

AMP 2020 Committee and Subdivision Annual Reports

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Karen Weck, MD

Antonia R. Sepulveda, MD, PhD Victoria M. Pratt, PhD Betsy A. Bove, PhD Dan Jones, MD, PhD Samuel K. Caughron, MD Rami Mahfouz, MD, MPH Midhat S. Farooqi, MD, PhD Jordan Laser, MD Jane Gibson, PhD Larissa V. Furtado, MD Nathanael Bailey, MD* Thomas W. Prior, PhD Maria E. Arcila, MD Frederick S. Nolte, PhD Somak Roy, MD Lawrence J. Jennings, MD, PhD Mary Steele Williams, MNA, MT(ASCP)SM, CAE

* Assumed role August 2020; previously held by Yassmine Akkari, PhD

COMMITTEE MEMBERS:

Chair Member Member Member Member Antonia R. Sepulveda, MD, PhD Lynne Abruzzo, MD, PhD Alexis B. Carter, MD Thomas W. Prior, PhD Vivianna Van Deerlin, MD, 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 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

- 2020 Jeffrey A. Kant Leadership Award: Karen P. Mann, MD, PhD
- 2020 Meritorious Service Award: Ronald M. Przygodski, MD
- 2022 Award for Excellence in Molecular Diagnostics: To be announced in Spring 2022

AMP Clinical Practice Committee Annual Report, 2020

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 Solid Tumors Subdivision Representative Junior Member Junior Member Daniel Jones, MD, PhD Pinar Bayrak-Toydemir, MD, PhD Fatimah Nahhas, PhD Marian Harris, MD, PhD Rashmi Goswami, MD, PhD Daniel N. Cohen, MD, PhD Joseph Yao, MD Annette L. Meredith, PhD Joshua Coleman, MD Jonathan Earle, MD Susan Hsiao, MD Celeste Eno, PhD Andres Madrigal, MD

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

• May 2020: Recommendations for Clinical Warfarin Genotyping Allele Selection: A Report of the Association for Molecular Pathology and College of American Pathologists. Led by Victoria Pratt with Andria del Tredici, Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Stuart Scott, Larisa Cavallari, Ann Moyer, Michelle Whirl-Carrillo and Karen Weck, *The Journal of Molecular Diagnostics*. (https://doi.org/10.1016/j.jmoldx.2020.04.204)

Additional Accomplishments

- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- Multiple AMP working group projects are underway.
- CPC gathered AMP member input on Artificial Intelligence and Big data in molecular genomics.
- CPC members actively brainstormed and launched two new projects in 2020. Several additional project ideas are awaiting launch next year.
- Assisted the ID Subdivision with providing feedback to the COVID testing surveys.
- 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 <u>https://www.amp.org/clinical-practice/clinical-practice-overview/</u> for more details or email <u>ampclinicalpractice@amp.org</u>.

AMP Clinical Practice Guidelines Program

Working Group / Task Force	Members
Recommendations for Clinical CYP2D6	Victoria Pratt (Chair), Larisa Cavallari, Lisa Kalman, Andria
Genotyping Allele Selection	Del Tredici, Houda Hachad, Yuan Ji, Stuart Scott, Karen
	Weck, Ann Moyer (CAP representative), Michelle Whirl-
	Carrillo (CPIC representative), Ron van Schaik (DPWG)
	and Reynold Ly
Recommendations for Laboratory	Madhuri Hegde (Chair), Elaine Lyon, Carolyn Sue Richards
Detection and Interpretation of	and Birgit Funke
Intragenic (Exonic Level)	
Deletions/Duplications	
Variant Interpretation Test Across Labs	Elaine Lyon, (Chair), Madhuri Hegde, Julie Gastier-Foster,
(VITAL) Inherited Conditions	Carolyn Sue Richards, Sherri Bale and Glenn Palomaki;
	unrestricted educational grant support from QIAGEN, Inc.
Guidance for Non-standard or Emerging	Christina Lockwood (Chair), Laetitia Borsu, Christopher
Applications: Liquid Biopsy	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	Kristy Crooks (Chair), Avni Santani, Diana Mandelker,
Variant Confirmation	Steve Lincoln, Kelly Hagman (NSGC representative) and
	Ryan Schmidt
NGS Utility for Assessment of T/B-cell	David Viswanatha (Chair), Keyur Patel, Maria Arcila,
Clonality	Timothy Greiner, Joseph Khoury (CAP representative),
	David Wu, Devon Chabot-Richards (SH representative)
	and Habibe Kurt
New Frontiers in Infectious Diseases	Michael Lewinski (Chair), Susan Butler-Wu, Kevin Alby,
Multiplex Testing	Jennifer Dien Bard, Alex Greninger, Esther Babady (PASCV
	representative), Duane Newton (ASM representative) and
	Kimberly Hanson (IDSA representative)
Guidance/Standards for Tumor	Larissa Furtado (Chair), Jeffrey Gregg, Benjamin Kipp,
Mutational Burden Testing by Molecular	Jonathan Nowak, Susan Hsiao, Antonia Sepulveda, Ahmet
Methods	Zehir, Jeremy Segal, Lauren Ritterhouse, Mark Boguski,
	Carlo Bifulco (SITC representative), Neal Lindeman (CAP
	representative), Solange Peters (ASCO representative)
	and Daniel Dolderer
Implementation of AMP/ASCO/CAP	Marilyn Li (Chair), Somak Roy, Cindy Vnencak-Jones,
Reporting and Interpretation of Somatic	Catherine Cottrell, Kai Wang and Scott Turner

Sequence Variants Recommendations in	
Clinical Practice (VITAL Somatic)	
Guidance/Standards for the Use of In	Eric Duncavage & Justin Zook (Co-chairs), Mark Routbort,
Silico Approaches for Validation of NGS	Joshua Coleman, Annette Meredith, Carlos Jose Suarez,
Bioinformatics Pipelines	Sabah Kadri, Somak Roy (CAP representative), Monica de
	Baca (API representative) and Chad Vanderbilt
Molecular MRD Monitoring in Acute	Keyur Patel (Chair), Noah Brown, Dan Jones, Marian
Myeloid Leukemia	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	Rong Mao (Chair), Birgit Funke, Pinar Bayrak-Toydemir,
Inherited Conditions as a First Line Test:	Jianling Ji, Megan Wachsmann, Celeste Eno, Avni Santani
Spectrum of applications and standards	(CAP representative), Karen Wain (NSGC representative)
	and Jeffrey SoRelle

AMP External Representatives Program

AMP Representative	Collaborating Organization(s)	Workgroup / Committee
Daniel Farkas	College of American Pathologists	Molecular Oncology Committee
Scott Topper	American College of Medical Genetics	Interpretation of Sequence
	and Genomics, ClinGen, College of	Variants Update Workgroup
	American Pathologists	
Monica Basehore	National Institute of Standards and	Genome in a Bottle Steering
	Technology	Committee
Carolyn Sue Richards	American College of Medical Genetics	Incidental Findings in Inherited
	and Genomics	Diseases Update Workgroup
Lauren Ritterhouse	College of American Pathologists,	PD-L1 Testing in Lung Cancer
AhmetZehir	American Society of Clinical Oncology	Workgroup
Federico Monzon	American Society of Clinical Oncology	CancerLinQOncology Leadership
		Council
Marilyn Li	American College of Medical Genetics	Somatic Cancer Clinical Domain
	and Genomics, ClinGen	Workgroup
Maria Bettinotti	Foundation for the National Institutes	Biomarkers Consortium Steering
	of Heath	Committee for Inflammation and
		Immunity
Ming Rong	Foundation for the National Institutes	Biomarkers Consortium Steering
	of Heath	Committee for Metabolic
		Diseases
Snehal Patel	Foundation for the National Institutes	Biomarkers Consortium Steering
	of Heath	Committee for Cancer
Christina Lockwood	Foundation for the National Institutes	Biomarkers Consortium
	of Heath	Identification and Validation of
		ctDNA Reference Materials
		WorkingGroup
Sinchita Roy-	American Society of Cytopathology	Organizational liaison
Chowdhuri		

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- analytics 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
Winand N.M. Dinjens	World Health Organization	International Collaboration for Cancer Classification and Research (IC3R) Meeting
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, Societyfor Thoracic Radiology	Appropriate Collection and Handling of Thoracic Specimens for Laboratory Testing Workgroup
Mary Lowery-Nordberg Jennifer Yoest	American Association of Clinical Chemistry	Lab Tests Online Editorial Board
Eric Duncavage	Association of Community Cancer Centers	Advisory Committee
Daniel Jones	Clinical Laboratory Imprevement Advisory Committee (CLIAC)	Next Generation Sequencing Best Practices Forum
Jonathan Earle	The Joint Commission	Technical Advisory Panels (TAP) for Molecular Pathology and Pathology

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

AMP Economic Affairs Committee Annual Report, 2020

COMMITTEE MEMBERS:

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

Samuel K. Caughron, MD Jay L. Patel, MD Pranil Chandra, DO Jennifer Dien Bard, PhD Rajyasree Emmadi, MD Jeffrey Gagan, MD, PhD Tanner Hagelstrom, PhD, MBA Amanda Harrington, PhD Mathew Hiemenz, MD Susan Hsaio, MD, PhD Lloyd Hutchinson, PhD Loren Joseph, MD Jordan Laser, MD Elaine Lyon, PhD Federico Monzon, MD Victoria Pratt, PhD Aparna Rajadhyaksha, MD Oana C. Rosca, MD Anthony N. Sireci, MD, MS Antonia Sepulveda, MD Ester Stein, MBA Katherine Tynan, PhD Eric Vail, MD Karen Weck, MD Salvatore Priore, MD, PhD Aaron D. Bossler, MD, PhD 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.

2020 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 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 2020, 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.

Coronavirus Pandemic-focused Advocacy

AMP Leads Advocacy to Ensure Coverage of ALL COVID-19 Diagnostic Tests

Throughout 2020, AMP met with numerous offices on Capitol Hill regarding concerns about Medicare coverage and pricing, with a major focus on coverage of COVID-19. This was a major effort in which EAC worked alongside the Professional Relations Committee. In March, Congress began preparing the first of four federal relief packages enacted to date to respond to the COVID-19 public health emergency. Unfortunately, inconsistencies between FDA regulatory requirements for laboratory developed testing procedures (LDPs) and provisions meant to ensure coverage of COVID-19 testing in the Families First Coronavirus Response Act left thousands of patients without the ability to obtain no-cost testing even though they had health care insurance. AMP strongly advocated for inclusion of language to remedy the coverage issue in the third COVID-19 package, the Coronavirus Aid, Relief, and Economic Security (CARES) Act enacted in late March. AMP engaged in a number of conversations with Congressional offices, solicited support from other laboratory organizations, and sent out an Action Alert for AMP members to contact their Senators and Representatives to encourage them to include the language fix. AMP's advocacy efforts proved to be successful and the CARES Act contained language that closed the coverage gap for specific COVID-19 diagnostic tests and finally ensured that all COVID-19 tests would be covered and free from cost-sharing.

AMP Advocates for Reasonable Coverage Policies for Respiratory Viral Panels

In the spring, AMP, along with a number of other stakeholders, sent a joint letter to CMS requesting immediate national coverage for multiplex polymerase chain reaction (PCR) respiratory viral panel (RVP) tests and to include coverage for COVID-19 when it becomes available in testing panels. As a critical component of triage protocols, laboratories are experiencing an exponential increase in the number of requests for RVPs by clinicians during the COVID-19 outbreak to rule out other respiratory pathogens, and to help guide a patient's immediate and appropriate treatment during this public health emergency. Over the summer, AMP and CAP met with CMS on this issue to ensure that these panels are covered.

AMP Advocates for Reasonable Payment for COVID-19 Diagnostic Services

Further, AMP worked with a number of stakeholders that are closely following the development and pricing of COVID-19 diagnostic testing codes. Dr. Jay Patel, the AMP Economic Affairs Committee Vice-Chair for New Codes, presented pricing recommendations for the COVID-19 diagnostic testing codes at the annual CMS Clinical Laboratory Fee Schedule Summer Pricing Meeting. AMP and other united stakeholders advocated for all COVID-19 diagnostic tests to be reimbursed at approximately \$100, regardless of if they are considered high-throughput, as defined by CMS.

National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries

Throughout 2019, AMP was actively involved in advocating for improving the CMS National Coverage Determination (NCD) for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (referred to here as the NGS NCD). Originally, the NGS NCD was intended to focus on somatic testing, but AMP and other stakeholders learned that CMS included germline testing within the scope of the NGS NCD. Last fall, CMS published their proposed decision memo for the NGS NCD, which -- contrary to AMP's request -- included germline testing and would have a number of negative repercussions for tests that were already being covered by the Medicare Administrative Contractors (MACs).

In January 2020, the final coverage determination was released. AMP was pleased to see that the final decision memo incorporated many of the recommendations that AMP submitted to CMS last fall. First and foremost, coverage has been expanded in the final decision to allow MACs the discretion to create local coverage

determinations for NGS-based testing for all inherited cancers, including breast and ovarian cancers. The memo also includes important clarifications to distinguish between the germline and somatic sections of the policy and the title was altered to become "Next Generation Sequencing (NGS) for Patients with Somatic (Acquired) and Germline (Inherited) Cancer." This title change reflects the inclusion of both germline and somatic testing and more accurately reflects the policy, as germline testing is not restricted to those with advanced stage cancer.

AMP remains concerned that providing coverage based upon a single technology (i.e., NGS) will require CMS to revisit and reconsider this policy on a regular basis. AMP is monitoring how this policy is implemented and plans to work with CMS, local MACs and other stakeholders as required. We remain focused on preserving broad patient access and ensuring coverage for all of the thousands of clinically and analytically validated NGS-based testing for cancer and other conditions that benefit patients each and every day.

Professional Reimbursement

In late 2018, members from both EAC and the Professional Relations Committee (PRC) decided to address anew two significant deficiencies in reimbursement for professional services. The first being that only physicians (MD/DO) are reimbursed for clinical interpretation of molecular results, even though a substantial amount of interpretation work is done by PhDs. This was a major policy focus for AMP 2011-2012, until the new molecular pathology CPT codes were placed on the CLFS. The second issue is that the current coding structure does not align well with the professional services of interpreting these results and preparing a test report. On July 6th, AMP launched a novel Professional Work survey. The survey 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 assess the work that is performed by MDs and qualified PhDs during molecular testing. The results of the survey will be presented at the 2020 AMP Annual Meeting & Expo and will be used to guide advocacy efforts in this space for the next few years.

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 took effect on January 1, 2019. In 2019, AMP worked with stakeholders to have the changes withdrawn and that any future manual updates be developed in consultation with the relevant stakeholders. Additionally, AMP signed on to a letter with eight other organizations. In 2020, AMP was pleased that CMS had made some updates to the manual, which mitigated some of our concerns. However, some updates remain problematic and have the potential to restrict access to medically appropriate molecular testing. AMP continues to meet with CMS and work with stakeholders on this issue.

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 (CY2021 CLFS). **Dr. Jay Patel** represented AMP at the annual CLFS meeting at CMS on June 22, 2020. He presented crosswalk recommendations for the new and reconsidered CY2021 CLFS molecular pathology, genomic sequencing, and microbiology procedures.

Additionally, the Advisory Panel on Clinical Diagnostic Tests (The Advisory Panel) reviewed stakeholder recommendations present to CMS in June and voted on the best approach to pricing new and reconsidered codes. The Panel was established by 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 CY2021 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.

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. This manuscript was published in 2020 in the *Journal of Molecular Diagnostics*. In August, **Drs. Dara Aisner, Samuel Caughron, Jay Patel, and Anthony Sireci** held a webcast, which provided an overview of the manuscript.

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

AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). Thus far in 2020, AMP has provided responses to various MACs for approximately 13 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. Monitoring emerging policies continued to be a major focus of the committee and was led by **Dr. Pranil Chandra.** 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.

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. 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. Jay Patel** serving as the technical advisor.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members Drs. Anthony Sireci, Roger Klein, Elaine Lyon, and Victoria Pratt.

AMP Finance Committee Annual Report, 2020

COMMITTEE MEMBERS:

Chair President President-Elect Past President Member Member Member Executive Director Betsy A. Bove, PhD Karen Weck, MD Antonia R. Sepulveda, MD, PhD Victoria M. Pratt, PhD Sharathkumar Bhagavathi, MD Steven A. Schichman, MD, PhD Xiao-Ming Yin, MD, PhD 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, 2020

COMMITTEE MEMBERS:

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

PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- Enhances AMP as an international organization
- o Promotes AMP's vision and mission internationally
- o 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

2020 ACTIVITIES:

- AMP 2020 Annual Meeting Event:
 - COVID-19 Testing Around the World A Virtual Global Networking Event
- Presented nine Registration Support Awards to meeting attendees from India, Pakistan, Syria and the Philippines.
- o Awarded 2020 International Membership Grants to scientists from India and Nepal.

AMP Membership Affairs Committee Annual Report, 2020

COMMITTEE MEMBERS:

Chair Member International Affairs Liaison Midhat S. Farooqi, MD, PhD Elizabeth Azzato, MD, PhD Yi Ding, MD, PhD James Fuller, PhD Lisa M. Haley, MS Cristiane Ida, MD Giovanni Insuasti-Beltran, MD Cynthia L. Jackson, PhD Shelby Melton, MD Irene Newsham, PhD Nikoletta Sidiropoulos, MD Yaolin Zhou, MD Talent Theparee, 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.

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

2020 ACTIVITIES:

- Selected the winners of the AMP 2020 Technologist Registration Awards
- Selected the winners of the AMP 2020 Underrepresented in Medicine Registration Awards
- Developed and executed the 2020 Regular, Trainee, and Technologist Membership Engagement Surveys
- Planned and hosted Meet a MAC Member Chat Program at the AMP 2020 Annual Meeting
- 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 with Meet a MAC Member Chat Program
- 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
- Cooperating with Molecular Genetic Technology undergraduate programs to provide access to AMP memberships to encourage participation in AMP early in their careers
- 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, 2020

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 President Executive Director Victoria M. Pratt, PhD Qiulu Pan, MD, PhD Alka Chaubey, PhD Keyur Patel, MD, PhD Rena Xin, MD Blake W. Buchan, PhD Amy Leber, PhD Nefize Sertac Kip, MD, PhD Matthew Lebo, PhD Anna Yemelyanova, MD Jennifer Laudadio, MD Karen Weck, 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 or June each year.

2020 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2020 annual elections.

AMP Professional Relations Committee Annual Report, 2020

COMMITTEE MEMBERS:

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

Jordan Laser, MD Eric Q. Konnick, MD Linnea M. Baudhuin, PhD David Bosler, MD Samuel Caughron, MD Andria Del Tredici, PhD Andrea Ferreira-Gonzalez, PhD Jill Hagenkord, MD Roger Klein, MD, JD Amy Lo, MD Jill Murrell, PhD George J. Netto, MD Nirali M. Patel, MD Jason Rosenbaum, MD Antonia Sepulveda, MD David Viswanatha, MD Karen Weck, MD Barbara Zehnbauer, PhD Betty Chung, DO, MPH, MA David E. Barton, PhD Betsy A. Bove, PhD 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.

2020 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 and Megan Anderson Brooks 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. Jennifer Leib, Megan Anderson Brooks, AMP Senior Director of Public Policy and Advocacy, Tara Burke, AMP Policy Analyst, 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 2020 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). Since FDA announced their decision not to finalize their draft guidance for LDPs, conversations about LDP oversight have shifted to Congress. AMP remains actively engaged with legislators on Capitol Hill. 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 March, Senator Rand Paul (R-KY) introduced the Verified Innovative Testing in America Laboratories (VITAL) Act of 2020. AMP was supportive of the bill's 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.

Coronavirus Pandemic-focused Advocacy

AMP Surveys Membership on SARS-CoV-2 Testing Supplies and Practices

In order to better understand the contribution laboratories are making and the challenges they are facing during the COVID-19 pandemic response, AMP created a series of robust surveys to collect and document laboratories' efforts and experiences throughout the course of the pandemic. These surveys allowed us to monitor, understand, and collect real-time data on laboratories' efforts and experiences during the COVID-19 pandemic response. The survey results were instrumental in AMP's advocacy and clinical practice efforts. AMP released a preliminary report of the survey conducted from April 23-May 5, 2020 ("April Survey") and another preliminary report from the survey conducted between August 13-September 11, 2020. These surveys were a joint effort of Advocacy & Clinical Practice.

AMP Leads Advocacy to Ensure Coverage of ALL COVID-19 Diagnostic Tests

In March, Congress began preparing the first of four federal relief packages enacted to date to respond to the COVID-19 public health emergency. Unfortunately, inconsistencies between FDA regulatory requirements for laboratory developed testing procedures (LDPs) and provisions meant to ensure coverage of COVID-19 testing in the Families First Coronavirus Response Act left thousands of patients without the ability to obtain no-cost testing even though they had health care insurance. AMP strongly advocated for inclusion of language to remedy the coverage issue in the third COVID-19 package, the Coronavirus Aid, Relief, and Economic Security (CARES) Act enacted in late March. AMP engaged in a number of conversations with Congressional offices, solicited support from other laboratory organizations, and sent out an Action Alert for AMP members to contact their Senators and Representatives to encourage them to include the language fix. AMP's advocacy efforts proved to be successful and the CARES Act contained language that closed the coverage gap for specific COVID-19 diagnostic tests and finally ensured that all COVID-19 tests would be covered and free from cost-sharing.

AMP and other Stakeholders Work to Address Testing Supply Shortages and Lack of Transparency

AMP worked with a series of laboratory stakeholders to communicate testing supply shortages and other laboratory issues to the White House Coronavirus Taskforce. AMP and others advocated and continue to advocate for greater transparency into the testing supply chain and allocation. On July 8th, AMP along with 7 other laboratory organizations submitted a letter to Vice-President Pence and the Coronavirus Task Force to highlight existing concerns with the supply chain. AMP and others continue to meet and engage with the coronavirus taskforce to communicate concerns from our members and ensure that laboratories can continue to provide vital testing services during the pandemic.

AMP Advocates for Hazard Pay for Laboratory Professionals

In April, the Administration signaled that it was considering whether or not to provide hazard pay to "frontline" healthcare workers who are treating patients with COVID-19. This is a priority for House Speaker Nancy Pelosi (D-CA) who introduced the HEROES Act, which proposes the establishment of a \$200 billion "Heroes Fund" to ensure that essential workers on the front lines of the COVID-19 pandemic receive hazard pay. AMP applauded this effort but anticipated that laboratory professionals might not automatically be included in these legislative efforts. For this reason, AMP championed a sign-on letter to preemptively advocate that Congress include laboratory professionals (pathologists, laboratory directors, laboratory staff, etc.) in any hazard pay legislation that they are considering in the next COVID-19 legislation package.

Preparing for the Next Pandemic

AMP provided comments and suggestions on how the lessons learned from the COVID-19 pandemic testing response should be incorporated in Senate HELP Committee Chairman Lamar Alexander's (R-TN) white-paper on "Preparing for the Next Pandemic" as well as future legislation.

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 2020, AMP held a virtual Lunch and Learn focused on the COVID-19 diagnostic testing. The lunch and learn was widely attended by many patient groups. **Drs. Jennifer Dien Bard, Jordan Laser** and **Eric Konnick** provided an overview of the testing performed during the pandemic and answered questions on how laboratories are responding to the pandemic.

Additionally, in 2020, to help inform patients & advocates about diagnostic testing's role in patient care, AMP created a new website with free infographics, descriptions of testing types, answers to frequently asked questions & regularly updated educational resources. The Patient Engagement Subcommittee worked hard to get this project across the finish line and has plans to expand the website in 2021.

Advocacy Push for PhDs to be Deemed 'Qualified Healthcare Professionals'

Since 2011, AMP has campaigned with a number of societies to advocate that qualified PhDs should be deemed as "Qualified Health Care Professionals" (QHPs) by CMS, which would allow doctoral scientists who perform molecular diagnostic testing to be able to bill CMS for their work. At the same time, AMP and others were advocating that CMS introduce a new coding structure for molecular diagnostic procedures that would have two components: a code on the Clinical Laboratory Fee Schedule (CLFS) that would represent the cost to run the assay and a corresponding code on the Physician Fee Schedule (PFS) that would represent the professional work involved in interpreting and reporting the result. Ultimately, CMS decided to place all the molecular pathology codes on the CLFS.

In late 2018, AMP launched a joint workgroup with members from both the Economic Affairs Committee and the Professional Relations Committee to revisit these issues and reignite these advocacy efforts. The goals of the workgroup are to advocate for reasonable reimbursement for the interpretive work that goes into preparing a patient-specific molecular diagnostics report and to get qualified PhDs to be deemed QHPs within CMS. On July 6th, AMP launched a novel Professional Work survey. The survey 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 assess the work that is performed by MDs and qualified PhDs during molecular testing. The results of the survey will be presented at the 2020 AMP Annual Meeting & Expo and will be used to guide advocacy efforts in this space for the next few years.

AMP Expresses Concern About Recent FDA Actions that Restrict the Reporting of Pharmacogenomic Testing Results

In the fall of 2019, AMP became aware that FDA was requiring laboratories that perform pharmacogenomic (PGx) tests to restrict their testing reports to only include the patient's genotype, without including any information about the patient's metabolizer status or the implications that a patient's genotype would have for medication decisions. AMP was alarmed by the Agency's actions and made aware that laboratories found the new requirements to be even more confusing, as they were restricted from communicating information included in FDA drug labels as part of their reports.

In December, the law firm Hyman, Phelps, & McNamara, P.C. filed a citizen petition to FDA in response to the Agency's recent actions taken against laboratories offering PGx tests. The citizen petition was filed on behalf of the Coalition to Preserve Access to PGx Testing Information, which is comprised of laboratories providing PGx testing, companies that provide support to laboratories to enable testing, including software, and clinicians who utilize the PGx information to optimize therapies for their patients. The submission of a citizen petition automatically required FDA to open a public comment docket and AMP submitted a response on May 4th. AMP fully endorsed the recommendations made in the original citizen petition and highlighted how FDA's recent actions encroached on the practice of medicine for molecular diagnostics professionals. AMP explained that laboratory directors are required to include the relevant clinical information in their molecular pathology reports by their accrediting organizations and that FDA's actions would result in laboratory directors not complying with these requirements and other federal recommendations. AMP further expressed grave concern that FDA's actions would lead directly to patient harm and set a dangerous precedent by disregarding the merit of professional guidelines and their role in healthcare decision-making. Beyond the requests in the citizen's petition, AMP also requested that FDA disclose any reported adverse events or specific examples of harm from providing PGx report interpretations.

Capitol Hill

AMP continues to nurture existing and grow new relationships on Capitol Hill. Throughout 2019, AMP met with approximately 20 offices on Capitol Hill regarding topics including oversight and regulation of LDPs and the Coronavirus Pandemic. Specifically, AMP held two virtual congressional briefings on May 29 and October 7. During those briefings, staffers from Congressional offices and policy staff from both professional medical organizations and patient advocacy organizations heard **Drs. Jordan Laser and Eric Konnick** outline the results of

AMP's April and August COVID-19 testing survey and present policy recommendations for addressing the current pandemic and future pandemics based on the survey findings.

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, 2020

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 Jane S. Gibson, PhD Laura J. Tafe, MD Peter Kang, MD, MS, FCAP Ryan Schmidt, MD, PhD Mark D. Ewalt, MD Noah A. Brown, MD Esther Babady, PhD Erin McElvania, PhD Angshumoy Roy, MD, PhD Ahmet Zehir, PhD Rajyasree (Raj) Emmadi, MD Jonathan Andrew Nowak, MD, PhD C. Renee Webb, BS, MT (ASCP) Jennifer Bergendahl

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.

2020 ACTIVITIES:

Planned and moderated the sessions for the 2020 Annual Meeting & Expo (Virtual Education & Networking Experience) from November 16-20, 2020 held online.

AMP Publications Committee Annual Report, 2020

COMMITTEE MEMBERS:

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

PURPOSE SUMMARY: Members of the Publications Committee are appointed by the Board for a two-year, renewable term, up to a maximum of six years.

- 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.

2020 ACTIVITIES:

- Solicited volunteer applications for an Infectious Diseases SME and Junior committee members
- Solicited and reviewed AMP Case Reports submissions for CAP Today
- Discussed ways to encourage AMP members to sign-up to become a reviewer, share information in a timely fashion with regards to COVID-19 and supporting rapid communications in *JMD*
- Conducted a member survey to determine how well *The Journal of Molecular Diagnostics (JMD)* currently serves AMP member's professional needs and identify potential areas for improving the journal

AMP Strategic Opportunities Committee Annual Report, 2020

COMMITTEE MEMBERS:

Chair	Antonia R Sepulveda, 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
President	Karen Weck, MD
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.

2020 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

AMP Training & Education Committee Annual Report, 2020

COMMITTEE MEMBERS:

Chair Vice-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

Nathanael Bailey, MD* Yassmine Akkari, PhD Alanna Church, MD Honey V. Reddi, PhD Kristin Hunt Karner, MD Nathan Montgomery, MD, PhD Erin Graf, PhD Gerald Capraro, PhD Sabah Kadri, PhD Weiwei Zhang, PhD Christian Kunder, MD, PhD Lauren Ritterhouse, MD, PhD Cinthya Zepeda Mendoza, PhD Annie Garcia, MD Barbara Anderson, MS Lisa Haley, MS Cynthia Jackson, PhD Roberta Sitnik, PhD

* Assumed Chair role August 2020; previously held by Yassmine Akkari, 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

GetAMPed! Updates and Case Studies in Molecular Pathology:

The T&E Committee organized a virtual outreach course held just prior to the Annual Meeting, on November 15, 2020. The program was geared to individuals with limited experience in molecular diagnostics and 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.

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 who attended the AMP 2020 virtual Annual Meeting & Expo to present an interesting and/or challenging case study during a virtual session. Trainee/technologist presenters in 2020 are listed below:

Case Studies in	Case Study: Molecular Characterization of Aspergillus	Eun Kim, MS,	IDbyDNA
Infectious Diseases	Infectious Diseases Fumigatus by Next-generation Sequencing in Neonates		
and Solid Tumors	Diagnosed with Invasive Fungal Dermatitisat a Tertiary		
(Mon Nov 16)	Care Hospital – Florida, 2019		
	Case Study: SARS-CoV-2 and Cytomegalovirus Co-	Debbie Walley, MD	Houston Methodist Hospital
	infection in Patients Over 45: A Case Series		
	Case Study: Generalized Weakness and Fever in a	William Webster, DO	University of South Carolina School
	Female with Polymyositis		of Medicine-Prisma Health
	Case Study: Papillary Thyroid Carcinoma with	Adam Fisch, MD, PhD	Brigham and Women's Hospital
	Has himoto Thyroiditis: Detecting the Driver Signal in		
	the Inflammatory Noise		
	Case Study: Next Generation Sequencing Catches a	Matthew Gayhart, MD	Cedars-Sinai Medical Center
	Cytopathology Pitfall		

Case Studies in Hematopathology	Case Study: Recurrent Mediastinal Neoplasm of Unknown Origin	Jessica Ziemba, MD	Beth Israel Deaconess Medical Center
and Solid Tumors (Mon Nov 16)	Case Study: Fortuitous Detection of a NUP214-ABL1 Fusion Through Copy Number Changes	Jonathan Tsai, MD	Brigham & Women's Hospital
	Case Study: Targeted RNA Sequencing Revealsa Cryptict(9;11) Leading to KMT2A-MLLT3 Fusion in Accelerated Phase Primary Myelofibrosis Evolving into Acute Myeloid Leukemia	Audre y Jajosky, MD, PhD	University of Michigan
	Case Study: Undifferentiated Neuroblastoma with Unique Molecular Features	Sara Akhavanfard, MD, PhD	Nationwide Children's Hospital
	Case Study: A Compound EGFR Exon 21 Mutation in a Metastatic Liver Mass	Eric Goold, MD	ARUP/University of Utah

Case Studies in	Case Study: Persistent high Levels of Donor Cells	Kelly Rafferty, PhD	Virginia Commonwealth University
Genetics and	netics and Following Solid Organ Transplant Confirm Diagnosis of		Health System
Hematopathology	Graft vers us Host Disease		
(Tues Nov 17)	Case Study: Co-Occurrence of Mosaic Turner	Diana Toledo, PhD,	Dartmouth-Hitchcock Medical
	Syndrome and Mosaic Spinal Muscular Atrophy Carrier	MS,	Center
	Status in an Adult Female		
	Case Study: A Rare Occurrence of Three Compound	Sjja wal Ahmad, Msc	Aga Khan University Hospital,
	Heterogeneous Mutations of HBBGene Leading to B-		Karachi, Pakistan
	Tha lassemia Major in a Pakistani Family		
	Case Study: When Old Meets New: Sophisticated	Marilena Melas, MSc,	Nationwide Children's Hospital
	Interplay of Multiple Technologies to Diagnose a Case	PhD	
	of SOPH Syndrome		
	Case Study: Identification of Targetable NUP214-ABL1	Won Lee, MD	Virginia Commonwealth University
	Fusion in T-lymphoblastic Leukemia		

2020 Webcasts and Recorded Online Content (ROCs):

Date	Title	Speaker/T&E Moderator	NOTES (Registrants/Attendees)
Date	Inte	Speaker/ Tal Moderator	(Registrants/Attendees)
Maior Initiative	e: Emerging and Evolving Biomarkers: Recent Fi	ndings. Laboratory Consid	erations. and Clinical
Implications		0,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,
•	MGMT: Updated Perspectives, Laboratory		
June 30	Considerations, and Clinical Implications	Tejus Bale	358/182
	HRD Score : Updated Perspectives, Laboratory		
July 21	Considerations, and Clinical Implications	Melinda Telli	335/165
	METex14: Updated Perspectives, Laboratory		
September 29	Considerations, and Clinical Implications	Nikoletta Sidiropoulos	314/148
	NTRK: Updated Perspectives, Laboratory		
December 8	Considerations, and Clinical Implications	Lynette M. Sholl	TBD
Series Bundles			
	Lab Management: A lab management content series	Erin Graf	
August	using content augmented with materials dictated by		10 hours, enduring only
	the content-director		
	Bioinformatics: A bioinformatics content series using	Sabah Kadri and Weiwei	
August	existing LMS content augmented with materials	Zhang	6.5 hours, enduring onl
	dictated by content-directors		
Webinar Series	s: Horizons II - Hot Topics		
	The 2019 Novel Coronavirus Outbreak: What		
	La boratories Need to Know a bout the Virus,	James Versalovic and Gerald	
February 20	Epidemiology, and Diagnostic Testing	Capraro	648/399
•	Sample Collection and Molecular Diagnosis of SARS-		
Ma y 14	CoV-2Infection	Tim O'Leary and Yan-Po Tu	1072/661
	Applications of Molecular Diagnostic Modalities in	David Meredith and Adrian	
June 2	Tumors of the Central Nervous System	Dubuc	416/211
	Beyond Reference Genomes: Population-scale Analysis		
August 11	of Genomes with Long Reads	Mi cha el Schatz	244/131
	COVID 19 - Tales from the Trenches: Small Victories	Yassmine Akkari, Gerald	
October 8	and Persistent Challenges	Capraro and Erin Graf	215/104
	DNA Methylation Profiling in Clinical Diagnostics of		
December 3	Brain Tumors	Matija Snuderl	TBD
		•	•
Additional Wel	bcasts/Webinars		
Recorded	Recommendations for Clinical Warfarin Sensitivity		
		March Robert Angeleter Diel Tassaltet	140/76
3/10/2020; Aired	Genotyping Allele Selection - A Joint Report of AMP	Yuan Ji and Andria Del Tredici	148/76

2020 Education Initiatives

• Continuing Education credits (SAMs, 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 2020 virtual Annual Meeting & Expo, 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.

• <u>Online education - AMPED</u>™:

The T&E Committee and staff spent significant time designing and developing additional educational materials for populating the new, more versitile online learning platform at <u>educate.amp.org</u>. Most online educational offerings are complimentary for AMP members. Current content includes a 4-part series on <u>Emerging and Evolving Biomarkers</u>, the Training and Education Committee "Horizons" Series on hot topics, including COVID-19, a 5-webinar series on <u>Tumor Mutational Burden</u>, a 5-webinar series on <u>NSCLC</u>, and a 3-webinar series on <u>PARP inhibitors</u>. The site also features the online (enduring) <u>2019</u> <u>MGP Review Course</u>, 2018 and 2019 Molecular Pathology Outreach course recordings, and 2019 Annual Meeting recordings. There are many <u>self-study review tools</u>, including two sets of flashcards (on Colorectal Cancer and on Multiple Myeloma) and a Fellowship In-service Examination (FISE) question bank.

• <u>Course Bundles/AMP Certificate Programs</u>:

Also available on AMP*ED*[™] are two new course bundles available as certificate programs. They are:

1. "Next Generation Bioinformatics: Beyond Simple Variant Calling" and

2. "Molecular Laboratory Management & Reporting: A Short Course for Laboratory Professionals"

These are in addition to existing certificate programs, including "Circulating Tumor DNA Testing" and "Hot Topics in Infectious Disease."

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 <u>multiple myeloma</u> and a 20+ card set on <u>colorectal cancer</u>. These were launched in August of 2020.

• FISE Question Bank:

This is the third year of a continuing collaboration with the MGP-PD Council to provide fellows with a <u>Fellowship In-service Examination</u> (FISE) at the beginning and at the end of their fellowship year. Additional FISE exam questions were written by MGP faculty from many MGP-Fellowship institutions to cover a range of topics. The Council and the T&E Committee screen all existing questions annually and proof and check all new examination questions. For each attempt, a total of 45 questions randomly pulled from a question bank of >260 questions populate the examination, yielding a different test each

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time. 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).

• <u>Molecular-in-My-Pocket[™] cards:</u>

The T&E Committee continued expanding the Molecular-in-My-Pocket[™] reference card collection. Additional Oncology cards as well as new cards in Bioinformatics and Pediatric Molecular Pathology were made available in 2020. The latter cards were prepared in collaboration with the Society of Pediatric Pathology (SPP). There are now 21 cards, total. Cards are reviewed annually by T&E Committee members for accuracy and for any required updates. All MIMP Cards are available <u>online</u>, and hard copies are also distributed at the MGP Review Course, the Global Congress, the USCAP annual meeting, and the AMP Annual Meeting and Expo (when possible). 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 <u>Member Spotlights page</u> on the AMP website. Interviews and profiles highlight the training and career paths of various molecular professionals.

AMP 2020 Virtual Annual Meeting & Expo Activities

• Trainee Activities (Residents, Fellows, and Students)

This is the trainee Virtual Happy Hour & Mixer (Subtitle: "Livin' La Vida COVID"). Trainees are upholding AMP's Trainee Luncheon tradition in COVID times by transforming it into a Virtual Happy Hour & Mixer. This virtual event features an opportunity for trainees at all levels to interact and network with peers in their field as well as with prominent molecular pathologists. AMP's extensive trainee member benefits are outlined during the Happy Hour opening, and then four Mixer sessions, each focusing on relevant pandemic topics, are chosen. These include: How to make the best out of remote learning; virtual job interviews tips and tricks; "Should I worry about fewer jobs in the field due to COVID?" and the Impact of Molecular Pathology in development and deployment of COVID testing.

• <u>Technologist Activities</u>

This is the technologist Happy-hour (Navigating Opportunities for Career Advancement and Certification for Molecular Technologists). Organizers provide a road-map for navigating the confusing and sometimes frustrating field of career development in the molecular lab. Whether participants are trying to determine eligibility requirements for molecular certification, deciding which certifying body is best for them, or hoping to increase their certification level and broaden their career opportunities, this happy hour discussion will be an information-packed session.

• <u>Awards</u>

- Young Investigator Awards 27 poster candidates
- Technologist Poster Awards 12 poster candidates
- Registration Support Awards 15 trainee recipients

• The Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Council

The MGP Program Directors (MGP PD) Council consists of Keyur Patel (Chair), Rizwan Naeem (Chair-Elect), and Allison Cushman-Vokoun (Past-Chair). Kristen Hunt Karner 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)

Curriculum and Educational Manuscript Development Task Forces

- **PARP Manuscript:** This working group was led by Lynette Sholl and included Diana Mandelker and Tracy Stockley. This <u>manuscript</u>, titled, "Poly (ADP Ribose) Polymerase Inhibitors for Cancer: Essential Biologic, Diagnostic, and Therapeutic Concepts for Today's Practitioner" outlines the 2019 webinar series on PARP Inhibitors and was recently published in the *Journal of Molecular Diagnostics*.
- <u>A Molecular/Cytogenetic Curriculum for Hematopathology Fellows</u>: This <u>manuscript</u> was prepared in collaboration with the Society for Hematopathology (SH) and is titled, "Molecular/Cytogenetic Education for Hematopathology Fellows: A Recommended Curriculum from the Society for Hematopathology and the Association for Molecular Pathology." It was published in the *American Journal of Clinical Pathology*. Annette Kim was the official AMP Representative to the SH working group.
- <u>Genomics Education for Primary Care Residents</u>: 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 Yassmine Akkari, Maria Arcila, Devon Chabot-Richards, Preeti Pancholi and Anthony Snow.
- <u>MGP Fellow Training and Curriculum in Genomics Task Force</u>: The Task Force is headed by coleaders Jason Rosenbaum and Mark Ewalt and includes working group members Kristy Crooks, Jeff Gagan and David Wu. The manuscript is under review. 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.
- <u>Molecular Genetic Pathology (MGP) Curriculum Update (MGP-CUP</u>): 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.

Co-Sponsorships, Companion Meetings, and/or Collaborations

- (Virtual) United States and Canadian Academy of Pathology (USCAP) 2020
 - The AMP 2020 Companion Society Symposium, "Making Molecular Work: Maximizing Efficiency and Cost-Effectiveness in Complex Testing", was a virtual event co-moderated by Jason Rosenbaum, MD and Amir Behdad, MD, MBA. Speakers were: Gabriel Bien-Willner, MD, PhD Dara Aisner, MD, PhD
 - Dan Jones, MD, PhD
 - An AMP Short Course, *AMPlicons: Molecular Case Studies for the Practicing Pathologist* was co-presented by Annette Kim, MD, PhD and Cecilia Yeung, 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

• (Virtual) American Society for Clinical Pathology (ASCP)

ASCP 2020 AMP Workshop

"Molecular Diagnostics Primer: Advanced Principles" was presented by Alanna Church, MD and Erin Graf, PhD

• (Virtual) College of American Pathologists (CAP)

CAP 2020 Course Presentation

"Understanding NGS and Interpreting Reports for Oncologic Pathology" was presented by Sabah Kadri, PhD and Cecilia Yeung, MD

- <u>Cambridge Health Institute (CHI) Conferences</u>
 - Next Generation Dx Summit, August 25-27, 2020 (Virtual)
 - *Plenary Panel Discussion: Lessons Learned for Diagnostic Testing During the COVID-19 Pandemic.* Susan Hsiao, Alex Greninger, Jordan Laser, and David Walt.
 - COVID-19 Survey of Labs from the Association for Molecular Pathology: Recommendations for a Better Pandemic Response. Jordan Laser, Susan Butler-Wu, Frederick Nolte, and Eric Konnick.

• ASCO-CAP-AMP Multidisciplinary Molecular Tumor Boards (MMTBs)

The <u>Multidisciplinary Molecular Tumor Boards (MMTBs)</u> 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. AMP collaborates with the American Society for Clinical Oncology (ASCO) and the College of American Pathologists (CAP).

o AMP Representative: Susan Hsiao

AMP Subdivision Leadership Annual Report, 2020

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
Chair	Thomas Prior	Maria Arcila	Frederick Nolte	Somak Roy	Larry Jennings
Clinical Practice	Pinar Bayrak- Toydemir	Marian Harris	Daniel Cohen	Annette Leon	Jonathan Earle
Committee	Fatimah Nahhas	Rashmi Goswami	Joseph Yao	Joshua Coleman	Susan Hsiao
Economic Affairs Committee	Victoria Pratt	Maria Arcila	Jennifer Dien Bard	Jeffrey Gagan	Susan Hsaio
Nominating Committee	Qiulu Pan	KeyurPatel	Blake Buchan	Nefize Sertac Kip	Anna Yemelyanova
	Alka Chaubey	Rena Xian	Amy Leber	Matthew Lebo	Jennifer Laudadio
Program	Peter Kang	Mark Ewalt	Esther Babady	Angshumoy Roy	Rajyasree Emmadi
Committee	Ryan Schmidt	Noah Brown	Erin McElvania	AhmetZehir	Jonathan Nowak
Professional Relations Committee	Andria Del Tredici	Betty Chung	Frederick Nolte	Jordan Laser	Amy Lo
Training &	Alanna Church	Kristin Karner	Erin Graf	Sabah Kadri	Christian Kunder
Education Committee	Honey Reddi	Nathan Montgomery	Gerald Capraro	Weiwei Zhang	Lauren Ritterhouse

SUBDIVISION LEADERSHIP

PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair and Representatives to the Clinical Practice, Economic Affairs, Nominating, Program, Professional Relations, 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
- 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

2020 ACTIVITIES:

New in 2020 – All Subdivision Leadership groups contribute to biannual Subdivision Spotlight email digests that highlights AMP activities and *JMD* articles related to Subdivision member's interests.

<u>Genetics</u> - Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, variant interpretation and classification, next-generation sequencing, pharmacogenomics, whole genome and exome sequencing standards, forensics, diversity in genomic databases, and artificial intelligence/big data initiatives. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) by providing input for their efforts toward drafting a response to the FDA docket on *CYP2D6* genotyping for children under 12 and provided feedback to Scott Turner, AMP representative to the ACMG-led Interpretation of Sequence Variants Update Workgroup.

<u>Hematopathology</u> - Addressed current issues and topics in molecular hematopathology, including advances in translational research related to myelomas, MRD monitoring in hematologic malignancies, next-generation sequencing, immunology and artificial intelligence/big data initiatives. Curated and provided a "Must Reads" list of hematopathology-relevant literature to the Subdivision membership. Subdivision Leadership members also assisted the Economic Affairs Committee (EAC) by providing input for their efforts toward drafting a response to the proposed Local Coverage Determinations (dLCD) from the Medicare Administrative Contractor (MAC) Palmetto on molecular circulating tumor DNA (ctDNA) tests that detect minimum residual disease (MRD) in patients with a personal history of cancer.

Infectious Diseases - Addressed current issues and topics related to the clinical molecular diagnostics laboratory, including diagnostic microbiology and liquid biopsy in infection, SARS-CoV-2 and artificial intelligence / big data initiatives. Developed and published *Responding to the Challenges of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2): Perspectives from the Association for Molecular Pathology Infectious Disease Subdivision Leadership in JMD* (https://doi.org/10.1016/j.jmoldx.2020.06.003). Subdivision leadership helped design the SARS-CoV-2 molecular testing survey and the Chair participated as a panelists in both Virtual Town Halls summarizing and discussing the survey results. Subdivision Leadership members also assisted the New Codes and Pricing Subcommittee of the AMP Economic Affairs Committee (EAC) by providing input on National Correct Coding Initiative (NCCI) edits for ID codes that may affect AMP member laboratories.

<u>Informatics</u> - 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, body of knowledge (BoK) for Clinical Genomics Bioinformaticists and artificial intelligence/big data initiatives.

<u>Solid Tumors</u> - Addressed current issues and topics related to clinical applications of circulating tumor cells, tumor mutational burden, liquid biopsies, other factors related to clinical practice of cancer and artificial intelligence/big data initiatives. Subdivision Leadership members also assisted the Economic Affairs Committee (EAC) by providing input for their efforts toward drafting a response to the proposed Local Coverage Determinations (dLCD) from the Medicare Administrative Contractor (MAC) Palmetto on molecular circulating tumor DNA (ctDNA) tests that detect minimum residual disease (MRD) in patients with a personal history of cancer.

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.