21 awards, 3 in progress



Award Recipients

AK - 1	ID - 1	NJ - 1	MT - 2
AL - 1*	HI - 2	NM - 1	PA - 1
FL - 1*	KY - 1	MI - 1	WI - 3
IA - 2	NH - 2*	MN - 1	WV - 2
City of Milwaukee - 1			*application withdrawn after acceptance

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CLIA Training Awards



P H L ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Target Audiences

- Over 2650 participants
- Types of students

o POL staff

- o Certificate of Waiver Laboratory staff
- o Hospital Laboratory staff
- o Public Health Laboratory staff
- o Public Health Nurses
- o Clinical laboratory scientist students



Training Modalities

• Seminar (less than ¹/₂ day)

- Workshop (all day)
- Online courses
- CD or DVD

CLIA Training Topics

o CLIA Overview

o Waived testing for POLs

- Good Laboratory Practice
- How to Read a Package Insert
- Urine Dip Stick Testing
- Hemacue Test
- Laboratory Safety

o Preparing for a CLIA Inspection

- Top 10 Deficiencies
- Competency testing
- Proficiency Testing
- Wet Mounts



QMS Topics

- Quality Management for AST
 - Streamlined QC
 - Verification and QC of a new drug panel
- Using CLSI Guidelines for Training and Competency Assessment
- Management of Non-conforming Laboratory Events and Development and Use of Quality Indicators
- Providing Quality Laboratory Services

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Supplemental Materials

• CDC's "Ready, Set, Test!"

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- MMWR (2005) "Good Laboratory Practice"
- APHL's Bench Aids
- CLSI Documents
- APHL Webinar

Training Partners

- CMS regional offices
- State CLIA surveyors
- Public health agencies
- Hospital laboratories
- Universities

Measuring Impact

- Pre and post test scores
- Participant evaluations
- Surveyor feedback



Pre and Post Test Examples

• Certificate of waiver

o Average pre test = 81.5%o Average post test = 93.8%

• QMS

 \circ Average pre test = 48%

 \circ Average post test = 81%



Participant Evaluations

- Feedback was extremely positive at all sites and for all modalities
- Many requests for additional training
- Many promises for changes to current practices

Changes to Practices

- Will use a timer for urine dip sticks
- Will run controls and write down the results
- Will write "positive" instead of a check mark
- Will buy a timer and use it
- Will check staff for color blindness
- Will read package inserts
- Will take ambient air temp



Sample Participant Comments

- Good laboratory practice goes beyond meeting requirements.
- Proper testing procedure is very useful to getting proper results.
- The glucometer is not a diagnostic tool, use for monitoring only.
- I must make sure I perform the correct test for the testing device.



Surveyor Feedback

• "State Surveyors have noticed during Certificate of Waiver (CoW) inspections that participants were very satisfied with the training and pointed out changes to the surveyors that they had made to their laboratory practices as a result of the training."

Surveyor Feedback

• 24 certificate of waiver surveys conducted

o 16 had attended training

- Received congratulations or recommendation letters
- o 8 had not attended training

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- Received requirement or enforcement letters
- Surveyor stated:

Pay it Forward

- APHL sponsored workshop for 25 using materials developed by MT
- NJ used materials developed by AK for their 6 workshops
- WV used material from round 1 to train more
- ID created extra materials for attendees to take to train others

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- ID
 - "The better outcome on the knowledge of good laboratory practices demonstrates that the project did have a positive impact on laboratories viewing the product."



Round 4 Proposals

- RFP released May 2014
- Funding for 4-6 awards
- Must partner with a PHL
- All projects complete by June 15, 2015

For More Information

• <u>www.aphl.org/mrc</u>

o use CLIA as the search word

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Thank you to CDC

Laboratory Practice Standards Branch Division of Laboratory Programs, Standards, and Services Center for Surveillance, Epidemiology, and Laboratory Services

Office of Public Health Scientific Services

