

AMP 2010 Committee Annual Reports

COUNCIL MEMBERS:

Karen Mann MD PhD, President
Timothy J. O’Leary MD PhD, President-Elect and Liaison to the Strategic Planning Committee
Jan A. Nowak MD PhD, Past President and Nominating Committee Chair
Ted Schutzbank PhD, Secretary-Treasurer and Publications Committee Chair
Iris Schrijver MD, Clinical Practice Committee Chair
Jeffrey A. Kant MD PhD, Economic Affairs Committee Chair
Helen Fernandes PhD, Membership & Professional Development Committee Chair
Elaine Lyon PhD, Professional Relations Committee Chair
Barbara Zehnbauer PhD FACMG, Program Committee Chair
Jennifer Hunt MD MEd, Program Committee Chair-Elect
Karen Weck, MD, Training and Education Committee chair
Arlene Buller-Burckle PhD, Genetics Committee Chair
Timothy C. Greiner MD, Hematopathology Subdivision Chair
David Persing MD PhD, Infectious Diseases Subdivision Chair
Loren Joseph MD, Solid Tumors Subdivision Chair

EX OFFICIO COUNCIL MEMBERS:

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

Clinical Practice Committee (CPC)

COMMITTEE MEMBERS:

Iris Schrijver MD, Chair
Narasimhan Nagan PhD, Genetics Representative
Christine A. Curtis PhD, Genetics Representative
Joseph F. Pulliam MD, Hematopathology Representative
Jane S. Gibson PhD, Hematopathology Representative
Donna M. Wolk PhD, Infectious Diseases Representative
Jeffrey D. Wisotzkey PhD, Infectious Diseases Representative
Federico Monzon MD, Solid Tumors Representative
Neal Lindeman MD, 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

- Analytical evaluation of genotyping assays – AMP guideline for membership, available on the website (members-only). The guideline is a brief practical reference to be used during the validation process. Additionally, a sample summary checklist is provided as a template.
Status: completed (November 2009)
- CPC created a comprehensive table of AMP publications on practice guidelines/guidances. This index of AMP Guidelines/Guidances and Position Statements & Letters is available on the public website under

“Clinical Practice Committee Comments and Projects” and below the link to “>>Press Releases” at <http://www.amp.org/Gov/Positions.htm>
Status: completed (November 2009)

- CPC commented to the CAP regarding their KRAS POET report
Status: completed (January 2010)
- In September of 2010 AMP, CAP and IASLC have joined forces to create practice guidelines for non-small cell lung cancer testing
Status: Active
- CPC provided input to the House Science and Technology Committee (to Rep. Gordon) regarding the need for and priorities in the development of NIST reference materials (June 2009). Since then, the House Science and Technology subcommittee reported their component of the America Competes Act. The language does not authorize funding for standards development, so AMP efforts on the appropriations front continue to be important. Mary Williams, Jennifer Leib and CPC and PRC members continue to work on authorization and appropriations and continue the dialogue with NIST.
Status: Active

Publications/Presentations

- Muralidharan, K., Wilson, R.B., Ogino, S., Nagan, N., Curtis, C., Schrijver, I.: AMP Position Statement on population carrier screening for Spinal Muscular Atrophy. In press, J Mol Diagn., 2010
Status: completed (In press as of July 15, 2010)
- Nagan, N., Faulkner, N.E., Curtis, C., Schrijver, I.: Laboratory Guidelines for Detection, Interpretation and Reporting of Maternal Cell Contamination (MCC) in Prenatal Analyses: A Report of the Association for Molecular Pathology. In press, J Mol Diagn., 2010
Status: completed (In press as of August 22, 2010)
- Analytical evaluation of genotyping assays – an AMP guideline for our membership, available on the website (members-only). The guideline is a brief practical reference to be used during the validation process. Additionally, a sample summary validation checklist is provided as a template.
Status: completed (October 2009)

Projects, active

Genetics (Narasimhan Naqan and Christine Curtis)

- Cytogenetic characterization (karyotypes) of cell lines that are commonly used in clinical genetic labs as controls for assays. CPC is discussion this with ATCC.

Hematopathology (Joseph Pulliam and Jane Gibson)

- Concerns about IP and possible monopolies for hematopathology assays

Infectious Disease (Donna Wolk and Jeffrey Wisotzkey)

- AMP is developing guidelines for ID panel grouping through its “hybrid” Respiratory Pathogen Working Group. The priority is assessment of utility and billing codes for influenza testing. The second priority will be assessment of utility of viruses in the Resp. panels via literature review (planned for publication in JMD).

Solid tumors (Federico Monzon and Neal Lindeman)

- MSI testing manuscripts (*Bill Funkhouser*):
A 1st paper will include a broader range of mismatch repair defects beyond Lynch Syndrome.
A 2nd paper will explore the detection of Lynch Syndrome patients by screening of extra-colonic tumors.
Status: Active
- Practice guidelines for tissue fixation. A manuscript is in preparation regarding the effects of ischemia and fixation on DNA, mRNA, and microRNA.
Status: Active

Other

- AMP formed a new, clinical practice-driven “hybrid” committee: the Whole Genome Analysis Working Group, which has a variety of members from AMP, including from the CPC and the PRC. It is chaired by Jane Gibson.
Status: Active
- CPC formed a new International Working Group and conducted a survey among international AMP members to assess needs and to determine how AMP can reach out to and serve the international molecular pathology community. The International Affairs Working Group (IAWG) was approved by Council (Chair, Patrik Vitazka) and assigned to the Membership and Professional Development Committee.
Status: Active
- Synoptic reporting. Ad Hoc member Ira Lubin leads a project on the reporting of genetic test results. Authored by a group of those who have been directly involved in past work, including Jean Amos Wilson, Elaine Lyon, and Vicky Pratt, who have also been past members and chairs of the CPC. The current CPC has provided input.
Status: Active, manuscript resubmitted
- Clinical utility project. A CPC working group has proposed a “road map” on how AMP could proceed when payers pose questions about test utility and reimbursement. The working group outlined the steps that should be followed when a request is received from third party payers. Now, the Utility Project Working Group (Neal Lindeman) has expanded and is using the MGMT assay as a pilot test. A manuscript is in preparation.
Status: Active
- Creation of a Nomenclature Database (with standard nomenclature and the common names), to be posted on the AMP website (members only). Nearly completed during 2010.
Status: Active

Requests from the CPC

- We encourage all AMP members to alert council or appropriate committees when laboratory guidelines or recommendations are opened for public comment.
- We encourage AMP members to actively contribute to calls for information from the CPC.

Economic Affairs Committee (EAC)

COMMITTEE MEMBERS:

Jeffrey A. Kant MD PhD, Chair
Elaine Lyon PhD, Professional Relations Committee Liaison (*ex officio*)
Aaron D. Bossler MD PhD, Member and PCC Representative
Samuel Caughron MD PhD, Member
Jill Hagenkord MD, Member
Roger D. Klein MD JD, Member
Jan A. Nowak MD PhD, Member
Paul A. Raslavicus MD, Member
Linda Sabatini PhD, Member
Michele Schoonmaker PhD, Member
Jon ten Bosch PhD, Junior Member

Committee Activities

1. CPT Code Proposals

- a. **CPT Coding Reform and the AMA CPT Molecular Workgroup:** As noted in this report to Council last year, momentum has been growing for a 'fix' of a number of problems with CPT coding for non-molecular microbiology tests (not that there are some problems in that area also). Indeed, EAC has spent a very large amount of time this year discussing these issues in conjunction with the activities of a Workgroup put together by the AMA CPT Editorial Panel last fall in whose activities a number of EAC members are participating.

The major impetus for the Workgroup is payer complaints that the current system of 'stacking' codes (83890 – 83914) are non transparent. Payers do not know what services they are paying for. Moreover, high units of service for individual codes (e.g. for an assay requiring many amplification reactions such as full gene sequencing, or many probes such as a multi-mutation screening assay) are an area of payer confusion and suspicion.

Because of AMA confidentiality requirements, specifics of Workgroup activities cannot be discussed until authorized by AMA, but as indicated above, AMP has provided intellectual and ground-level input into this process including the suggestions for reform of the CPT system which were discussed last year at the Committee update at the AMP Business Meeting.

- b. **Influenza CPT Codes:** Three new CPT codes for Influenza A, influenza B, and subtyping of influenza virus samples, such as the pandemic H1N1 strain, will debut in 2011 thanks to AMP EAC efforts in 2009 to draft and submit a code change proposal. Codes were not available when this report was prepared but in general format they include: 875XX1 for testing directed at a single strain, 875XX2 for testing directed at two strains as a multiplex assay, and 875XX3 for each additional virus tested beyond 2 when the multiplex code is used. Jan Nowak served as the point person for this submission.

As part of the valuation process for these new codes on the Clinical Laboratory Fee Schedule, EAC proposed accommodating the lower practice expense associated with testing for 'each additional' target in single multiplex format assays, a format that is becoming increasingly popular. The approach is to crosswalk 'each additional target' to the sum of an amplification (83898) and a probe (83896) code. We are awaiting final determination and announcement on code values as this report is submitted. An update will be provided if available at the AMP Business Meeting.

- c. **Multiplex Respiratory Virus Panels:** EAC has worked with the Respiratory Panel Work Group (RPWG) of the Clinical Practice Committee over this past year and has assembled recommendations and literature from that group for a CPT code change proposal. At the moment, for the most part these services are being paid in many jurisdictions at multiples of the number of organisms tested.
- d. **Medically Unlikely Edits (MUEs):** EAC has responded to proposed values for MUEs and has drafted a specific response to a proposed MUE for manual microdissection (88381) on the Physician Fee Schedule.

- e. **Whole genome analysis workgroup:** EAC discussed with representatives of this new AMP workgroup the sorts of issues which will need to be addressed to obtain a CPT code for whole genome sequence analysis by next generation sequencing technologies.
- f. **More formal ongoing relationship to the CPT Editorial Panel:** EAC drafted a letter of application to AMA that AMP become a member of the CPT Health Care Professionals Advisory Committee to AMA CPT. The Committee has discussed AMP obtaining formal Advisor status to AMA CPT; this would require at least 50% of physician members of AMP to also be members of AMA.

2. Coverage Policy actions

- a. **'Overzealous coverage decisions':** EAC's hope (and expectation) is with CPT code reform in the near future that non-molecular microbiology tests currently coded using the 'stacking' procedural codes issues with narrowly-drawn coverage policies excluding many legitimate tests for non-included ICD codes will greatly diminish. AMP members, particularly in the Northwest have been successful in working with Medicare contractors to obtain at least partial relief.
- b. **Professional component billing for PhDs:** While not a coverage policy action per se, EAC has devoted considerable effort in 2010 working toward crafting a coalition and strategy to obtain favorable Congressional action establishing appropriately trained PhD laboratorians interpreting molecular assays as "qualified healthcare practitioners" for professional component billing. Several conference calls and face-to-face meetings have been held to discuss the issues and strategy, and it has been very encouraging to see the collegiality of MDs and PhDs working on this issue. Language is being drafted for introduction in the new Congressional session.
- c. **MEDCAC:** AMP has provided representatives to speak to meetings of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). A member of AMP EAC is also a voting member of MEDCAC.

3. Legislative and healthcare reform-related activities

- a. **Wyden amendment:** This report noted AMP efforts last year with other groups to forestall the 'Wyden amendment' which would allow independent (non-hospital) laboratories to bill Medicare immediately outside of the disease related group (DRG) payment for a hospitalized patient for 'new technology' tests performed on samples acquired while a patient was in-hospital. Such tests are currently payable as long as they are requested and performed 14 days after patient discharge. The Wyden amendment is basically an earmark designed to benefit certain boutique laboratories offering new technology tests. Despite opposition from AMP and other groups, the Wyden amendment was included in the healthcare reform bill which passed Congress in early 2010, however as a demonstration project. Regulations governing the demonstration projects are expected to be available sometime in the first half of 2011. The language is drawn such that it may be possible for laboratories not strictly in the biotechnology setting but with new technology tests to participate.
- b. **Kennedy personalized medicine bill:** EAC commented on a section dealing with reimbursement in the draft of a bill (The 'Genomics and Personalized Medicine Act of 2010) sponsored by representative Patrick Kennedy, who chose not to seek re-election in the 1st Congressional District, Rhode Island. We do not know if this bill will be picked up by another legislator(s) for the upcoming Congress.
- c. **Personalized Medicine Coalition (PMC):** AMP is a member of the Personalized Medicine Coalition, a group whose primary focus is on biotechnology company interests in providing services for personalized medicine. AMP EAC has provided a representative to participate in conference calls regarding coding and reimbursement issues for new technologies and assays of interest to the PMC. The PMC have circulated an issue brief draft which proposes a completely new system from the current one for obtaining and submitting billing codes as well as their reimbursement for tests involving new technology. AMP feels at this time we are probably best off refining some of the concepts articulated within the current system.

4. Education and Communication with members

- a. **Coding and Coverage Corner:** In addition to periodic reports in the AMP Newsletter, EAC has established the 'Coding and Coverage Corner,' a Newsletter sidebar for articles on issues of potential Economic Interest for AMP members. CCC did background research to offer updated information on the

appropriateness of using CPT codes 83904 of 83909 together for DNA sequencing which was published in the AMP spring Newsletter.

- b. **Webinar:** The EAC Chair provided a webinar to AMP members on September 30, 2010 to review the basics of CPT coding for molecular assays.
- c. **Coding Conundrums:** EAC will again host an early bird session (November 19, 7:00 AM) at the AMP 2010 Annual Meeting to discuss areas of coding confusion or interest for meeting attendees.

EAC would again like to acknowledge assistance provided through an unrestricted grant from Abbott Diagnostics which has provided support for Committee activities including attendance at CPT Editorial Panel Meetings and at meetings of the professional coalition seeking to obtain qualified healthcare practitioner status for PhD laboratorians interpreting molecular assays.

Membership & Professional Development Committee (MPDC)

COMMITTEE MEMBERS:

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

Nominating Committee

COMMITTEE MEMBERS:

Jan A Nowak MD PhD, Chair
Min Fang MD PhD, Genetics Representative
Thomas J Monroe PHD, Genetics Representative
John W. Longshore PhD, Hematopathology Representative
Domnita Crisan MD PhD, Hematopathology Representative
Jeanne Carr PhD, Infectious Diseases Representative
Preeti Pancholi PhD, Infectious Diseases Representative
Deborah Dillon MD, Solid Tumors Representative
Catherine Dumur PhD, 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 Annual Report (11-2009 through 11-2010)

PRC Members: Continuing members for this committee are Elaine Lyon, Chair, Roger Klein, Chair-elect, Jean Amos Wilson, Vicky Pratt, Jan Nowak, Tim O'Leary, Roberta Madej, Shelby Melton, Andrea Ferreira-Gonzalez. Four new members who joined the committee in February are Daniel Sabbath, Stephen Day, Rajyasree Emmadi and Daniel Farkas. The committee reflects representation from a variety of scientific, institutional and commercial backgrounds. All members have agreed to serve next year.

AMP Professional Relations Committee's role is to communicate and coordinate activities with the appropriate government, patient, and professional organizations to inform policy discussions that influence the practice of molecular pathology. This year, we have interacted with and commented to the following organizations:

MEDCAC: AMP responded to MEDCAC's request for comments regarding usefulness of pharmacogenetic tests for oncology, namely, *Her2*, *bcr/abl*, *CYP2D6*, *K-Ras* and *UGT1A1*. We surveyed AMP membership, and your responses formed the basis of AMP's comments. Jan Nowak developed the survey and presented for AMP at MEDCAC's meeting in January.

SACGHS: AMP presented comments to the SACGHS meeting several times each year. In February, AMP endorsed the SACGHS Report on *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* and urged the SACGHS to finalize the report with the recommendations as they stood. SACGHS did finalize the existing recommendations during that meeting.

In June, we presented comments (drafted by the Training & Education Committee) on Genetics Education and Training of Health Care Professionals, Public Health Providers, and Consumers, emphasizing post-doctoral training programs for laboratory professionals and recommending that pathologists and qualified laboratory professionals be included in the report. Comments included the need for adequate reimbursement for genetic testing and interpretation of genetic test results.

The charter for SACGHS was not renewed and at the Committee's very last meeting in October, AMP presented comments on the challenges associated with clinical applications of whole genome sequencing. AMP also commented on the need for provider training and education to enable clinicians to interpret and best utilize genomic information in their practices.

FDA: PRC responded to the FDA's **IVDMIA Final Guidance**, emphasizing points from our statements previously developed. AMP encouraged the agency to use the rulemaking process to complete this guidance and encouraged them to use an external advisory committee to classify tests based on risk.

On June 24th, the FDA's held a public workshop on **Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development**. Our PRC industry members prepared comments, requesting that the FDA be "clear and consistent" with their regulation of IVDs. Mark Sobel presented verbal comments that day, and written comments were submitted.

Our members with background in cytogenomic microarrays responded to the FDA public meeting **Array-Based Cytogenetic Tests: Questions on Performance Evaluation, Result Reporting and Interpretation**, held on June 30th. We stressed the higher resolution of the array-based methods than traditional methods and emphasized that testing is performed in the context of patient phenotype and interpreted in collaboration with the clinical scientist and treating physician. The working group also addressed specific questions posted by the FDA. Oversight of laboratory developed tests has been a high-profile issue. The PRC developed a statement outlining the value of laboratory developed tests (LDTs), as a mainstay of clinical testing. The statement was taken to the FDA as talking points for our visit with them in January, when we requested a meeting with the FDA and laboratory stakeholders. The FDA held this meeting on July 19-20, focusing on the **Oversight of Laboratory Developed Tests**. This two-day forum began by the FDA introducing their concerns and stating that all options were on the table. Elaine Lyon read AMP's position, and AMP President, Karen Mann, was part of a panel discussion and reinforced our position. Press coverage by GenomeWeb was very favorable to AMP (<http://www.genomeweb.com/blog/fda-has-three-ldt-cards-play-how-will-it-play-them>). Since then AMP has been part of a multi-laboratory association coalition that has requested further discussions with the FDA. A meeting has been set for November 22nd.

NIH: NIH called for comments regarding a **Genetic Test Registry**. Vicky Pratt developed a CHAMP survey regarding the use of the GTR that formed the basis of our comments. We provided an overview of elements our members deemed important to include in a registry. We met with Kathy Hudson and Jim Ostell at the NIH and relayed concerns that members had expressed and discussed our points in person. The PRC further responded to specific questions, and Elaine Lyon presented these at a half-day forum held November 2nd.

NIST: Karen Mann presented at a NIST advisory committee meeting where the director of the agency was present. She also participated in their discussion over the mission of the agency and future goals.

On the Hill: We are progressing with "Hill Days" with our government relations consultant, Jennifer Leib from HealthFutures. We've made significant progress with AMP's language being accepted by the appropriations committee to fund NIST for molecular standards – advocacy we are performing on behalf of the Clinical Practice Committee, which first brought this issue to the attention of Congress. Karen Mann provided testimony to the

House Science and Technology Committee Subcommittee on Technology and Innovation regarding how NIST can serve the needs of the Biomedical Research Community. Her testimony is posted on the House committee's website. We have met with Senate and House office staff discussing gene patents, LDTs, appropriate regulation, strengthening CLIA molecular standards and reference material, and the Genetic Test Registry. We offer AMP's help in reviewing draft legislation on health care-related bills. Some of the offices AMP has visited include those of Senator Arlen Specter, Congresswomen Debbie Wasserman Schultz, Senator Ron Wyden, Senator Orrin Hatch, Congresswomen Anna Eshoo, Senator Mike Enzi and Senator Tom Harkin.

All of the comments and statements to these organizations are on the AMP website.

Program Committee

COMMITTEE MEMBERS:

Barbara A. Zehnbauer PhD, Chair
Jennifer Hunt MD MEd, Chair-Elect
Arlene Buller-Burckle PhD, Genetics Subdivision Chair
D. Brian Dawson PhD, Genetics Subdivision Chair-Elect
Timothy C. Greiner MD, Hematopathology Subdivision Chair
Charles E. Hill MD PhD, Hematopathology Subdivision Chair-Elect
David H. Persing MD PhD, Infectious Diseases Subdivision Chair
Randall T. Hayden MD, Infectious Diseases Subdivision Chair-Elect
Loren Joseph MD, Solid Tumors Subdivision Chair
George J Netto MD, Solid Tumors Subdivision Chair-Elect
Steven C. Cook MT(ASCP), Technical Topics Representative
Dawn R. Maghakian MS MP(ASCP) CLSp(MB), Technical Topics Representative

Publications Committee

Committee Members (Voting)

Ted E. Schutzbank PhD, D(ABMM), Chair
Qiulu Pan MD PhD, CHAMP Moderator
Bernadette Wildemore MD PhD, Associate CHAMP Moderator
Timothy L. O'Leary 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

Publications

AMP-Owned Manuscripts

Two AMP-owned papers have been reviewed and will appear in the January 2011 edition of JMD ("Population Carrier Screening for Spinal Muscular Atrophy: A Position Statement of the Association for Molecular Pathology" and "Laboratory Guidelines for Detection, Interpretation and Reporting of Maternal Cell Contamination (MCC) in Prenatal Analyses: A Report of the Association for Molecular Pathology")

AMP Affiliated Articles

Characterization of 107 genomic DNA reference materials for CYP2D6, CYP2C19, CYP2C9, VKORC1, and UGT1A1: A GeT-RM and Association for Molecular Pathology collaborative project (November JMD).

Published in the *Molecular Edge* special feature of *Advance for Medical Laboratory Professionals*:

- *HPV Genotyping*
S. Terrence Dunn, PhD
- *CDx for Drug Eligibility*
Federico A. Monzon, MD
- *Expanding Role of HLA Labs*
Lawrence Jennings, MD, PhD
- *Mainstream Adoption of MDx*
Kerri Weinert et al
- *Molecular Testing for Brain Tumors*
Dimitri (Yuri) Trembath, MD, PhD, FCAP

Pending Publication

- *Will the microscope be displaced by molecular pathology and molecular diagnostic tools?*
Suzanne K. Coberly, MD

Advance articles scheduled through July, 2011

Issue	Author	Title
January	Roberta Sitnik, PhD	<i>The clinical utility of hepatitis genotyping</i>
March	Bernadette Wildemore, MD	<i>Molecular microbiology - will culture-based methods become obsolete</i>
May	Rodney Shackelford, DO, PHD	<i>KRAS diagnostic testing</i>
July	Dahui Qin, MD, PhD	<i>Micro-satellite instability and cancer</i>
September	Carrie Cresenzi, MS	<i>Lab Automation for Molecular Diagnostic Testing</i>
November	Mary C. Lowery Nordberg PhD	TBD

Web Editorial Board

The *Web Editorial Board* successfully launched the newly designed AMP website in April, 2010. The website has an all new look, which is much better organized, and significantly easier to navigate than the previous version.

AMP Test Directory

The *AMP Test Directory* is currently being redesigned. Alexis Carter MD is heading this effort, and is currently working on the redesign of the database, which is the back-bone of the directory.

Web Library

The Web Library has been updated with the AMP presentations from the 2010 USCAP meeting. Two new sections have been added to the Library Resources tab. The first is the collection of all AMP sponsored webinars. The second is the collection of *Molecular Case Study Learning Modules* produced by the Training and Education committee. Both of these new sections provide an excellent educational resource for our membership. One major disappointment is the lack of participation by AMP members with respect to posting educational materials in the form of power point presentations to the Library. The publications committee is discussing ways to motivate membership participation in this regard.

JMD

Tim O'Leary MD, PhD started his tenure as the new EIC of JMD in 2010. Fred Barr MD, PhD and Vicky Pratt, PhD are assisting Tim as the new associate editors. Manuscript submissions continue to rise over 2009 levels with a new record of over 234 submissions. Mark Sobel and his colleagues at AMP/ASIP have successfully negotiated a contract with Elsevier to become the publisher of JMD.

CHAMP

Qiulu Pan MD, PhD took up his duties as CHAMP Moderator in 2010. Assisting Qiulu is Bernadette Wildemore MD who was appointed as the CHAMP Associate Moderator.

Newsletter

The electronic version of the AMP Newsletter continues to be a success. The Co-Editors, Teresita Redondo MD and Marlene Sabbath-Solitare PhD, are continuing to find ways to get increased member involvement for submission of special feature articles. One such article, *Gene Patents, What Now*, by Roger Klein MD, JD, was published in the May issue.

Strategic Planning Committee

COMMITTEE MEMBERS:

Debra G. B. Leonard MD PhD, Chair

Kenneth Bahk PhD

Russel K Enns PhD

Karen L Kaul MD PhD

Steven A Schichman MD PhD

Timothy J O'Leary MD PhD, President-Elect and Liaison to Council (*ex officio*)

The Strategic Planning Committee carries out long range assessments regarding opportunities and challenges in the molecular pathology profession and other environments that affect AMP interests.

Training & Education Committee

Committee Members

Karen Weck, MD, Chair

Linda Jeng, MD, PhD, Genetics Representative

Caroline Astbury PhD, Genetics Representative

Megan S. Lim, MD, PhD, Hematopathology Representative

Y. Lynn Wang MD PhD, Hematopathology Representative

Carol Holland, PhD, Infectious Diseases Representative

Janice Matthews-Greer PhD, Infectious Diseases Representative

Jennifer Laudadio, MD, Solid Tumors Representative

Tina Edmonston MD, Solid Tumors Representative

Dara Aisner MD PhD, Junior Member

Alexander Craig MacKinnon MD PhD, Junior Member

Projects:

Webinars (Subcommittee co-chairs Jennifer Laudadio and Linda Jeng)

The committee hosted seven webinars in 2010, an increase from five webinars in 2009. Partial financial support was provided for three webinars from external corporations: Illumina (7/21/10), Nanosphere (8/30/10), and

iKaryos Diagnostics (12/9/10). A series of post webinar questions was instituted in May, 2010 to monitor achievement of success (1-5 ranking with 5 being the best):

Q1. How well did the webinar meet your educational objectives?

Q2. Rate your overall satisfaction with the content of the webinar.

Q3. Rate your overall satisfaction with the quality of the presentation format.

Date	Topic	Speaker	Attendance (Registered)	Attentiveness (%)	Evaluation - (Education/Content /Quality)
2/23/2010	Microsatellite instability testing in colon cancer	Antonia Sepulveda, MD, PhD	214 (336)	76.49	n/a
4/29/2010	Molecular testing in AML with normal cytogenetics	Stephen Nimer, MD	244 (346)	71.22	n/a
5/20/2010	Interpretation of Copy Number Changes	Karen Tsuchiya, MD	213 (312)	71.25	4.34 / 4.44 / 4.50
7/21/2010	Molecular diagnosis of hospital acquired infections	Duane Newton, PhD	221 (335)	69.10	4.30 / 4.37 / 4.47
8/30/2010	Lessons Learned from the H1N1 Pandemic	Christine Ginocchio, PhD	139 (226)	48.17	4.35 / 4.51 / 4.58
9/30/2010	Molecular Coding and Billing 101	Jeffrey Kant, MD, PhD	233 (345)	72.5	4.37/ 4.41/ 4.32
12/9/2010	Genomic Arrays in Pediatric Oncology	Jaclyn Biegel, PhD	TBD	TBD	TBD

Overall, the webinar program has been quite successful, with an average attendance of 211 participants per webinar in 2010, increased from an average attendance of 179 in 2009, and an average overall evaluation rating of 4.44 out of 5.0. The committee plans to host five to ten webinars in 2011 and has compiled a list of suggested topics and speakers.

Outreach Course

For the past several years, the T&E committee has organized an outreach course held just prior to annual meeting which is geared to community pathologists and others with little experience in molecular diagnostics. This year the course is entitled "Current Applications of Molecular Pathology: Real Time Updates and Case Studies". The course includes an overview of applications of molecular pathology by invited speakers in each of the four subdivision areas (Greg Tsongalis, Iris Schrijver, Adam Bagg, Alexandra Valsamakis, Jennifer Hunt) followed by case studies presented by T&E members. As of October 7, 2010, there were 69 paid registrants for the course.

Judging of Young Investigator Awards

The T&E committee is responsible for judging the posters eligible for the three young investigator awards. This year, there were 20 eligible YIA applicants in the following subdivision areas: 6 infectious diseases, 6 solid tumors, 2 hematopathology, 1 genetics, 3 technical topics, and 2 other. As in recent years, the YIA poster submissions were required to be submitted prior to the meeting in September to allow for pre-meeting evaluation by the committee and will also be judged at the annual meeting.

Online Case Studies (Subcommittee chair Megan Lim)

The committee has sponsored a series of online case studies in Molecular Pathology that are available on the AMP website. There are currently six case studies that have been added: one in 2008, three in 2009 and two in 2010. Overall, it has been difficult to solicit volunteers to add case studies; the committee plans to evaluate the success of this program and consider whether to continue.

Trainee Exchange Program Update (Subcommittee co-chairs Tina Edmonston and Dara Aisner)

Information from approximately 1 dozen training programs has been updated with regard to potential inclusion in an informal trainee exchange program, for which relevant information will be posted on the web as a resource for interested trainees

Trainee Activities (Craig Mackinnon and Dara Aisner)

The junior members of the committee organized a trainee luncheon at the annual meeting featuring a panel discussion of recent MGP graduates with a focus on early career advice for trainees. In addition, they organized a book display and lottery featuring over 35 books, donated by individuals and publishers, to be given away at the trainee luncheon.

Routes to Certification in Molecular Pathology (Craig Mackinnon, Web Education Board Liaison)

The National Credentialing Agency (NCA) no longer offers certification in molecular diagnostics for medical laboratory professionals. The NCA merged this past year with the American Society for Clinical Pathology (ASCP) to form a single certification agency for medical laboratory professionals called the ASCP Board of Certification, which offers certification as a Medical Technologist in Molecular Biology (MB). This information was updated on the AMP website.

Review Courses

The committee oversees the implementation and evaluation of several review courses and AMP companion courses. An AMP-AACC course entitled "Molecular Pathology Essentials: Principles and Practice" was offered in May, 2010, featured 21 speakers, and received an overall course evaluation of 4.27 out of 5.0; the AACC has requested that a similar course be offered in 2011. The College of American Pathologists program committee requested suggestions for two to three AMP-sponsored courses at the CAP 2011 annual meeting; the committee solicited course proposals from the AMP membership and suggested three AMP sponsored courses for the CAP 2011 meeting, which will be finalized in November 2010. The MGP Board Review Course, directed by Kevin Halling, is held every other year and will take place in from April 28 - May 1, 2011 in Washington DC.