

SACGHS Priority-Setting Process and Outcomes

Paul Wise, M.D., MPH

Chair, SACGHS Priority-Setting Task Force

July 7, 2008

Task Force Members

Paul Wise, M.D., MPH (Chair)

Mara Aspinall, MBA

Paul Billings, M.D., Ph.D., FACP, FACMG

James P. Evans, M.D., Ph.D.

Andrea Ferreira-Gonzalez, Ph.D.

Steven Teutsch, M.D., MPH

Muin J. Khoury, M.D., Ph.D.

Gurvaneet Randhawa, M.D., MPH

Goals for Discussion

- Review the priority-setting process
- Review and discuss results to date
- Reach preliminary consensus on high priority issues and next steps in process

Priority-Setting Process Milestones

Feb-May: Identified 73 possible issues

June: SACGHS members and *Ex Officios* scored the issues

July 7-8: Decisions regarding preliminary priority issues

July-Nov: Compile additional information about issues and send to Committee for review

Dec: Make final decisions on study priorities

Process for Identifying Issues

- Brainstorming session at February SACGHS meeting
- Additional issues suggested by SACGHS members
- Conference call with *ex officios*
- Request for public comments
- Conversations with “horizon scanners”

Request For Public Comments

April 17, 2008 – May 16, 2008

Comments sought through:

- Federal Register
- SACGHS website
- Distribution list: Expanded to include a greater range of:
 - consumer organizations
 - major medical organizations (e.g., the AMA)
 - groups representing health care disparities
 - representatives of business groups and payers

Horizon Scan: Experts Interviewed

- **Thomas Caskey**, M.D., Director, CEO-elect of the Brown Foundation Institute of Molecular Medicine for the Prevention of Human Diseases; by Jim Evans
- **Juan Enriquez**, Chairman and CEO of Biotechonomy, LLC; by Paul Billings
- **Catherine M. Baase**, M.D., Corporate Medical Director, Dow Chemical; by Steven Teutsch
- **Myrl Weinberg**, CAE, President, National Health Council; by Steven Teutsch
- **Ian Morrison**, Ph.D., President Emeritus, Health Advisory Panel Chair, Institute for the Future; by Mara Aspinall

SACGHS Scoring of Issues

June 9 – June 20

Total Number of Issues: 73

From:

- Public Comments: 33 (in 26 submissions)
- Horizon Scanning: 16
- SACGHS/EOs/Staff: 18
- Office of the Secretary: 5
- Journal: Nature Review Genetics: 1

Scoring Process

June 2008

- Likert scale used to assign the relative importance of each issue, with **1** being **Not Important** and **5** being **Very Important**.
- Scoring Form was provided to SACGHS members and *ex officios* June 2008

Criteria for SACGHS Priority Issues

- The urgency and national importance of the issue
- The extent to which the Federal Government has jurisdiction/authority over the issue
- The need for Federal guidance or regulation on this issue
- Whether the issue raises concerns that only the Federal Government can address
- Whether the issue raises ethical, legal, or social concerns that warrant Federal Government involvement/leadership
- Whether the Committee's policy advice on this issue would significantly benefit society

Criteria for SACGHS Priority Issues, Con'd

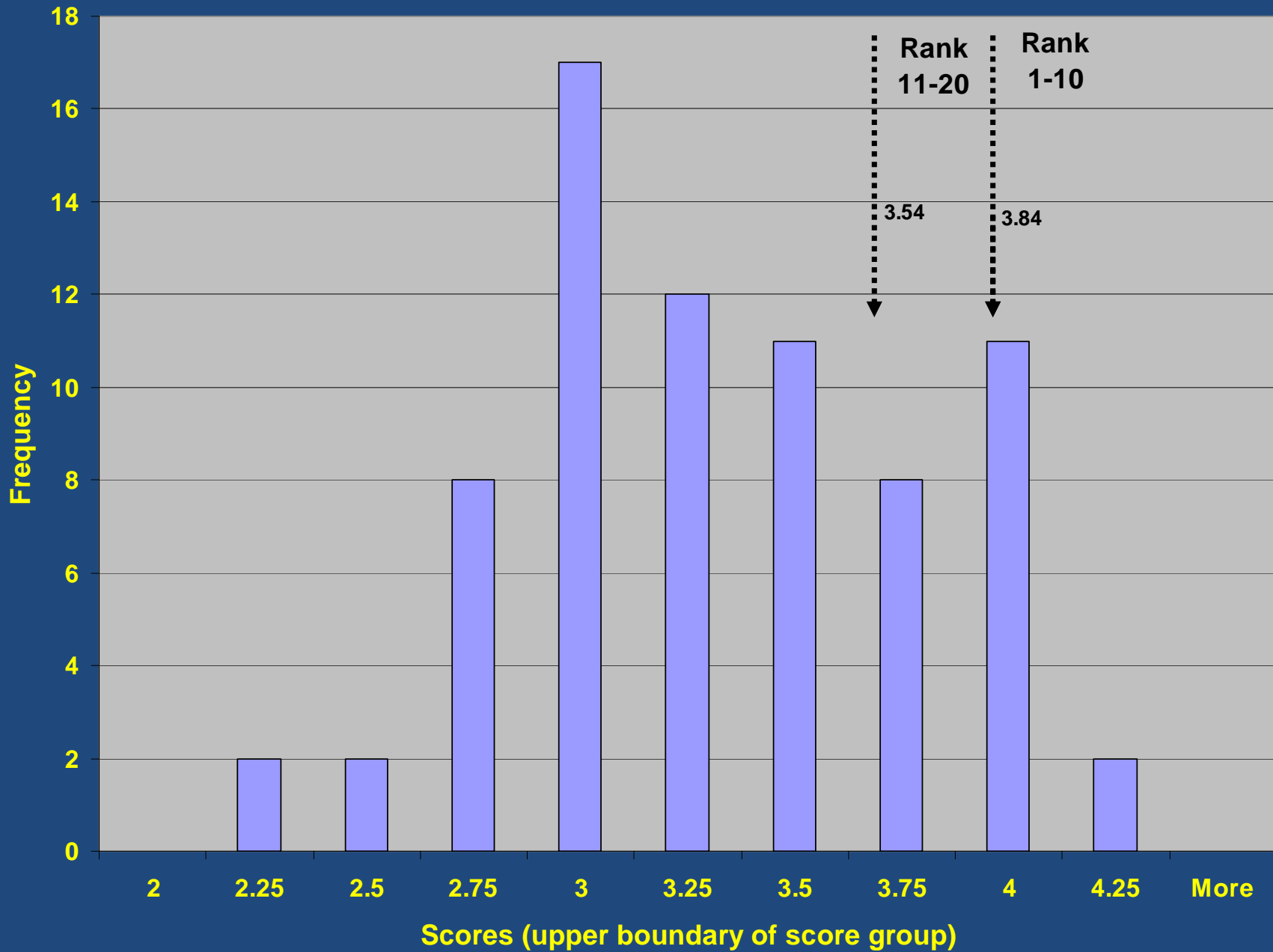
- Whether failure to address the issue would prolong any negative impact the issue may be having on society
- Whether sufficient data about the issue exist for the Committee to develop informed policy advice
- Whether another body is already addressing the issue or is better equipped to address it
- Whether the issue is within the SACGHS charter (charter provided in the request)

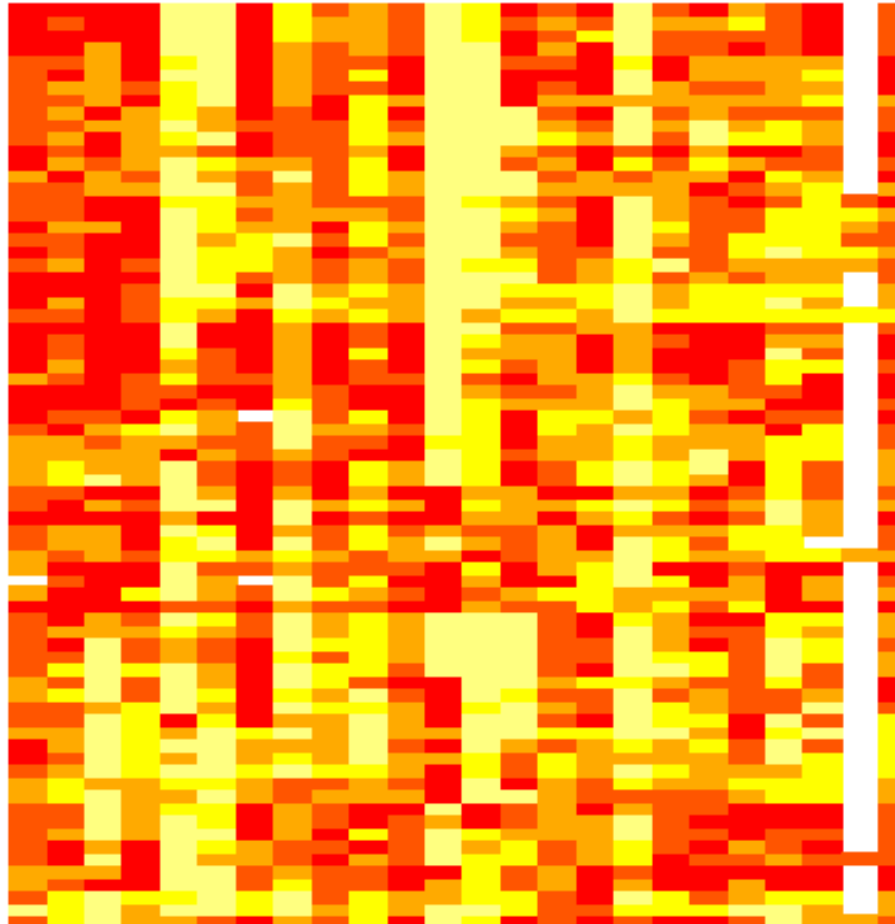
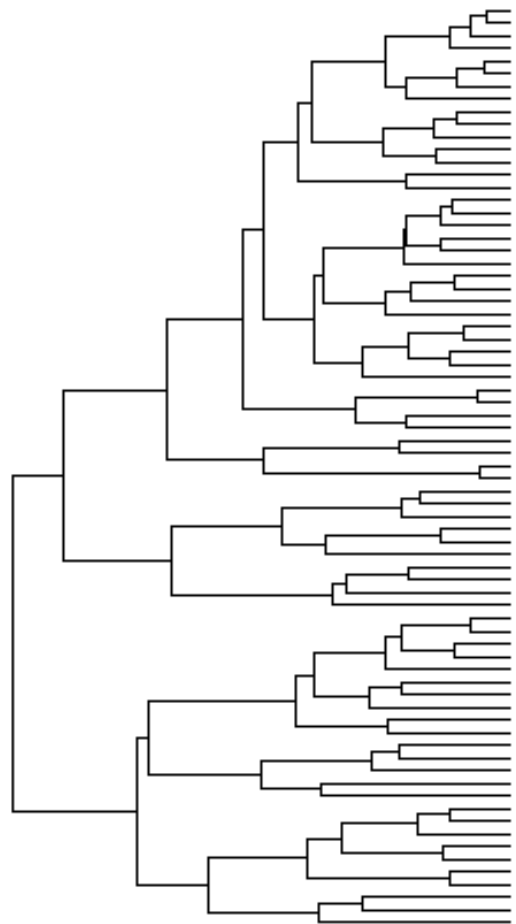
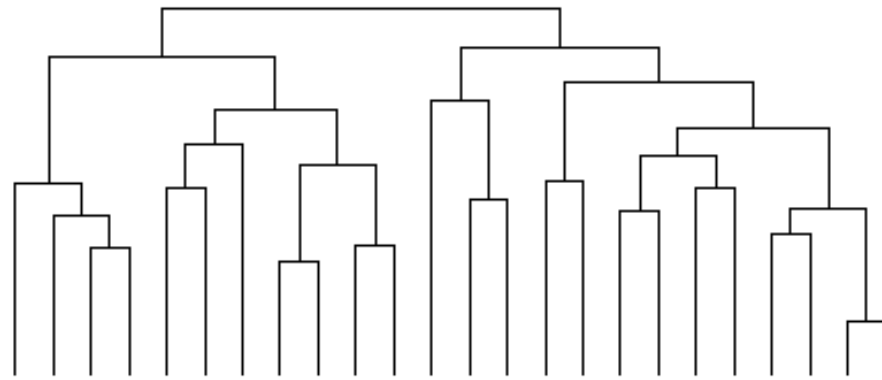
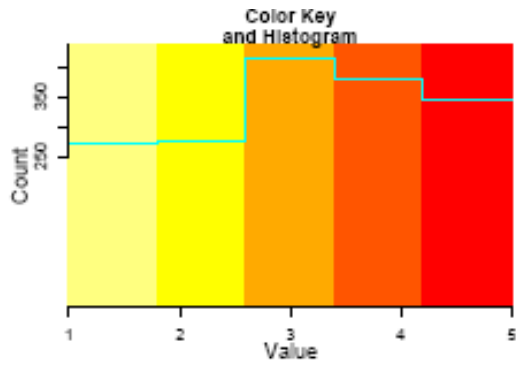
Results of Scoring—Top 20

Rank	Issue #	Issue	MEAN SCORE
1	33	Standards for Monitoring of DTC Genetic Tests	4.04
2	15	Evidence Development for Personalized Medicine	4.04
3	38	Adequacy of the Education and Training of Health Professionals in Genetics/Genomics	4.00
4	18	Evidenced-based Guidelines for Genetic Technologies	4.00
5	53	Public Health Applications of Genomics Research	3.96
6	30	Clinical Validity and Clinical Utility of DTC Genetic Tests for Common Disorders	3.96
7	34	Comprehensive Consumer Protection Strategies	3.88
8	31	Consumer Interest in Personal Genomics	3.88
9	32	Medico-legal Implications of DTC	3.84
10	36	Integration of Genomic Information and Clinical Decision Support	3.84
11	49	Impact of Personalized Medicine on Health Care	3.84
12	47	Role of Genetics/Genomics in Health Care Reform	3.80
13	17	Outcomes Research for Diagnostics Tests	3.76
14	48	Implications of Structural Changes in Health Care Delivery	3.68
15	46	Continuing Issues with Coverage and Reimbursement of Genetic Tests	3.68
16	35	Incorporation of Genetics into PHR/EHR	3.64
17	50	Implications of the Affordable Genome Sequence	3.64
18	45	Coverage and Reimbursement of Genetic Counseling	3.60
19	44	Medicare/Medicaid Reimbursement for DNA Tests	3.56
20	21	Informed Consent for Genomic Data Sharing	3.54

Distribution of Total Scores

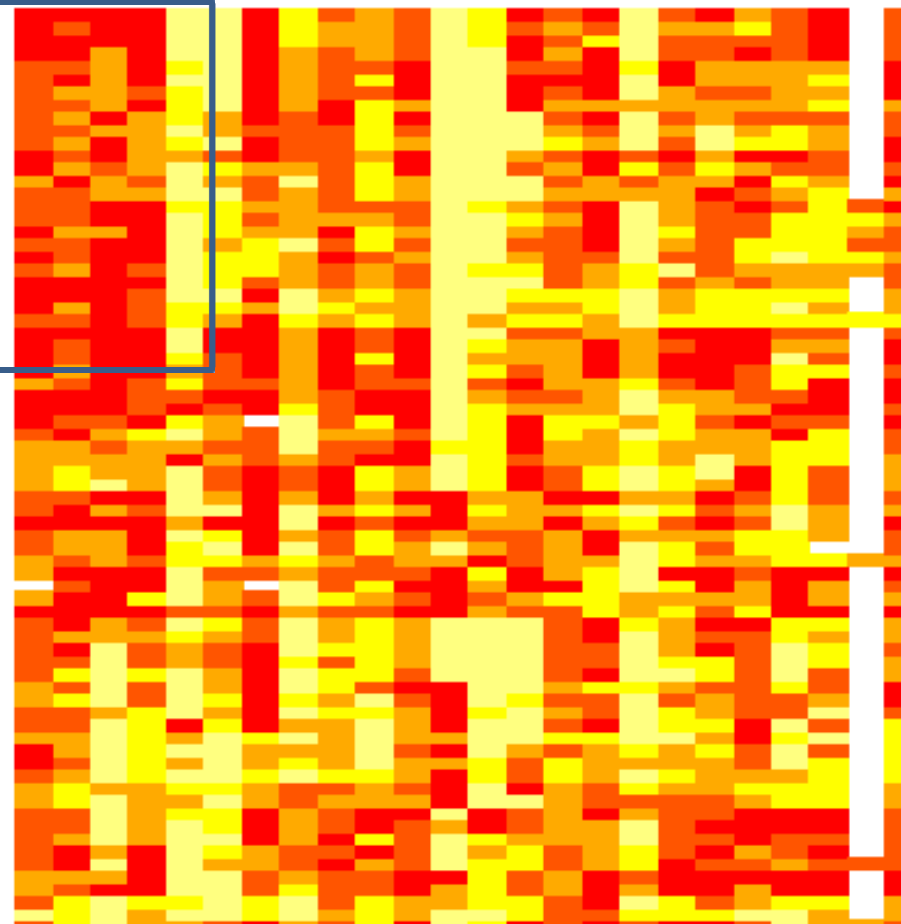
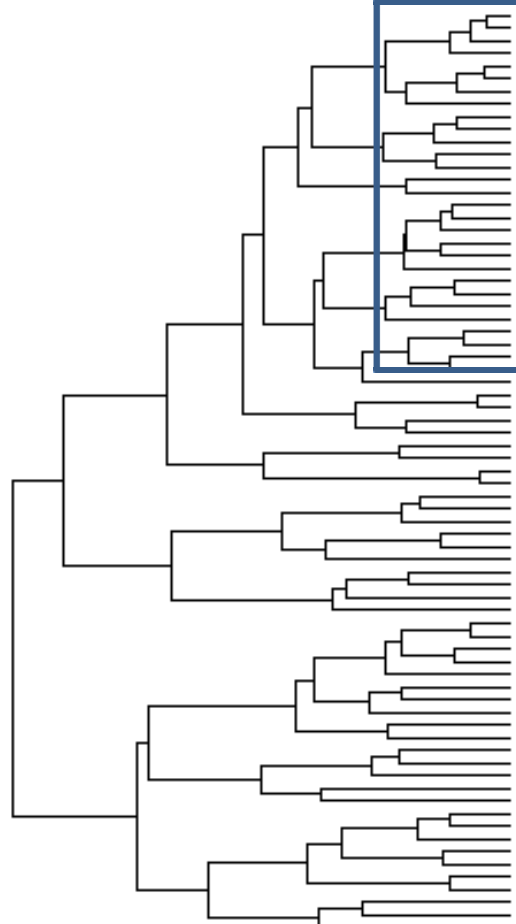
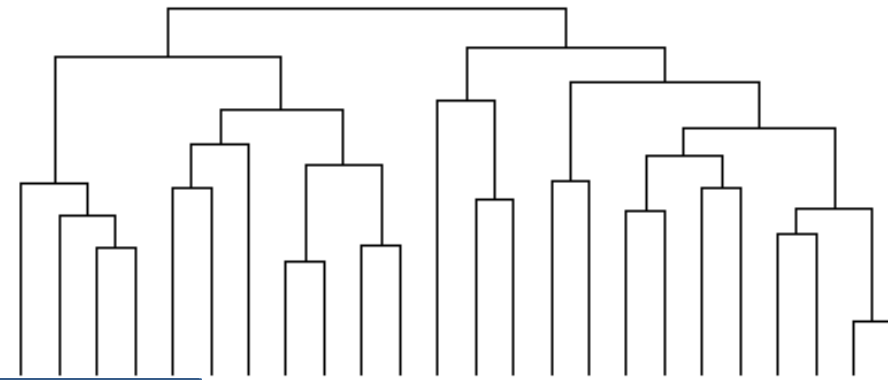
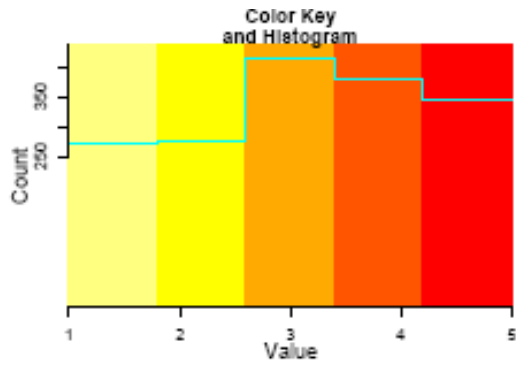
(n = 73 Issue Items)





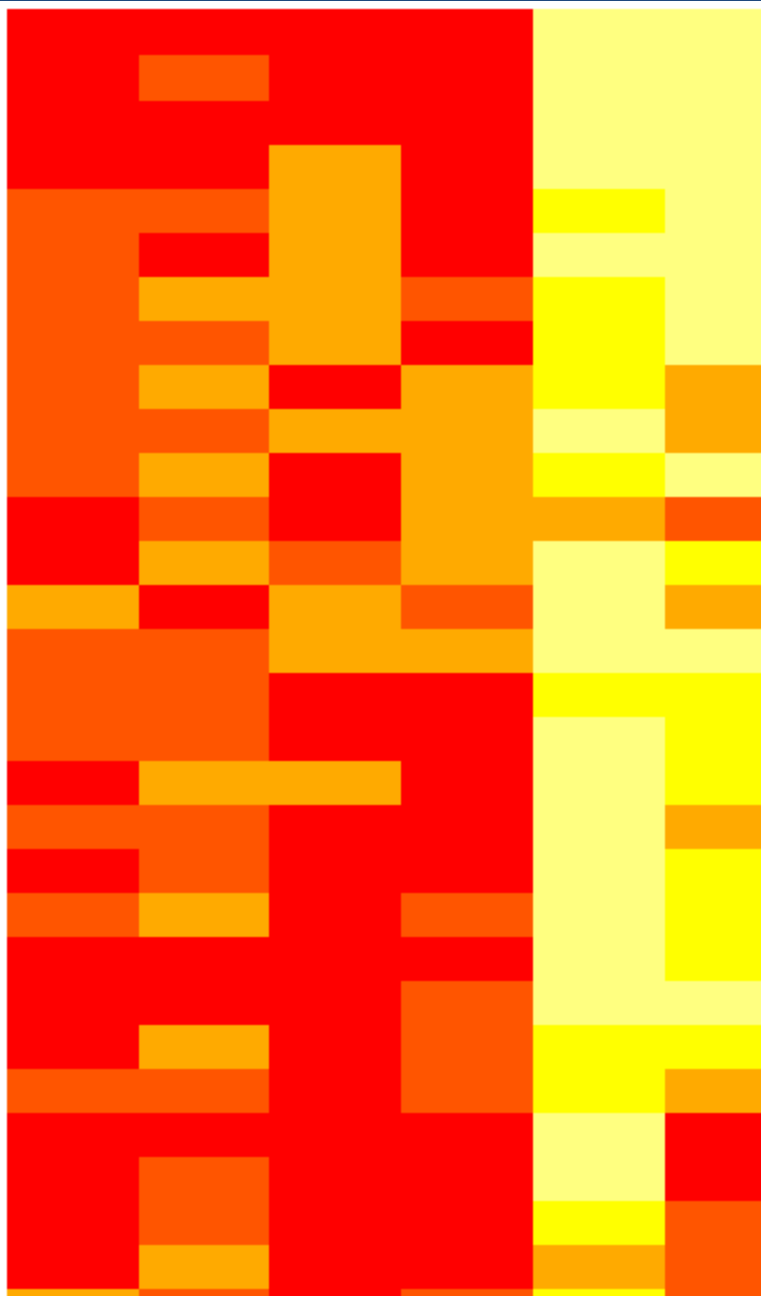
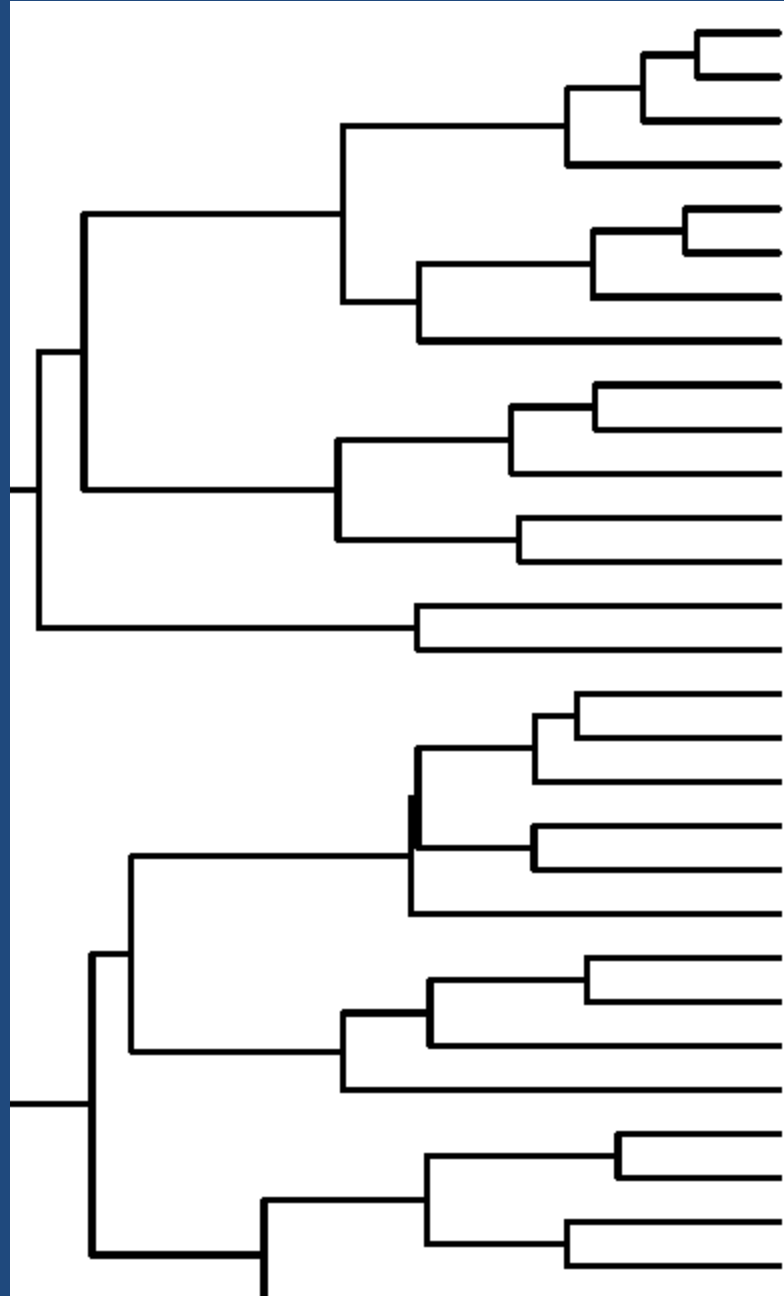
- Continuing Issues with Coverage and Reimbursement of Genetic Tests
- Comprehensive Genetic Testing Policy Considerations for Medicaid
- Medicare/Medicaid Reimbursement for DNA Tests
- Coverage and Reimbursement of Genetic Counseling
- Data Gaps Related Access of Minorities to Genetic Testing
- Role of Genetics in Addressing Health Disparities
- Special Issues for Minority Populations Related to Genetic Testing
- Health Care Issues of Aging Populations Related to Genetics
- Health Care Provider Awareness as an Overarching Issue
- Understanding the Role of the Media in Genetics Literacy
- Genetics Education and Training Needs of Addition-Based Health Professionals
- Adequacy of the Education and Training of Health Professionals in Genetics/Genomics
- Public Access to Information about Genetic Technologies
- Ethical Implications of Behavioral Predictive Testing
- Ethical/Legal Issues in Pharmacogenomics (PGx)
- Informed Consent for Genomic Data Sharing
- Consumer's Role in Clinical Trials
- Ethical Guidelines for the Use of DNA in Research
- Needs and Expectations of Research Participants in Data Registries
- Consent of Samples
- Return of Research Results from Whole Genome Research Studies
- Informed Consent Issues in Clinical Practice and Public Health Applications of Genet
- Speeding Development of Therapeutics
- Postmarket Surveillance of New Drugs
- Impact of Regulation of Pharmaceutical Research
- Standards for Monitoring of DTC Genetic Tests
- Medico-legal Implications of DTC
- Comprehensive Consumer Protection Sequence
- Consumer Issues in Personal Genomics
- Implications of the Affordable Genome Sequence
- Evidence-based Guidelines for Genetic Technologies
- Outcomes Research for Diagnostic Tests
- Implications of New Risk-Screening Methods
- Analysis of Costs in Genetic Test Development
- Use of PGx for Improving the Safety and Efficacy of Existing Medicines
- Research Priorities for Pharmacogenomics (PGx)
- Protection of Gene Patents
- PTO Conciliation Process
- Public Health Applications of Genomics Research
- Public Health Benefits of Biomonitoring of Chemical Exposures
- Clinical Validity and Clinical Utility of DTC Genetic Tests for Common Disorders
- Expansion of Population Genetic Screening
- Criteria for Assessing the Clinical Utility of Newborn Screening
- Research and Harmonizing Data
- Impact of Personalized Medicine on Health Care
- Identification and Integration of New Technologies
- Co-Development of Therapeutics and Companion Diagnostics
- Evidence Development for Personalized Medicine
- Ethical Implications of Prenatal Genetic Testing
- Ethical Implications of Carrier Testing
- Genetic Testing in the Workplace
- Health Insurance Policy Related to Pre-existing Conditions
- Genetic Exceptionalism
- International Genomics Infrastructure for Clinical Research
- Global Cooperation and Harmonization
- Technological Barriers to Genomics-based Personalized Medicine
- NIH Funding Policy
- Analysis of Genetic Data on Autoimmune Diseases
- Stem Cell Research Policy Issues
- The State of Gene Therapy Research
- Technical Standards for Bioprecursors
- Definition of Health-related Genetic Tests
- Scope and Definition of Genomics
- Integration of Genomic Information and Clinical Decision Support
- Incorporation of Genomics into PHR/EHR
- Consumer Understanding of Electronic Health Records
- Incorporation of Genetic Information into DRGs
- Healthcare of Genetic Information
- Role of Genetics/Genomics in Health Care Reform
- Implications of Structural Changes in Health Care Delivery
- Single Gene Disorder Pathways and Common Conditions
- Evolution from CLIA Certification Requirements for Research Laboratories
- Impact of GINA

- Ex Officio 13
- Member 12
- Ex Officio 14
- Member 7
- Ex Officio 22
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- Ex Officio 17
- Member 3
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- Member 11
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- Member 10
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- Member 5
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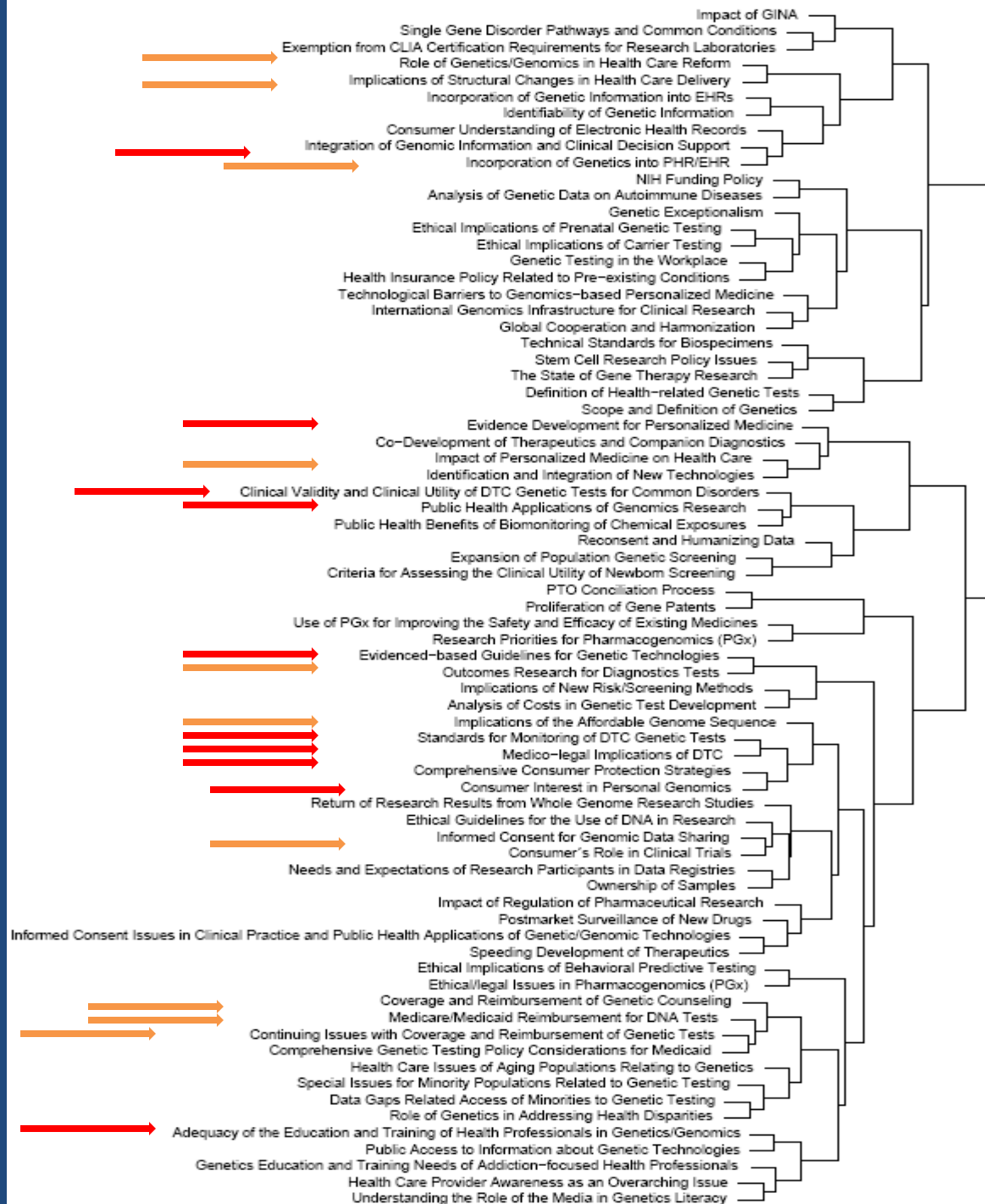


Issue Dendrogram with Voting Rank

RANK 1-10



RANK 11-20



Suggested Clusters of Issues with Highest Scores

- Genetics and health care reform
- Ensuring the clinical utility of genetic information
- Public health applications of genomic research
- Consumer access to genomic information
- Informed consent for genomic data sharing
- Coverage and reimbursement for genetic services
- Education of health professionals on genetics
- Genetics, minorities and health disparities

Suggested Clusters of Issues with Highest Scores

		<u>Issue #</u>
3.80	Role of Genetics/Genomics in Health Care Reform	47
3.84	Integration of Genomic Information and Clinical Decision Support	36
3.64	Incorporation of Genetics into PHR/HER	35
3.68	Implications of Structural Changes in Health Care Delivery	48
4.04	Evidence Development for Personalized Medicine	15
3.84	Impact of Personalized Medicine on Health Care	49
3.96	Clinical Validity and Clinical Utility of DTC Genetic Tests for Common Disorders	30
4.00	Evidenced-based Guidelines for Genetic Technologies	18
3.76	Outcomes Research for Diagnostics Tests	17
3.96	Public Health Applications of Genomics Research	53
3.64	Implications of the Affordable Genome Sequence	50
4.04	Standards for Monitoring of DTC Genetic Tests	33
3.84	Medico-legal Implications of DTC	32
3.88	Consumer Interest in Personal Genomics	31
3.88	Comprehensive Consumer Protection Strategies	34
3.54	Informed Consent for Genomic Data Sharing	21
3.60	Coverage and Reimbursement of Genetic Counseling	45
3.56	Medicare/Medicaid Reimbursement for DNA Tests	44
3.68	Continuing Issues with Coverage and Reimbursement of Genetic Tests	46
4.00	Adequacy of the Education and Training of Health Professionals in Genetics/Genomics	38
3.48	Health Care Provider Awareness as an Overarching Issue	40
3.52	Data Gaps Related Access of Minorities to Genetic Testing	56
3.44	Special Issues for Minority Populations Related to Genetic Testing	71
3.44	Role of Genetics in Addressing Health Disparities	55

Genetics and Health Care Reform

3.80 Role of Genetics/Genomics in Health Care Reform (Issue #47)

3.84 Integration of Genomic Information and Clinical Decision Support (Issue #37)

3.64 Incorporation of Genetics into PHR/HER
(Issue #45)

3.68 Implications of Structural Changes in Health Care Delivery (Issue #48)

Ensuring the Clinical Utility of Genetic Information

- 4.04 Evidence Development for Personalized Medicine** (Issue #15)
- 3.84 Impact of Personalized Medicine on Health Care** (Issue #49)
- 3.96 Clinical Validity and Clinical Utility of DTC Genetic Tests for Common Disorders** (Issue #30)
- 4.00 Evidenced-based Guidelines for Genetic Technologies** (Issue #18)
- 3.76 Outcomes Research for Diagnostics Tests** (Issue #17)

Public Health Applications of Genomics Research

**3.96 Public Health Applications of Genomics
Research (Issue #53)**

Consumer Access to Genomic Information

- 3.64 Implications of the Affordable Genome Sequence** (Issue #50)
- 4.04 Standards for Monitoring of DTC Genetic Tests** (Issue #33)
- 3.84 Medico-legal Implications of DTC** (Issue #32)
- 3.88 Consumer Interest in Personal Genomics** (Issue #31)
- 3.88 Comprehensive Consumer Protection Strategies** (Issue #34)

Informed Consent for Genomic Data Sharing

3.54 Informed Consent for Genomic Data Sharing (Issue #21)

Coverage and Reimbursement for Genetic Services

- 3.60 Coverage and Reimbursement of Genetic Counseling (Issue #45)**
- 3.56 Medicare/Medicaid Reimbursement for DNA Tests (Issue #44)**
- 3.68 Continuing Issues with Coverage and Reimbursement of Genetic Tests (Issue #46)**

Education of Health Professionals on Genetics

- 4.00 Adequacy of the Education and Training of Health Professionals in Genetics/Genomics (Issue #38)**
- 3.48 Health Care Provider Awareness as an Overarching Issue (Issue #40)**

Genetics, Minorities and Health Disparities

- 3.52 Data Gaps Related to Access of Minorities to Genetic Testing (Issue #56)**
- 3.44 Special Issues for Minority Populations Related to Genetic Testing (Issue #71)**
- 3.44 Role of Genetics in Addressing Health Disparities (Issue #55)**

Next Steps

- Development of Issue Briefs
- Distribution of Issue Briefs to SACGHS Members for Review
- SACGHS Members Vote on Issue Briefs
- SACGHS Members Select Priority Issues for Action Steps