



**MID-YEAR FORUM 2021
VIRTUAL | APRIL 23-34**

SESSION/HEARING REPORTS

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Mid-Year Forum 2021 Report

Session Name: 2020 Hindsight: Lessons Learned as We Look Ahead

I. Abstract

The COVID-19 pandemic brought about sudden and unplanned for impact on health care systems globally that required immediate and effective response on multiple fronts with patient care being first and foremost. This session explores the impact from several vantage points and what was done to address the needs of a changed environment.

II. Background Information

Not in 100 years has the world faced a pandemic as severe as was experienced with the advent of COVID-19. Yet the world, and in particular health care, was pressed to respond quickly and as effectively as possible.

III. Summary of Comments from Guest Speakers

Moderator:

Tamara R. Fountain, MD – President, American Academy of Ophthalmology

David C. Herman, MD – Chief Executive Officer, Essentia Health
Directing a Healthcare System

Dr. Herman, as a CEO of a major healthcare system, provided an overview of the different phases of the pandemic, its impact and the ways they were able to respond.

Initially, there was a significant decrease in the volume of care provided and the associated revenue. This led to administrative leaves, layoffs, and compensation cuts.

Next preparations were made for the anticipated surge of COVID patients by ensuring sufficient hospital and ICU beds, staff, and PPE. This impacted their bandwidth in caring for urgent non-COVID patients. There was also concern for the interrupted care of other patients with chronic conditions. Finally, there was a toll on health care providers who faced burn out from the intensity and length of the pandemic and the high mortality rate.

The pandemic pointed out the weaknesses in our health care system and the social, economic and physical impact and inequities borne by those who are least advantaged. We must take action to eliminate health inequities in our sphere of influence.

David W. Parke II, MD – Chief Executive Officer, American Academy of Ophthalmology
Impact on the Profession and the Way Forward

Dr. Parke stated that physicians become the key combatants and sources of trusted information during the pandemic. The Academy provided disease education and information, as well as practice help in a timely way. COVID information on the Academy website grew to 300 pages within one month and had 1 million views.

Telemedicine has not evolved to the point that is useful for ophthalmological care. Ophthalmology telemedicine visits were under 1%.

The Academy successfully managed through COVID, emerging in a strong position. Expenses

were slashed, the meeting pivoted to a successful virtual format, and staff count decreased by attrition. All major programs are intact.

Academy education programs are more web-based and interactive. Advocacy activities were conducted virtually; issues were reprioritized. Ophthalmic practice focused on the changing structures and economics. The Academy engaged in public health issues that are in its “lane”. The Academy emerged fiscally and functionally sound as it increasingly serves as an “umbrella” for the entire profession.

Joan W. Miller, MD – Chief of Ophthalmology, Mass Eye & Ear
Challenges Faced by Academic Medical Centers

Dr. Miller’s department immediately pivoted at the start of the pandemic. Non-urgent surgeries and clinic visits were eliminated, resulting in an 85% decrease in visit volume and an 88% decrease in OR volume. Residents and faculties were deployed to care for COVID patients.

By December 2020 patient visits resumed and exceeded the pre-pandemic baseline by 3%, although overall the annual cumulative volume was down by 18%.

Research was reduced and limited to essential onsite activities. However, grant submissions increased. Mass Eye and Ear had a \$12.6M increase in new award funding for FY20.

Educational activities moved to a virtual format. With decreased surgical volume, there was increased reliance on simulation. A virtual surgical training lab curriculum was developed. Residents graduated with near normal surgical volume.

Focus was placed on diversity, equity, and inclusion. Care is being expanded in resource poor communities. Residents are involved in community health center work with plans to begin a curriculum in anti-racism. Research data should include data on social determinants, including race and ethnicity. Mentorship is being provided for under represented minority medical students.

Paul L. Lee, MD, JD – Chair, Ophthalmology & Visual Sciences
Ophthalmology’s Social Compact

Dr. Lee stated that physicians social compact with society has been strengthened by its response to the pandemic. Putting themselves at personal risk, physicians from all specialties cared for COVID-19 patients. Adaptations to COVID-19 have accelerated needed change to models of care delivery and to lifelong learning.

The pandemic brought to the forefront the disparities in care, including eye care, and the importance of reducing those disparities in visual health.

Dr. Lee suggested that as physicians we should.

- Expand our use of social histories to better understand the social determinants of care and outcomes.
- Examine and change our policies and practices that create differential opportunities.
- Educate ourselves about different communities and cultures.
- Recognize and acknowledge our own biases to mitigate negative effects.

IV. Summary of Audience Comments

- It is important to heighten awareness/education among physicians – both residents and clinicians - about the social determinants of health that impact patients.

V. High Priority Objectives

- Provide practical information about social determinants of health that members can incorporate into their patient encounters. Academy DEI information can be found here <https://www.aao.org/diversity-equity-and-inclusion>



Mid-Year Forum 2021 Report

Session Name: Outlook for Physician Payment: Navigating a Rapidly Changing Landscape

I. Abstract

Physicians are the only providers under Medicare without a cost-of-living update. The Medicare Access and CHIP Reauthorization Act provided a pathway for increased payments for physicians based on quality performance and alternative payment model success but has not delivered significant change for most physicians. Challenges such as fiscal cliffs and budget neutrality rules that create severe negative impacts on the Medicare fee schedule have the house of medicine infighting and calling a 0% update year after year a win. What Medicare reimbursement and physician payment reforms are on the horizon and how does Medicine break out and restore equity for physician payment?

II. Background Information

The rapidly changing landscape of physician payments — which threatens to hammer providers in 2022 — was the focus of a riled-up panel at Mid-Year Forum 2021. The Academy was joined in the panel by the President of the American Medical Association (AMA), two of ophthalmology's congressional champions and a representative of the American College of Surgeons (ACS).

III. Summary of Comments from Guest Speakers

Susan Bailey, MD, President, American Medical Association

Dr. Bailey stated that “physician payment cuts are clearly not sustainable as physicians continue to recover from the financial impact of the COVID-19 pandemic. We know that certain office-based practices and specialties, especially ophthalmology, experienced some of the greatest economic impacts from the pandemic as patients postponed eye exams and surgery.”

Dr. Bailey gave background on recent events. The physician community, working with the AMA, recently got Congress to extend the moratorium on the Medicare 2% sequestration cut until the end of 2021. However, Bailey cautioned that the looming cuts for 2022, which will apply to all physicians, are very steep even in the best of times.

Dr. Bailey reiterated that it is time for a physician payment update and the AMA is also advocating for global surgical payment equity, a top priority for the Academy.

Michael X. Repka, MD, MBA, Medical Director for Governmental Affairs Division, AAO

Dr. Repka discussed how Ophthalmology has fared in recent history and how the outlook is not good for surgical subspecialties going forward. Although ophthalmology narrowly escaped a 6% reduction in physician payment for 2021 and ended up with a 1% increase overall, the specialty, along with the rest of medicine is potentially facing a combination of payment cuts beginning Jan. 1, 2022 that could amount to more than 10%.

Christian Shalgian, Director Policy, American College of Surgeons

Christian discussed the need for the surgical community to come together to tell the surgeons story and advocate for fair reimbursement. He hammered home that payment cuts for physicians must stop, and grassroots advocacy is paramount. Christian also discussed the importance of coalition building and working together to be successful particularly in the face of deference in favor of primary care.

David Glasser, MD, Secretary, Federal Affairs, AAO

Dr. Glasser discussed how ophthalmologist can navigate and survive the current payment landscape today. He touched on the use of the new evaluation and management codes, telemedicine, and practice productivity improvements. Dr. Glasser also covered consequences of payment reductions over time and how that has played business decisions for practices.

Ami Bera, MD, D-Calif, Representative, U.S. Congress

Dr. Bera led efforts that resulted in the short-term solution to budget neutrality issues and payment cuts and spoke about the outlook for further Congressional action this year. He acknowledged that the Medicare Access and CHIP Reauthorization Act (MACRA) is not the program that was promised and going forward there is a need to develop an alternative mechanism to address physician payment reductions. Dr. Bera highlighted the importance of being reimbursed on outcomes and value as well as care being patient centric. Like Christian he also discussed how the house of medicine, specialty care and primary care, needs to work together to find solutions. Dr. Bera stated he will continue to push for “common-sense legislation” to address the “ongoing issues with the [physician] fee schedule in the new Congress.”

Larry Bucshon, MD, R-Ind, Representative, U.S. Congress

Dr. Bucshon also highlighted the need for robust advocacy to get solutions to these issues through congress. He emphasized that the physician payment landscape pitting house of medicine against each other is an unfortunate issue. Dr. Bucshon also discussed the impending fiscal cliff in Medicare and the importance of not cutting physician pay during a pandemic. Dr. Bucshon committed to addressing the global surgical payment equity issue with his colleague Dr. Bera. Both agreed that they want

all boats to rise together, and the current zero-sum game of budget neutrality is increasingly frustrating.

IV. Summary of Audience Comments

The audience was engaged and asked several questions highlighted below:

- How can we in organized medicine bring the focus on the “budget neutral environment” that results in we as physicians just continuing to take a smaller compensation while other areas of the healthcare sector get richer.
- Questions on physician compensation over time and being able to attract the best and brightest to medicine and ophthalmology.
- Questions regarding insight as to perspectives and point of view that President Biden’s administration has on government payment and support for physicians.
- A request for discussion on physician reimbursement decreasing when hospitals purchase surgery practices.

V. High Priority Objectives

The Academy’s focus this year is on:

Preventing the 2022 payment cuts, which could come from the following:

- Expiration of the extended moratorium on the 2% Medicare sequestration cuts
- Expiration of the one-year 3.75% payment boost Congress applied to all codes in 2021.
- A new statutorily mandated 4% cut for Medicare providers because the recently passed COVID-19 relief package increased the deficit. Congress has until the end of this year to address those cuts by overriding a pay-as-you-go provision.
- Increasing payment to Ophthalmology and other surgeons from the application of E/M payment boost (equity) to postoperative visits in the global period of surgical codes

The Academy and its Surgical Care Coalition partners worked with Reps. Bera and Bucshon in the 116th Congress to advance bipartisan solutions to provide relief from Medicare payment cuts in 2021. The Academy will continue working with Reps. Bera and Bucshon along with the AMA, ACS, and our Surgical Care Coalition partners to preserve patient access to surgical care and fight for fair reimbursements for ophthalmologists in the 117th Congress.



Mid-Year Forum 2021 Report

Session Name: Hearing 2: Technology, AI and Telehealth

I. Abstract

The COVID-19 pandemic has precipitated the digital transformation of healthcare, exposing many physicians to new technologies and different ways of using technologies. Ophthalmologists can leverage these digital health technologies to improve efficiencies and enhance patient satisfaction, including telehealth, wearables, implanted sensor technology, and artificial intelligence. These technologies can also help re-engineer clinical trials in the future to be less burdensome for patients and less expensive to conduct.

II. Background Information

Information technology has revolutionized medicine, from digital imaging, electronic health record (EHR) systems, big data, telemedicine, artificial intelligence (AI), autonomous diagnosis and clinical decision support systems, etc. The Academy has addressed this major development with a volunteer committee structure, dedicated staffing and significant initiatives in terms of creating standards for EHRs in ophthalmology, developing standards for digital imaging, terminology, and clinical document architecture (CDA) interoperability between providers and organizations, and developing a registry, and performing big-data analyses on millions of patients and interventions. In addition, the Academy has provided many educational resources to inform ophthalmologists about the state of the art, to provide guidance and to advise them about advantages, disadvantages and considerations of information technology and other digital developments.

III. Summary of Comments from Guest Speakers

Emily Chew, MD, Director, Division of Epidemiology and Clinical Applications, Medical Office, National Eye Institute, National Institutes of Health
Introduction: Future of Digital Ophthalmology

Dr. Chew introduced the 3 speakers and noted that the future of digital ophthalmology is bright. From mobile apps and fitness trackers to software that supports the clinical decisions physicians make every day, digital technology is driving the revolution in healthcare. The US Food and Drug Administration (FDA) created a Digital Health Innovation Action Plan to reimagine their approach to ensure that all Americans have timely access to high-quality, safe and effective digital health products, and have created the Digital Health Center of Excellence to align and coordinate digital health work across the agency. A recent FDA publication, Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action plan describes a multipronged approach. It describes a tailored regulatory framework that has the following components: good machine learning practice, a patient-centered approach incorporating transparency to users, regulatory science methods related to algorithm biases and robustness, and real-world performance. Dr. Chew also reviewed the changes in telehealth as a result of the COVID-19 pandemic, with a 150% increase in telehealth visits over the prior year after the issuance of CDC guidance for social distancing and waivers for telehealth, and a sharp decrease in emergency room visits. Continued telehealth waivers and reimbursement policies could provide increased access to acute, chronic, primary and subspecialty care after the pandemic. The Collaborative Community in Ophthalmic Imaging (CCOI) was created in 2019 to clarify challenges, best practices, standards and strategies

while advancing innovation in ophthalmic imaging, and has broad representation among academic institutions, government agencies, including the FDA, professional organizations and industry. The CCOI is focused on innovations in technology such as OCT and functional imaging, potential use of technologies to develop new disease markers and foundational principles of ophthalmic imaging and algorithmic interpretation. There are currently four workgroups in retinopathy of prematurity, glaucoma, ocular oncology and macular degeneration.

J. Peter Campbell, MD, MPH, Professor of Ophthalmology, Oregon Health and Sciences University

Advances in Artificial Intelligence in Eye Care

Dr. Campbell provided a 30,000 foot view of Artificial Intelligence (AI) and focused implications for ophthalmology in the categories of research, education and patient care. For research, image classification has been demonstrated to be done well by a computer that is reproducing physicians' behavior, if there is well-annotated and high quality data. The question that hasn't been answered is if this improves care and has value in the clinical care pathway. Algorithms and data can be biased as well, and we need ways to ensure equitable and unbiased application. Image segmentation has also been performed well by computers that are trained to create quantitative outputs from images, such as levels of intraretinal or subretinal fluid. These quantitative biomarkers could be valuable in screening for disease and monitoring response to treatment in a way that we cannot do with our own eyes. Another fascinating application is disease prediction, both systemic and ocular disease. The theme is that the eye is a window to the body. For example, ocular images could be predictive of systemic neurodegenerative disease, chronic disease, hypertensive status, etc., and OCT could help predict which patients progress from nonexudative to exudative AMD. We have learned that the technology undergirding AI is very powerful. One of the limiting factors to expanding AI has been the challenge of amassing large data sets and lack of device interoperability. One potential solution is federated learning, where the data remains at each institution, but a centralized algorithm can learn from each local institution and work across the diverse datasets.

Education will be very important for the Academy in terms of how we integrate AI into the clinical workflow. First, ophthalmologists should become clinically competent to apply AI appropriately as these tools become more available. Second, ophthalmologists need to critically evaluate to see when AI is of value or not in the clinic. Third, ophthalmologists need to be able to contribute to knowledge, generate new ideas and technology to achieve our mission to prevent blindness. In patient care, autonomous AI is a new care delivery paradigm, and not just a new technology, by moving the point of interaction between a patient at risk of disease into the primary care office first. An important aspect that needs thorough evaluation is the ethics surrounding AI, preserving patient safety, equity and autonomy. Implementation not only requires that the tools be proven efficacious but also be effective in real-world settings, and sustainable and scalable. In summary, AI is a powerful tool, and has the potential for great benefit or harm, for maximal or minimal impact, depending how it is implemented. Important issues to advocate for our profession are greater interoperability in medical imaging and for appropriate reimbursement and research funding. Dr. Campbell concluded that issues important to advocate on behalf of our patients are that these technologies demonstrate added value and not just added costs, and are implemented in an ethical, equitable and effective approach.

Michael Chiang, MD, MA, Director, National Eye Institute, National Institutes of Health
Digital Transformation of Research in Ophthalmology

AI is actually not a new technology in medicine. Indeed, in the 1970s, Dr. Paul Lichter observed the variability of expert observers in evaluating the optic disc, and Dr. Edward

Shortliffe created a rule-based expert system, MYCIN. In 1987, an editorial on *Artificial Intelligence in Medicine* noted that skepticism is understandable, given unfulfilled expectations, but there was hope for the future of AI in medicine. What was said in 1987 could also be said today.

There are still unanswered research questions. One question is how to deal with the variability of findings. The performance of AI improves as the task narrows, such as rule out macular edema or rule out plus disease. But clinical diagnosis involves many parallel tasks, with numerous images and cross-sectional images per patient, multiple diseases and findings in a single patient, and a need to integrate with the image itself to make the appropriate diagnosis. Potential solutions could be multiple instance learning, an integrated system for imaging and clinical data, and assistive systems that advise physicians at the point of care. A second question is the generalizability of findings. Clinical trials often contain biases from the spectrum of patients enrolled: the very sick to the very healthy and when rolled out in the real world, the treatments don't work nearly as well. Often homogeneous datasets from a few centers are used as the training set for AI. Real-world images are often poorer quality than the training sets. There is heterogeneity among the different imaging devices, and the numbers that come out of one machine don't always match the numbers that come out of another machine. Potential solutions could include large and diverse datasets, validation across populations, including medically underserved populations, and across imaging devices, quality validation of images and data sharing such as the federated learning approach. The third unanswered question is that the "ground truth" is unclear in many situations. There is variability in diagnosis and the diagnostic process itself, unclear definitions of clinically significant endpoints (e.g., moderate disease, risk of progression, rapidly progressive glaucoma), lack of standardization among imaging devices, and challenges in labeling large databases. Potential approaches are to develop consensus definitions, crowdsourcing, standards adoption by device vendors and unsupervised learning.

The question has been raised, "Will machines replace doctors?" We don't think so. This comes down to the two major added values that physicians bring to this equation. For diagnosis, even though AI systems are promising, physicians provide value because clinical judgment is required to collect data. For management, physicians provide value because human connection is necessary to understand the patient preferences and needs. Thus, physicians need to understand the technology and also maintain their uniquely "human" skills. To advance digital ophthalmology, data representations can be harmonized through consistency in documentation in EHRs, and standards, like DICOM, can be promoted for data exchange and making data elements from devices available for analysis. In response to the question of what ophthalmologists can do, Dr. Chiang summarized that it's important for ophthalmologists to learn about AI and digital health technology to improve the quality of care, to deliver care more effectively and reduce health disparities and to cultivate their unique "added value".

Wendy Weber, ND, PhD, MPH, Branch Chief, Clinical Research in Complementary and Integrative Health, National Institutes of Health
Pragmatic Trials Leveraging EHRs

Dr. Weber discussed the benefits of pragmatic clinical trials that leverage EHR data. Enrollment criteria in clinical trials can be quite restricted. The question is how to perform research that is more generalizable to patients who are seen by clinicians in their everyday settings. There is a call for more pragmatic research to inform clinical practice and policies are needed for decisionmakers such as patients, clinicians, payers and policymakers. We are most familiar with traditional or explanatory clinical trials that are randomized controlled clinical trials, very tight enrollment criteria, strict data collection standards and adjudicated endpoints. Explanatory clinical trials are designed to establish efficacy of a treatment, often under idealized conditions.

Pragmatic clinical trials are designed to inform decisionmakers of the comparative balance of benefits, burdens and risks of an intervention at a patient or population level. Characteristics of an embedded pragmatic clinical trial include the following: conduct within health care systems; intervention is integrated into real-world health care settings; use of streamlined procedure; leverage existing infrastructure and EHRs; answer important medical questions; and utilize prospective randomization to minimize bias, perhaps by randomizing health care systems or clinicians. However, this might not always mean lower costs but often a more diverse and more generalizable population and a larger scale can be attained. The hope is that pragmatic clinical trials are a bridge between research and clinical care by including input from health system stakeholders in the study design, having the intervention incorporated into the routine workflow, collecting the data through the EHR, selecting sites for diverse, representative patient populations, and focusing on outcomes that are important to decisionmakers. Currently in the NIH Health Care System Collaboratory, there are 21 pragmatic clinical trials across 15 NIH Institutes, Centers and Offices, that involve more than 850 clinical sites, 20 health care systems and 800,000 participants. (Reference: www.rethinkingclinicaltrials.org). Dr. Weber concluded by answering the question, when should pragmatic clinical trials be conducted? The ideal scenario is when prior trials have demonstrated that an intervention is efficacious in an idealized, well-controlled setting, and the intervention can be integrated into routine health care delivery such that we can evaluate effectiveness beyond the tightly controlled scenarios of the efficacy designed trial. Another scenario is when health care systems are really interested in the research question. Importantly, an embedded pragmatic trial is the right study design when the outcomes of interest are captured in the EHR or can be easily captured by additional data collection such as in a patient portal for patient-reported outcomes, with minimal burden.

IV. Summary of Audience Comments

- One Mid-Year Forum session participant asked if AI could narrow gaps in health equity. There is the potential for digital health to improve access by putting it more in the reach of patients such as in drugstores. However, to understand if AI can apply across diverse populations, broad datasets are required to validate the tools.
- One participant asked if robotic surgery would become more prevalent in ophthalmology, as it is in other specialties. This remains to be seen because we don't know what the cost/benefit ratio is. We need to understand the role of robotic surgery and see if it demonstrates value, and not just added cost.
- Another participant asked what is necessary for residents to learn about AI and digital health tools. Residents need to understand what the tools do, and what the tools can't do, and importantly, what is their role and added value to the tools.
- Another attendee asked whether this technology could improve care where it matters the most? Telemedicine is an example of a technology that has been around a long time but has not improved access to care in many parts of the world. This demonstrates that it's not a technology issue so much but more of an implementation issue. A recent article addresses the implementation/systems issues in different parts of the world that prevent the realization of the benefits of digital health. (Campbell JP et al. Artificial Intelligence to Reduce Ocular Health Disparities: Moving from Concept to Implementation. *Translational Vision Science & Technology*. 2021; 10:19.)

V. High Priority Objectives

- To help inform and educate ophthalmologists on how to use AI and other digital health tools appropriately to manage patients
- To define the role of the ophthalmologist and the added value of the physician to the patient care experience with the use of these digital health tools in their diagnostic and treatment armamentarium

Mid-Year Forum 2021 Report

Hearing 3: The Rise, Fall...and Rise of Private Equity and Corporatization

Moderator: Ravi D. Goel, MD

I. Abstract

Private equity continues to march forward in ophthalmology with the constant challenges of aggregation and integration. This session will highlight recent trends, legal pitfalls, and highlight unique challenges faced in a post-COVID world. This session includes expert advice to navigate a post-private equity world for small and large groups.

II. Background Information

The business models of healthcare delivery are continuously changing and COVID has impacted the business of medicine for the smallest to largest of practices. No practice type has been immune from the pandemic's impact. From how to continue seeing patients to managing practice expenses and use of PPP funds, practice management has experienced some of the most dramatic stresses and challenges of our lifetime.

There is increasing consolidation of practices within ophthalmology and health care in general. Private Equity (PE) companies have a more prominent presence in ophthalmology than in past years. Practices considering a move to PE have potentially seen high valuations in recent years making a sale more attractive to senior partners. While selling may be attractive to some ophthalmologists, weighing the financial impact against the loss of practice management control and impact on the younger physicians and future recruiting opportunities must be considered. Even in a period of consolidations, there continues to be successful start-ups of the small and solo practice. One size business does not fit all. Planning and researching various business models will result in the best outcome. Whether you are in solo practice, University, Health System, or multi-specialty ophthalmology, your practice may be impacted by PE.

III. Summary of Comments from Guest Speakers

Ravi D. Goel, MD, Senior Secretary for Ophthalmic Practice, American Academy of Ophthalmology, Member American Academy of Ophthalmic Executives Board of Directors.

Moderator

Introduction of topic and panel members

Covid 19 taught us quickly the importance of resilient leadership as essential to practice continuity, survival and growth. Physician leaders and administrators look to the Academy and AAOE to provide cutting edge resources to navigate a rapidly changing landscape. The AAOE has developed a member resource "The Resilient Practice" positioning the practice for success post COVID. Resilient Leadership, Financial Resilience, The Patient Experience, Lessons Learned and Disaster Planning are some of the highlighted topics in these modules.

Chris Albanis, MD, CEO Ocular Partners, Inc., President, Arbor Centers for Eyecare

The Keys to Successful Co-Investing

- why are you considering/doing it
- diligence in finding the right group

- aligning vision and direction
- physician leadership
- understanding your investment

Arbor Centers for EyeCare underwent a PE transaction on Feb 7, 2020. The practice is pleased with the outcome.

Why? The practice was always looking for ways to grow and innovate but realized as the complexities of health care continued to be more and more complex, they needed help with capital and administrative assistance. Minimizing risks was a goal. The practice wanted to find appropriate administrative expertise and understand the market. Cash and investment opportunity was also key. Some partners were looking for appropriate exit strategies but wanted to ensure the entity would live on. It was critical to find the right PE partners for the entire practice, both senior and other members.

When is the right time? For many, it is never. It is not a perfect decision for all. Investors look at multi years of financials when considering a buy and look for successful practices. Going in early usually allows more decision-making authority. The practice looked for an investor that would bring capital but also allow the doctors to practice medicine. Should you wait until your final years before retirement? Generally, the answer is no. Investors are looking for ongoing growth.

Who Should I partner with and who decides? Solo practices should consider carefully as losing full control can be difficult and multi partner practices can be more complex when attempting a single decision to sell. Hospital systems are an option for some looking to sell/partner, as well as payer systems. PE investors are looking to build platforms in larger cities. Who decides depends on the practice. Who makes the management decisions? Who leads the group? Who is in/out? All the “who’s” are important in the process of making a practice decision.

What were the keys to successful co-investing? Align vision and direction, understand your options, do your due diligence in finding the right match, physician governance, established channels of communication, be prepared to provide a lot of reports and data, understand your investment at close and thereafter. Have fun and succeed!

Robert E. Wiggins, MD, MBA, Managing Partner, Asheville Eye Associates, President Elect, American Academy of Ophthalmology

The magnitude & growth of private equity in eye care.

The origins of modern private equity began in the mid 1900’s though PE as we know it today was developed in the 1960’s and 70’s and became known for the leveraged buyout. A large-scale buyout of physicians firms in the 1990’s was accomplished by PE firms known as Physician Practice Management Companies. This wave of purchases was fueled by consolidation in healthcare and a fear of managed care organizations. However, by the end of the decade most of these companies had failed. Several reasons for the failures were postulated including the negative synergy created by these purchases, use of capital for acquiring more practices rather than improving practices purchases, and overpricing of the stock, among others.

Healthcare organizations continued to generate healthy returns, and a second wave of PE purchases of practices began in the past decade. Although purchases slowed during the COVID-19 pandemic, by the end of 2020 practice purchases were resuming. It is estimated that about 8% of ophthalmologists are affiliated with PE or about 12% of eligible ophthalmologists. As the pandemic wanes, the fundamental reasons PE firms are interested in ophthalmology practices have not changed nor have the reasons that ophthalmologists may wish to sell their practices to PE firms. Therefore, PE purchases are expected to continue in 2021.

Concerns have been raised, particularly in the dermatology literature, regarding PE involvement in healthcare. Whereas one can argue the pros and cons of PE purchases on the practice of ophthalmology, there is little data currently to support one side or the other in terms of the impacts on quality, cost, use of care, and on the patient and physician experience. To be successful PE firms must provide a true value proposition for physicians, and physicians working in those firms should continue to lead in making the best decisions for their patients.

Julia Lee, JD, President, NorthStar Vision Partners, LLC

The hopes and challenges of large physician led vs. private equity organizations.

In 2017 Vantage EyeCare, LLC (VEC) was formed. VEC was comprised of 7 private practice groups in Metro Philadelphia under a single Tax ID and NPI. One overarching corporate infrastructure with each formerly independent practices now a division of VEC. VEC was entirely physician owned and funded. Vantage EyeCare launched in 2018 with 45 providers across 24 service locations. By 2019 VEC grew to almost 120 providers across 47 service locations. In 2020 with the COVID pandemic, a decision was made to unwind VEC and revert back to separate independent practices.

Vantage Eye Care aspired to have continued independence by investing in ourselves and growth value. VEC hoped to preserve multi-generational ownership and succession planning while remaining patient focused and answering to only our patients. VEC was built on existing administrative infrastructure and knowledge of industry. The physicians had a shared vision and common goals. Sweat equity, not private equity!

Vantage EyeCare achieved market density and aggregated negotiating power, including vendor relationships. Payer contracting resulted in an enhanced fee schedule with national payers (Not all standard fee schedules are created alike). VEC had direct communication with THE largest regional payer and multiple national payers. This resulted in value-based partnerships:

- 1) Anchor group for Ophthalmology Alliance of Tandigm Health and
- 2) Remote diabetic retinopathy screening with Crozer-Keystone Health System.

There were numerous challenges: Vantage EyeCare vs. Division priorities, moving from aggregation to integration, thinking and behaving like a true single practice group, up front capital investment for longer-term returns, rebranding and marketing, common PM and EHR platforms, continued centralization, risk tolerance - in the face of COVID became much lower. Crisis management in the face of COVID was amplified. For example, with 800 employees they were not able to apply for the Paycheck Protection Program (PPP). It became clear during the crisis that the practice would be best managed as smaller units. Some of the same challenges faced by VEC are part of the PE world as well. PE showed great interest in Vantage EyeCare. Interestingly, only one of the smaller division/practices sold to PE when VEC was disbanded. There are numerous other groups in the country expressing interest in the Vantage EyeCare model and replicating the experiment.

Since dissolving Advantage EyeCare, Julia has joined her ophthalmologist spouse in launching a solo practice. The practice provides concierge level care for all patients. It is a family-run, community-based practice. Every staff member is cross trained from front end to check-out. The practice is high tech but also high touch.

From solo to very large PE backed groups, there are a range of options for ophthalmologists - choose wisely and well - choose the right fit for you.

Ravi D. Goel, MD
Conclusion Remarks

Alignment, vision, direction, innovation, disruption, an aging population and succession planning, fragmented markets, declining reimbursements, administrative burdens, market consolidation, quality, costs and the patient experience are all considerations in practice management.

IV. Summary of Audience Comments

Small practices can compete with larger practices for PE acquisition. Generally, there is a place for any practice in PE. It depends on the specialty, market region, profitability, and desired growth plan of the practice.

How should we advise YOs and MDs in training on practice structure choices? Journal clubs during Residency, invite local docs from PE and other private practice types to speak with MDs in training. It is important to encourage involvement and allow MDs in training to attend the Annual Meeting of the AAO and MYF meetings.

Consolidation of practices such as Vantage EyeCare is still a model that is worth aspiring to. Consolidation is another option of choice for market competitiveness. Must recognize the pros and cons be strategic in exploring the options.

PE and larger practice organizations can have roles in advocacy of our profession but depends on the leadership. Being members of the Academy and other organizations relevant to the profession is important to include in the contracting. Leadership is the key!

Is the PE purchase boom sustainable long term? If the mission is aligned and growth not cut oriented, sustainability is achievable, but again leadership is key. The current lifecycle is new and second capitalizations have been few so far. COVID put a pause on PE companies and they have readjusted their timelines. Much depends on the lessons learned from the 90's.

What resources would you give to YOs or any members for considering PE or staying independent? Most important is the question "what kind of environment do you want to provide patient care in." There are still multiple options for the ophthalmologist. You should consider the future health of the organization you chose regardless of PE, Hospital System, academic, large practice, or solo. During the interview process, it is important for the YO to focus on each type of group. One PE firm deal is one PE firm. All are different. Not all are good or bad.

V. High Priority Objectives

COVID's impact on medical practices created new and unexperienced stresses. Ophthalmology has not been immune from these new challenges. Private Equity continues to be a more prominent presence in ophthalmology than past years. While selling may be attractive to some, weighing the financial impact against the loss of control and impact on the younger physicians and future recruits should be carefully considered. Due diligence and understanding the right match are critical when considering a sale to PE, a Hospital System or any other investor. Involving those impacted by a sale and open communication is key. There are options for the ophthalmologist. Integration of practices as shown by the Vantage EyeCare group can be a successful way to develop stronger business relations while protecting the integrity of physician directed practices. The solo and small practice continues to be a viable option for the ophthalmologist. The AAOE is committed to providing all members with tools useful in whatever practice type you feel is best for you.

Mid-Year Forum 2021 Report

Session Name: Scope of practice

I. Abstract

This session highlighted current trends and future prospects on optometric scope of practice from three key perspectives: The Veterans Health Administration (VHA), the House of Medicine, and the Academy's efforts to preserve safe surgery at the state level. The speakers addressed policy and practical implications for Academy members.

II. Background Information

As states convened their 2021 legislative sessions in January, organized optometry wasted no time securing champions for their surgery proposals. Optometrists have targeted State Senate and House leadership to champion their initiatives long before promoting their bills in the legislature. It is the most aggressive effort by optometry to secure surgery privileges via legislative fiat, rather than through necessary medical education, clinical experience, and surgical training. The optometric campaigns have evolved from "Catch-as-Catch-Can" efforts to well-organized and targeted pushes for surgical authority.

III. Summary of Comments from Guest Speakers

John Peters, MD, Secretary for State Affairs

The State of the States

Dr. Peters gave a brief overview of the history of the Academy's Surgery by Surgery Campaign from its inception in 1998 to the present, having battled for patient safety in 46 states plus Puerto Rico and the District of Columbia. In all but seven states, we have been successful in upholding the standards of safe surgical eye care in the hundreds of battles we've waged over the last 23 years. However, two of the seven state battles where optometry has been successful came in 2021, and the road ahead in protecting patient safety is becoming more difficult to navigate.

Dr. Peters elaborated on the many challenges facing ophthalmology and its patients. These include the current "post-truth" era where the best arguments and clinical data are simply one enough to debunk misinformation associated with the optometric attempts at legislative surgical privileges. Solid working relationships with key lawmakers wins the day over facts and clinical evidence, and right now the ODs have those relationships. Also, discussed is that we are facing political trends where mid-level providers are serving as key leaders in state legislators, while their provider groups are coalescing nationally to assist each other with interstate licensure proposals. Other challenges include legislator fatigue, and the fact that too many ophthalmologists are either too timid to become engaged out of fear of referral loss, or are co-managers too eager to weigh in on supporting the ODs.

Lisa Nijm, MD, JD, Delegate, Ophthalmology Section Council, American Medical Association

Scope of Practice Expansion: The House of Medicine Under Threat

Dr. Nijm reviewed challenges currently facing the House of Medicine from APRNs, nurse anesthetists, physician assistants, and naturopaths.

- Dr. Nijm described the 2020 APRN Multistate Compact authored by the National Council of State Boards of Nursing. The compact would authorize a multi-state license for nurse anesthetists, nurse midwives, nurse practitioners and clinical nurse specialists. State legislatures in seven states must approve the compact to take effect. APRNs are representing the Compact as not expanding scopes of practice. However, Dr. Nijm explained that the Compact calls for independent practice and would expand prescriptive authority, superseding existing state scope of practice laws in a majority of states.
- Dr. Nijm described an effort by the American Association of Nurse Anesthetists to urge policymakers, employers and healthcare institutions to adopt the terms “certified registered nurse anesthesiologist” or “nurse anesthesiologist” as optional descriptors or official titles for nurse anesthetists. State boards of nursing in Florida and Idaho have already adopted the term. Dr. Nijm stated that the New Hampshire Board of Medicine had promulgated a rule to block use of these terms. The ruling was challenged in court. However, in 2021 the New Hampshire Supreme Court affirmed the board’s ruling, preserving the term “anesthesiologist” for medical board licensees.
- Dr. Nijm described an effort by the American Academy of Physician Assistants to enact legislation to reshape the relationship between physicians and physician assistants. The new construct, called “Optimal Team Practice” (OTP), calls for PA independent practice, scope determined by training, PA majority boards, and direct payment to PAs by private and public payers.
- Dr. Nijm described efforts by naturopaths to include cosmetic procedures in their scope of practice, including botox injections, platelet rich plasma, and micro-needling. Dr. Nijm described an effort in 2018 by the Washington State Board of Naturopathy to promulgate regulations that would have authorized naturopaths to prescribe and administer botox and inert substances for cosmetic procedures. The proposed rule was withdrawn after intensive opposition by the House of Medicine, including the Washington Academy of Eye Physicians and Surgeons and the Academy.

Dr. Nijm concluded that midlevel practitioners are advocating for expanded scope using organized optometry’s playbook of political influence, confusion about appropriate roles, and misleading terminology. The American Medical Association has actively opposed scope expansion efforts, including contributing funds to support the Arkansas Safe Surgery Referendum to overturn legislation authorizing surgery by optometrists. Dr. Nijm stated, however, that success in the scope fight depends upon individual ophthalmologists building the political relationships to ensure quality care and safe surgery for patients.

**Jennifer L. Lindsey, MD, President, Association of Veterans Affairs
Ophthalmologists**

VA Proposed Directive: Scope of Practice

Dr. Lindsey described the importance and scale of the VHA and its consequent impact on state scope of practice fights. Dr.

Lindsey acknowledged that Covid-19 pandemic had accelerated the push to expand scope by non-physicians.

- Dr. Lindsey reported that long-standing policy that only ophthalmologists will perform laser eye surgery in the VA was renewed without modification. The stand-alone policy, however, was rescinded and then incorporated VHA Directive 1121. The directive is scheduled for recertification in October 2024. Dr. Lindsey noted that the VA looks to standards of practice in the community and in the states. Therefore, the optometric scope of practice in the states influence VA decisions. Therefore, the state scope of practice laws are important.
- Dr. Lindsey reviewed a Directive on Advance Practice Registered Nurses that sparked a multi-year battle between anesthesiology and CRNAs. Anesthesiology prevailed in maintaining physician-led anesthesia teams in the VA. However, CRNAs have not abandoned their efforts.
- Dr. Lindsey described the Interim Final Rule (IFR) published in November 2020 declaring that VA Health care professionals may practice consistent with the scope and requirements of their VA employment notwithstanding state licensure, registration, certification, or other requirements that unduly interfere with their practice. The IFR confirms the VA's authority to establish national standards of practice. The VA cited need for rapid EHR implementation and rapid deployment of personnel during the pandemic as justification for the rule. The Academy joined 85 co-signers, including the AMA, formally opposing the IFR. Dr. Lindsey stated that co-signers of the letter pointed out that the IFR does not adequately account for differences in education and training between physicians and NPPs and does not set forth a clear process for stakeholder input. The VA has neither responded to the letter nor has reportedly provided transparency regarding the process for establishing national standards of practice.

Dr. Lindsey concluded that both state and federal advocacy are essential to protect the sight and empower the lives of those who served.

Lee Snyder, MD, Chair, Surgical Scope Fund

Surgery by Surgeons: The Tipping Point

Dr. Snyder addressed the hard financial costs of successfully waging a Surgery-by-Surgeons legislative battle at the state level, and how those costs went to protecting patient safety in 2021. She stressed that even in small rural states (i.e. Alabama or Idaho), a successful campaign can cost upwards of \$150,000, and upwards of \$1 million in a large state such as California or Florida. These costs include lobbying, paid advertising (such as radio), polling, public relations, and social media. She

showed concrete examples of these expenditures in 2021, and how they have contributed to the ophthalmology's successes.

Dr. Snyder emphasized that it's the Academy's Surgical Scope Fund (SSF) through which state ophthalmological societies are able to fight—and win—these advocacy battle. With optometry's becoming more and more aggressive in its national effort to secure surgical privileges at the state level, SSF is more important now than ever and that more ophthalmologists must become engaged and financially contribute.

In addition to financial costs, Dr. Snyder articulated the human costs of what happens when a state loses a surgery battle. This includes lower standard of surgical care, a devaluation of ophthalmologists' medical education and clinical training, and the human cost of the harm that can happen to a patient when optometrists perform surgery.

IV. Summary of Audience Comments

- Q. One attendee observed that there are some VAs clinics that are optometry-only facilities and refuse to have ophthalmologists on staff. What can be done to assure there is employment of VAs?
- A. It is important to reach out to those VA facilities that do not have ophthalmologists and attempt to establish a presence there.
- Q. What steps can be taken to increase the number of residency spots, thus obviating the need for mid-level providers?
- A. This requires federal funding and we have had recent success in increasing residency spots, though not enough. AUPO can have an impact by showing the need for more ophthalmologists, whether funded through the VA or through the academic affiliates. It is much easier to add additional residency optometry slots as opposed to ophthalmology slots. This has been an on-going problem because of the extreme amount of work that goes into establishing new spots and opening new programs.
- Q. What can be done besides giving money to have more of a voice with legislators?
- A. Get to know your own local legislator before any issue arises. Become a trusted resource on ophthalmology and other health issues. This prevents problems down the road. Also, listen to what those legislators need and find how you can help them with their causes. All these legislators have ophthalmologists caring for them. Invite them to your practice. Let them see what you do. Also, develop relationships with legislative staff and offer to help educate them on what we do as ophthalmologists and how different that is from optometry. The ultimate situation is to be that sounding board for legislators when they are approached by optometry with a legislative proposal.



Mid-Year Forum 2021 Report

Session Name: Health Policy and the New Administration

I. Abstract

Changing Government – 2021 brings one of the biggest changes in governance – new/different Administration and a new Congress with a Democratic Senate and Democratic House but with razor-thin margins.

II. Background Information

President Biden was sworn in January 2021 immediately targeting the pandemic, shoring up ACA and halting numerous last-minute regulations by the outgoing Trump Administration. Democrats kept their majority in the House by a slimmer margin and took back control of the Senate by a margin of 1.

III. Summary of Comments from Guest Speakers

Rodney Whitlock, PhD
Vice President
McDermott+ Consulting
Topic Name: Overview – what these changes will mean for the health/physician sector

The new Congress will see deep partisan divisions. Each party/Representative is justifying their votes/positions as the message they got from the electorate. Bipartisanship opportunities will be few and far between on consequential legislation. In fact, the Republicans may not support anything.

Congressional action in quarters

First quarter—passed COVID Rescue bill (\$2 trillion),

Second quarter—already extended the waiver for the 2% Medicare Sequestration cut on payments to providers until the end of 2021. Additional legislation this quarter will be driven by the need to lift the debt limit—could be the vehicle for infrastructure.

Third quarter—Drug pricing would likely require another Reconciliation bill. Must do is to extend Puerto Rico Medicaid that is expiring.

Forth quarter—Leftovers. Medicare physician payment?

Whitlock advised us to “listen carefully to the drumbeat” -- that Medicare for All isn’t going to happen in this Congress but if the Democrats have a good election in 2022, it could be come more of a possibility.

Paul Rudolf, MD, JD
Partner, A&P, Past Carrier Medical Director
Arnold and Porter Law Firm
Topic Name: Why the new Administration should ban MA plan Step Therapy

The Trump Administration implemented Step Therapy authority for Medicare Advantage plans initially through a change in (subregulatory) guidance in 2018. In 2019, to codify the change, they went through new rulemaking. Initially, step therapy would have been allowed for

everything but in the final rule, they narrowed the scope in response to comments. It is now limited to only new administrations of a treatment with a 365 day look back on what is considered “new”. The step therapy must be approved by a P&T Committee and reviewed annually. But does not have to be a clinically superior treatment. Exceptions and appeals are allowed but the plan doesn’t have to say yes.

Still, there appears to be a legal issue in that MA plans must cover all items and services that are covered by “original” (FFS) Medicare. Medicare patients with MA plans may not have the same access to Part B drugs as FFS patients. In FFS Medicare, step therapy is not allowed. They have something called prerequisites but these are few and far between and must be based solely on clinical considerations. MA plans may initiate step therapy for cost reasons but they are also required to account for clinical considerations. They try to justify their step therapy requirements based on lower beneficiary co-insurance.

MA plans have other inappropriate requirements including requiring patients to use a drug that has been shown to be clinically inferior. Or require patients to fail multiple doses of a medication, such as Avastin, when one or two doses may be sufficient to make a determination. Although step therapy cannot be used to change a drug regimen, for example, a Medicare Advantage plan may ask patients to “talk with their doctors” about changing to a lower cost medication which may interfere with the physician patient relationship.

Dr. Rudolph’s urged us to hold Medicare Advantage plans accountable and challenge inappropriate requirements and issues that arise with the appeal process. His advice meshes with the Academy plans to proactively advocate to the new administration to reverse the current regulations.

David Glasser, MD
Secretary for Federal Affairs
AAO

Topic Name: Administration’s drug cost control agenda (includes Part B Drug payment reform (MFN))

New leaders at the Department of Health and Human Services include Secretary Xavier Becerra who served in the House as a member of the Ways and Means Committee and as California Attorney General. In these roles he supported fair payment update for physicians and HHS authority to negotiate drug prices. He fought dismantling of the ACA and opposed Prior Authorizations for needed care. He sued generic drug makers for price fixing and banned drug company’s “pay for delay” in California.

Chiquita Brooks-LaSure, CMS Administrator nominee worked on the hill and at DHHS and OMB/White House under Obama. Most recent position was Deputy Director of Policy at the CMS Center for Consumer Information and Insurance Oversight. She is an attorney and was a managing director at Manatt Health.

The problem is that drug expenditures are increasing as a percent of GDP

The Grassley/Wyden Prescription Drug Pricing Reduction Act never made it to the Senate floor for a vote in the last Congress. It did have a number of provisions that merit consideration in resolving growing costs. Senator Wyden, as the new Chairman of the Senate Finance Committee, is in a position to advance this priority but has yet to introduce new legislation in this Congress. A key provision in the past legislation was capping drug cost increases at inflation, requiring companies that raised their prices higher to pay a rebate to the Medicare program.

The Senate HELP Committee recently had a hearing on Drug Pricing Reform, focusing on the following proposals:

Allow Medicare to directly negotiate drug prices
Require pharmaceutical companies to justify significant price increases
Eliminate tax breaks for drug company advertising
Align prices to those in other countries (like Most Favored Nation model)
Increase biosimilar use with higher reimbursement

The House is preparing to consider drug payment reform legislation based on HR 3, legislation that passed the House in the last Congress. The “Lower Drug Cost Now Act provided for direct negotiation on drug pricing which CBO estimated would cut prices 55% in the short-term and 40-50% in the longer term. That bill also limited Part B and Part D drug price increases to inflation saving potentially \$36 billion over 10 years. In that bill, savings were used to fund Medicare expansions including new dental, vision and hearing benefits. House leaders may focus the drug cost savings on shoring up the ACA and other coverage subsidies this time around.

Physicians know only too well that price controls work (look at physician and hospital fee schedules)
Advocacy forces will be at work in resolving these issues and Dr. Glasser notes that health is the biggest lobby sector at \$615 million (compared to the Defense industry at \$103 million)
In the health industry sector, Pharmaceuticals/Health products is by far the largest sector at \$306 billion with health professionals/including physicians at only \$88 billion.
Brand -name drug price increases have regularly exceeded inflation but has exploded with 15-16% increases in recent years. Companies spend much more on marketing now than they do on research and development.

The Trump Administration proposed a Most Favored Nation (MFN) pricing demonstration at the end of 2020 aimed at spending on costly Part B drugs (e.g. Eylea, Lucentis). Initially, it was proposed as a CMMI International Pricing Initiative (IPI) in 2018.
The Academy did not support these approaches. Instead, we have offered an alternative to MFN: Pay more for Avastin. Inadequate Avastin payments limit market share. CMS should equalize dollar cost margin with Eylea: increasing Avastin payment to around \$125. A 10% increase in Avastin market share for Medicare could save \$468 million annually. Patients could save \$119 million annually.

We have had some recent success, increasing allowables but still below the equal dollar cost margin.

Noridian: \$94 (15% increase)
WPS: \$90 (76% increase)
Novitas: \$85 (70% increase)
Palmetto: pending

IV. Summary of Audience Comments

- In response to questions about challenging MA plans on step therapy and other non-sensical requirements, Dr. Williams provided the recent example of a BCBS plan non-coverage decision on Eylea. We got them to ultimately reverse the policy and we found that if the first attempt doesn't work locally, members should work with the Academy to take it up to plan leadership.
- Additional advice from Dr. Rudolph on step therapy is to try to get ophthalmology/the appropriate specialty on the P&T Committee's for these plans.

V. High Priority Objectives

Advocate to the Administration to reinstate the ban on Step Therapy for Medicare and

reduced administrative burdens with Advantage plans
Advocate for continued increases in Fee for Service payment for Avastin
Advocate for fair treatment for physicians and protect access for patients in reform of Part B drug payments.