Overview and Goals of Oversight Session

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Chair, SACGHS Oversight Task Force
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HHS Secretary's Charge

Undertake the development of a comprehensive map of the steps needed for evidence development and oversight for genetic and genomic tests, with improvement of health quality as the primary goal.

- Existing pathways that examine the analytic validity, clinical validity, and clinical utility
- Evidence of harm attributable to analytic validity, clinical validity, or clinical utility
- Roles and responsibilities of involved agencies and private sector organizations
- Distinctions between genetic tests and other laboratory tests , for oversight purposes

HHS Secretary's Charge (cont'd)

- Information provided by and resources needed for proficiency testing
  - *Adequacy and transparency of proficiency testing processes*
- Potential communication pathways to guide test use
- New approaches or models for private and public-private sector engagement in demonstrating clinical validity and developing clinical utility (effectiveness measures)
- Added value of revisions/enhancements to government oversight

Oversight Task Force (n=33)

Steering Group (6 SACGHS Members) **–** Andrea Ferreira-Gonzalez (Chair), Sylvia Au, Kevin FitzGerald, Steve Teutsch, Marc Williams, Paul Miller

Ad Hoc and Federal Experts – Michael Amos, Linda Bradley, Joe Boone, Amy Brower, Marie Earley, Barbara Evans, Phyllis Frosst, Scott Grosse, Steve Gutman, Mark Hoffman, Kathy Hudson, Lisa Kalman, Muin Khoury, Ira Lubin, Marie Mann, Elizabeth Mansfield, Joanne Mei, Richard Naples, Tim O'Leary, Glenn Palomaki, Vicky Pratt, Gurvaneet Randhawa, Sue Richards, Jim Robb, Gail Vance, Ann Willey, and Judy Yost

Oversight Task Force Activities

- March – May 2007 – created an expanded Task Force with *ad hoc* members
- Periodic “chapter” meetings – task force teams assigned to each chapter and met as needed to refine drafts
- Face-to-face meetings in July and September 2007 to advance the report and develop draft recommendations
- November 5 through December 21 – draft report available for public comment

Summary of Public Comments

64 sets of comments

- 25 professional organizations
- 12 industry
- 11 government agencies
- 5 health care professionals
- 6 advocacy organizations
- 4 academicians
- 1 individual

Analysis of Public Comments

- Copies of the comments sent to all task force members in early January
- Initial analysis performed by oversight steering group
- Input from task force
- Conference call with SACGHS members to provide a preview of revised recommendations

General Tenor of Public Comments

- Report comprehensively responded to the Secretary's charge
- Report provides an excellent review of issues associated with oversight of genetic testing
- Recognition that report's development involved diverse stakeholders
- Most comments offered specific edits or modifications to the report

Recurring Themes of Comments

- Report's broad definition of genetic tests might capture nongenetic tests
- Agreement that genetic tests are not different from other laboratory tests for oversight purposes
- Strong support for increased proficiency testing
- Support for a mandatory test registry, but no clear stance on where it should be housed (CMS, FDA?)
- Concerns about direct-to-consumer advertising of genetic tests and consumer-initiated testing
- Improve enforcement of current regulations related to laboratory testing

Recurring Themes of Comments

- Enhanced oversight of genetic testing is needed
- FDA's authority to regulate laboratory developed tests not questioned; its risk-based approach affirmed
- Gaps in evidence of clinical validity that can lead to harms; important to establish clinical validity
- General agreement with FDA's role to assess clinical validity of tests, but some comments favored CMS' role
- More attention is needed in the areas of clinical utility and genetics education
- Before increasing oversight, benefits and harms to patient access and cost should be considered

Revisions to Report

- Added public health surveillance as a key consideration (executive summary)
- Added introductory paragraph explaining trends in genetic testing (chapter 1)
- Added methodology section to explain report's development (chapter 1)
- Revised definition of genetic test to include genomic test and examples of tests excluded from the definition (chapters 1, 3)

Revisions to the Report

- Added Senate bill 1858 (Newborn Screening Saves Lives Act of 2007) to legislative discussion (chapter 2)
- Added role of States in oversight of newborn screening (chapter 2)
- Added activities of the Secretary's Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC) to roles of federal agencies in R&D and evidence synthesis (chapter 2) and knowledge generation (chapter 4)

Revisions to Report

- Augmented discussion of nanotechnology to include devices using extremely small amounts of materials (chapter 3)
- Added “reproducibility” as a key term (chapter 4)
- Updated or corrected information about CAP products and PT performance (chapter 4)
- Corrected information about transport of biological materials (chapter 4)
- Augmented list of professional societies (chapter 4)

Revisions to Report

- Added activities of ACHDGDNC and HRSA to discussion of clinical utility (chapter 5) and patient access to genetics expertise (chapter 6)
- Added discussion of harms due to inadequate information about clinical utility (chapter 5)
- Corrected information about OncotypeDX; it is not FDA-approved or –cleared (chapter 6)
- Updated statistics for board-certified geneticists—MDs, laboratory disciplines, and genetic counselors (chapter 6)

Revisions to Report

- Added information about privacy concerns related to DTC testing and commercially operated PHRs (chapter 6)
- Added ACMG-AAP developed ACT sheets and algorithms as examples of clinical decision support tools (chapter 6)

Next Steps

- **Feb 12-13**
  - SACGHS meets to discuss and finalize recommendations and to approve transmission of final recommendations to the Secretary and to approve in principle the draft report
- **February 20**
  - Deadline for additional edits to draft report
- **February 29**
  - Final recommendations and revised draft report submitted to OS
- **March**
  - Draft report finalized (copy editing)
- **April 16**
  - Final review by SACGHS
- **April 30**
  - Final report formally submitted

Goal of Today's Session

- **To finalize recommendations.**
- **To approve final report in principle.**

Edits to report content can be sent to Cathy Fomous (deadline February 20)