



Marketing Good Laboratory Practices for Waived Testing - Update

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Outline



- Background
- Initial Dissemination Efforts
- Efforts by Others
- Development of Materials to Increase Awareness
- Concept Testing of Materials
- Preliminary Implementation Plans
- Preliminary Evaluation Efforts
- Questions for CLIAC



Background





Background



- CMS on-site surveys and CDC-funded studies identified gaps in testing quality in waived testing sites.
- To address these quality gaps, CLIAAC recommended that Good Laboratory Practices (GLPs) for Waived Testing Sites be:
 - ❖ Developed and published in *Morbidity and Mortality Weekly Report (MMWR)*
 - ❖ Marketed in a simple format to promote adoption in waived testing sites
- November 11, 2005, "Good Laboratory Practices for Waived Testing Sites" was published in *MMWR Reports and Recommendations*

(<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>)



Background- Target Audience



- Physician office laboratories (POLs) selected as initial target audience
- Rationale-
 - ❖ POLs represent 46% of waived testing sites
 - ❖ Marketing to these sites may have the most impact



Background



Health Marketing and Communication Planning Process*

- Problem description and analysis
- Intervention planning and development
- Formative research activities (concept testing)
 - ❖ Audience segmentation
 - ❖ Communication/marketing strategy development
 - ❖ Partnership planning and establishment
- Plan evaluation
- Program Implementation
 - ❖ Dissemination activities
 - ❖ Feedback opportunities

*Information is based on CDCynergy 3.0.
(<http://www.cdc.gov/healthmarketing/cdcynergy>)



Initial Dissemination Efforts





Review- Initial Dissemination Efforts (CDC)



Following publication in *MMWR*:

- CDC sent announcements with link to full document via e-mails, Listservs
- Requested that recipients share the information with professional colleagues and/or post on websites
- Informed recipients of Continuing Education credits linked to publication



Review (cont.)- Initial Dissemination Efforts (CDC)



- E-mail announcements –
 - ❖ Current and former CLIAC members
 - ❖ Professional organizations and PT programs
 - ❖ State Health Departments
 - ❖ Industry
 - o AdvaMed, Health Industry Distributors Association (HIDA)

- Listserv announcements –
 - ❖ Clinician Outreach and Communication Activity (COCA) listservs
 - o Network of >100 physician and healthcare organizations
 - o Approximately 40,000 physicians, nurses, states, and public health workers
 - ❖ Public Health Service Listserv
 - o Nurses, physicians, and pharmacists employed in the Public Health Service



Dissemination Efforts (CDC)



- Promotion during presentations at professional meetings
 - ❖ COLA - Physician Office Laboratory Symposia
 - o May 2006, and October 2006
 - o Future meeting - May 2007
 - o Sponsored by COLA and the University of Wisconsin
 - o Attendees include physicians and laboratory personnel in COLA-accredited laboratories



Efforts by Others





Efforts by Others



- CMS Surveyors
 - ❖ Distributed educational documents that reference *MMWR* publication during on-site surveys of CW sites
- New York State Health Department
 - ❖ Purchased copies of *MMWR* publication for all NY's Limited Service Laboratories performing waived testing
- Health Industry Distributors Association (HIDA) –
 - ❖ Developed and distributed flyers specific to “Good Laboratory Practices for Waived Testing Sites”
 - ❖ available to HIDA members



Efforts by Others (cont.)



- APHL- Developing Job Aids specific to “Good Laboratory Practices for Waived Testing Sites”
- Workshops based on GLPs in *MMWR* article
- Several professional publications and newsletters
- Individual Advocates



Efforts by Others (cont.)

Websites



- As of 2/2/07, information about the *MMWR's* GLPs for waived testing sites was posted on 33 websites, including:
 - ❖ Federal government agencies
 - ❖ Professional laboratory and PT organizations
 - ❖ Clinical medicine organizations
 - ❖ State departments of health
 - ❖ Industry
 - ❖ On-line journals
 - ❖ On-line newsletters for various organizations



Development of Materials





Development of Materials to Increase Awareness - CDC



- Consulted with experts in CDC's National Center for Health Marketing (NCHM)
- Developed draft posters & tri-fold brochures
 - ❖ Developed a list of most critical *MMWR* recommendations for waived testing
 - ❖ Held a Division-wide contest for creating a theme for materials
 - o PAR – golf theme
 - o Waived testing- surfer theme
 - ❖ CDC's Division of Creative Services, NCHM designed draft materials



Draft Poster



Is Your Waived* Testing Up To PAR?



PREPARE

- Confirm test orders and be sure the patient has followed any pre-test instructions (e.g., fasting, etc.)
- Collect the right specimen in the right way
- Label the specimen immediately

ANALYZE

- Be sure the manufacturer's instructions are current
- Follow the manufacturer's instructions exactly as written
- Test Quality Control materials with the recommended frequency

REPORT/
RECORD

- Provide legible, timely reports to the appropriate person
- Maintain records for all patient and quality control testing
- Notify public health agencies of positive results for reportable infectious diseases

*Testing waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

For additional information, refer to MMWR- Good Laboratory Practices for Waived Testing Sites (<http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>)





Draft Poster



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Draft Poster



Waived Testing^{*} Mind Your Ps & Qs

Preparation + Performance + Persistence = Quality

PREPARATION

+

PERFORMANCE

+

PERSISTANCE

= Quality Test Results

- Confirm test orders and identify the patient
- Collect the right specimen in the right way and label it immediately
- Prepare the testing area, test system and reagents according to instructions
- Test QC materials at the proper frequency to be sure the test performs as expected and to recognize problems
- Follow procedural steps in exact order as written
- Interpret all results according to product insert instructions and record results according to test site policy
- Provide legible, timely reports to the appropriate person
- Be sure confirmatory testing is performed when needed
- If required, report positive results for infectious diseases to public health agencies

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Concept Testing





Concept Testing of Materials



- **Phase One**

- ❖ October 2006 - COLA Meeting
 - o Collaboration with APHL
- ❖ Information gathered from participants visiting exhibits, COLA, and AAFP representatives

- **Outcome**

- ❖ Feedback helpful, but we did not reach target audience
- ❖ Preferences for themes equally divided, but comments on details included:
 - o Text hard to read and too wordy; need to simplify
 - o Surfboard looks cracked (first surfboard had a zigzag pattern)
 - o Golfer looks grim ("grim reaper")
 - o Suggested non-gender golf theme



Draft Poster



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ANALYZE

- Be sure the manufacturer's instructions are current
- Follow the manufacturer's instructions exactly as written
- Test Quality Control materials with the recommended frequency

REPORT

- Provide legible, timely reports to the appropriate person
- Maintain records for all patient and quality control testing
- Notify public health agencies of positive results for reportable infectious diseases

*Simple Testing classified as waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)



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Concept Testing of Materials, cont.



- Phase Two

- ❖ Visit POLs with Certificate of Waiver-

- o To target personnel performing waived testing, and the laboratory directors
- o Plan to visit 9 POLs with diverse specialties, including rural and urban
- o Sample of convenience; not generalizable
- o Revise materials following analysis of feedback
- o If revisions are significant, visit additional POLs



Implementation Plans





Implementation Plans



- Post materials on Division of Laboratory Systems, CDC website
 - ❖ Will provide posters, tri-folds, future materials
 - ❖ Send wide-spread email and listserv announcements to notify availability of materials
- Promote materials in appropriate professional journals (to be identified through feedback from concept testing)
- Promote materials at appropriate professional meetings
- Develop partnerships to promote and distribute materials



Preliminary Evaluation Efforts





Preliminary Evaluation of Awareness



- Added evaluation questions to 2007 CMS CW Survey
 - ❖ Does the laboratory have a copy or are they aware of the 2005 MMWR Recommendations and Reports publication “Good Laboratory Practices for Waived Testing Sites?”
 - ❖ Has the laboratory changed any of its practices as a result of the information in this publication? If YES, what practices were changed?
- NY shared evaluation results from survey of their Limited Service Laboratories
- Received analysis of *MMWR* Continuing Education responses



MMWR Continuing Education Report



November 2005-December 2006

- 1,695 participants
- Types of continuing education credits:
 - ❖ 783 Continuing Education Units (CEU)
 - ❖ 398 Continuing Medical Education (CME)
 - ❖ 95 Continuing Medical Education- Non Physician (CME-NP)
 - ❖ 419 Continuing Nursing Education (CNE)
- Professions:
 - ❖ Nurse (30%)
 - ❖ Physician (20%)
 - ❖ Office Staff (15%)
 - ❖ Health Educator (10%)
 - ❖ Other (25%)



MMWR Continuing Education Report (cont.)



- "I plan to use these recommendations as the basis for -"

❖ Health education materials	43%
❖ Local practice guidelines	37%
❖ Public policy	5%
❖ Insurance reimbursement policies	3%
❖ Other	33%



MMWR Continuing Education Report (cont.)



- “These recommendations will improve the quality of my practice -” (n=1682)
 - ❖ Agree/strongly agree 81%
 - ❖ Neither agree nor disagree 18%
 - ❖ Disagree/strongly disagree 15%



Evaluation of Awareness



Future evaluation efforts –

- Survey a sample of POLs with Certificate of Waiver to determine degree of awareness of GLPs for Waived Testing Sites
- Possible mechanisms-
 - ❖ CDC to develop, distribute, and analyze survey
 - ❖ Collaborate with partners
 - ❖ Hire external contractor to perform evaluation



Questions for CLIAC





Questions???



- Can you suggest additional ways we can reach the segment of the POL target audience that only performs waived testing?
- Can you suggest specific organizations that may be of help with increasing awareness of the GLPs in the target audience, or distribution of materials?

