

SACGHS Inter-Meeting Task Force: Priority Setting Process and Results

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Chair

SACGHS Inter-Meeting Task Force

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Members

- Emily Winn-Deen, Ph.D., Chair
- Cynthia Berry, J.D.
- Barbara Harrison, M.S., CGC
- Debra Leonard, M.D., Ph.D.
- Reed Tuckson, M.D.
- Huntington Willard, Ph.D.

Task Force Charge

- Conduct a systematic issue identification and prioritization process
- Develop the agenda for the March meeting
 - Identify key meeting goals
 - Identify topics for presentation

Multi-Step Process

- Reviewed issues identified as warranting further discussion at the June and October meetings
- Reviewed top ten issues identified by the SACGHS *Ex Officio* agencies for the June meeting
- Assessed appropriateness, clarity, and completeness of these issues
 - Resulted in the identification of nineteen (19) relevant issues

Multi-Step Process (cont)

- Surveyed Members on their top three to five priority issues (out of the 19)
- Organized the results according to frequency of vote
 - Twelve top issues emerged
 - The full Committee was notified of the top twelve issues

Multi-Step Process (cont)

- Surveyed Members again and *Ex Officios* for the first time to rank the top twelve issues (1-12)
- Guided the development of background information on each of the top twelve issues
- Identified additional fact-finding that may be useful in understanding the issues
 - Coverage and Reimbursement session

Round I Results

| ISSUES | VOTES |
|---|----------|
| | |
| Large Population Studies; Education and Training | 7 |
| Coverage and Reimbursement; Access | 6 |
| Patents and Access; Nature of Genetic Information; Oversight; Public Awareness | 4 |
| Vision Statement; DTC; Pharmacogenomics | 3 |
| Enhancement vs Treatment; Bioterrorism; New Health Related Applications; Genetic Discrimination | 1 |
| Scope of Genetic Technologies; Informed Consent; Forensics; Privacy and Confidentiality | 0 |

Round I Results

- 11 issues (of the 19) rose to the top
- Genetic Discrimination was retained as a standing Committee priority
 - Monitoring vs. Action
- 7 issues were dropped (all with either 1 or 0 votes)

Round II: Guiding Questions

- How urgent is the issue?
- Does the issue warrant the Committee's attention?
- Is there media attention to and/or public concern about the issue and is there a need for public discussion and understanding of the issue?
- Does the government have jurisdiction/authority over this issue?
- Is federal guidance or regulation on the issue warranted and is the government poised to act on policy advice of the committee?
- Does the issue raise concerns that only the government can address or would government involvement be duplicative?
- Does the issue raise moral or ethical concerns that warrant government involvement/leadership?
- Will the committee's policy advice on the issue significantly benefit society or will the failure to address the issue prolong any negative impact?
- Does sufficient data about the issue exist for the committee to develop informed policy advice; and is there another body addressing the issue or better equipped to address the issue?
- Have the policy solutions to the issue already been worked out?

Round II

- Surveyed Members and *Ex Officios*
- Some differences emerged between Members and *Ex Officios*:
 - Access was ranked 1st by Members and 10th by *Ex Officios*
 - Coverage and Reimbursement was ranked 2nd by Members and 9th by *Ex Officios*
 - Public Awareness was ranked 7th by Members and 1st by *Ex Officios*

Rankings from Round II

| Members | <i>Ex Officios</i> |
|---------------------------------|---------------------------------|
| Access | Public Awareness |
| Coverage/Reimbursement | Genetics Education and Training |
| Genetic Discrimination | Oversight |
| Large Population Studies | Pharmacogenomics |
| Genetics Education and Training | Vision Statement |
| Vision Statement | Large Population Studies |
| Public Awareness | DTC Marketing |
| Oversight | Genetic Discrimination |
| Pharmacogenomics | Coverage/Reimbursement |
| Exceptionalism | Access |
| Patents and Access | Patents and Access |
| DTC Marketing | Exceptionalism |

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Top 12 Issues

(Task Force Member Assignment)

- Access (Harrison)
- Coverage and Reimbursement (Harrison)
- Direct to Consumer Marketing (Berry)
- Genetic Discrimination (Berry)
- Genetic Education and Training (Willard)
- Genetic Exceptionalism (Willard)
- Large Population Studies (Willard)
- Oversight (Leonard)
- Patents and Access (Leonard)
- Pharmacogenomics (Winn-Deen)
- Public Awareness (Berry)
- Vision Statement (Winn-Deen)

Access Issue Statement

- Barriers in access to genetic services and technologies prevent the realization of the full benefit of advances in genetics
- Access can be impeded at several points along the genetic technology development continuum

Access Issue Statement

- *Test development and marketing process.* Patents may be enforced and licensed in ways that:
 - Impede the conduct of genetics research
 - Reduce the clinical availability of genetic technologies
 - Increase their cost
- *Genetics research.* The choice of research populations and diseases may impact clinical access to genetic technologies.

Access Issue Statement

- *Clinical integration phase.* Inadequate patient and provider knowledge about genetics and its availability and value can affect access.
- *Financial barriers.* Barriers include:
 - Lack of insurance
 - Lack of coverage
 - Inadequate reimbursement
 - Costs of genetic technologies

Access Issue Statement

- *Social considerations.*
 - Fear of genetic discrimination and stigmatization
 - Disparities in access
- A Relevant Policy Question
 - Are there specific areas in which intervention by the Federal government might minimize barriers in access to genetic technologies?

Coverage and Reimbursement Issue Statement

- Health insurance affects:
 - The cost of health care at both a system and individual level
 - The quality of care delivered
 - Access to care
- Therefore, coverage and reimbursement decisions also impact cost, quality and access

Coverage and Reimbursement Issue Statement

- Coverage and reimbursement decisions for genetic technologies may be particularly problematic because of:
 - Insufficient data for making decisions
 - Misunderstandings about the costs associated with genetic technologies
 - New challenges that genetic technologies pose to the paradigm of health insurance (e.g. testing family members)

Coverage and Reimbursement Issue Statement

- Some Relevant Policy Questions:
 - Is coverage and reimbursement a significant barrier to consumer access to genetic technologies?
 - What actions would facilitate coverage and reimbursement decisions about genetic technologies?
 - Are there any unique characteristics of genetic services generally that impact coverage and reimbursement decisions?

Direct-to-Consumer Marketing Issue Statement

- Direct marketing of medical services and products to consumers has become a common and generally accepted practice
- Potential risks:
 - Exaggerated claims or lack of independent confirmation of clinical validity and utility
 - An average consumer typically lacks the background to critically evaluate marketers' claims
 - Direct access testing can bypasses necessary interpretation by trained health professionals

Direct-to-Consumer Marketing Issue Statement

- Potential benefits:
 - Enable consumers to be better informed with respect to genetics generally
 - Enable consumers to participate more fully in health care decisions and exert more control over their health
- Current oversight:
 - FDA and FTC protect consumers from false and misleading advertisements in the health care arena
 - FTC has responsibility for truth-in-advertising in all areas
 - Currently, neither FDA nor FTC are monitoring genetic test advertisements specifically

Direct-to-Consumer Marketing Issue Statement

- Some Relevant Policy Questions:
 - Do the risks of DTC advertising of genetic technologies outweigh its benefits?
 - Does DTC advertising of genetic technologies raise greater concern and warrant more attention than DTC advertising of other medical products?
 - Is direct access to genetic technologies a concern?
 - Do current uncertainties, questions and policy considerations require the attention of SACGHS?

Genetic Discrimination Issue Statement

- Genetic technologies have the potential to greatly improve human health and the health status of the population
- Patients may not utilize genetic services or participate in genetic research studies because of a fear of genetic discrimination

Genetic Discrimination Issue Statement

- Perceptions persist that genetic discrimination is occurring or will occur in the future
 - However, very few actual cases of genetic discrimination in health insurance and employment have been documented
- This fear, and its impact on the potential benefit of genetic technologies, has led to genetic nondiscrimination laws

Genetic Discrimination Issue Statement

- Some Relevant Policy Questions:
 - Will a federal law be effective in preventing discrimination in these areas?
 - Are there other areas beyond health insurance and employment—disability insurance, life insurance, education, adoption, immigration policy—where the potential for the misuse of genetic information warrants concern and attention?
 - What further steps, if any, should SACGHS take with regard to the genetic discrimination issue?

Genetic Education and Training Issue Statement

- A better understanding of the role of genetics in health and disease should yield targeted approaches to improving health
- A wide range of health professionals need genetics education and training to facilitate appropriate integration of genetics into health care
- Currently, health professionals are not sufficiently trained and educated in genetics to meet these goals
 - Efforts are lacking both during professional education and training and throughout clinical practice

Genetic Education and Training Issue Statement

- Some Relevant Policy Questions:
 - What are the existing gaps in the education and continuing education of health professionals?
 - Are current efforts to address these gaps sufficient or are additional efforts needed?
 - Should the primary locus of responsibility for closing these gaps be educational institutions, professional societies, foundations, government or some combination?
 - What is the appropriate role of the Federal government in addressing this issue?

Genetic Exceptionalism

Issue Statement

- “*Genetic exceptionalism*”. Genetic information is inherently unique, should receive special consideration, and should be treated differently from other medical information
- *Critics*. Genetic information is not special or unique:
 - The unique or special characteristics of genetic information are also shared by other types of medical information
 - Separating genetic information from other medical information is impractical
 - Defining genetic and non-genetic information is impossible

Genetic Exceptionalism

Issue Statement

- *Advocates.* Genetic information is unique or special because:
 - It is a unique identifier
 - It is heritable and shared through generations
 - It has relevance to family members
 - It can be predictive of future disease
 - It can, and has been, used to stigmatize and discriminate
 - It can be sensitive and have psychological impacts

Genetic Exceptionalism

Issue Statement

- Some Relevant Policy Questions:
 - Is genetic information inherently unique?
 - If so, do its qualities warrant special attention?
 - Should our public policies be premised on genetic exceptionalism?
 - Does the idea of genetic exceptionalism serve a social good that should be advanced through our laws and institutions?
 - Is there an alternate concept that would allow the special features of genetic information to be acknowledged without necessitating a genetic exceptionalist approach?

Large Population Studies Issue Statement

- Genetic variability within and across populations is becoming the focus of research into the cause of complex disease
- A number of countries around the world have begun to undertake national population studies
 - Capitalize on genome-wide scanning for single nucleotide polymorphisms (SNPs) and haplotypes
 - Provide population-based information about associations between common polymorphisms and common disease
- Many U.S.-based smaller-scale studies
 - Lack the statistical power needed to definitively detect associations between environmental factors, polymorphisms, and disease

Large Population Studies Issue Statement

- Some Relevant Policy Questions:
 - How important is it to mount a large population cohort study in the U.S.?
 - What role does the heterogeneity of the U.S. population play in assessing the value and importance of such a study?
 - How should the many complicated scientific, ethical, and practical challenges of conducting such a study be addressed?
 - What should be the role of the federal government in such a study?
 - Are there obstacles that would make the conduct of such a study especially difficult in the United States?

Oversight Issue Statement

- Genetic technologies are evolving rapidly and new genetic tests are constantly being introduced into clinical care
 - The clinical validity and utility of many tests have not been independently established
- FDA, CMS, CDC, and FTC all have roles in the oversight of the development, use, and marketing of genetic technologies
- In 2000, SACGT issued a report recommending that the current oversight of genetic tests be augmented

Oversight Issue Statement

- SACGHS was briefed on current agency efforts to strengthen their oversight programs
- Some Relevant Policy Questions:
 - Does SACGHS consider these efforts sufficient?
 - If so, is any further attention needed?
 - If not, what steps, if any, should be taken?

Patents and Access Issue Statement

- *Pros*
 - Patents promote innovation by granting exclusive rights for a limited period of time
- *Cons*
 - Exclusive rights can limit future use of an invention
 - Licensing fees add costs to biomedical research and to the health care system
- Gene patents and/or licensing practices may:
 - Inhibit research
 - Decrease development and utilization of and access to genetic testing services

Patents and Access Issue Statement

- Some Relevant Policy Questions:
 - Do patent and licensing policies affect research in genetics and access to clinical genetic technologies in unique ways?
 - Can the public good derived from basic research and access to health care be maximized without compromising the intent of patent protection?

Pharmacogenomics Issue Statement

- *Pharmacogenomics*. Individual differences in genes or gene expression that could predict susceptibility to disease or response to drugs
 - Genes play a role in both the safety (AEs) and efficacy of drugs
 - Genetic heterogeneity of disease impacts treatment options
- Potential benefits:
 - Individualized approach to medicine
 - Genetic determinants can target pharmaceutical interventions to individuals
 - Identification of new targets for drug development and evaluation of candidate drugs in the laboratory and in clinical drug trials

Pharmacogenomics Issue Statement

- Some Relevant Policy Questions:
 - Does current evidence indicate that these technologies can improve healthcare outcomes, costs and quality?
 - How will the clinical validity and utility of pharmacogenetic tests be established?
 - How will pharmaceuticals already on the market be reassessed?
 - How will access to clinical trials and marketed technologies be enhanced?

Pharmacogenomics Issue Statement

- Some Relevant Policy Questions (cont):
 - Are there measures that the Federal government can take to improve the chance of success?
 - Is current research sufficient for the full potential of pharmacogenomics to be realized?
 - Might these technologies have unintended adverse consequences, such as creating more orphan diseases or increasing health care costs and health disparities?
 - How will this technology best be integrated into the health care system?

Public Awareness Issue Statement

- Public understanding of genetic technologies may facilitate their appropriate integration into healthcare and society
- Genetic technologies are highly complex
 - Require some understanding of basic genetic and biological principles to be fully comprehended
- Incomplete or misleading media coverage of genetic advances complicates public understanding

Public Awareness Issue Statement

- Some Relevant Policy Questions:
 - How essential is public awareness and understanding to the appropriate integration of genetic technologies into health care and society?
 - Is assuring the genetic literacy of the public an appropriate role for the Federal government?
 - In general, should the Federal government be doing more in this area and, if so, what additional efforts should be undertaken?

Vision Statement

- A vision statement could serve as a framework for future SACGHS recommendations
- The vision statement would:
 - Describe how a future with fully integrated genetics should and should not look
 - Highlight activities that should be encouraged
 - Identify the gaps, barriers and potential hazards that need to be addressed

Vision Statement

- Some Relevant Policy Questions
 - Would the development of such a vision statement be of value to the Secretary of Health and Human Services?
 - Would it be of broader value to the Federal government and the public?