CAP Genomic Medicine Policy Framework: Clinical Issues

The College of American Pathologists
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NHGRI Genomic Medicine V
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CAP GM Policy Framework 2013

- Provides a global perspective for the role of pathologists in genomic medicine
- Discusses issues affecting incorporation of genomic testing into pathology practices
- Makes recommendations to guide genomic medicine advocacy efforts for pathologists

Issues applicable across Medicine

CGPA-PHC Work Group Members

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CAP Genomic Medicine Policy Framework White Paper

- Introduction
- Overview of issues
- Principle Statement: Pathologists in Genomic Medicine
- 12 Issues
  - Background
  - Work to date
  - Needs
  - Recommendations
- Summary of recommendations

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- Introduction
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- Principle Statement: Pathologists in Genomic Medicine
- 12 **Clinical Issues**
  - Background
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- Summary of **Recommendations**

Genomic Medicine Clinical Issues

2. Infrastructure and Resource Needs
3. Patents and Exclusive Licensing
4. Interoperability and HIT Issues
5. Federal Regulatory Oversight
6. Pathologists as Patient Consultants
7. Reimbursement Issues
8. Privacy, Ethical, Legal and Social Issues
9. Population and Public Health Genomics, Genomic Epidemiology and Clinical Outcomes Analysis
12. Coordinated Care and Genomic Medicine

2. Infrastructure Needs

ISSUE: Lack tools for NGS interpretation

- **Clinical variant database development**
  - **Recommend open source, clinical variant database(s) for genotypes and phenotypes**
  - **Sequence and clinical data key for optimal clinical interpretation and for discovery**
- **Advocate for reference genomes for different racial and ethnic groups**

3. Gene Patents & Exclusive Licensing

ISSUE: Gene patents limit patient access & restrict medical practice

CAP Position: Gene patents should not limit ability to provide molecular/genomic information for patient care

- **CAP is a plaintiff on *AMP et al. v. Myriad***
- **Oral arguments to Supreme Court on 4/15/13**
- **Decision expected in June 2013**

4. Health Information Technology

ISSUE: Extremely large NGS data sets

- **Promote interoperability standards (instruments, LIS, HER, PHR), working with policymakers and stakeholders**
- **Participate in national discussions of standards for clinical genomic data storage and management**
- **Incorporate standards into CAP accreditation processes**

5. Regulatory Oversight

ISSUE: Oversight uncertainty for LDTs (NGS tests)

- **Advocate for rational oversight of both commercial in vitro diagnostic test kits (IVDs) and laboratory developed tests (LDTs)**
- **Promote rigorous laboratory & interpretive standards for clinical genomic testing**
- **Strive for balance between:**
  - **Patient safety,**
  - **Technology advances, and**
  - **Translation of new scientific knowledge into clinical tests for patient care**

6. Genomic Consultations

ISSUE: Not a recognized role for pathologists

- **Advocate for pathologists' access to patient medical records for interpretation & consultation on genomic test results**
- **Develop billing codes for genomic consultations, for all physician providers**
- **Advocate for development of user-friendly model reports for genomic tests**
  - **Understandable by ordering provider**
  - **Help patients understand genomic results reported in PHR**

7. Reimbursement

ISSUE: Payment uncertainty for genomics

- **Advocate that interpretation of genomic data is the practice of medicine**
- **Advocate for appropriate coverage of genomic & molecular technical and professional work**
  - **CPT codes for genomic tests (CLFS)**
  - **Compensation appropriate for professional time for interpretations (PFS)**
  - **Compensation for consultations with providers, patients and families (PFS)**

8. Privacy and ELSI

ISSUE: Privacy balanced with clinical access

- **Genomic information has high potential for impact on health care decision making…and for misuse**
- **Assess legal/policy needs to assure privacy for generating, storing and protecting genetic health information for patients**
- **Advocate for patient privacy protections that allow for clinical access and use**

9. Genomic Epidemiology & Outcomes

ISSUE: Need evidence for genomic medicine

- **Advocate for funding for clinical studies that will generate clinical outcomes data to provide evidence-based support for the clinical utility and cost effectiveness of genomic testing in**
  - **Routine clinical practice and**
  - **Population health management**
- **Assure that interdisciplinary teams that design & implement outcomes-based clinical studies are inclusive of all needed expertise**

12. Genomic Medicine & ACOs

ISSUE: Two separate national discussions

- **The "Promise of Genomic Medicine"**
  - **Improve patient outcomes**
  - **Reduce overall healthcare costs**
- **Genomic Medicine Promise aligns with managed care goals & could be synergistic**
- **Support genomic evidence development**
- **Share evidence of genomic value in managed care settings**

Moving Forward

- **Develop advocacy approaches to key issues**
- **Annual update of Policy Framework**

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