AMP 2008 Committee Annual Reports

COUNCIL MEMBERS:

Gregory J. Tsongalis PhD, President

Jan Nowak MD PhD, President-Elect and Liaison to the Strategic Planning Committee Andrea Ferreira-Gonzalez PhD, Past President and Nominating Committee Chair S. Terence Dunn PhD, Secretary-Treasurer and Publications Committee Chair Vicky Pratt PhD, Clinical Practice Committee Chair Helen Fernandes PhD, Membership & Professional Development Committee Co-Chair Jean Amos Wilson PhD, Professional Relations Committee Chair Jeffrey A. Kant MD PhD, Program Committee Chair Timothy J. O'Leary MD PhD, Program Committee Chair-Elect Jennifer L. Hunt, MD, Training and Education Committee Chair

EX OFFICIO COUNCIL MEMBERS:

Mary C. Lowery Nordberg PhD, Genetics Committee Chair Dan Jones MD PhD, Hematopathology Subdivision Chair Franklin Cockerill III MD, Infectious Diseases Subdivision Chair William P. Bennett 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 Representative
Daniel E. Sabath MD PhD, Hematopathology Representative
Aaron D. Bossler MD PhD, Infectious Diseases Representative
William K. Funkhouser MD PhD, Solid Tumors Representative
Michelle Dolan MD, Ad Hoc Member
Ira Lubin PhD, Ad Hoc Member
M. Fernanda Sabato Charreun MS, Ad Hoc Member
Patrik Vitazka MD PhD, Ad Hoc Member

Clinical Practice Guidelines and Comments

CPC responded to the EMEA's Guidance on Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories. The document was opened for public comment and the CPC responded to the proposed definitions.

Status: Completed (Mar. 08)

CPC responded to the draft guidelines by NACB: Guidelines and Recommendations for Laboratory Analysis and Application of Pharmacogenetics to Clinical Practice. The document was opened for public comment and the CPC responded to the proposed guidelines. Status: Completed (Mar. 08)

CPC responded to the FDA's Guidance for Industry: E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories. The document was opened for public comment and the CPC responded to the proposed definitions.

Status: Completed (Apr. 08)

CPC responded to the FDA Genomic Classifier of Tumors.. The document was opened for public comment and the CPC responded to the proposed guidelines.

Status: Completed (Apr. 08)

CPC responded to the NIH RFI on Challenges and Barriers to

Pharmacogenetics/Pharmacogenomics Research.

Status: Completed (Apr. 08)

CPC and PRC jointly responded to the Comments to CMS regarding Pharmacogenetic Testing of Warfarin Response.

Status: Completed (Aug. 08)

CPC and Michelle Schoonmaker of the PRC responded to the FL licensing regulations.

Status: Completed (Sept. 08)

Publications/Presentations

"Consensus Characterization of 16 FMR1 Reference Materials: A Consortium Study" Jean Amos Wilson¹, Victoria M. Pratt², Amit Phansalkar³, Kasinathan Muralidharan^{4*}, W. Edward Highsmith Jr⁵, Jeanne C. Beck⁶, Scott Bridgeman⁷, Ebony M. Courtney^{4**}, Lidia Epp⁸, Andrea Ferreira-Gonzalez⁸, Nick L. Hjelm⁴, Leonard M. Holtegaard⁵, Mohamed A. Jama³, John P. Jakupciak⁹, Monique A.Johnson¹⁰, Paul Labrousse¹¹, Elaine Lyon^{3,12}, Thomas W. Prior⁷, C. Sue Richards¹⁰, Kristy L. Richie⁹, Benjamin B. Roa^{13***}, Elizabeth M. Rohlfs¹¹, Tina Sellers^{6****}, Stephanie L. Sherman⁴, Karen A. Siegrist¹⁴, Lawrence M. Silverman¹⁴, Joanna Wiszniewska¹³, Lisa V. Kalman¹⁵

A joint document of the Clinical Practice Committee of the Association for Molecular Pathology and CDC.

Status: Completed (Published in JMD Jan. 08)

"Ordering Molecular Genetic Tests and Reporting Results. Practices in Laboratory and Clinical Settings." Lubin IM, Caggana M, Constantin C, Gross SJ, Lyon E, Pagon RA, Trotter TL, Amos Wilson J, McGovern MM.

Status: Completed (Published in JMD Sept. 08)

"Multi-site PCR CMV viral load assessment: Assays demonstrate linearity and precision, but lack numeric standardization"

Daynna J. Wolff, Denise LaMarche Heaney, Paul D. Neuwald, Kathleen A. Stellrecht, Richard D. Press, and the AMP Clinical Practice Committee.

Status: in progress (submitted to JMD)

"Laboratory Practice Guidelines for Detecting and Reporting BCR-ABL Drug Resistance Mutations in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia" From the ABL Mutation Working Group of the Association for Molecular Pathology (AMP) Clinical Practice Committee . The ABL Mutation Working Group is a subcommittee of the Association for Molecular Pathology (AMP) Clinical Practice Committee and consists of Dan Jones, Suzanne Kamel-Reid, David Bahler, Henry Dong, Kojo Elenitoba-Johnson, Richard Press, Neil Quigley, Paul Rothberg and Dan Sabath, David Viswanatha, Karen Weck and James Zehnder

Status: in progress (submitted to JMD)

"CpG Methylation Analysis: Current Status and Potential Applications in Molecular Diagnosis"

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

Status: in progress (submitted to JMD)

Projects

Infectious Disease (Aaron Bossler)

Aaron has been working with the CPT coding group. They have submitted a request to the AMA for a new CPT code for organism identification using sequence information. The ID is continuing to work with NIST to develop CMV quantitative standard reference material.

Status: Active

Genetics (Julie Gastier Foster)

Information was also gathered regarding the mutation databases used by laboratories performing sequence-based testing. Julie develop a list for AMP members that will be accessable on the AMP website.

Status: Active.

Solid tumors (Bill Funkhouser)

Bill is following up on the work initiated by Jan Nowak on MSI testing guidelines

Status: Active

Hematopathology (Dan Sabath)

Dan is working on submitting a proposal to develop FLT3/NPM1 testing guidelines

Status: Active

Other

Result Reporting and Clinical Decision Support (Ira Lubin, CDC)

Two manuscripts are completed that will summarize findings relevant to laboratories in the design of their reports for DNA-based tests for heritable conditions. The first one has been accepted for publication by JMD. The second one will be submitted to Genetics in Medicine. Ira will provide an overview and update at the Genetics luncheon at annual meeting in Dallas.

Status: Active

Reference Materials (GeT-RM) (Lisa Kalman, CDC).

The CDC is sponsoring a 1-day meeting in Dallas just prior to the AMP meeting. The meeting is to review the progress of the GeT-RM program and discuss current and future projects for development of reference materials for genetic testing, pharmacogenetics, molecular oncology and infectious diseases. The CPC representatives and subdivision chairs for both 08 and 09 have been invited to attend. In addition, an AMP list serve has been created to facilitate communication between CPC, CDC, NYSDOH, and CAP. A GeT-RM paper on characterization of additional cystic fibrosis reference materials has been submitted to JMD. Several AMP members were involved and are co-authors.

Status: Active

Analytical Validation of Genotyping Assays (Michelle Dolan) – AMP Guideline As there is much confusion related to analytical validation, the CPC will develop a guideline/checklist to help laboratories with analytical validation that will be available on the AMP website.

Status: Active

Recommendations:

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

<u>CPT Coding Committee</u> (a Subcommittee of the Professional Relations Committee) COMMITTEE MEMBERS:

Jan A. Nowak MD PhD, Chair
Elaine Lyon PhD, Professional Relations Committee Liaison
Aaron D. Bossler MD PhD, Member
Andrea Ferreira-Gonzalez PhD, Member
Jeffrey A. Kant MD PhD, Member
Roger D. Klein MD JD, Member
Joan Logue MT BS, Member
Michele Schoonmaker PhD, Member
Paul A. Raslavicus MD, Member
Jill Hagenkord MD, Junior Member

The CPT Committee advised the Pathology Coding Caucus (PCC) on proposals related to molecular tests. Jan Nowak represented AMP at the PCC meeting earlier this year. Jeff Kant was named the alternate AMP representative to the PCC and attended the September meeting.

In an effort to establish a beneficial relationship with Medicare Carrier Medical Directors (CMDs), Committee members had a number of discussions with Dr. Mitch Burken exploring ways in which AMP could assist Medicare CMDs in correct utilization of molecular CPT codes. Jeff Kant addressed a national meeting of Medicare CMDs to elaborate how molecular CPT codes are used.

The Committee established a Working Group to develop a CPT code proposal for assays for micro-organism identification by sequencing methods. This effort was led by Aaron Bossler and included a number of ad hoc members. A joint proposal from AMP and ASM was submitted to the AMA CPT Editorial Panel and presented to the PCC in September by Aaron Bossler. Refinements to the proposal are in progress.

The Committee committed to a major effort to develop a revised system for future molecular test CPT coding. A conceptual framework for this topic was proposed by Paul Raslavicus who was invited to join the Committee. Funding for several day long face-to-face conferences to address this new coding framework was sought and obtained from Abbott Molecular Systems. Information regarding molecular test practice variations was sought in a member survey performed via Champ. This information will be utilized in a comparison of test costs across the spectrum of practices encountered.

The Committee discussed AMP's 2004 position statement on the OncotypeDx test with a Medicare CMD. This inquiry initiated a discussion in the Committee and ultimately within AMP regarding the need to establish a mechanism for the development and maintenance of clinical utilization policy statements.

The Committee initiated a discussion with test manufacturers regarding the development of CPT codes for multianalyte panels, noting the complexities and issuses involved, and discussed several possible approaches.

The Committee developed an AMP response to CMS regarding necessity for National Coverage Determinations (NCD) for pharmacogenomic testing for warfarin sensitivity and for gene expression testing.

The Committee developed an AMP response to CMS regarding proposed the most recent series of proposed Medically Unlikely Edits (MUEs) for molecular tests.

The Committee discussed a proposal from McKesson Health Solutions for changes to molecular test coding, and offered suggestions and potential directions for consideration.

Membership & Professional Development Committee

COMMITTEE MEMBERS:

Helen Fernandes PhD, Co-Chair Richard Press MD PhD, Co-Chair Shuji Ogino MD PhD, Member Robyn Temple-Smolkin PhD, Member

MPDC was created in 2008 with a charge to provide recommendations to Council and assistance to other committees and subdivisions regarding matters of membership and professional development. MPDC coordinates the requests of its committees for additional personnel with suitable volunteer members to facilitate the selection process. Volunteer positions are posted on CHAMP and updated on the AMP website (http://www.amp.org/AboutAmp/getinvolved.htm) along with a link to the application form.

AMP volunteer positions

The committee received requests for volunteers from three AMP committees. The responses from AMP members were excellent. In 2008 four *ad hoc* members were successfully appointed to the Professional Relations (1 junior member), CPT Coding (1 regular and 1 junior member) and Publications Committees (Associate CHAMP Moderator).

New / Revised Membership Categories

Emeritus Membership

The emeritus membership category was revised to encourage participation of AMP members who are no longer receiving either full or part-time salary from an institution, company or organization and to clarify emeritus membership benefits and requirements. The committee established new specifics of emeritus membership status and set up an application process.

Special Membership Category for Residents of HINARI Band 1 and 2 Countries

Recognizing the particular challenges of laboratory colleagues who reside in economically struggling countries, a new membership category was established, with annual dues set at \$25.00. Residents of HINARI Band 1 and 2 countries will be eligible (http://www.who.int/hinari/eligibility/en/).

Outreach

Currently, the MPDC is developing policies and strategies to establish AMP chapters around the world. Council has received requests from international members for an affiliate status to AMP. The guidelines and regulatory issues for the development of chapters are being developed and an application form for this purpose is being drafted.

Nominating Committee

COMMITTEE MEMBERS:

Andrea Ferreira-Gonzalez PhD, Chair Rizwan Naeem MD, Genetics Representative Siby Sebastian PhD, Genetics Representative Y. Lynn Wang MD PhD, Hematopathology Representative Jane S. Gibson PhD FACMG, Hematopathology Representative Kenneth Bahk PhD, Infectious Diseases Representative Randall Hayden MD, Infectious Diseases Representative Shugi Ogino MD PhD, Solid Tumors Representative Marina N. Nikiforova MD, Solid Tumors Representative

The Nominating Committee nominates Officers and Committee Representatives for the annual elections and recommends the recipients of the AMP Award for Excellence in Molecular Diagnostics and the AMP Leadership Award.

Professional Relations Committee

COMMITTEE MEMBERS:

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

Committee Membership

We welcomed Shelby Melton, MD as our first Junior Member. Shelby is an MGP Fellow in the Department of Pathology at the University of Texas Southwestern Medical Center. We look forward to welcoming Vicky Pratt as a new PRC member in 2009.

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 2008 follows:

CPT Coding Subcommittee (see separate report)

In January, Council confirmed the creation of the CPT subcommittee of the PRC, chaired by Jan Nowak, to address and advise on proposals before the PRC related to molecular pathology; to address and advise AMP membership on utilization of current CPT codes; to discuss imminent coding issues and develop potential action plans; to develop and implement long term plans to address CPT coding issues related to molecular pathology; and to interact with other organizations with common goals

HEALTHfutures, LLC

We established a public policy consulting relationship with HEALTH futures, LLC this past spring. Jennifer Lieb and Robert Wells, founding partners, will help us track the state, US and global government activities in regulation, legislation and public policy that may affect the practice, implementation and compensation of molecular diagnostics in particular and laboratory medicine in general. This partnership has helped the PRC in strategic planning for efficient and effective use of our resources. In addition to participation on our monthly conference call and activities "behind the scenes", Jennifer and Robert participate in a monthly leadership call with the PRC Chair and Chair-Elect and AMP COO to plan and review our monthly activities.

Visits to the Hill

With Jennifer Leib and Robert Wells, Mary Williams will meet with 25 key legislators on Capital Hill this fall to highlight AMP as a resource organization for health policy and legislation. We have developed key talking points for these conversations that describe AMP and our membership and emphasize our positions on to 1) safety, quality, innovation and access for molecular testing; 2) clarity in oversight pathways; 3) a registry of laboratory developed tests; 4) reimbursement. These visits will help set the stage for AMP involvement in the new administration and will appropriately follow introduction of the, "The Genomics and Personalized Medicine Act of 2008 (H.R.6498)", by Rep. Patrick Kennedy (D – RI); this bill was introduced in September has been referred to the House Ways and Means Committee and to the House Energy and Commerce Committee.

SACGHS

The PRC provided comments to SACGHS prior to the June 08 publication of the report entitled, "A Roadmap for the Integration of Genetics and Genomics into Health and Society". In these pre-report comments, we asked the committee to revise its definition of a genetic test, consider pathways to oversight of direct to consumer genetic testing, harmonize personnel requirements for molecular genetic testing with the CLIA requirements for cytogenetics personnel, and volunteered to be an organization resource for matters relating to oversight of laboratory-developed tests, proficiency testing, clinical validity issues and effective communication and decision support. The PRC also responded to a SACGHS invitation to provide comments regarding future priorities with recommendations to provide insight on research funding for genetic testing clinical outcomes research, development clinical decision support tools and to continue to consider oversight of genetic testing in non-traditional settings

Program Committee

COMMITTEE MEMBERS:

Jeffrey A. Kant MD PhD, Chair
Timothy J. O'Leary MD PhD, Chair-Elect
Mary C. Lowery Nordberg PhD, Genetics Subdivision Chair
Hanna Rennert PhD FACMG, Genetics Subdivision Chair-Elect
Dan Jones MD PhD, Hematopathology Subdivision Chair
Kojo S.J. Elenitoba-Johnson MD, Hematopathology Subdivision Chair-Elect
Franklin Cockerill III MD, Infectious Diseases Subdivision Chair
Frederick S. Nolte PhD, Infectious Diseases Subdivision Chair-Elect
William P. Bennett MD, Solid Tumors Subdivision Chair-Antonia R. Sepulveda MD PhD, Solid Tumors Subdivision Chair-Elect
Karen E. Bijwaard MS, Technical Topics Representative
Joan T. Gordon, BS, MT(ASCP), Technical Topics Representative

The program significantly expanded the number of sessions for this year's Annual Meeting. Your feedback is welcome.

Publications Committee

COMMITTEE MEMBERS:

S. Terence Dunn PhD DABCC, Chair

EX OFFICIO MEMBERS (VOTING)

Shuji Ogino MD PhD, CHAMP Moderator Qiulu Pan, MD, PhD, CHAMP Associate Moderator Karen L. Kaul MD PhD, JMD Editor-in-Chief Teresita C. Redondo MD, Newsletter Co-Editor Marlene Sabbath-Solitare PhD, Newsletter Co-Editor Alexis Carter MD, Test Directory Editor Kathleen M. Murphy PhD, Web Library Editor Mary C. Lowery Nordberg PhD, Website Editor

AMP-Associated Articles

Council-Approved (for Submission to JMD):

- Laboratory Practice Guidelines for Detecting and Reporting BCR-ABL Drug Resistance Mutations in Chronic Myelogenous Leukemia and Acute Lymphoblastic Leukemia. The ABL Mutation Working Group of the Clinical Practice Committee.
- Multi-site PCR CMV Viral Load Assessment Assays Demonstrate Linearity and Precision, but Lack Numeric Standardization: A Report of the Association for Molecular Pathology.
 - The CMV Sample Exchange Working Group of the 2003–2008 Clinical Practice Committee.
- CpG Methylation Analysis Current Status of Clinical Assays and Potential Applications in Molecular Diagnostics: A Report of the Association for Molecular Pathology.
 The Methylation Working Group of the 2006-2007 Clinical Practice Committee.

Submitted to Pubs Committee for Review (for Submission to JMD):

 Competency-Based Education for the Molecular Genetic Pathology Fellow: Guidlelines from the Association for Molecular Pathology.
 T&E Committee (due for submission for review in next few months).

Scientific publications arising from AMP Working groups will in future acknowledge AMP in the title, such as the addition of ": A Report of the Association for Molecular Pathology" to the title. In addition, the author of these articles will be the Working Group, with the contributing authors listed as members of the Working Group in the footnotes. The committee is preparing a revised Publications Policy.

AMP-Acknowledged Articles (did not originate in AMP)

Accepted for Publication in JMD:

 Ordering Molecular Genetic Tests and Reporting Results: Practices in Laboratory and Clinical Settings.
 CDC Project led by Ira Lubin.

AMP Articles Invited by Other Publications

Food and Drug Law Institute - Update Magazine:

Personalized Medicine: The Role of Laboratories.
 Vicky Pratt, Terry Dunn, and Karen Weck.

ADVANCE for Administrators or the Laboratory Magazine (special December issue):

 Trends in Molecular Diagnostics. Sameer S. Talwalkar, a Molecular Pathology Fellow at UPMC.

AMP "Molecular Edge" Articles in ADVANCE for Administrators of the Laboratory

| • | Information Systems for MDx Laboratories, Part 2 Alexis Carter | January 2008 |
|---|--|------------------|
| • | Germline, Somatic Distinction Paul Rothberg and Mary Lowery Nordberg | March 2008 |
| • | Reimbursement For Molecular Pathology Assays Jeffrey Kant | May 2008 |
| • | Validating Lab Developed Tests (Part 1) Margaret Gulley | July 2008 |
| • | Validating Lab Developed Tests (Part 2) Margaret Gulley | . September 2008 |
| • | Pharmacogenetics of Warfarin Metabolism Testing Mary Lowery Nordberg | November 2008 |

AMP Newsletter

The AMP Newsletter was printed in color in-house in the AMP offices, which both saved money and yielded a better-looking newsletter. The publication averaged 20 pages in its three 2008 issues.

CHAMP

An Associate CHAMP Moderator was appointed, Qiulu Pan, who will share moderation duties with Shuji Ogino on a regular basis.

AMP Test Directory

The overhaul to the search capability and specimen source field are ongoing projects.

Strategic Planning Committee

COMMITTEE MEMBERS:

Margaret L. Gulley MD, Chair Debra G. B. Leonard MD PhD Timothy T. Stenzel MD PhD FACMG Raymond R. Tubbs DO

EX OFFICIO COMMITTEE MEMBER (VOTING)

Jan A. Nowak MD PhD, President-Elect

AMP is widely considered to be THE professional society for molecular laboratory professionals because AMP combines very practical services to our members with a tight focus on molecular pathology. Given the rapid advances in this field, AMP must choose wisely among many opportunities and directions to insure that our member's interests are best served using limited available resources. Growing new resources is one strategy, and teaming with other groups to share resources is another strategy for success. We should continue to survey our members' needs and prioritize our programs accordingly. A number of recommendations were formulated for AMP Council during the course of the year.

Training & Education Committee

COMMITTEE MEMBERS:

Jennifer L. Hunt MD Med, Chair Madhuri Hegde PhD, Genetics Representative Charles E. Hill MD PhD, Hematopathology Representative Matthew J. Bankowski PhD DABMM HCLD, Infectious Diseases Representative Adekunle M. Adesina MD PhD, Solid Tumors Representative Hunter Best PhD, Junior Member Karin Finberg MD PhD, Junior Member

Webinars

The committee tested new webinar system before purchasing subscription and also organized the first trial webinar lecture. It was a tremendous success, with 236 registered attendees who had a very high interest level (99% had the webinar on their computer as for primary viewing during the session). The rating for whether the webinar met its objectives was 4.19 out of a possible score of 5. T&E will be hosting quarterly formal webinars and adhoc webinars as hot topics arise from CHAMP discussions.

Annual meeting

The T&E Committee is primarily responsible for judging the abstracts in the Trainee award category and selecting the Young Investigator Award recipients. The Committee also hosts and teaches the Pathology Outreach Course on the first day of the annual meeting and the Trainee Luncheon session, which highlights a panel discussion moderated by the Trainee members of the T&E Committee. A new event at the Annual meeting will be a Book Table and Raffle, where donated copies of molecular textbooks can be perused and then will be raffled to trainees at the Trainee Luncheon. The on-line textbook listing for molecular pathology book references is being updated for the Annual Meeting as well.

Review courses

T&E and AMP helped to co-sponsor the AACC-AMP review course on Molecular Pathology in May, 2008. Many AMP members were faculty there. For 2009, the AMP will return to hosting its own review course, which will again be directed by Dr. Kevin Halling. Plans are underway for scheduling of faculty. It will be held in June of 2009.

New project proposals approved

Two new T&E projects were developed with formal proposals that were approved by Council in August. The Committee will be piloting a Molecular pathology Teaching Case series starting in 2009, where brief teaching cases will be presented in an electronic format for AMP members. The Committee will also be piloting a Trainee Exchange system, where trainees who desire short experiences at other institutions for specialized training will be matched with host institutions that can offer these experiences. Data collection will begin in early 2009 from program directors, to update the current MGP training program information.

Trainee listserv

The trainee members have been moderating the Trainee Listserv and handling the ask-amentor questions that have been coming through to coordinate responses from various faculty mentors.