



## AMP 2021 Committee and Subdivision Annual Reports

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President-Elect; Awards and Strategic Opportunities Committee Chair	Daniel E. Sabath, MD, PhD
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Informatics Subdivision Chair	Jason D. Merker, MD, PhD
Solid Tumors Subdivision Chair	Lawrence J. Jennings, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

## AMP Awards Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Daniel E. Sabath, MD, PhD
Member	Lynne Abruzzo, MD, PhD
Member	Alexis B. Carter, MD
Member	Megan S. Lim, MD, PhD
Member	Ronald M. Przygodzki, MD

### 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 staggered 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, if any

### Selected Award Recipients

- 2021 Jeffrey A. Kant Leadership Award: Charles E. Hill, MD, PhD
- 2021 Meritorious Service Award: Marina N. Nikiforova, MD
- 2023 Award for Excellence in Molecular Diagnostics: To be announced in Spring 2023

## AMP Clinical Practice Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Jane Gibson, PhD
Genetics Subdivision Representative	Fatimah Nahhas, PhD
Genetics Subdivision Representative	Steven M. Sperber, PhD
Hematopathology Subdivision Representative	Rashmi S. Goswami, MD, PhD
Hematopathology Subdivision Representative	Michael J. Kluk, MD, PhD
Infectious Diseases Subdivision Representative	Joseph D. C Yao, MD
Infectious Diseases Subdivision Representative	Blake W. Buchan, PhD
Informatics Subdivision Representative	Joshua F. Coleman, MD
Informatics Subdivision Representative	Elaine Gee, PhD
Solid Tumors Subdivision Representative	Susan J. Hsiao, MD
Solid Tumors Subdivision Representative	David A. Eberhard, MD, PhD
Junior Member	Andres Madrigal, MD, PhD
Junior Member	Jack Tung, 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. The AMP Clinical Practice Guidelines Program is comprised of multiple AMP-led working groups that 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. The majority of these projects include representation from other professional organizations and groups. AMP's External Representatives Program additionally fosters collaboration by providing AMP subject matter experts to clinical practice projects led by other professional organizations and groups.

### Publications

- **June 2021:** *Recommendations for Clinical CYP2D6 Genotyping Allele Selection: A Joint Consensus Recommendation of the Association for Molecular Pathology, College of American Pathologists, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, and European Society for Pharmacogenomics and Personalized Therapy.* Led by Victoria Pratt with Andria del Tredici, Andrea Gaedigk, Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Stuart Scott, Larisa Cavallari, Ann Moyer, Michelle Whirl-Carrillo, R.H.N. van Schaik and Karen Weck, *The Journal of Molecular Diagnostics.* (<https://doi.org/10.1016/j.jmoldx.2021.05.013>)

### Additional Accomplishments

- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- Multiple AMP working group projects are underway.
- CPC members actively brainstormed new project ideas. Several of these project ideas are awaiting launch next year.
- Assisted AMP Advocacy and the various Subdivisions with input for their various initiatives where applicable.
- Multiple early career AMP members working on CPC working groups as Junior members.

### 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 <https://www.amp.org/clinical-practice/clinical-practice-overview/> for more details or email [ampclinicalpractice@amp.org](mailto:ampclinicalpractice@amp.org).

### AMP Clinical Practice Guidelines Program

<b>Working Group / Task Force</b>	<b>Members</b>
Recommendations for Clinical <i>TPMT/NUDT15</i> Genotyping Allele Selection	Victoria Pratt (Chair), Larisa Cavallari, Lisa Kalman, Houda Hachad, Yuan Ji, Stuart Scott, Karen Weck, Andrea Gaedigk, Reynold Ly, Ann Moyer (CAP representative), Michelle Whirl-Carrillo (CPIC representative), Ron van Schaik (DPWG) and Makenzie Fulmer
Recommendations for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications	Madhuri Hegde (Chair), Elaine Lyon, Carolyn Sue Richards and Birgit Funke
Variant Interpretation Test Across Labs (VITAL) Inherited Conditions*	Elaine Lyon, (Chair), Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Sherri Bale and Glenn Palomaki; unrestricted educational grant support from QIAGEN, Inc.
Guidance for Non-standard or Emerging Applications: Liquid Biopsy	Christina Lockwood (Chair), Laetitia Borsu, Christopher Gocke, Milena Cankovic, Kandelaria Rumilla, Meera Hameed, Laura Tafe (CAP representative), Apostolia Tsimberidou (ASCO representative), Jonathan Earle, Jean Lopategui, Jacquelyn Reuther and Panieh Terraf
Guidance/Standards for NGS Germline Variant Confirmation	Kristy Crooks (Chair), Avni Santani, Diana Mandelker, Steve Lincoln, Kelly Hagman (NSGC representative) and Ryan Schmidt
NGS Utility for Assessment of T/B-cell Clonality	David Viswanatha (Chair), Keyur Patel, Maria Arcila, Timothy Greiner, Joseph Khoury (CAP representative), David Wu, Devon Chabot-Richards (SH representative) and Habibe Kurt
New Frontiers in Infectious Diseases Multiplex Testing	Michael Lewinski (Chair), Susan Butler-Wu, Kevin Alby, Jennifer Dien Bard, Alex Greninger, Esther Babady (PASCV representative), Duane Newton (ASM representative) and Kimberly Hanson (IDSA representative)
Guidance/Standards for Tumor Mutational Burden Testing by Molecular Methods	Larissa Furtado (Chair), Jeffrey Gregg, Benjamin Kipp, Jonathan Nowak, Susan Hsiao, Antonia Sepulveda, Ahmet Zehir, Jeremy Segal, Lauren Ritterhouse, Carlo Bifulco (SITC representative), Neal Lindeman (CAP representative), Solange Peters (ASCO representative) and Daniel Dolderer
Implementation of AMP/ASCO/CAP Reporting and Interpretation of Somatic	Marilyn Li (Chair), Somak Roy, Cindy Vnencak-Jones, Catherine Cottrell, Kai Wang and Scott Turner

<b>Working Group / Task Force</b>	<b>Members</b>
Sequence Variants Recommendations in Clinical Practice (VITAL Somatic)	
Guidance/Standards for the Use of <i>In Silico</i> Approaches for Validation of NGS Bioinformatics Pipelines	Eric Duncavage & Justin Zook (Co-chairs), Mark Routbort, Joshua Coleman, Annette Meredith, Carlos Jose Suarez, Sabah Kadri, Somak Roy (CAP representative), Monica de Baca (API representative) and Chad Vanderbilt
Molecular MRD Monitoring in Acute Myeloid Leukemia	Keyur Patel (Chair), Noah Brown, Dan Jones, Marian Harris, Rashmi Goswami, Duane Hassane, Todd Druley, Brian Parkin, Annette Kim, Christopher Watt (CAP representative), Aaron Shaver (ASH representative), David Wu (SH representative) and Harrison Tsai
Clinical Whole Exome Sequencing for Inherited Conditions as a First Line Test: Spectrum of applications and standards	Rong Mao (Chair), Birgit Funke, Pinar Bayrak-Toydemir, Jianling Ji, Megan Wachsmann, Celeste Eno, Avni Santani (CAP representative), Karen Wain (NSGC representative) and Jeffrey SoRelle
Homologous recombination deficiency (HRD) assessment using next generation sequencing (NGS)	Susan Hsiao (Chair), Lawrence Jennings, Diana Mandelker, Vera Paulson, Michelle Shiller, Tracy Stockley, Eric Vail, Anna Yemelyanova, Destin Black (ACCC representative), Ian Hagemann (CAP representative), Praveen Vikas (ASCO representative) and Kelly Devereaux
CAP/ IASLC/AMP Molecular Testing Guideline for Selection of Lung Cancer Patients for <i>EGFR</i> and <i>ALK</i> Tyrosine Kinase Inhibitors – Revision	Neal Lindeman, MD (AMP Co-Chair), Maria Arcila, MD, David Kwiatowski, MD, PhD & Lynette Sholl, MD

\* manuscript submitted to the Journal of Molecular Diagnostics

### **AMP External Representatives Program**

<b>AMP Representative</b>	<b>Collaborating Organization(s)</b>	<b>Workgroup / Committee</b>
Daniel Farkas	College of American Pathologists	Molecular Oncology Committee
Scott Topper	American College of Medical Genetics and Genomics, ClinGen, College of American Pathologists	Interpretation of Sequence Variants Update Workgroup
Monica Basehore	National Institute of Standards and Technology	Genome in a Bottle Steering Committee
Carolyn Sue Richards	American College of Medical Genetics and Genomics	Incidental Findings in Inherited Diseases Update Workgroup
Lauren Ritterhouse Ahmet Zehir	College of American Pathologists, American Society of Clinical Oncology	PD-L1 Testing in Lung Cancer Workgroup
Federico Monzon	American Society of Clinical Oncology	CancerLinQ Oncology Leadership Council
Marilyn Li	American College of Medical Genetics and Genomics, ClinGen	Somatic Cancer Clinical Domain Workgroup
Maria Bettinotti	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Inflammation and Immunity

<b>AMP Representative</b>	<b>Collaborating Organization(s)</b>	<b>Workgroup / Committee</b>
Snehal Patel	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Cancer
Christina Lockwood	Foundation for the National Institutes of Health	Biomarkers Consortium Identification and Validation of ctDNA Reference Materials Working Group
Sinchita Roy-Chowdhuri	American Society of Cytopathology	Organizational liaison
Benjamin Pinsky	American Society for Microbiology	Next Generation Sequencing Coalition
Pranil Chandra	College of American Pathologists	Personalized Healthcare Committee Incidental Findings in the Context of Tumor Genomic Evaluations Project Workgroup
Nikoletta Sidiropoulos Jane Gibson	College of American Pathologists	Cytopathology Committee/Personalized Healthcare Committee Pre-analytcs for Precision Medicine Cytology Preparations for Molecular Testing Project Team
Ryan Schmidt	College of American Pathologists	Genomic Medicine Resource Committee
Avni Santani	Clinical Laboratory Standards Institute	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition (MM09) Working Group
Frederick Nolte	Test Renaming for Understanding and Utilization (TRUU-Lab) coalition	Steering Committee
Peter Canoll Dolores Lopez-Terrada Meera Hameed	College of American Pathologists, American Association of Neuropathologists, American Society of Clinical Oncology, Society for Neuro-Oncology	Diagnostic Testing for Diffuse Gliomas Workgroup
Antonia Sepulveda	College of American Pathologists, American Society of Clinical Oncology	Checkpoint Inhibitor Testing in Body Sites Other Than Lung
Jan Nowak Dara Aisner	College of American Pathologists, American College of Chest Physicians, American Society for Cytopathology, American Thoracic Society, Pulmonary Pathology Society, Papanicolaou Society of Cytopathology, Society of Interventional Radiology, Society for Thoracic Radiology	Appropriate Collection and Handling of Thoracic Specimens for Laboratory Testing Workgroup
Eric Duncavage	Association of Community Cancer Centers	Advisory Committee

<b>AMP Representative</b>	<b>Collaborating Organization(s)</b>	<b>Workgroup / Committee</b>
Daniel Jones	Clinical Laboratory Improvement Advisory Committee (CLIAC)	Next Generation Sequencing Best Practices Forum
Christina Lockwood	BloodPAC	Advisory Committee & Analytical Validation Workgroup
Sanja Dacic	Cancer Support Community	Lung Biomarker Digital Tool Advisory Board
Lynette Sholl	NLCRT Biomarker Summit	National Lung Cancer Round Table
Frederick Nolte	Coronavirus Standards Working Group	The Joint Initiative for Metrology in Biology
Jason Rosenbaum	LUNGevity	Oncologist Friendly Reporting Project
Jane Gibson	LUNGevity	Patient Friendly Reporting Project
Dara Aisner Sinchita Roy- Chowdhuri	Association of Community Cancer Centers	Operational Pathways in Lung Cancer
Antonia Sepulveda	World Health Organization International Agency for Research on Cancer	International Collaboration for Cancer Classification and Research (IC3R)
Somak Roy	Clinical Laboratory Standards Institute	MM25 Document Development Committee on Bioinformatics “Sequencing Bioinformatics for Human Genetics and Oncology” work group

## AMP Economic Affairs Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Vice Chair, New Codes & Pricing	Jay L. Patel, MD
Vice Chair, Coverage	Pranil Chandra, DO
Member ( <i>Ad-Hoc</i> – Hemepath Subdivision Rep.)	Maria E. Arcila, MD
Member	Jennifer Dien Bard, PhD
Member	Rajyasree Emmadi, MD
Member	Jeffrey Gagan, MD, PhD
Member	Tanner Hagelstrom, PhD, MBA
Member	Mathew Hiemenz, MD
Member	Susan Hsaio, MD, PhD
Member	Lloyd Hutchinson, PhD
Member	Loren Joseph, MD
Member ( <i>Ex Officio</i> – PRC Chair)	Jordan Laser, MD
Member	Elaine Lyon, PhD
Member	Federico Monzon, MD
Member	Victoria Pratt, PhD
Member	Salvatore Priore, MD, PhD
Member	Aparna Rajadhyaksha, MD
Member	Oana C. Rosca, MD
Member ( <i>Ex Officio</i> President-Elect)	Daniel Sabath, MD, PHD
Member	Navid Sadri, MD, PhD
Member	Jennifer Sanmann, PhD
Member	Anthony N. Sireci, MD, MS
Member ( <i>Ex Officio</i> – President)	Antonia Sepulveda, MD
Member	Ester Stein, MBA
Member	Katherine Tynan, PhD
Member	Eric Vail, MD
Committee Advisor	Aaron D. Bossler, MD, PhD
Committee Advisor	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.

### 2021 ACTIVITIES:

CMS, who has oversight of Medicare, has increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests. The increasing restrictions create a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP's government relations consultants, Erika Miller, Stefanie Reinhart, and Michaela Hollis of Cavarocchi, Ruscio, Dennis Associates (CRD) provide advice regarding advocacy strategies, and help to guide AMP's relationships at

key federal agencies and on Capitol Hill. AMP continues to work with the broader professional community to address policy challenges and opportunities, and engage and inform payors who aim to achieve rightful reimbursements for appropriate patient care services. In 2021, EAC was very focused on ensuring that coverage and payment policies for COVID-19 diagnostic services were appropriate and ensured patient access to these important services.

## **COVID-19 Advocacy**

Throughout the COVID-19 pandemic, AMP has engaged in a number of ongoing education and advocacy efforts to help support the laboratory community. Since February 2021, the AMP COVID Response Steering Committee Blog has kept the AMP membership and general public informed on key issues impacting molecular professionals on the front lines of the COVID-19 pandemic. The AMP “Testing Resources for COVID-19” webpage continues to be updated with new resources enabling members to stay up to date on the most recent advances in COVID-19 diagnostic testing, including changes to regulatory policy and clinical practice announcements. Additionally, AMP has continued to routinely engage with other laboratory stakeholder groups to monitor the testing supply chain issues and discuss advocacy activities to help support the diverse clinical laboratory community. In 2021, the AMP EAC continued to advocate on reimbursement issues related to COVID-19 and the committee is the process of completing a white paper outlining key coding, coverage, and reimbursement recommendations for COVID-19 pandemic and future pandemics.

### *AMP Advocates for Reasonable Coverage Policies for Respiratory Viral Panels*

In February, AMP and the College of American Pathologists (CAP) provided a joint comment letter on a recent draft coverage policy from Medicare Administrative Contractors Novitas and First Coast. AMP and CAP asked for clarification of language regarding administrative requirements listed in the LCD and provided a list of ICD-10 codes for consideration of inclusion within the final LCD. Moreover, AMP and CAP requested allowance for coverage of panels with more than five pathogens when they are determined to be clinically warranted. The letter detailed clinical scenarios when such testing is warranted. This letter was compiled with input from Infectious Disease Subdivision Leadership. Additionally, in July, AMP, CAP and the American Gastroenterological Association (AGA) provided comments on a draft LCD from the MoIDX jurisdictions on multiplex nucleic acid amplification panels for infectious disease testing. AMP, CAP and AGA were supportive of MoIDX’s efforts to include coverage of respiratory viral panels, including those containing detection of SARS-CoV-2.

## **Advocacy Push for Appropriate Reimbursement for Professional Analysis, Interpretation, and Reporting of Molecular Diagnostic Testing Procedures**

Throughout 2020, a joint AMP workgroup with members from both the Economic Affairs Committee and the Professional Relations Committee oversaw the development and launch of a novel Professional Work survey. The survey both gathered data on the professional work that is performed to interpret a molecular diagnostic test result in the context of a patient’s history and assessed the work that is performed by MDs and qualified PhDs during molecular testing. The much-anticipated results were released in March, 2021, and will be crucial in providing data to inform discussions with payers, federal agencies, and members of Congress. The PRC and EAC will continue to actively work with many professional organizations as part of its ongoing commitment to informing and influencing public policies that ensure fair and reasonable reimbursement solutions.

## **Payer Engagement**

In 2016 and 2017, 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. In 2020, AMP organized a series of talks for a payer summit built by Illumina. In 2021, AMP decided to build upon these previous engagement and education efforts by hosting a payer engagement virtual meeting focused on hepatobiliary cancer testing. AMP found tremendous value in these meetings as the conversations are an important opportunity for dialogue on critical issues and an ability for payers 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**.

### **National Correct Coding Initiative (NCCI) Manual**

In late 2018, the National Correct Coding Initiative (NCCI) contractors and the Centers for Medicare and Medicaid Services (CMS) released revisions to the Pathology/Laboratory Services section of the NCCI Policy Manual for Medicare Services, and corresponding updates to the Policy Manual for Medicaid Services, that conflicted with current practice. In 2019 and 2020, AMP worked with a group of aligned stakeholders to have the changes withdrawn and that any future manual updates be developed in consultation with the relevant stakeholders. While the advocacy had resulted in some positive changes to the manual language, some updates remain problematic and have the potential to restrict access to medically appropriate molecular testing. In 2021, AMP continued to work with aligned stakeholders on this issue; advocacy included a sign on letter and meeting with CMS and the NCCI edit contractor.

### **Clinical Lab Fee Schedule for Calendar Year 2021**

During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2021 Clinical Lab Fee Schedule (CY2022 CLFS). **Dr. Jay Patel** represented AMP at the annual CLFS meeting at CMS on June 24, 2021. He presented crosswalk recommendations for the new and reconsidered CY2022 CLFS molecular pathology, genomic sequencing, and microbiology procedures.

Additionally, the Advisory Panel on Clinical Diagnostic Tests (The Advisory Panel) reviewed stakeholder recommendations presented to CMS in July and voted on the best approach to pricing new and reconsidered codes. The Panel was established by the Protecting Access to Medicare Act (PAMA) and advises CMS on various issues under PAMA including payment rates for new tests, including whether to use the crosswalk or gapfill methodology for initial price determination. Several AMP members are members of The Panel, with **Drs. Aaron Bossler, Elaine Lyon, and Pranil Chandra** nominated by AMP to serve.

In late September, CMS released the CY2022 CLFS Preliminary Determinations for the new and reconsidered services. While some of the preliminary CMS determinations align with AMP and other laboratory organizations' recommendations, some of the preliminary recommendations provided by CMS differ vastly from both the 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 at the end of October. Pricing determinations will be finalized later this year.

### **Medicare and Private Payer Coverage Policies**

Monitoring emerging policies continued to be a major focus of the Coverage subcommittee and was led by **Dr. Pranil Chandra**. AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). Thus far in 2021, AMP has provided responses to various MACs for approximately 8 draft local coverage determinations (LCDs). Currently, AMP is in the process of drafting comments to additional draft LCDs, which will be submitted to the MACs in November. AMP and the 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. Additionally, AMP is in the process of responding to a private payer coverage policy on next generation sequencing for cancer and inherited conditions, where AMP identified problematic parameters for these services and aims to work with the payer to update the policy to achieve a policy that better reflects the utility of these services.

### **CPT Codes**

The EAC New Codes and Pricing Subcommittee, led by **Dr. Jay Patel**, advises and reviews new CPT code applications submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Subcommittee may submit new CPT code change proposals to AMA based on member need and input. The subcommittee also provided input to CMS' National Correct Coding Initiative (NCCI) to help ensure national correct coding methodologies of procedure to procedure (PTP) and medically

unlikely edits (MUEs) for molecular procedures and is working with a broad group of stakeholders to address issues with updates to the NCCI manual.

#### **Outside Organization Involvement**

- **Dr. Aaron Bossler** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jay Patel, Joseph Yao, Aaron Bossler** serve on the AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- **Dr. Jay Patel** serves on the PCC, with **Dr. Anthony Sireci** serving as the technical advisor.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs. Anthony Sireci, Aaron Bossler, Ann Moyer, Madhuri Hegde, Jeremy Segal, Larry Jennings, and Victoria Pratt.**

## AMP Finance Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Betsy A. Bove, PhD
President	Antonia R. Sepulveda, MD, PhD
President-Elect	Daniel E. Sabath, MD, PhD
Past President	Karen Weck, MD
Member	Sharathkumar Bhagavathi, MD
Member	Steven A. Schichman, MD, PhD
Member	Xiao-Ming Yin, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

The Finance Committee oversees AMP's financial affairs, including reviewing 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, 2021

### COMMITTEE MEMBERS:

Chair and Membership Affairs Liaison (Middle East)	Rami Mahfouz, MD
Member (Africa)	Adewunmi Oluseye Adeoye, MD
Member and Professional Relations Liaison (Europe)	David E. Barton, PhD
Member (East Asia)	Benedict Yan, MBBS
Member (Latin America)	Renata A. Coudry, MD, PhD
Member and India Affiliate Liaison (South Asia)	Bibhu R. Das, PhD
Member (Australia)	Andrew P. Fellowes, PhD
Member and Korea Affiliate Liaison (East Asia)	Jin Kyung Lee, MD, PhD
Member and Training & Educ Liaison (Latin America)	Roberta Sitnik, PhD
Member and Hong Kong Affiliate Liaison (East Asia)	Lei Po (Chris) Wong, PhD
Member (Africa)	Denis Francis York, PhD
German Affiliate Coordinator	Silke Lassmann, PhD
Italy Affiliate Coordinator	Massimiliano (Max) M. Corsi Romanelli, MD, PhD
Advisor	Helen Fernandes, PhD
Advisor	Jin-Yeong Han, MD, PhD

### PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- Enhances AMP as an international organization
- 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
- Enables the interaction of scientists and molecular pathologists in the various parts of the world

### 2021 ACTIVITIES:

- Planned Global Networking session - The Impact of COVID Pandemic on Molecular Pathology Practice: The Experience of the International Community. It will be held virtually in the upcoming months.
- Selected 3 International Trainee Travel Awards to support attendees from Cyprus and India. Due to international travel restrictions, the awardees received complimentary registration to the enduring 2021 Annual Meeting sessions and materials.
- Awarded 2021 International Membership Grants to scientists from India and Nepal
- Assisted the Membership Affairs Committee in the promotion of free Associate Memberships available starting in 2021, to international trainees

## AMP Membership Affairs Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Shelby Melton, MD
Member	Kevin E. Fisher, MD, PhD
Member	Lisa M. Haley, MS
Member	Jin-Yeong Han, MD, PhD
Member	Cristiane Ida, MD
Member, Representative to Training & Education	Cynthia L. Jackson, PhD
Member	Jennifer Morrissette, PhD
Member	Irene Newsham, PhD
Member	Nikoletta Sidiropoulos, MD
Member	Jessica Thomas, MD
Member	She Yang, MD
Member	Yaolin Zhou, MD
Junior Member	Eitan Halper-Stromberg, MD
Junior Member	Talent Theparee, MD
International Affairs Liaison	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.

Ongoing Responsibilities Include:

- 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

### 2021 ACTIVITIES:

- Selected the members of the newly formed AMP Diversity, Equity, and Inclusion Working Group
- Selected the winners of the AMP 2021 Technologist Travel Awards
- Selected the winners of the AMP 2021 Underrepresented in Medicine Travel Awards
- Analyzed the Regular, Associate, and Technologist Member Satisfaction Surveys to identify ways AMP and the MAC can best serve members, and recruit new members to join
- Selected and appointed an AMP representative to the Coordinating Council on the Clinical Laboratory Workforce

- Researched and reported to the Board of Directors on the current state and future of the Technologist and laboratory workforce
- Developed committee member-driven projects to increase recruitment, retention, and member satisfaction. These ongoing projects include:
  - Using graphic design to better convey the value of membership
  - Working with the Program Committee to enhance technologist specific content at the Annual Meeting
  - Maximizing networking events at the Annual Meeting, including Speed Networking
  - Fostering membership opportunities for trainees in low income countries
  - Engaging with attendees from previous First Timers Luncheons to inform them of AMP programming throughout the year
  - Creating a comprehensive suite of projects to inform and recruit trainees as part of the new free Associate Membership program
  - Executing a review of demographic options available for new members to self-select when creating a member profile with AMP, making our member profiles more inclusive
  - Expanding AMP's microvolunteer program so that everyone who wants to share their time and expertise with AMP has an opportunity to do so.
- Worked closely with the International Affairs and Training & Education Committees to ensure that membership needs are met around the globe and through educational offerings.

## AMP Nominating Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Karen Weck, MD
Genetics Subdivision Representative	Alka Chaubey, PhD
Genetics Subdivision Representative	Jennelle C. Hodge, PhD
Hematopathology Subdivision Representative	Rena Xin, MD
Hematopathology Subdivision Representative	Marian H. Harris, MD, PhD
Infectious Diseases Subdivision Representative	Amy Leber, PhD
Infectious Diseases Subdivision Representative	Ted E. Schutzbank, PhD
Informatics Subdivision Representative	Matthew Lebo, PhD
Informatics Subdivision Representative	Julie Woolworth Hirschhorn, PhD, HCLD
Solid Tumors Subdivision Representative	Jennifer Laudadio, MD
Solid Tumors Subdivision Representative	Allison Cushman-Vokoun, MD, PhD
President	Antonia R. Sepulveda, MD, PhD
Executive Director	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 or June each year.

### 2021 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2021 annual elections.

## AMP Professional Relations Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Co-Chair	Jordan Laser, MD
Co-Chair	Eric Q. Konnick, MD
Member	Esther Babady, PhD
Member	Linnea M. Baudhuin, PhD
Member	David Bosler, MD
Member ( <i>Ex officio</i> – EAC Chair)	Samuel Caughron, MD
Member	Betty Chung, DO, MPH, MA
Member	Andria Del Tredici, PhD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Jill Hagenkord, MD
Member	Amy Lo, MD
Member	Jill Murrell, PhD
Member	George J. Netto, MD
Member ( <i>Ad-Hoc</i> – ID Subdivision Rep.)	Frederick Nolte, PhD
Member	Nirali M. Patel, MD
Member	Jason Rosenbaum, MD
Member ( <i>Ex officio</i> – President-Elect)	Daniel Sabath, MD, PhD
Member ( <i>Ex officio</i> – President)	Antonia Sepulveda, MD
Member	David Viswanatha, MD
Member	Karen Weck, MD
Member	Barbara Zehnbauer, PhD
Junior Member	Emilia Calvaresi, MD, PhD
Junior Member	Xiaoli Du, PhD
International Affairs Committee Liaison ( <i>Ex Officio</i> )	David E. Barton, PhD
AMP Rep. to FASEB Science Policy Committee ( <i>Ex Officio</i> )	Betsy A. Bove, PhD
Committee Advisor	Roger Klein, MD, JD
Committee Advisor	Elaine Lyon, 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.

## **2021 ACTIVITIES:**

The PRC continues to monitor the activities of, and in some cases work with, federal agencies 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 Jay Qiu of Innovation Policy Solutions, LLC (IPS), 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. IPS along with AMP Senior Director of Public Policy and Advocacy, Tara Burke, AMP Senior Manager of Public Policy and Advocacy, Sarah Thibault-Sennett, 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 2021 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). AMP maintains that updating the Clinical Laboratory Improvement Amendments (CLIA) oversight will preserve a flexible system that fosters innovation and is also the most streamlined, cost-effective approach to addressing clinical and analytic validity and establishing enhanced transparency.

In May, Senator Rand Paul (R-KY) re-introduced the Verified Innovative Testing in America Laboratories (VITAL) Act of 2021. AMP was supportive of the bill's re-introduction and continues to focus on growing sponsors and supporters of this bill. The legislation was a product of great dialogue following an incredibly successful meeting during AMP Advocacy Day in November 2019 and is a wonderful example of AMP member advocacy. Major provisions of the bill include:

- Clarifies that the regulation of laboratory developed testing procedures (LDPs) rests within CLIA and not the FDA, including during a public health emergency.
- Defines LDPs as a professional medical service that utilizes a laboratory examination in the context of clinical care or public health services.
- Directs CMS to hold a public meeting no later than 90 days after the enactment of this Act to solicit recommendations on ways to modernize CLIA's regulations.
- Directs the HHS Secretary to report to the Senate HELP Committee and House Energy and Commerce Committee on recommendations for updating CLIA as well as provide an assessment of the availability and utilization of LDPs during the 2020 COVID-19 pandemic response.

AMP remains actively engaged with legislators on Capitol Hill and other stakeholders on this bill. In September, AMP championed a sign-on letter in support of the VITAL Act along with the American Association for Clinical Chemistry (AACC), the Association of Pathology Chairs (APC), and the American College of Medical Genetics and Genomics (ACMG). The letter was sent to Congressional offices with an interest in this issue in September, with the support of 30 groups representing academic institutions and departments, hospitals, and health systems across the country. Additionally, in October, AMP, AACC, APC, and ACMG produced a joint webinar that discussed LDP oversight, current and anticipated activity on the Hill, and how members could get involved in advocating on this topic. Additionally, in October, AMP joined numerous other stakeholders in a request for the Clinical Laboratory Improvement Advisory Committee (CLIAC) to begin discussing CLIA modernization.

## **COVID-19 Advocacy**

Throughout the COVID-19 pandemic, AMP has engaged in a number of ongoing education and advocacy efforts to help support the laboratory community. Since February 2021, the AMP COVID Response Steering Committee Blog has kept the AMP membership and general public informed on key issues impacting molecular professionals on the front lines of the COVID-19 pandemic. The AMP “Testing Resources for COVID-19” webpage continues to be updated with new resources enabling members to stay up to date on the most recent advances in COVID-19 diagnostic testing, including changes to regulatory policy and clinical practice announcements. Additionally, AMP has continued to routinely engage with other laboratory stakeholder groups to monitor the testing supply chain issues and discuss advocacy activities to help support the diverse clinical laboratory community.

In February, AMP published the preliminary results of its “Molecular Testing for Cancer during COVID-19” survey of clinical laboratories. The anonymous survey assessed how important aspects of molecular diagnostic testing for cancer, including testing volumes, laboratory operations, clinical trial testing, patient samples, and turnaround times, were affected by the COVID-19 pandemic. The preliminary results included feedback from 163 representatives from academic medical centers, commercial reference laboratories, and community hospitals in the US and around the world. The results from this survey underscore the significant supply chain and staffing shortages that AMP reported in 2020 and show that they reverberate to molecular diagnostic testing for cancer. This survey was a joint effort of Advocacy & Clinical Practice.

In August, AMP signed on to a Cancer Leadership Coalition letter advocating that all health care employers require their workers to receive the COVID-19 vaccine and that all health care professionals accept vaccination without delay. The letter was supported by twelve other cancer patient, health care professional, and research organizations.

## **Patient Advocacy Group Engagement**

Since 2016, AMP has held “Lunch and Learn” events with patient groups, with the objective of identifying and establishing relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP aims 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 events have been incredibly well-received with both the representatives from patient groups and AMP members excited by the things that were discussed. In 2021, AMP held two virtual Lunch and Learns. In June, **Drs. Eric Konnick, Karen Weck, and Jill Murrell** discussed the results of AMP’s survey to determine how molecular diagnostic testing for cancer was affected by the COVID-19 pandemic. In August, **Drs. Esther Babady, Eric Konnick, and Jill Murrell** spoke with patients about “COVID-19 Update: Vaccines, Variants, and (Continued) Virtual Events.” Both Lunch and Learns were well attended and highly regarded by the participants.

Additionally, in early September, the Patient Engagement Subcommittee expanded the AMP patient-facing Outreach website with a new section focusing on COVID-19. The expanded website answers many questions that patients and the general public have asked about testing methodologies and the role that diagnostic testing plays in the pandemic response. The Outreach website has been very well received and the Patient Engagement Subcommittee plans to continue expanding the content on the Outreach website with educational materials for diagnostic testing for inherited disorders over the next year.

## **Advocacy Push for Appropriate Reimbursement for Professional Analysis, Interpretation, and Reporting of Molecular Diagnostic Testing Procedures**

Throughout 2020, a joint AMP workgroup with members from both the Economic Affairs Committee and the Professional Relations Committee oversaw the development and launch of a novel Professional Work survey. The survey both gathered data on the professional work that is performed to interpret a molecular diagnostic test result in the context of a patient’s history and assessed the work that is performed by MDs and qualified PhDs during molecular testing. The much-anticipated results were released in March, 2021, and will be crucial in providing data to inform discussions with payers, federal agencies, and members of Congress. The PRC and EAC

will continue to actively work with many professional organizations as part of its ongoing commitment to informing and influencing public policies that ensure fair and reasonable reimbursement solutions.

### **Gene Patents**

AMP continues to strongly advocate against efforts on Capitol Hill to revise Section 101 of the Patent Act, which defines what is and is not patent eligible. Throughout 2021, AMP has remained heavily engaged with other stakeholders and the sponsors' offices to express opposition to legislation that would abrogate Supreme Court precedent and expand patent-eligible subject matter to encompass "abstract ideas", "laws of nature", or "natural phenomena". In September, AMP submitted detailed comments to the United States Patent and Trademark Office (USPTO) in response to a USPTO patent eligibility jurisprudence study, which sought to evaluate "how the current jurisprudence has impacted investment and innovation." AMP's comments focused on case studies and highlighted the growth of molecular pathology as a practice and the positive impact on the US economy, which would both have been impossible with patents on genes.

Additionally, in June, AMP signed onto a letter to the Biden Administration, led by the American Civil Liberties Union (ACLU), expressing concern and stating opposition to any legislative or regulatory proposals that would revisit Section 101 and overturn years of court precedent. ACLU and AMP were joined by thirty-six other civil rights, medical, scientific, technology, patient advocacy, and environmental organizations.

### **Variant Data Sharing**

In July, AMP released a position statement supporting the sharing of variant data by clinical laboratories in public repositories. The free sharing of this variant data will help address health inequities, advance precision medicine, and improve clinical diagnosis and care for patients with cancer and rare inherited disorders. In developing the statement, AMP convened a working group to explore the barriers to robust clinical laboratory participation and to put forth recommendations to encourage all relevant stakeholders to promote the engagement of these practices and facilitate ease of access to this important information. In the future, AMP will continue to update recommendations and guidelines as more information becomes available.

### **Capitol Hill**

AMP continues to nurture existing and grow new relationships on Capitol Hill. Throughout 2021, AMP met with over 25 offices on Capitol Hill regarding topics including oversight and regulation of LDPs and the Coronavirus Pandemic. Additionally, AMP will be holding a Virtual Advocacy Day on December 8, 2021 to advocate for the CLIA modernization and discuss LDP oversight in the context of the Coronavirus Pandemic.

### **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. Roger Klein, and Amy Lo**), National Academies of Sciences, Engineering, and Medicine Roundtable on Genomics and Precision 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, 2021

### COMMITTEE MEMBERS:

Chair	Laura J. Tafe, MD
Chair-Elect	Nirali M. Patel, MD
Genetics Representative	Ryan Schmidt, MD, PhD
Genetics Representative	Pinar Bayrak-Toydemir, MD, PhD
Hematopathology Representative	Noah A. Brown, MD
Hematopathology Representative	Valentina Nardi, MD
Infectious Diseases Representative	Erin McElvania, PhD
Infectious Diseases Representative	Erin Graf
Informatics Representative	Ahmet Zehir, PhD
Informatics Representative	Annette Leon, PhD, FACMG
Solid Tumors Representative	Jonathan Andrew Nowak, MD, PhD
Solid Tumors Representative	Sinchita Roy Chowdhuri, MD, PhD
Technical Topics Representative	Jennifer Bergendahl
Technical Topics Representative	Ashley Elizabeth Shean, BS, MS

### 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. **Note: No poster awards this year due to virtual format.**

### 2021 ACTIVITIES:

Planned and moderated the sessions for the 2021 Annual Meeting & Expo, then converted to the Digital Experience from November 15-20, 2021 held online, along with the recorded content that will be available in January 2022.

## AMP Publications Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Larissa V. Furtado, MD
<i>JMD</i> Editor-in-Chief	Barbara A. Zehnauer, PhD
Member	Jennifer Dien Bard, PhD
Member	Juehua Gao, MD, PhD
Member	Arivarasan Karunamurthy, MBBS, MD
Junior Member	Benjamin Kukull, MD
Member	Thuy L. Phung, MD, PhD
Member	Ronald M. Przygodzki, MD
Member	Paul G. Rothberg, PhD
Member	Daniel E. Sabath, MD, PhD
Member	Patricia Tsang, MD, MBA
<i>JMD</i> Managing Editor	Emily Essex
<i>JMD</i> Scientific Editor	Chhavi Chauhan, PhD

**PURPOSE SUMMARY:** Members of the Publications Committee are appointed by the Board to serve up to six (6) two-year, renewable terms, and a junior member to serve a two-year term.

- The Publications Committee has certain responsibilities for AMP's official journal, *The Journal of Molecular Diagnostics (JMD)*, which is co-owned by the American Society for Investigative Pathology (ASIP), including advisory to AMP's Board and ASIP's Council regarding *JMD* policy issues; scope statement; business success; publisher Request for Proposal and selection; selection of Editors and Editorial Board members; performance expectations for Editors.
- The Publications Committee does not oversee *JMD*'s production or editorial functions; however, it may request or receive information and make recommendations to the Editor-in-Chief and Managing Editor.
- The Committee reviews AMP member submissions of Case Reports for potential publication in *CAP Today*.
- The Committee meets monthly by conference call, face-to-face before the annual meeting, and by electronic communication.

### 2021 ACTIVITIES:

- Solicited and reviewed AMP Case Reports submissions for potential publication in *CAP Today*.
- Solicited volunteer applications across all subdivisions for subject matter experts and a junior member.
- Discussed ways the Committee can contribute to the AMP member's professional needs and potential areas for improving *JMD* (e.g., collaborative paper, review articles).

## AMP Strategic Opportunities Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Daniel E. Sabath, MD, PhD
Member	Michael Hadjisavas, PhD
Member	Lawrence J. Jennings, MD, PhD
Member	Jordan Laser, MD
Member	Robert L. Nussbaum, MD
Member	Ester Stein, BS, MBA
Advisor	Jonathan Baden, MS
Advisor	Jill Hagenkord, MD
Advisor	Terri E. Ozegovich, BS, MBA
Advisor	Anthony N. Sireci, MD, MS
President	Antonia R. Sepulveda, MD, PhD
Executive Director	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.

### 2021 ACTIVITIES:

- Identified and assessed the opportunities and challenges in the molecular pathology profession and other environments that affect AMP interests, including:
  - external threats that could prevent AMP from attaining its goals
  - external opportunities that can help AMP attain its goals
  - organizations for potential relationships that can help AMP attain its goals
- Provided relevant recommendations to the Board of Directors

## AMP Training & Education Committee Annual Report, 2021

### COMMITTEE MEMBERS:

Chair	Nathanael Bailey, MD
Vice-Chair	Yasmine Akkari, PhD
Genetics Subdivision Representative	Honey V. Reddi, PhD
Genetics Subdivision Representative	Ying Zou, MD, PhD
Hematopathology Subdivision Representative	Nathan Montgomery, MD, PhD
Hematopathology Subdivision Representative	Amir Behdad, MD, MBA
Infectious Diseases Subdivision Representative	Gerald Capraro, PhD
Infectious Diseases Subdivision Representative	Allen Bateman, PhD, MPH
Informatics Subdivision Representative	Weiwei Zhang, PhD
Informatics Subdivision Representative	Eduardo Castro-Echeverry, MD, MPH
Solid Tumors Subdivision Representative	Lauren Ritterhouse, MD, PhD
Solid Tumors Subdivision Representative	Marjorie Parker David, MD, MS
Junior Member	Annie Garcia, MD
Junior Member	Jeffrey Kleinberger, MD, PhD
Medical Technologist Member	Lisa Haley, MS
Medical Technologist Member	Timothy Daniels, MLS(ASCP) <sup>CM</sup> , MB <sup>CM</sup> , QLS <sup>CM</sup>
Membership Affairs Committee Liaison	Cynthia Jackson, PhD
International Affairs Committee Liaison	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*

#### **2021 GetAMPed! Updates and Case Studies in Molecular Pathology:**

The T&E Committee plans to organize a virtual outreach course on January 13, 2022. The program will be geared to individuals with limited experience in molecular diagnostics and included an overview of pre-analytic considerations in molecular pathology, followed by interactive case studies presented by T&E members that illustrated a wide range of molecular diagnostic applications.

**Early Bird Sessions at the Annual Meeting & Expo - Case Studies presented by Trainees or Technologists:**

The T&E Committee hosted an opportunity for fellows, residents, postdocs, graduate students, or technologists to present an interesting and/or challenging case study for the AMP 2021 Digital Experience-FULL. Trainee/technologist presenters in 2021 are listed below:

Case Studies in Genetics	Case Study: Sebaceous Adenoma of the Penis Suspicious for Muir-Torre Syndrome	Blaire Anderson	Dartmouth Hitchcock Medical Center
	Case Study: Molecular Diagnosis of a Patient with a Novel Suspected Hereditary Amyloidosis	Lauren Choate, PhD	Mayo Clinic
	Case Study: A case of familial cytopenias and cerebral cavernous malformations presenting with seizures and brain abscesses	Runjun Kumar, MD, PhD	Baylor College of Medicine

Case Studies in Hematopathology	Case Study: Clinical Whole Genome Sequencing Characterizes an Unusual Case of B-lymphoblastic Leukemia/Lymphoma	Brooj Abro, MD	Washington University in St. Louis
	Case Study: Clonally Related Marginal Zone Lymphoma and Classic Hodgkin Lymphoma: A Rare Case Highlighting the Importance of IGH Rearrangement Testing	Bradley Drumheller, MD	Emory University Hospital
	Case Study: Molecular and histopathologic findings in a case of large B-cell lymphoma with IRF4 rearrangement	Farah El-Sharkawy, MD	Hospital of the University of Pennsylvania
	Case Study: A Genetically Novel Mantle Cell Lymphoma	Ahmed Lazim, MD	Temple University Hospital
	Case Study: Incidental discovery of acute myeloid leukemia during liquid biopsy of a lung cancer patient	Dingani Nkosi, MBBS, PhD	University of Rochester Medical Center
	Case Study: Inadvertent allogeneic hematopoietic stem cell transplant from a lung allograft	Laura Schultz-Rogers, PhD	University of North Carolina Chapel Hill Hospital

Case Studies in Infectious Diseases	Case Study: Even if it looks like a ductal and walks like a ductal. . .	Jeremy Adler, MD	University of Chicago
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Case Studies in Solid Tumors	Case Study: A rare case of CIC-rearranged sarcoma diagnosed with integrated RNA and DNA sequencing	Annie Garcia, MD	Baylor college of Medicine
	Case Study: Clonal Evolution of Glioblastoma after Therapy	Tasos Gogakos, MD, PhD	Mass General / Brigham Womens
	Case Study: A case series of FGFR3-KLF15 Fusion in Non-Small Cell Lung Cancer	Parsa Hodjat, MD	Houston Methodist Hospital
	Case Study: Potentially Targetable FGFR2-INA Fusion in Intraductal Tubulopapillary Neoplasm of Pancreas (ITPN)	Irena Manukyan MD, PhD	Columbia University
	Case Study: Detection of a rare fusion event to confirm metastasis and primary	Drew Williamson, MD	Brigham and Women's Hospital
	Case Study: Identification of identical BAP1 mutations in a patient's peritoneal mesothelioma and mucosal melanoma: A precision medicine case study	Paul Zamiara, MD	Dalhousie University

**2021 Webcasts and Recorded Online Content (ROCs):**

Date	Title	Speaker/T&E Moderator	NOTES (Registrants/Attendees)
<b>Major Initiative:</b> <a href="#">Emerging and Evolving Biomarkers: Recent Findings, Laboratory Considerations, and Clinical Implications</a>			
April 15	ERBB2 (HER2) in Colorectal Cancer: Recent findings, laboratory considerations, and clinical implications	Sinchita Roy-Chowdhuri, MD, PhD	384/186
June 29	Myeloid Malignancy MRD: Recent Findings, Laboratory Considerations, and Clinical Implications	David Wu, MD, PhD	521/243
October 12	KRAS: Recent Findings, Laboratory Considerations, and Clinical Implications	Craig Mackinnon, MD, PhD	481/213
<b>Major Initiative:</b> <a href="#">Utility of Cell-free DNA in the Clinic: Current State and Future Directions</a>			
May 18	Basic Biology and Detection of Cell-Free DNA	Rena Xian, MD and Lynette M. Sholl MD	700/398
July 27	Practical Analytical and Clinical validation Strategies for Cell-Free Tumor DNA Assays	Christina Lockwood, PhD	577/258
September 28	Opportunities and Challenges Toward the Clinical Application of ctDNA MRD Testing in Solid Cancers	Everett Moding, MD PhD	574/289
<b>Webinar Series: Horizons II - Hot Topics</b>			
January 28	Molecular Testing in Thyroid Cancer: Technical Approaches and Clinical Breakthroughs	Dora Dias-Santagata. / Moderated by Honey Reddi	309/168
February 11	AMP Advocacy in the Biden Administration and the 117th Congress: What to expect in 2021	Eric Konnick and Jordan Laser. / Moderated by Yasmine Akkari	208/117
March 4	Enhancing COVID-19 Pandemic Response with SARS-CoV-2 Whole Genome Sequencing	Allen Bateman and Duncan MacCannell. / Moderated by Jerry Capraro	296/164
March 9	Myeloid Neoplasms with Germline Predisposition	Lucy Godley. / Moderated by Nate Montgomery	376/209
June 15	Recommendations for Clinical CYP2D6 Genotyping Allele Selection	Ann Moyer	325/179
July 20	Whole Genome Sequencing for Clinical Cancer Diagnostics	Eric Duncavage / Moderated by Nathanael Bailey	381/199
November 4	Electronic Health Records and Genomic Data – Challenges and Opportunities	Alexis B. Carter, MD	TBD

## 2021 Education Initiatives

- **Continuing Education credits (CME and CMLE):**

AMP offers Continuing Education credits for most educational activities. Accredited activities include the MGP Review Course (live and online), the GetAMPed! Outreach course and enduring program, live and enduring webinars, the 2021 AMP Digital Experience and Recorded Online Content (ROC) lectures. Currently, there are nearly 200 hours of CME and CMLE credit available on the learning management system. In addition, the vast majority of live programming is available for continuing education credit.

- **Online education - AMPED™:**

The T&E Committee and staff spent a significant amount of time designing and developing additional educational materials for populating [educate.amp.org](https://educate.amp.org). It boasts over 350 hours of content and have attracted 3,700 active users in 2021 (January 2021-October 29, 2021). The site also hosted the AMP 2021 Digital Experience (November 16-19).

- **NEW Webinar Series for 2021:** One-hour webinars are live broadcasted and then placed on AMPED™ as on-demand. All of the webinars are complimentary for AMP members and some are complimentary for nonmembers as well. T&E programmed and/or oversaw 10 of the 13 CE eligible webinars broadcasted this year. See page 3 for new webinars placed on AMPED™.
- **Course Bundles/AMP Certificate Programs:** Courses are live programs that were recorded and translated to a self-paced online course. Certificate programs are self-paced on-demand content designed to provide a deep dive on specific areas of interest. New courses and certificate programs launched in 2021 include:
  - [NGS101 v2.0: A Re-Introduction to the Fundamentals of Next-Generation Sequencing Certificate Program](#)
  - [2021 MGP Review Course](#)
  - [2020 GetAMPed! course recordings](#)
  - [JMD 2021 CME Program](#)
- **AMP Flashcards:** The T&E Committee initiated the creation of a new self-study review tool – the AMP flashcards. There are two currently available: a 40+ card set on [multiple myeloma](#) and a 20+ card set on [colorectal cancer](#). These were launched in August of 2020. One more will be coming soon on AML.
- **FISE Question Bank:** This is the fourth year of a continuing collaboration with the MGP-PD Council to provide fellows with a Fellowship In-service Examination (FISE) at the beginning and at the end of their fellowship year. Additional FISE exam questions were written by MGP faculty and reviewed by the T&E. All existing questions are also reviewed annually. The bank currently consists of >350 questions and learners are presented with 45 randomly selected questions for their examination. AMP staff provides non-attributed results to participating institutions at the beginning of the fellowship year (in October) and at the end of the year (in May/June).
- **Molecular in a Minute:** New this year, the T&E Committee initiated the microlearning modules called Molecular in a Minute. This features 5-15 minute videos on a variety of molecular pathology competency topics.

- **Molecular-in-My-Pocket™ cards:** The T&E Committee continued expanding the Molecular-in-My-Pocket™ reference card collection. Two new oncology cards on Bone and Soft Tissue Tumors were made available in 2021. There are now 23 cards, total. Cards are reviewed annually by T&E Committee members for accuracy and for any required updates. There have been more than 2,000 downloads of these cards from the AMP website in the past year.
- **Member Spotlights:** The T&E committee continues this collaboration with the Membership Affairs Committee by identifying and interviewing AMP members for the Member Spotlights page on the AMP website. Interviews and profiles highlight the training and career paths of various molecular professionals.

**AMP 2021 Virtual Annual Meeting & Expo Activities:** While the AMP 2021 Annual Meeting & Expo Conference has been cancelled, two of the planned events will be rescheduled on a virtual platform.

- **The Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Council**  
The MGP Program Directors (MGP PD) Council consists of Rizwan Naeem (Chair) Rena Xian (Chair-Elect), and Keyur Patel (Past-Chair). Nathan Montgomery acts as the T&E committee representative to this group. 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 worked with the T&E Committee to launch the in-service practice exam question bank for MGP Fellows (FISE; see above). They will be meeting virtually in December 2021.
- **The Education Community of Practice (EdCoP) Group**  
The T&E committee launched the AMP Education Community of Practice Group lead by Yasmine Akkari, PhD with working group members Alanna Church, MD; Marjorie David MD; Cynthia Jackson, PhD; and Sabah Kadri, PhD. The EdCoPs listserv was activated on CHAMP and currently have 69 members (as of October 29, 2021). They held a virtual general meeting in June 2020 with ~35 attendees. The group will hold another virtual meeting in February, 2022.

### ***Curriculum and Educational Manuscript Development Task Forces***

- **Genomics Education for Primary Care Residents:** This Task Force is led by Laura Tafe. Their task is to develop a modified basic genomics curriculum for primary care residents, *i.e.*, internal medicine, family practice, and pediatrics. Other working group members are Yasmine Akkari, Maria Arcila, Devon Chabot-Richards, Preeti Pancholi and Anthony Snow. This manuscript is under review.
- **MGP Fellow Training and Curriculum in Genomics Task Force:** This [manuscript](#) was prepared by co-leaders Jason Rosenbaum and Mark Ewalt and includes working group members Kristy Crooks, Jeff Gagan and David Wu. The manuscript is now published. Additional 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.
- **Molecular Genetic Pathology (MGP) Curriculum Update (MGP-CUP):** This task force is led by Karen Kaul and includes working group members Rashmi Goswami, Allison Cushman-Vokoun, Mark Ewalt, Harriet Feilotter, Julie Gastier-Foster, Jennifer Laudadio, Randy Olsen, Lauren Ritterhouse, Jason

Rosenbaum and Priya Velu. The goal of this project is to prepare a set of recommendations and guidelines by which MGP training programs can develop curricula for MGP fellowship trainees.

- **Lab Management Manuscript:** This practice advance manuscript (accepted), titled “Leading in a Clinical Molecular Laboratory: It’s Not Just About the Science” was led by Erin H. Graf. The practice advance outlines the 2020 Laboratory Management AMP Certificate Program.
- **Emerging and Evolving Biomarker Manuscripts:** These practice advances, led by Kurtis Davies, Lauren Ritterhouse, and Anthony Snow, will feature the science, laboratory considerations, and clinical implications of the individual biomarkers presented in the Emerging and Evolving Biomarker webinar series. Upcoming featured biomarkers will be *NTRK* (written by Lynette Sholl, under review), *Metex14* (written by Nikoletta Sidiropoulos, under review), and *ERBB2(Her2)* (written by Sinchita Roy-Chowdhuri).

#### ***Co-Sponsorships, Companion Meetings, and/or Collaborations***

- **(Virtual) United States and Canadian Academy of Pathology (USCAP) 2021**  
***The AMP 2021 Companion Society Symposium,***  
“Utilization of Cell free DNA (cfDNA) in Oncology”, was a virtual event co-moderated by Amir Behdad, MD, MBA and Alanna Church, MD. Speakers were:
  - Lynette M. Sholl, MD
  - Pedram Razavi MD, PhD
  - Tejus Bale, MD, PhD
- **(Virtual) American Society for Clinical Pathology (ASCP)**  
***ASCP 2021 AMP Workshop***  
“NGS Tips and Tricks for Technologists” was presented by Lisa Haley, MS and Timothy Daniels
- **(Virtual) College of American Pathologists (CAP)**  
***CAP 2021 Course Presentation (postponed from CAP 2020)***  
“Understanding NGS and Interpreting Reports for Oncologic Pathology” was presented by Sabah Kadri, PhD and Cecilia Yeung, MD
- **Cambridge Health Institute (CHI) Conferences**
  - **Next Generation Dx Summit, August 2021 (Virtual)**
  - **Plenary Panel Discussion: Lessons Learned about COVID-19 Testing and Recommendations for Future Emerging Outbreaks: Advocacy, Education and Clinical Practice.** Antonia Sepulveda, PhD; Erin H. Graf, PhD; Jordan S. Laser, MD; Donna M. Wolk, PhD

## AMP Subdivision Leadership Annual Report, 2021

### SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
<b>Chair</b>	Avni Santani	Maria Arcila	Donna Wolk	Jason Merker	Larry Jennings
<b>Clinical Practice Committee</b>	Fatimah Nahhas-Alwan	Rashmi Goswami	Joseph Yao	Joshua Coleman	Susan Hsiao
	Steven Sperber	Michael Kluk	Blake Buchan	Elaine Gee	David Eberhard
<b>Economic Affairs Committee</b>	Victoria Pratt	Maria Arcila	Jennifer Dien Bard	Jeffrey Gagan	Susan Hsiao
<b>Nominating Committee</b>	Alka Chaubey	Rena Xian	Amy Leber	Matthew Lebo	Jennifer Laudadio
	Jennelle Hodge	Marian Harris	Ted Schutzbank	Julie Woolworth Hirschhorn	Allison Cushman-Vokoun
<b>Professional Relations Committee</b>	Andria Del Tredici	Betty Chung	Frederick Nolte	Jordan Laser	Amy Lo
<b>Program Committee</b>	Ryan Schmidt	Noah Brown	Erin McElvania	Ahmet Zehir	Jonathan Nowak
	Pinar Bayrak-Toydemir	Valentina Nardi	Erin Graf	Annette Leon	Sinchita Roy Chowdhuri
<b>Training &amp; Education Committee</b>	Honey Reddi	Nathan Montgomery	Gerald Capraro	Weiwei Zhang	Lauren Ritterhouse
	Ying Zou	Amir Behdad	Allen Bateman	Eduardo Castro-Echeverry	Marjorie Parker David

#### PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair, representatives to the Clinical Practice, Economic Affairs, Nominating, Program, Professional Relations, Training & Education Committees, and Ad hoc representatives to the Subdivision Leadership groups from the Professional Relations and Economic Affairs 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
- Providing feedback regarding projects to the Clinical Practice Committee, Training and Education Committee, or other relevant committees
- Providing input and suggestions regarding content for the Annual Meeting and other educational events
- Assisting to identify and recommend future AMP volunteers and leaders
- Resource for advocacy-related initiatives

## **2021 ACTIVITIES:**

All Subdivision Leadership groups contribute to biannual Subdivision Spotlight email digests that highlights AMP activities and *JMD* articles related to Subdivision member's interests.

**Genetics** - Addressed current issues and topics related to genetics, including variant interpretation and classification, next-generation sequencing, pharmacogenomics, whole genome and exome sequencing standards, forensics, polygenic risk scores, and diversity in genomic databases. Subdivision Leadership members provided feedback to Scott Topper, AMP representative to the ACMG-led Interpretation of Sequence Variants Update Workgroup. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to variant database sharing barriers; and the Economic Affairs Committee (EAC) by providing input on a collaborative response from AMP and CAP on the Local Coverage Determinations (dLCD) with genetic testing for cardiovascular testing.

**Hematopathology** - Addressed current issues and topics in molecular hematopathology, including advances in translational research related to myelomas, MRD monitoring in hematologic malignancies, next-generation sequencing, and immunology. Participated and contributed to projects related to the different AMP Committees. Subdivision Leadership members also assisted the Economic Affairs Committee (EAC) by reviewing updates and providing input on a collaborative response from AMP and CAP to MoDX for NGS Testing in Myeloid and Suspected Myeloid Malignancy Coverage Policy. Curated and provided a "Must Reads" list of hematopathology-relevant literature to the Subdivision membership.

**Infectious Diseases** - Addressed current issues and topics related to the clinical molecular diagnostics laboratory, including related to SARS-CoV-2. Subdivision Leadership members also assisted the Economic Affairs Committee (EAC) by providing input on a collaborative response from AMP and CAP on the Local Coverage Determinations (dLCD) with respiratory pathogen panel testing. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to variant database sharing, HHS RFI Lyme Disease Diagnostics, and patient-facing information on COVID-19 testing; and provided input to the New Codes and Pricing of the AMP Economic Affairs Committee on blood culture identification.

**Informatics** - Addressed current issues and topics related to development of bioinformatics pipelines for clinical next-generation sequencing, informatics tools in metagenomics, electronic health record (EHR) interoperability for clinical genomics data, and body of knowledge (BoK) for Clinical Genomics Bioinformaticist. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to variant database sharing barriers; and the Professional Relations Committee (PRC) by providing a response to the FDA/NIH RFI on tools for NGS test validation and development.

**Solid Tumors** - Addressed various current issues and topics related to clinical applications of circulating tumor cells, HR deficiency (HRD), liquid biopsies, tumor mutational burden, and other factors related to clinical practice of cancer. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to variant database sharing barriers; and the AMP Economic Affairs Committee (EAC) by providing input on their response to Anthem's coverage policy on Whole Genome Sequencing, Whole Exome Sequencing, Gene Panels, and Molecular Profiling.

### **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.