

2017 AAAAI Election for Secretary-Treasurer Questions from the Membership



David A. Lang, MD, FAAAAI



Andrew W. Murphy, MD, FAAAAI

Question: How can the AAAAI create greater participation in registries and how can this activity be better leveraged to create specialty specific measures? Do you feel registries should be shared with other specialties, such as ENT, that also provide services similar to our members? If so, how would you avoid the appearance of supporting ENT allergy at the expense of our members?

Lang: Implementing registries is a means to obtain information on patient outcomes that can address knowledge gaps in current care patterns and their relationship to outcomes of care. Registries are being implemented by AAAAI specifically based on our quality measures, which in turn have been based on strong recommendations from our Practice Parameters. Registries can provide feedback for our specialty that can lead to quality and performance improvement and enhanced outcomes of care, and also can provide important feedback for the process of developing and refining our Practice Parameters.

We are currently transitioning from a volume-based healthcare system to one in which value-based care will be an increasingly important component of reimbursement. As quality measures are endorsed by organizations such as the National Quality Forum, and are adopted by payers, a registry coordinated via the AAAAI can serve to aid members in this transition.

I would foresee a system in which participating in AAAAI registries would potentially lead to identifying gaps in achieving compliance with quality measures; AAAAI could then work with each individual member or group to develop strategies to improve compliance as warranted. This would aid participants in being compliant with quality measures that are related to actual reimbursement from payers.

Initially I would not favor collaborating with other specialties; rather I would focus more narrowly, on a limited number of quality measures for our registry: (1) demonstrating an improvement in asthma control that exceeds a minimum important difference -- which is an outcomes measure; (2) assessment of IgE sensitivity to aeroallergens prior to initiation of immunotherapy and documentation of this in the medical record. AAAAI registries would subsequently expand to include additional measures, and a process by which patients would also report outcomes (from the allergist's office and/or from home or elsewhere).

The lack of robust data from registries in our specialty is a gap that needs to be remedied. I believe the above strategy will lead to the AAAAI registries being more successful in encouraging participation as well as quality and performance improvement.

Murphy: The implementation of MACRA and MIPS is probably one of, if not the most significant, programs impacting medical practice today. MACRA/MIPS is replacing the previous reimbursement system based upon volume to one that will now be based upon “quality.” This new system consolidates the previous PQRS and MU reporting into a new system with four distinct parts - three of which can be met with the AAAAI Quality Clinical Data Registry (QCDR). Over the past year, working with Hart Health Strategies, one of our consultants in Washington DC, the AAAAI has developed several webinars related to MACRA/MIPS and the QCDR. Most recently in mid-November after the final MACRA rule was published, we were able to quickly develop a webinar for AAAAI members, which reviewed the final rule and the implications for A/I practices.

Several years ago the AAAAI recognized the shift toward quality-based reimbursement and made the very significant investment of time and money in development of quality measures and the QCDR. This foresight has positioned the AAAAI as one of the leading specialties in this area and has allowed the AAAAI QCDR to be in the unique position to help facilitate member participation in this new payment model. The AAAAI has continued to devote significant time and energy to support the QCDR, recognizing the impact these monumental changes will have on its members. Numerous webinars and resources are available on the AAAAI website for members to utilize as an aid in implementing MIPS. The AAAAI will continue educational efforts related to the QCDR; we will continue to reach out to various EHR vendors to encourage them to utilize the AAAAI QCDR and we will continue to support members as they implement the QCDR in their practices.

The AAAAI as one of the early pioneers in QCDR development has been viewed as a leader in this area. The development of quality measure(s) and the QCDR is a very costly endeavor. Collaboration with other specialties to develop these quality measures and use of the AAAAI QCDR will potentially help offset these costs. Collaborating with other specialties allows the AAAAI to significantly influence the quality measure development process which ultimately may result in measures that are more impactful and potentially improve care and benefit patients. I welcome collaboration with other specialties. In fact the dynamic nature of medical practice today, I think, demands collaboration.

Question: What approach should the AAAAI take to help ensure medications are affordable and available to our patients without actually getting directly into pricing issues that could have legal ramifications? How can we balance our advocacy knowing that pharma is part of the medical community bringing new products forward and supportive of our Annual Meeting?

Lang: As noted in an article earlier this year (*N Engl J Med* 2016; 374:1807-1809), public debate in past decades over the clinical toxicity of drugs has recently given way to concerns about their “financial toxicity.” Almost three of four Americans find the cost of drugs to be unreasonable. While there may be boundaries for the AAAAI in terms of legal ramifications, I believe the AAAAI leadership should advocate in this and other situations to address barriers that can interfere with our patients achieving the goals of management (e.g., well controlled asthma) – in this instance due to the cost of medications.

While newly introduced drugs should be priced to support R&D investment, the frequently advanced argument that R&D costs are the most important factor related to the high cost of medications was dispelled by our recent experience with the dramatic surge in the price of injectable epinephrine. In a marketplace in which companies can charge whatever the market will bear, I believe our efforts should include advocating for: (1) regulators to streamline the current approval process, so that generics, “me-too” drugs, and biosimilars can be approved more rapidly; (2) pharmaceutical companies to expand their patient assistance programs; (3) pharmacoeconomic studies to appraise new medications, focusing on patient-centered outcomes and measuring *value* – to our patients and the healthcare system.

Murphy: The mission statement of the AAAAI is “...dedicated to the advancement of the knowledge and practice of allergy, asthma and immunology for optimal patient care” and must form the basis of any interaction with pharmaceutical companies and any other organizational relationship that the AAAAI develops. I firmly believe that

adherence to this principle will hold the AAAAI in good stead and will not negatively affect relationships with others. If the occasion arises where the AAAAI is asked to compromise this principle, the answer is simple: we will not!

The issue of the cost of medicines, and health care in general, to our patients are ongoing issues that continue to effect delivery of healthcare. Those of us who have practiced long enough have seen the cost of medicines rise in ways that seem to confound common and well as economic sense. This issue is not unique to A/I and impacts all medical specialties. As the questioner points out, the AAAAI must avoid making statements that appear to have negative implications. Having said that, I do think that the AAAAI, and A/I physicians, can take steps to advocate on behalf of our patients for affordable treatment options. I would propose the following:

- The AAAAI will develop inter and intra-specialty collaborations to develop joint statements to present to appropriate regulatory and legislative bodies that respectfully advocates for affordable medications for patients.
- The AAAAI, under appropriate guidance, will consider direct communication with pharmaceutical company leadership to express concern on behalf of A/I patients about the cost of medication(s). The AAAAI must not advocate for particular medicines but rather that the medication costs must be affordable.
- The AAAAI needs to continue to provide outstanding medical education resources such that A/I physicians are able to make correct and accurate diagnosis and develop treatment plans that are consistent with best A/I practices.

The practice of A/I is the paradigm of personalized precision medicine and as such can have a profound impact upon the cost of medical care and our patients' ability to afford care. As A/I physicians we need to understand the cost of the medications and diagnostic tests we recommend and the impact that this will have on our patients. We need to foster candid communication with our patients so that we truly act as our patients' advocate and trusted healthcare provider.

Question: Where do you see our specialty and the AAAAI in the next 5 years in the present landscape? How do you intend to attract new members and maintain membership?

Lang: I have heard a number of concerns expressed by allergists in different areas of the United States: declining reimbursement for services; increasing use of *in vitro* testing by other healthcare providers; a lack of appreciation of the role of subcutaneous allergen immunotherapy for properly selected patients (with hymenoptera venom anaphylaxis, asthma and/or allergic rhinitis). In his book, *Go Put Your Strengths To Work*, Marcus Buckingham makes the point that we achieve the greatest results by making the most of our strengths, rather than striving to work on perceived weaknesses or deficits.

I believe our strategy for the next 5 years should entail promoting our strengths *in areas that we own*: maintaining and expanding our role in diagnosis and management of patients with food allergy, drug allergy, and anaphylaxis. Asthma and allergic rhinitis are also among our strengths. However, our specialty is underappreciated. Many patients with conditions such as asthma and allergic rhinitis, who would experience improved outcomes from allergy/immunology care, do not come to see us. The AAAAI must lead efforts to secure our future by capitalizing on opportunities to demonstrate that allergy/immunology care brings *value*, and is associated with improved patient care outcomes and patient satisfaction.

In the present landscape, I believe it is important for us to expand our scope of practice. The AAAAI has taken strides to initiate a curriculum that will encourage expansion of clinical practice for care of patients with conditions such as COPD, contact dermatitis, and immune dysregulatory states. This curriculum merits continued support.

These activities need to be coupled with expanded advocacy: at governmental agencies, with legislators, and healthcare plans, organized in collaboration with RSLAAIS activities at regional and local levels.

Promotion via enhanced public relations will also aid in creating greater visibility for our specialty, and achieving the goal of allergy/immunology being perceived as bringing value to the table.

We will soon have a more substantial proportion of AAAAI members who are Generation Y learners. The AAAAI needs to support a process by which the curriculum at our Annual Meeting will continue to evolve. We need to move forward in developing educational sessions that are interactive, multi-faceted, and mixed didactic-interactive. Such sessions will foster more successful educational outcomes. This will likely entail a series of trial and error strategies not only at the AAAAI Annual Meeting but also in online programs. Strides can be taken to enhance the connectedness of young members to the AAAAI via initiatives such as the Leadership Institute and curricula at our Annual Meeting directed at fellows and recently graduated fellows. It is imperative for the AAAAI to encourage young members who have recently completed or are still completing fellowship training to join and become active in interest sections and committees, and mentor them to enhance their leadership and management skills so they can become more effective in their current roles, and prepare them for assuming leadership roles in the AAAAI

Murphy: The practice of medicine is currently in a state of flux that has not been seen for a generation. I am not sure that the “present landscape” we are in today will be present in the next 6 months, let alone the next 5 years. Having said that, I think this is a time of great opportunity for A/I. I base this on lessons learned from several significant projects that I have either had direct involvement in or provided support to in the various leadership roles I have had in the AAAAI.

First, the proposed changes to USP 797. This radical regulatory overreach has allowed the AAAAI to emerge as a leader in advocacy for the physician - patient relationship and the practice of medicine. In our advocacy efforts on this issue, we have developed and/or deepened significant relationships with a multitude of professional organizations and specialties including the Federation of State Medical Boards, AMA, ENT, Dermatology and Mohs Surgery Society to name a few. In addition we have demonstrated to USP, the FDA and members of Congress that the AAAAI is absolutely committed to the care of A/I patients and we will strenuously advocate for our patients and our specialty.

Second, the importance of antibiotic stewardship and diagnosis of penicillin (PCN) allergy. Over the past 2 years or so, there has been national attention paid to the development of drug resistant infections and the lack of antibiotics available for these infections. What has been lacking is the realization that PCN allergy is most times misdiagnosed and a lack of awareness about the importance of PCN skin testing and drug desensitization. Recognizing this, the AAAAI established the Penicillin Allergy and Antibiotic Resistance (PAAR) Work Group, of which I have been a member. PAAR recently developed, and published, the AAAAI Position Statement on Penicillin Skin Testing. The AAAAI, working through our Washington lobbyists and others has been able to provide information to legislators working on the 21st Century Cures legislation as well as providing information to the Presidential Commission on Antibiotic Resistance (PCARB) on the importance of proper diagnosis of those labeled as penicillin allergic. Further, we have engaged in conversations with the Infectious Disease Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) about the critical role A/I can play in properly identifying (or de-identifying) PCN allergic patients and, if needed, providing drug desensitization treatment options. This collaboration with IDSA has resulted in the IDSA being invited to the November meeting of the AAAAI lay organizations to educate them and engage our lay organizations on this topic.

The School-based Asthma Management Program, or SAMPRO™, an initiative of Dr. Lemanske’s presidency, has engaged a wide swath of medical, nursing and governmental officials that has further cemented the AAAAI as the leader in asthma and allergic diseases. Like other advocacy efforts, the SAMPRO™ project has allowed the AAAAI to present itself and A/I as the “go to” organization with questions related to asthma and allergic diseases.

What does this all mean for the AAAAI and A/I practice? The above examples have placed the AAAAI and A/I in a position to be recognized as the leading professional organization for issues related to A/I. The development of the PCN allergy skin testing position statement gives the community A/I physician the opportunity to positively impact antibiotic stewardship on the local level. The implementation of SAMPRO™ will give the community A/I physician the tools needed to continue to be recognized as the local expert for asthma and related allergic diseases. The AAAAI, drawing from these

successful multi-organizational collaborative programs will continue to expand our outreach and advocacy to ensure the future of A/I.

I want to take a moment and make very clear that I and the AAAAI will be deeply committed to the practice of A/I. Over the past several years I have served in numerous leadership roles from the chair of the RSLAAIS Assembly, chair of the Advocacy Committee, to chair of Practice & Policy as a member of the Board of Directors, and I will state unequivocally that the AAAAI is fully and deeply committed to the clinicians who practice A/I! The establishment of the Office of Practice Management (OPM), of which I am an inaugural member, was the vision of Dr. Jim Li and is a very tangible demonstration of this commitment. The OPM provides oversight and guidance to the myriad of practice-related issues including: Quality/QCDR; advocacy; healthcare organization relationships; coding information and resources; the Practice Management Workshop and the e-publication Practice Matters. The OPM will continue under my leadership and we will devote the appropriate resources that are needed to ensure that AAAAI members—wherever they practice—will have access to the most timely and updated practice information needed to provide outstanding A/I care.

Finally, a word about communication. I have seen up close the extraordinary number of resources that the AAAAI has devoted to A/I practice. I will also acknowledge that the AAAAI, in the past, has not communicated effectively about these resources. I am very proud to have been a part of the team that conceptualized, developed, implemented and continues to publish Practice Matters. This e- publication has become one of, if not the most successful, e-publication of the AAAAI. Practice Matters is the go-to monthly publication that provides timely updates on RSL Matters, Advocacy Matters and Practice and Policy Matters. In addition, in partnership with JACI: *In Practice* we provide members two must-read articles that will impact patient care. This communication will continue to evolve to ensure that all AAAAI members will benefit from the resources of the AAAAI.

I know I have been long winded, but I see a bright future for A/I. We will continue to be the strong national voice for A/I and our patients. We will continue to develop multi-organizational and multi-specialty collaborations that will secure the future of A/I. The AAAAI will be absolutely committed to the clinical practice of A/I and we will continue to effectively communicate with our members on important and practical information related to the practice of A/I.

Question: Over the past several years, there has been a lack of opportunities for graduate students within the AAAAI; in particular, there have been no travel award opportunities, nor is there a recruitment/retention program analogous to the Chrysalis program for MS and PhD students, or postdocs. What would you do to encourage young basic scientists to pursue basic and clinical research careers in the field of allergy/immunology?

Lang: I believe it is important to maintain the success of the Chrysalis Program and also to enhance participation of young basic scientists in AAAAI. The AAAAI Strategic Plan was developed to "... capture the essence of who we are and what we intend to accomplish." Among our core values, stewardship includes identifying and recruiting as members highly qualified MD/DO fellowship candidates, allied health professionals, *and PhDs*. Our Strategic Plan values the role of AAAAI to inspire and foster the next generation of leaders in research in the field of allergy/immunology.

I was fortunate to be invited to participate as a "mentor" in the AAAAI Leadership Mentorship Program. I would expand this program to include established investigators as "mentors" and young basic scientists as "mentees." Other initiatives can include travel awards and curricula (both at the AAAAI meeting and online) to encourage participation of PhD students and postdocs.

With respect to pursuing research or academic careers in allergy/immunology, it is important to note that our specialty is not represented at many academic medical centers. An initiative that would share features of the Phoenix program, that will promote new allergy/immunology programs, can address this challenge. Worthy junior faculty would be identified during their first year of fellowship, and receive additional training in an academic track, to provide them with the skills needed to be successful in this endeavor. Support from the AAAAI Foundation, in collaboration with a host institution, can encourage the success of this program.

Murphy: This is absolutely correct. The AAAAI needs to engage the basic science community in a more meaningful manner. Several years ago this was made very clear through the work of the Basic and Mechanistic Science Presidential Task Force. This must be changed. The advances of biologic therapeutics into the clinical realm reinforces the importance of supporting and engaging basic science researchers and the next generation of researchers in allergic and immunologic diseases. To address this issue in a very immediate and concrete manner, I would establish the following:

Presidential Basic Science Poster Session - The poster session would be akin to the late breaking abstract program that already exists but be uniquely focused on research done by PhD students, post-doctoral fellows and established researchers. I envision this session to be a competitive program that will accept only the best of the best posters.

Basic Science Research Award - This award would be presented to the best PhD student or post-doctoral research presented at the AAAAI. I would envision this award consisting of a plaque, potentially a cash award and public recognition by the AAAAI.

PhD Leadership/Mentorship Program - The AAAAI several years ago established the Leadership Institute to develop future leaders in the AAAAI. While the leadership program is open to all members of the AAAAI, the reality is that it is predominated by physicians. I would develop a parallel PhD leadership/mentorship program and challenge current PhD leaders in the AAAAI to collaborate with the Leadership Institute to see this to fruition. Clearly there would be significant overlap in terms of resources that would be utilized but a specific outreach to the PhD community is appropriate and needed. I would develop a PhD mentorship program that would allow pairing of senior AAAAI PhD members with more junior members to be a resource for career development.

During Dr. Estelle Simons' presidency she initiated the ST*AR program that sought to engage and highlight the work of our basic science colleagues. I see no reason why this program could not be reevaluated and be reworked to meet present day realities. I would propose the establishment of a work group to define this program (eligibility, number of participants, goal(s), funding) and develop an action plan to present to the Board of Directors for consideration. I believe a well thought out program with clear goals that is financially sound would be well received and supported by the AAAAI.

Lastly, I would suggest that the relaunching of the Hypersensitivity School is an additional opportunity for the AAAAI to engage the PhD community. This intense research-focused forum has been an opportunity for junior physician scientists to interact and learn from senior physician scientists and has been very successful. I would propose that junior PhD researchers be considered for this program as well. I fully anticipate that PhD participants will find this program just as rewarding and applicable to their careers.

Question: How do you propose to address the proposed changes in USP 797 and FDA rules on insanitary office-based compounding, both of which will substantially affect our ability to provide allergy immunotherapy?

Lang: Compounding allergen immunotherapy treatment vials is a complicated process that when carried out appropriately can optimize care outcomes. The Joint Commission actively enforces compliance with the US Pharmacopeia (USP) Chapter 797, as required by many state boards of pharmacy. USP 797 includes extensive procedures for sterile compounding. Adoption of the proposed policies currently under consideration for office-based compounding would restrict patient access to allergen immunotherapy.

This is a very important issue for our specialty.

I believe the AAAAI should continue current initiatives, in collaboration with the American College of Allergy, Asthma & Immunology, the American Rhinologic Society, the American Academy of Otolaryngology – Head and Neck Surgery, the American College of Physicians, and the Allergy and Asthma Network, to advocate for our specialty and our patients to:

legislators – including newly elected members of the 115th U.S. Congress, the USP Compounding Expert Committee, the FDA, the Federation of State Medical Boards, and other relevant organizations and regulatory agencies.

In the field of epidemiology, multiple studies reporting the same finding can provide a higher level of certainty that the finding is definitive. Additional centers should be encouraged to publish articles similar to the study from Massachusetts General Hospital, in which administration of more than 136,000 immunotherapy injections to over 3,200 patients in a 10-year period was associated with no infectious complications (J Allergy Clin Immunol 2016; 137; 6: 1887-1888).

We should be prepared for the controversies surrounding sterile compounding to continue in the future. It is imperative that our collaborations with other societies are maintained, and that our strategies are coordinated such that our message is consistent and we speak with one voice. We must continue to advocate strongly in this arena.

Murphy: As chair of the Advocacy Committee for the past 2 years, I am intimately familiar with the actions of the USP and the FDA regarding in office compounding of allergen extracts. This, along with the implementation of MACRA/MIPS, are the two most important issues that will impact A/I practice in the immediate future. I have been working with AAAAI senior leadership, AAAAI staff and our lobbyists in Washington, DC, to make the USP and FDA aware of our concerns related to this issue and to effect changes to this proposed modification of USP 797.

In the past 18 months we have sought out and developed multi-organizational relationships with other professional entities surrounding this issue of in office compounding of allergen extracts. We have, working with A/I colleagues, defeated a resolution at the Federation of State Medical Boards (FSMB) that would have significant negative implications for in office compounding. In the process we educated the FSMB about the negative impact on patient care that limiting a physician's ability to compound medicine would have. We have worked with AMA staff to make them understand the importance of in office allergen extract compounding and this has led to a resolution at the recent AMA House of Delegates meeting that directs the AMA to directly advocate on this issue. In addition, since in office compounding affects other specialties, we have been working collaboratively with ENT, Dermatology, the Mohs Surgery Society and others to advocate strongly with various regulatory agencies about the role and importance of in office compounding of select medicines. We have engaged and achieved significant input from the A/I community and our patients about in office allergen extract compounding. The USP received over 8,000 comments about chapter 797 with 4,000 of these comments coming from the A/I community. The change.org petition we organized resulted in almost 17,000 comments that were forwarded to USP. These actions have had a direct impact. The USP has established a steering committee, with significant A/I representation, to plan a USP Roundtable on Compounding Allergen Immunotherapy in February 2017. I have had the opportunity to speak directly with representatives of USP, FSMB and the AMA as well as present comments directly to the FDA on the behalf of the AAAAI regarding allergen extract compounding in physician offices. Finally, we have been speaking directly to members of Congress and have reached out to President-Elect Trump's transition team about the gross regulatory overreach, the direct interference with patient care and significant negative patient care consequences that these proposed actions of the USP and FDA will have.

Moving forward, we will continue to develop this broad based coalition of professional organizations and engage others as appropriate; we will continue to reach out to members of Congress and the Senate to make them understand that the USP and FDA are making a decision regarding in office allergen extract compounding that has: no basis in medical literature, that current data suggests is safe and does not place our patients at risk for infectious complications, that the actions of the FDA are a gross regulatory overreach that will harm patients, that the action of the USP and FDA are interfering with the practice of medicine and that allergen immunotherapy is a safe, effective therapy that has saved lives, improved patient care and lowered healthcare costs; and we will continue to actively engage the USP and the FDA at every opportunity possible. When needed we will engage you, the members of the AAAAI and your patients to speak up and advocate for the continued access to a therapy that has 100 years of safety and efficacy.