SACGHS Task Force on the Oversight of Genetic Testing Update

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SACGHS Oversight Task Force
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Oversight Task Force (n=33)

SACGHS Members -- Andrea Ferreira-Gonzalez (Chair), Sylvia Au, Kevin FitzGerald, Steve Teutsch, Marc Williams

Ad Hoc Members -- Amy Brower, Barbara Evans, Mark Hoffman, Kathy Hudson, Paul Steven Miller, Richard Naples, Vicky Pratt, Sue Richards, Jim Robb, Gail Vance, Ann Willey

Federal Experts -- Michael Amos, Linda Bradley, Joe Boone, Phyllis Frosst, Steve Gutman, Muin Khoury, Tim O'Leary, Ira Lubin, Elizabeth Mansfield, Gurvaneet Randhawa, Judy Yost

Consultants -- Marie Earley, Scott Grosse, Lisa Kalman, Marie Mann, Joanne Mei, Glenn Palomaki

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.

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

Secretary's Charge

- 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

Previous Reports on Oversight

NIH-DOE Task Force issued a report in 1997 on assuring safe and effective genetic testing:

- Recommended consideration of a genetics testing specialty under CLIA
- Recommended that proficiency testing be mandated for all laboratories conducting genetic testing
- Led to the formation of SACGT

Previous Reports on Oversight

SACGT Report of 2000 recommended:

- FDA should be responsible for the review, approval, and labeling of all new genetic tests that have moved beyond the basic research phase using a novel, streamlined process
- CLIA should be augmented with specific provisions to ensure the quality of laboratories conducting genetic tests
- Data collection efforts should continue after genetic tests reach the market and CDC should coordinate public-private sector collaborations

HHS Response
(January 2001)

- Accepted recommendations and indicated that they would be implemented over time as resources allowed
  - FDA's oversight of genetic tests to include laboratory developed tests and genetic test kits
  - Post-market data collection to be performed by CDC and might be required of the test developer and other payers
  - CMS to develop new CLIA regulations for expanded oversight of genetic testing laboratories

2001-2007

- Questions raised about FDA's authority to regulate LDTs
- FDA issues guidance clarifying
  - ASR regulation
  - review requirements for laboratory developed IVDMIAs
- CMS plans for augmentation change in 2006

CMS Rationale for Change

- CLIA already certifies genetic testing labs
- Standards will be outdated before publication
- Specialty will not solve gap in clinical validation of LDTs
- Specialty will not address concerns about the lack of proficiency testing
- Lack of data on unique problems with genetic testing laboratories
- Other regs are higher priority

CMS Plan in Lieu of Genetic Specialty

- Provide CMS surveyors with expert guidance to assess genetic testing labs
- Develop alternative PT mechanisms (e.g., inter-laboratory comparisons)
- Develop educational materials
- Maximize expertise of accreditation organizations
- FDA and CDC to provide guidance for review of complex analytical test validations
- Collect data on genetic testing lab performance

Oversight Task Force Activities

- Beginning March 2007 – Created an expanded Task Force with *ad hoc* members/consultants
- Six meetings of the full Task Force – Developed an outline for a report, discussed the report's scope, and debated the use of key terms
- Periodic meetings of the "Steering Committee" (which consists of the five SACGHS members)
- "Chapter" meetings – Teams assigned to each chapter received writing assignments and met as needed to refine drafts

Focus of activity

- Identification of Gaps in knowledge
- Discussion of Harms
  - Real harms
  - Potential harms
- Develop recommendations

Report Outline

- Chapter 1: Background, scope of the report, spectrum of harms, overview of each chapter
- Chapter 2: Laboratory technologies
- Chapter 3: Analytic validity, proficiency testing and clinical validity
- Chapter 4: Clinical utility and evidence development
- Chapter 5: Effective communication and Clinical Decision support
- Chapter 6: Summary of recommendations

Chapter 1

- What is oversight for the purposes of this report
  - Inclusive use of term rather than strict regulatory perspective
- Genetic exceptionalism will be acknowledged as a social and policy reality, but will not necessarily drive content
- Text to be written on broad ethical issues/spectrum of harms and benefits
  - Overestimation of ‘potential harm’ may interfere with realization of benefit
- Will address harm due to ‘reductionism’

Chapter 1

- Will explicitly tie this in with Secretary's Personalized Health Care initiative
- Roles of different entities (e.g. regulatory agencies, government, knowledge generation agencies, provider, payer, etc.)
- Will identify issues that are peripheral to focus explicitly that will not be addressed in the report
- Status: Draft outline. Content will evolve based on content of other chapters

Chapter 2

- Define genetic test for the purpose of the report
  - Incorporates definitions in use
  - Will include intended use of test (examples will be provided)
- Comprehensive list of methodologies being considered
- Identify future trends
- Status: Near complete

Chapter 3

- Most extensive content area
- Analytic validity—Proficiency Testing—Clinical Validity
- Status:
  - Large number of gaps identified
  - Consolidating gaps and soliciting additional information on topics raised at meeting
  - Begin characterization of harms and benefits
  - Use these to develop recommendations
  - On target for timeline

Chapter 4

- At present no regulatory oversight for clinical utility (and this may not be appropriate)
- No existing infrastructure
- Largest gap in realization of benefit (value)
- Biggest opportunity to build processes for improvement

Chapter 4

- Group has chosen to take a broad approach for identification of actionable items
- Consistent with the direction of health care in the US
  - Quality improvement
  - Evidence based best practice
  - Pay for performance

Chapter 4

- Status:
  - Viewing utility from different perspectives (Patients, Providers, Payers, Public health, Quality improvement organizations, Guideline developers, etc.)
  - Exploring governmental, quasi-governmental, private methods for the generation, synthesis and management of new evidence
  - Draft written but under revision based on input from meeting and breakout session

Chapter 5

- Focus on effective communication
  - Pre- and post-analytic
  - Roles of laboratory, provider and patient
  - Genetic specialty vs. non-genetic specialty (provider and laboratory)
  - Direct-to-consumer

Chapter 5

- Focus on clinical decision support
  - Pre- and post-analytic
  - Passive vs. active
  - Incorporation of evidence-based clinical guidelines
  - Opportunity to achieve greater impact based on experience in other sectors of health care
  - Clarify how CDS will be regulated

Chapter 5

- Status
  - Written and referenced
  - Gaps and harms delineated and recommendations developed
  - Some revisions based on meeting and breakout

Development of Recommendations

- Will follow 7/9 meetings
- Will synthesize based on gaps and harms
- Develop within each chapter.
- Steering committee members will review, consolidate and prioritize

Report Timeline

May-June	Task Force met and developed first draft
July 9	In-person Task Force meeting to discuss first draft; work on gaps and recs.
July 10	**Progress report to SACGHS**
July-Sept	Second draft developed
Sept 5	Second in-person Task Force meeting

Report Timeline, Con’d

Sept–Oct	TF members consult with key stakeholders and gathers feedback on report
Oct–Nov	Report revised based on stakeholder input
Nov 7	Draft report sent to SACGHS
Nov 19-20	**Approval by SACGHS for public comment solicitation**
Nov 21-30	Modifications to report to reflect SACGHS comments and preparation of report for public comment
Dec 3-Jan 7	Solicitation of broad public comments

Report Timeline, Con’d

Jan 2008	Analysis of public comments
~ Feb 15	**SACGHS meets to discuss public comments and proposed revisions to draft report, approves penultimate draft for submission to Office of the Secretary**
Feb 28	Final edits based on SACGHS input
Feb 29	Penultimate draft submitted to OS
March	Final report developed
April 16	**Final review by SACGHS via email**
April 30	Formal submission of final report to the Secretary

Questions for the Committee

- Does the report structure reflect the direction received from the committee in March?

Questions for the Committee

- Scope of report
  - SACGT report addressed regulatory oversight (CLIA, FDA) and need for data collection
  - SACGT developed a large focus on education (broadly interpreted its charter)
  - This report addressing broader issues including communication, education, process improvement etc.

Questions for the Committee

- Does this broad approach appropriately reflect the Secretary's charge?
- Are there things we're including that should be considered out of scope?
- Are there issues we have missed?