Presidents Message:

Dear PASCV Members-

Welcome to another academic year of activity. It is an honor to take the reins of the organization from Greg Storch under whose leadership we accomplished a great deal. Here’s the 2015/2016 recap:

- We now have a new web portal that has improved functionality. It has simplified the member joining/renewal process, allowed for the rapid dissemination of critical information about emerging infections, and houses a growing repository of educational materials. We also have infrastructure to hold on-line education events. Many thanks to our administrative team – Jess Warner and Karen Wolowski – for researching possible solutions and helping us implement once we decided which would likely work best.
- The Education Committee made good use of these resources almost immediately to hold two webinars – one on rapid influenza NATs and one on Zika virus, held jointly with AMP.
- The Clinical Practice Committee members Melissa Miller, Matt Binnicker, and Greg Storch worked alongside ASM and IDSA colleagues to author a letter to the FDA and a position paper on the impact of FDA oversight of LDT’s. This collaboration and the Zika virus webinar are illustrations of how advantageous fruitful partnerships can be for growing societies like PASCV.
- PASCV’s membership grew, thanks to the energetic efforts of the Membership Committee. Our membership now stands at 329. 49 of you are new members. Welcome!
- The Fundraising Committee formulated a development plan and ran a successful campaign that raised the revenue required for infrastructure and staffing costs. These sponsors can be found on a revolving banner on PASCV’s home page.
- The Molecular Virology Workshop (MVW), PASCV’s educational jewel, was held on May 18, 2016 (Wednesday) prior to CVS and featured information-packed sessions on syndromic testing and an afternoon interactive session on practical challenges in molecular virology testing. Many thanks to the speakers and to the Program/Organizing Committee (Randy Hayden, Melissa Miller, and Matt Binnicker).
- At the CVS meeting, PASCV recognized the important contributions of treasured colleagues Belinda Yen-Lieberman, Herbert G.M. Niesters, and a new colleague Patricio L. Acosta. PASCV extends its thanks to its sponsors – BD Diagnostics, MBL Bion International, and Roche Diagnostics Corporation whose unrestricted educational grants made these awards possible. Congratulations Belinda, Bert, and Patricio!
Where do we go from here? My vision is to build strength from within, and recognition from outside PASCV. To accomplish this, my goals are to work with our members to foster activities that keep us on this path of growth and change and to encourage us to find novel ways to partner with other societies to increase our visibility and recognition. To this end, committees have spent the summer at work planning and implementing activities for the year. We are heading off in new creative directions in terms of educational content, under the leadership of Esther Babady and Angella Charnot-Katskikas. At least one webinar in partnership with another society is currently in the planning stages. Clinical Practice Committee formulated a response to FDA guidance on NGS in partnership with other societies, Membership Committee is working on creative ways to partner with other societies to increase our visibility and recognition, and the program for MVW 2017 (mark your calendars for May 6, 2017 in Savannah, Georgia, the day before CVS).

It is clear that PASCV is vibrant, active, and energetic in its support, advocacy, and representation of clinical virologists in the Americas. I look forward to working with you to continue blazing this trail.

2016 CVS – Daytona Beach, Florida – Steve Specter

The 32nd Annual Clinical Virology Symposium was held May 19-22, 2016 in Daytona Beach, FL. There were more than 1000 registrants from more than 30 countries who attended the meeting. Many great presentations were featured and details can be seen on the symposium website at www.clinicalvirologysymposium.org.

Highlights of the program include a late breaker session that featured the latest information on Zikavirus and the ongoing outbreak presented by Claudia Raja Gabiglia, MD, PhD, The Biomedical Res. Inst. of Southern California, Oceanside, CA. In addition David Morens, MD, NIAID, NIH, Bethesda, MD gave a fascinating talk on influenza and the lessons learned from reconstruction of the 1918 pandemic influenza; Staged Approaches to Viral Laboratory Diagnosis was presented by Thomas Briese, PhD, Columbia Univ.; New York, NY and William Jacobs, PhD, Albert Einstein Coll. of Med., Bronx, NY gave a provocative talk about studies in mice of a herpes simplex virus vaccine under development, among other outstanding talks. Interactive sessions included Virology Jeopardy and the Philip Hanff Clinical Cases.

Meeting Awards

The PASCV Award winners were – Ed Nowakowski Senior Memorial Clinical Virology Award - Herbert Niesters (University Medical Center, Groningen), Diagnostic Virology Award - Belinda Yen-Lieberman (Cleveland Clinic), and the Young Investigator Award- Patricio L Acosta (Consejo Nacional de Investigaciones Cientificas y Tecnologicas, Buenos Aires, Argentina).
There were 12 travel award presentations, the top 4 scoring abstracts received ASM travel awards and gave oral presentations – Mario Escobar Travel Award was received by Alex Greninger (University of Washington), Herman Friedman Travel Award was received by Sergei Belanov (University of Helsinki, *not pictured*), Edith Hsiung Travel Award was received by Ramzi Fattouh (University of Toronto) and the Edwin Lennette Travel Award was received by Allen Bateman (University of Washington).

There were 8 individuals who received PASCV-sponsored travel awards based on their abstract submissions – Colleen Courtney (New Your University), M Victoria Farquharson (Children’s Hospital of Philadelphia), Yury Kuzmichev (Johns Hopkins Bloomberg School of Public Health), Brianna Kyburz (Johns Hopkins University), Anum Liaquat (Dow University of Health Sciences), Armen Sanosyan (INSERM), Dharamveeer Singh (Sahjay Gandhi Post Graduate Institute of Medicine and Science), and finally the Latin American travel award to Adrianna Luchs (Adolfo Lutz Institute). Congratulations to all!! Please check the website for these awardee pictures.

Thank you to all of the committee members who helped create the program and to all of the commercial support which allows us to bring in quality speakers. PASCV also extends their thanks to the American Society for Microbiology for working so closely with us to keep the Molecular Virology Workshop and the CVS as consecutive co-located meetings.
Those involved in the CVS program creation were Symposium Chair Steven Specter and Vice-Chair Richard L. Hodinka along with their excellent program committee -

- Angela Caliendo
- Christine Ginocchio
- Randall Hayden
- Colleen Kraft

- Marie Landry
- Benjamin Pinsky
- Greg Storch
- Steven Young

The Molecular Virology workshop was co-Chaired by Matthew Binnicker, Randall Hayden, and Melissa Miller.

After 9 successful years in Daytona Beach, FL the CVS is going to try something new! The 33rd CVS will be held May 7-10, 2017 in Savannah, GA and the 34th CVS will be held May 8-11, 2018 in Palm Beach, FL. Looking forward to seeing everyone at our upcoming meetings.

**Finances and Membership – Michael Loeffelholz**

"It's my pleasure and honor to provide my first financial statement as Secretary/Treasurer. I'd like to thank Kathy Stellrecht, immediate past Secretary/Treasurer, for her years of service to PASCV and for helping me to get started in my new position. PASCV maintains a healthy financial position. Financial support provided by our industry colleagues for the 2016 Molecular Virology Workshop was excellent.

Regarding membership, PASCV is happy to announce a revised membership renewal period running January 1 through December 31, 2017. The 2016 memberships will expire on December 31, 2016, NOT September 30, 2016. Members will be able to renew for 2017 beginning in November 2016.

Membership and new members – We are growing! A total of 49 new members have joined us so far this year, including 20 new members who joined at the CVS meeting/PASCV workshop. Welcome to all!! We now have about 325 members for the year, with more to come hopefully.

**Why be a member?** The Pan American Society for Clinical Virology is much more than a group of professionals dedicated to the field of virology. The PASCV gives you the invaluable opportunity to network with hundreds of other professionals whose life’s work is the same as yours. Through this network, you’ll find the clinical, scientific, and technical resources and support you need to achieve outstanding patient care and research. Renew or join at [www.pascv.org](http://www.pascv.org). Membership rates are: MD, PhD, DVM, Industry - $100 Technical Staff - $50 Students - $25. Members get discounted registration for the Molecular Virology Workshop and a discounted subscription rate for the Journal of Clinical Virology.
Regulatory Issues Update

FDA NGS Guidance Document - On September 11, PASCV in conjunction with ASM, AMP, APHL and IDSA submitted a comments document concerning the FDA guidance document, FDA-2016-D-0971, “Infectious Disease Next Generation Sequencing based diagnostic devices: Microbial identification and detection of anti-microbial resistance and virulence markers”. A link to a copy of the submitted comments letter can currently be found on the main page of the PASCV (pascv.org, click on the PASCV Position Statements and Letters picture box). The statement called attention to the potential impact of “agnostic” testing, where the organism of interest is unknown prior to the NGS testing. Unfortunately, the FDA guidance document does little to address this issue, rather has a focus on a “panel-based” approach for identification of known organisms. The regulatory issues of agnostic testing are complex around items like the limit of detection or the level of risk of a testing device (i.e., looking for Hepatitis B or C but finding a Class III agent instead). The comment response suggests that “the FDA needs to reformulate the draft guidance to address how each section applies to agnostic testing” and volunteers our experts to assist the FDA in this effort. The comment document also suggests a needed flexibility in the guidance document concerning the personnel and interpretive sections of the document, and suggests that interpretation of complex mixtures of microorganisms will require significant expertise to determine pathogenic potential of all identified organisms. Another major comment was directed towards the requirements of sequence databases and comments that curated regulated databases as “required” in the FDA documents either do not currently exist or are less complete than needed. Please review the FDA document and the PASCV response, and contact Melissa Miller or Matt Binnicker if you have additional insight to consider.

FDA Conferences and Hearings –
There are several upcoming government sponsored meetings which are being held that the Clinical Practices committee are attending, providing comments, or giving expert testimony for –

- FDA Medical Devices Advisory Committee (Microbiology Medical Devices Panel) – Nov 9th, Gaithersburg, Md. This panel will be considering “Reclassification of quantitative CMV viral load devices from Class III to Class II”. See the “Better Tests, Better Care: Improved Diagnostics for Infectious Diseases” article from the IDSA in CID 2013:57:S139 for more information about this subject.


- Government Accountability Office – Response to Zika virus including diagnostics. – Nov 9-10, National Academies of Sciences, Washington, D.C. A letter addressing Zika virus diagnostics can be found on the pascv.org website under Educational Resources/Clinical Practice/Advocacy.

-Contact the one of the co-chairs of the Clinical practice committee for more information about these issues or to provide input.

CHECK OUT – new to the web site in the Educational Resources section a summary of all abstracts about EV-D68 presented at the April CVS meeting.