



CDC Update

CLIAC Meeting
September 2, 2009
Roberta B. Carey, Ph.D.

New CDC Leadership

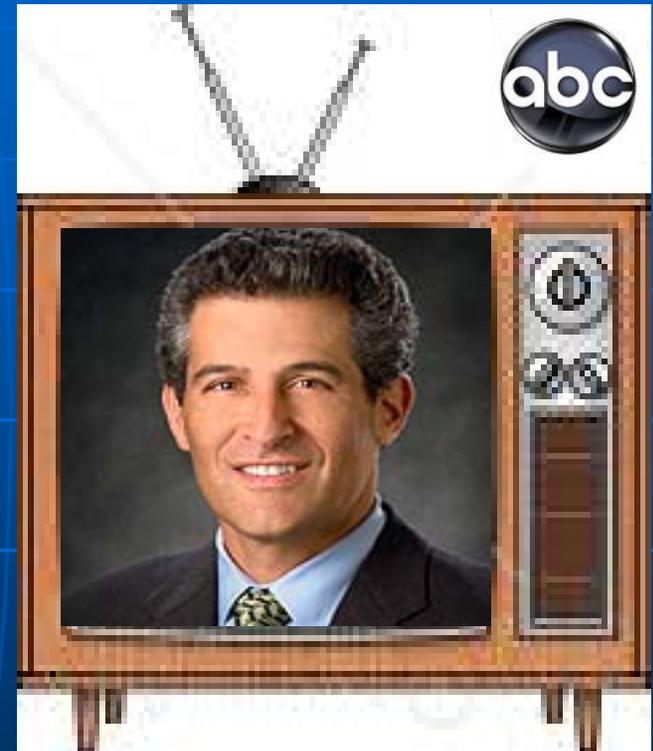
- Dr. Thomas R. Frieden
 - Appointed May 15, 2009
 - Director, CDC
 - Administrator, ATSDR

- Dr. Ileana Arias
 - Acting Deputy Director
 - Former Dir. Injury Prevention and Control



Organizational Change

- Richard Besser, MD, who served as the Acting Director of CDC from January until June, joined ABC News as senior health and medical director on August 15.



Organizational Improvement

“All successful organizations continuously assess demands, opportunities and challenges and make appropriate adjustments...to increase effectiveness. Although change is never easy, CDC needs to adapt.

Our goal is to solidify CDC's role as a respected leader....”

—*Thomas R. Frieden, MD, MPH*
June 29, 2009

Key Strategic CDC Directions

Organizational Improvement Team is working on recommendations based on Dr. Frieden's five priorities:

1. Improving support to states and localities
2. Strengthening surveillance and epidemiology
3. Strengthening CDC's global health work
4. Improving policy effectiveness
5. Positioning CDC to address health reform

Lab Services: Core to PH

- Key line of defense to protect public from disease and environmental threats
 - Diagnosis and outbreaks
 - Research and investigation
 - Mandatory reporting
- Laboratory registration, safety and QC are core PH services
- CDC often regarded as *de facto* reference lab for the world

Phase I: Organizational Improvement Timeline

July 27: DDC
July 28: ELB/CLC/MC
July 29/30: NAACHO
July 29: Director's Announcement to staff

Meetings conducted on Focused Efforts

CDC Director consults with HHS offices and Congress

Draft memo to the HHS Secretary

Phase II: Implementation



July 14: OI Team Formed

July 30: CDC Connecting Conversations Begins

Engage with partners (e.g., ASTHO, APHL, CSTE, others)

August 17: ALL INPUT DUE TO OI TEAM

OI develops options paper for the Director. Staff provide input.

CDC Director announces organizational structure
ACTION PLAN DEVELOPED

Newborn Screening



CLIAC Work Groups and Other Work Groups



CLIAC Proficiency Testing Workgroup

- Workgroup Composition
 - Chair: James Nichols, Ph.D.
 - Members have been identified and include:
 - Laboratory experts (10)
 - Proficiency testing program experts (7)
 - Accreditation/state licensure experts (6)
 - Government *ex officios* (5)
- Meeting dates: March 10-11, 2010
 - Pre-meeting teleconference to be scheduled
- Workgroup report to CLIAC:
September 1-2, 2010

PT Workgroup Charge

- Provide input to CLIAC for consideration in making recommendations to HHS regarding revisions to the CLIA requirements for proficiency testing (PT) specified in subparts H and I of the regulations

Topics for PT Workgroup to Address

- Updating the list of CLIA-regulated analytes
- Revising the criteria for acceptable performance, including target values and acceptable limits, for CLIA-regulated analytes (current and proposed)
- Changes to specialties or subspecialties that do not have regulated analytes (microbiology)
- Clarification of the requirements that address PT referral
- Appropriate PT in light of evolving technology, such as telemedicine
- Other changes needed to update and improve CLIA PT

Biochemical Genetic Testing Workgroup

- Charge: Provide input to CLIAC to develop recommendations for good laboratory practices for biochemical genetic testing (BGT)
- Chair: Carol Greene, MD
 - 13 external experts
 - 2 CMS, 1 FDA
 - 10 CDC members

Timeline for Developing and Publishing Recommendations



BGT Workgroup Progress

- Orientation conference call on March 11, 2009
- Meeting held on June 1-2, 2009, in Atlanta
 - Reviewed 19 crosswalks prepared by CDC
 - Initial input developed on:
 - Scope of GLP consideration and applicability
 - Total testing process (preanalytic, analytic, postanalytic phases)
 - Personnel competency assessment, qualifications and responsibilities
 - Confidentiality practices
 - Considerations before introducing BGT or offering new tests
 - Identified additional issues to be resolved
- Follow-up conference calls: June 30, Aug. 5, Aug. 17, September and October

Highlights of BGT Workgroup

- Defined scope - WG suggested the scope of GLPs for biochemical genetic testing should include newborn screening for inborn errors of metabolism and other heritable conditions
- Identified areas and issues needing guidance, including many issues unique to biochemical genetic testing
- Future document - The CLIAC recommendations to be developed and published should provide guidance both for clinical biochemical genetic testing and public health testing

Laboratory Medicine Best Practices

- Goal
 - Make evidence-based practice recommendations for quality improvement in laboratory medicine
- Status
 - Developed new methods for evaluating quality improvement evidence of effectiveness
 - Developed network with stakeholder organizations to mine data
 - Pilot testing of systematic review methods
 - Developing sustainable organization/infrastructure for routine production, publication, and dissemination of evidence-based recommendations

Laboratory Medicine

Best Practices

- 3 pilot test topics & practices
 - Specimen identification (barcoding systems, POCT barcoding)
 - Critical values communication (call centers, automated electronic notification)
 - Blood culture contamination (dedicated phlebotomy team, pre-packaged collection kits)
- New topics being solicited
- For more information and to register for updates go to: www.futurelabmedicine.org

Evidence-Based Lab Medicine Quality/Performance Measures

- Laboratory tests for chronic kidney disease
 - Kaiser Permanente Center for Health Research
 - Anemia, proteinuria, est. glomerular filtration rate, parathyroid hormone
- Newborn screening timeliness of diagnosis/treatment
 - Texas Dept of State Health Services
 - Endocrine-, metabolic- and hemoglobin-related conditions
- Pre and postanalytic laboratory medicine indicators
 - Univ. of Colorado (Denver)
 - Specimen ID errors, TDM test ordering, BC contamination, inpatient POC glucose accuracy, K+ critical value reporting, TAT for cancer diagnostic test to treatment

Laboratory Medicine Roadmap Workgroup

- Goal
 - Create an action plan to help the laboratory community move from the present state to optimized patient care, as defined by the 6 IOM domains
- Status
 - Preparing a “white paper” to describe the actions needed to meet the goal

Laboratory Medicine Integration Workgroup

- Goal

- Develop systems to improve the selection and interpretation of laboratory tests

- Status

- Completed literature review
- Preparing algorithms for test selection related to coagulation
- Understanding clinician's needs for laboratory consultations
- Determining current laboratory training curricula in medical schools



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