

## **AMP 2007 COMMITTEE SUMMARIES**

### **COUNCIL MEMBERS:**

Andrea Ferreira-Gonzalez PhD, President  
Gregory J. Tsongalis PhD, President-Elect  
Barbara A. Zehnbauser PhD, Past President and Nominating Committee Chair  
Karen Mann MD PhD, Secretary-Treasurer and Publications Committee Chair  
Karen Weck MD, Program Committee Chair  
Jeffrey A. Kant MD PhD, Program Committee Chair-Elect  
Vicky Pratt PhD Clinical Practice Committee Chair  
Wayne W. Grody MD PhD, Professional Relations Committee Chair  
Thomas W. Prior PhD, Training & Education Committee Chair

### **EX OFFICIO COUNCIL MEMBERS:**

Paul G. Rothberg PhD, Genetics Subdivision Chair  
Lynn V. Abruzzo MD, Hematopathology Subdivision Chair  
Alexandra Valsamakis MD PhD, Infectious Diseases Subdivision Chair  
Deborah Dillon MD, Solid Tumors Subdivision Chair  
Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT (ASCP) SM, COO & Director of Scientific Programs

### **Clinical Practice Committee**

#### **COMMITTEE MEMBERS:**

Vicky Pratt PhD (Chair)  
Julie Gastier-Foster PhD (Genetics)  
Daniel Jones MD PhD (Hematopathology)  
Aaron D. Bossler MD PhD (Infectious Disease)  
Antonia Rogado Sepulveda MD PhD (Solid Tumors)  
Michelle Dolan MD (*ad hoc* member)  
Ira Lubin PhD (*ad hoc* member),  
Girish V. Putcha MD PhD (*ad hoc* member)  
M. Fernanda Sabato MS (*ad hoc* member)  
Patrik Viztaka PhD (*ad hoc* member)

#### **EX OFFICIO COMMITTEE MEMBERS:**

Andrea Ferreira-Gonzalez PhD, President  
Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT(ASCP)SM, COO & Director of Scientific Programs

#### **Clinical Practice Communications/Documents**

CPC responded to the request for information regarding electronic health records and personalized medicine.

Status: Completed (Jan. 07)

Proficiency Testing Work Group, a CDC contract, was developing guidelines for proficiency testing. The document was opened for public comment and the CPC responded to the proposed document.

Status: Completed (March 07)

A worldwide community was developing guidelines for premature ovarian failure. The document was opened for public comment and the CPC responded to the proposed guidelines.

Status: Completed (May 07)

SACGHS issued its report on Pharmacogenetics. The document was opened for public comment and the CPC responded.

Status: Completed (May 07)

The FDA issued draft guidance to Industry on QC materials. As these manufactured materials can significantly affect laboratory practice, the CPC responded.

Status: Completed (Oct 07)

The FDA issued draft guidance to Industry on Pharmacogenetics and Heritable Markers. As these manufactured materials can significantly affect laboratory practice, the CPC responded.

Status: Completed (Oct 07)

### **Publications/Presentations**

“Consensus Characterization of 16 FMR1 Reference Materials: A Consortium Study”

Jean Amos Wilson<sup>1</sup>, Victoria M. Pratt<sup>2</sup>, Amit Phansalkar<sup>3</sup>, Kasinathan Muralidharan<sup>4\*</sup>, W. Edward Highsmith Jr<sup>5</sup>, Jeanne C. Beck<sup>6</sup>, Scott Bridgeman<sup>7</sup>, Ebony M. Courtney<sup>4\*\*</sup>, Lidia Epp<sup>8</sup>, Andrea Ferreira-Gonzalez<sup>8</sup>, Nick L. Hjelm<sup>4</sup>, Leonard M. Holtegaard<sup>5</sup>, Mohamed A. Jama<sup>3</sup>, John P. Jakupciak<sup>9</sup>, Monique A. Johnson<sup>10</sup>, Paul Labrousse<sup>11</sup>, Elaine Lyon<sup>3,12</sup>, Thomas W. Prior<sup>7</sup>, C. Sue Richards<sup>10</sup>, Kristy L. Richie<sup>9</sup>, Benjamin B. Roa<sup>13\*\*\*</sup>, Elizabeth M. Rohlf<sup>11</sup>, Tina Sellers<sup>6\*\*\*\*</sup>, Stephanie L. Sherman<sup>4</sup>, Karen A. Siegrist<sup>14</sup>, Lawrence M. Silverman<sup>14</sup>, Joanna Wiszniewska<sup>13</sup>, Lisa V. Kalman<sup>15</sup>

A joint document of the Clinical Practice Committee of the Association for Molecular Pathology and CDC. In press for January 2008 issue of JMD.

“CpG Methylation Analysis: Currents Status and Potential Applications in Molecular Diagnosis”

\*Antonia R. Sepulveda, Dan Jones, Shuji Ogino, Wade Samowitz, Peggy Gulley, Robin Edwards, Victor Levenson, Vicky Pratt, Bin Yang, Khedoudja Nafa, Liying Yan, Patrick Vitazka.

In progress.

### **Projects**

*Infectious Disease (Aaron Bossler)*

Work is ongoing with Lisa Kalman and Shannon Barker from the CDC Genetics Testing Reference Materials (GeT-RM) program in evaluating the results from the “Assessment of Molecular Infectious Disease Reference Material Availability and Needs” survey. The goals are to develop a listing of quality control materials in use by representative laboratories, to further characterize controls that are difficult to obtain or that lack characterization data, and to provide this information to the clinical laboratory community. Arising from the work is the collaboration with Vivianna Van Deerlin and Mary Paton at the College of American Pathologists (CAP) to develop or enhance proficiency testing materials to meet new laboratory needs for standardized materials for infectious disease proficiency testing.

Status: Active

*Genetics (Julie Gastier Foster)*

A survey was sent to all AMP members to identify gaps in available proficiency surveys for molecular genetic tests. These data will be forwarded to the PTWG for molecular genetic tests. Information was also gathered regarding the mutation databases used by laboratories performing sequence-based testing. These data will be compiled to determine if the AMP CPC should work to establish additional curated mutation databases.

Status: Active.

*Laboratory Reporting Project (Recently transitioned to Result Reporting and Clinical Decision Support) (Ira Lubin CDC)*

Two manuscripts are in preparation that will summarize findings relevant to laboratories in the design of their reports for DNA-based tests for heritable conditions. Earlier this year, AMP (Elaine Lyon / Ira Lubin - Clinical Practice Committee) participated along with CDC and Wadsworth Center, New York Department of Public Health in one of three clinician workgroups in gathering data pertaining to the development of laboratory reports. The current status of this work is that CDC recently awarded funding to RAND

Corporation to continue looking at laboratory result reporting in the context of clinical decision support and the expectation is that AMP will continue to be an important partner in this work.

Status: Active

*Solid tumors (Antonia Sepulveda)*

Methylation testing working group: The Methylation testing working group has put together a manuscript entitled "CpG Methylation Analysis: Currents Status and Potential Applications in Molecular Diagnosis". The manuscript is currently in revision. The manuscript provides a review on 1) Methods used for CpG methylation testing. 2) Applications of CpG methylation testing in neoplastic disorders. 3) CpG methylation and infectious diseases related to cancer development. The group is presenting a workshop at the 2007 annual meeting. The methylation testing working group is currently preparing a proposal for sample exchange and validation of CpG methylation testing of MLH1 in colon cancers.

Status: Active

*Other*

"Molecular Diagnostics Data Specification Project": Frederico Monzon submitted a proposal for a joint API/AMP joint informatics project. The CPC committee felt that the proposal was vague in its current state. The AMP office will coordinate an agreement with API before the CPC participates in the project.

Status: On-hold pending agreement conditions

Reference Materials (GeT-RM) (Lisa Kalman): The CDC is sponsoring this 1-day meeting in Los Angeles just prior to the AMP meeting. The meeting is to review the progress on QC materials for genetic testing, molecular oncology and infectious diseases. The CPC representatives and subdivision chairs for both 07 and 08 have been invited to attend. In addition, an AMP list serve has been created to facilitate communication between CPC, CDC, NYSDOH, and CAP.

Status: Active

Analytical Validation of Genotyping Assays – AMP Guideline: As there is much confusion related to analytical validation, the CPC will develop a guideline/checklist to help laboratories with analytical validation.

Status: Active

**Recommendations:**

Encourage all AMP members to alert council or appropriate committees when laboratory guidelines or recommendations are opened for public comment.

**Nominating Committee**

**COMMITTEE MEMBERS:**

Barbara A. Zehnauer PhD, Chair  
Iris Schrijver MD, Genetics Subdivision  
Rizwan Naeem MD, Genetics Subdivision  
Timothy J. O'Leary MD PhD, Hematopathology Subdivision  
Y. Lynn Wang MD PhD, Hematopathology Subdivision  
Stephen P. Day PhD, Infectious Diseases Subdivision  
Kenneth Bahk PhD, Infectious Diseases Subdivision  
Kevin C. Halling MD PhD, Solid Tumors Subdivision  
Shuji Ogino MD PhD, Solid Tumors Subdivision

**EX OFFICIO COMMITTEE MEMBERS**

Andrea Ferreira-Gonzalez PhD, President  
Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT (ASCP) SM, COO & Director of Scientific Programs

## **Professional Relations Committee**

### **COMMITTEE MEMBERS:**

Wayne W. Grody MD PhD, Chair  
Jean Amos Wilson PhD, Chair-Elect  
Angela M. Caliendo MD PhD  
Andrea Ferreira-Gonzalez PhD  
Debra G. B. Leonard MD PhD  
Elaine Lyon PhD  
Roberta Madej BS MS MBA  
Jan A. Nowak MD PhD  
Michele Schoonmaker PhD  
*Cepheid*

### **EX OFFICIO COMMITTEE MEMBERS**

Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT (ASCP) SM, COO & Director of Scientific Programs

The PRC has been intensively involved this year in a number of crucial issues at the national level affecting regulation, reimbursement, scope and oversight of molecular diagnostic testing. Because of their broad sweep, potentially impacting all areas of molecular diagnostics, we have consulted frequently with AMP Council, other AMP committees, and sister organizations (CAP, ACMG, ACLA, AACC, and others) with whom we can partner. A sampling of the key issues addressed in 2007 follows:

### **FDA Guidance Documents**

Our committee developed, and Council approved, letters to FDA detailing our concerns about two guidance documents: one aimed at narrowing the definition of analyte-specific reagents (ASRs) used in molecular tests, the other targeting complex multivariate analyses (MIAs) that use interpretive algorithms to generate a clinical report that would not be obvious to the ordering physician if only the raw test data were released. FDA has since issued a final guidance on the ASRs and a further definition of the MIAs. After an informal survey of the impact of the latter on the AMP membership, it was felt that no further comment was needed at this point.

### **Legislative Issues**

We continue to monitor closely the fate of two Senate bills that, if passed, would result in much more burdensome federal oversight of genetic tests, particularly by FDA. These bills were introduced by Senators Kennedy and Obama, and both continue to undergo revisions. The PRC has been working with other organizations to communicate our concerns with the respective staffs in these Senate offices.

### **Direct-to-Consumer Marketing of Genetic Tests**

The committee developed an AMP policy statement about direct marketing and direct access of molecular diagnostic (especially genetic) tests to the public, particularly those advertised via the internet which have dubious clinical claims and which do not involve any pre-test screening or post-test interpretation and counseling by a health care professional. Our statement is in line with those previously issued by other organizations (ACMG, AMA), expressing concern for the potential harm to patients and to the reputation of the profession that can result from the continued unregulated marketing of these tests.

### **Genetics Specialty**

During this year's tenure of the committee, the long-simmering issue of incorporating a defined genetics specialty within the CLIA regulations was finally resurrected by CMS, only to be rejected as unnecessary. The PRC, with the input of Council, is still wrestling over how or whether to send a response to the CLIA Advisory Committee regarding this development. There are both perceived advantages and potential disadvantages to re-writing CLIA in this way, and opinions even within our organization are quite varied. We are continuing to monitor the situation and solicit member input.

**Pathology Coding Caucus**

We continue to work proactively, through the Pathology Coding Caucus on which PRC member Jan Nowak serves, to ensure that new CPT coding proposals reflect the actual nature of our work and that reimbursement levels are fair and adequate. Most of the attention this past year was in the area of molecular microbiology testing. We also have responded on an *ad hoc* basis to particular threats of noncoverage for certain tests by individual carriers or states.

**SACGHS**

The Secretary's Advisory Committee on Genetics, Health and Society continues to exert its influence on an expanding number of issues relevant to genetic testing. The committee has excellent inroads to this influential body, thanks to the appointment at the start of this year of Andrea Ferreira-Gonzalez to its membership, and the continuing participation of past member Debra Leonard, both of whom serve on the PRC. We regularly present our positions on these issues at their meetings, and feel they have been receptive to our concerns.

*Wayne W. Grody, M.D., Ph.D.*  
*Chair, Professional Relations Committee*

**Program Committee****COMMITTEE MEMBERS:**

Karen Weck MD, Chair  
Jeffrey A. Kant MD PhD, Chair-Elect  
Paul G. Rothberg PhD, Genetics Subdivision  
Mary C. Lowery Nordberg PhD, Genetics Subdivision  
Lynn V. Abruzzo MD, Hematopathology Subdivision  
Daniel Jones MD PhD, Hematopathology Subdivision  
Alexandra Valsamakis MD PhD, Infectious Diseases Subdivision  
Franklin Cockerill III MD, Infectious Diseases Subdivision  
Deborah Dillon MD, Solid Tumors Subdivision  
William P. Bennett MD, Solid Tumors Subdivision  
Malinda L. Butz CLSp (MB), Technical Topics Representative  
Karen E. Bijwaard MS, Technical Topics Representative

**EX OFFICIO COMMITTEE MEMBERS**

Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT (ASCP) SM, Director of Scientific Programs  
Maricel Herrera CMP, Director, Meetings and Membership Services

## Publications Committee

### **EX OFFICIO COMMITTEE MEMBERS (Voting)**

Karen Mann MD PhD, Chair  
Shuji Ogino MD PhD, CHAMP Moderator  
Karen L. Kaul MD PhD, *JMD* Editor-in-Chief  
Teresita C. Redondo MD and Marlene Sabbath-Solitare PhD, Newsletter Co-Editors  
Alexis Carter MD, Test Directory Editor  
Kathleen M. Murphy PhD, Web Library Editor  
Vivianna Van Deerlin MD PhD, Website Editor

### **EX OFFICIO COMMITTEE MEMBERS (Non-Voting)**

Andrea Ferreira-Gonzalez PhD, President  
Mark E. Sobel MD PhD, Executive Officer  
Mary Steele Williams MT(ASCP) SM, Director of Scientific Programs

### **ADVANCE for Administrators of the Laboratory**

This has been the second year of AMPs agreement to provide a column "The Molecular Edge" to be published in *ADVANCE* every other month. Six articles have been published or accepted for publication this year. Additional authors and topics have been chosen for the beginning of 2008. The association between AMP and Advance will continue next year and the column will now be highlighted on the front cover.

### **AMP-Associated Articles**

The procedure for review AMP associated articles has been streamlined in response to concern by authors of prior articles. This new process has been implemented, and we have reviewed a number of articles, have made comments, and passed approved articles on to Council. Three of these were published in the Journal of Molecular Diagnostics this calendar year and one additional article has been accepted. Additional articles are in the pipeline.

### **Website**

We are undertaking a new initiative with a focus on the website. This is the electronic face of AMP and needs to remain up-to-date, timely and easy to use. We are in the process of forming a Web editorial board to ensure that both the structure and content of the website serve our membership well.

### **Test-Directory**

The test directory is undergoing two major changes. Firstly, an improved search function is being added. Secondly, the method by which you enter new tests is being improved. We look forward to implementation of these changes soon.

### **Web Library**

The Web Library continues to focus on capturing presentations from the annual meeting for the use of our membership.

### **CHAMP**

CHAMP continues to be a helpful source of molecular pathology and community for our members. Thanks to Shuji Ogino, for his excellent moderation of the list-serve. We anticipate some exciting updates, including the ability to search for archived messages in the year to come.

### **Newsletter**

Teresita C. Redondo MD and Marlene Sabbath-Solitare PhD continue to do an excellent job editing and producing the Quarterly Newsletter.

*Karen Mann MD PhD  
Chair, Publications Committee*

### **Strategic Planning Committee**

#### **COMMITTEE MEMBERS:**

Daniel H. Farkas PhD HCLD, Chair  
Margaret L. Gulley MD  
Raymond R. Tubbs DO  
Timothy T. Stenzel, MD, PhD  
Gregory J. Tsongalis PhD, President-Elect

#### **EX OFFICIO COMMITTEE MEMBER:**

Mary Steele Williams MT (ASCP) SM, COO & Director of Scientific Programs

### **Training and Education Committee**

#### **COMMITTEE MEMBERS:**

Tom W. Prior PhD (Chair)  
Marsha Speevak PhD (Genetics)  
Charles E. Hill MD PhD (Hematopathology)  
Ted Schutzbank PhD (Infectious Diseases)  
Adekunle M. Adesina MD PhD (Solid Tumors)  
Annika Svensson MD PhD (Junior Member)  
Bernadette M. Wildemore MD (Junior Member)

The committee's major activity has been planning the 20d Pathology Outreach Course, which will be targeted to non-molecular laboratory professionals and will be held on Wednesday, Nov. 7, 2007. The course "**Molecular Diagnostics Applications in Pathology: A Case-Oriented Approach**," will provide an update on the current developments through actual case studies covering the four major clinical molecular pathology disciplines: solid tumors, hematopathology, infectious disease, and human genetics. Most of our speakers are members of our T&E committee and will highlight how molecular testing impacts disease management.

We are also sponsoring several educational sessions at the national meeting including early bird session on Mutation Nomenclature and Method Validation. For the Trainee luncheon, several industry-employed molecular pathologists will share their perspectives and employment opportunities. Members of the training and education committee will judge the young investigator posters at the AMP meeting.

This year the committee also approved the Residency Competency document, provided by Michael Talbert.

*Thomas W. Prior, PhD  
Chair, Training and Education Committee*