AMP 2011 Committee Annual Reports

COUNCIL MEMBERS:
Timothy J. O'Leary MD PhD, President
Iris Schrijver MD, President-Elect and Liaison to the Strategic Planning Committee
Karen Mann MD PhD, Past President and Nominating Committee Chair
Ted Schutzbank PhD, Secretary-Treasurer and Publications Committee Chair
Janina Longtine 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
Jennifer Hunt MD MEd, Program Committee Chair
Daniel Farkas PhD, Program Committee Chair-Elect
Karen Weck, MD, Training and Education Committee chair
D. Brian Dawson PhD, Genetics Committee Chair
Charles Hill MD PhD, Hematopathology Subdivision Chair
Randall Hayden MD, Infectious Diseases Subdivision Chair
George J. Netto MD, Solid Tumors Subdivision Chair

***EX OFFICIO* COUNCIL MEMBER:**
Mary Steele Williams MNA MT(ASCP)SM, Executive Director

Clinical Practice Committee (CPC)

COMMITTEE MEMBERS:
Janina Longtine MD, Chair
Christine A. Curtis PhD, Genetics Representative
Siby Sebastian PhD, Genetics Representative
Jane S. Gibson PhD, Hematopathology Representative
Cyrus V. Hedvat MD PhD, Hematopathology Representative
Jeffrey D. Wisotzkey PhD, Infectious Diseases Representative
Kathleen T. Montone MD, Infectious Diseases Representative
Neal Lindeman MD, Solid Tumors Representative
Loren Joseph MD, Solid Tumors Representative
Michelle Dolan MD, *Ad Hoc* Member
William Funkhouser MD PhD, *Ad Hoc* Member
M. Fernanda Sabato Charreun MS, *Ad Hoc* Member
Patrik Vitazka MD PhD, *Ad Hoc* Member
Laura J. Tafe MD, *Ad Hoc* Member, Web Liaison

Genetics - Christine Curtis and Siby Sebastian

Cytogenetic and molecular characterization of cell line reference material for laboratory quality controls, assay development and proficiency surveys. The cell lines would be characterized for a variety of assays (karyotype, FISH, sequencing, array CGH etc). AMP is partnering with CAP Molecular Oncology and CDC's GeT-RM to achieve this. Our initial project is focused on cell lines relevant to molecular hematopathology. We are in discussion with ATCC to characterize their appropriate cell lines.

Hematopathology -Jane Gibson and Cyrus Hedvat

In collaboration with Loren Joseph, creating a commentary discussing the

impact of IP generating monopolies for hematopathology assays.

Solid Tumors – Neal Lindeman and Loren Joseph

Guideline on MSI testing has been completed under the leadership of Bill Funkhouser and is in final review at JMD.

Under AMP leadership of Neal Lindeman, AMP, CAP and IASLC are creating practice guidelines for non-small cell lung cancer biomarkers – near completion.

Under AMP leadership of Federico Monzon, AMP, CAP and ASCP are creating guidelines for colorectal carcinoma biomarkers.

Loren Joseph is the AMP representative for developing practice guidelines with the Papanicolaou Society of Cytopathology for pancreaticobiliary cytology.

AMP Mutation Nomenclature Database- Fernanda Sabato and Michelle Dolan.

Have created a prototype for a gene mutation nomenclature resource for AMP members that includes the approved gene symbol, the reference sequence/version, the nucleotide change, amino acid change (protein name), the commonly used/colloquial name and examples of standard nomenclature used for reporting. The prototype had been populated for CFTR and KRAS mutations and is available on the AMP website library. We have issued a call for additional volunteers to contribute to this valuable resource.

Whole Genome Amplification Working Group – Jane Gibson

Have completed a draft of a comprehensive, state-of-the art white paper, which covers current thoughts on next-generation sequencing and whole genome amplification as well as best practices and quality measures. Will be completed in next few months. Jane will also serve as the AMP representative on a CAP committee for NGS.

International Affairs Working Group – Patrik Vitazka

Established a draft sample exchange program on the AMP website to assist international labs in obtaining samples for lab assay development and validation.

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
Katherine Tynan PhD, Member
Jon ten Bosch PhD, Junior Member

The committee currently includes 12 members (see AMP web site). EAC provides a representative from AMP to the Pathology Coding Caucus (Aaron Bossler MD PhD). The Chair of the Professional Relations Committee (Elaine Lyon PhD in 2011, Roger Klein MD in 2012) sits on EAC *ex officio*.

The Economic Affairs Committee has been productively engaged since the last AMP Annual Meeting in several areas. The ongoing development of a new system of molecular CPT codes has involved members of EAC both on the AMA Molecular CPT Workgroup as well as behind the scenes in discussions within EAC. I don't know if members realize, but the new system adopted by the AMA CPT Editorial Panel is pretty much entirely the one developed independently by AMP EAC in 2009 as a potential 'solution' to the (lack of) transparency associated with current molecular coding using the 'stacking codes.' In a stroke of serendipity, the Editorial Panel decided a fix was essential just as the AMP work product was being completed, and the rest, as they say, is history. An update and historical reprise of this process will be sponsored by EAC Friday morning, November 18 at this year's Annual Meeting. While the new CPT codes will be published in the 2012 CPT book, they will not be adopted by CMS (and probably other payers, although we're not sure) until 2013. The placement of codes on the Clinical Laboratory or Physician Fee Schedule will also be determined in 2013. At a special meeting to discuss the new codes last July at CMS, AMP and a number of other professional societies argued for placement of most or all of these codes on the Physician Fee Schedule because the data from the large majority of such assays requires professional interpretation to be useful to a clinician.

A subgroup of EAC has led a multi-stakeholder effort involving six professional societies to get agreement on principles to support professional component reimbursement of such tests by qualified non-physician PhD laboratorians which is currently not authorized. This will require Congressional action, no small feat in the current political climate, but after over a year of hard work, we are coming down the home stretch, finalizing details and looking for members of Congress to sponsor this legislation. Look for us to have you lobby your legislator, probably early in 2012. Passage of a bill prior to a CMS decision on fee schedule placement might facilitate placement on the Physician Fee Schedule, so the large majority of AMP members have a common stake in this legislation.

Working in conjunction with a workgroup from the Clinical Practice Committee, AMP crafted a code change proposal which would lead to new codes for multiplex testing of viruses, a current area that is problematic to code. These codes could appear in the CPT book in 2013.

Having solved the coding problem for molecular, and with an eye now on payment policy for useful molecular pathology assays, EAC has embarked on an ambitious exploratory initiative to identify areas of common interest with groups we have found ourselves opposing regularly on actions in Washington. Following a productive initial session in late September with a representative of that community, we believe there is potential for significant concerted action and progress.

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, Chair
Richard Press MD PhD, Vice Chair
Shuji Ogino MD PhD, Member / Incoming Chair
Robyn Temple-Smolkin PhD, Member

Early this year AMP council made the MPDC an official committee. The task of the committee is to help AMP respond to the needs of its members and facilitate the development of leaders in the field of molecular pathology. Over the past year the MPDC has surveyed the membership to determine the factors that contribute to sustained and increased membership in AMP. We strive to meet the needs to retain and increase the membership while facilitating the involvement of members with various AMP committees and workgroups.

AMP Volunteers: The MPDC assisted in selection of volunteers for the CPC and PRC. We maintain and update the database of volunteers who have applied for various positions. Requests for volunteers for specific projects and/or committees are solicited through CHAMP. Over the past year we have had more than twenty enthusiastic volunteers involved in AMP-related committees/projects.

AMP Awards- recognition of members: In addition to the awards given at the annual meeting, the MPDC requested council to approve a new "Meritorious service Award". This special award will be given to deserving recipient(s) at the AMP annual meeting. The MPDC is in the process of formulating a second "Research Award".

Geographic and Topical Interest groups: Several groups were initiated by enthusiastic AMP members. Unfortunately these groups have dwindled and several of them are dormant. We encourage AMP members to be proactive in this area and be involved in the formation & use of interest groups to further collaborations and discussions of interest.

International relationships:
International Affairs Working group http://www.amp.org/committees/membership_prof_dev/iawg/index.cfm : This group headed by Patrik Vitazka has been instrumental in promoting visibility for AMP at the global level. The group consisting of seven members represents some of the breadth of the AMP membership. The group actively participates in the establishment of international guidelines for molecular testing and supports AMP members interested in organizing international meetings.

International meetings: Over the past year the MPDC has requested support and sponsorship from AMP for two international meetings (http://www.amp.org/othermeetings/index.cfm). The first one coordinated by Rami Mahfouz in Beirut is a Pre-Congress Molecular Pathology Workshop to be held on November 29-30, 2011 as part of the 23rd Congress of the IAP Arab Division. The second one organized by Bhiburanjan Das is an International Symposium on Molecular Pathology scheduled for January 28 7 29th in New Delhi, India. Requests for "Guidelines for AMP sponsorship at International meetings" can be directed to the chair of the MPDC.

Membership Grants: Seven international members were awarded membership grants for 2011. The recipients of these grants enjoy all of the privileges of an AMP member with online access to JMD. The complimentary registration at the annual meeting that is offered to the awardees has facilitated thie attendance and participation at the AMP annual meeting.

AMP Liaisons: The MPDC maintains a list of liaisons that serve in various capacities in related organizations. If you serve as officer(s)/representative(s) for organizations associated with molecular pathology, please contact the Chair of the MPDC Helen Fernandes (fernande@umdnj.edu) or Shuji Ogino (Shuji_Ogino@dfci.harvard.edu).

Nominating Committee

COMMITTEE MEMBERS:
Karen Mann MD PhD, Chair
Thomas J Monroe PHD, Genetics Representative
Qiulu Pan PhD, Genetics Representative
Domnita Crisan MD PhD, Hematopathology Representative
Rita M. Braziel MD, Hematopathology Representative
Preeti Pancholi PhD, Infectious Diseases Representative
Robyn Temple-Smolkin PhD, Infectious Diseases Representative
Catherine Dumur PhD, Solid Tumors Representative
Antonia Sepulveda MD 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 (PRC)

COMMITTEE MEMBERS:
Elaine Lyon PhD, Chair
Roger Klein MD JD, Chair-Elect
Jean Amos Wilson PhD, Member
Stephen P. Day PhD, Member
Rajyasree Emmadi MD, Member
Daniel Farkas PhD, Member
Andrea Ferreira-Gonzalez PhD, Member
Roberta Madej BS MS MBA, Member
Shelby Melton MD Member
Jan Nowak MD PhD, Member
Timothy J. O"Leary MD PhD, Member
Vicky Pratt PhD, Member
Daniel Sabath MD PhD, Member
Robert F. Klees PhD, Junior Member
Iris Schrijver MD, (President-Elect)

The committee reflects representation from a variety of scientific, institutional and commercial backgrounds.

The AMP Professional Relations Committee is the primary liaison between AMP and other organizations. Major responsibilities of the Committee include: 1. Communicating and coordinating activities with the appropriate government, patient, and professional organizations to inform policy discussions that influence the practice of molecular pathology, 2. Developing AMP positions on emerging issues affecting molecular pathology, 3. Interacting with a wide variety of entities, including other professional associations, Congress and U.S. Federal Agencies such as FDA, CDC, DHHS.

Department of Health and Human Services:
The PRC prepared a response to the advanced notice of proposed rule-making by the Department of Health and Human Services **"Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators."** AMP commended the agency on its efforts to streamline the regulations governing human research protections and allowing a multi-site study to use a single IRB. However, AMP has some concerns and made the following requests. 1. AMP is concerned that all

biospecimens may be considered identifiable and encourages regulators to consider a more practical approach. 2. We request that the rule include language that clearly identifies using samples for validation or verification are quality control and quality assessment activities rather than research to prevent misinterpretation.

AHRQ:
We provided comments to the Agency for Healthcare Research and Quality on the draft Technology Assessment (TA), **Update on Horizon Scans of Genetic Tests Currently Available for Clinical Use in Cancers.** In summary, we commented on their broad use of the term "genetic", requested authors to consult with subject matter experts prior to finalizing the report, requested that tests be described based on their molecular entities rather than using brand names, and requested that the TA be modified to distinguish between test manufacturers and clinical laboratories developing LDTs. In August, we also met with Dr. Gurvaneet Randhawa, the agency's Senior Advisor on Clinical Genomics & Personalized Medicine, to continue this conversation.

NIH:
The PRC responded to the request for comments regarding the **Genetic Test registry**. The main points are summarized below. 1. The format as proposed includes levels of details that may result in confusing information. The GTR should differentiate between the data elements for manufacturers, research and clinical laboratories. Some data elements address detailed issues of laboratory policy that are inappropriate for inclusion in the GTR and raise legal and liability concerns. Some data fields request information that is not relevant or useful for the purposes of the GTR. 2. The NIH has grossly underestimated the burden to provide the information as to the average number of submissions per respondent, the estimated time for submission, and the mean hourly wage for data entry. In addition, no burden estimate is included for updating the Registry as tests are improved. 3. AMP recommends several ways to minimize the burden for those submitting data such as a centralized, online location for test developers, manufacturers, and researchers, and information such as clinical validity and utility that are not laboratory-specific, but will be common among all laboratories need to be addressed in a centralized manner using materials from experts in the field.

FDA:
Meetings: In November, 2010, AMP participated in a coalition of nine professional organizations in a full-day meeting on the **Regulation of LDTs**. This meeting discussed the following topics: What constitutes an LDT? How can unique advantages of an LDT continue within FDA regulation?; Registration and Listing – Forum to discuss various alternatives to registering clinical laboratories as a medical device manufacturer and listing LDTs; and FDA Regulation of LDTs in a CLIA Framework - Forum to discuss the overlaps, gaps and possible efficiencies. PRC members **Vicky Pratt**, **Andrea Ferreira-Gonzalez** and **Elaine Lyon**, and AMP's **Mary Williams** participated in panel discussions.
In June 2011, the FDA hosted a public meeting on **"Ultra High Throughput Sequencing for Clinical Diagnostics Applications – Approaches to Assess Analytical Validity"**. AMP gave both written and oral comments. AMP's main points were 1. The FDA needs to partner with professional associations; 2 Different standards are needed for different types of applications; 3. Some aspects of analytical validity fall within the practice of medicine; 4. The FDA needs to review the analytical validity and bioinformatics together and separately.

Responses to FDA draft guidance documents: The PRC prepared responses to a number of FDA draft guidance documents. The document and summary of AMP's points are listed below.
'Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of *Clostridium difficile"*
AMP expressed concern that the guidance document may increase the cost of assay development and that some of the new requirements may not be necessary to develop high quality assays. We asked for clarification on cross-reactivity, confirmatory testing and study design.
"**Establishing the Performance Characteristics of Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant Staphylococcus aureus and Staphylococcus aureus".**
AMP requested clarification of the focus of the document, (e.g. test systems or specific assays). Further, AMP requests that the FDA provide additional clarity on the types of clinical performance data required for an application, as the descriptions of data requirements for analytical and clinical performance are conflicting.

***"*Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only: Frequently Asked Questions".**

To avoid the disruption of patient care, AMP asked the FDA carefully to consider enforcement discretion or alternative regulatory pathways to address circumstances where no FDA cleared/approved products are available, particularly for those products with limited sales volume. AMP gave several recommendations, including 1.Direct enforcement requirements for 510(k) or PMA submissions toward test kits and test systems. 2. Create a consistent and clear pathway to encourage and facilitate ASR, 510(k) or PMA applications for RUO and IUO products, with a reasonable compliance timeline. 3. Accommodations should be made to enable certain reagents such as primer or probe mixes to be sold as ASRs; 4. Clearly state the scope of the guidance.

"In Vitro Companion Diagnostic Devices"

AMP developed a position statement entitled "**Reference to Diagnostic Tests in Drug Labels'** that is available on the website. We sent a letter to Janet Woodcock, MD, Director for the Center for Drug Evaluation and Research re-stating our position. Our main point is as follows: **To promote patient safety and high quality care, AMP respectfully asks FDA to specify that diagnostics be described by the biological description of the gene or mutation on drug labels and that identification of recommended diagnostic testing not be by brand name.** We were pleased that our recommendation was included in the FDA's draft guidance; however, there were other concerns that the PRC addressed in its written comments. We reiterated that FDA's primary FDA's primary focus should be the companion biomarker rather than specific tests to measure it. We commented on the following points: 1. FDA's policy of limiting approval of novel therapeutic products linked to biomarkers to those for which an FDA cleared or approved assay is available is too restrictive. 2. Reflexive classification of tests for companion biomarkers as high risk may impede the commercial development of new assay and the advancement of new test methods. 3. Final determination of significant risk for the purposes of compliance with IDE regulations should primarily be made by the institutional review board overseeing the study. 4. Pharmaceutical and diagnostic sponsors should be required to provide data on the negative predictive value of a test used to predict drug or biologic responsiveness. 5. Pharmaceutical and diagnostic sponsors should be required to submit studies of all assays for companion biomarkers for peer reviewed publication.

CMS:

In July, AMP attended the public meeting on determining pricing for the Clinical Lab Fee Schedule. CMS decided to defer the addition of the newly formed codes for genetic tests for at least a year and instead, held a listening session on the topic. While the EAC took the lead on this issue and in the public comments, the PRC plans to meet with CMS in the future to discuss reimbursement policy including PhD billing.

<u>Capitol Hill:</u>

We continued educating congressional staff members in the House of Representatives and the Senate, focusing on issues relating to DNA patents, standardized reference materials, regulation of LDTs, and PhD billing. AMP spent numerous days on the Hill and met with more than twenty offices.

DNA patents:

We worked with Congresswoman Debbie Wasserman Schultz's (D-FL) staff on her amendment to H.R 1249, the America Invents Act, a comprehensive reform to the US patent system. The intent of the amendment was to allow testing of patented genes for the purpose of obtaining second opinions; however, the language included so many exceptions and loopholes that it failed to reach this goal and actually reinforced the patents. Fortunately, this language was removed, thanks to the great efforts of Mary Williams and Jennifer Leib, and replaced with a study to investigate the effects of gene patents on access to testing. The bill has passed both the Senate and the House, and was signed into law by President Obama. During the debate on the Senate floor, Senator Patrick Leahy stated that this legislation does not imply Congressional support for or against the gene patent case, and in doing so, mentioned AMP. And, AMP's name is now officially part of the *Congressional Record* for this vote.

LDT regulation:

We've met with congressional and senate office to discus FDA oversight of LDTs: We shared AMP's main concerns with FDA oversight as being 1. Defining risk, 2. Labeling our services as "device manufacturers" rather than "health care professionals", 3.Having oversight from two regulatory bodies, CLIA and FDA. We are in discussions with The American Clinical Laboratory Association (ACLA) regarding the possibility of introducing legislation to

clarify that LDTs remain under an enhanced CLIA rather than under the FDA. We recently received legislative language on a CLIA-centric model introduced by Rep. Burgess (R-TX) that the PRC is reviewing for content.

International:
AMP has been invited to attend an international workshop on the regulation of Genetic Testing in Leuven, Belgium, organized by the EuroGentest network. The workshop will bring together a full range of stakeholders including clinicians, scientists, industry, patient/consumer groups and policymakers. Participants include representatives from the European Commission, FDA's Office of In Vitro Diagnostics, and European Diagnostic Manufacturers Association, to name a few.

Program Committee

COMMITTEE MEMBERS:
Jennifer Hunt MD MEd, Chair
Daniel Farkas PhD, Chair-Elect
D. Brian Dawson PhD, Genetics Subdivision Chair
Ira Lubin PhD, Genetics Subdivision Chair-Elect
Charles E. Hill MD PhD, Hematopathology Subdivision Chair
James R. Cook MD PhD, Hematopathology Subdivision Chair-Elect
Randall T. Hayden MD, Infectious Diseases Subdivision Chair
Lance Peterson MD, Infectious Diseases Subdivision Chair-Elect
George J. Netto MD, Solid Tumors Subdivision Chair
Federico Monzon MD, Solid Tumors Subdivision Chair-Elect
Dawn R. Maghakian MS MP(ASCP) CLSp(MB),Technical Topics Representative
Leonard (Tad) M Holtegaard BS 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
Mary C. Lowery Nordberg PhD, Website Editor

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

- *The clinical utility of hepatitis genotyping*
  Roberta Sitnik
- Molecular microbiology - will culture-based methods become obsolete
  Bernadette Wildemore
- KRAS diagnostic testing
  Rodney Shackelford
- Micro-satellite instability and cancer
  Dahui Qin
- Lab Automation for Molecular Diagnostic Testing

Carrie Cresenzi
- Molecular Diagnostics of Thyroid or Prostate Cancer
  Rodney Shackelford

10 more publications are in the pipeline, scheduled thru July, 2013

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 presentations from the 2010 AMP meeting and the AMP presentations at USCAP 2011. Two new sections have been added to the Library Resources tab. The Webinars Tab has been continuously updated with the AMP sponsored webinars. The second is the *Molecular Case Study Learning Modules* tab was removed at the request of the T&E committee. Most of the PowerPoint presentations posted to the Library over the past several years were removed from the due to their being deemed out of date, and/or no longer relevant.

Newsletter
Terry Redondo and Marlene Sabbath-Solitaire stepped down after serving 9 years as the co-editors of the Newsletter. In recognition of their contributions to AMP, both were chosen as the first recipients of the AMP Meritorious Service Award. After a great deal of discussion, it was decided to discontinue the newsletter in its present form, pending the launch of CHAMP 2.0. It is anticipated that the new social networking site will be a more timely and efficient vehicle for disseminating information to the AMP membership.

Publications Committee
In advance of the implementation of CHAMP 2.0, the Publications Committee started discussions on future role of the Committee, and how it will best serve the organization regarding oversight of communications. It is expected that the end result could be a significant change to the current structure and function of the Publications Committee.

Strategic Opportunities Committee (Formerly Strategic Planning Committee)

COMMITTEE MEMBERS:
Karen L Kaul MD PhD, Chair
Kenneth Bahk PhD, Member
Russel K Enns PhD, Member
Steven Gutman MD MBA, Member
Steven A Schichman MD PhD
Iris Schrijver MD, President-Elect and Liaison to Council (*ex officio*)

The Strategic Opportunities 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
Caroline Astbury PhD, Genetics Representative
Amrik Sahota PhD, Genetics Representative
Y. Lynn Wang MD PhD, Hematopathology Representative

Sara Taylor PhD, Hematopathology Representative
Janice Matthews-Greer PhD, Infectious Diseases Representative
Melinda Poulter PhD, Infectious Diseases Representative
Tina Edmonston MD, Solid Tumors Representative
Kathy A. Mangold PhD, Solid Tumors Representative
Nikoletta Sidiropoulos, MD, Junior Member
Cecilia Yeung, MD, Junior Member
Alexander Craig MacKinnon MD PhD, *ad hoc* Member, Web Liaison

Projects:

Webinars
The online webinar series was launched by T&E in 2009 and has continued to grow. The committee hosted nine webinars in 2011, with another one planned for December 2011 or early 2012. Partial financial support was provided for four webinars from external corporations. In addition, the T&E committee co-sponsored a series of four webinars hosted by Asuragen on BCR-ABL quantitation and standardization on the International Scale. Overall, the webinar program has been quite successful, with an average attendance of 240 participants per webinar in 2011, and an average overall evaluation rating of 4.45 out of 5.0. See page 3 for a summary of 2011 webinars.

Molecular Pathology 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 individuals with little experience in molecular diagnostics. Last year, a poll of participants indicated that the majority of participants attended the annual meeting following the course. 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 (Greg Tsongalis, Iris Schrjiver, Adam Bagg, Alexandra Valsamakis, Jennifer Hunt) followed by case studies presented by T&E members. As of October 19, 2011, there were 74 paid registrants for the course, which represents an increase of 7% from 2010.

Molecular Curriculum Task Force
The T&E committee has selected a molecular curriculum task force as recommended by council. The chair of the task force is Charlie Hill. The task force consists of the four outgoing subdivision chairs, a representative from the AMP council of MGP directors, and (4) individuals selected from a list of volunteers. Ted Schutzbank, as incoming chair of the Training and Education Committee, will be an *ex oficio* member. The major goals of the task force are 1) to write a publication (presumably for JMD) on a recommended curriculum for education in molecular pathology and genomics for pathology residents and 2) to present a draft curriculum proposal at the 2012 USCAP meeting in March. The task force will report their progress to the Training and Education committee.

Manuscript on Routes to Certification in Molecular Pathology
A working group of the T&E committee has written a manuscript to describe the various routes available for certification in molecular diagnostics: *A.C. Mackinnon, Jr., Y. L. Wang, A. Sahota, C.C. Yeung, and K.E. Weck, Certification in Molecular Pathology in the United States: A 2011 Update from the Association for Molecular Pathology Training and Education Committee.* This manuscript is an update to a 2002 T&E publication (*Killeen AA, et al. Certification in Molecular Pathology in the United States J Mol Diagn 2002*) and has been expanded to include certification and licensing requirements for laboratory technologists. The manuscript has been approved by council with recommended changes for submission to JMD.

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 26 eligible YIA applicants, which represents a 30% increase from 2010. As in recent years, the YIA posters were required to be submitted prior to the meeting for pre-meeting evaluation by the committee and will also be judged at the annual meeting.

Trainee Activities (Cecilia Yeung and Nikoletta Sidiropoulos)

The junior members of the committee organized a trainee luncheon at the annual meeting featuring a panel discussion of recent MGP graduates and a presentation by Craig MacKinnon on certification routes in molecular pathology. In addition, they organized a book display and lottery of books in molecular pathology, donated by individuals and publishers, to be given away at the trainee luncheon. Finally, the junior members organized a "take a trainee to lunch" event at the annual meeting to facilitate interaction between trainees and molecular professionals ("senior members") at the annual meeting.

RISE Exam

At the request of the American Society of Clinical Pathology, T&E selected volunteers to write exam questions for the Pathology Resident In-Service Exam (RISE). The selected RISE Question Writers are:
William Bellamy, Allison Cushman-Vokoun, Tina Edmonston, Jordan Laser, Amrik Sahota, Silvia Spitzer.

Online Case Studies Update

In past years, the committee sponsored a series of online case studies in molecular pathology on the AMP website. Overall, it was difficult to solicit volunteers to add case studies. In addition, an evaluation of website statistics indicated that the number of hits for the case studies was small and the average time spent per visit was under two minutes. Based on the low interest rate in the online case studies, the committee decided not to continue this activity.

Trainee Exchange Program Update (Tina Edmonston)

In 2009 the T&E committee began a pilot trainee exchange program that identified molecular pathology laboratories willing to host external trainees and provided a listing of programs on the AMP website (http://www.amp.org/trainee_exchange/trainee_exchange.cfm). A total of eight programs agreed to being listed in 2010. In the summer of 2011, participating laboratory directors were surveyed about their experience. Responses from five directors were received. Three of the responding laboratories were contacted by interested trainees and each hosted between 1 and 3 trainees; a few exchanges were cancelled due to travel/expense issues. The visiting trainees included residents from other programs (USA and foreign) as well as one medical technologist. It was unclear whether the trainees found the hosting laboratory through the AMP trainee exchange program or through other resources. Overall, the uptake of the trainee exchange program has been very limited, both from program directors and trainees. Comments from participating laboratory directors referred to liability issues and administrative issues that are time consuming and complicated. The committee will evaluate whether to continue this program.

Review Courses

The T&E committee oversees the implementation and evaluation of several review courses and AMP companion courses. The MGP Board Review Course, directed by Kevin Halling, takes place every other year and was held from April 28 - May 1, 2011 in Washington DC.
An AMP-AACC co-sponsored course entitled "Molecular Pathology Essentials: Principles and Practice" has been offered for the past several years. This year, the course will be from May 7-8, 2012 in Chicago. Linda Sabatini is the current AMP representative on the organizing committee.
The College of American Pathologists Program Committee requested AMP sponsored course proposals for the CAP September 2011 meeting and accepted all three courses recommended by T&E: 1) A practical guide to molecular testing in neoplastic conditions of the skin (Julia Bridge and Alexander Lazar), 2) An integrated approach to the subclassification of acute myeloid leukemia (Scott Rodig, Neal Lindeman, Olga Pozdnyak), and 3) Molecular hematopathology in the era of personalized medicine (Kojo Elenitoba-Johnson and Megan Lim). We have not yet received feedback from the CAP regarding the course evaluations.

Interest Groups and Working Groups

AMP Canadian Interest Group

Co-Chairs, AMP Canadian Interest Group:

Dr. Suzanne Kamel-Reid, PhD, DABMG, FACMG
Dr. Wenda Greer, PhD., FCCMG

Formalizing an association with AMP as an Interest group

For many years, a number of Canadian members of AMP have taken the opportunity to meet during the annual meeting to discuss common issues such as quality assurance, emerging technologies, sample exchange and patents affecting molecular diagnostics. The format of the meetings is a brief pre-meeting opportunity to mingle and meet one another followed by 2 or 3 short lectures with opportunity for discussion. Dinner is served after the lectures, with an opportunity for further discussion of topics of interest during dinner. The format of these meetings has allowed us to get to know each other on both a professional and a personal level. As these interactions are of value to Canadian members and because we would like to encourage further attendance through the AMP annual meeting we believe that formalizing our interactions as an AMP interest group would benefit both the Canadian members and AMP as a whole.

A list of members has been generated by asking all Canadian AMP members if they were interested in becoming a founding member of the AMP Canadian interest group.

Planning for the Canadian Dinner at the Annual Meeting

Dinner will be held at 7pm on Thursday, November 17 at the Gaylord Hotel after the welcome reception. This year, 2 lectures will be given, focusing on QA/QC issues specific to new technologies. For 2012, we would like to focus on developing networks to aid in standardizing testing across the provinces, through the sharing of protocols and sample exchanges. Further goals and objectives will be discussed at the meeting.

This event has been sponsored by a number of Pharmaceutical companies, including Roche Canada, Novartis Canada and Bristol-Myers Squibb Canada.

AMP Pharmacogenetics (PGX) Interest Group

Co-Leads, PGX Interest Group:

Steven Schichman
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Following a brief face-to-face meeting in San Jose, CA at the AMP Annual Meeting, an online survey was created (with the assistance of Kathleen Carmody) and announced via the CHAMP listserve. The brief survey items were designed to assess AMP members' activities and interests in PGX.
There were 93 responses, with more than 85% from individuals who were actively performing PGX testing. Other principal findings were:

- >70% were performing clinical diagnostic PGX testing.
- Nearly 25% were planning future PGX testing.

- 80% of respondents supported addressing model PGX test reports by the PGX Interest Group.
- An equal number of respondents (68%) indicated testing for somatic and inherited PGX signatures.
- More than 35 different genes were listed as PGX testing targets; 16 were involved in drug metabolism and 21 were mutated in tumors. The need for appropriate reference materials was indicated.
- Several survey responses also reported microbial drug resistance as PGX testing.
- Almost two-thirds of respondents were participating in proficiency testing or alternative quality assessment.
- Most respondents used both commercial testing kits and laboratory developed test for PGX.

These results will form the priorities for future projects of PGX Interest Group members. Model test reports and proficiency testing were top items of interest and value to members. Integration of PGX test findings into clinical decision-making will be essential to the understanding and effective use of these genetic signatures as complementary to other diagnostic testing and therapeutic drug monitoring. Some of the areas of concern identified by survey responses will also be included in a new CLSI guidance document in development focusing on Molecular Diagnostic Methods for Nonhematologic Cancers with the contributions of many AMP members. The PGX Interest Group leaders also wish to request an opportunity to post a brief item in the AMP Newsletter to keep members informed about the very active areas of regulatory, technological, and clinical PGX developments.