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Status Report for Council Advisory Recommendation: August, 2020

20-01: Title: Vision Therapy for Post-TBI Visual Symptoms

Report From: Timothy W. Olsen, MD – Secretary for Quality of Care

Analysis: The Council Advisory Recommendation from the Arizona Ophthalmological Society and the North American Neuro-Ophthalmology Society (NANOS) proposed that the Academy establish a working group to provide guidelines for the treatment of TBI patients with visual symptoms, using the Preferred Practice Pattern model. The Response from the Arizona Ophthalmological Society to the Academy’s Background statement agreed that this should not become nor be perceived as a self-serving effort, but that we need more information to determine what rehabilitation strategies work for patients.

Rating: 1 - Currently being addressed by the following AAO activities:

Report: As described in the Background report, the Academy is working with other medical physicians to address traumatic brain injury that provides broader credibility and more effectively reaches the public. This initiative started in 2017 with the American Academy of Pediatrics (AAP), the American Association of Pediatric Ophthalmology and Strabismus (AAPOS), and our Academy agreeing develop a joint statement, “Vision & Concussions: Symptoms, Signs, Evaluations & Treatment”. Both the AAO and AAPOS have voiced concerns about the initial make-up of the AAP workgroup, the initial draft statement and fundamental vision rehabilitation stance. In fact, in April 2019, AAPOS and the Academy would not support the draft statement and would withdraw as an authoring organization unless significant changes were addressed. Then, the AAP workgroup meaningfully revised the statement (March 29, 2020 revision), making appropriate changes that addressed the AAPOS and the Academy’s concerns. Our Academy offered additional comments on May 15, 2020, and the edits were accepted by the AAP. As of August 4, 2020, the AAP workgroup is working to incorporate edits from AAPOS. Once the statement is signed by all the authoring organizations, the document will be sent to the AAP Board and Executive Staff for final approval.

The Response to the Background Statement also proposed that a joint approach with the American Academy of Neurology (AAN) could augment the effort with the AAP by addressing the highest evidence-based management of visual symptoms in adults with traumatic brain injury/concussion. On May 1, 2020, the Academy reached out to the AAN to propose the creation of a joint workgroup. A discussion among the staff of both organizations was held on May 5, and subsequently on May 29, the AAN physician leaders agreed to support AAN representation and participation on this workgroup. We anticipate that the AAN leadership will review, comment, and endorse the final work product. We have received the nomination of a formal representative of the AAN and have discussed the addition of this representative to existing NANOS Task Force, chaired by Dr. Prem Subramanian, as well as providing Academy staffing and coordination to help address this issue. Two members of the NANOS Task Force published an article in the Annals of Neurology in

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June 2020, "Vision Therapy: Ocular Motor Training in Mild Traumatic Brain Injury." The authors concluded, "Although the efficacy of exercises for primary convergence insufficiency is plausible and supported by data, there is not yet strong evidence of benefit for the post-traumatic variant. It is not established that abnormalities in fixation, pursuit, and saccades in mTBI [mild traumatic brain injury] are the cause of post-concussive symptoms, or that these abnormalities arise from ocular motor damage rather than being secondary effects of cognitive problems with attention or executive control. The few studies to date have significant methodological weaknesses. More substantial evidence is required before vision therapy can be accepted as a useful tool in the rehabilitation of patients with brain trauma."



Status Report for Council Advisory Recommendation: August, 2020

20-02: Title: Corneal Donation by Gay Men

Report From: David B. Glasser, MD – Secretary for Federal Affairs; Michael X. Repka, MD – AAO Medical Director for Governmental Affairs

Analysis:

The Academy agrees with the historic background and original basis of the action as outlined in the CAR for the 1994 Public Health Service (PHS) informal guidelines, eventually codified in 1997 in 21 CFR 1270 as the final donor eligibility rule and delineated in 2007 in the Food and Drug Administration's (FDA) Donor Eligibility Guidance for Industry. The donor eligibility rule excludes men who have had sex with another man (MSM) within 5 years prior to death from being tissue donors. The authors of the CAR provide evidence that this criterion excludes more than 1600 donors a year without any evidence that they do or do not harbor a relevant communicable disease or disease agent (e.g. HIV, hepatitis B or C).

Recognizing that advancements in serology and nucleic acid testing (NAT) provided assurance that donors carrying HIV, HBV, or HCV could be detected and excluded from the donor pool based on that testing, the FDA and PHS reduced the MSM exclusionary criteria as applied to blood and organ donors to 12 months prior to death. The US Public Health Service has recently proposed reducing the exclusionary period to 30 days for organ donors. This was done in order to expand the donor pool. However, the 5-year MSM exclusion remains for tissue donors.

The Academy is coordinating with the Eye Bank Association of America (EBAA) in advocating for a change to reduce the MSM exclusionary period.

Rating: 1 - Currently being addressed by the following AAO activities:

Report:

The Academy is working in collaboration with the Eye Bank Association of America (EBAA) to address the MSM exclusion. AAO and EBAA are going to highlight the request for change via a joint written letter to FDA, with a formal presentation of the request for shortening the exclusionary period to occur at the next opportunity to meet with FDA. A meeting with FDA could occur in late 2020, if able to meet remotely, if not the next opportunity for a face-to-face meeting will be in early 2021.



Status Report for Council Advisory Recommendation: August, 2020

20-03: Addressing Ophthalmology Suicide and Mental Illness

Report From: Aaron M. Miller, MD, MBA – Secretary for Member Services

Analysis:

This CAR asks the Academy to dedicate resources to assess the extent of mental health concerns among ophthalmologists, promote physician well-being and help alleviate work related stressors that increasingly threaten ophthalmologists' career satisfaction.

Rating: 1 - Currently being addressed by the following AAO activities:

Report:

The Academy is committed to improve the well-being and professional satisfaction of ophthalmologists through a multipronged approach.

With the COVID-19 pandemic as a new stressor to ophthalmologists, the Academy has expanded the physician wellness section on the website, aao.org/wellness to include tools, strategies and information to help members cultivate well-being and resilience. These include a variety of on-demand tools, such as articles on how to cope with emotional trauma and manage stress authored by a licensed therapist, a curated list of mental health apps and short video vignettes of simple energizing and strengthening exercises to enhance physical well-being. The Academy will continue to expand the physician wellness section with resources, including exploring channels for counseling support and referrals, to empower members to improve their practice life and professional fulfillment.

Additionally, the Academy will continue to refine its communication plan to increase the awareness of the wellness section among Councilors and at-large members. The wellness section has been promoted on a monthly basis on the Academy's website homepage, *EyeNet* magazine, featured in various Academy e-newsletters and highlighted in social media feeds, resulting in increased pageviews to the section.

Given the impact of COVID-19 on ophthalmology, the Academy has shifted its plans to conduct a practice environment survey to launch a series of member pulse surveys to quickly identify top concerns and challenges members' practices experience during this trying time. The practice environment survey is postponed for launch in May 2021 and aims to include questions related to workplace stress and well-being.

Efforts are underway to integrate the Physician Well-Being Index into aao.org/wellness and to encourage members to utilize this confidential self-assessment that evaluates multiple dimensions of distress and burnout. Academy members receive free access to this tool and can use the platform to gain a better understanding their overall well-being and areas of risk compared with other physicians across the nation. Deidentified aggregate data gathered from the Physician Well-Being Index will be used to help the Academy ascertain the state of well-being among the ophthalmologist community and assess the prevalence and causes of physician burnout across the career span. The Academy will explore establishment of a physician wellness task force to evaluate stressors and barriers to healthy practices and well-being and to investigate approaches to improve member well-being.

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Lastly, the Academy will explore opportunities for collaboration with state and subspecialty/specialized interest Societies to better understand challenges relating to physician well-being and to address systemic causes at the regulatory level with a unified voice.



Status Report for Council Advisory Recommendation: August, 2020

20-04: Title: Resource Allocations for State Government Affairs

Report From: Kurt F. Heitman, MD – Secretary for State Affairs; Daniel J. Briceland, MD – Senior Secretary for Advocacy

Analysis:

CAR 20-04, submitted by the Connecticut Society of Eye Physicians, suggests that Resources allocated to SGA must stay current with the projected needs during upcoming legislative sessions as they work with SSA and state ophthalmological societies defending patient safety protections.

The Secretariat for State Affairs and the Senior Secretary for Advocacy very much appreciate the Council support of the Academy's State Affairs function. This support ensures that the Secretariat will continue to build a strong state governmental affairs function within in Academy's Governmental Division. Just as importantly, the Senior Secretary for Advocacy and the State Affairs Secretariat continue to clearly and strongly communicate to Board of Trustees that the future health of the ophthalmology profession is closely tied to the activities and success of the Academy's state governmental function.

Rating: 2 - Cannot implement right now because:

Report:

At the July 2020 State Secretariat virtual annual policy meeting, the Secretariat reviewed and discussed the Council CAR 20-04. The State Secretariat was most thankful for Council advocacy support. Without such strong support from both the Council and the Academy Board of Trustees, the State Secretariat's effectiveness to assist state society's in their surgery battles to protect patient surgical safety and preserve surgical standards would be greatly thwarted.

This support is evidenced in the State Secretariat's continued success to assist state societies in these crucial state legislative/regulatory battles. For example, in 2020, State Societies and the State Secretariat in partnership secured patient victories in ID, WY, NE, MN, IA, MS, AL, and VT.

Obviously the COVID -19 crisis that we as a country and a profession are now experiencing places a great strain on our patients and member practices. We believe the Council would agree that under these circumstances, increased

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financial support of the Academy's State Affairs function is not feasible. But working together, we will continue to battle and win state victories that protect patient surgical safety and preserve surgical standards.

American Academy of Ophthalmology
Council Advisory Recommendation

20-01

Title: Vision Therapy for Post-TBI Visual Symptoms

Problem Statement:

There is a gap of data and care for treating patients with visual symptoms post traumatic brain injury (TBI) that is being filled by optometry. As patient advocates and leaders of the eye care team, we should be striving to establish preferred practices for the care of these patients.

Summary of facts and background information:

Traumatic brain injury/concussion is a subject of increased focus in the medical and lay communities. The increased awareness has led to improvements in diagnosis by detecting the signs and symptoms after high risk traumatic events. Patients with TBI or presumed TBI are now frequently referred to concussion clinics staffed by neurologists with associated OT and PT providers specializing in the diagnosis and rehabilitation of patients with TBI.

Having reviewed the records of many patients referred to concussion clinics in Arizona, a pattern has emerged. When visual signs or symptoms are present, these patients are routinely referred to "neuro-optometry"- a handful of optometrists who evaluate and perform visual therapy for post TBI visual issues- for evaluation and treatment. These O.D.s perform examination and a computer generated eye tracking test, often recommending and performing VEP and OCT testing, and the patients are diagnosed with motility disorders including convergence insufficiency, disorders of saccades, disorders of pursuits, etc. Multiple sessions of vision therapy are recommended, and in some cases are ongoing for years despite a lack of improvement in symptoms.

A search for data regarding visual therapy for all patients with visual symptoms following TBI yields findings that post-concussion convergence insufficiency improves faster in patients receiving visual therapy than not, with eventual recovery in both groups the most common result. No good data could be found regarding other diagnosed eye movement or visual disorders post TBI.

Part of our role as leaders in the eye care community is to be cognizant of the appropriate use of time and resources for these patients. In a worst case scenario, a patient with a self limited motility and visual disturbance may be convinced they have a permanent disability that limits their quality of life unnecessarily. We need to do what we can to make sure these patients receive care that is effective, and that resources are directed to the best available tests and treatments to help TBI patients recover as much function, and as quickly, as possible.

Possible Solutions:

We propose that the Academy establish a working group to provide guidelines for the treatment of TBI patients with visual symptoms, using the Preferred Practice Pattern model. This group can access resources that would likely be very useful in this project, such as our VA colleagues (and pertinent data from the VTRP studies), IRIS registry data, and possibly working in collaboration with O.D. researchers within the AAO2AAO framework.

Submitted by:

Brian T Rose MD

Approval Date:

12/7/2019

On Behalf of:

Arizona Ophthalmological Society

Other Society:

North American Neuro-Ophthalmology Society 1/16/2020



Academy Background Statement
Council Advisory Recommendation

20-01: Vision Therapy for Post-TBI Visual Symptoms

Assigned to: Secretary for Quality of Care

From: Timothy W. Olsen, MD

Analysis:

The American Academy of Ophthalmology appreciates the proposal put forward by the Arizona Ophthalmological Society and the North American Neuro-Ophthalmology Society. As noted, traumatic brain injury/concussion is currently at a heightend state of interest, and there is an expanding evidence based effectiveness for neuro-cognitive interventions.¹ However, most of the level 1 data is focused on the effectiveness of visual scanning following hemispheric strokes.¹ The American Academy of Ophthalmology agrees with the author that the topic is important, and should be addressed.

The Academy could establish a workgroup to provide guidelines based on the scientific literature to treat patients with TBI/concussion and visual rehabilitation outcomes. This would have the benefit of providing a well-balanced review of current evidence-based recommendation to promote effective care of patients. Based on a broad meta-analysis by Cicerone et al on overall post-TBI neuro-cognitive rehabilitation, the authors have performed a careful assessment of measurable patient outcomes, yet this review is not solely focused on visual rehabilitation.¹ Without a careful analysis of the visual rehabilitation component of TBI/concussion subjects, criticism of visual rehabilitation could possibly be perceived by the public and other medical practitioners to favor ophthalmology. An alternative is to work with other medical physicians to provide broader credibility and reach into the public. One coordinated effort is already underway to address visual symptoms in children with concussion which is described below.

This topic was first discussed at the Ophthalmic Advocacy Leadership Group Meeting in January 2017, and the three organizations, Academy, American Academy of Pediatrics and American Association of Pediatric Ophthalmology and Strabismus agreed to work on a joint statement. On January 28, 2018, the American Academy of Pediatrics Section of Ophthalmology proposed a AAP SOOp/AAPOS Concussion Workgroup with the following members: AAP SOOp/AAPOS Concussion Workgroup: Darron Bacal, MD (Co-Chair); Christina Master, MD, FAAP (Co-Chair); Rich Hertle, MD, FAAP; Mitchell Strominger, MD, FAAP; Ankoor Shah, MD, Sarah Whitecross BSc, CO; and an optometrist. The Academy and AAPOS objected vigorously to the inclusion of the optometrist on the Workgroup, and after discussion with the AAP co-authors and coordination with AAPOS and the Ophthalmology Section of AAP, on March 18, 2018, the AAP agreed to maintain only pediatricians, pediatric ophthalmologists and an orthoptist on the workgroup. Subsequently, on March 18, 2019, the AAP provided a first draft of the joint Policy Statement and supporting Technical Report on "Vision & Concussions: Symptoms, Signs, Evaluations & Treatment." The paper was found to cite 10 references from optometric literature and described the treatments they provided and stated that patients should be referred to a vision specialist, instead of an



ophthalmologist. The Academy and AAPOS coordinated their strong objections to the paper to AAP and stated that they would not join the statement unless these issues were addressed. On April 18, 2019, the 3 groups (AAO, AAPOS and the AAP Section on Ophthalmology) stand united that we cannot support the statement without significant revisions. As of February 25, 2020, we are still awaiting a revision of the proposed statement.

Another effort could be developed to refer TBI/concussion patients initially to Neurology for neurocognitive rehabilitation, then subsequently to ophthalmology for determining the most appropriate, evidence-based care, including rehabilitation efforts. Developing a plan to address visual symptoms in adults with concussion with the American Academy of Neurology seems to place the highest evidence based data for overall TBI/concussion therapy in a step-wise approach. Based on the interest and priority placed by the Council, the Academy could explore the interest of the American Academy of Neurology and determine whether and how to create a workgroup.

1. Cicerone KD, Goldin Y, Ganci K, et al. Evidence-Based Cognitive Rehabilitation: Systematic Review of the Literature From 2009 Through 2014. *Arch Phys Med Rehabil* 2019;100:1515-1533.

Response to AAO Background Statement Re: CAR 20-01 - Vision Therapy for Post-TBI Visual Symptoms

From: Brian Rose, MD – Councilor, Arizona Ophthalmological Society

April 2, 2020

The Arizona Ophthalmological Society greatly appreciates the background statement from Dr. Olsen on behalf of the AAO Board of Trustees.

We welcome the proposal to establish a workgroup for the purpose of providing scientific literature-based guidelines regarding visual rehabilitation in post TBI patients with visual symptoms.

The information about the efforts to develop a joint statement regarding this issue in children with the American Academy of Pediatrics, the AAO and AAPOS is instructive, and hopefully will produce consensus.

We agree that this should not become nor be perceived as a self-serving turf battle effort. It is not our contention that none of the optometric testing and treatment being done have potential merit, but that it is consuming a lot of resources and we need more information to know if that is justified, and we need to determine and define rehabilitation strategies that work for these patients. Including optometrists whose interests are scientific and not political in this effort could add credence to the process and its result. If the Academy's efforts to build relationships with optometry could facilitate this, that would be useful.

In our experience, most adult TBI patients are at least initially evaluated and usually continue to be monitored and treated by neurologists, and it is precisely these neurologists who are referring the patients to optometrists (or "neuro-optometrists") for vision rehabilitation/training currently. Reaching out to, and developing science-based, coordinated strategies with the American Academy of Neurology would be a valuable avenue to extend the work done with the AAP to the adult population.

The North American Neuro-Ophthalmology Society (NANOS) has petitioned to start a taskforce regarding this issue and has expressed willingness to participate in the process of working with the AAO and AAP on this effort.

**American Academy of Ophthalmology
Council Advisory Recommendation**

20-02

Title: Corneal Donation by Gay Men

Problem Statement:

Author: Michael A. Puente, Jr., MD; University of Colorado School of Medicine, Department of Ophthalmology
Sponsor Society: Colorado Society of Eye Physicians and Surgeons A little-known FDA policy instituted in 1993 during the AIDS crisis states that men who have had sex with another man (MSM) in the preceding five years are ineligible to donate their corneas, even when all infectious disease testing is negative.¹ This policy was put in place at a time when our ability to screen for HIV was limited, yet the rule remains in place today even though our ability to test for HIV and other infectious diseases has improved significantly since 1993.

Summary of Facts and Background Information:

No case of HIV transmission through corneal transplantation has ever been reported, even in the ten transplants from HIV-positive donors recorded in the literature.^{2,3,4,5} This is largely because corneas are an avascular tissue, and cadaveric studies have consistently concluded that corneas are not a major reservoir for the virus. For example, a study of 90 corneas obtained from HIV-positive people only managed to find HIV antigen in 6 of 90 corneas tested,⁶ and a separate study only detected HIV in 4 of 22 corneas collected from patients who died of AIDS.⁷

HIV screening tests available in 1993 were unreliable, leading the FDA to institute its MSM exclusion policy banning corneal donation by any man who has had sex with another man in the preceding five years. Canada similarly enforces a twelve-month MSM deferral policy for corneal donation.⁸ However in 2020, all corneal donors in the US and Canada must have negative results for three separate and extremely reliable modern HIV tests performed on donor serum: HIV-1 ELISA, HIV-2 ELISA, and HIV nucleic acid testing (which is reliable when performed as soon as 4-8 days after HIV exposure).^{9,10,11} Reported sensitivities and specificities for these tests are greater than 99.5%.^{12,13} Armed with modern testing and the knowledge that corneal transplants are unlikely to be able to transmit HIV, it is no longer medically justified to exclude MSM donors with negative infectious disease testing for five years after their last sexual encounter.

Neither the FDA, Health Canada, nor the Eye Bank Association of America keep any statistics regarding the number of corneal donors disqualified due to this policy. Therefore, a team led by Michael Puente, MD, at the University of Colorado recently contacted every eye bank in the United States and Canada individually to determine how many corneas were turned away in 2018 due to this policy. Of the 65 eye banks contacted, 25 (38%) were able to provide data. They reported that they collectively turned away 353 referrals in 2018 solely because of MSM status, equating to 706 corneas. Those 25 eye banks represented 44% of the total corneas recovered in the United States and Canada in 2018, allowing us to extrapolate that at least 1600 corneas were turned away from MSM donors in 2018 for no other reason than the donors' sexual orientation. This is likely a gross underestimate, as many eye banks reported that their MSM deferral data were incomplete.

The FDA subjects MSM donors to harsher scrutiny than other groups considered to be at high risk of having sexually transmitted diseases. For example, the FDA says that a heterosexual person who has had a sexual relationship with someone known to be HIV-positive is only ineligible for one year after their last sexual

encounter with the HIV-infected individual,¹⁴ while MSM donors must be abstinent for five years even if they have never had an HIV-positive sexual partner.

The FDA also defers MSM donors for a longer period prior to corneal donation than other donations. For example, MSM donors can donate blood after only one year of abstinence and can donate organs such as hearts, lungs, livers, and kidneys with no deferral period whatsoever. This is despite the fact that HIV has been repeatedly reported to be transmitted from blood transfusions and through transplantation of vascular organs, but has never been reported from corneal transplants even from HIV-positive donors.

Only three countries consistently recover enough corneas to meet local demand each year: the United States, Italy, and Sri Lanka. All other nations either rely on surplus corneas from these countries or require their patients to wait on often years-long waitlists for a cornea. Recent estimates find that over 12.7 million people worldwide are in need of a corneal transplant.¹⁵ Since the United States exports thousands of surplus corneas across the world each year, the ban on MSM corneal donation directly prevents over 1600 people across the world from receiving vision-restoring surgery each year.

Possible Solutions:

We suggest that the American Academy of Ophthalmology should formally recommend to the FDA that it revisit its outdated policy from 1993. Given that modern infectious disease testing is reliable within days of HIV exposure, there is no reason to continue to disqualify MSM donors for an arbitrary five-year period of abstinence.

Several alternative policies are being safely used by our peer nations and should be considered for implementation in the United States, as well as Canada:

- A) The MSM deferral period could be shortened from an arbitrary five years to a period based instead on modern virologic testing. HIV and hepatitis screening are reliable within only 8 and 27 days of viral exposure, respectively.¹¹ Out of an abundance of caution given the increased rates of sexually transmitted infections in the MSM population, the MSM deferral period could be set at double or triple the window period for modern viral testing. This would result in shortening the current MSM deferral period from an arbitrary five years to a more scientifically based period of 2-3 months. This follows the example of the United Kingdom and France, which only defer MSM corneal donors for 3 and 4 months, respectively.
- B) Many other countries, such as Italy, Spain, Portugal, Russia, and Mexico have no deferral policy for MSM donors whatsoever, making no distinction between heterosexual and homosexual donors.¹⁶ Following this example, the FDA could mandate screening procedures which assess all donors for high-risk sexual behavior equally, thereby allowing monogamous MSM donors to donate their corneas but continuing to exclude both heterosexual and MSM donors found to have had sex with people at high risk of having sexually transmitted infections (e.g. prostitution, sex with an HIV-positive partner).

In conclusion, the FDA's policy banning corneal donation by MSM donors who have been sexually active in the past five years is not evidence-based and is not justified by modern science. The recent estimate that over 1600 corneas are being discarded each year because of this policy suggests that this ban has real-world implications and prevents thousands of patients from receiving vision-restoring surgery. We strongly recommend that AAO petition the FDA to shorten or eliminate its MSM deferral period in light of current scientific evidence.

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- ¹ Food and Drug Administration. Human tissue intended for transplantation. *Federal Register*. 1993; 58(236):65514-21.
- ² Pepose JS, Macrae S, Quinn TC, Ward JW. Serologic Markers After the Transplantation of Corneas from Donors Infected with Human Immunodeficiency Virus. *American Journal of Ophthalmology*. 1987; 103(6): 798-801.
- ³ Schwarz M, et al. Human Immunodeficiency Virus Transmission by Organ Donation. Outcome in Cornea and Kidney Recipients. *Transplantation*. 1987; 44(1): 21-4.
- ⁴ Simonds RJ, et al. Transmission of human immunodeficiency virus type 1 from a seronegative organ and tissue donor. *New England Journal of Medicine*. 1992; 326(11): 726-32.
- ⁵ Keen GA, et al. Corneal transplantation from an HIV seroconverting donor. *S Afr Med J*. 1993; 83(2): 132-3.
- ⁶ Qavi HB, Green MT, Segall GK, Lewis DE, Hollinger FB. Frequency of dual infections of corneas with HIV-1 and HHV-6. *Current Eye Research*. 1992; 11(4): 315-323.
- ⁷ Garcia-Ferrer FJ, et al. Screening Corneas for Human Immunodeficiency Virus Type 1 Proviral DNA by Polymerase Chain Reaction. *Amer J Ophth*. 1995; 119(1): 7-13.
- ⁸ CSA Group. (2017). *CAN/CSA-Z900.1-17 National Standard of Canada: Cells, tissues, and organs for transplantation: General requirements*.
- ⁹ Fiebig E, et al. Dynamics of HIV viremia and antibody seroconversion in plasma donors: implications for diagnosis and staging of primary HIV infection. *AIDS*. 2003; 17(13):1871-1879.
- ¹⁰ Kucirka LM, et al. Risk of Window Period HIV Infection in High Infectious Risk Donors: Systematic Review and Meta-Analysis. *American Journal of Transplantation*. 2011; 11(6): 1176-1187.
- ¹¹ World Health Organization. (2017). *Guidelines on Estimation of Residual Risk of HIV, HBV or HCV Infections via Cellular Blood Components and Plasma*. Retrieved from <https://apps.who.int/medicinedocs/documents/s23323en/s23323en.pdf>.
- ¹² Galel SA, et al. Sensitivity and specificity of a new automated system for the detection of hepatitis B virus, hepatitis C virus, and human immunodeficiency virus nucleic acid in blood and plasma donations. *Transfusion*. 2017; 58(3): 649-659.
- ¹³ Vargo J, et al. Clinical specificity and sensitivity of a blood screening assay for detection of HIV-1 and HCV RNA. *Transfusion*. 2002; 42(7):876-85.
- ¹⁴ U.S. Food and Drug Administration. Center for Biologics Evaluation and Research. (2007). *Guidelines for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*. Retrieved from <https://www.fda.gov/media/73072/download>.
- ¹⁵ Gain P, et al. Global Survey of Corneal Transplantation and Eye Banking. *JAMA Ophthalmol*. 2016; 134(2):167-173.
- ¹⁶ Benjamin RJ, et al. Deferral of males who had sex with other males. *Vox Sanguinis*. 2011; 101: 339-367.

Submitted by:

Rebecca Sands Braverman, MD

Approval Date:

1/24/2020

On Behalf of:

Colorado Society of Eye Physicians and Surgeons

Other Societies:

Montana Academy of Ophthalmology

Utah Ophthalmology Society

Wyoming Ophthalmological Society

Idaho Society of Ophthalmology

All board approved on Jan. 30, 2020

Academy Background Statement
Council Advisory Recommendation

20-02 Corneal Donation by Gay Men

Assigned to: Federal Affairs

From: David B. Glasser, MD – Secretary for Federal Affairs

Analysis: The Academy agrees with the historic background and original basis of the action as outlined in the CAR for the 1994 Public Health Service (PHS) informal guidelines¹, eventually codified in 1997 in 21 CFR 1270 as the final donor eligibility rule and delineated in 2007 in the Food and Drug Administration’s (FDA) Donor Eligibility Guidance for Industry². The donor eligibility rule excludes men who have had sex with another man (MSM) within 5 years prior to death from being tissue donors. The authors of the CAR provide evidence that this criterion excludes more than 1600 donors a year without any evidence that they do or do not harbor a relevant communicable disease or disease agent (e.g. HIV, hepatitis B or C).

Recognizing that advancements in serology and nucleic acid testing (NAT) provided assurance that donors carrying HIV, HBV, or HCV could be detected and excluded from the donor pool based on that testing, the FDA and PHS reduced the MSM exclusionary criteria as applied to blood³ and organ⁴ donors to 12 months prior to death. This was done in order to expand the donor pool. However, the 5-year MSM exclusion remains for tissue donors.

The Academy is coordinating with the Eye Bank Association of America (EBAA) in advocating for a change in the MSM exclusion. An FDA liaison attends the EBAA Medical Advisory Board meetings twice a year and EBAA staff meet annually with officials from the Center for Biologics Evaluation and Research (CBER) that regulates tissues.

The EBAA’s last formal comments submitted to FDA on this topic were in December 2017 (attached). They support reduction of the exclusionary window to 12 months, consistent with other organ and blood donor regulations. The FDA’s stated rationale for being more conservative with tissue donors is that MSM remains a significant risk factor for HIV and hepatitis and that the donor risk questions are answered by a family member who may not know the deceased’s behaviors, although this ignores the ability of current serology and NAT protocols to detect donors at risk of disease transmission.

At the annual liaison meeting in February 2017, the EBAA reiterated the position that the exclusion for historical risk factors such as MSM should be reduced from

5 years to 12 months in light of serologic and NAT donor screening. The FDA response was typically non-committal, reserving comment for proposed rulemaking and industry guidance documents.

Options

The Academy agrees with the CAR and the EBAA that the MSM exclusion should be revised. In considering how to approach the FDA about changing the exclusion, it is important to understand that they operate on the precautionary principle. Risk tolerance at FDA is extremely low as long as regulations do not impact the tissue supply in the United States. Tissue availability in other countries, costs related to increased testing requirements and false positives, and perceived differential treatment of donors based on sexual orientation do not enter into the FDA's calculus as long as there is an adequate supply of tissue in the United States.

1. Advocate for elimination of the MSM exclusion for tissue donors based on the availability of adequate serology and NAT screening. This seems unlikely to succeed based on FDA's risk tolerance.
2. The AAO would recommend support for EBAA's position requesting a reduction of the MSM exclusionary period to 12 months, consistent with the blood and organ regulations by continuing to coordinate with them. This has a greater chance of success.

Potential avenues of collaboration with EBAA include letters of support to EBAA and/or FDA, joining EBAA in formal comments, and in-person participation in liaison meetings.

References

1. Public Health Service. PHS Guideline for Preventing Transmission of HIV Through Transplantation of Human Tissue and Organs. Morbidity and Mortality Weekly Report 1994; 43(RR8):1-17.
2. Food & Drug Administration. Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps). August 2007.
3. Food & Drug Administration. Guidance for Industry: Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products. December 2015.
4. Public Health Service. PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation. Public Health Reports: July/August 2013. Vol 128.

Response to AAO Background Statement Re: CAR 20-02 - Corneal Donation by Gay Men

From: Rebecca Sands Braverman, MD – Councilor, Colorado Society of Eye Physicians and Surgeons

April 2, 2020

The Colorado Society of Eye Physicians and Surgeons will not be submitting a response.

American Academy of Ophthalmology
Council Advisory Recommendation

20-03

Title: Addressing Ophthalmology Suicide and Mental Illness

Problem Statement:

Work related stressors among physicians have led to a significant increase in mental illness and suicide reflected in a published suicide rate of 28-40 per 100,000, with a disproportionate rate of incidence among our female colleagues. Recent surveys have suggested a relationship between this increase in suicide, and the profound changes in the practice of medicine created by outside forces over the past 15 years.

Summary of facts and background information:

Findings presented at the 2018 Annual Meeting of the American Psychiatric Association, show that the rate of suicide among physicians in the United States now leads all professions, including active duty military. The rate of suicide among physicians in the United States is 28-40 per 100,000 compared to a rate of 12.3 per 100,000 in the general population. This rate is higher among female physicians. This leads to an estimated total of 300 deaths by suicide among physicians in the United States per year. This is equivalent to almost three medical school classes per year!

When these surveys are broken down by specialty, we see suicidal ideation at a rate of 11% among Ophthalmologists. In addition, this may be higher, given that 5% of respondents chose not to answer the question. We also see that only 39% of Ophthalmologists report being happy at work, and that as many as 14% of Ophthalmologists report being depressed. Unfortunately, the surveys that we rely upon are a wide sample of all specialties, and the representation of Ophthalmology is small by comparison.

However, the fact remains that there is a significant problem within the physician, and Ophthalmic, population that is leading to an increase in mortality. We are only at the beginning of addressing it.

In response, there has been an increase in discussion in the past few years. The focus has initially been, understandably, on identifying suicidal ideation and to address it before it leads to completion. This has resulted in measures such as advertisement of suicide hotlines, recommendations for mental health care and scattered local efforts at providing online assessment surveys to try and direct those in need to professionals. These efforts have been a step forward, however, they are not yet uniform or adequate to address the problem.

Recently, the attention has begun to turn towards identifying the cause of this upswing in mental health issues for physicians. The underlying cause has routinely been referred to as burnout. This has become a point of contention in the healthcare community. Wendy Dean MD and Simon Talbot MD have made the point that when comparing the professional lives of soldiers to those of the modern physician, there are significant similarities in their work environment that suggests that the causes are injurious, rather than a matter of appropriate coping with the circumstances.

This fact is reflected in the limited survey material that we have, that appears to be remarkably consistent. They note the greatest burden/injury is coming from bureaucratic tasks and increasing government/insurance barriers to providing care. It is also noted that the increasing burden of reduced compensation, going hand in hand with increased workload, is taking its toll. It is also important to note, that as the population ages, this workload will only increase. These surveys remain consistent across specialties, and Ophthalmology shares the burden that should be addressed.

Possible Solutions:

We ask the following possible solutions to attempt to address the above.

A: The AAO should adopt the official phrase “moral injury,” or find some other equivalent phrase, to refer to the condition that is currently referred to as “burnout.” “Burnout” denotes a failing on the part of physicians for not acclimating to the current system. Given that the way a condition is described is a vastly important factor in treating the condition, we feel that the AAO should adopt a stance that reflects the injury inflicted on physicians, thus providing a roadmap to addressing the system itself.

B: We ask that the AAO dedicate resources to surveying the membership to ascertain the true extent of mental health concerns among the population of ophthalmologists. This would, hopefully, provide the most accurate data regarding a specific population of physicians. In turn, this would help to identify the problems that need to be addressed.

C: We ask the AAO to begin coordinating with other specialty societies to provide easy access to assessment and treatment. This can be in the form of online assessments, and local provider resources that can be spearheaded by our state societies.

D: We also ask the AAO to make use of this data to aggressively lobby government entities to address the underlying causes of moral injury. This will serve to change the healthcare system in ways that will improve the well-being of physicians, and, by extension, our patients.

Submitted by:

Matthew F Appenzeller MD

Approval Date:

1/31/2020

On Behalf of:

Nebraska Academy of Eye Physicians and Surgeons

Other Society:



Academy Background Statement Council Advisory Recommendation

20-03: Addressing Ophthalmology Suicide and Mental Illness

Assigned to: Secretary for Member Services

From: Aaron M. Miller, MD, MBA

Analysis:

A significant increase in mental illness and suicide attributed to burnout is a topic of growing professional and public health concern. The COVID-19 pandemic is another major stressor to practicing ophthalmologists as more develop a sense of hopelessness considering the gravity of the current situation. The Academy acknowledges the CAR author's sentiment that everchanging governmental regulations, declining reimbursements, increasing workload and other challenges add up to a volatile state of health care that increasingly threatens ophthalmologists' career satisfaction and joy to protect sight and empower patients' lives. The Academy understands this undue stress stems from regulatory, workplace and individual drivers and will require multifaceted solutions.

As background, the Academy developed a physician wellness section on the website, aao.org/wellness, designed to help ophthalmologists cope with stress and improve well-being. Since its inception in 2017, the section offers tools, strategies and information to help ophthalmologists cultivate well-being and resilience in their lives.

Recognizing ophthalmologists tend to avoid reporting their distress due to the perceived stigma of failure, potential career repercussions and other negative consequences, the Academy is in the process of incorporating the Physician Well-Being Index to the wellness section. This tool, developed by the Mayo Clinic and used by more than 600 medical institutions and organizations worldwide, enables Academy members to complete a confidential self-assessment and provides the Academy with deidentified aggregate data to develop resources to support those most in need.

Additionally, the Academy plans to survey the membership to identify stressors and ascertain the state of well-being among the ophthalmologist community. Questions related to career satisfaction and physician wellness will be included in the Academy's practice environment survey. Data collected will be benchmarked against Medscape's annual physician burnout and suicide report.

The Academy aims to enhance member satisfaction, well-being and resiliency with resources that support members throughout their careers. We will assess appropriate terminology used to address physician distress and resiliency in Academy communications. We will work with state societies and member societies of the Council of Medical Specialty Societies to better understand challenges relating to physician well-being, increase awareness among members, and promote evidence-based solutions that improve patient care by enhancing physician well-being.

Response to AAO Background Statement Re: CAR 20-03 - Addressing Ophthalmology Suicide and Mental Illness

From: Matthew Appenzeller MD – Councilor, Nebraska Academy of Eye Physicians and Surgeons

April 6, 2020

It is amazing how much the landscape has changed in the time that has passed since this CAR was submitted. We at NAEPS thank you greatly for the consideration of CAR 20-03. We wish to convey that, while we recognize the gravity and disruption created by the COVID 19 Pandemic, this issue is just as pressing as it was in November of 2019 when the executive committee of NAEPS decided to approach it. In reality, it may very well become even more acute given the level of financial stress this pandemic will clearly create. The surface landscape may of changed, but we believe that the underlying geology has not only persisted, but it has become even more volcanic in it's potential for damage.

Given this, we would like to offer the following thoughts in response to the Academy's background statement:

- 1) We are impressed and pleased at the efforts that have been made thus far regarding the wellness program offered by the Academy. However, the members of our committee were not aware of its existence. Thus, especially in light of the current situation, we ask the Academy to take a more aggressive stance in making the membership aware of its presence. In addition, we encourage the Academy to find a way to incorporate access to counselors, either via telehealth or locally. It appears that the future addition of the Physician Well-Being Index moves in this direction and provides a confidential platform within which to operate. If this is correct, it is applauded and encouraged. We stress the probable need to move this project forward with great haste, given the current environment. We, again, hope that it will include access to mental health providers.
- 2) We applaud the Academy for planning to move forward with a survey of the membership regarding workplace stress and well-being. We ask that a special task force, or committee, be formed to address this issue, using the wellness program, deidentified data, and survey information to formulate responses and initiatives for the Academy to consider to address membership well-being. The Academy has a long history of advocacy, and we must continue to do so, not only in policy, but also in healing.
- 3) Finally, we appreciate that the Academy is willing to work with other medical societies to address this issue. We ask that this be done, not only to enhance the wellness of the membership, but also to provide a unified voice of advocacy for policy makers to listen to. We would like to see new terminology, appropriate based on evidence derived from the above efforts, adopted in these

communications. Lastly, we would like to see any systemic causes that are identified to be addressed at regulatory level via this unified effort.

Thank you for the attention. I hope that this sees everyone through to the end of our latest challenge.

American Academy of Ophthalmology
Council Advisory Recommendation

20-04

Title: Resource Allocations for State Government Affairs

Problem Statement:

Resources allocated to SGA must stay current with the projected needs during upcoming legislative sessions as they work with SSA and state ophthalmological societies defending patient safety protections.

Summary of facts and background information:

The advocacy effort within the AAO has been keenly aware of the increasing resource draw on the office of State Government Affairs and individual State Ophthalmologic Societies as they promote patient surgical safety and preservation of surgical standards.

Recommendations have been proposed to the Council for several years. The 2018 response to CAR 18-04 asking for increased SGA funding, thoughtfully concluded: “The State Affairs Secretariat believes that independent funding sources such as the SSF and an independent public entity could become a major funding source for additional revenue in the states’ battle for patient safety and preservation of surgical standards.”

The year 2019, had twenty-four at-risk states for legislation that threatened patient surgical safety and standards. The Council is aware that recently we have had extreme resource use in states like North Carolina and we have had significant adverse outcomes in states including Alaska and Arkansas during the time leading up to the 2018 response to CAR 18-04. Despite significant resource use to promote patient safety, we are now looking at 2020 and wonder how SGA funding will be able to sustain its impact on legislation throughout the nation, if earlier intervention is not implemented. To plan on doubling or tripling Surgical Scope Fund contributions to support a robust 2020 battle seems falsely optimistic, but adding additional State Government Affairs personnel armed with a robust budget, that would work with states vulnerable to scope bills facing legislative action, could make a difference.

There is an understanding that the AAO has limited resources and many interests to support. Those states that will be facing legislation in 2020 and beyond are carrying out the mission of the Academy to promote patient safety and surgical standards. The States cannot do it without the support of the State Government Affairs Office and therefore we must insure the proper funding and resources for this important office.

The Academy effort to develop a patient coalition and a broadly applicable web-presence template should continue as well as getting greater membership participation in the SSF

contributions for 2020. However, the need for additional funding of SGA is immediate while the Academy develops more long-term solutions.

Possible Solutions:

1. Immediate increase funding for SGA in the 2020 legislative session.
2. A determination of the current SGA resources, in both human and capital resources, should be assessed and compared to the projected SGA demands for the upcoming year.
3. The results be made available to the Secretariat of State Affairs for review and input.
4. A recommendation for altering SGA resources including potential capital or human increases if projections warrant such an increase.
5. That this become a yearly assessment with historical context regarding funding adequacy.

Submitted by:

Edward S Lim MD

Approval Date:

1/12/2020

On Behalf of:

Connecticut Society of Eye Physicians

Other Society:

North Dakota Society of Eye Physicians and Surgeons 1-27-2020

Texas Ophthalmologic Association 1-24-2020

Puerto Rican Society of Ophthalmology 1-24-2020

New York State Ophthalmological Society 1-24-2020

Maine Society of Eye Physicians and Surgeons 1-28-2020



Academy Background Statement **Council Advisory Recommendation**

20-04: Resource Allocations for State Government Affairs

Assigned to: Secretary for State Affairs; Senior Secretary for Advocacy

From: Kurt F. Heitman, MD; Daniel J. Briceland, MD

Analysis:

The Secretariat for State Affairs and the Senior Secretary for Advocacy very much appreciate the Council support of the Academy's State Affairs function. This support ensures that the Secretariat will continue to build a strong state governmental affairs function within in Academy's Governmental Division. Just as importantly, the Senior Secretary for Advocacy and the State Affairs Secretariat continue to clearly and strongly communicate to Board of Trustees that the future health of the ophthalmology profession is closely tied to the activities and success of the Academy's state governmental function.

As CAR 20-04 points out, in 2019, twenty-four states were identified as at risk for optometric surgery push. To date, Alabama, Idaho, Massachusetts, Minnesota, Pennsylvania, Puerto Rico, Vermont, Mississippi, Nebraska, Kansas, and Wyoming state ophthalmic societies have faced a major push by optometry to gain surgical authority. And these states with staff and financial assistance from the Academy have defeated or are defeating optometric surgery initiatives that pose a risk to patient safety and to surgical standards.

In 2020, the Academy has continued its strong commitment to the state affairs function as demonstrated with continued staff and financial support of this important member function – state surgical advocacy. Obviously the COVID -19 crisis that we as a country and a profession are now experiencing places a great strain on our patients and member practices. We believe you would agree that under these circumstances, increased financial support of the Academy's State Affairs function is not feasible.

No doubt, SSF contributions from members will drop in the coming months. However, the State Affairs Secretariat has already initiated 2021 state advocacy planning which takes into consideration a reduction in SSF dollars.

**Response to AAO Background Statement Re: CAR 20-04 - Resource
Allocations for State Government Affairs**

Connecticut Society of Eye Physicians

No reply received as of April 6, 2020.