



**Indian Health Service**

The Federal Health Program for American Indians and Alaska Natives

# Current Trends And Issues In Diabetic Retinopathy Screening

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UNIVERSITY OF CALIFORNIA

# Today's Topics:

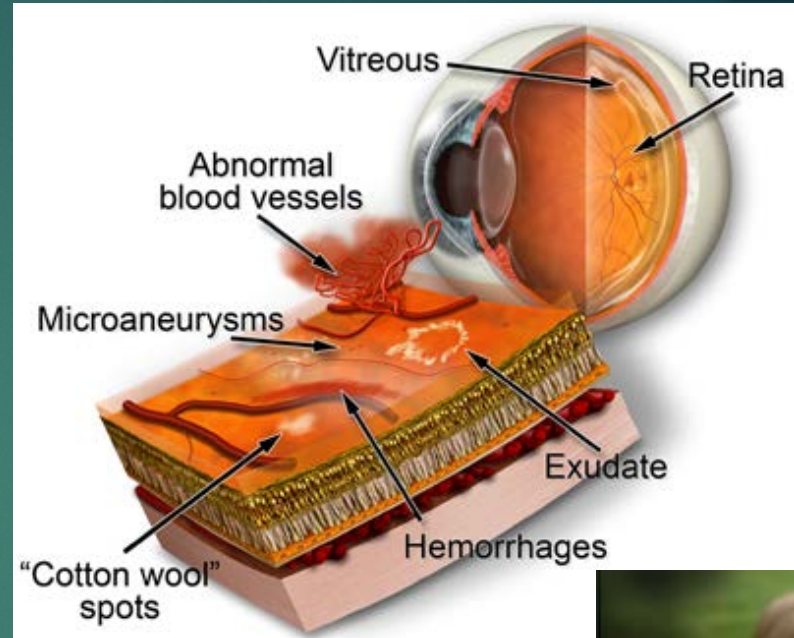
- ▶ Benefits of retinal screening in early detection of diabetic retinopathy
- ▶ Current retinal cameras and criteria for retinal screening: what is good enough?
- ▶ New technology in retinal imaging
  - ▶ Imaging technology: automation, miniaturization, smart phones
  - ▶ Artificial intelligence
- ▶ Barriers to retinal photography in the clinical setting and how to work around these
- ▶ Does retinal screening actually prevent blindness?

Questions and Comments Welcomed



# Diabetic Retinopathy (DR)

- ▶ Microvascular complication of prolonged elevated blood sugar
  - ▶ 35% of people with diabetes have some retinopathy, 7.5% have sight-threatening retinopathy
- ▶ Still the main cause of blindness among working-age adults despite improvements in diabetes and retinal treatment
- ▶ 95% preventable with early detection and treatment, but typically 50% effective due to delays
- ▶ Retinal photography is highly sensitive for detecting DR



Example of  
how DR  
affects  
vision

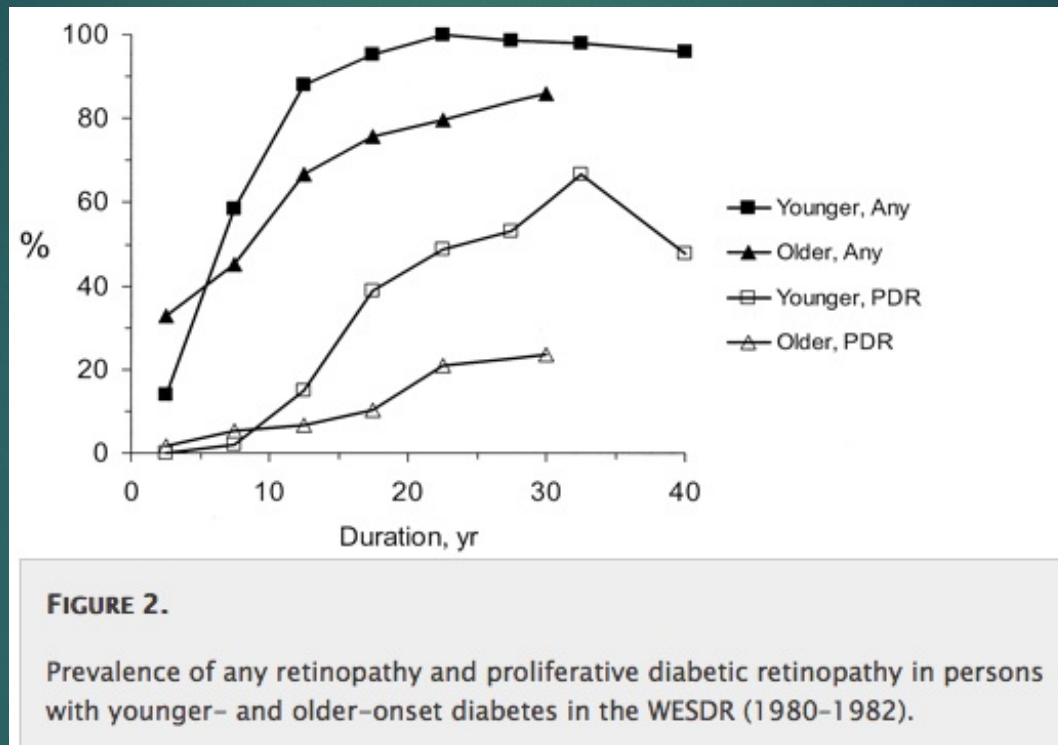


# Risk Factors For Diabetic Retinopathy:

- ▶ Hyperglycemia
  - ▶ 1% reduction in HgA1c → ~40% reduction in incidence of retinopathy, ~25% reduction in retinopathy treatment, and ~15% less vision impairment
- ▶ Hypertension
  - ▶ 10 mmHg reduction in systolic pressure → ~35% less retinopathy and treatment, ~50% less vision impairment
  - ▶ Lowering systolic pressure to < 120 mmHg does not impart greater benefit compared to lowering systolic pressure to < 140 mmHg
- ▶ Dislipidemia (reduction in DR with fenofibrate)
- ▶ Pregnancy
- ▶ Cataract surgery
- ▶ Obesity, alcohol, nephropathy, anemia, hypothyroidism, endothelial dysfunction
- ▶ Duration of diabetes



# The longer the diabetes duration, the higher the risk of retinopathy



Klein R et al "The Epidemiology of Eye Disease: From Glycemia to Genetics The Friedenwald Lecture" *Ophthalmol. Vis. Sci.* May 2006 vol. 47 no. 5 1747-1753

# Diabetic Retinopathy: A Risk Factor For Other Conditions:

- ▶ 2x to 3x increased risk of:
  - ▶ Cerebral hemorrhage,
  - ▶ Heart disease,
  - ▶ Heart failure
- ▶ Independent of other risk factors
- ▶ Indicator of end-organ microvascular damage.



*Team approach to diabetes  
featured in Time, 2003*



# Why Perform Retinopathy Screening In Primary Care/Diabetes Care Clinics?

- ▶ **Quality Measures:**  
Improves Rate of Retinal Exams for Diabetic Patients
- ▶ **Referral Effectiveness:**  
Detects Sight-Threatening Conditions Before It's Too Late
- ▶ **Self-Management:**  
Improves Patient Education About Diabetic Blindness Prevention and About Glycemic Control



Clinician Training, Seattle,  
Washington


# ADA Retinal Exam Recommendations (2017):

Classification	Exam By Ophthalmologist or Optometrist
Type 1 Diabetes	Within 5 years after onset of diabetes
Type 2 Diabetes	At time of diagnosis
Women with preexisting diabetes planning pregnancy or who have become pregnant	Before pregnancy or in first trimester
If there is no evidence of retinopathy for one or more annual eye exams	Exams every 2 years may be considered



# AAO Preferred Practice Patterns For DR (Revised 2016):

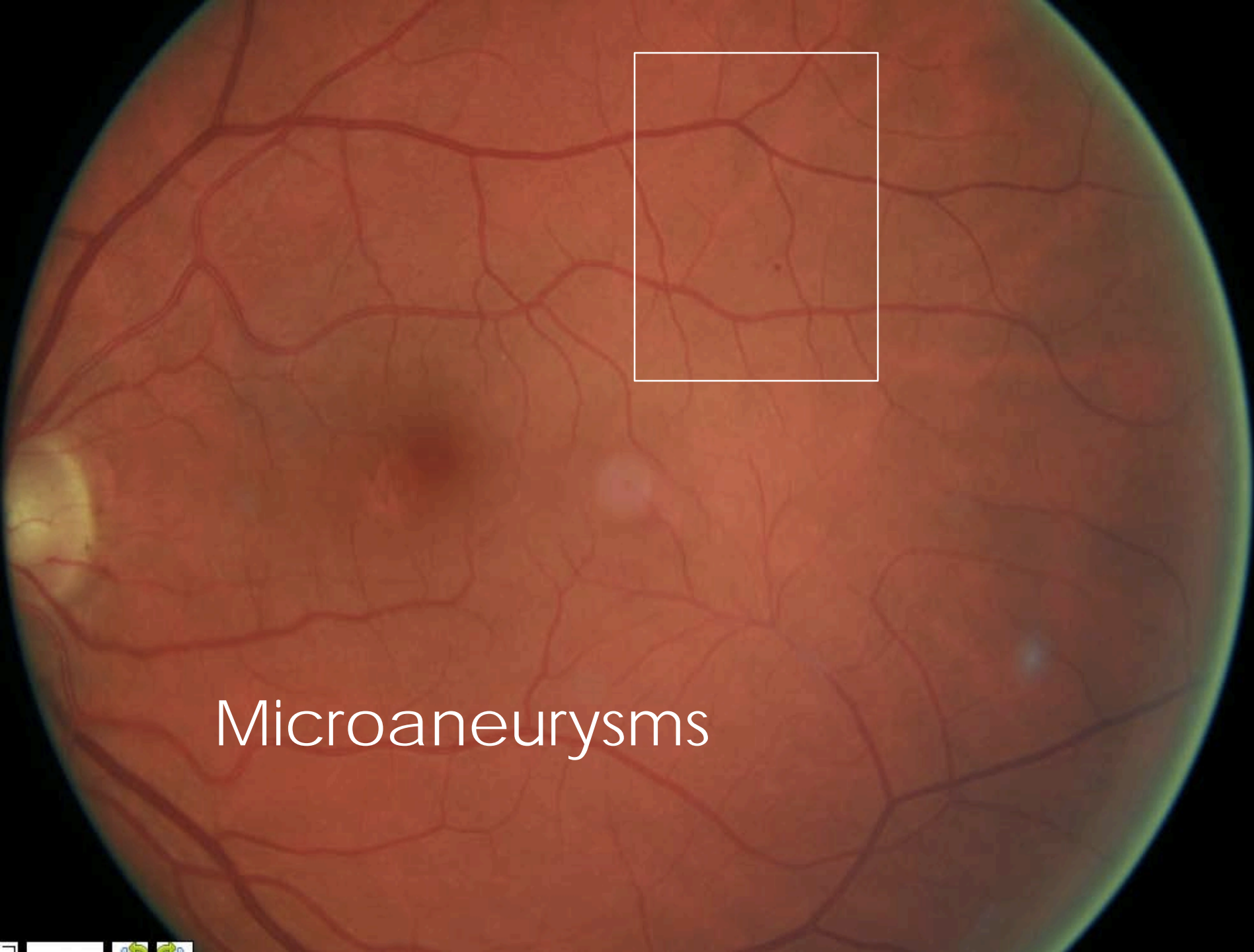
DR Severity	Follow up	Treatment With Laser or Injections	
None or Mild DR	1 year	No	Non-Sight Threatening
Moderate Nonproliferative DR	1 year (sooner if approaching severe level)	No	
Severe Nonproliferative DR	4 months	Sometimes	Sight Threatening
Proliferative DR – Not High Risk	4 months	Sometimes if low-risk; Yes if high-risk	
Macular Edema	3 to 6 months; 1 month if clinically significant	Yes, if clinically significant	



# What do we look for in the retinas of patients with diabetes?

(Knowing what we look for will inform  
your decisions regarding retinal  
cameras)

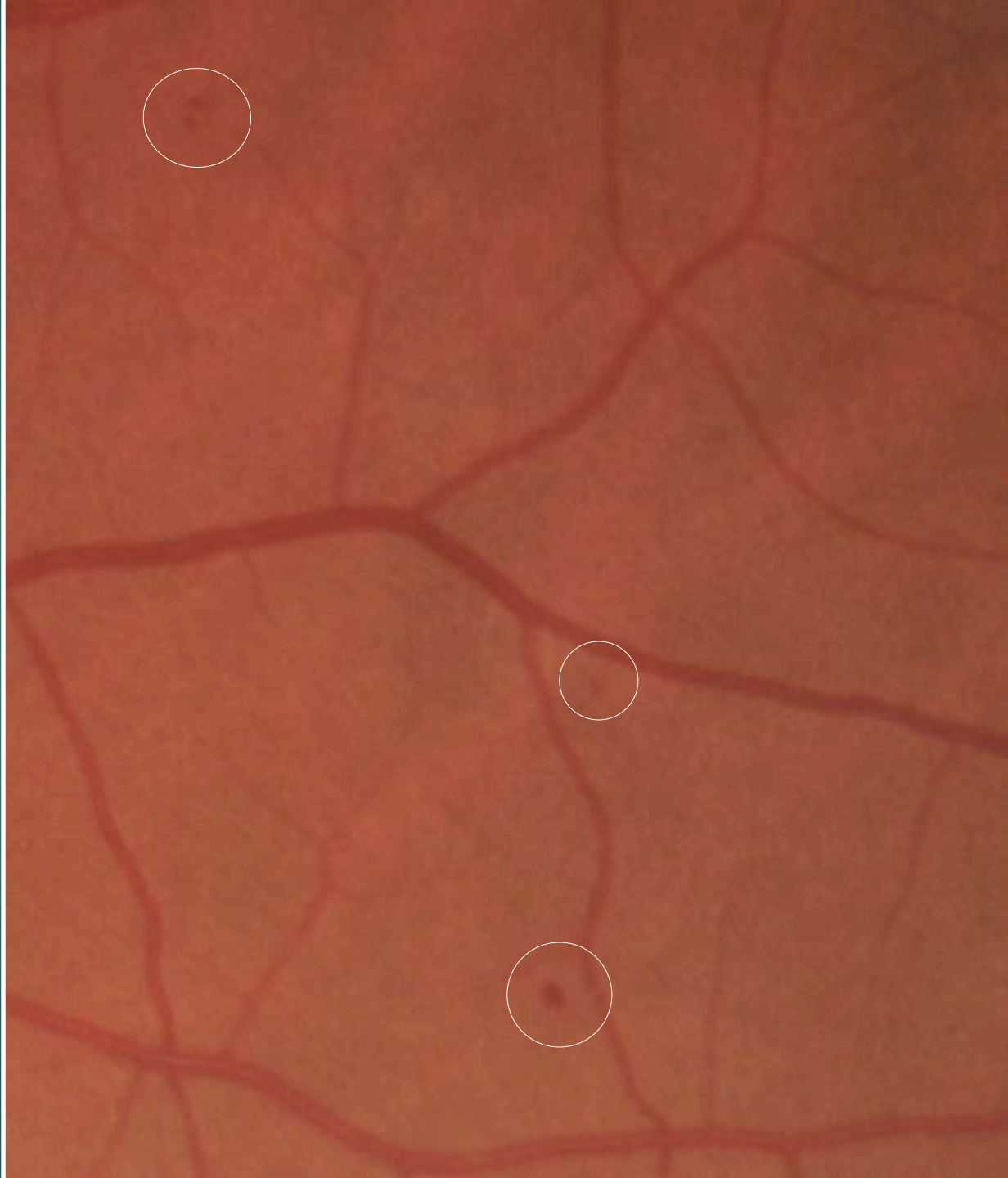




Microaneurysms

## Microaneurysms:

- Mild DR
- Not important for ophthalmic triage
- Important for patient management
- First sign of microvascular damage





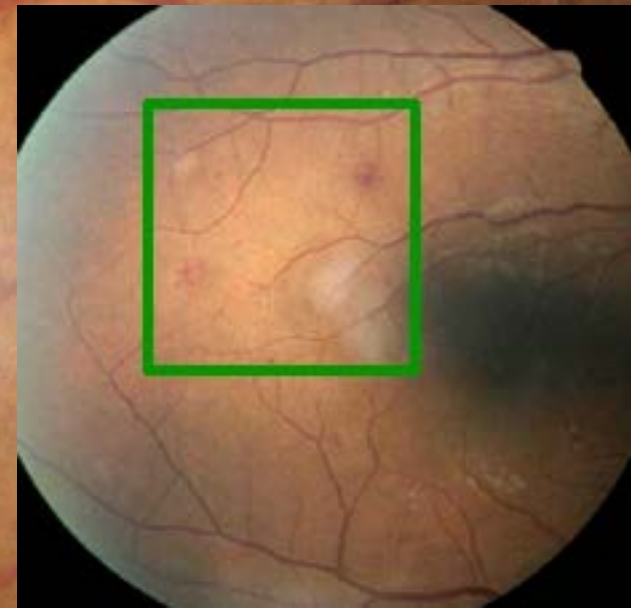
A fundus photograph of the retina. The optic disc is visible on the right side, appearing as a bright, circular area. Several retinal blood vessels radiate from the disc. Two pale, fluffy patches, identified as cotton wool spots, are visible: one in the upper left quadrant and another in the lower left quadrant. Red arrows point from the text 'Cotton Wool Spots' to these two patches. A third red arrow points from the same text to a retinal vessel on the right side of the image.

## Cotton Wool Spots

- Neural infarct
- Not important for ophthalmic triage
- Important for patient management
- Associated with hypertension and other conditions

# Hemorrhages

Amount of hemorrhages  
distinguishes moderate from  
severe (sight-threatening)  
nonproliferative DR





A fundus photograph of the retina, showing a network of retinal vessels. Two red arrows point to specific areas of venous beading, which is a sign of severe nonproliferative diabetic retinopathy. The vessels appear irregular and beaded in these areas. The background of the retina is a light orange-brown color.

Definite Venous Beading is  
also an indicator of severe  
nonproliferative DR



# IRMA

- Intraretinal microvascular abnormalities (IRMA) form in areas of capillary drop out
- Severity of IRMA separates moderate from severe (sight-threatening) DR



# Review Of Current Retinal Photography:

- ▶ Standard retinal cameras are getting better and smarter:
  - ▶ Canon, Topcon, Zeiss, Nidek, Kowa..
  - ▶ “Bells and whistles”
    - ▶ Limited usefulness for us except red-free
- ▶ Automated capture: a double edge sword
  - ▶ Ogunyemi, 2013: “the introduction of automated cameras should be approached with caution and may require extensive training to increase user acceptability”
- ▶ DICOM and proprietary storage: interoperability still elusive, but improving



Canon  
CR2



Nidek  
330



Topcon  
NW400



Centervue  
DRS

# Review Of Current Retinal Photography:

## ► Hand-held cameras

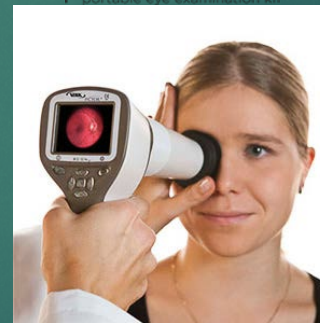
- Pictor, Visuscout, Optomed, Retinavue, Horus, iExaminer, D-Eye, PEEK, EyeGo, Remidio...

- Many more models in development, e.g. U. Rochester contact retinal camera, MIT Media Lab "eye-selfie"

- Few validation studies – not favorable



Eye-Go  
CellScope



Optomed



U. Rochester Contact  
Camera



Remidio

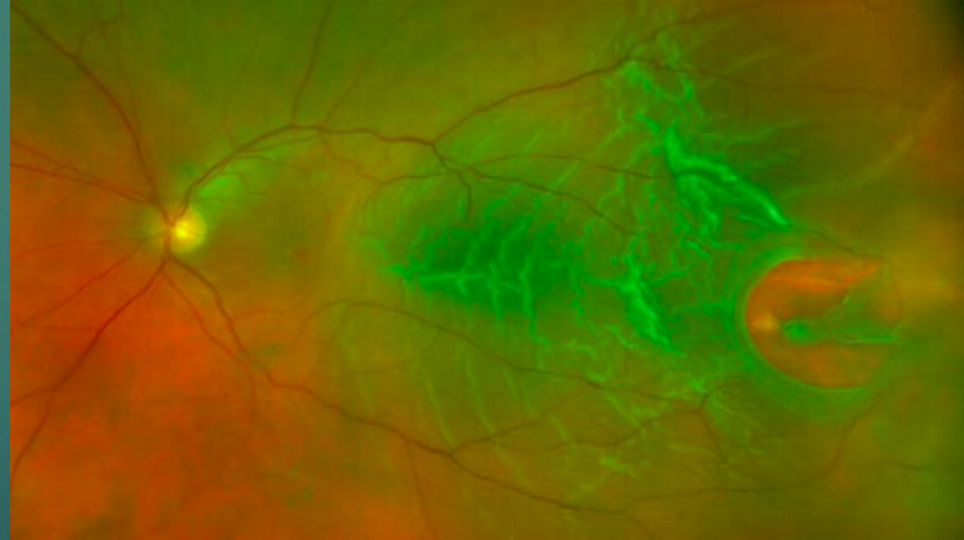


# About Validation..

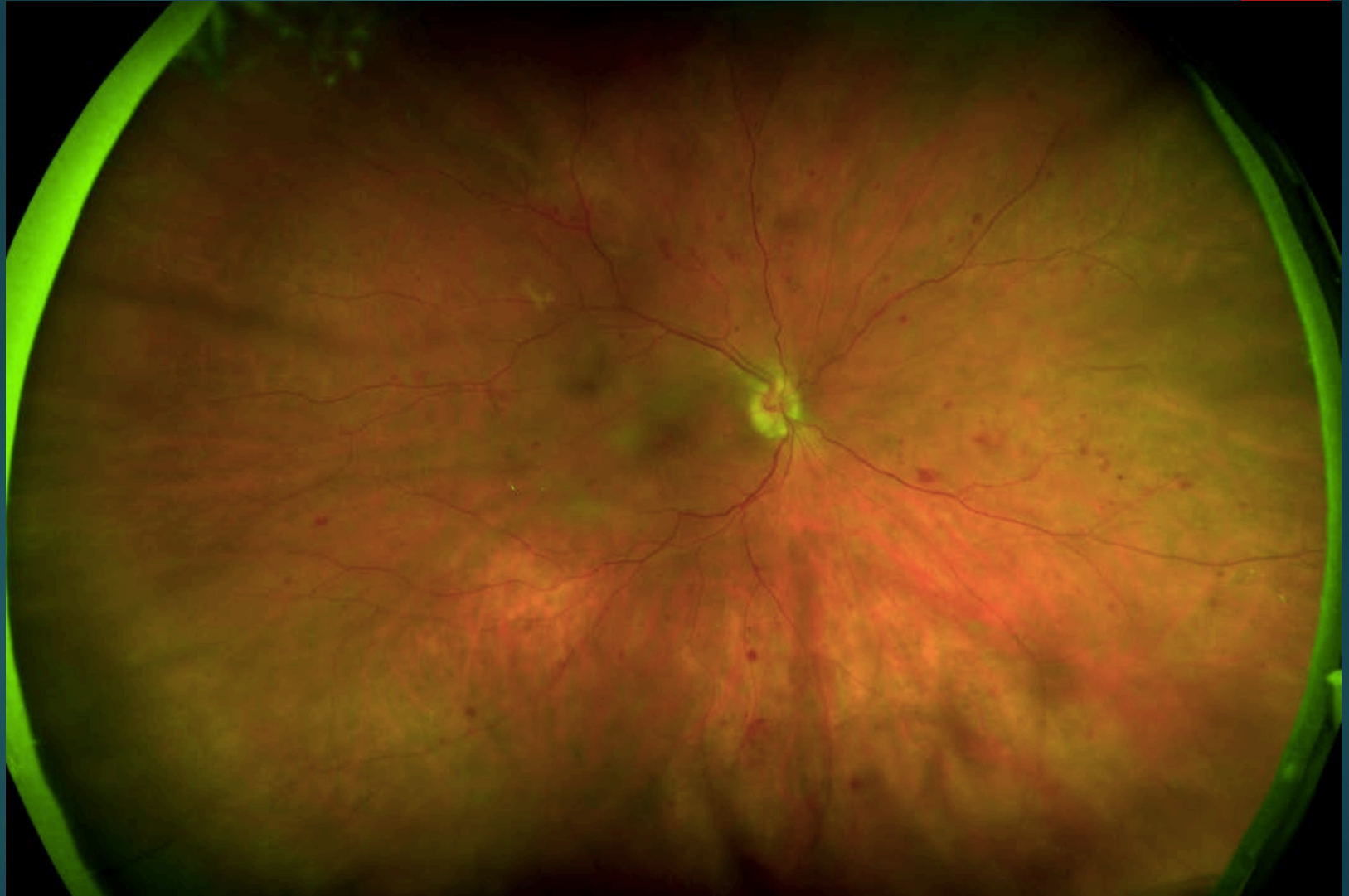
- ▶ Pictor compared to dilated clinical exam
  - ▶ 64-88% sensitivity; 72-84% specificity (is that good?)
  - ▶ Compare to European standard for screening (80% sens/95% spec)
- ▶ Comparison of D-Eye to slit-lamp: 85%
  - ▶ Should have been compared to gold standard
- ▶ Example: retinal diagnostic study (reteval) found NPV = 99% - However, sensitivity was still just 80%
- ▶ British diabetes association requires minimum 80%/94% sensitivity/specificity
- ▶ Three general factors affecting image quality:
  - ▶ optical properties - illumination, light scatter, pupil size requirements, retinal field of view, and depth of focus, and optical artifacts
  - ▶ image file properties - resolution, color depth, and image file type and size,
  - ▶ user properties - alignment, computer-user interface, information system interface, and ergonomics)
- ▶ United Kingdom NHS evaluates new retinal cameras every 6 months to ensure they can detect subtle diabetic pathology, are robust and easy to use. .
  - ▶ No handheld retinal cameras appear on their approved list of 20 non-mydratic retinal cameras for retinal screening

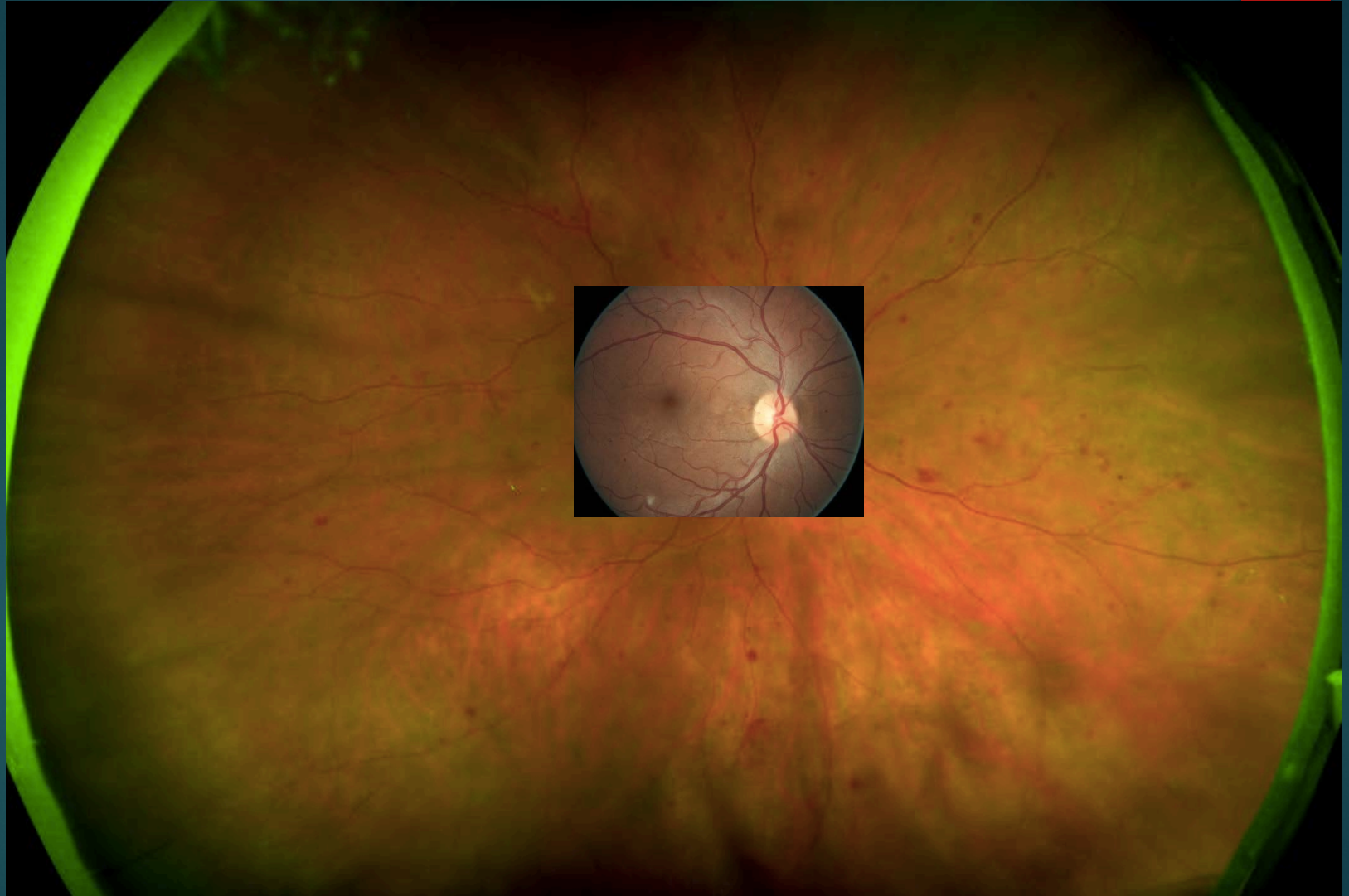
# Wide Field Imaging:

- ▶ Laser scanning device
  - ▶ Cost
  - ▶ Colorized laser scanned images initially more difficult to interpret
  - ▶ Resolution: 23 pixels per degree (NHS minimum is 30/degree, optics of eye: ~40/degree, 5Mpixel camera: 55/degree)

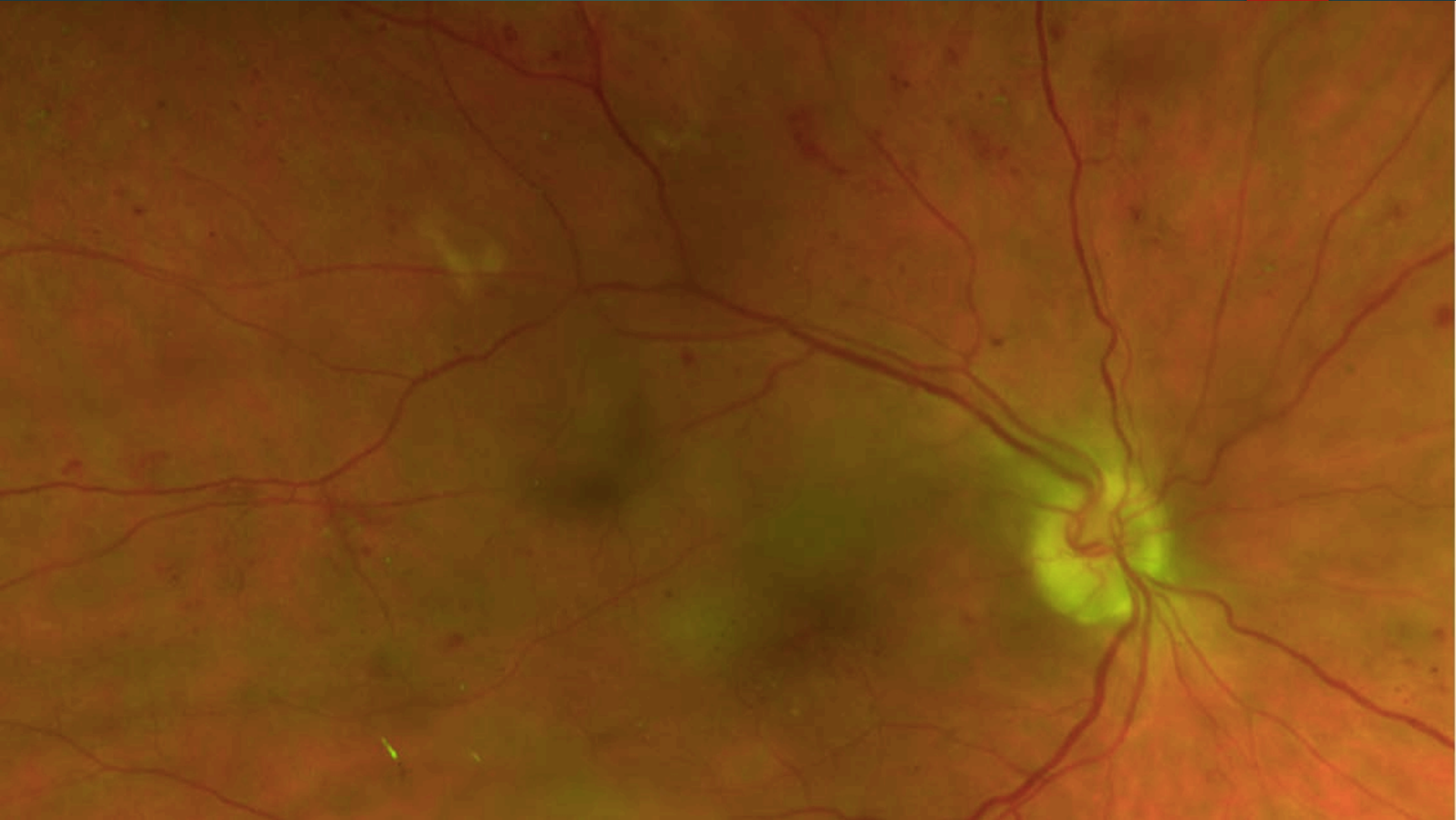


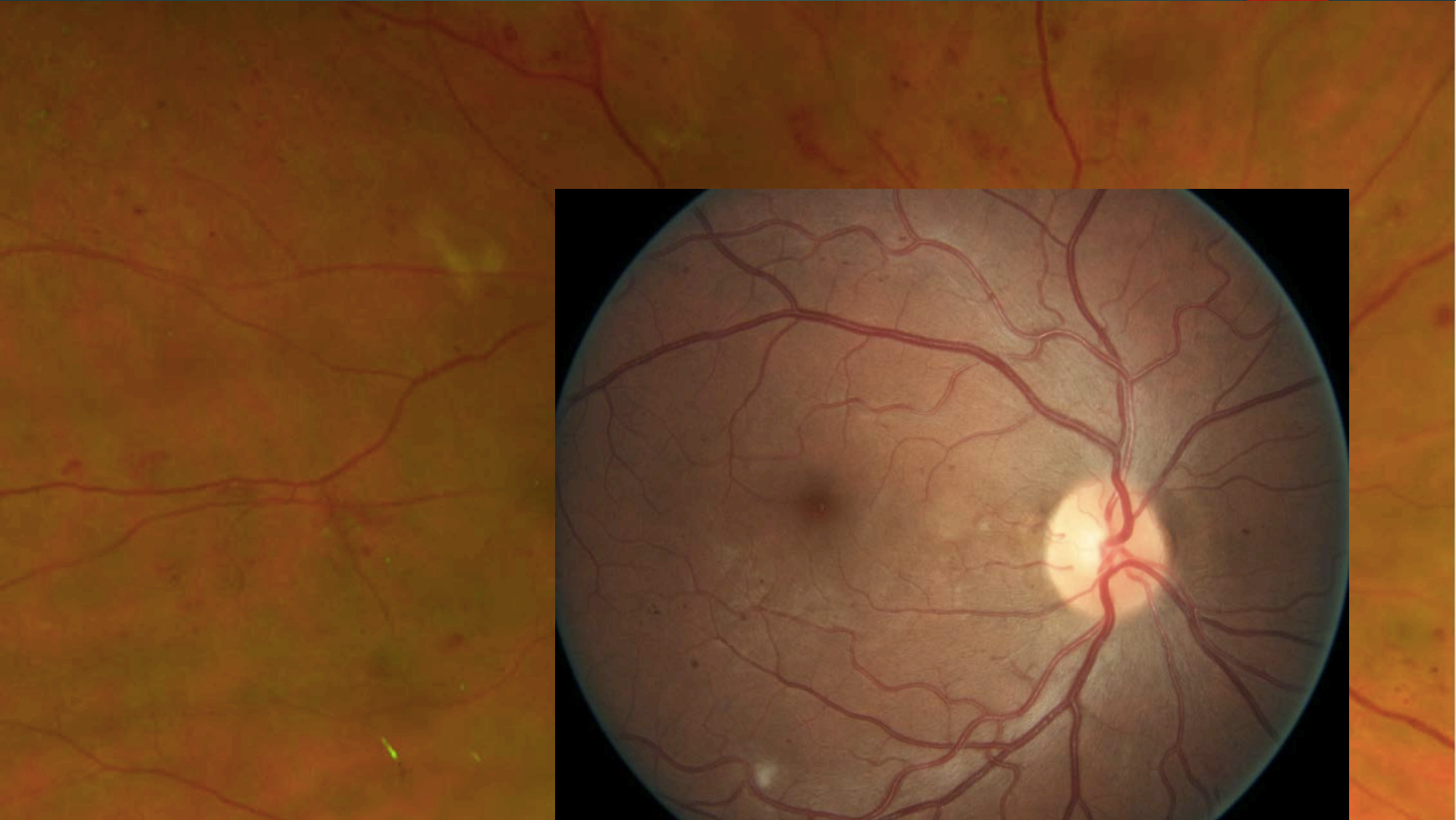




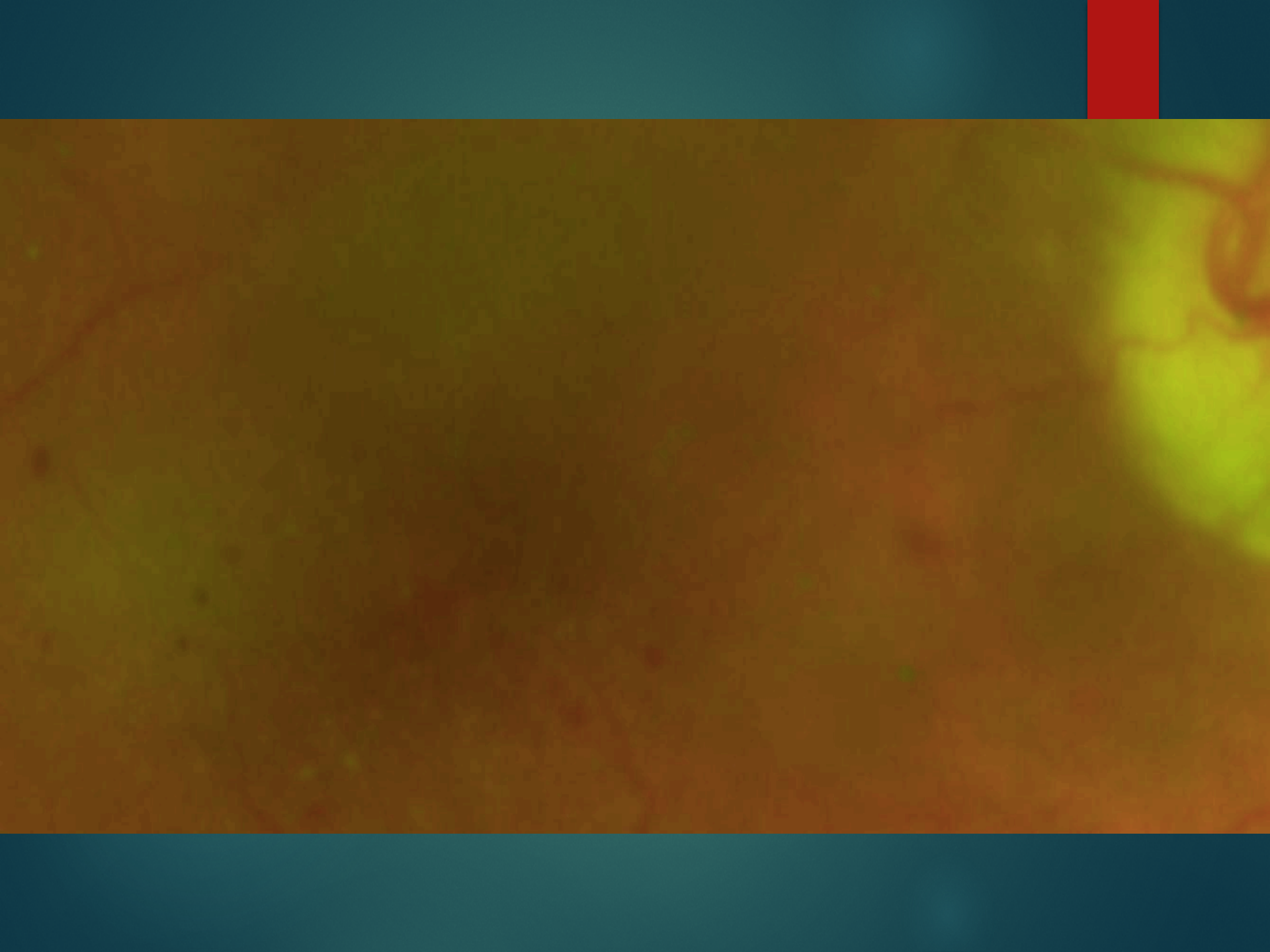
















# Wide Field Retinal Imaging

## Optomap 200 vs Two 45 Degree Photos:

- ▶ Kappa Correlation (Munich, 2013):
  - ▶ DR = .54 (moderate)
  - ▶ ME = .39 (fair)

## Optomap 100 vs ETDRS 7 fields:

- ▶ Percent agreement (Joslin, Harvard, 2014)
  - ▶ 84% agreement with DR level
  - ▶ 91% agreement within 1 DR level

# Artificial Intelligence & Diabetic Retinopathy

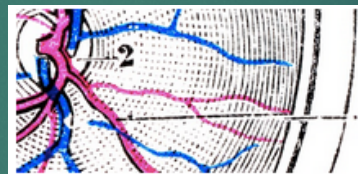
- ▶ Thousands of programs evolving since 25 years ago
- ▶ CAFIA (2001-2003) over one hundred algorithm developers at each meeting – none were good enough for implementation back then
- ▶ Diagnos, Retinalyze, Idx, Eyenuk, Hubble, IRIS seeking or have sought FDA approval. So far, none approved
- ▶ Deep Learning algorithms changed the landscape → performed better than humans



# Kaggle Competition Grand Challenge

- ▶ Launched with 100,000 "curated" images in February, 2015
- ▶ Ended on July 27, 2015
- ▶ 661 teams 6,999 entries
- ▶ Best quadratic  $\kappa$  score is .86 – (better than humans who have best score of .83)
- ▶ Prize is \$100,000 won by Prof. Benjamin Graham, Warwick U., UK
- ▶ Most entries are open source, therefore, made freely available to users

kaggle



\$100,000 • 268 teams

**Diabetic Retinopathy Detection**

Tue 17 Feb 2015



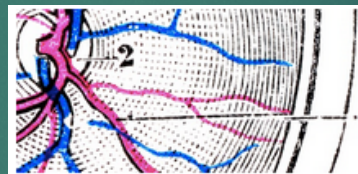
**CALIFORNIA HEALTHCARE FOUNDATION**

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**Original Investigation** | Innovations in Health Care Delivery

December 13, 2016

# Development and Validation of a Deep Learning Algorithm for Detection of Diabetic Retinopathy in Retinal Fundus Photographs

Varun Gulshan, PhD<sup>1</sup>; Lily Peng, MD, PhD<sup>1</sup>; Marc Coram, PhD<sup>1</sup>; [et al](#)

» [Author Affiliations](#)

JAMA. 2016;316(22):2402-2410. doi:10.1001/jama.2016.17216

- ▶ 98.1% Sensitivity; 98.5% specificity for detecting referable retinopathy
- ▶ Detects level of diabetic retinopathy and macular edema
- ▶ Validated with over 10,000 highly curated retinal images



## Example 1: Clinic Experience

- ▶ 11 Locations (9 medical, 5 dental, 2 SBHC, Homeless Program)
- ▶ NCQA Patient Centered Medical Home: Level 3 Recognition
- ▶ ~180,000 Medical Visits in 2014
- ▶ ~78,000 Patients served in 2014
- ▶ ~15,000 Patients remain uninsured (2014 Annual Report)
- ▶ ~5800 Patients with Diabetes



# Why cameras for us?

- ▶ Easy access for patients
  - ▶ Addresses transportation barriers
  - ▶ Cost effective
  - ▶ Avoids no-shows to specialists
  - ▶ Quality of care
- ▶ Provide better care (improved screening)
- ▶ More emphasis on quality metrics
  - ▶ Regional Health Plan Incentive program

# Barriers

- ▶ Location of the camera: separate floor
- ▶ Same day imaging is a challenge
  - ▶ Leave without being photographed
  - ▶ Patient preference
- ▶ High No Show rates
  - ▶ Higher N/S for recalled patients
- ▶ Not enough photographers
- ▶ Not the right people trained
  - ▶ Medical Assistants vs. Non-clinical staff
- ▶ Turnover of photographers
- ▶ Staffing shortages divert resources
- ▶ Interpreted visits
- ▶ We don't dilate: some patients need this



# Successes

## ▶ Improved Screening Rates

- ▶ Auburn hit 65% this year
- ▶ 32% increase in screen rate at Renton
- ▶ 22% increase overall since 2012 (27 to 49%)

## ▶ Improved Identification of Disease

- ▶ Abnormal findings trigger work up/treatment
- ▶ Use of Project Access
- ▶ ID of other conditions(e.g. glaucoma, cataracts)

## ▶ Timeliness

- ▶ Reports come very quickly
- ▶ Decreases the time from screening to referral

## ▶ Access

- ▶ Many patients still sliding scale
- ▶ Convenience for insured patients as well

## ▶ Training

- ▶ One site has 8 certified MA's

- **PDSAs to address barriers**

- Use of visual aids
- Processes to track causes for lack of screens



**CHICK** to see if pt is due for EYE EXAM!



HAVING AN EYE EXAM DONE?



Hand this to the 4th floor  
receptionists!

HAVING AN EYE  
EXAM DONE?



4th  
floor

Site with Camera

# Diabetic Retinal Eye Screening Flow

**Purpose:** To have patients who come into the clinic for a visit and are due for a diabetic retinal eye exam complete the eye exam before leaving the clinic.

## QJC

- Screens Services Due Report the day before.
- Adds patients to the Retinal Eye Screening schedule in EPM at the same time as the provider visit (if able).
- Writes "Add-On" in front of the patients name.
- Writes the provider name and appointment time in the details of the appointment.
- Writes language in the Outside Interpreter Language field.

Patient comes in to clinic for their provider visit.

## FO

- Check in patient for provider visit **AND** Retinal Screening.

## Provider MA

- Room patient for their provider visit.
- While rooming patient, screen chart and verify if patient can complete in-house retinal exam.
  - If they can, continue through retinal flow.
  - If not, **cancel** Retinal Exam and stop following flow.
- Let patient know they are due for a retinal eye exam and this will be completed today.
- When patient is ready (either **before** or **after** provider visit) change Patient Tracking in EHR to "Waiting for Retina".

## Retinal MA

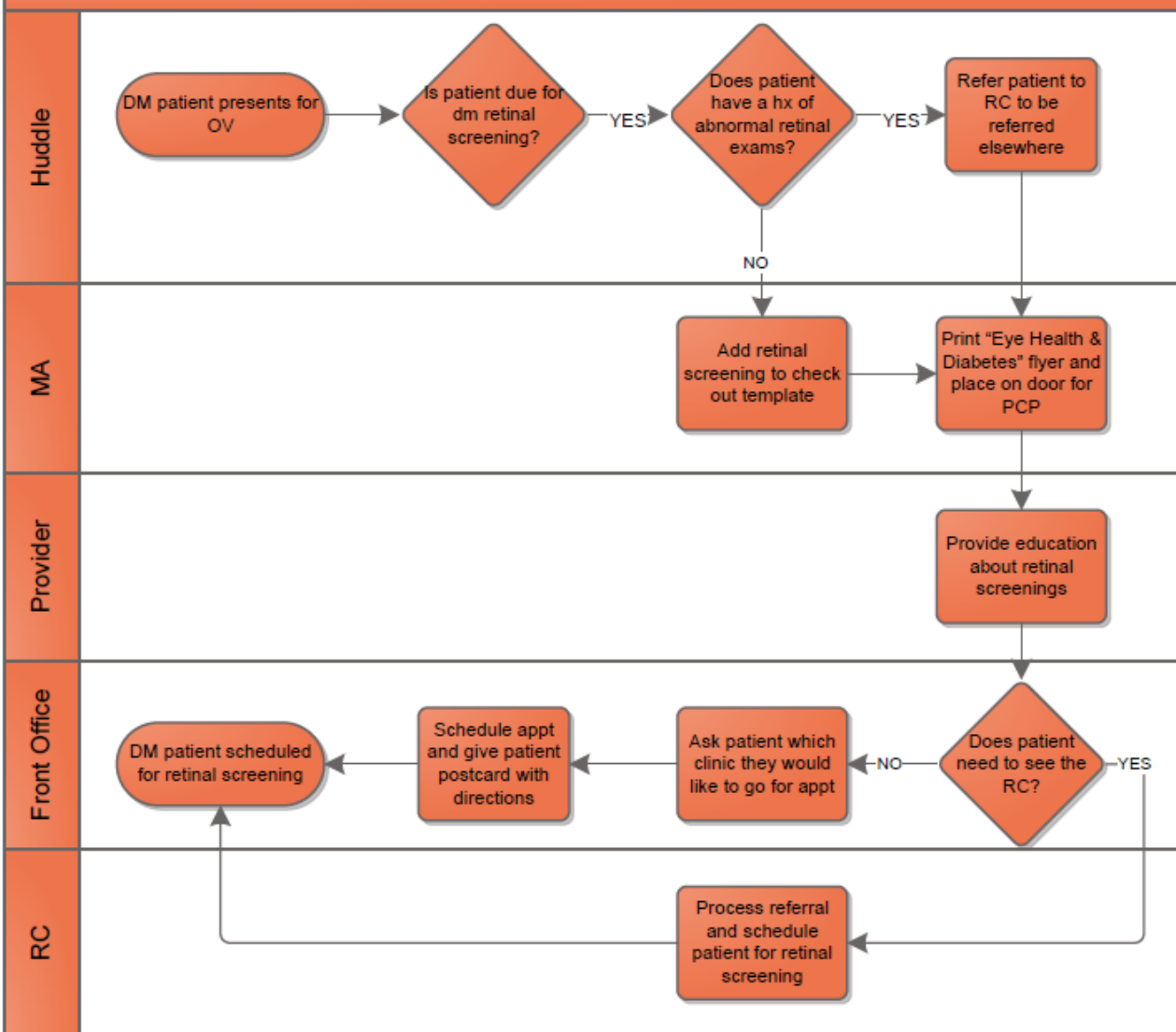
- Look in the Inbox to verify which room the patient is in.
- Go to the exam room and bring patient to the procedure room for the retinal exam.
- Escort patient back to provider exam room or to checkout depending on whether the patient has seen the provider or not.



# Site without Camera

## Referring and Scheduling Diabetic Patients for Retinal Screenings

10/03/14



### Why should diabetic patients get retinal screenings yearly?

Diabetic patients can develop retinopathy, damage to the tiny blood vessels in the retina. Untreated and severe retinopathy can lead to the loss of vision.

### What will happen during their diabetic retinal screening?

A certified photographer will take a total of eight images, four of each eye. The images are sent to an ophthalmologist for analysis. The report is then sent to the PCP. **Patients will not get a comprehensive, dilated eye exam, nor will they receive a prescription for glasses.**

### What is the cost?

There is no charge for uninsured patients. If insured, we will bill their insurance company.

### Where can I find the flyers and postcards?

X:\MIMC\Patient Handouts & Resources\Diabetes

# What is the impact?

- ▶ 5858 diabetic patients
- ▶ 49% screen rate means 2870 patients screened
- ▶ 31% with some disease = 890 patients
- ▶ 9% with sight threatening disease = 258 patients
- ▶ If **70% screened** then we identify 369 (**110 more**) patients with sight threatening disease\*

\*Assuming a stable 9% rate of sight threatening disease



# Lessons Learned

- ▶ Redundancy: Train enough people
- ▶ Planning: Have good workflows for same day visits
- ▶ Quality: Patients get screened who might not have otherwise
- ▶ Access: Moving towards cameras at each site
- ▶ Security: Keep the laptops secure





# Training

- ▶ Manual & online process:
  - ▶ Staff review & study the user handbook
  - ▶ Take practice photos and upload to training site
  - ▶ Notified of the quality of practice photos
    - ▶ Will submit additional photos as requested
  - ▶ Take certification test
  - ▶ Shadow other certified staff to study their workflow (PCHS requirement)
- ▶ Time to certification:
  - ▶ 2 weeks to 1 month depending on how quickly test photos are captured



# Patient Capture

- ▶ A variety of methods are used to capture patients due for testing:
  - ▶ Care gaps report using Arcadia Analytics
  - ▶ Open orders
  - ▶ Direct physician/pharmacist referral

# Scheduling

- ▶ If screening is ordered at the time of an in office visit:
  - ▶ Provider inputs order
  - ▶ Provider tasks designated staff, alerting them to the patient
  - ▶ MA/front office will schedule patient for screening prior to leaving the office
- ▶ If ordered outside of an office visit:
  - ▶ Designated staff contact patients due for screening.
    - ▶ Patients are asked prior to scheduling if they have had an eye exam in the last 12 months
      - ▶ If yes, they are asked where and if pictures were taken of the eyes.
        - ▶ If pictures were not taken, the patient is scheduled
        - ▶ If pictures were taken, staff request records



# Scheduling cont.

- ▶ Set days for testing
  - ▶ Currently testing occurs on Wednesday and Thursday each week
  - ▶ Certified staff rotate to camera site
- ▶ Camera available other days of the week
  - ▶ Two certified staff are stationed at the camera site and are available to see patients on an urgent basis

# Scheduling cont.

- ▶ Confirmations:
  - ▶ Certified staff confirm the appointments on their schedules
- ▶ No Shows:
  - ▶ If a patient no shows they are contacted same day to reschedule
    - ▶ Morning no shows are offered afternoon time slot (if available)



# Day of Appointment

- ▶ Staff ensure the procedure is explained to the patient in detail including:
  - ▶ The pictures do not replace the need to see an eye doctor
  - ▶ The room will be dark
  - ▶ Eight pictures will be taken of each eye
  - ▶ The pictures will be sent out for review
- ▶ The pictures are reviewed by PCHS staff prior to checking out the patient to ensure they are of good quality

# Billing/Reimbursement

- ▶ The images are submitted for review to your contracted service
- ▶ Charges are submitted through EHR once final report obtained
  - ▶ Procedure code 92250 utilized
  - ▶ Amount billed depends on your clinic situation (FQHC, private insurance, Medi-Cal, etc.). Check with your Billing Department.
  - ▶ Wide spectrum of insurance reimbursement rates
    - ▶ Rates fall anywhere between \$21.86 to \$108.56 per exam



# Closing the Loop

- ▶ Designated staff will retrieve results and file into the EHR, assigning the patient's PCP to sign off.
- ▶ Order is then marked received with the date the result was received.
- ▶ The Diabetic Protocol in Care Guidelines is then updated to show "fundus photography" performed.
- ▶ Patient is either called or sent a letter with results and if any further testing is needed.

# Survey Results Of CHPW Partner Clinics – August, 2015

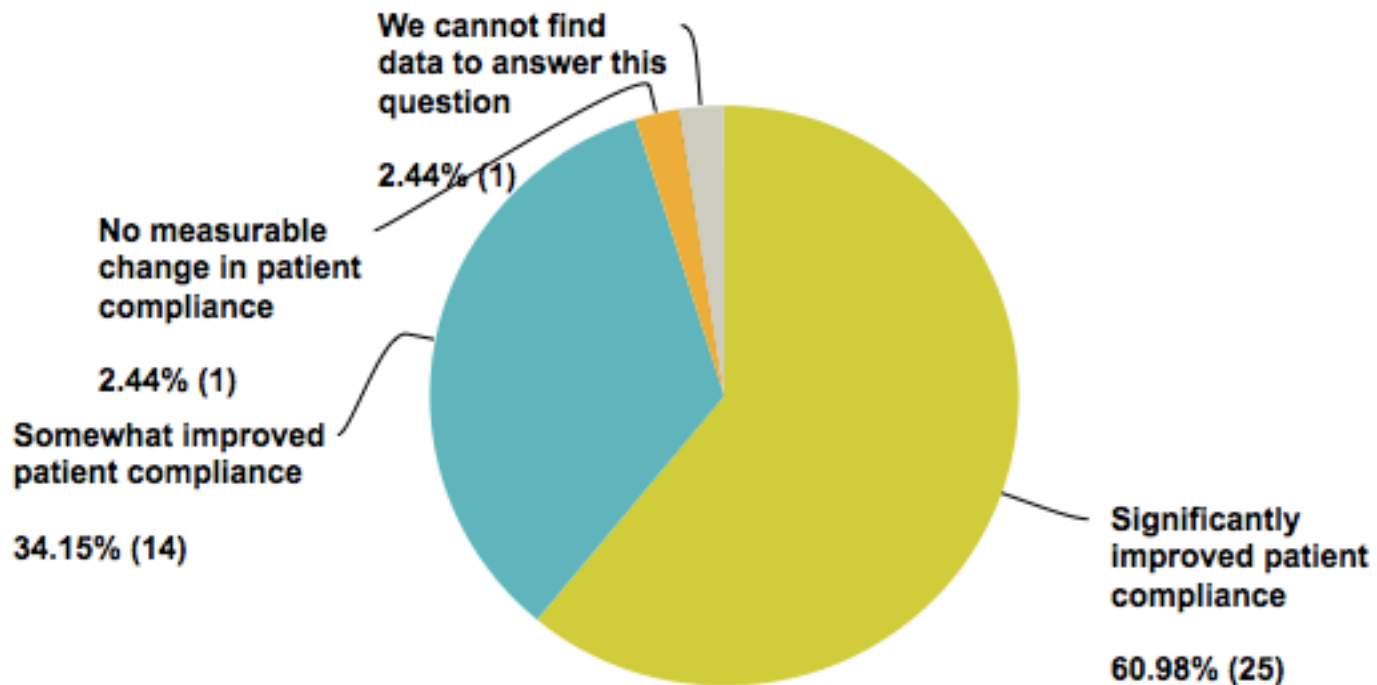
- ▶ Online and phone surveys requested of 55 unique clinics from 14 out of 17 FQHC networks actively using DRS
- ▶ 44 out of 55 responded by deadline (80%)
- ▶ Half of respondents were C-level executive, or supervisors
- ▶ 4 respondents had an optometrist on site
- ▶ 87% were “satisfied” or “extremely satisfied” with the service
- ▶ 1 respondent was dissatisfied



# Improved Patient Compliance

**How has your patient compliance rate with recommended retinal exams changed since you started**

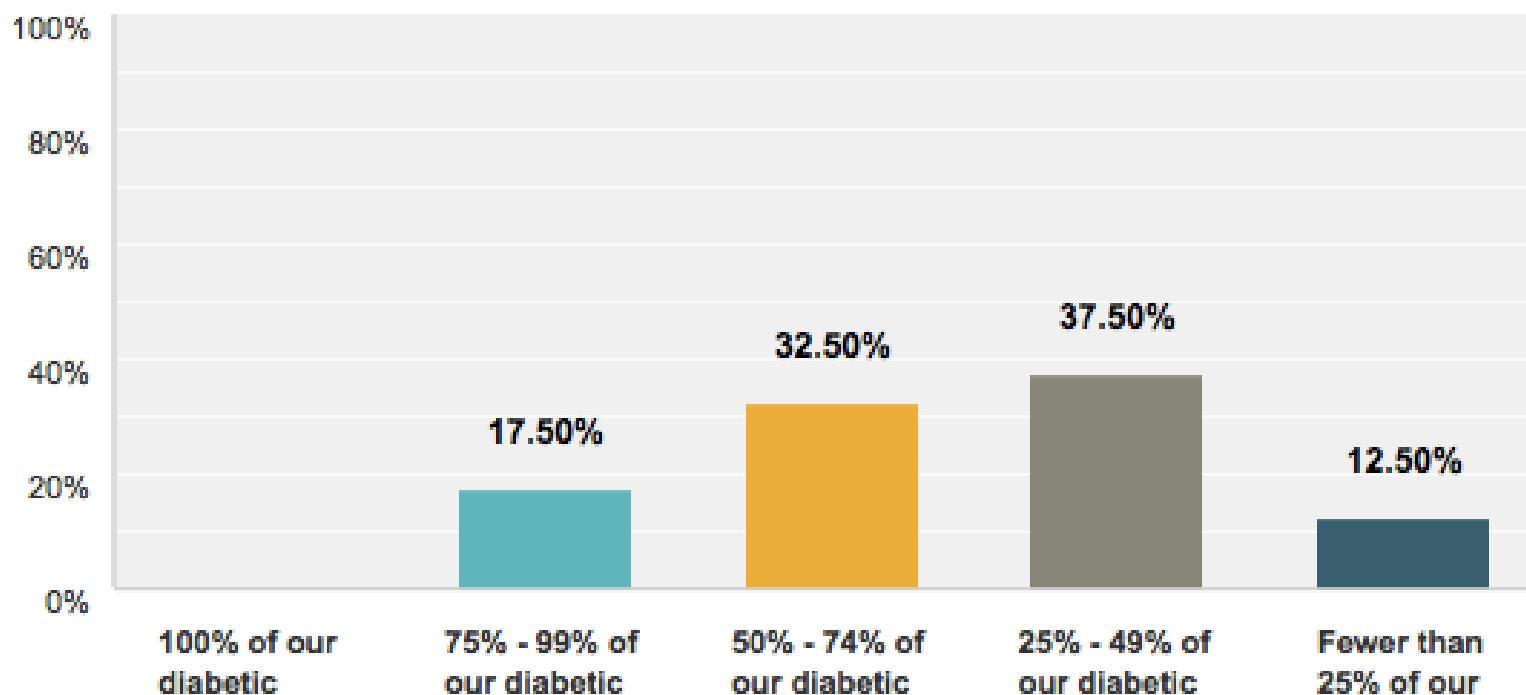
Answered: 41 Skipped: 3



# Still a long way to go..

**Please estimate the percentage of your diabetic population that is now undergoing the recommended retinal exam for diabetic retinopathy:**

Answered: 40 Skipped: 4





# Challenges To Increase Rate Of DRS:

- ▶ Patient engagement issues:
  - ▶ Patients will no show to their appt.
  - ▶ Patients sometimes do not have time to come back or stay a couple of minutes after visit
  - ▶ Patients have to pay out of pocket
  - ▶ Patients have their regular eye doctor
- ▶ Staff engagement issues:
  - ▶ Lack of care management
  - ▶ Hard to get providers to remember to recommend it
  - ▶ High employee turnover – constant training needed.
- ▶ Resource issues:
  - ▶ Multiple rural sites only one camera
  - ▶ Lack of staff available to do the retinal scans

# Comments On Costs Of Program:

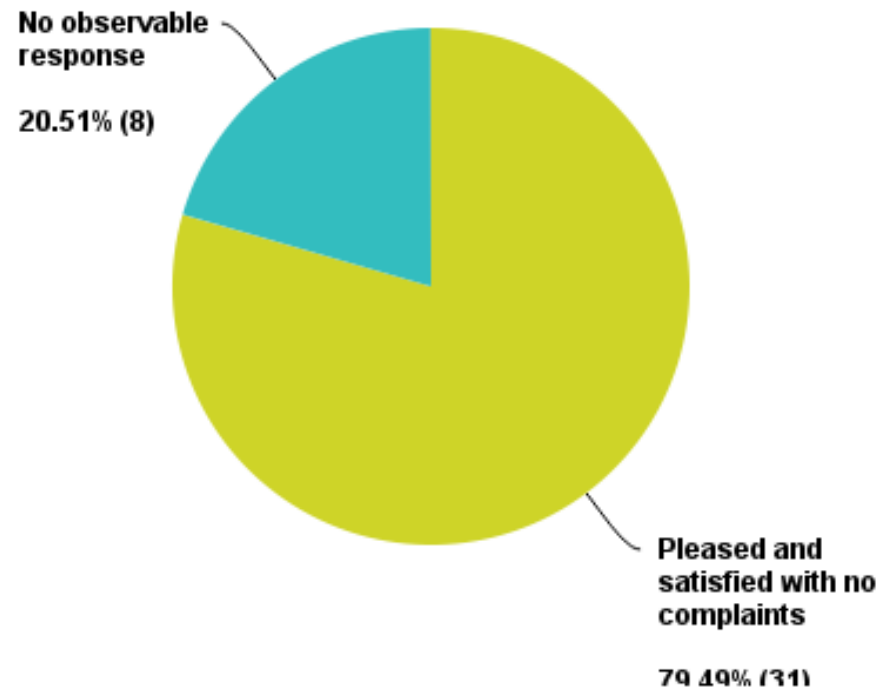
- ▶ Procedure is not generating any complaints from the coding department
- ▶ Not all insurance plans pay for it if it is done outside of the vision benefit
- ▶ We have a good system set up for billing. It only gets difficult when there is no identified regular PCP
- ▶ I have only heard of a few problems related to coding mistakes
- ▶ Risk adjustment creates a cost savings
- ▶ big cost savings to patients. neutral for clinic



# Patients Accept The Procedure

## Q25 What is the typical patient response to the exam itself?

Answered: 39 Skipped: 5



# Comments Regarding Patient Experience with DRS

- ▶ Patients are very positive about the eye exam and how quick and seamless it is to get them in.
- ▶ Patients appreciate the convenience of having the exam performed at PCP's office
- ▶ They mainly don't understand what the exam does or why it is important, but once it is explained to them they are on board
- ▶ Sometimes patients don't have time to get it done at appt., they were already waiting to see pcp and didn't want to wait any longer to do Screening also
- ▶ We rarely are able to do the eye exam same day as the pt is here for an appt



# Build Your Own DRS Program

- ▶ What is your realistic goal for retinal exams for your diabetic patients?
- ▶ What is your current rate of retinal exams for your diabetic patients?
- ▶ How many patients with diabetes are in your organization?
- ▶ What is your payer mix? Medicare, Medicaid, HMO, Private Pay, and Uninsured Indigent?
- ▶ How does DRS fit into your organization's mission?



# Are We Actually Preventing Blindness?



# Closing The Loop: Report on Referral Outcomes - Robert Quade for CHCF - 2009

Study: 288 patients from 4 high-performing California clinics referred through EyePACS in 2008 for specialist care of sight-threatening retinopathy:

- ▶ 85% received notification of referral – median 46 days after EyePACS screening
- ▶ 70% received appointment – Average 65 days
- ▶ 48% of appointments were kept (96 out of 184)
- ▶ 22.5% of referred patients received treatment or entered monitoring with specialist.
- ▶ 10 patients were treated for retinopathy (10 out of 288)

# Closing The Loop: Alameda County Retinopathy Treatment Study

- ▶ 2010: Contacted 56 patients who missed ophthalmology referral appt. for retinopathy: 32% of patients did not believe treatment would help them
  - ▶ 21 failed due to logistics (didn't get appt, couldn't leave work, no child care, etc.)
  - ▶ 17 failed due to lack of money, eligibility, or insurance
  - ▶ 18 failed due to belief that treatment would not help ("I see fine so I don't need tx", "my friend went blind from laser", "they just want my money", etc.)
- ▶ 2014: 254 referred patients from county health system with SNPDR, PDR, or probable CSME from January, 2011 to December 2013 with no prior visit to ophthalmology clinic
  - ▶ Only 34 attended visit to ophthalmology
  - ▶ Only 12 were treated



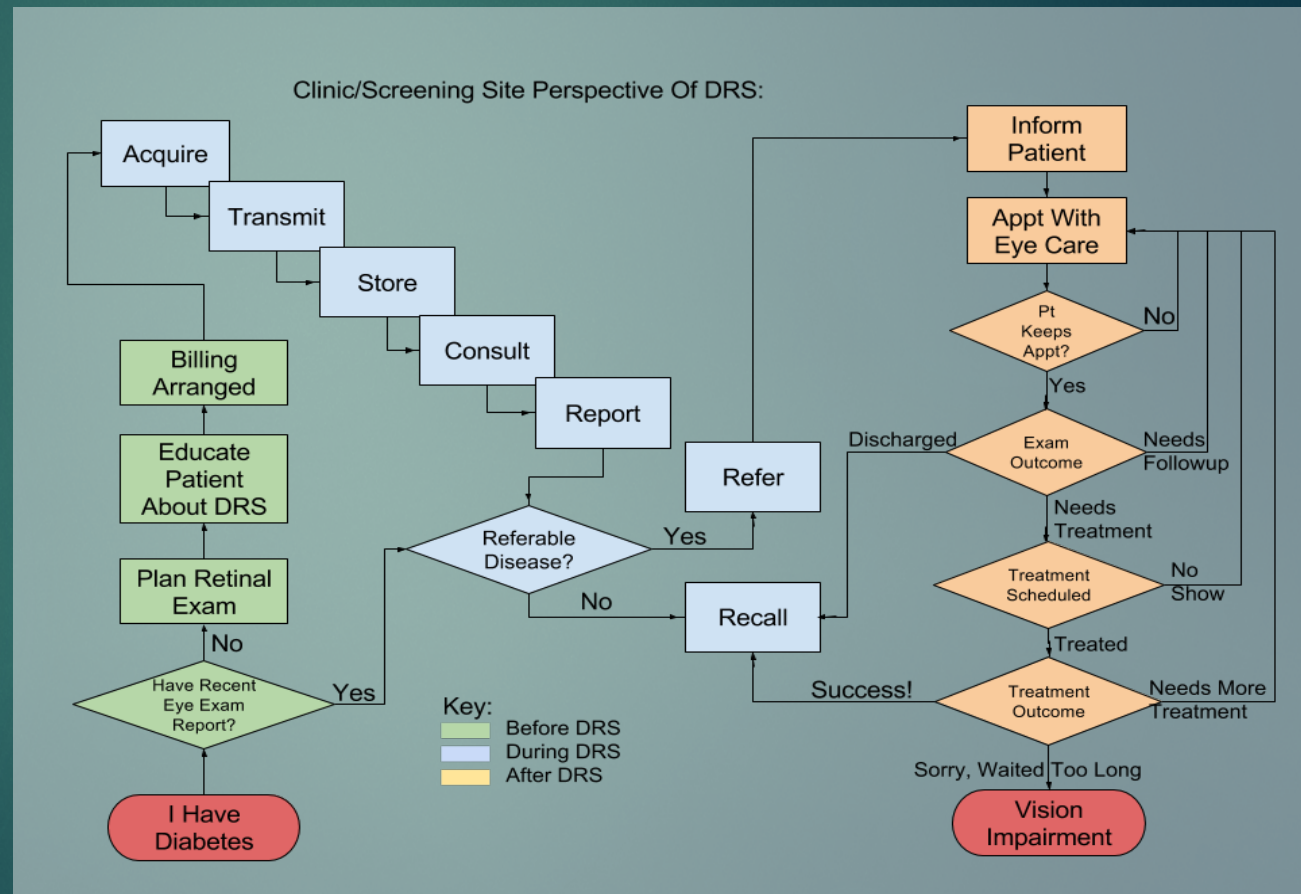
# Improving Access To Retinal Care (Ethnographic Study 2015)

Purpose:

- ▶ Exploratory ethnographic study to understand barriers to retinal treatment

Team:

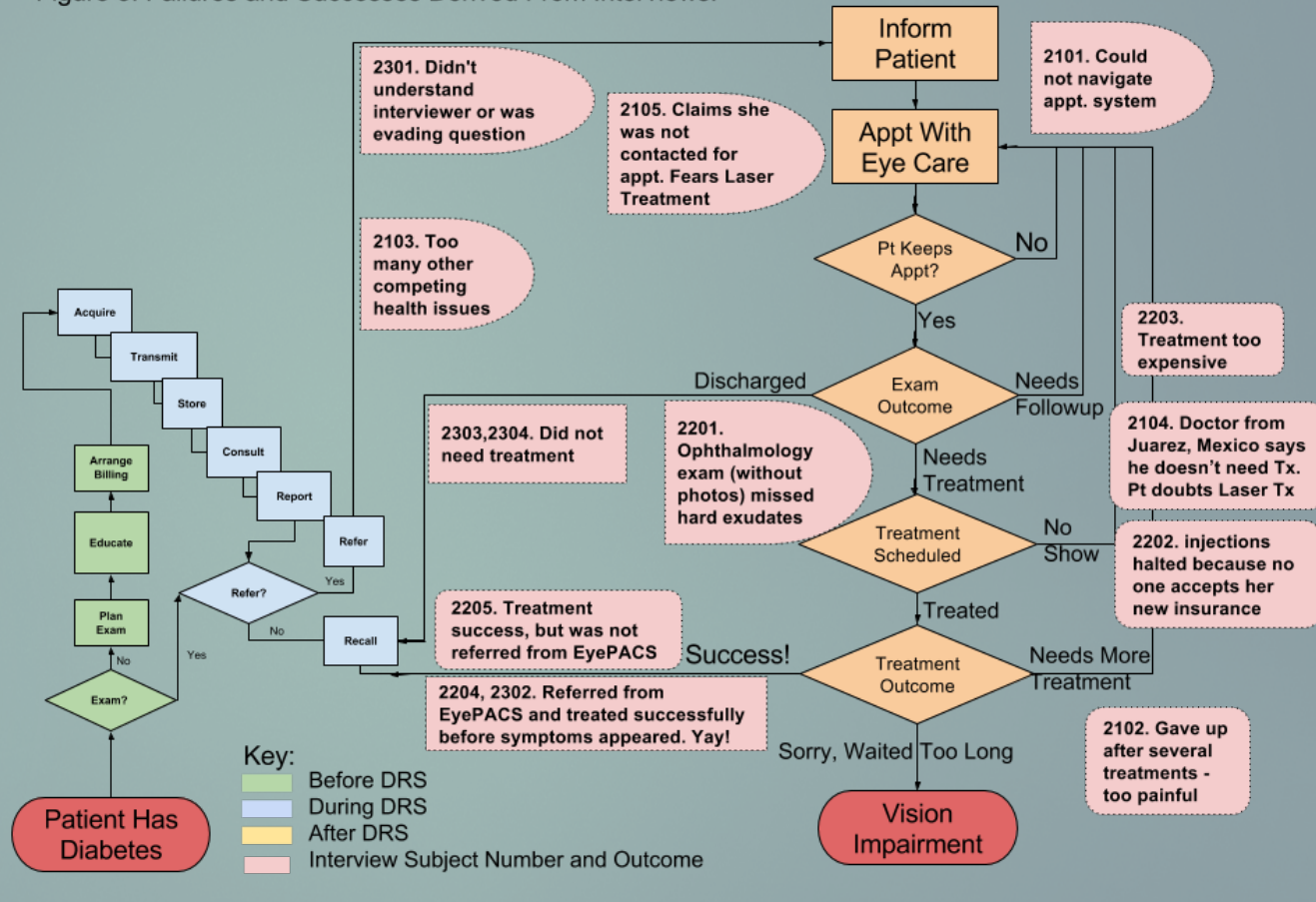
- ▶ Carolyn Smith-Morris, PhD Anthropologist, Southern Methodist University
- ▶ Catherine Bouskill, PhD Anthropologist, Emory U
- ▶ Elin Pedersen, PhD Computer-Human Interface Specialist, Google Research



# Results:

- ▶ Barriers to getting appointment – phone and lack of time slots
- ▶ Poor integration of results with EMR and providers
- ▶ Low patient education and engagement about eyes by primary care
- ▶ Multiple comorbidities and responsibilities
- ▶ Low patient motivation
- ▶ Social isolation is both a cause and consequence

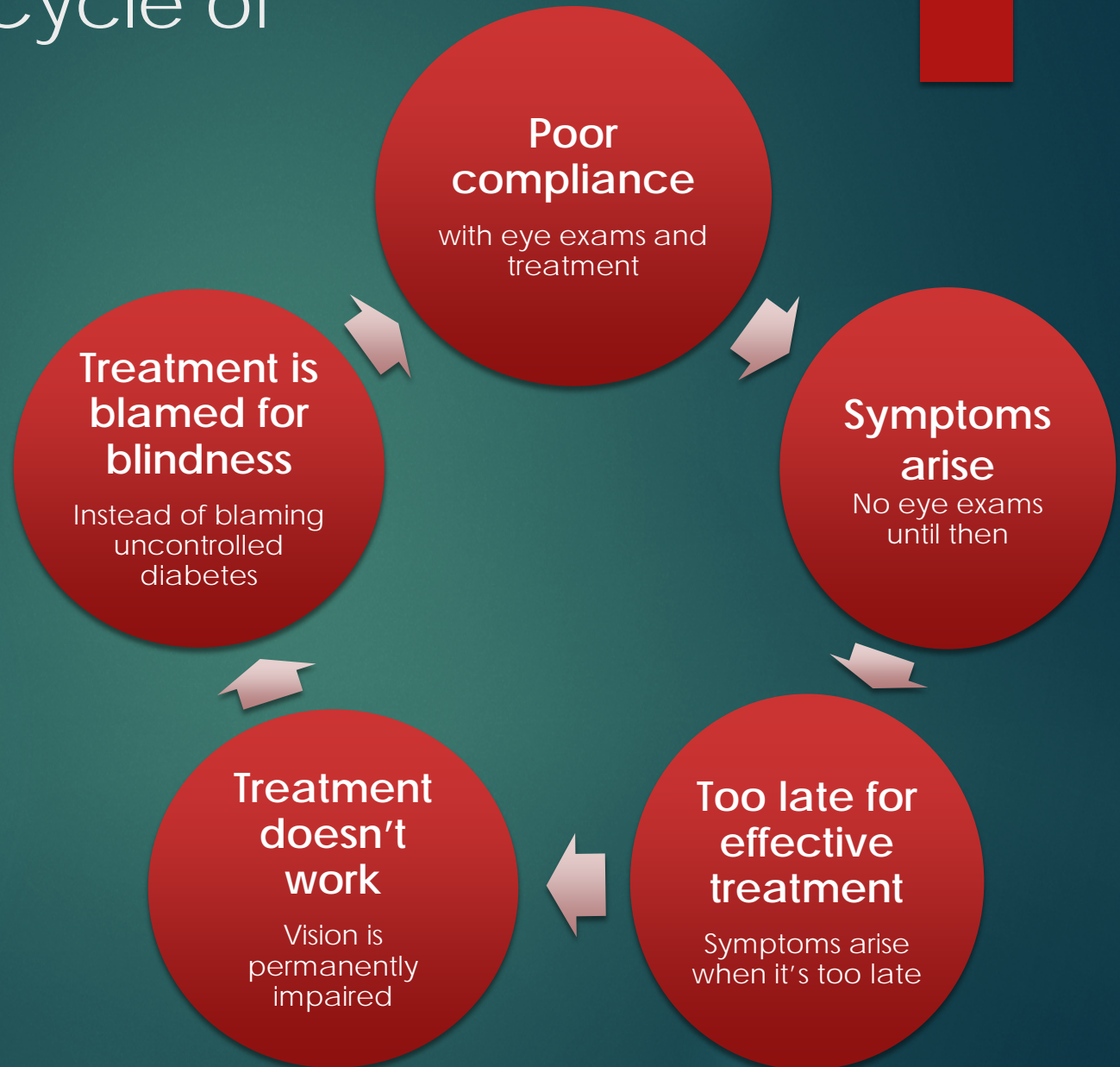
Figure 3. Failures and Successes Derived From Interviews:





# The Vicious Cycle of Blindness

- Main cause of permanent blindness among working age adults (age 25-70) in most countries
- Blindness from diabetes is 90% preventable with early detection and treatment of diabetic eye disease
- Yearly eye exams are recommended for surveillance, and treatment is recommended from these exams, but most people don't go, creating vicious cycle.



# Lessons Learned:

- ▶ Teleretinal technology is evolving → be adaptable
- ▶ However, success depends on organizational factors, not technology
  - ▶ Need (motivation)
  - ▶ Resources
  - ▶ Leadership
  - ▶ Mission
- ▶ Minimizing barriers to access is the most essential factor for success
  - ▶ Integrated workflow and integrated support
  - ▶ Interface with EHR and data system
  - ▶ Disruptive innovation without disruption
- ▶ Closing the loop is difficult!

16% referred with sight-threatening conditions  
8.2% severe diabetic retinopathy,  
7.8% cataracts, glaucoma, and other conditions