

Panel 2: Safety and Efficacy Concerns for Ophthalmic Digital Devices in Differing Use Settings

The Ophthalmic Office
Non Eye-Care Clinical Environments
Non Clinical Environments Including the Home and
Workplace

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Panel 2 *Safety and Efficacy In and Out of the Office*

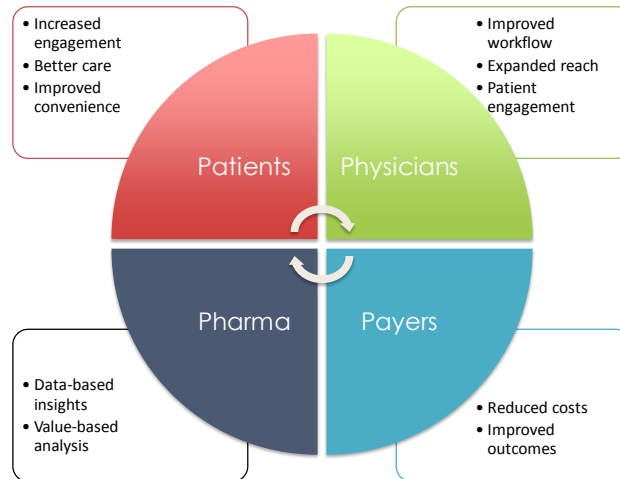
Moderators:

Ken Nischal University of Pittsburgh
Mark Blumenkranz Stanford University

Panelists:

Michael Abramoff University of Iowa
Zach Bodnar Stanford University
Michael Chiang Oregon Health Sciences University
Michael Goldbaum UCSD
Quinton Oswald Notal Vision
Linda Zangwill UCSD

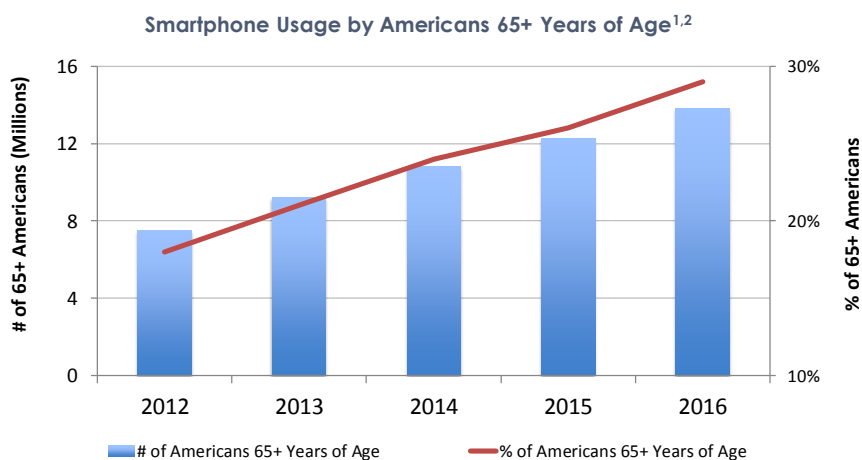
Digital Health Provides Value Propositions To All Stakeholders In Healthcare System



SOURCE: "The road to digital success in pharma," August 2015, McKinsey&Company

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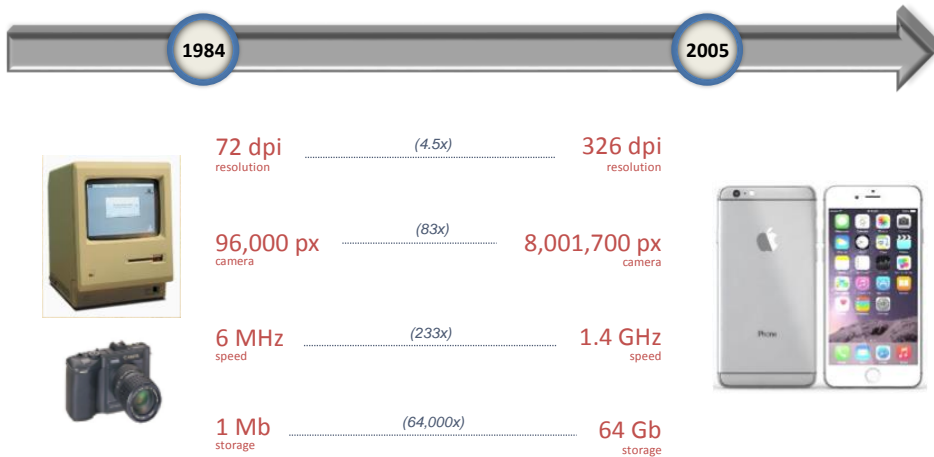
Ageing Of 50-64 Demographic Driving Rapid Increase Of Smartphone Utilization In Senior Population



SOURCES: ¹Pew Research Center's Internet & American Life Project, April 17-May 19, 2013 Tracking Survey (n=2,252).
²eMarketer, April 2012, US Smartphone Users by Age, 2011-2016.

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Smartphone Capabilities Are Orders Of Magnitude Greater Than Legacy Computing Systems



SOURCES: www.Apple.com, www.Canon.com





















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Smart Devices Are Capable Of Diagnostic/Test Functions And Can Be Seen Across Healthcare



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Mobile / Portable Technologies In Eyecare

Home Use		Clinician Use	
Vision Testing	Refractive Testing	Ophthalmoscopy	Other
			
			
			
			
			

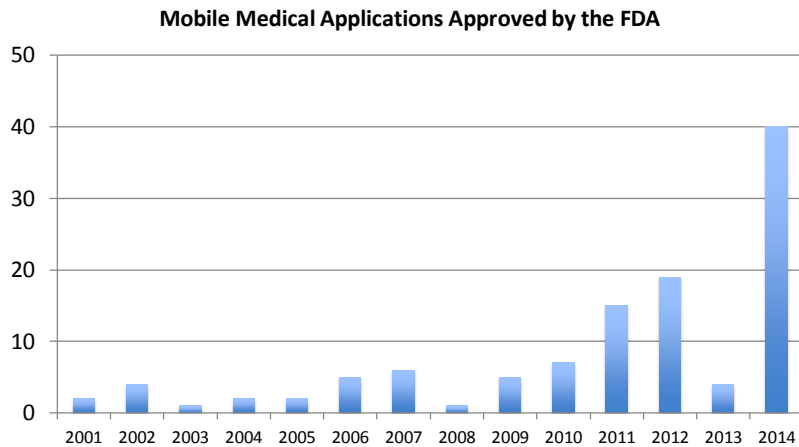
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A Number of Portable Smartphone Based Photographic Systems Are Now Commercially Available



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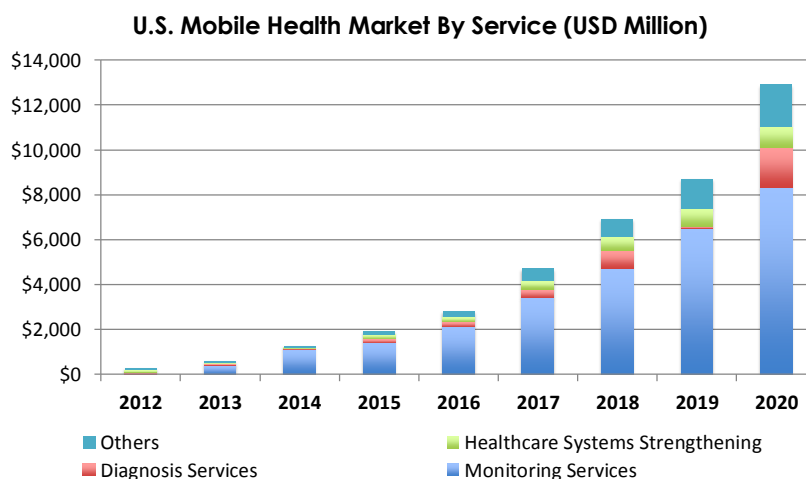
The FDA Has Cleared More Than 100 Mobile Health Apps For Medical Use



SOURCE: www.FDA.gov

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U.S. mHealth Market Size Is Expected To Grow By More Than 6x Between 2015 And 2020



SOURCE: Adapted from Grandview Research. "mHealth Market Analysis By Service, By Participants And Segment Forecasts To 2020," August 2015.

Confidential

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Safety and Effectiveness Specifics

- What are the important safety and effectiveness concerns for an ophthalmic digital health device for the screening or monitoring progression of
- ***Macular Disease***
- ***Glaucoma***

In an Eye Care Clinical Environment

- Who if anyone needs to be specifically trained in the office to ensure efficiencies of workflow and the accuracy reproducibility and safety of the testing
- Do specific roles need to be developed to facilitate that process
- Should we now be tackling the question of specific reimbursement for testing with digital tools in the office versus outside the home

What about in other Clinical Environments Such as Primary Care or the ER

- What experience do we have now for interfacing between eye healthcare professionals and primary and urgent care providers
- What lessons can we draw from those experiences

What about Non-Clinical Environments Such as the Workplace or Home

- Is symptom diagnosis and triage analysis safely left to the potential patient
- Are there digital pharma innovations that could be applied in these circumstances such as tailoring of return visits or modifying treatments

Artificial Intelligence (AI)

- How will (AI) Affect the Use of Ophthalmic Digital Tools in the Future
- Are there Specific AI examples that help us negotiate these issues now, eg Interpretation of fundus photos for retinal disease screening

AI Enabled Image Analysis Questions

- Are we ready for fully automated interpretation?
- Does the AI/DL algorithm give the patient or doctor a diagnosis and/or plan?
- Or....Does the patient's MD make the reading enabled by the AI?
- Or....Does a third party doctor read the results?

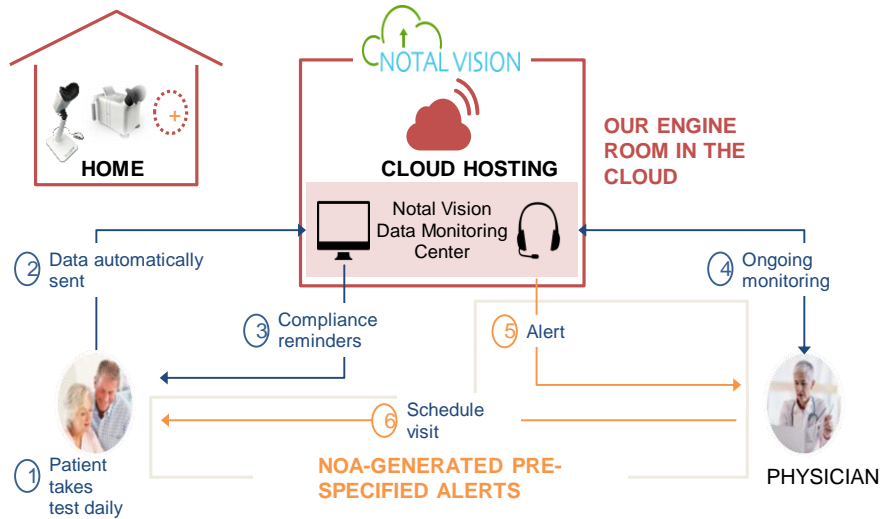
Correlations to Current Testing

- How closely do the results from in office or out of office testing have to correlate with traditional non digital measures to be effectively used in clinical practice
- How much training is required for patients in office and in home to insure reasonable accuracy and reproducibility

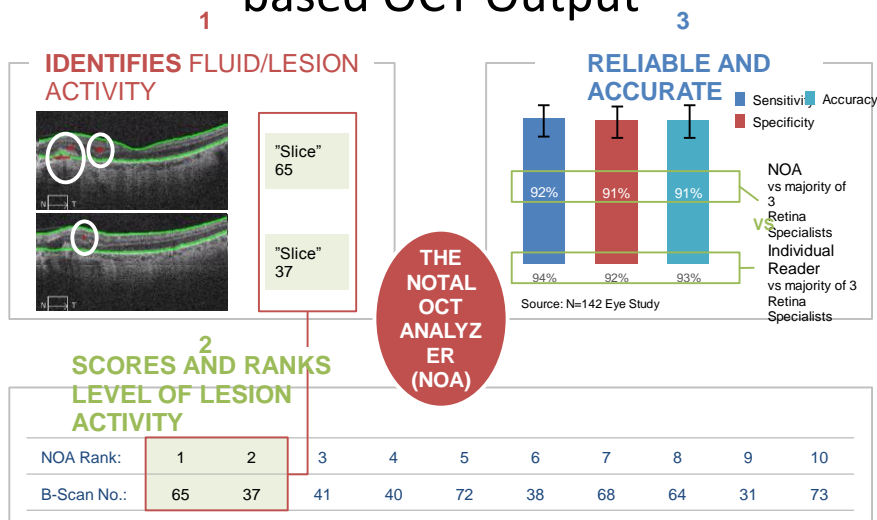
Safety and Privacy Concerns

- How do we these concerns regarding the storage of information on personal devices in the era of common cloud backup for other data on personal phones for technicians and patients
- How does monitoring of patient behavior and location relate to safety and efficacy concerns

Patient-activated, Cloud-based Platform: 3 Million Tests Complete, Personalized Monitoring System



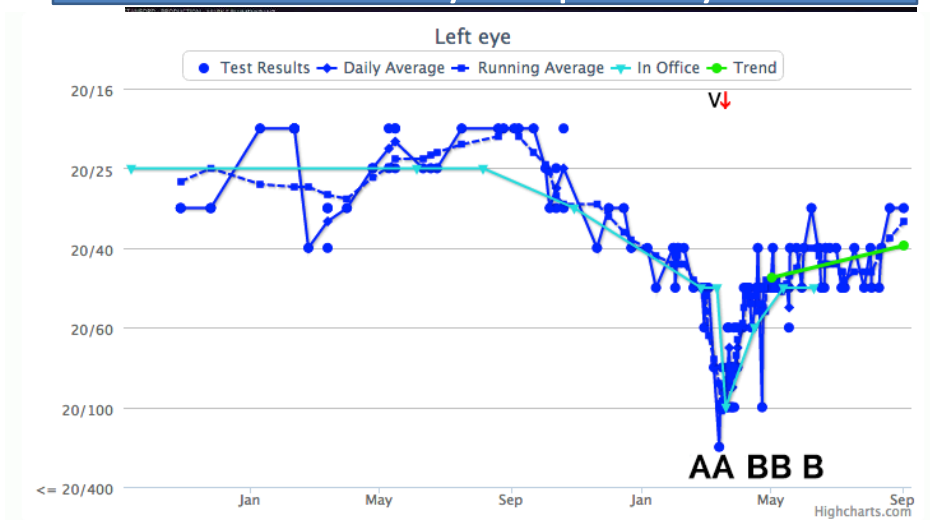
Using AI to Automate Analysis of Home-based OCT Output



General Observations on Frequent Home Testing Data

- Much easier to track changes with **graphic** rather than traditional tabular output
- There is a short learning curve for the first several measurements but in **normal** eyes measurements are typically very consistent after 2-3 tests
- In **affected** eyes there tends to be intraday and day to day variability and data spread/noise possibly related either to diurnal variation and gravitational influences affecting macular fluid volume and/or variable response to photo-bleaching secondary to disease

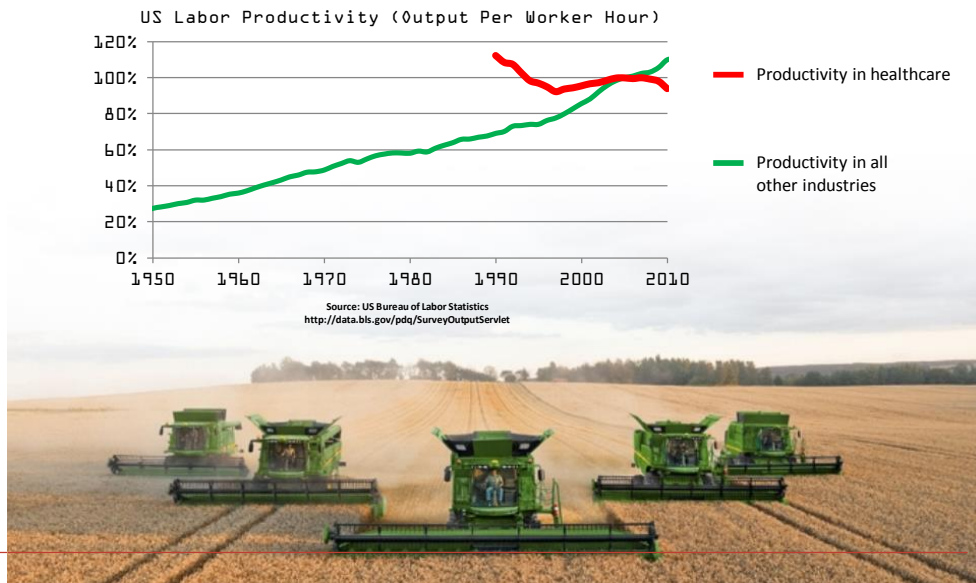
Demonstration of Differential Drug Sensitivity Graphically



26 October 2017

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Why Healthcare Needs Automation



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Electronic Patient Records lower physician productivity

Electronic health record impact on productivity and efficiency in an academic pediatric ophthalmology practice

Travis K. Redd, BS,^{a,b} Sarah Read-Brown, BA,^a Dongseok Choi, PhD,^{a,h,c} Thomas Daniel C. Tu, MD PhD,^{a,e} and Michael F. Chiang, MD^{a,d}

PURPOSE To measure the effect of electronic health record (EHR) implementation on productivity and efficiency in the pediatric ophthalmology division at an academic medical center.

METHODS Four established providers were selected from the pediatric ophthalmology division at Oregon Health & Science University Casey Eye Institute. Clinical volume before and after EHR implementation for each provider. Time elapsed from chart completion (OTC time) and the proportion of charts completed during 1 were monitored for 3 years following implementation.

RESULTS Overall there was an 11% decrease in clinical volume following EHR implementation which was not statistically significant ($P = 0.18$). The mean OTC time rose to 28.3 hours among providers in this study, and trends over time were similar to the four providers. Forty-four percent of all charts were closed outside of business hours (30% on weekdays, 14% on weekends).

CONCLUSIONS EHR implementation was associated with a negative impact on productivity in our pediatric ophthalmology division. (J AAPOS 2014;18:584-589)

Lam et al. BMC Health Services Research (2016) 16:7
 DOI 10.1186/s12913-015-1251-8

BMC Health Services Research

RESEARCH ARTICLE

Open Access

The effect of electronic health records adoption on patient visit volume at an academic ophthalmology department

Jocelyn G. Lam, Bryan S. Lee and Philip P. Chen*

Abstract Background: Electronic health records (EHRs) have become a mandated part of delivering health care in the United States. The purpose of this study is to report patient volume before and after the transition to EHR in an academic outpatient ophthalmology practice.

Methods: Review of patient visits per half-day and number of support staff for established faculty ophthalmologists between July and October for five consecutive years beginning the year before EHR implementation.

Results: Eight physicians met inclusion criteria for the study. The number of patient visits was lower in each year after EHR adoption compared to baseline ($p < 0.002$). Patient volume per provider was reduced an average of 56.8% over the 4 years (range 15.3–103.3%) and charts for the previous studies no longer had returned to the pre-EHR number of charts per chart. Support staffing was unchanged ($p > 0.14$).

Conclusions: Adoption of EHR was associated with a significantly reduced number of patient visits per physician in an academic setting in which support staffing remained stable. Maintaining clinic volume and access in similar settings may require use of additional staffing.

Keywords: Ophthalmology, Electronic health record, Electronic medical record, Health information technology, Medical informatics, Health care delivery, Health law

Background During the pre-penalty phase, ophthalmologists have not yet EHRs compared to other specialties.

Electronic health record

Research

JAMA Otolaryngology-Head & Neck Surgery | Original Investigation

Association Between Electronic Medical Record Implementation and Otolaryngologist Productivity in the Ambulatory Setting

Setting up AI based DR interpretation in four hours



	Hrs.	Personnel	Qty	Personnel Req.	Materials
Installation Set Up Configuration	2.0	Technician	1	None	Site Setup Checklist
Training	4.0	Trainer	1	IDx Cert.	Operator Training Manual IDx-DR Quick Reference Guide
					Training PowerPoint Presentation Training Checklist
		Operator	2-3	High School Degree Consent	Training Photography Consent Form
		Volunteer Subjects	10		



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Reimbursement

- AI in Ophthalmology enormous potential to increase efficiency
- enormous dependence of the business model / ROI on reimbursement
- If there is a path for reimbursement, investment will follow. If path is iffy, investment much riskier.
- All Medicare reimbursement is clinician-workload derived.
- AI diagnostics have just never been on the radar

The Science Coalition presents:

In conjunction with the
House R&D Caucus

12-1 PM • Rayburn 2043
Lunch Provided

RSVP "HOUSE" by Mon, Oct. 23 to
sciencecoalition@hudsonlake.com



Wednesday October 25

Comments by Sen. Jerry Moran and
Sen. Chris Coons, co-chairs of the
Senate Competitiveness Caucus

2-3:30 PM • CVC (S-214)
Snacks Provided

RSVP "SENATE" by Mon, Oct. 23 to
sciencecoalition@hudsonlake.com

The panel discussion will explore the *innovations* these companies are bringing to market, the *role of federal funding* in company formation, *opportunities and obstacles* encountered along the way, and *ideas for encouraging more American-made innovation*.

Participants include:



Jessica Winter, Founder, Core Quantum Technologies
CQT's MultiDot technology uses quantum dots to highlight and track disease progression. It is based on NSF-funded research conducted at The Ohio State University.



Jack O'Toole, Founder, FreshAir Sensor
FreshAir Sensor's technology provides real time monitoring and detection of smoking in unauthorized areas. It is based on NIH and NSF-supported research at Dartmouth College.



Jeb Connor, Chairman, CEO & Co-Founder, Genome Profiling
Based on NSF-sponsored research at the University of Delaware, GenPro supports precision medicine through discovery of novel epigenetic biomarkers.



Andrew Hansen, President, HylaPharm
HylaPharm, a University of Kansas spinout is developing chemotherapies to treat locally advanced cancers based on research supported by DOD and NIH.



Michael Abramoff, President & Founder, IDx LLC
IDx is a University of Iowa spinout that has developed a fully automated tool for retinal disease detection based on USDA, NIH and VA-supported research.



Carmela Abraham, Founder, Co-Chair Science Advisory Board, Klogene Therapeutics
Klogene is developing neuroprotective therapeutics based on decades of research into Alzheimer's disease at Boston University with support from NIH.



Robin Berthier, President, Network Perception
Spun out of the University of Illinois at Urbana-Champaign and based on research supported by DHS and NSF, Network Perception's software illuminates firewall risks in complex computer networks.



Robert Hamers, Chief Science Officer & Co-Founder, Silatronix
Silatronix, which grew out of NIST and NSF-sponsored research at the University of Wisconsin-Madison, is improving the safety and performance of lithium ion batteries.



Discussion Moderator:
Orin Herskowitz, Senior Vice President, Intellectual Property and Technology Transfer,
Columbia University and Executive Director, Columbia Technology Ventures

View The Science Coalition *Sparking Economic Growth* report: www.sciencecoalition.org/successstories

AI indications for use

Discussing with FDA the following use case items

- Autonomous use including in primary care
- Used by non eye-care providers
- Specific levels of diabetic retinopathy
- For subjects who have not been previously diagnosed with diabetic retinopathy.

Interfacing: Interpretation issues

- Current DR screening rates ~10-30%
- Autonomous interpretation will lead to giant increase in (retinal) diagnostics
 - non eye-care professionals
 - emphasis on primary care
- Here, comfort with ICDR, let alone ETDRS, outputs is low
 - Align outputs with PPPs and other standards

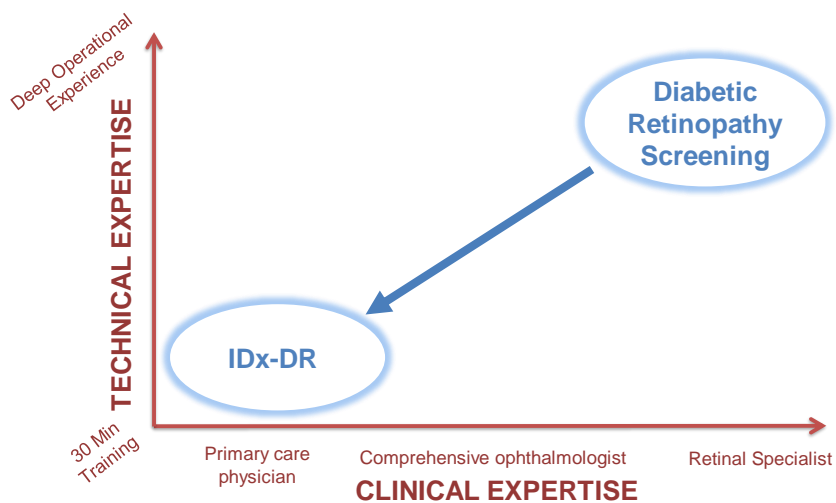
Align outputs with PPP

AI system Output		AAO PPP Disease Level	Progression to High Risk PDR (1 Year)	Referral
No or Mild DR		Normal or Minimal NPDR Mild NPDR		No
mtmDR		Moderate NPDR	1.2% - 8.1%	Commonly
	vtDR	Severe NPDR Non-High Risk PDR Macular Edema	17.1%	Yes

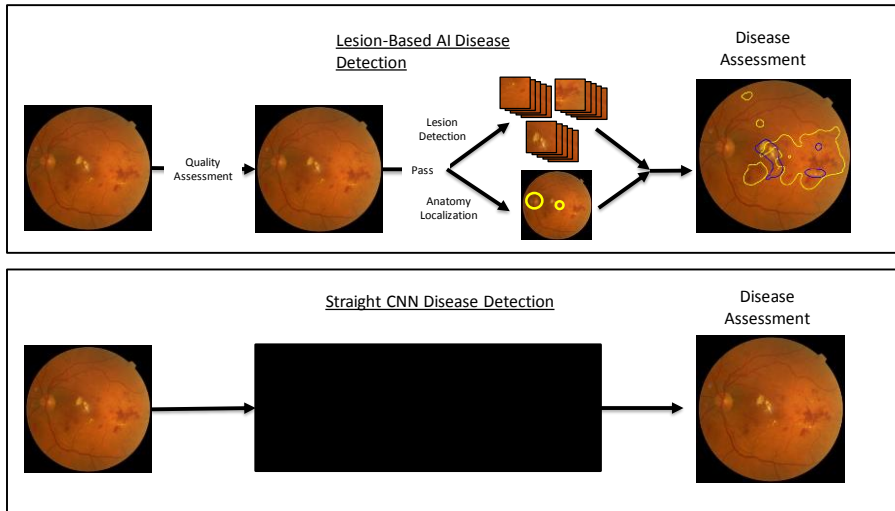
Interfacing: Hand-off issues

- If AI identifies need for eye-care referral
 - Can I get patient in
 - Did patient get examined / treated and what was outcome
- Continuity of care report or similar way to track path of patient through system

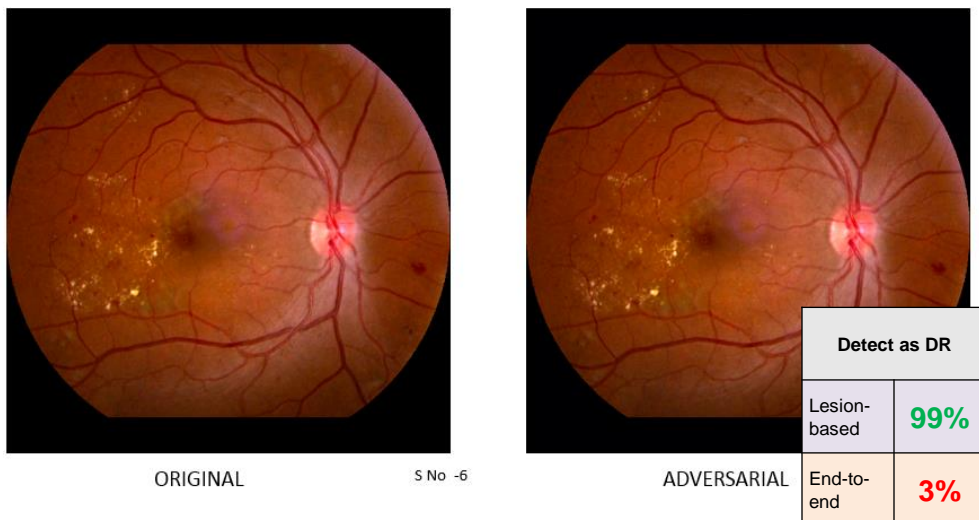
Shift from Eyecare Diagnostics to Non-Eyecare AI



AI Algorithm design



Straight CNN algorithms susceptible to catastrophic failure:
Lesion based algorithms are robust



Lynch et al, ARVO 2017; submitted, PLOS One

Draft October 12 01

ATA Guidelines for Systems for Automated and Computer Assisted Detection, Staging and Diagnosis of Diabetic Retinopathy

Authors: Michael D. Abramoff^{1,2,3,4,5,6}, XXX⁷, Carlos M Oliveira⁷, Kyu Rhee⁸, Michael Chiang^{9,10}

¹ Department of Ophthalmology and Visual Sciences, The University of Iowa, Iowa City, IA

² iDx LLC, Iowa City, IA

³ Stephen A. Wynn Institute for Vision Research, The University of Iowa, Iowa City, IA

⁴ Department of Biomedical Engineering, The University of Iowa, Iowa City, IA

⁵ Department of Electrical and Computer Engineering, The University of Iowa, Iowa City, IA

⁶ Iowa City VA Health Care System, Iowa City, IA

⁷ XXXX [no agreement yet]

⁸ Retmarker, Coimbra, PORTUGAL

⁹ IBM Watson Health, Cambridge, MA

¹⁰ Department of Ophthalmology, Oregon Health & Science University, Portland, OR

¹⁰ Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University, Portland, OR

1. Introduction

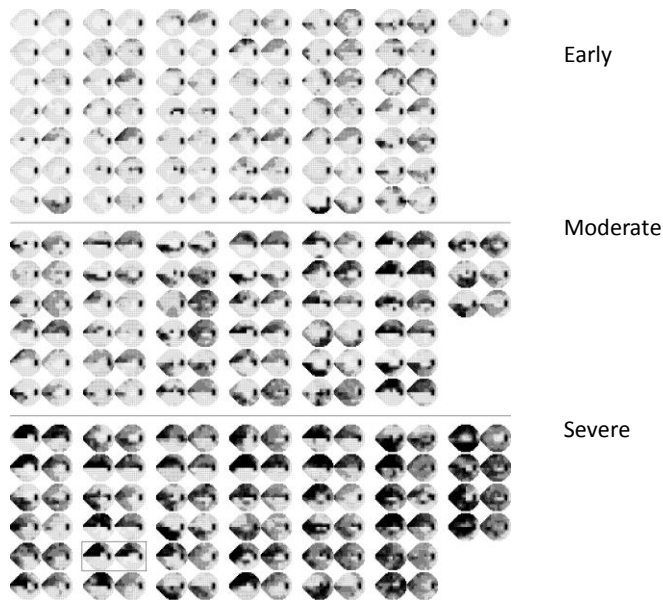
Automated and computer assisted detection, staging, and diagnosis of diabetic retinopathy (DR) can potentially improve clinical efficiency and accuracy. Guidelines for implementation can contribute to clinical introduction and quality of care. Thoughtful introduction of AI is especially important, because productivity in healthcare has been lagging behind that in other sectors, and may in fact be declining.[1] Low productivity and the resulting high cost lead to lack of accessibility and affordability, partially caused by inappropriate introduction of information technology.[2-5] Automated medical diagnosis, a pre-requisite to improve health care efficiency, affordability, and accessibility[6], is a subject of great interest. Diagnostic algorithms have now achieved parity or even superiority to clinical experts for an increasing number of clinical tasks that use images as input, including diabetic retinopathy detection.[7] In addition to their potential to improve productivity, diagnostic algorithms that base their output on the analysis of medical images eliminate the diagnostic variability that is common in expert review of medical images. [8-14] Such algorithms also have the potential to reduce or eliminate healthcare disparities due to geographic and socioeconomic barriers by increasing accessibility and affordability

The American Diabetes Association has estimated that 30.3 million Americans, or 9.4% of the population, have diabetes;[15] and diabetes is still the primary cause of visual loss and blindness in the working age population. Approximately 25,000 people lose vision every year because of diabetic retinopathy.[16] Adherence to regular eye examinations is essential to diagnose diabetic retinopathy.

ATA Guidelines for Systems for Automated and Computer Assisted Detection, Staging and Diagnosis of DR

Level	Autonomy Level description	Specialist Physician Actions	Disease aware	Example
1	No automation	Viewing	-	Any photoviewer
2	Viewing with non-disease specific tools	Viewing measuring	-	ImageJ[17], Photoshop[18]
3	Computer assisted lesion/abnormality enhancement	Viewing Disease specific enhancement	yes	Intelligent PACS with lesion enhancement
4	Automated detection / staging with expert readover of subset	Viewing All of the above	yes	Research prototype systems only (US)
5	Automated detection / staging / diagnosis	No viewing	yes	Research prototype systems only (US)

Pipeline: Humphrey 24-2 perimetry from OCT



Bogunovic, IOVS 2015
Guo, IOVS 2017



CASEY EYE
Institute

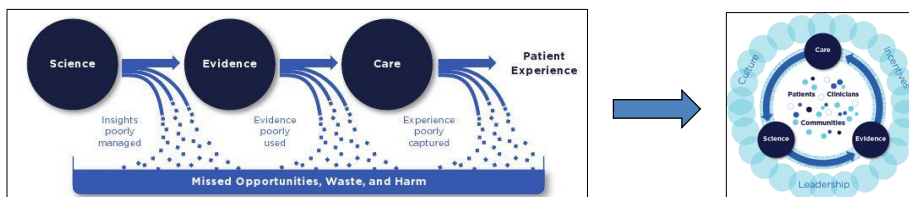
Panel 2 Discussion

Michael F. Chiang, MD

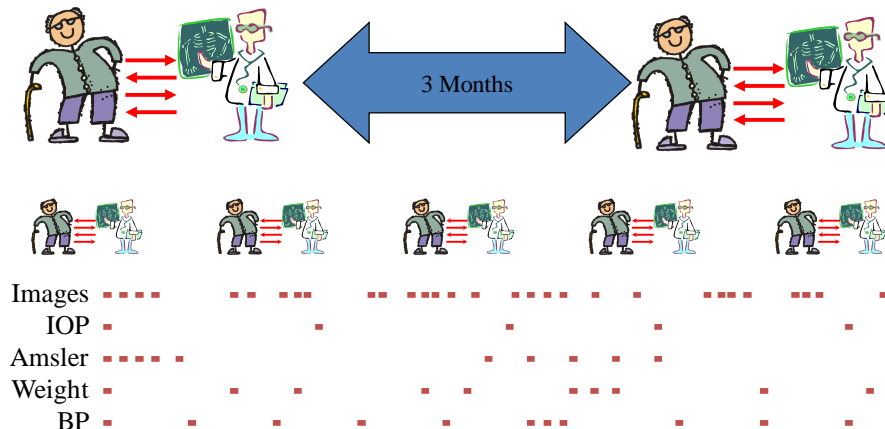
Knowles Professor of Ophthalmology & Medical Informatics and Clinical Epidemiology
Vice-Chair (Research), Department of Ophthalmology
Casey Eye Institute at Oregon Health & Science University

National Vision for Quality Improvement

- NAM (2012): Best Care at Lower Cost
 - **“Continuously learning health care system”**: developing knowledge, translating new information into medical evidence, applying new evidence to patient care
 - **Role of big data, registries, expert systems**
 - FDA: expert systems can learn from feedback, **benefits of flexibility** in maintenance of approval



Telehealth Evolution



- (a) **Telemedicine**: different patient-doctor interaction → better delivery?
 (b) **Remote screening**: improved accessibility → wider net? Who interprets?
 (c) **Remote monitoring**: more frequent visits → better outcomes? Who interprets?

In the Eye Care Environment

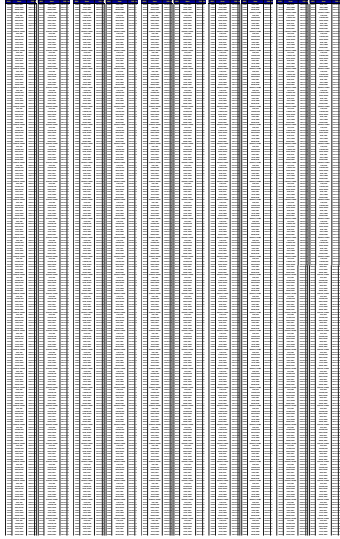
- Who captures the data?
 - Potential role for **certification**: not a new problem (e.g. certification of photographers for new ophthalmic imaging devices)
- Who interprets the data to make diagnostic & management decisions? Potential safety & variability issues:
 - **If done by managing ophthalmologist**: same patient-doctor relationship, not a new problem (e.g. lab tests, ABO, credentialing)
 - **If done by remote reading center with "doctor" or "trained readers"**: potential FDA issue for system (different patient-doctor relationship) & reader certification & delegation of responsibilities [especially if in non-eye care clinical environment or patient homes]
 - **If done automatically by system**: FDA issue for system
 - Who is liable from medicolegal perspective?

Outside the Eye Care Environment

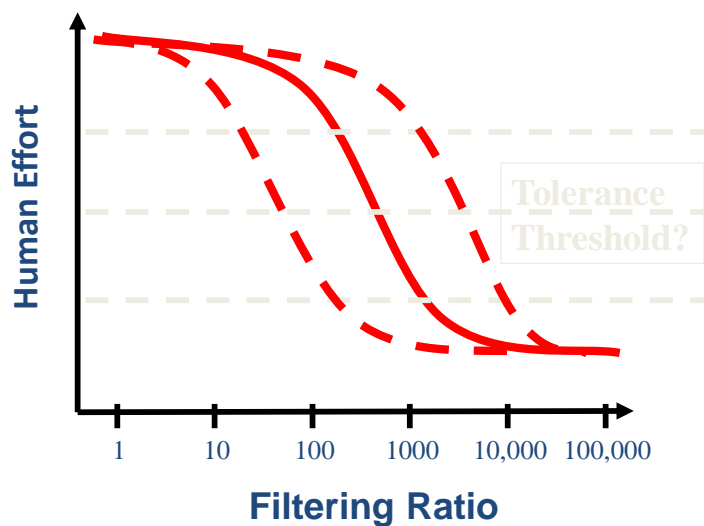
- How is the diagnosis made?
 - If done by remote reading center with "doctor" or "trained reader": **potential FDA issue** for system (no patient-doctor relationship) & reader certification & delegation of responsibilities
 - If done automatically by system: **FDA issue** for system
- If system is for non-eye clinical environment:
 - Who is responsible for collecting data? Potential **certification** issues
 - Who is responsible for interpreting & following-up on data? Above issues, plus reimbursement questions
- If system is for non-clinical environment → data overload:
 - Managed by patients? Not a new problem (e.g. home BP cuff)
 - Automated monitoring? New problems...

Outside Office: Remote Monitoring

MRN	Name	DOB	Sex
3386531	GAGE, LINDA	1947-04-19	M
4141414	JOYCE, JAMES	1949-01-01	F
8888888	MOORE, DEMO	1980-01-15	F
3131313	SANDIEGO, CARMEN	1951-05-26	M
2121212	STAR, TREK	1966-09-01	F
3937549	STRANGE, BOB	2000-02-02	M
3931749	MOON, DOGGIE	1001-01-01	M
3386531	GAGE, LINDA	1947-04-19	M
4141414	JOYCE, JAMES	1949-01-01	F
8888888	MOORE, DEMO	1980-01-15	F
3131313	SANDIEGO, CARMEN	1951-05-26	M
2121212	STAR, TREK	1966-09-01	F
3937549	STRANGE, BOB	2000-02-02	M
3931749	MOON, DOGGIE	1001-01-01	M
3386531	GAGE, LINDA	1947-04-19	M
4141414	JOYCE, JAMES	1949-01-01	F
8888888	MOORE, DEMO	1980-01-15	F
3131313	SANDIEGO, CARMEN	1951-05-26	M



Remote Monitoring Challenge



Justin Starren, MD, PhD

Outside Eye Setting: Data Concerns

- Data accuracy
 - Analogy to patient-entered questionnaires
 - Who captured it? Level of trust?
 - Implications for EHRs and registries: **importance of identifying source** ("garbage in, garbage out", IRIS Registry experience)
- Who will review it from the health care team (if anyone)?
 - Training, reimbursement, can it be patients themselves
- Who will perform the diagnosis and management?
- Where is the medicolegal liability?

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Panel 2

AI in Medicine

Michael Goldbaum

Shiley Eye Institute, University of California San Diego

Origins

- William Gray Water
 - Machina speculatrix
 - Connections between few brain cells yield complex behavior
- John McCarthy
 - Coined “artificial intelligence”
 - Science and engineering of making intelligent machines

AI themes

- | | |
|-------------------------------------|------------------------------------|
| • Knowledge engineering/acquisition | • Distributed, cooperative systems |
| • Ontogenies, terminologies | • Management of uncertainty |
| • Natural language | • Machine-learning data mining |
| • Temporal information management | • Image processing |
| • Case-based reasoning | • Bioinformatics |

Machine learning & Data mining

- Computers that learn from data (vs being “taught”)
- Artificial neural networks
- Connection of nodes
 - Units and weighted connections
 - Feature set Dendrites
 - Processor Neuron body
 - Output Axon
- Decision tree learning
 - CART
 - Random forest trees
- Back propagation
 - Learning adjusts connection weights
 - Multilayer perceptron
 - Deep learning neural networks

Image processing

- Image segmentation
- Object classification
- Grammar
 - Objects:images::words:sentences
- Context-based image retrieval
- Image interpretation
 - Segmentation → objects classification → image interpretation
 - Deep learning merges steps into a single classifier

Generational Perception of AI



"She thinks it's a touchscreen."

FDA Workshop

Panel 2

Cloud

Michael Goldbaum

Shiley Eye Institute, University of California San Diego

Cloud Computing

- Definition
 - Web-based technology where
 - Users share hardware and software in the cloud
- Service providers
 - Amazon Web Services
 - Google Compute Engine
 - Windows Azure
 - Aruba Cloud
- Can provide
 - Software and support platforms for software
 - Database for storage
 - Aggregating and harmonizing data
 - Analysis
 - Compute nodes for calculation
 - System infrastructure development

Software Tools for Cloud

- Web client
 - Application framework manages clinical use interaction through browser
- Web service
 - Services supporting data
 - Submission
 - Analysis
 - Retrieval of results
- Validation
 - User try common process on their data
 - Users apply their processes on common data
- User
 - User information
 - Authentication

Security

- EU General Data Protection Regulation
 - EUGDPR.org
- Access
 - Authorized users
 - 2 factors, e.g., DUO
- Transmission
 - HTTPS = hypertext transfer protocol
 - SFTP = secure transfer protocol
 - SCP = Secure copy protocol
 - VPN = Virtual private network
- Person going rogue



FDA Workshop

Panel 2

Who Does the Interpretation

Michael Goldbaum

Shiley Eye Institute, University of California San Diego

Three Types of Interpretation

- Machine does interpretation
 - Machine learning classifier
 - Deep learning
 - Physician assist
 - Available 24/7
 - Consistent
 - Black box
- Patient's regular doctor reads
 - Interface physician and patient
 - Not 24/7
 - Inconsistent
 - Affected by mood, alertness, bias
- Third party doctor reads results
 - No interface to patient
 - Domain expertise
 - Not 24/7
 - Inconsistent
 - Affected by mood, alertness, bias

FDA Workshop

Panel 2

Interfacing between Eyecare and Non-Eyecare Professionals

Michael Goldbaum

Shiley Eye Institute, University of California San Diego

Perceptions of Communication

Table 1 GPs' and specialists' perceptions on aspects of communication (17)

	GPs agree	Specialists agree (%)	p-value
GPs telephone accessibility is good	85.3	32.8	< 0.001
Referral letter of GP is of good quality	—	29.1	
Questions are addressed by the specialist	50.0	87.5	< 0.001
GPs follow the advice given by the specialist	92.2	49.5	< 0.001
Specialist letter is sent back in a timely manner	22.5	61.8	< 0.001

Communication in healthcare: a narrative review of the literature and practical recommendations

P. Vermeir,^{1,2} D. Vandijck,^{1,3,4} S. Degroote,^{1,3} R. Peleman,^{2,5} B. Verhaeghe,^{3,5} E. Mortier,⁵
G. Hallaert,¹ S. Van Daele,³ W. Buylaert,^{3,6} D. Vogelaers^{1,2,3}

© 2015 The Authors. *International Journal of Clinical Practice* Published by John Wiley & Sons Ltd.
Int J Clin Pract, November 2015, 69, 11, 1257–1267. doi: 10.1111/ijcp.12686

Interface

- Goal: to overcome incommunicable silos in medical records
- Interface between eye care to non-eye care professionals
- Equivalence to professional-to-professional communication
- Different from concept of physician-to-patient

Methods of communication

- Hard copy
- Telephone/cell phone
- email
- Electronic medical records
- Multidiscipline team
- Social networks

Hard copy

- Letter
- Patient carries information Overcomes HIPAA
 - Paper
 - Thumb drive/DVD
- In-hospital consult
- Translation
- Disadvantages
 - Time consuming
 - No proof of receipt

Phone (Cell Phone)

- Voice
 - Recipient must be found and available
 - Interactive
 - Proof of receipt
- Message
 - Invariant to time, place, geography
 - Can be interactive
 - No proof or receipt

email

- Security
- Invariant to time, place, geography

Electronic Medical Records

- Professional-to-professional note
- Autopopulated report
 - Template
 - Letter
- Holistic view of patient
- DICOM-like interface for communication between different EMRs
- Disadvantages
 - Access to EMR is necessary
 - No proof of receipt

Professional Team

- Multidiscipline team
 - Time consuming
 - Location specific, or
 - Conference call or Skype

Social Networks Professional Networks

- Good way to distribute knowledge