

AMP 2017 Committee and Subdivision Annual Reports

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COMMITTEE MEMBERS:

Chair Member Member Member Member Kojo S. J. Elenitoba-Johnson, MD Margaret Gulley, MD Marc Ladanyi, MD Ted E. Schutzbank, PhD Barbara A. Zehnbauer, PhD

PURPOSE SUMMARY:

The Awards Committee consists of 5 members (4 appointed) who oversee the nomination and selection of the recipient of the Award for Excellence in Molecular Diagnostics, the Jeffrey A. Kant Leadership Award, and, if determined applicable, the recipient(s) of the Meritorious Service Award(s). The Committee evaluates the current awards, addresses the need for new awards, and conducts the formal nomination process for potential award recipients.

The President-Elect serves as the Chair of the Awards Committee. The remaining 4 committee members are appointed by the Board and serve rotating two-year terms. The annual selection of 2 incoming committee members is conducted by the committee and the candidates' names are brought forward for Board approval and appointment.

Timeline for AMP Awards

The Awards Committee coordinated the timing of the AMP recognition awards as follows: November through February: Nominations from the Board, Committees, and Membership March: Review and selection by Awards Committee April through May: Notification of recipients May through September: Assess need for new recognition awards

Award Recipients

- 2017 Jeffrey A. Kant Leadership Award: Gregory J. Tsongalis, PhD
- 2017 Meritorious Service Award: Alexis B. Carter, MD
- 2019 Award for Excellence in Molecular Diagnostics: To be announced

AMP Clinical Practice Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair

Genetics Subdivision Representative Genetics Subdivision Representative Hematopathology Subdivision Representative Hematopathology Subdivision Representative Infectious Diseases Subdivision Representative Infectious Diseases Subdivision Representative Informatics Subdivision Representative Subdivision Representative Solid Tumors Subdivision Representative Solid Tumors Subdivision Representative Junior Member Junior Member Antonia R. Sepulveda, MD, PhD Monica Basehore, PhD Jess F. Peterson, MD David S. Viswanatha, MD Keyur P. Patel, MD, PhD Benjamin Pinsky, MD, PhD Susan Butler-Wu, PhD Mark J. Routbort, MD, PhD Mark Boguski, MD, PhD Meera R. Hameed, MD Kandelaria Rumilla, MD Ryan J. Schmidt, MD, PhD Alex Greninger, MD, PhD

PURPOSE SUMMARY:

The Clinical Practice Committee (CPC) is comprised of AMP members with expertise in one or more of the molecular specialties: infectious diseases, hematopathology, solid tumors, genetics and informatics. Its purpose is to address the challenges of clinical laboratories and, therefore, improve the service we provide. Separate working groups plan, organize and coordinate efforts such as practice guidelines, sample exchanges, reporting surveys, validation and quality control measures, and advocate for policies that will advance the practice of high quality clinical molecular pathology services.

Publications

- January 2017: Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists. Led by Marilyn Li with Michael Datto, Eric Duncavage, Shashikant Kulkarni, Neal Lindeman, Somak Roy, Apostolia Tsimberidou, Cindy Vnencak-Jones, Daynna Wolff, Ana Younes and Marina Nikiforova, The Journal of Molecular Diagnostics. (http://dx.doi.org/10.1016/j.jmoldx.2016.10.002)
- March 2017: Molecular Biomarkers for the Evaluation of Colorectal Cancer: Guideline From the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology. Led by Antonia R. Sepulveda with Stanley Hamilton, Carmen Allegra, Wayne Grody, Allison Cushman-Vokoun, William Funkhouser, Scott Kopetz, Christopher Lieu, Noralane Lindor, Bruce Minsky, Federico Monzon, Daniel Sargent, Veena Singh, Joseph Willis, Jennifer Clark, Carol Colasacco, Bryan Rumble, Robyn Temple-Smolkin, Christina Ventura, and Jan Nowak. Simultaneously published in The Journal of Molecular Diagnostics (http://dx.doi.org/10.1016/j.jmoldx.2016.11.001), American Journal of Clinical Pathology, Archives of Pathology & Laboratory Medicine, and Journal of Clinical Oncology.

 May 2017: Guidelines for Validation of Next-Generation Sequencing–Based Oncology Panels: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists. Led by Lawrence Jennings with Maria Arcila, Christopher Corless, Suzanne Kamel-Reid, Ira Lubin, John Pfeiffer, Robyn Temple-Smolkin, Karl Voelkerding and Marina Nikiforova. The Journal of Molecular Diagnostics (http://dx.doi.org/10.1016/j.jmoldx.2017.01.011)

Clinical Practice Guidelines, Working Groups, and Task Forces

- Standards and Guidelines for Validating Next Generation Sequencing Bioinformatics Pipelines: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists. AMP-led workgroup chaired by Somak Roy with Christopher Coldren, Arivarasan Karunamurthy (Junior Member, CPC), Nefize Sertac Kip, Eric Klee, Stephen Lincoln, Annette Leon, Mrudula Pullambhatla, Robyn Temple-Smolkin, Karl Voelkerding (CAP), Chen Wang (AMIA) and Alexis Carter. Manuscript submitted to The Journal of Molecular Diagnostics.
- Clinical Significance of DNA Variants in Chronic Myeloid Neoplasms (CMNs): A Report of the Association for Molecular Pathology. AMP-led working group chaired by Jennifer Crow with Rebecca McClure, Mark Ewalt, Norman Cyr, Robyn L. Temple-Smolkin, Mrudula Pullambhatla, Rachel Sargent, and Annette Kim. Manuscript submitted to The Journal of Molecular Diagnostics.
- CYP2C19 Genotyping Recommendations: A Report of the Association for Molecular Pathology. AMP-led working group chaired by Victoria Pratt, Lisa Kalman, Andria Del Tredici, Houda Hachad, Yuan Ji, Stuart Scott and Karen Weck. Manuscript submitted to *The Journal of Molecular Diagnostics*.
- In development: Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors Revision. Update and extension of the April 2013 guideline developed jointly by the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP). J. Mol Diagn. 2013:15:415-453. Manuscript submitted for simultaneous publication in The Journal of Molecular Diagnostics, Archives of Pathology & Laboratory Medicine, and Journal of Thoracic Oncology. For more information: https://www.amp.org/clinical-practice/practice-guideline/

	САР	IASLC	AMP	
Co-Chair	Philip T. Cagle, MD	Yasushi Yatabe, MD, PhD	PhD Neal I. Lindeman, MD	
Expert Panelists	Keith Kerr, MD	Erik Thunnissen, MD, PhD	Dara L. Aisner, MD, PhD	
	Mary Beth Beasley, MD	Marc Ladanyi, MD	David Kwiatkowski, MD, PhD	
	Eric Bernicker, MD	Ming S. Tsao, MD	Lynette Sholl, MD	
	Sanja Dacic, MD, PhD	Benjamin Solomon, MBBS, PhD	Maria E. Arcila, MD	

- In development: AMP Guidelines for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications. Chaired by Madhuri Hegde with Elaine Lyon, Carolyn Sue Richards and Birgit Funke.
- In development: Variant Interpretation Test Across Labs (VITAL). Chaired by Elaine Lyon with Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Sherri Bale and Glenn Palomaki. Project supported by an unrestricted educational grant from QIAGEN, Inc.
- In development: Appropriate Collection and Handling of Thoracic Specimens for Laboratory *Testing*. The College of American Pathologists (CAP) in collaboration with the American College of Chest Physicians (CHEST), Association for Molecular Pathology (AMP), American Society for Cytopathology (ASC), American Thoracic Society (ATS), Pulmonary Pathology Society (PPS), Papanicolaou Society of Cytopathology (PSC), Society of Interventional Radiology (SIR), and Society for Thoracic Radiology (STR). AMP Expert Panelist and Steering Committee member Jan Nowak; AMP Expert Panelist Dara Aisner.
- In development: *Diagnostic Testing for Diffuse Gliomas*. The College of American Pathologists in Collaboration with Association of Neuropathologists (AANP), American Society of Clinical Oncology (ASCO), Association for Molecular Pathology (AMP), Society for Neuro-Oncology (SNO), Peter Canoll, Dolores Lopez-Terrada, Meera Hameed.
- In development: AMP Guidance for Non-standard or Emerging NGS Applications: Liquid Biopsy. Chaired by Christina Lockwood with Laetitia Borsu, Christopher Gocke, Milena Cankovic, Kandelaria Rumilla, Meera Hameed, Antonia Sepulveda, Jason Merker (CAP) and Geoffrey Oxnard (ASCO).
- In development: AMP Guidance/Standards for NGS Germline Variant Confirmation. Chaired by Kristy Crooks with Linda Jo Bone Jeng, Avni Santani, Diana Mandelker, Steve Lincoln and Ryan Schmidt.
- In development: AMP NGS utility for assessment of T/B-cell clonality. Chaired by David Viswanatha with Keyur Patel, Maria Arcila and Alex Greninger.
- In development: AMP report on New Frontiers in Infectious Diseases Multiplex Testing. Chaired by Michael Lewinski with Susan Butler-Wu, Linda Cook, Kevin Alby and Jennifer Dien Bard.
- In development: *CYP2C9 Genotyping Recommendations*. Chaired by Victoria Pratt, Lisa Kalman, Andria Del Tredici, Houda Hachad, Yuan Ji, Stuart Scott and Karen Weck.

Representatives to Other Organizations

- CAP Molecular Oncology Committee, Paul Rothberg
- CAP Cancer Biomarker Reporting Committee, Deborah Dillon
- ACMG Interpretation of Sequence Variants, Julie Gastier-Foster and Elaine Lyon
- NIST Genome in a Bottle Steering Committee, Monica Basehore
- CDC Laboratory Community of Practice Work Group, Alexis Carter
- ACMG Incidental Findings in Inherited Diseases Update Workgroup, Carolyn Sue Richards
- CAP/AMP/ASCO Roundtable, Marina Nikiforova

- ACMG ClinGen Somatic Cancer Clinical Domain Workgroup, Marilyn Li
- CAP/ASCP /ASCO HER2 Testing in Gastroesophageal Adenocarcinoma Guideline project, Advisory Panelist, William Sukov
- CAP NGS Project Team, Birgit Funke
- ASCO-CAP Liquid Biopsies White paper project, Christina Lockwood
- CAP NGS Test Validation/Metrics manuscripts Working group, Marina Nikiforova
- FNIH Biomarkers Consortium Steering Committee for Inflammation and Immunity, Maria Bettinotti
- FNIH Biomarkers Consortium Steering Committee for Metabolic Diseases, Ming Rong
- FNIH Biomarkers Consortium Steering Committee for Cancer, Allison Cushman-Vokoun
- American Society of Cytopathology, Sinchita Roy-Chowdhuri
- American Society for Microbiology (ASM) Next Generation Sequencing Coalition, Benjamin Pinsky
- Joint Commission Laboratory Accreditation Program Molecular Genetic Testing Technical Advisory Panel, Monica Basehore
- Joint Commission's Professional and Technical Advisory Committee (PTAC), Martin Fleisher and Lance R. Peterson
- CAP Personalized Healthcare Committee Incidental Findings in the Context of Tumor Genomic Evaluations Project Workgroup, Pranil Chandra
- CAP Cytopathology Committee/Personalized Healthcare Committee Pre-analytics for Precision Medicine Cytology Preparations for Molecular Testing Project Team, Nikoletta Sidiropoulos and Jane Gibson

Additional Accomplishments

- AMP hosted a Reference Materials Forum prior to the 2017 Annual Meeting on Tuesday, Nov 14, 2017 with representatives from CDC, NIST, and NCI.
- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- CPC members actively brainstormed and launched four new projects in 2017. Several additional project ideas are awaiting to be launched in the near future.
- Launched the new and revamped AMP Test Directory to the AMP membership. Members can list their labs in the Directory that can be freely searched by all.
- Launched the CPC Working Group Junior Member volunteer program. This new volunteer program is designed to develop early career AMP members for future AMP organizational leadership by exposing them to volunteer opportunities related to their subject matter expertise with additional AMP governance responsibilities.

Congratulations on a job well done!

Requests from the CPC:

- We encourage all AMP members to alert the Board 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.
- Suggestions from AMP members for new CPC initiatives are always welcome! Visit <u>https://www.amp.org/clinical-practice/clinical-practice-overview/</u> for more details.

AMP Economic Affairs Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair Vice Chair, New Codes Vice Chair, Coverage Vice Chair, Pricing Member Member Member (Ex Officio – President-Elect) Member Member Member Member Member Member (Ex Officio – PRC Chair) Member Member Member Member Member Member Junior Member **Committee Advisor**

Samuel K. Caughron, MD Aaron D. Bossler, MD, PhD Richard D. Press, MD, PhD Anthony N. Sireci, MD, MS Dara L. Aisner, MD, PhD Pranil Chandra, DO Kojo Elenitoba-Johnson, MD Andrea Ferreira-Gonzalez, PhD Stephanie Hallam, PhD Mathew Hiemenz, MD Lloyd Hutchinson, PhD Loren Joseph, MD Roger D. Klein, MD, JD Elaine Lyon, PhD Jay L. Patel, MD Victoria Pratt, PhD Aparna Rajadhyaksha, MD Ester Stein, MBA Katherine Tynan, PhD Oana C. Rosca, MD Jan A. Nowak, MD, PhD

PURPOSE SUMMARY:

The Economic Affairs Committee (EAC) addresses, advises, and educates the AMP Board of Directors, membership, payors, legislators, and the public on economic issues of importance to the field of molecular pathology; prepares documents of importance to the Centers for Medicare & Medicaid Services (CMS); and develops and advocates for sound economic policies that promote the availability to patients of high quality molecular pathology services. The Committee's scope encompasses short and long-term issues associated with the coding for molecular procedures, utilization of and coverage for molecular pathology, the determination of test pricing, and the potential economic impact of public policy decisions on molecular pathology practice. The Committee interacts with the American Medical Association and other interested organizations in order to achieve common goals.

2017 ACTIVITIES:

CMS, who has oversight of Medicare, has increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests through the activities of its Medicare Administrative Contractors (MACs). The increasing restrictions create a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP continues to work with the broader professional community to address policy challenges and opportunities, and engage and inform payors aiming to achieve rightful reimbursements for appropriate patient care services.

Genomic Medicine Payor Summit

In 2016, the EAC undertook a significant initiative to bring together molecular pathology experts and payors to discuss how traditional routes for establishing coding, coverage policy and pricing apply to molecular procedures. That initiative continues and the EAC has built upon this engagement with payors in 2017. AMP finds tremendous value in these meetings as the conversations are an important opportunity for dialogue on critical issues and an ability for payors to provide input and feedback to AMP's efforts at improving the

economic landscape for molecular testing. These efforts are directed by an EAC subcommittee, led by **Dr. Sam Caughron**. In 2017, this subcommittee held two virtual summit meetings. The May summit, focused on standards for and challenges of clinical utility for molecular testing. Over 15 representatives from Medicare Administrative Contractors and private insurance companies participated in the conversation. On August 8, AMP hosted another virtual summit focusing on the clinical utility and economic issues for liquid biopsies. AMP is now building upon the interest and feedback from the May summit on clinical utility for molecular testing and has formed a focus group with payors and EAC members devoted to delving further into the clinical utility of molecular procedures. The focus group held their first meeting in October and will aim to reach consensus about the levels of evidence that are appropriate and sufficient for prognosis, diagnosis and therapy selection.

Protecting Access to Medicare Act (PAMA)

CMS released the final Protecting Access to Medicare Act (PAMA) rule in June of 2016. Under PAMA, laboratories are required to report HCPCS laboratory codes, associated private payor rates, and volume data if they have more than \$12,500 in Medicare revenues from laboratory services on the Clinical Laboratory Fee Schedule (CLFS) and receive more than 50% of their Medicare revenues from laboratory and physician services during a collection period. The first round of data reporting began in 2017 with CMS exercising enforcement discretion after the March 31, 2017 deadline until May 31, 2017, after concerns about from stakeholders that laboratories needed more time to provide data.

Established by PAMA, the Advisory Panel on Clinical Diagnostic Tests (The Panel) advises CMS on various issues under PAMA including payment rates for new tests, including whether to use crosswalking or gapfilling processes for initial price determination; application of market rates for established tests; and evaluation and designation of tests as "advanced laboratory diagnostic tests" as defined by the Act. Several AMP members were selected for the Panel, including AMP nominee **Dr. Vicky Pratt**. Dr. Pratt will rotate off the Panel in early 2018 and AMP is grateful for the invaluable input she has provided to CMS. AMP is the in process of nominating additional members to the Panel.

With the attempt to better understand applicable laboratories' experiences with the PAMA process, CMS asked for feedback on the PAMA data collection and reporting process in the CY2018 Physician Fee Schedule proposed rule. AMP provided comments to CMS expressing concerns that the onerous reporting requirements and unresolved systemic problems leave room for grave concern that final pricing will not accurately reflect payor market rates and could harm Medicare beneficiaries by reducing patient access and choices in testing, decreasing innovation, and resulting in inaccurate payment rates. AMP urged CMS to make every effort to address the concerns surrounding data collection and integrity as the new pricing structure is implemented.

Clinical Lab Fee Schedule for Calendar Year 2018

During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2018 Clinical Lab Fee Schedule (CY2018 CLFS). **Dr. Anthony Sireci** represented AMP at the annual CLFS meeting at CMS on July 31, 2017. He presented crosswalk recommendations for the new 2018 CLFS molecular pathology procedures, genomic sequencing procedures (GSPs), and microbiology procedures. There were over 35 molecular procedures on which AMP provided crosswalk recommendations.

In late September, CMS released the CY2018 CLFS Preliminary Determinations for the new and reconsidered services as well as the new private payor rate-based system mandated under PAMA. AMP appreciates that the preliminary CMS determinations abandon gapfill for all of the new and reconsidered molecular codes and instead utilizes the crosswalk method for price determination. However, we are concerned that many of the preliminary recommendations provided by CMS differ vastly from both Advisory Panel recommendations and stakeholder input and, in many cases, do not represent the best options for crosswalks. AMP provided detailed comments to CMS on the preliminary determinations in mid-October. Pricing determinations will be finalized in later this year.

Additionally, AMP provided written comment in August 2017, verbal recommendations to CMS during the Advisory Panel virtual meeting in September 2017, and follow-up written comments in October 2017 on the list of 60 CLFS test codes for which CMS received no (i.e., values of zero) and/or insufficient data to calculate a weighted median private payor rate. AMP feels that it is premature to remove any of these 60 codes from the CLFS because any perceived lack of data during the reporting period does not mean that these codes are not being used. We recommended that CMS pursue stakeholder input by adding these codes to the agenda list for the next public meeting for the CLFS in 2018 and maintaining prices at the national limitation amount (NLA) where they exist until that time. However, if this is not acceptable to CMS, we urged CMS to adopt crosswalks recommended by AMP for a handful of molecular codes on the list.

After carefully reviewing the raw data and preliminary rates calculated under the new methodology established by PAMA, AMP has serious concerns about the data used for some pricing determinations and does not believe the preliminary rates for some tests accurately reflect market based private payor reimbursement. If finalized, these rates will negatively impact patient access to timely, high quality laboratory testing for Medicare beneficiaries. To ensure continued patient access to this vital testing, AMP recommends that CMS should leave the 2017 NLA in place for codes where the validity of the data is questionable until accurate data is collected. Although comments were submitted to CMS in October, AMP is continuing to evaluate the data as more time is required to comprehensively and adequately analyze the molecular pathology codes. AMP plans to follow-up with CMS with a more extensive review of the codes later this fall.

Educational Initiatives

Healthcare economics is a complex ecosystem comprised of players in the provider space (doctors, patients, professional societies), healthcare leaders, government agencies and payors in the private sector. Navigating this space can be very difficult but is vital for molecular professionals, particularly laboratory directors, to understand. In 2017, a workgroup formed within the EAC, led by **Drs. Dara Aisner and Anthony Sireci**, to develop a manuscript that builds off of previous efforts by the EAC to educate others on molecular diagnostic coding, coverage, and reimbursement process, procedures, and policies.

Medicare Administrative Contractors' (MACs) Local Coverage Determinations (LCDs)

AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). During 2017, AMP provided responses to various MACs for over 17 draft LCDs. Many of the coverage policies released contained substantial problems, either denying or narrowing coverage for important molecular pathology procedures. Currently, AMP is in the process of drafting comments to additional draft local coverage determinations (LCDs) which will be submitted to the MACs in late November. Monitoring emerging policies continued to be a major focus of the committee and was led by **Dr. Richard Press.** AMP and the College of American Pathologists (CAP) collaborated to draft joint responses. The EAC is very thankful to the AMP members who volunteered their time and subject matter expertise to assist in responding to the diverse coverage policy issues.

Of particular note was the joint letter submitted by 6 organizations, which was developed with substantial input from volunteers from the infectious disease subdivision. AMP, together with numerous other professional societies including the American Society for Microbiology, American Public Health Laboratories, Infectious Disease Society of America, College of American Pathologists, and Pan-American Society for Clinical Virology provided comment to the various MolDx jurisdictions on their infectious disease dLCDs pertaining to gastrointestinal panels and respiratory viral panels. The American Gastroenterological Association was also a signatory on the gastrointestinal letter.

Capitol Hill and Agency Activity

Throughout 2017, AMP met with numerous offices on Capitol Hill regarding concerns about Medicare coverage and pricing, including majority and minority staff of Senate Finance and House Ways and Means Committees. Additionally, AMP met with CMS representatives from the pricing and coverage groups at CMS about concerns regarding local coverage determination processes and policies.

CPT Codes

The EAC CPT Work Group, led by **Dr. Aaron Bossler**, advises on the AMP position on new CPT code proposals submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Work Group also submits new CPT code change proposals to AMA. In 2017, AMP submitted three CPT code change proposals.

Outside Organization Involvement

- **Dr. Jan Nowak** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jan Nowak, Aaron Bossler** serve on the AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- Dr. Aaron Bossler serves on the PCC, with Dr. Sam Caughron serving as Alternate.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs**. **Aaron Bossler**, **Roger Klein**, **Elaine Lyon**, and **Victoria Pratt**.

AMP Finance Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair President Past President President-Elect Member Member Member Executive Director Andrea Ferreira-Gonzalez, PhD Federico A. Monzon, MD Charles E. Hill, MD, PhD Kojo S. J. Elenitoba-Johnson, MD Sharathkumar Bhagavathi, MD Timothy T. Stenzel, MD, PhD Gail H. Vance, MD Mary Steele Williams, MNA, MT(ASCP)SM, CAE

The Finance Committee oversees AMP's financial affairs, including reviewing quarterly revenue & expense reports and recommending to the Board for approval an annual operating budget and the investment policy for the Association's assets.

AMP International Affairs Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair and Membership Affairs Liaison (Middle East) Member (Africa) Member (South Asia) Member and Professional Relations Liaison (Europe) Member (East Asia) Member (Latin America) Member and India Affiliate Liaison (South Asia) Member (Australia) Member and Korea Affiliate Liaison (East Asia) Member (Middle East) Member (Southeast Asia) Member and Training & Educ Liaison (Latin America) Member and Hong Kong Affiliate Liaison (East Asia) Member (Africa) Germany Affiliate Coordinator Assn of Indian Pathologists in North America Liaison Advisor

Rami Mahfouz, MD Adewunmi Oluseye Adeoye, MD Sheik Mohammad Khorshed Alam, PhD, MD David E. Barton, PhD Yoon-La Choi, MD, PhD Renata A. Coudry, MD, PhD Bibhu R. Das, PhD Andrew P. Fellowes, PhD Chang-Ho Jeon, MD, PhD Imran Mirza, MD Lynette Lin Ean Oon, MD Roberta Sitnik, PhD Lei Po (Chris) Wong, PhD Denis Francis York, PhD Joerg Maas Priti Lal, MD Helen Fernandes, PhD

PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- o Enhances AMP as an international organization
- o Promotes AMP's vision and mission internationally
- Facilitates international presence and participation in AMP groups and programs
- Expands excellence in education and advocacy on behalf of patients, clinicians, and lab professionals to an international audience
- o Enables the interaction of scientists and molecular pathologists in the various parts of the world

2017 ACTIVITIES:

- The inaugural 2017 Global Congress on Molecular Pathology, was held on April 3-5, 2017 in Berlin, Germany
- o AMP 2017 Annual Meeting Events
 - International Showcase Evening, "International Analysis of NGS Data: The Good & the Bad"
 - Going Global with AMP luncheon
- Selected International Trainee Travel Awardees from India and Georgia.
- o Awarded International Membership Grants to scientists from India and Nigeria.
- Welcomed new International Affiliate members, the Brazilian Society of Clinical Pathology (SBPC) and the Italian Society of Molecular Pathology.
- Accepted International Affiliate Member application from the Middle East Molecular Biology Society. Final decision in process.
- o Launched the Institutional Affiliate Member application and procedure.
- Relaunched the international Sample Exchange Program for members using the AMP Sample Exchange Community in the CHAMP platform.
- AMP speakers supported at international (non-U.S.) conferences:
 - Federico Monzon, MD at the Molecular Pathology Association of India (MPAI) 6th Annual Conference, KIIT University, Bhubaneshwar, India. Organizing Committee AMP Member: Bibhu R. Das, PhD

• Christina Lockwood, PhD at the 2017 Annual Meeting of Korean Society for Genetic Diagnostics, Seoul, Korea. Organizing Committee AMP Member: Chang-Ho Jeon, MD, PhD.

AMP Membership Affairs Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair Member International Affairs Liaison Ron M. Przygodzki, MD Betsy A. Bove, PhD Gerald Capraro, PhD Yi Ding, MD, PhD Midhat S. Farooqi, MD, PhD Katherine Geiersbach, MD Lisa M. Haley, MS Giovanni Insuasti-Beltran, MD Cynthia L. Jackson, PhD Wanda Reygaert, PhD Angshumoy Roy, MD, PhD Yaolin Zhou, MD Rami Mahfouz, MD

PURPOSE SUMMARY:

The AMP Membership Affairs Committee (MAC) provides recommendations to Board and assistance to other committees regarding matters of membership and professional development. The committee plays an important role in helping AMP respond to the needs of its members and in facilitating the development of leaders in the field of molecular pathology.

Responsibilities

- Assesses and makes recommendations that will enhance the professional development of AMP members and the benefits of AMP membership
- Provides regular and timely notification to members about opportunities for special projects within or outside of standing committees and subdivisions
- Facilitates leadership development for AMP through various initiatives such as the *ad hoc* and junior member volunteer process
- Receives requests from Chairs or Board for *ad hoc* members to work on projects and manages the volunteer application process
- Surveys member volunteers annually regarding their volunteer service experiences
- Surveys the membership periodically regarding how well their membership in AMP is meeting their needs and how well AMP is serving the needs of the profession
- Conducts a member recruitment and retention program

2017 ACTIVITIES:

- Developed a value proposition statement for AMP Membership: AMP Members are a collaborative community of laboratory professionals shaping molecular diagnostics and advancing patient care
- Designed and prepared the biennial Member Satisfaction Survey, to be distributed to members later this year.
- Designed and prepared the AMP Member Exit Survey, a survey distributed to members who choose not to renew their membership. This information helps AMP to identify reasons members might not choose to renew their membership and allows us to maximize retention of members.
- Selected the winners of the Technologist Travel Awards and Diversity Assistance Grant for 2017
- Solicited volunteers for the Career Mixers at AMP CENTRAL Program
- Planned and hosted the New Member & First Timer Lunch at the AMP 2017 Annual Meeting
- Welcomed new Trainee members who joined at the AMP Booth at the USCAP meeting with personal notes from current MAC Members.

AMP Nominating Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair

Genetics Subdivision Representative Genetics Subdivision Representative Hematopathology Subdivision Representative Infectious Diseases Subdivision Representative Infectious Diseases Subdivision Representative Informatics Subdivision Representative Informatics Subdivision Representative Solid Tumors Subdivision Representative Ex Officio Executive Director Charles E. Hill, MD, PhD D. Brian Dawson, PhD Carolyn Sue Richards, PhD Dan Jones, MD, PhD Rachel L. Sargent, MD Susan M. Novak-Weekley, PhD Jim Dunn, PhD Jorge Lemos Sepulveda, MD, PhD Brian Hanson Shirts, MD, PhD Loren Joseph, MD John Thorson, MD, PhD Federico A. Monzon, MD Mary Steele Williams, MNA, MT(ASCP)SM, CAE

PURPOSE SUMMARY:

The AMP Nominating Committee is composed of the Past President (Chair) and two representatives from each subdivision. The chair and subdivision representatives are responsible for recruiting qualified AMP members to run for elected offices. A ballot is compiled and made available for voting by all current Regular AMP members. Voting for elected offices takes place during the month of May each year.

2017 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2017 annual elections.

AMP Professional Relations Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair Vice Chair Member Member (Ex officio – President-Elect) Member Junior Member Junior Member International Affairs Committee Liaison AMP Rep. to FASEB Science Policy Committee (Ex Officio)

Roger D. Klein, MD, JD Jordan Laser, MD Linnea M. Baudhuin, PhD Kojo Elenitoba-Johnson, MD Rajyasree Emmadi, MD Jill Hagenkord, MD Robert F. Klees, PhD Eric Q. Konnick, MD Elaine Lyon, PhD Roberta Madei, PhD Shelby Melton, MD George J. Netto, MD Nirali M. Patel, MD Victoria M. Pratt, PhD Barbara Zehnbauer, PhD Amy Lo, MD Jill Murrell, PhD David E. Barton, PhD Betsy A. Bove, PhD

PURPOSE SUMMARY:

The AMP Professional Relations Committee (PRC) is the primary liaison between AMP and other organizations for public policy issues other than reimbursement, which is the purview of the Economic Affairs Committee. Major responsibilities of the Committee include:

- 1. Communicating and coordinating activities with the appropriate government offices, coalitions, trade associations, and patient and professional organizations to inform policy discussions that have an impact on 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;
- 4. Advocating for policy changes in legislation and regulation that will advance the practice of molecular pathology.

The committee membership includes individuals employed in a variety of medical, scientific, institutional and commercial capacities.

2017 ACTIVITIES:

The PRC continues to monitor the activities of, and in some cases work with, federal agencies and panels such as FDA and CMS as well as policy committees such as the Roundtable on Genomics and Precision Health at the National Academies of Sciences, Engineering, and Medicine. After extensive discussion, the committee drafts AMP's policy positions and comments to federal agencies and members of Congress. AMP's government relations consultants, Jennifer Leib, Megan Anderson Brooks, and Lindsey Trischler of CRD Associates, keep the Committee informed of all policy and legislative activity, assist in drafting policy positions, provide advice regarding advocacy strategies, and guide AMP's presence on Capitol Hill. Jennifer Leib, Megan Anderson Brooks, AMP Director of Public Policy and Advocacy, Tara Burke, and when possible, Committee or other AMP members

meet with congressional staff to educate them about issues relevant to molecular pathology, to offer AMP's expertise, and to advocate for AMP members' interests. (Note: As a 501c3 tax-exempt organization, AMP is prohibited from participating in any partisan activities and may not have a Political Action Committee (PAC). In addition, its direct and grassroots lobbying activities are limited per IRC 501h.)

Oversight of Laboratory Developed Testing Procedures (LDPs)

A major advocacy issue of 2017 continues to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). Late last year, FDA announced their decision not to finalize their draft guidance for LDPs and has deferred to Congress to provide a legislative solution moving forward. AMP remains actively engaged with legislators on Capitol Hill on this issue and maintains its position that the most reasonable and effective path forward is for Congress to insist that the CLIA program modernize, expand its current network of third party medical experts, and utilize scientific expertise from FDA and the Centers for Disease Control and Prevention (CDC) rather than relinquishing its duties regarding the accuracy and reliability of LDPs. AMP met with and provided two detailed comment letters to Reps. Buchson and DeGette on their discussion draft entitled "Diagnostic Accuracy and Innovation Act," which proposes to provide oversight to both IVDs and LDPs under one regulatory paradigm centered at the FDA. AMP's detailed comments reiterate that FDA is not the appropriate agency to regulate LDPs and highlight where FDA regulation of LDPs will drastically hinder the advancement of precision medicine and interfere with the practice of medicine.

In 2015, a working group of the Committee developed a proposal to modernize the CLIA regulations and maintain oversight of LDPs under those regulations. The proposal consists of a tiered, risk-based structure that avoids duplication of activities within and between federal agencies. Among the current proposals that have been circulated in Washington, AMP believes its proposal currently has the greatest consensus among the professional societies because it incorporates the perspectives, feedback, and requests from multiple stakeholders. In 2017, AMP reconvened the CLIA modernization workgroup to review the proposal and determine if any updates are warranted.

Patient Advocacy Group Engagement

At last year's annual meeting, AMP held its first dine and discuss event with patient groups, with the objectives of identifying and establishing relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP aimed to understand the goals and needs of the patient groups, identify ways we can work together, and effectively communicate that patient care is central to AMP members' practice. The event was incredibly well-received with both the representatives from patient groups and AMP members excited by the things that were discussed.

To build upon this momentum, AMP held Washington, D.C.-based lunch and learns in 2017, with one focusing on oncology, hosted by **Dr. Federico Monzon**, and the other focusing on inherited and rare diseases, hosted by **Dr. Linda Jeng**. A third event is in the works for infectious disease-related advocacy groups. The lunches ended with the patient groups having a better understanding of why molecular pathology needs to be better incorporated into standard of care, the hurdles to achieving that, and how they can partner with AMP to make this a reality. Additionally, AMP was able to identify ways that they can engage with the patient community in order to create the bidirectional conversation that will result in more informed patients and professional practice that reflects patients' needs. The PRC is continuing these efforts and this annual meeting and plans to continue this program in 2018.

Genetic Information Nondiscrimination Act

AMP joined over 60 other organizations in a letter to the U.S Committee on Education and the Workforce voicing opposition to H.R. 1313, the Preserving Employee Wellness Programs Act. The legislation seeks to exempt employer-based wellness programs from Genetic Information Nondiscrimination Act (GINA) and the Americans with Disabilities Act (ADA). AMP and the other organizations opposed the legislation as it would allow employers to inquire about the employees' private genetic information or medical information unrelated to their ability to do their jobs, and to impose draconian penalties on employees who choose to keep that

information private. The letter was instrumental in stalling the legislation and currently there is no Senate counterpart to this bill. AMP continues to monitor this issue.

Return of Research Results

AMP provided comment to the National Academies, Health, and Medicine's committee on the return of individual-specific research results generated in research laboratories. To help inform the work of the All of Us Research Study (a.k.a. the Precision Medicine Initiative), the NIH, FDA, and CMS have jointly sponsored this committee to request them to write a report on returning individual research results. AMP's comments supported those of the American Society for Investigational Pathology (ASIP), a major tenet being that laboratories providing results to be used in patient care should be CLIA-certified. As the committee continues to discuss this issue, AMP will continue to monitor the discussion and provide additional input to the committee.

Capitol Hill

Throughout 2017, AMP met with numerous offices on Capitol Hill regarding oversight and regulation of LDPs. Specifically, AMP met with staff for Senators Alexander, Murray, Gardner, Bennet, and Cantwell. AMP also met with staff working for Representatives Burgess, Bucshon, DeGette, Swalwell, and Jayapal.

Collaborations

AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, as well as coalition groups such as the Personalized Medicine Coalition (AMP representatives **Drs. Shelby Melton** and **Roger Klein**), National Academies of Sciences, Engineering, and Medicine Roundtable on Translating Genomic-Based Research for Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representative **Dr. Betsy Bove**), and the Cancer Leadership Council.

AMP Program Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair Chair-Elect Genetics Representative Genetics Representative Hematopathlogy Representative Hematopathlogy Representative Infectious Diseases Representative Infectious Diseases Representative Informatics Representative Informatics Representative Solid Tumors Representative Solid Tumors Representative Technical Topics Representative Technical Topics Representative Daniel E. Sabath, MD, PhD Lynne V. Abruzzo, MD, PhD William Edward Highsmith, Jr, PhD Linda Jo Bone Jeng, MD, PhD Bryan L. Betz, PhD Eric J. Duncavage, MD Amy L. Leber, PhD Belinda Yen-Lieberman, PhD Christopher D. Coldren, PhD Somak Roy, MD Alexander Craig MacKinnon, Jr, MD, PhD Lynette Marie Sholl, MD Cindy A. Meadows, MB(ASCP) Lynne Whetsell, BS

PURPOSE SUMMARY:

The Program Committee is responsible for overall planning and organization of the AMP Annual Meeting, including sessions and abstracts/posters. In addition, the Committee selects the winners of the Technologist Poster Awards.

2017 ACTIVITIES:

Programming the 2017 Annual Meeting, "Where Molecular Leads Medicine to Best Patient Care" from November 16-18, 2017 at the Salt Lake City Convention Center in Salt Lake City, UT.

AMP Publication and Communication Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair JMD Editor-in-Chief Test Directory Editor Web Editor Electronic Media Advisor Electronic Media Advisor Advisor Member JMD Managing Editor JMD Scientific Editor Jane Gibson, PhD Barbara A. Zehnbauer, PhD Alexis Carter, MD Mary C. Lowery-Nordberg, PhD Dahui Qin, MD, PhD Mohamadou Sene, BS, MB(ASCP) Shalini Verma, MD Shaochun Bai, PhD Emily Essex Chhavi Chauhan, PhD

PURPOSE SUMMARY:

The Publication and Communication Committee is comprised of appointed volunteers from the AMP membership. The task of the Committee is to review and monitor all AMP "publications," whether print or electronic. The committee communicates via monthly conference calls.

2017 ACTIVITIES:

- Solicited and reviewed submissions for the AMP/CAP TODAY Case Report Program
- Assisted the Test Directory Editor and Associate Editors on the successful launch of the newly redesigned AMP Test Directory
- Provided guidance on ways to monitor the efficacy and utility of CHAMP user groups

AMP Strategic Opportunities Committee Annual Report, 2017

COMMITTEE MEMBERS:

Chair Member Member Member Member Ex Officio Executive Director Kojo S. J. Elenitoba-Johnson, MD Steven I. Gutman, MD, MBA Ester Stein, MBA Karl V. Voelkerding, MD Andrea Ferreira-Gonzalez, PhD Roger D. Klein, MD, JD Federico A. Monzon, MD Mary Steele Williams, MNA, MT(ASCP)SM, CAE

PURPOSE SUMMARY:

The Strategic Opportunities Committee assesses the opportunities and challenges in the molecular pathology profession and other environments external to the organization that affect AMP interests.

2017 ACTIVITIES:

The Strategic Opportunities Committee carries out the activities listed below and provides relevant reports and recommendations to the Board of Directors:

- Assessing trends and activities in the broad environment external to AMP, *i.e.*, "Horizon Scanning"
- Identifying and assessing external threats that could prevent AMP from attaining its goals
- Identifying and assessing external opportunities that can help AMP attain its goals
- Identifying organizations for potential relationships that can help AMP attain its goals

COMMITTEE MEMBERS:

Chair

Genetics Subdivision Representative Genetics Subdivision Representative Hematopathology Subdivision Representative Hematopathology Subdivision Representative Infectious Diseases Subdivision Representative Infectious Diseases Subdivision Representative Informatics Subdivision Representative Informatics Subdivision Representative Solid Tumors Subdivision Representative Solid Tumors Subdivision Representative Junior Member Junior Member Medical Technologist Member Medical Technologist Member Membership Affairs Committee Liaison International Affairs Committee Liaison

Annette S. Kim, MD, PhD Avni Santani, PhD Kristy R. Crooks, PhD Jennifer Dunlap, MD Mark D. Ewalt, MD Kevin Alby, PhD Sophie S. Arbefeville, MD Jeremy P. Segal, MD, PhD Roy E. Lee, MD Anthony N. Snow, MD Anna Yemelyanova, MD Jason N. Rosenbaum, MD Jeffrey Gagan, MD, PhD Tessara Baldi, BS Barbara anderson, BS, MS Cynthia Jackson, PhD Roberta Sitnik, PhD

PURPOSE SUMMARY:

The Training and Education (T&E) Committee is comprised of representatives from each of AMP's subdivisions: genetics, hematopathology, infectious diseases, informatics and solid tumors as well as technologist representatives, junior members, and liaisons from the International Affairs and Membership Affairs Committees (IAC and MAC). It oversees important issues such as education and certification in molecular pathology and mentoring of trainees, as well as developing educational programs for different audiences.

Educational Programs

- **Molecular Pathology Outreach Course (MPOC 2017):** The T&E committee organized an annual outreach course held just prior to annual meeting on November 15, 2017, which was geared to individuals with little experience in molecular diagnostics. This year the course was entitled "AMPlicons: A Practical Molecular Toolkit and Case Studies." The course included an overview of pre-analytic considerations in molecular pathology, followed by case studies presented by T&E members that illustrated a wide range of molecular diagnostic applications.
- Molecular Genetic Pathology (MGP) Review Course: The T&E Committee identifies the Course Director for the MGP Review Course, which takes place every other year (odd years). The 2017 live course was directed by Gregory Tsongalis and was held June 1- June 4 in Bethesda, MD. An online, self-study course (a recorded version of the 2017 live course) is available through December 2018 at <u>http://amp.peachnewmedia.com/store/seminar/seminar.php?seminar=96057</u>
- Science Educator Workshop: The Science Educator Workshop was held on November 15, 2017. This all-day workshop event targeted high school and college science teachers and their students who live and/or work in the vicinity of Salt Lake City, Utah. The workshop included presentations on hot topics in precision medicine and molecular diagnostics, a panel on the career paths into the field of clinical diagnostics, and several hands-on, small group activities and teaching resources that educators could bring back to their classrooms.

• **Early Bird Sessions at the Annual Meeting - Case Studies presented by Trainees or Technologists:** The T&E committee hosts an opportunity for fellows, residents, postdocs, graduate students, or technologists who attended the AMP 2017 Annual Meeting to present an interesting and/or challenging case study during an Early Bird Session. Trainee/technologist presenters in 2017 were:

Case	Case Study: Hypertetraploid Partial	Elizabeth Barrie, PhD	Nationwide Children's Hospital,
Studies in	Molar Pregnancy Identified by	,	Columbus, OH
Infectious	Microarray and STR Analysis, with		
Diseases	Subsequent Choriocarcinoma		
and	Diagnosis		
Genetics	Case Study: Research Whole Exome	Patrick Blackburn, PhD	Rochester, MN
	Sequencing Identifies a Novel		
	SH2D1A Variant in a 51-Year-Old		
	Patient with CNS Lymphocytic		
	Vasculitis		
	Case Study: Acute Liver Failure Due	Alex Greninger, MD,	University of Washington,
	to Echovirus 9 Associated with	PhD	Seattle, WA
	Persistent B Cell Depletion from		
	Rituximab		
	Case Study: Pyrosequencing Solves	Damon R. Olson, MD	Baylor College of Medicine,
	the Case of the Conflicting Bacterial		Houston, TX
	Isolates		
Case	Case Study: A Case of MSI-high	Maryam Shirazi, MD	Columbia University Medical
Studies in	Colorectal Cancer Responsive to		Center, New York, NY
Solid	Checkpoint Blockade		
Tumors	Immunotherapy after Progression to		
	Metastatic Disease		
	Case Study: RBM10-TFE3: A	Deepu Alex, MD, PhD	Memorial Sloan Kettering
	Potential Diagnostic Pitfall Due to		Cancer Center, New York, NY
	Cryptic Intrachromosomal Xp11.2		
	Inversion Resulting in False-negative		
	TFE3 FISH Renal Cell Carcinoma		
	Case Study: Not So Ancillary: A Case	Adam Wilberger, MD	University of Colorado
	of Correction of Primary Diagnosis		Hospital, Aurora, CO
	with Molecular Studies		
	, .	Navin Mahadevan, MD, PhD	Hospital, Aurora, CO Brigham and Women's Hospital, Boston, MA

Case	Case Study: Inv(16) Incidentally	Andres E. Quesada,	The University of Texas M.D.
Studies in	Detected by Leukemia Translocation	MD	Anderson Cancer Center,
Hemato-	Panel Screen in a Patient with		Houston, TX
pathology	Therapy-related Acute Myeloid		
and	Leukemia		
Informatics	Case Study: A Confounding Case of	Aaron Atkinson, PhD	Dartmouth-Hitchcock Medical
	Polycythemia Vera		Center, Lebanon, NH
	Case Study: Identifying Patients at	Patrick Mann, MD	Washington University, St.
	Risk for Myelodysplastic Syndrome		Louis, MO
	through Next Generation		
	Sequencing of Cytopenias with		
	Equivocal or Absent Morphologic		
	Dysplasia		
	Case Study: Detection of the	Michael Alberti, MD,	Washington University, St.
	Controversial ASXL1 c.1934dupG	PhD	Louis, MO
	(p.G646Wfs*12) Insertion Variant		
	From Targeted Next-generation		
	Sequencing (NGS) Data		

• Webcasts and Recorded Online Content:

Date	Title	Speakers/T&E Moderators	
	Molecular Diagnostics Scientists: Defining, Training, Careers	Sara Taylor, PhD, MLS(ASCP), MB	
	Practice Guidelines: Molecular Biomarkers for the Evaluation of Colorectal Cancer	Antonia R. Sepulveda, MD, PhD (Anna Yemelyanova, MD)	
	HIV Diagnostics: Updates in Laboratory Testing and Algorithms Interpretation A Collaborative Educational Event Presented by AMP, PASCV and APHL	Sherry Michele Owen, PhD and Wayne Wang, MD, PhD (Esther Babady, PhD)	
	Horizons in Molecular Pathology: Cell Free DNA Testing for Cancer: Clinical Validation, Implementation and Applications	Lynette M. Sholl, MD (Anthony Snow, MD)	
	Horizons in Molecular Pathology: Dealing with Highly Homologous Genes in the Context of Medical Sequencing	Birgit Funke, PhD. FACMG (Avni Santani, PhD)	
	Horizons in Molecular Pathology: Interpretation and Reporting of Sequence Variants	Elaine B. Spector, PhD. FACMG (Kristy Crooks, PhD)	
	Global Congress Highlight : Somatic Variant Interpretation and Reporting - The Informatics Underpinning in the Light of Recent AMP Guidelines	Somak Roy, MD (Anthony Snow, MD)	
	Global Congress Highlight : Cancer Evolution as a Therapeutic Target	Mariangela Russo, PhD (Mark Ewalt, MD)	
	Global Congress Highlight : The Human Gastrointestinal Microbiome and Advances in Metagenomic Medicine	James Versalovic, MD, PhD (Sophie S. Arbefeville, MD)	

Education Initiatives

- Continuing Education credits (SAMs, CME, and CMLE): AMP offers Continuing Education credits for many of its educational activities. Accredited activities include the MGP Review Course (live and online), the MPOC, the 2017 Annual Meeting, and Recorded Online Content lectures.
- **AMP Online:** The T&E Committee and staff spent significant time designing and developing educational materials for populating the new online learning platform at <u>www.educate.amp.org</u>. Selected online educational offerings are complimentary for AMP members. Current content includes the Online MGP Review Course, the Molecular Diagnostic Toolkit and Practical Applications, 2016 Annual Meeting highlights, Global Congress highlights and webinar bundles on NGS 101 and Informatics 101.
- Target Audience Groups (TAGs): The T&E committee established TAGs within the T&E committee dedicated to the development of new educational materials to extend the positive influence and educational mission of AMP to meet the needs of molecular professionals and non-molecular audiences. The following TAGS were created: Trainees, Technologists, Oncologists, Primary Care Physicians, and the lay (non-medical) public.
- **Pocket Cards**: The T&E Committee designed "Molecular in my Pocket" reference cards with topics from the Infectious Diseases, Hematopathology, Solid Tumors and Genetics subdivisions. These cards were created to target trainees as well as oncologists/clinician audiences. These are available online, but hard copies were also distributed at the MGP Review Course, USCAP annual meeting, and AMP Central.

Trainee Activities (Residents, Fellows, and Students)

- AMP 2017 Annual Meeting
 - Annual Trainee Luncheon and Book Drawing: The T&E junior members organized table discussion topics between junior and senior faculty members at the 2017 Trainee Luncheon. Suggested discussion topics included finding securing a fellowship, career development, and research. Donated textbooks from AMP member authors were given away at the Trainee Luncheon.
- United States and Canada Academy of Pathology (USCAP)
 - o Complimentary AMP Associate Memberships were provided to 72 trainees new to AMP.

Technologist Activities

- Technologist luncheon at the Annual Meeting
- Future planning of the development and coordination of resources for technologists

Awards

- Young Investigator Awards 53 poster candidates
- Technologist Poster Awards 27 poster candidates
- International Trainee Travel Award (Supported by the Jeffrey A. Kant AMP Education Fund) Two recipients (from India and Georgia).

Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Working Group

The MGP Program Directors (MGP PD) Council consists of Dolores Lopez-Terrada (Chair), Shuko Harada (Chair-Elect), and David Wu (Past-Chair). The MGP PD Council facilitates the discussions of the MGP Program Directors Working Group and responds to the ABP and ACGME on matters related to MGP Fellowship programs. The Council is also working with the T&E Committee to launch an in-service practice exam question bank for MGP Fellows.

Curriculum Development Task Forces

- **Genomics Education for Primary Care Residents:** This Task Force is led by Laura Tafe, with T&E liaison Anthony Snow. Their task is to develop a modified basic genomics curriculum for primary care residents, *i.e.*, internal medicine, family practice, pediatrics to be submitted to a primary care-type journal. Other authors are Devon Chabot-Richards and Maria Arcila.
- **MGP Fellow Training and Curriculum in Genomics Task Force:** The Task Force, with T&E liaison members Jason Rosenbaum, Mark Ewalt, Kristy Crooks and Jeff Gagan, is in the final stages of outlining a suggested molecular pathology and genomics curriculum for fellows. Upon completion, the manuscript will be submitted to *JMD*. Authors are: Anna Berry, Alanna Church, Linda Jeng, Roger Klein, Mahesh Mansukhani, Federico Monzon, John Pfeifer, Hanna Rennert, Iris Schrijver, Laura Tafe, Vivianna Van Deerlin and David Wu.

Co-Sponsorships, Companion Meetings, and/or Collaborations

- Joint AMP Society for Hematopathology 2017 Webinar Series on the 2016 WHO Updates in Molecular Testing
- United States and Canadian Academy of Pathology (USCAP) 2017 The AMP 2017 Companion Society Symposium, "Lessons Learned in Molecular Pathology", was comoderated by James R. Cook and Cecilia Yeung:
 - Deploying Lung Cancer Molecular Pathology Guidelines in Real Life, Neal Lindeman, MD
 - Implementing Molecular Testing Guidelines for Colorectal Cancer, Antonia Sepulveda, MD, PhD
 - A Companion Diagnostic Test to the FDA for Detection of KIT D816V Mutations in Aggressive Systemic Mastocytosis, Todd Kelley, MD

An AMP-USCAP co-sponsored Special Course, *Molecular Diagnostic and Genomic Applications in Cancer: A Primer for the Pathologist*, was co-directed by George Netto, MD, and Karen Kaul, MD, PhD.

• American Society for Clinical Pathology (ASCP)

- ASCP 2017 AMP Workshop: September 6-8 in Chicago, IL: Molecular Diagnostics Primer- Basic Principles and Molecular Diagnostics Primer- Advanced Topics were presented by Annette Kim and Cecilia Yeung.
- College of American Pathologists (CAP)
 - CAP 2017 Course Presentations: October 8-11 in Washington, DC
 The WHO and Beyond: The Myeloproliferative Neoplasms was presented by Annette Kim and Todd Kelley.
- Regional/Local Conferences
 - Beaumont Symposium: September 13-14 in Troy, MI.
 Organizer: Bobby Boyanton. AMP faculty included: Maria Arcila, Sharathkumar Bhagavathi, Antonia Sepulveda and Gregory Tsongalis.
- Cambridge Health Institute (CHI) Conferences
 - o Molecular Medicine Tri-Conference, February 19-24, 2017, San Francisco
 - Short Courses:
 - NGS Assay Selection, Validation, and Compliance: Eric Duncavage, Christina Lockwood, and Shashikant Kulkarni.

- Clinical Informatics: Returning Results from Big Data: Mark Routbort, Somak Roy, and Annette Meredith.
- Keynote Session
 - Reimbursement Stories: Victoria M. Pratt, PhD, Pranil K. Chandra, DO, and Rajyasree Emmadi, MD.
 - Opening Remarks
 - Garnering Payer Support for Genomic Profiling by Demonstrating Clinical Utility
 - o NSCLC and Other Solid Tumors: Genetic Testing and Reimbursement
 - Panel Discussion
- Next Generation Dx Summit, August 15-18, 2017, Washington, DC
 - Plenary Keynote Session Panel: Washington Insight: Policy and Prediction for Diagnostics
 - Panel Discussion: Unmet Needs for Molecular Testing for Infectious Disease

• ASCO-CAP-AMP Molecular Oncology Tumor Boards

The Molecular Oncology Tumor Boards are a series of monthly user-driven discussions designed to help cancer care providers with the interpretation and understanding of tumor molecular profiling tests and studies: <u>http://university.asco.org/motb</u>. AMP collaborates with the American Society for Clinical Oncology (ASCO) and the College of American Pathologists (CAP).

• AMP Liaisons: Christopher Watt and Maria Arcila.

• ACCC-AMP Virtual Molecular Tumor Boards

AMP collaborated with the **Association of Community Cancer Centers** (ACCC) to develop a series of 12 virtual tumor boards available for on-demand viewing at: <u>http://accc-cancer.org/resources/virtual-tumor-boards.asp</u>.

• AMP Liaisons: Annette Kim and Eric Duncavage, who both spoke in the recorded webinar, "Key Concepts and Future Directions in Molecular Testing and Care Delivery" (7/19/2017).

AMP Subdivision Leadership Annual Report, 2017

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
Chair	Birgit Funke	Todd Kelley	David Hillyard	Alexis Carter	Laura Tafe
Clinical Practice Committee	Monica Basehore	David Viswanatha	Benjamin Pinsky	Mark Routbort	Meera Hameed
	Jess Peterson	Keyur Patel	Susan Butler- Wu	Mark Boguski	Kandelaria Rumilla
Nominating Committee	Brian Dawson	Dan Jones	James Dunn	Jorge Sepulveda	Loren Joseph
	Carolyn Sue Richards	Rachel Sargent	Susan Novak- Weekley	Brian Shirts	John Thorson
Program Committee	William Edward Highsmith	Bryan Betz	Amy Leber	Christopher Coldren	Alexander McKinnon, Jr
	Linda Jo Bone Jeng	Eric Duncavage	Belinda Yen- Lieberman	Somak Roy	Lynette Sholl
Training &	Avni Santani	Jennifer Dunlap	Kevin Alby	Jeremy Segal	Anthony Snow
Education Committee	Kristy Crooks	Mark Ewalt	Sophie Arbefeville	Roy Lee	Anna Yemelyanova

SUBDIVISION LEADERSHIP

PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair and Representatives to the Clinical Practice, Nominating, Program, and Training & Education Committees. Subdivision Chairs are responsible for the successful operation and development of the subdivision that they lead.

Each Subdivision Leadership group meets quarterly and functions in an AMP advisory panel of discipline-specific subject matter experts convened to address issues of importance to their Subdivision. They carry out their subdivision leadership responsibilities by:

- Identifying and ascertaining the needs of the Subdivision membership and of the discipline itself
- Discovering, vetting, and recommending projects to the Clinical Practice Committee, Training and Education Committee, or other relevant committee
- Providing input and suggestions regarding content for the Annual Meeting and other educational events
- Assisting to identify and recommend future AMP volunteers and leaders

2017 ACTIVITIES

<u>Genetics</u> - Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, including next-generation sequencing and whole genome and exome sequencing, pharmacogenomics and mitochondrial disease.

<u>Hematopathology</u> - Addressed topics in molecular hematopathology, including advances in translational research related to hematologic malignancies, next-generation sequencing and immunology.

Infectious Diseases

Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including nextgeneration sequencing and emerging molecular infectious disease testing platforms. Hosted additional special sessions on unmet needs in infectious disease diagnostics and a technologist roundtable focused on troubleshooting in a molecular infectious diseases lab. Developed and hosted ID Town Hall at the AMP 2017 Annual Meeting to engage AMP ID Subdivision members regarding challenges and opportunities for the infectious diseases community and explore how AMP might best address them.

Subdivision members assisted the Economic Affairs Committee greatly in providing input on a multi-society response to two Palmetto MoIDx (and other MoIDx jurisdictions) draft local coverage determinations (LCDs) for foodborne gastrointestinal panels and respiratory viral panels.

<u>Informatics</u> - Addressed topics related to clinical applications and development of validation guidelines for nextgeneration sequencing bioinformatics pipelines for somatic variants and other developments in clinical molecular informatics.

<u>Solid Tumors</u> - Addressed topics related to clinical applications and development of next-generation sequencing validation guidelines for somatic variants and other evidence-based clinical practice guidelines projects.

Subdivision members provided invaluable assistance to the Economic Affairs Committee on drafting responses to Palmetto MolDx (and other MolDx jurisdictions) on three solid tumor-related draft LCDs. These included comprehensive genomic profiling for advanced primary peritoneal, fallopian tube, and ovarian cancer, comprehensive genomic profiling for metastatic melanoma, and comprehensive genomic profiling for metastatic colorectal cancer. The responses were submitted jointly with the College of American Pathologists (CAP).

Members of the Subdivision Leadership participated in a Subdivision Meet and Greet event at the Annual Meeting to engage with their respective Subdivision members and inform them of AMP's initiatives and projects in their interest areas.

Requests from the Subdivision Leadership

- We encourage all AMP members to alert their Subdivision Chair or Representatives for current or emerging specific needs that AMP should consider and address.
- We encourage AMP members to actively contribute to requests for information from their respective Subdivision Leadership.