The Edward S. Harkness Eye Institute of Columbia University Medical Center Presents

Tele-Ophthalmology & Artificial Intelligence CONFERENCE

Applying Technology to Improve Healthcare Delivery and Outcomes

CONTINUING MEDICAL EDUCATION

FRIDAY, APRIL 6, 2018

PHILANTHROPY NEW YORK 1500 BROADWAY, NEW YORK, NY

The **College of Physicians and Surgeons** designates this live activity for a maximum of 7.75 AMA PRA Category 1 Credits[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This continuing medical Education Activity is supported by unrestricted educational grants from Lavelle Fund for the Blind, Topcon, Zeiss, Orbis International, Optos, and Save Vision Foundation.

CME INFORMATION

FEATURING

Cutting-edge topics in tele-ophthalmology, artificial intelligence, and the use of technology to improve access to care and healthcare outcomes.

A platform for education, exchange of experiences, and networking in the emerging field of Tele-ophthalmology for ophthalmologists, clinicians in other medical fields, and people in industry working on Tele-medicine and information technology.

TARGET AUDIENCE

Ophthalmologists, residents, fellows, optometrists, industry, and individuals interested in the field.

LEARNING OBJECTIVES

- Explore the need and potential role of tele-ophthalmology in blindness prevention and population management
- Review and compare early experiences with tele-ophthalmology nationally and internationally
- Describe current and emerging technologies in tele-ophthalmology
- Describe artificial intelligence in medicine and ophthalmology
- Elucidate future modalities in eye care
- Provide information on current legislation and reimbursement with the goal of recommending needed changes

ACCREDITATION STATEMENT

The **College of Physicians and Surgeons of Columbia University** is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AMA CREDIT DESIGNATION STATEMENT

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GRANTOR STATEMENT

This continuing medical education activity is supported by unrestricted educational grants from Lavelle Fund for the Blind, Topcon, Zeiss, Orbis International, Optos, and Save Vision Foundation.

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FACULTY DISCLOSURES

DISCLOSURE: Before the program, all faculty will disclose the existence of any financial interest and/or other relationship(s) (e.g. employee, consultant, speaker's bureau, grant recipient, research support, stock ownership or any other special relationship) they might have with a) the manufacturer(s) of any commercial product(s) to be discussed during their presentation and/or b) any commercial contributor to this activity. When unlabeled uses are discussed, these will also be indicated.

Michael Abramoff, MD, PHD

Salary & Ownership Interest Idx, Inc. – Founder, President & Consultant

Consulting Fees Idx, Inc.

Contracted Research

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Consulting Fees Genentech, Inc., Regeneron Pharmaceuticals, Inc., Bausch & Lomb Incorporated, Digital Angiography Reading Center

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Consulting Fees Novartis AG

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Consulting Fees Aerie Pharmaceuticals Contracted Research

Allergan plc Speaker Bureau Alcon Laboratories, Inc. & Allergan plc

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Aerie Pharmaceuticals, Alcon Laboratories, Inc., Allergan, Inc., Bausch & Lomb Incorporated, Carl Zeiss Meditec, Inc., FORSIGHT Vision5, Heidelberg Engineering Inc., Inotek Pharmaceuticals, Inc., Quark Pharmaceuticals, Inc., Reichert, Inc., Sensimed AG & Sustained Nano Systems, LLC

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Ownership Interest GlobeChek Enterprise, LLC

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Aerie Pharmaceuticals, Allergan plc, Valeant Pharmaceuticals International, Inc., Diopsys, Inc., Merck Sharp & Dohme Corp., Reichert, Inc., Shire plc, Sight Sciences, Inc. & Carl Zeiss Meditec, Inc.

None Louis Pasquale MD

Consulting Fees Bausch & Lomb Incorporated & Eyenovia, Inc.

Travel Support The Glaucoma Foundation

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Consulting Fees Novartis AG, Allergan, Inc. & Bayer AG

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None

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None

* Indicates that the speaker intends to discuss unlabeled uses of a commercial product, or an investigational use of a product not yet approved for this purpose. The speaker will disclose this information during his/her presentation.

"Why Tele-Ophthalmology?" (Definitions, History, Nomenclature) Lama Al-Aswad, MD, MPH

Tele-medicine, or tele-health, refers to the practice of medicine at a spatial and/or temporal distance by exchanging medical information via electronic communications. In the early 20th century Australians were using two-way radios to connect with doctors who travelled by plane to and from remote areas. The practice of ophthalmology lends itself to the practice of tele-medicine through its heavy reliance on imaging. Tele-ophthalmology has potential to improve the efficiency, quality, outcomes, and accessibility to healthcare, while decreasing costs.

"Time is Brain: Identifying an Unmet Need and Building a Successful Tele-Medicine Program: The NYP Stroke Experience" Olajide Williams, MD

This talk will review the time-dependent nature of acute stroke treatments and the role of tele-medicine in reducing delays to treatment. Specifically, this talk will discuss the NYP tele-stroke experience across ambulance and emergency room platforms.

"Diabetic Retinopathy: The Burden of Early Detection" Srilaxmi Bearelly, MD, MHS

Diabetic retinopathy is the most common cause of blindness in the working age population of the US. Early detection and treatment have been shown to prevent blindness in >95% of patients. Between these two statistics lies a huge unmet need in medicine. This talk will address the challenges of public healthcare capacity to provide care for the increasing numbers of people with diabetes.

"US Diabetic Retinopathy Programs"

Seema Garg, MD

Early detection of diabetic retinopathy (DR) is crucial to preventing vision loss. Medical and surgical therapies have dramatically reduced the progression of DR. Timely intervention with laser and anti-VEGF therapy can reduce the risk of severe vision loss by over 90%. While national and international guidelines promote regular annual retinal evaluation of patients with diabetes, evaluation rates in the US remain low in the conventional healthcare paradigm in which patients with diabetes are referred from primary care providers to ophthalmologists for dilated eye examinations to determine whether DR is present. On average, less than 50% of patients with diabetes meet current annual screening recommendations. Thus, the public health challenge lies first in the early identification of patients at risk of vision loss from DR on a larger scale.

Tele-medicine is an emerging strategy for improving DR evaluation through retinal imaging with remote expert interpretation. Introducing this technology at the point of care of the primary physician could reduce many barriers and improve early detection of retinopathy. While other countries such as the United Kingdom and France have demonstrated high rates of DR screening through tele-medicine programs, in this talk, we will examine the status of DR tele-medicine programs in the US, including the Veterans Administration system, the North Carolina Diabetic Retinopathy Tele-medicine Network (NCDRTN), and others.

International Diabetic Retinopathy Programs

Alexandre Taleb, MD, PHD

Since 2008, NUTTs (Tele-medicine and Tele-health Nucleus – at Federal University of Goias) has established a statewide Tele-medicine Blindness Prevention program as part of the Brazilian Tele-health Initiative from the Brazilian Health Department. Two non-mydriatic retinal cameras are taken to primary care settings to acquire fundus and external eye images from diabetic patients and from people over 55 years old. Some 31,487 patients have been screened since the program started. All images are sent to the NUTTs Reading Center and reports are forwarded to the general practitioner at the primary care center. One hundred six cities and 451 primary care units were visited. Approximately 12,865 (40,86%) were diabetic patients, for whom diabetic retinopathy prevalence occurred in 13,72% (1,765 patients). Cataracts were identified in 2,617 patients (8,31%); glaucoma was suspected in 6.57%; and AMD was also identified in 1.03%. This Tele-medicine Blindness Prevention Program proved to be an important tool in the Brazilian Public Health Strategy, and will be expanded to all 27 states in 2018.

KEYNOTE: "Tele-ROP Implications for Diagnosis and Management" Michael Chiang, MD, MA

Tele-medicine has potential to improve the quality, accessibility, and cost of retinopathy of prematurity (ROP) management. This talk will review evaluation studies involving tele-medicine for ROP, will discuss the evolution in the standard of care for ROP, and will discuss future trends in ROP care, based on advances in information technology.

"Glaucoma: 'The Burden of Early Detection'"

Dana Blumberg, MD, MPH

Disease burden is the impact of a disease as measured by both its prevalence and incidence, as well as financial cost, morbidity and impact on quality of life. Disease burden may be measured relative to the individual or to society, and is often quantified in terms of quality-adjusted life years, a measure that incorporates quantity and quality of life lived. Understanding functional impairment in glaucoma is critical to disease burden. From a clinical perspective, an understanding of when and how glaucoma produces visual impairment will allow physicians to target at-risk individuals and to tailor therapies to minimize visual disability. From a policy perspective, this knowledge will provide information for preventative screening guidelines and disability recommendations.

"Tele-Ophthalmology and Glaucoma in the United States"

Jonathan Myers, MD

Currently, most tele-ophthalmology initiatives in the United States focused on glaucoma have involved the remote evaluation of optic nerve photographs in "store and forward" approaches. Studies have shown reasonably good positive and negative predictive values for this approach, but the limitations of disc photography to diagnose glaucoma are well known. More recently, some programs, such as the Philadelphia Telemedicine Glaucoma Detection and Follow-up Study, have incorporated additional information such as IOP measured with a rebound tonometer, and family/medical/and ocular history in their data collection for consideration. More sophisticated testing, such as OCT imaging and standard automated perimetry, requires trained technicians and specialized equipment, but has been utilized in some projects, such as the Eye Care Quality and Accessibility Improvement in the Community study that screens patients for glaucoma at 2 Wal-Mart Vision Centers.

Generally, reports have found these efforts to be reasonably sensitive and specific for the detection of glaucoma, with shorter visits and reduced costs and travel time compared to full ophthalmic exams. Challenges for broader adoption include issues regarding reimbursement, licensure, and physician acceptance as well as the further development of modes for care beyond screening.

International Initiatives

Karim Damji, MD

The purpose of this talk is to describe the 'STOP Glaucoma in Sub Saharan Africa (SSA)' initiative whose aim is to train a first generation of highly qualified glaucoma subspecialist leaders, and to develop interconnected centers of excellence for glaucoma care throughout SSA. Another of its aims is to also share lessons learned from tele-glaucoma pilots in Ethiopia and Kenya.

Remote Functional Testing Gustavo De Moraes, MD, MPH

Remote Functional Testing According to the Guidelines of the World Glaucoma Association, confirmation of glaucoma diagnosis requires structural abnormalities corroborated by functional deficits detected with standard automated perimetry (SAP). Notwithstanding, SAP is a subjective behavioral test, time-consuming, and inherently influenced by numerous sources of variability that can lead to false-positive and false-negative results. In addition, it is expensive and not always available for community outreach. This talk will focus on current and new modalities of functional testing that may be useful is tele-ophthalmology settings and which can potentially mitigate the limitations of SAP.

Remote Structural Testing

Albert Khouri, MD

Retina and optic nerve head imaging is central to the field of tele-ophthalmology. Imaging is used during tele-screening and tele-consultation. Traditional table top cameras provide high resolution images. Non-mydriatic image acquisition is favorable as long as quality does not degrade. More recently smaller hand held devices or cell phones have been used and incorporated in tele-ophthalmology. Optical coherence tomography can also be integrated and has the advantage of providing accurate and objective measures of the retina and optic nerve. Software filters can be applied to enhance image processing and the detection of pathology. Tele-ophthalmology protocols are needed to ensure that image quality and network safety standards are developed.

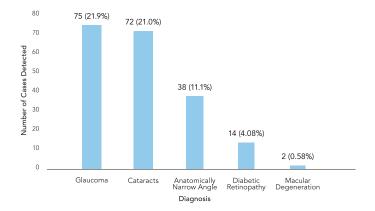
KEYNOTE:

"International Tele-Ophthalmology and Population Health: The Indian Experience" Kim Ramasamy, MBBS, DO, DNB, MD

The overall goal of a population health approach is to maintain and improve the health of the entire population and to reduce inequalities in health between population groups. In India, the challenges are huge with gross inequality in economy an also in access. The primary eye care centers also known as Vision centers is being implemented to address these inequalities. These vision centers use technology and trained manpower to reach into the community for eye care, giving a very high level of health intervention. More importantly this is a scalable model and is currently being replicated across the country in many of the states of India and Bangladesh.

"Tele-Ophthalmology for an Underserved Community: The CUMC Remote Screening Experience" Lama Al-Aswad, MD, MPH

Access to care is problematic in high-risk and underserved communities in New York City due to myriad reasons. In our study published in 2017, (Screening for glaucoma in populations at high risk: The eye screening New York project), we found that 57% of individuals screened never saw an eye doctor in their lifetime regardless of having insurance. Subsequently, we initiated a study to screen for the four leading causes of blindness using a mobile tele-ophthalmology unit that is equipped with state of the art devices and staffed with technicians, and linked in real-time to a reading center. We screened 340 individuals in 3 months.



Tele-ophthalmology has the potential to play a role in blindness prevention through improving access to care in high-risk and underserved communities.

U REACH – A Technology-Enabled, Large School Eye Health Initiative Rahul Ali, MD, MBA

School is the first formal space for learning. And using this space to reach the vast cohort of schoolaged children, a particularly vulnerable group because of the high prevalence of refractive error, is common practice. The Orbis Refractive Error Among Children (REACH) program is a technology-enabled, standardized intervention that aims to provide high-quality eye care to school-going children in India.

With standard implemention guidelines, standardized hardware, and a bespoke software solution, REACHSoft makes this a unique program. From the first step of scheduling a visit to a school, REACHSoft supports every step of the planning process and implementation: developing the school database; collecting the school-wise student database; scheduling, planning, and delivering services; collecting data at the individual student level during service delivery, (primary screening, detailed examination, spectacle prescription and dispensing, referral management, compliance monitoring, etc.); as well as monitoring progress, and generating reports to aid management of the program.

"Pushing the Envelope on Distance Learning: Creation of the Global Classroom" Yousuf Khalifa, MD

Globally, there is inequitable access to well-trained eye surgeons. As it currently stands, there are not enough ophthalmologists and health workers with specialization in eye health to meet the growing need for surgical services. Low and middle-income countries are disproportionately affected.

To target global need, Orbis conducted a global learning needs analysis to inform the development of broad-reaching, low-cost and effective solutions to develop competent surgeons in low-resource countries. In our analysis, we considered programmatic needs, sources for content, global learner cadres and instructional technologies among other variables. For this talk, we will discuss results and conclusions driven by this important work.

Mobile Devices Siddarth Rathi, MD, MPH

This lecture will review the rapid advances made in ophthalmic applications of mobile devices; discuss status quo applications of mobile device enabled decision support and artificial intelligence in eye care; and finally, review future applications of mobile devices in our specialty.

Virtual Reality

Louis Pasquale, MD

Virtual reality (VR) is a computer-generated environment where subjects can perform tasks or simply be observers. VR has been exploited for entertainment, artistry and design, education, simulation, tourism and exploration, meditation, tele-presence and much more. The cheapest VR can be generated with a foldable cardboard box, a smart phone running appropriate applications and inexpensive embedded lenses, +/- wireless earphones. VR also has many ophthalmic uses that we are just beginning to realize. Some of these will be discussed.

"Minimal Image Requirements to Maximize Image Assessment" Hannah Coleman, MD

Digital Imaging has revolutionized ophthalmology. Among other things, it has allowed for precise documentation, immediate diagnostics, and remote consultation. However the ability to "point and shoot" does not always translate into useful images. Poor images are difficult for both clinicians and machines to assess since they cause automated diagnostic algorithms to fail. This talk will review tips on technique and minimum image requirements aimed at maximizing the assessment potential of the images taken.

"Scaling Down Your Office"

William Mallon, MD

GlobeChek[™] was conceived with the idea that comprehensive eye screening should be fast, affordable, and readily accessible. We have developed a platform for screening and for enhancing public awareness regarding the importance of eye screening in the prevention of blindness and maintenance of overall health. Our tele-medicine system, consisting of a novel hardware platform and connected network of physicians, screens, detects, and refers conveniently, economically, safely, and efficiently.

KEYNOTE: "What Is AI?"

Michael Abramoff, MD, PHD

Methods: A prospective, multi-center, intent-to-screen design study was conducted in a primary care setting, in people with diabetes. The study assessed diagnostic performance of an Artificial Intelligence (AI) system, incorporating deep learning based lesion detectors, for identification of DR including Diabetic Macular Edema (DME). The AI system was evaluated relative to standardized imaging and grading protocols by the Wisconsin Fundus Photograph Reading Center (FPRC). FPRC grading included Early Treatment Diabetic Retinopathy Study Severity Scale (ETDRS) and DME determinations from widefield stereoscopic photographs and macular Optical Coherence Tomography (OCT). More than mild DR (mtmDR) was defined as ETDRS level 35 or higher, and/or DME, in at least one eye. AI system operators underwent a standardized training protocol before study start; FPRC imaging was conducted by FPRC certified photographers.

Results: A total of 900 participants were prospectively enrolled; a subset of 819 participants could be fully evaluated by both AI and FPRC. 198 (23.8%) had mtmDR; the AI system detected mtmDR at a sensitivity of 87.2% (95% CI, 81.8-91.2%) and specificity of 90.7% (95% CI, 88.3-92.7%). Imageability, the percentage of participants with completed FPRC grading and a disease level AI output, was 95.6% (95.0% CI, 94.0-96.8%).

Conclusions: The AI system met predetermined sensitivity and specificity endpoints for the autonomous detection of more than mild DR, inclusive of DME, in people with diabetes in primary care settings. (Sponsored by IDx)

"AI: The Deep Mind Google Experience"

Sunny Virmani, MS

Deep learning is a family of computational methods that allow an algorithm to program itself by learning from a large set of examples that demonstrate the desired behavior, removing the need to specify rules explicitly. It has been shown to be remarkably effective in the past 6 years and is on a path to play a vital role in the field of medical imaging.

In the context of ophthalmology, Diabetic retinopathy (DR) is a complication of diabetes and the fastest growing cause of blindness. There are 415 million diabetic patients worldwide. All of them should be screened annually for DR since early detection is key to preventing blindness. However, access to eye specialist and screening remains a big issue. Automated detection would assist in the interpretation of fundus photos taken for DR/DME screening, allowing for an immediate result, and for appropriate referral and follow up appointments to be scheduled the same day.

We developed software that uses deep learning to screen diabetic eye disease. Based on a 2016 study published in JAMA, this software promises to perform on par with ophthalmologists in classifying diabetic retinopathy from fundus images. This talk will explore outcomes and review findings.

Watson IBM

Lloyd Hildebrand, MD, FACS

We tend to overestimate the effect of a technology in the short run and underestimate its effect in the long run. Drivers of artificial intelligence (AI) include rapid expansion of computing power (Moore's Law), emergence of big data, ubiquitous access to the Internet and cloud-based computing, and the rapid evolution of cognitive technologies.

To meet expectations, AI systems for eye care developed in collaboration with IBM Watson require a robust knowledge base, imaging analytics and genomic bioinformatics. A key barrier to developing machine learning systems is the paucity of robust longitudinal clinical/imaging databases (big data).

Imaging analytic algorithms to detect biomarkers can be used to detect and stage disease, but must be put into context with a comprehensive knowledge base. The rapid expansion of sequencing enables phenotype-genotype (P2G) mapping enabling precision medicine. Clinician engagement is critical to facilitate creation of comprehensive curated and annotated image sets within relevant clinical context.

Visulytix

Sameer Trikha, MD

Visulytix is an artificial intelligence (AI) company based in London, United Kingdom. Utilising cutting edge AI and computer vision techniques, the company focuses upon visual analytics of retinal imaging and Optical Coherence Tomography (OCT) scans. Their comprehensive image analytics suite, Pegasus, can screen for a variety of diseases such as macular degeneration, diabetic retinopathy and glaucoma, as well as identify specific features in a fraction of a second, and therefore, at a fraction of the cost to the healthcare provider. Our mission is to develop comprehensive decision support tools for eye care providers, enabling them to make the most effective management decisions. The solutions are currently available for investigational use in United States.

"Is OCT Ready for AI"

Donald Hood, PHD

Existing summary statistics based upon optical coherence tomographic (OCT) scans are suboptimal for distinguishing between healthy and glaucomatous eyes in a clinical setting or for screening purposes. Thus, we explored the use of Al. In a proof of concept study, single wide-field OCT scans were obtained from a group of 102 eyes from 102 patients, with or suspected of having open-angle glaucoma, previously classified by two glaucoma experts as either glaucomatous (57 eyes) or healthy/suspects (45 eyes), based upon information available. The best metric (quadrant thickness) misclassified 13 (4FP and 9FN), while visual field metrics did considerably worse. Hybrid deep learning method (HDLM) performed better than any OCT or visual field metric, with only 7 eyes misclassified (4FP and 3FN). While an expert reader outperformed (1 FP and 1 FN) the HDLM, a post hoc analysis suggested that it should be possible to improve the performance of the HDLM by providing additional information (e.g., the location of major vessels).

IT SECURITY

Timothy Crimmins, MD, RPVI

Not available at the time of printing

Data Management Daniel Barchi, MEM

This presentation will cover the challenges of managing millions of patient records and the technology, stewardship, information security, and research implications of doing so.

"American Tele-Health Device Comparison" Mark Horton, OD, MD

Tele-ophthalmology is growing rapidly, with diabetic retinopathy (DR) the most mature domain. The legacy promise of tele-medicine was access to care, but modern tele-medicine for DR (Tmed-DR) adds opportunities for improved quality and cost efficiency. There is a great deal of heterogeneity across Tmed-DR programs that is not always apparent to the end-user.

The American Tele-medicine Association has published guidelines for Tmed-DR since 2005 that define categories of performance and validation criteria. The clinical, technical, and operational characteristics of a particular program determine its performance and position within the ATA categories. The ATA Tmed-DR validation categories are discussed in the context of clinical and operational dependencies, as well as how they may be aligned with program constraints and community needs.

кеумоте: Regulatory and Government Issues Malvina Edyelman, MD

Food and Drug Administration (FDA) recognizes that an efficient, risk-based approach to regulating digital health technology will foster innovation of digital health products. FDA's traditional approach to moderate and higher risk hardware-based medical devices is not well suited for the faster iterative design, development, and type of validation used for software-based medical technologies. Traditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients.

For the American people to see the full potential of digital health technologies, FDA must lean forward and adapt our processes.

FDA recognized the need for a new approach for digital health oversight, and created a Digital Health Program that is helping advance this technology by establishing new relationships and fostering collaboration with digital health developers, patients, and providers. In addition, this program is tasked with developing and implementing regulatory strategies, policies, and processes in this area—and then providing transparency and clarity on those policies and processes.

Over the past five years, the Digital Health Program has developed several practical policies and approaches towards certain digital health products, balancing the benefits and risks to patients.

For example:

- We focused our oversight on mobile medical apps to only those that present higher risk to patients, while choosing not to enforce compliance for lower risk mobile apps;
- We confirmed our intention to not focus our oversight on technologies that receive, transmit, store or display data from medical devices
- We chose not to focus our oversight on products that only promote general wellness;
- We provided clarity on our expectations on cyber security and collaborated with stakeholders to form a community to exchange cyber security information; and
- Working with our customers and other federal agencies, we published the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT report proposing a new framework for Health IT.

These policies were designed to allow lower risk beneficial technologies to be readily available to Americans while assuring connected products continue to be high-quality, safe and effective.

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