CDC Update

CLIAC Meeting

February 9, 2010

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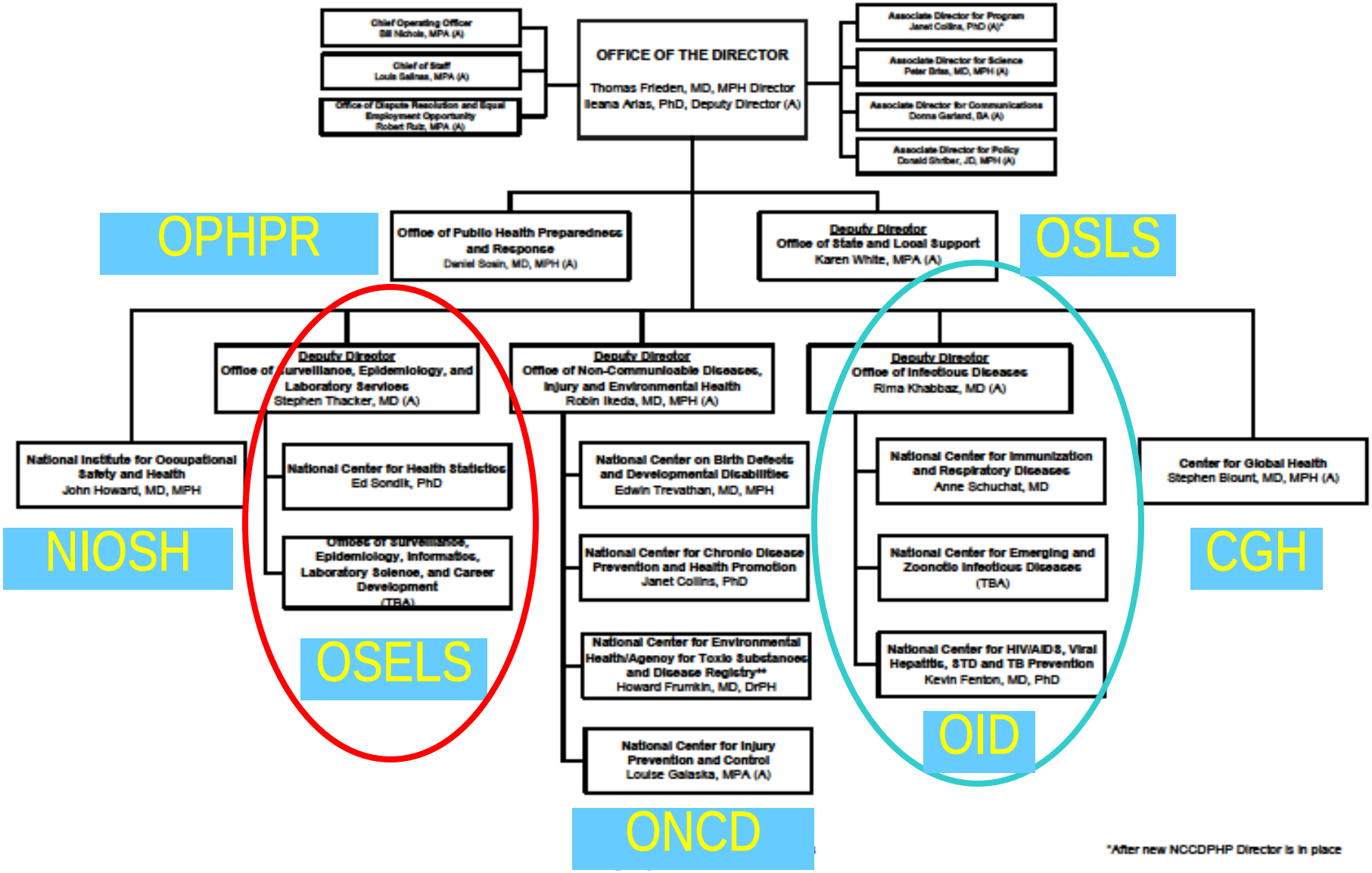
Organizational Improvement

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

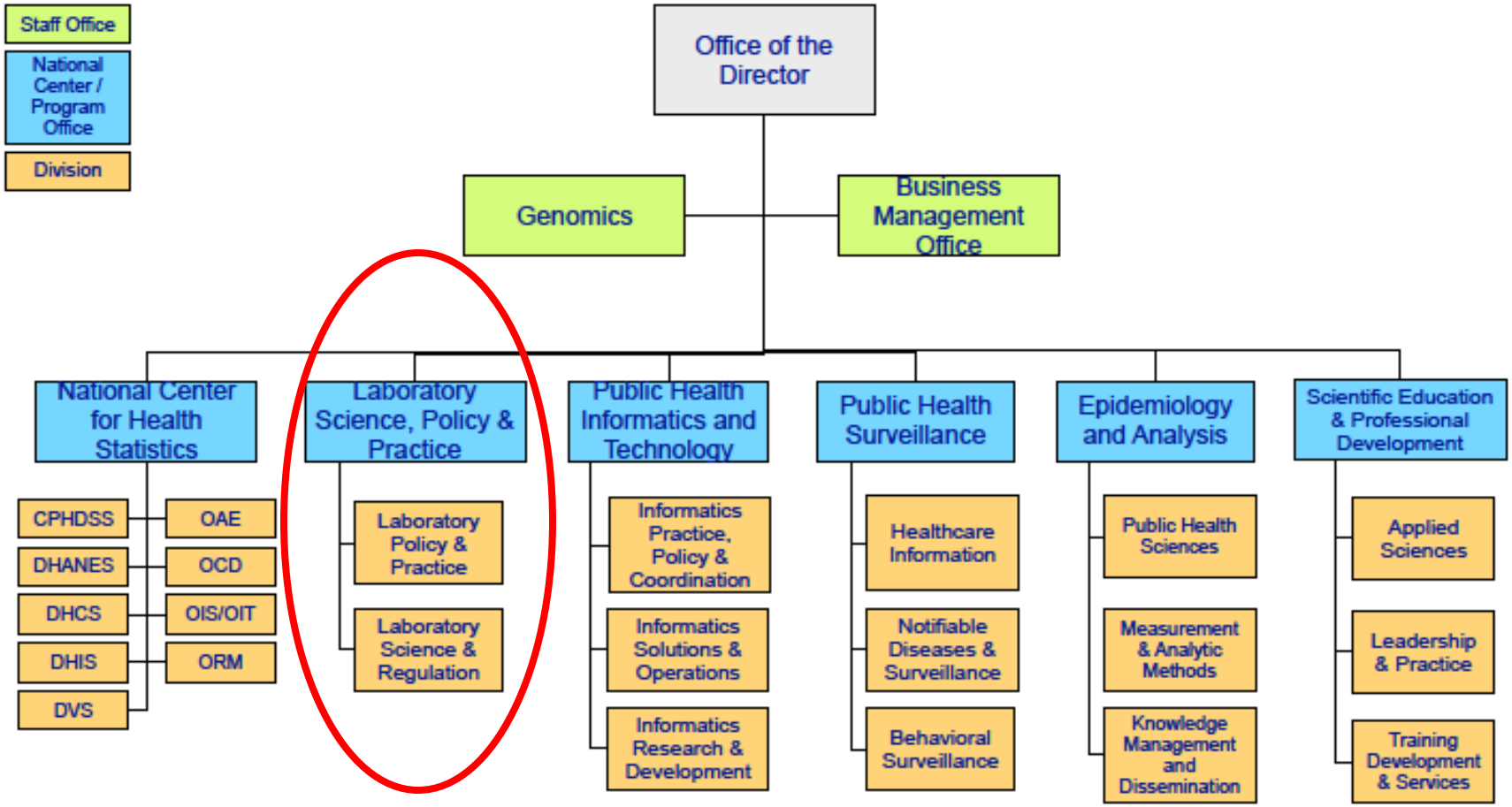
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

PROPOSED



*After new NCCDPHP Director is in place

Office of Surveillance, Epidemiology and Laboratory Services



DRAFT - Updated January 23, 2010

CLIAC
Clinical Laboratory Improvement Advisory Committee

CLIAC Work Groups and Other Work Groups

LABORATORY MEDICINE
Best Practices

cla

CLIAC Proficiency Testing Workgroup 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 (lab) and I (PT programs) of the regulations

Includes all laboratory specialties except cytology

CLIAC Proficiency Testing Workgroup

- Meeting planned for Mar 10-11, 2010
  - Laboratory experts, accreditation/state licensure representatives, PT program officials will contribute
- Teleconference held Jan 20, 2010
  - Provide background on CLIA law, regulations
  - Explain meeting goals
  - Solicit input from their constituents

Topics for PT Workgroup to Address at March Meeting

- Updating the list of CLIA-regulated analytes and prioritization
- Determining criteria for acceptable performance and PT sample grading for CLIA-regulated analytes (current and proposed)
- Changes to PT for microbiology and subspecialties that do not have regulated analytes
- Clarification of the statutory requirements that address PT referral

Cytology Cooperative Agreements

- Two awards funded in 2010-2011
- College of American Pathologists
  - Survey all cytology labs
  - Review current practices (specimen types/methods, QC, PT, problem solving
  - Analyze response, post on CAP website, convene consensus conference in 2011
- Michigan Public Health Institute
  - Survey pap smear providers
  - Review test request and report formats, lab role in clinical management
  - Partner with MI Cancer Consortium

MMWR™

Morbidity and Mortality Weekly Report

www.cdc.gov/mmwr

Recommendations and Reports June 12, 2009 / Vol. 58 / No. RR-6

Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions

Molecular Genetic Testing MMWR Post-Publication Activities

- Published commentaries and articles
- Created fact sheets, “one-pagers” for laboratorians and clinicians
- Write new CLSI guidance (MM20) on quality management for MGT (Dr. Chen)
- Presented at professional conferences (AMP, ACMG, SIMD, AACC)
- Developing training courses and workshops

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 (published or unpublished)

Laboratory Medicine Best Practices

- 3 pilot test topics & 7 practices
  - Improving specimen identification
    - Barcoding
    - POCT barcoding
  - Improving critical values reporting
    - Automated electronic notification
    - Call center
  - Reducing blood culture contamination
    - Venipuncture vs. Catheter
    - Phlebotomy team
    - Commercial prep kit
- 4/7 practices had sufficient evidence to recommend as a best practice

Laboratory Medicine Best Practices

- Products – in preparation
  - Manuscript - methods of the evidence-based laboratory medicine project
  - Technical guide - transparent procedures for replication of the study methods
  - Individual manuscripts for the 3 topic-specific evidence reviews
  - Web-based tutorial to educate laboratory scientists to include key elements in study design that can provide evidence for review
  - Multiple scientific presentations are planned

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

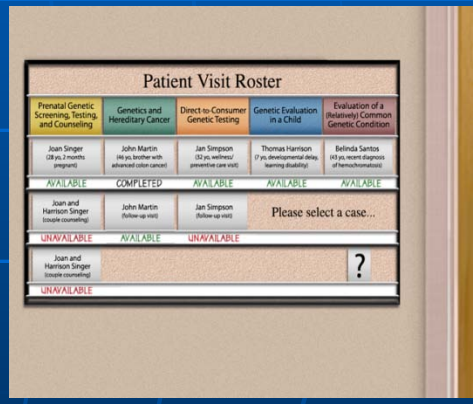
Evidence-Based Lab Medicine Quality/Performance Measures

- Progress
  - Standardized, evidence-based quality measures developed for diverse lab settings
    - Prepaid health plans - outpatient chronic disease
      - 4 measures
    - Public health labs – newborn screening
      - 16 pre- and 18 post-analytic measures
    - University hospitals – anatomic pathology
      - 6 quality indicators
- Planned
  - Pilot testing of the identified measures
  - Data collection to verify QI outcome
  - Methods and findings to be published in peer-reviewed journals and disseminated at professional conferences

Genetic Testing in Clinical Practice: A Team Approach
Interactive Multimedia Learning

http://iml.dartmouth.edu/education/cme/Genetics/index.html

Focus: Learning about the use of genetic tests in clinical practice through simulation

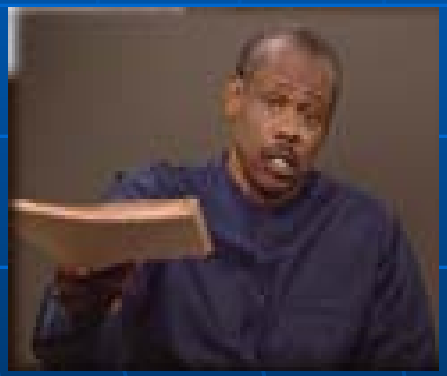


Interactive Media Laboratory
Dartmouth Medical School

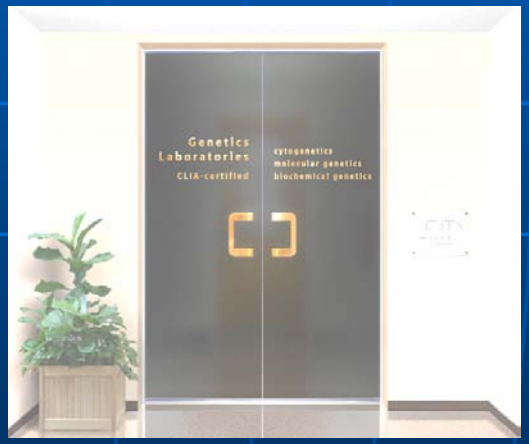
Users: Clinicians, Medical Schools

Genetic Testing in Clinical Practice: A Team Approach
Interactive Multimedia Learning

"The Team"



Patient encounter

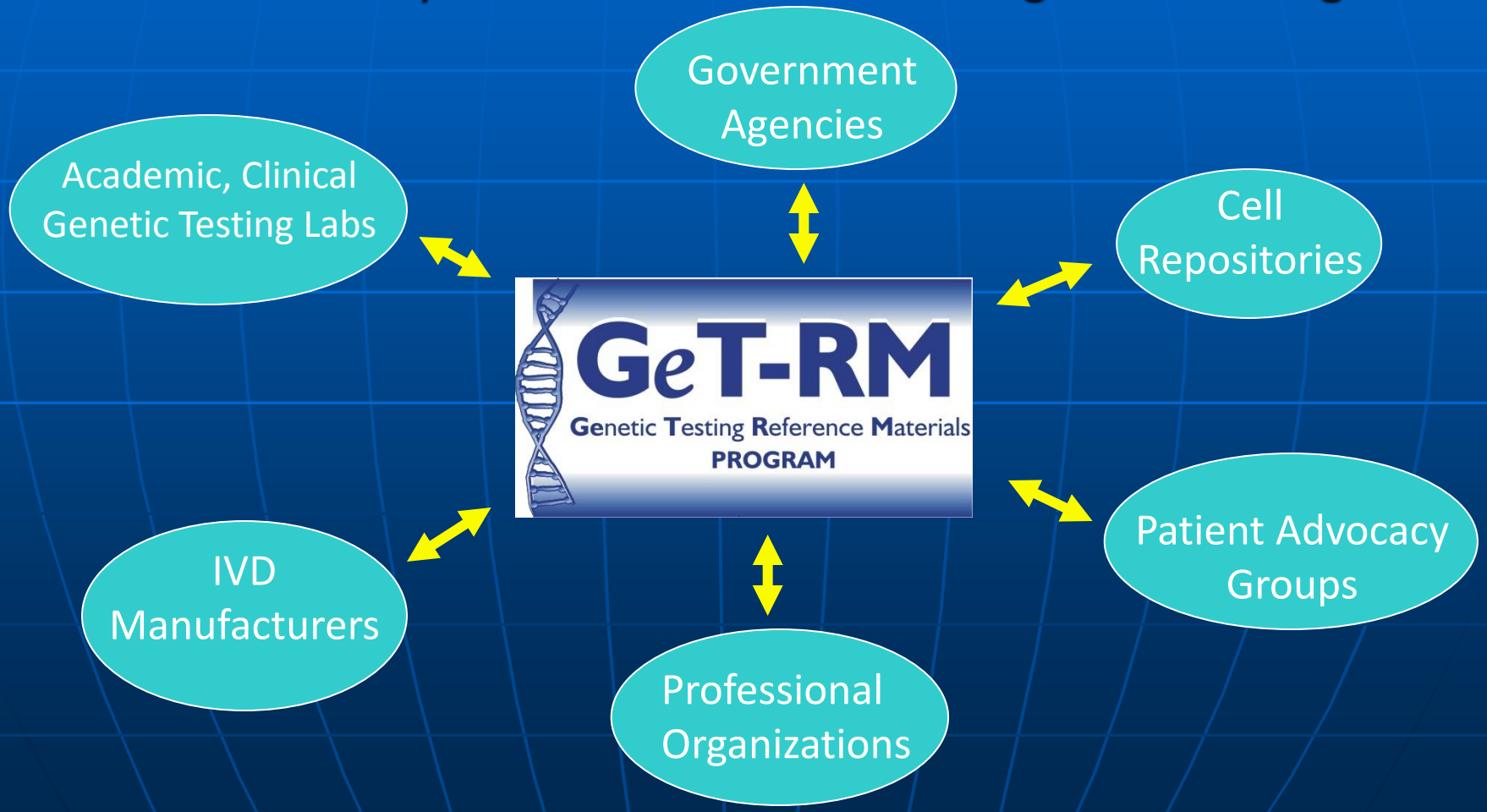


Laboratory Tour
- Molecular
- Cytogenetic
- Biochemical

Counseling session

Genetic Testing Reference Material Program (GeT-RM)

A Collaborative CDC-based program to improve the availability of reference materials for genetic testing



GeT-RM Projects

Completed Projects

- Fragile X
- Huntington Disease
- Cystic Fibrosis
- Ashkenazi Jewish Panel
  - 9 disorders including Tay-Sachs and Canavan disease
- BRCA1/2
- MTHFR
- Multiple endocrine neoplasia Type 2A
- Alpha1-antitrypsin deficiency

Ongoing Projects

- Pharmacogenetics (20 markers!)
- Newborn Screening
- Cytogenetics
- Molecular oncology
- Biochemical Genetics

Over 200 DNA RM characterized by GeT-RM

Rapid Influenza Testing Survey with The Joint Commission

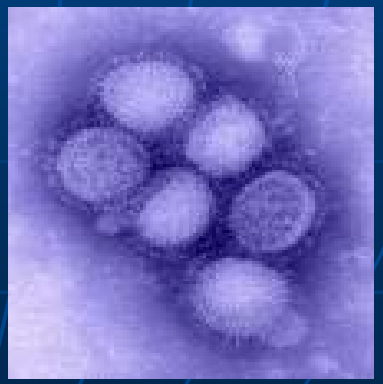
- Goal
  - To assess pre- and post-analytic quality in rapid influenza test usage in Emergency Dept. (ED), comm. health centers (CHC), physician offices (PO)
    - Types of rapid influenza diagnostic test (RIDT) in use
    - Training and competency of personnel
    - Adherence to Good Laboratory Practice
    - Impact on Rx - antivirals and antibiotics
    - Perceived utility of test

Rapid Influenza Testing Survey with The Joint Commission

- First survey (2008) findings:
  - PO and CHC performed RIDT on site
  - Confirmatory testing not performed
  - <72% reported +RIDT to state/local HD
  - Positive RIDT results contributed to
    antiviral Rx antibiotic Rx
  - Most CHC and PO implemented quality assurance programs
  - Only 18 – 40% participated in proficiency testing

Rapid Influenza Testing Survey with The Joint Commission

- Second survey to be done 2010
- Revised based on H1N1 outbreak
  - Sensitivity 40-70% for Influenza A H1N1
  - Changes in testing practices since H1N1
  - Impact of H1N1 on diagnosis and treatment of patients with Influenza Like Illness



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
  - Drafted paper to describe the actions to increase the value of laboratory medicine through research and innovation, information systems and IT, incentives, outreach, prioritization and implementation of activities

Laboratory Medicine Integration Workgroup

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

- Status
  - Prepared 6 algorithms for test selection related to coagulation
  - Define challenges in test ordering and result interpretation
    - Focus group 3/17/10 for clinicians
    - Survey of medical school curricula
    - Develop clinical vignettes for testing residents
    - Develop protocol for inspecting CP residency programs to determine consultation education provided

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