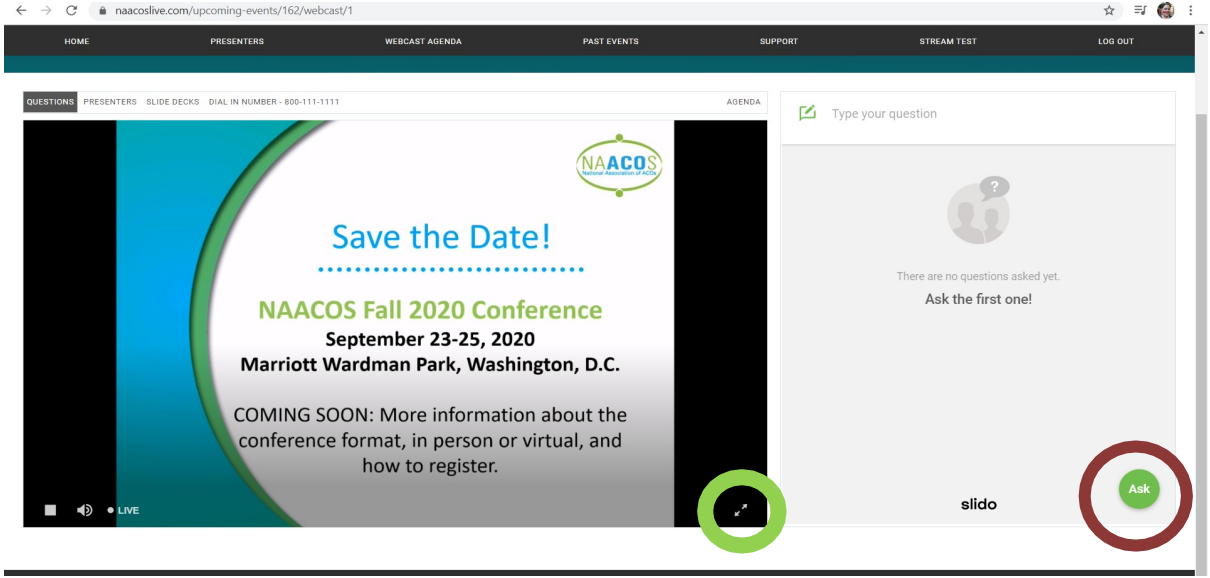
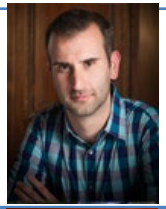
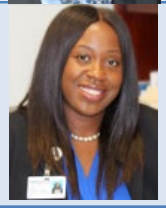
ACOs' Use of Digital Health Tools

Housekeeping

1. If you would like to make the presentation full screen on your device, hover over the presentation and hit the double arrow button circled in the screen shot below in green.
2. To ask a question, click on the green “ask” button in the bottom right of the questions box. Please see the red circle in the screen shot below.
   - You can type in a question at any time during the presentation.



Speakers

	**David Pittman** Health Policy and Communications Advisor National Association of ACOs
	**Micheal Abramoff** Founder and Executive Chairman Digital Diagnostics
	**William Biggs** CEO and Medical Director Amarillo ACO
	**Jasmin Danso** Director of Operations and Ambulatory Population Health Richmond Quality ACO and Richmond Health Network

Telehealth

- ACOs' use of telehealth has exploded during the pandemic, driven by numerous waivers and flexibilities offered by CMS which largely end once the PHE is lifted
  - Two-sided risk ACOs who use prospective assignment *do retain* flexibilities around telehealth regarding where the patient is located

What's next?

- More than a dozen bills have been introduced in Congress since the PHE to make those waivers permanent
- MedPAC talked about expanding telehealth use within Advanced APMs
- The 2021 MPFS seeks comment on additional audio-only or remote patient monitoring codes

What NAACOS is doing?

- Advocating to Congress and CMS to allow broader flexibility for telehealth use within ACOs – CMS has the authority now but hasn't used it
- Made a number of comments to the Physician Fee Schedule
- Planning to analyze Medicare claims to see what telehealth utilization has been in 2020

Telehealth

- **DATA ON EVIDENCE AND OUTCOMES ARE NEEDED!**
  - A lack of demonstrated savings has limited Congress and CMS expanding telehealth to more providers
- Data we could use:
  - Overall numbers demonstrating uptake, outcomes, etc.
  - The extent to which telehealth services replaced existing in-person services vs. were new or additional services
  - Health outcomes of beneficiaries using telehealth vs. those who did not
  - The types of telehealth services most commonly used
  - The rural vs. non-rural breakdown of beneficiaries using telehealth
- Anecdotes help too
  - Individual stories of people who received telehealth during COVID and benefitted from it
- Reach out to advocacy@naacos.com to follow

We want to successfully advocate for the expansion of telehealth post-COVID but in a way that doesn't disadvantage ACOs!

JASMIN EVERSLEY-DANSO, MS
DIRECTOR, ACO & AMBULATORY POPULATION HEALTH
RICHMOND QUALITY, LLC
RICHMOND HEALTH NETWORK

Richmond Quality ACO

- Located in Staten Island, NY
- Started in CMS MSSP Track 1 in 2015
- Currently serving over 6,000 Medicare beneficiaries
- Third year of our second contract period (2018 Renewal)
- Practice Led , Hospital Sponsored. [Employed vs. Voluntary Community Physicians] ACO

Richmond Quality, LLC

Richmond Quality ACO
Savings 2015-2019

Richmond Quality ACO						
Total Savings and Shared Savings Summary 2015-2019 Performance Years						
	2015	**2016**	**2017**	**2018**	**2019**	**Total**
Total Savings	$ 3,737,843	$ 7,389,470	$10,883,888.00	$1,515,076	$7,213,193.40	**$30,739,470.61**
Shared Savings	$ 1,867,869.00	$ 3,473,744	$ 4,971,339.00	-	3,462,332.83	**$13,775,284.83**

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COVID 19 & Healthcare Delivery

- Adjusting to our “new normal” of healthcare delivery
- Keeping up with new regulations
- Safety of staff & patients at the forefront
- Relying on science and data to make informed decisions

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Using Technology & Data

- In the beginning of the pandemic we relied heavily on the data available to us to re-pivot our care management strategy
- We used our population health platform to identify high risk patients that would be severely impacted by COVID if contracted. Our RN care managers began to reach out to these patients to ensure they had everything needed for their current chronic conditions
- During this time we also identified those due for screenings and closed those gaps thru telehealth visits when possible

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Quality During Crisis

- Why care about Quality during a pandemic?
- We continued our work behind the scenes with tracking quality performance & continuing to send progress reports to providers & working with staff
- Ramped up Annual Wellness Visits, Chronic Care Management, Care gap closure, and HCC capture.
- Kept in close contact with ACO providers to assess needs and volume
- Worked with State agencies, RHIOs and HIE's to identify COVID patients
- Engaged Home Care agency to close the loop on referrals
- Collaborated with local SNFs to coordinate patient care

Richmond Quality, LLC

Leveraging Telehealth to meet ACO Requirements

- Nationwide, office visits decreased between **30-70** % during the height of the pandemic
- A survey conducted in April showed that only **9%** of visits took place via telehealth pre-pandemic. Compared to **51%** during quarantine.
- Telehealth is expected to continue long after the pandemic ends at a rate of **21%**

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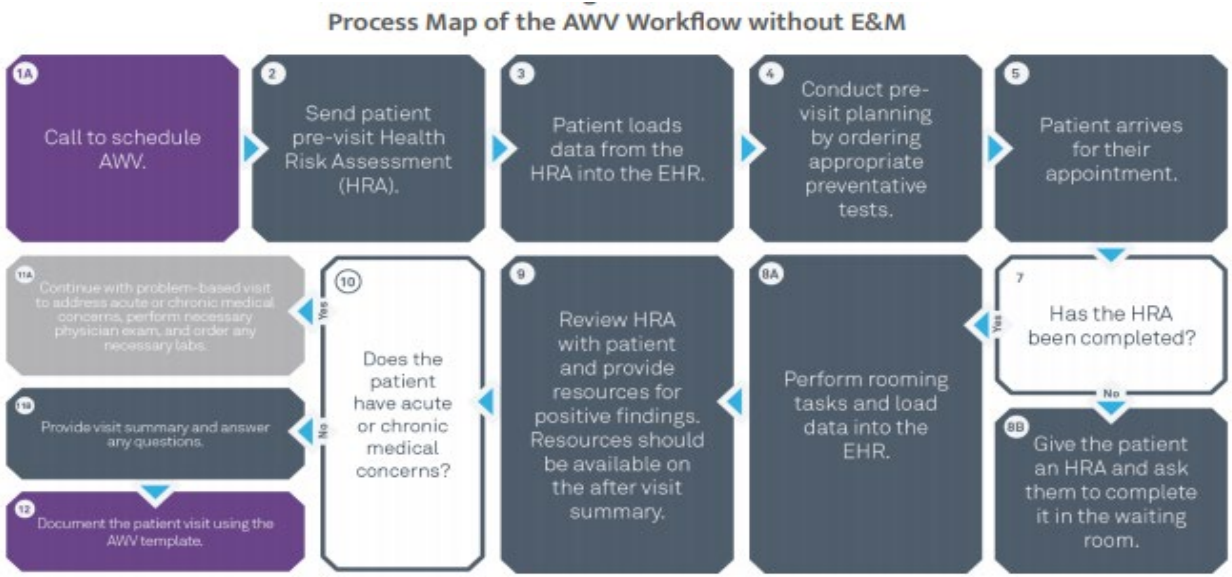
Sources:

hhs.gov
The Commonwealth Fund

Using Telehealth to complete AWVs : Process Map



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Source: https://edhub.ama-assn.org/steps-forward/module/2757861

Using Telehealth to complete AWVs: Virtual Process

- MA still completes intake and histories
- Vitals taken by patient if possible
- Provider would review information and develop 5- year plan for patient
- Can also complete Advanced Care Planning at visit

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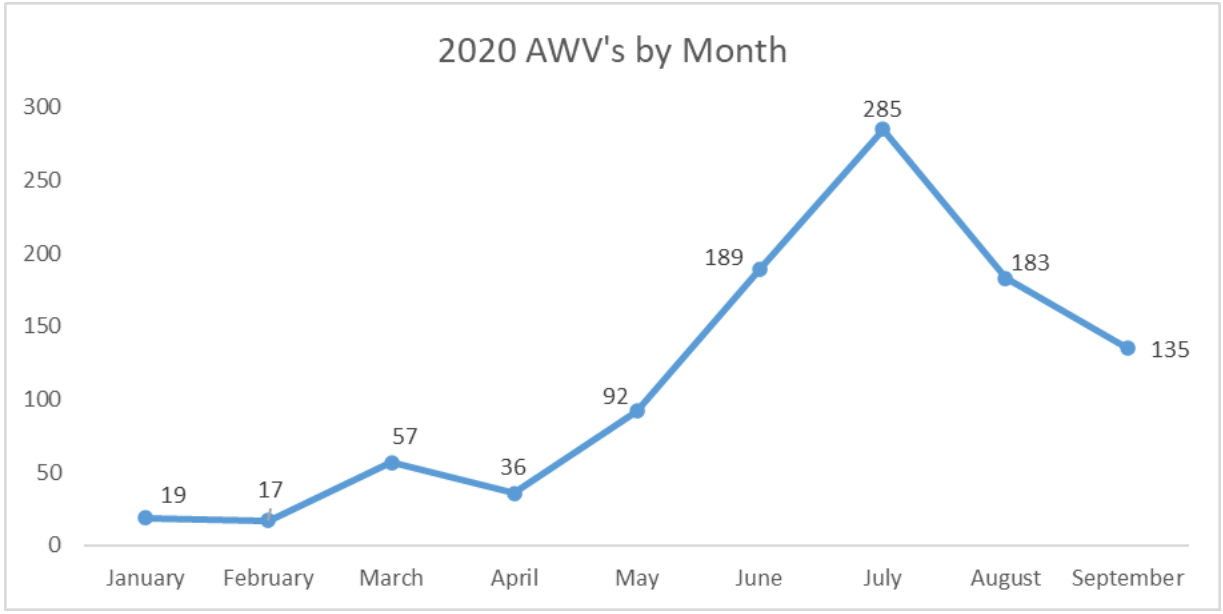
Sample: 2020 AWVs by Month



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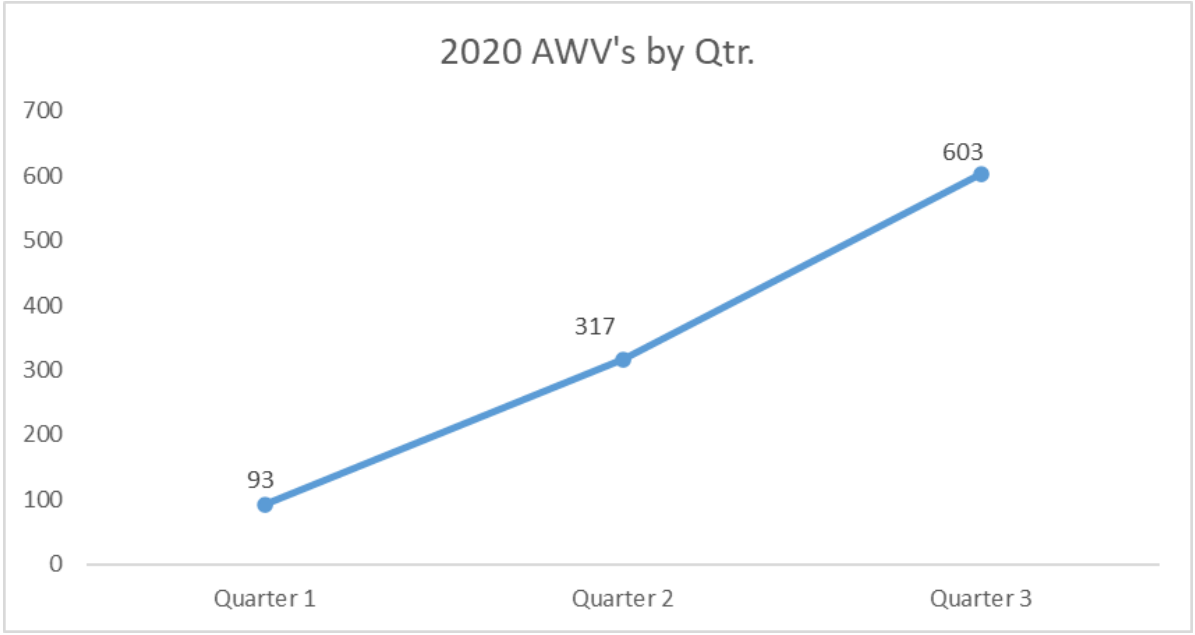
Sample: 2020 AWVs by Quarter



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Lessons Learned: Preparing for a second wave

- What can we improve on?
- Create a PPE stockpile/exchange amongst ACO practices
- Expand Social Media and Internet presence
- Importance of strong care management to support clinical practice
- Set up Technology **now** that will assist you **later**
- Increase focus on patient satisfaction

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Questions?

Thank you!

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RUMC Ambulatory Health Network

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Phone: 718-818-1990

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Putting the Pieces Together

One ACO's experience with
Remote Patient Monitoring

Amarillo Legacy Medical ACO
Amarillo, Texas

William C. Biggs, MD, FACE

CITY OF
AMARILLO
OPEN SPACES + ENDLESS POSSIBILITIES

Conflict of Interest Disclosures

- Clinical Research Grants:
  - Dexcom Inc, Novo Nordisk A/S, Sanofi US, Astra Zeneca, Roche, Mylan, Gan & Lee.

- Consulting
  - Roche Diabetes Care

Our view of mHealth

- Primary goal :
  - Mobile health monitoring should provide actionable information, improve safety of patients, improve patient quality of life, and reduce cost.
- Secondary goals:
  - Avoid a low ‘signal to noise’ ratio that annoys doctors with false alarms and distracts providers from higher priority problems.
  - Avoid proprietary solutions designed primarily as revenue generators.
  - Validate whether our interventions work and prioritize those methods that provide the most benefit.

American Diabetes Association. ClinicalDIABETES

Clin Diabetes. 2019 Jul; 37(3): 269–275.
doi: 10.2337/cd18-0081

PMCID: PMC6640884
PMID: 31371858

Optimizing mHealth Technologies in Real-World Clinical Practices

Pablo Mora,[1] William C. Biggs,[2] and Christopher G. Parkin[3]

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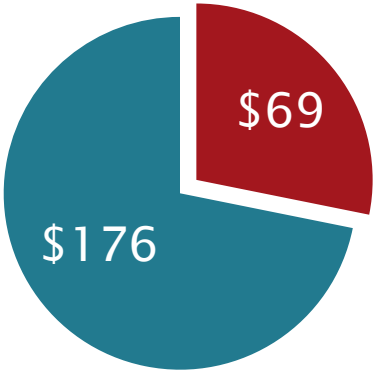
Abstract

Go to:

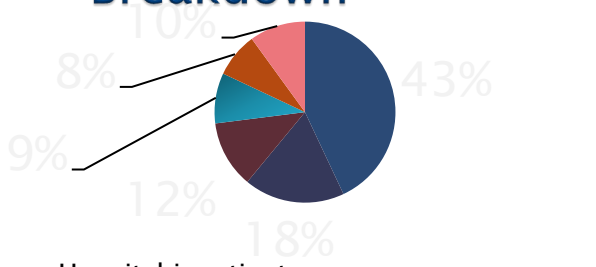
IN BRIEF Therapeutic inertia and suboptimal treatment adherence remain the key drivers of chronic poor diabetes control. Advances in mHealth technologies have spurred the development of a new generation of blood glucose monitoring systems that enable individuals with diabetes to automatically transfer glucose data and other information from their smartphones to their health care providers for analysis and interpretation via diabetes data-management software. This report discusses key lessons learned from two investigations that assessed the effects of interventions using the Accu-Chek Connect diabetes-management system (Roche Diabetes Care, Indianapolis, Ind.) within diverse diabetes populations.

Cost of Care for Patients with Diabetes in the United States

Fully Burdened Costs

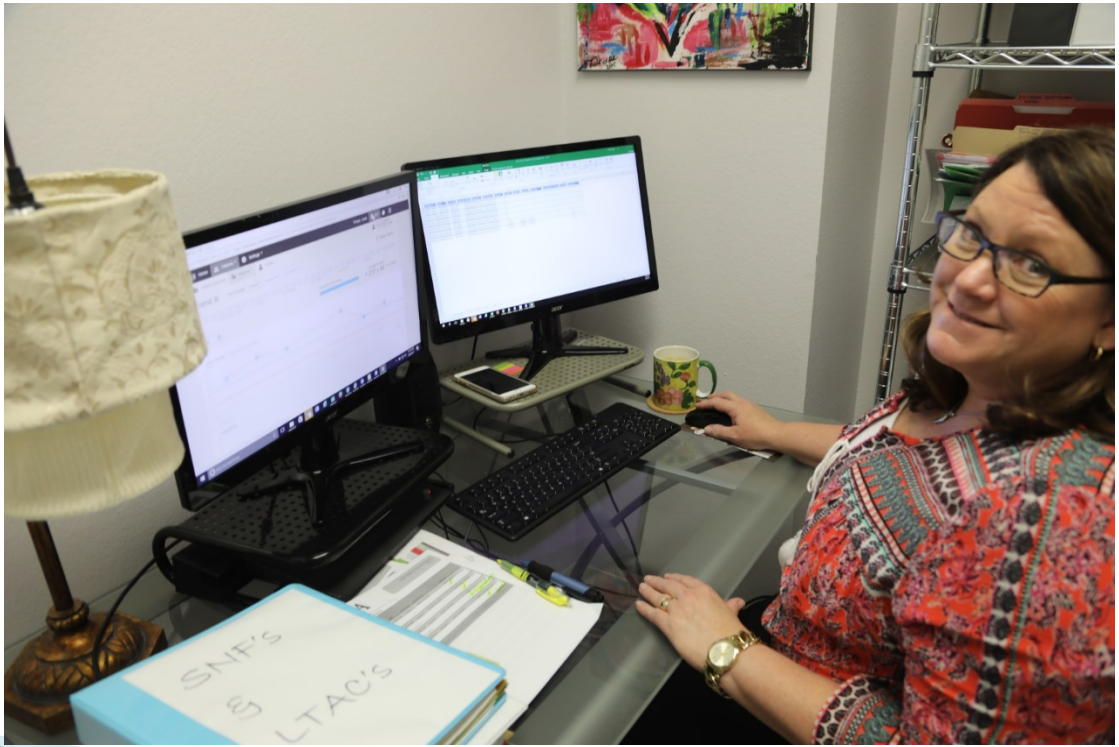


Direct Cost Breakdown



Source: Diabetes Care, March 6,2013

Care Managers

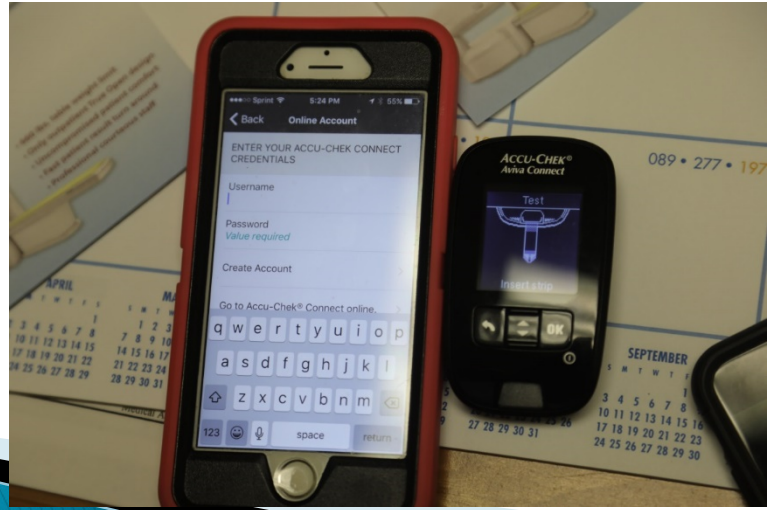


Hypothesis

Use of Remote Monitoring as an intervention delivered by Care Coordinators and Endocrinologists with…

..high cost / high risk diabetes patients

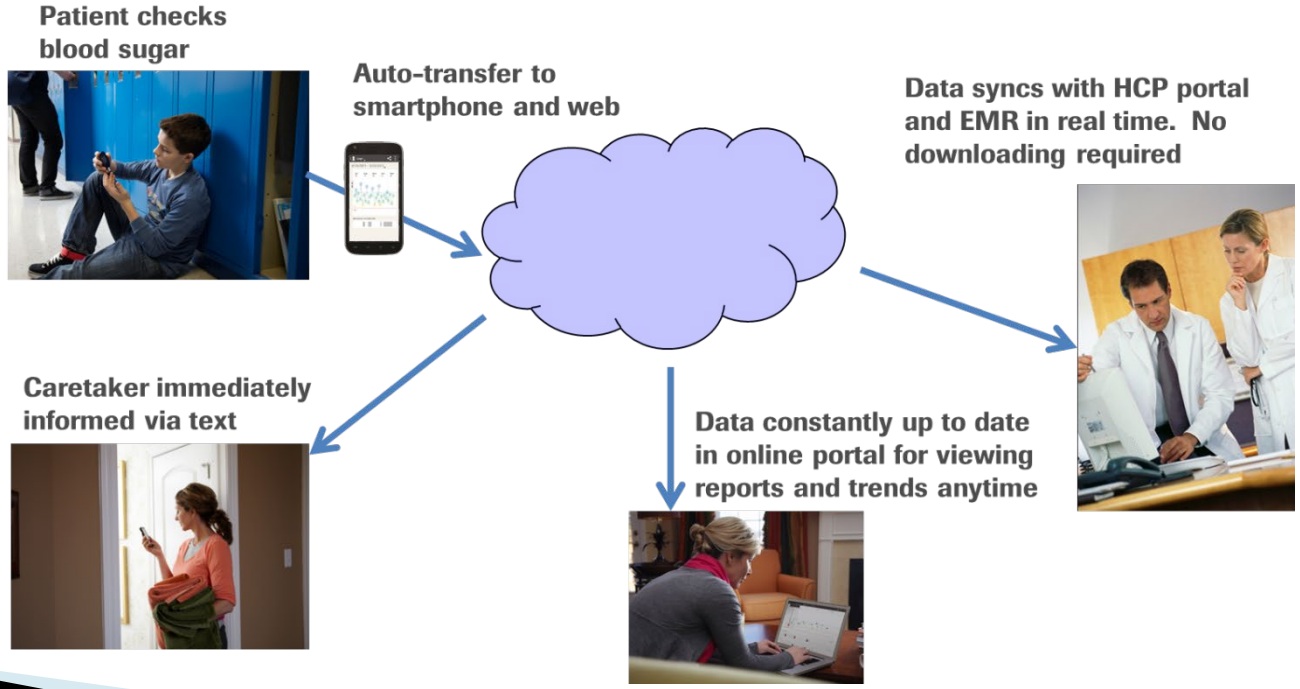
…can reduce hospitalization and other costs and have a positive impact on glycemic control.



Our Pilot Approach

Cloud-connected glucose meters automatically transmit glucose readings from devices to smartphone apps or Web-based platforms (“the Cloud”).

Remote Monitoring with Accu-Chek Connect System



Our Process- Set-up

Office

- Staff R&R
- Workflow
- System

Patient

- ID Pilot Patient
- Cost
- Clinical

On-Board Patient

- System

Roles and Responsibilities

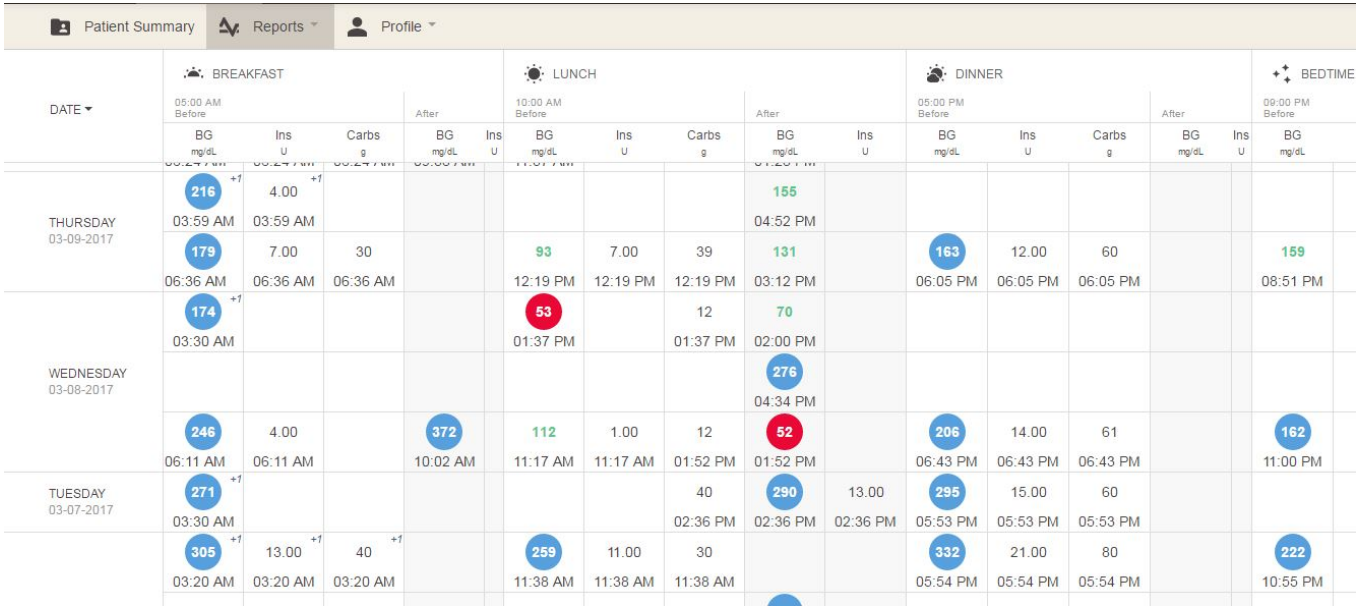
Point of contact	Medical assistant or physician extender
Point of decision	Physician extender, case manager, or certified diabetes educator
Supervision of process	Physician, pharmacist, certified diabetes educator, or other qualified staff member
Coordination of care	Case manager, medical assistant, or other qualified staff member
Quality control	Case manager, physician, or other qualified staff member

CCM Nurse
Dashboards to screen patients

	11-21-1932	CCM10	Insulin	185 +/- 51 mg/dL	2.3	03-09-2017	— ↑	✎
	10-27-1950	CCM8	Multiple Daily Injections (MDI or ICT), Diet, Exercise	166 +/- 61 mg/dL	2.2	03-10-2017	— ↑	✎
	12-25-1932	CCM1	Insulin, Diet	249 +/- 83 mg/dL	3.1	03-04-2017	↑	✎
	01-19-1938	CCM2	Basal / Bolus (Long-Acting and Rapid-Acting)	209 +/- 65 mg/dL	2.8	03-04-2017	↑	✎
	12-01-1970	WCB7	Insulin	141 +/- 56 mg/dL	2.4	03-10-2017	— ↑	✎
	07-31-1989	WCB4	Insulin	347 +/- 165 mg/dL	1.4	03-10-2017	— ↑	✎
	03-23-1957	CCM4	Diet, Basal / Bolus (Long-Acting and Rapid-Acting)	217 +/- 68 mg/dL	0.7	03-10-2017	— ↑	✎
	09-09-1965	CCM3	Multiple Daily Injections (MDI or ICT), Diet	194 +/- 86 mg/dL	6.7	03-10-2017	↓ ↑	✎

Patients per Page 25 ▾ ◂ 1 ▸

Logbook views for individual patients



Patient Summary | Reports | Profile

DATE	BREAKFAST 05:00 AM Before			After		LUNCH 10:00 AM Before			After		DINNER 05:00 PM Before			After		BEDTIME 09:00 PM Before
	BG mg/dL	Ins U	Carbs g	BG mg/dL	Ins U	BG mg/dL	Ins U	Carbs g	BG mg/dL	Ins U	BG mg/dL	Ins U	Carbs g	BG mg/dL	Ins U	BG mg/dL
THURSDAY 03-09-2017	216 +1 03:59 AM	4.00 +1 03:59 AM							155 04:52 PM							
	179 06:36 AM	7.00 06:36 AM	30 06:36 AM			93 12:19 PM	7.00 12:19 PM	39 12:19 PM	131 03:12 PM		163 06:05 PM	12.00 06:05 PM	60 06:05 PM			159 08:51 PM
	174 +1 03:30 AM					53 01:37 PM		12 01:37 PM	70 02:00 PM							
WEDNESDAY 03-08-2017									276 04:34 PM							
	246 06:11 AM	4.00 06:11 AM		372 10:02 AM		112 11:17 AM	1.00 11:17 AM	12 01:52 PM	52 01:52 PM		206 06:43 PM	14.00 06:43 PM	61 06:43 PM			162 11:00 PM
TUESDAY 03-07-2017	271 +1 03:30 AM							40 02:36 PM	290 02:36 PM	13.00 02:36 PM	295 05:53 PM	15.00 05:53 PM	60 05:53 PM			
	305 +1 03:20 AM	13.00 +1 03:20 AM	40 +1 03:20 AM			259 11:38 AM	11.00 11:38 AM	30 11:38 AM			332 05:54 PM	21.00 05:54 PM	80 05:54 PM			222 10:55 PM

Tool developed for Care Managers

Do they have Glucagon Kit? (Y/N)				
If no, is it Ok to send in an order for one? (Y/N)				
When to notify physician of blood glucose parameters		Call Patient	Call Physician	If a weekly trend, notify physician
Severe Hyperglycemia/Needs Intervention	>300	X	X	X
Hyperglycemia-trend	201-300		X	X
Mild Hyperglycemia	150-200			X
Target Blood Glucose	70-150			
Mild Hypoglycemia	60-69			X
Hypoglycemia-Trend	56-60		X	X
Severe Hypoglycemia	<55	X	X	X
Adherence Notice: Patient has not synced meter:	Call Patient	Call Physician		
No data within 1 Day	X			
No data within 5 Days		X		
Frequency of taking own blood glucose reading:				
Less than 2 times per day	X			
Less than 1 time per day		X		
Notes:				

Case Study 1

"Pick the very hardest patients first"

54 yo man with type 2 diabetes, multiple complications including:

Deaf / Mute
Diabetic retinopathy, now blind
ESRD on dialysis

Frequent ER visits for infections
Poor compliance with dialysis visits
Frequent ER visits and admissions for uncontrolled DM

Out of 17,719 patients, had 3rd highest cost of care

Case Study 1

"Pick the very hardest patients first"

Additional problems:

- Wife (caretaker) also deaf / mute
- Daughter was deaf / mute, ***but used an iPhone***
- Had home health agency which was not particularly effective

Opportunities :

- Daughter motivated to help, and willing to do blood testing.

Case Study 1

"Pick the very hardest patients first"

Daughter:

Instructed in home glucose testing
Instructed in insulin administration
Instructed in use of Roche Connect App

ACO Technical Staff

Linked daughter's phone to Connect App, and enrolled pt

ACO Care Managers

Monitor patient BG from their offices
Contact wife or daughter via service if BG out of range
Contact MD if insulin dose needs adjustment or for other medical issues arise.

Case Study 1

"Pick the very hardest patients first"

Results:

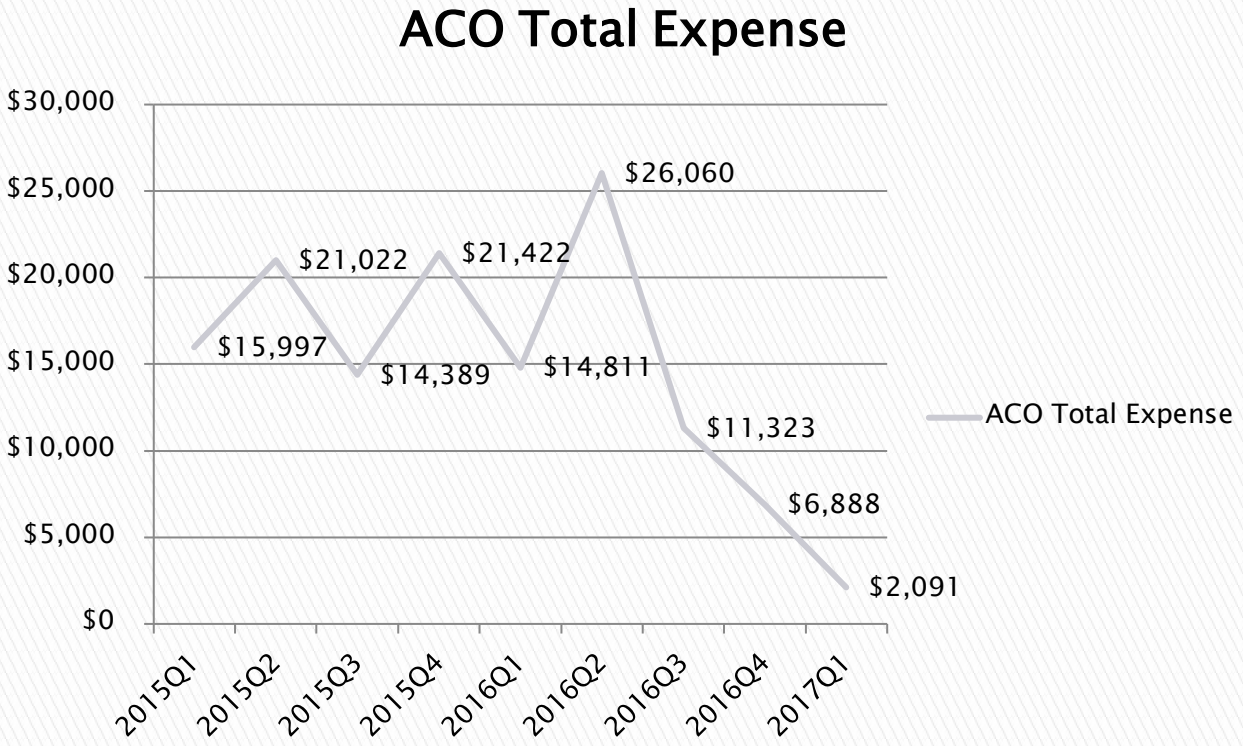
No further ER visits or admissions during duration of the study

Home Health Agency was felt to be unnecessary, and was discontinued

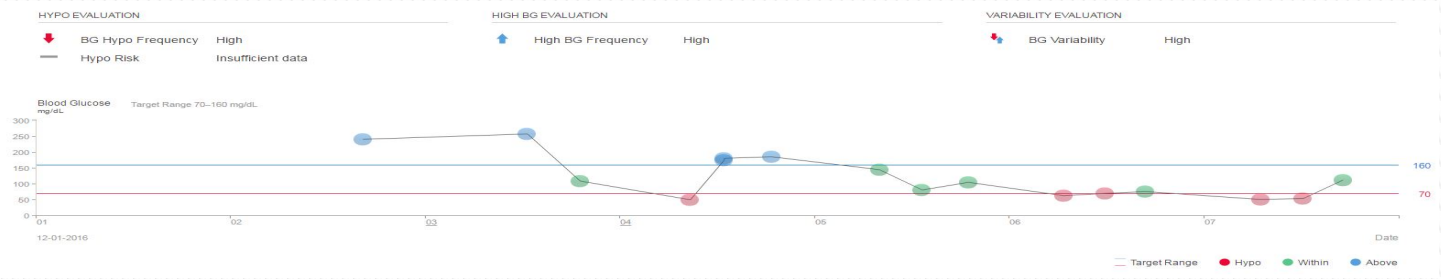
No further skin infections

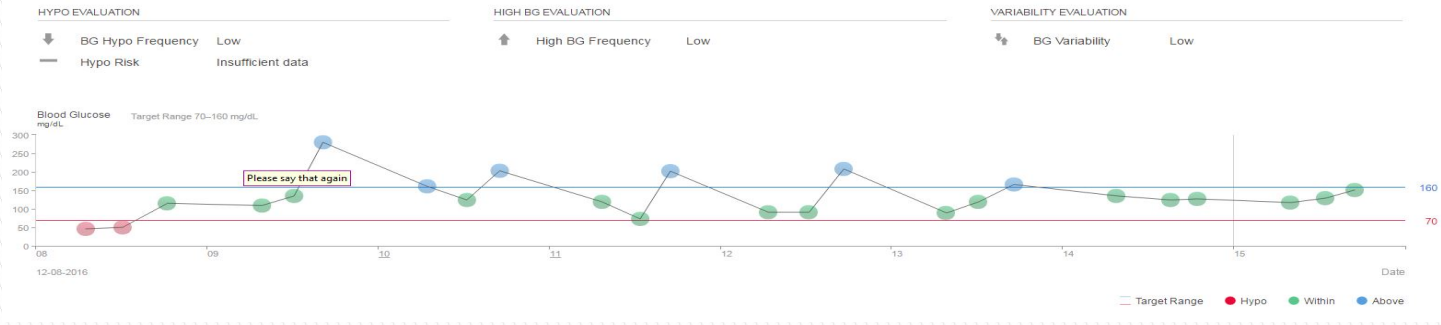
No missed dialysis appointments

Quarterly Expenses Pt 1



Case Study 2

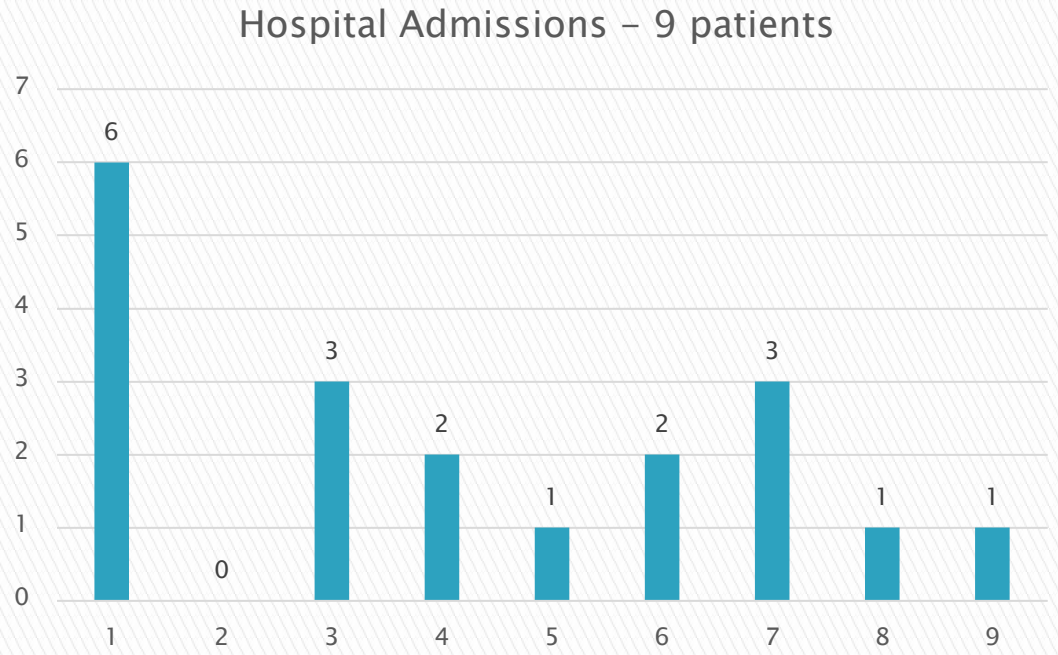




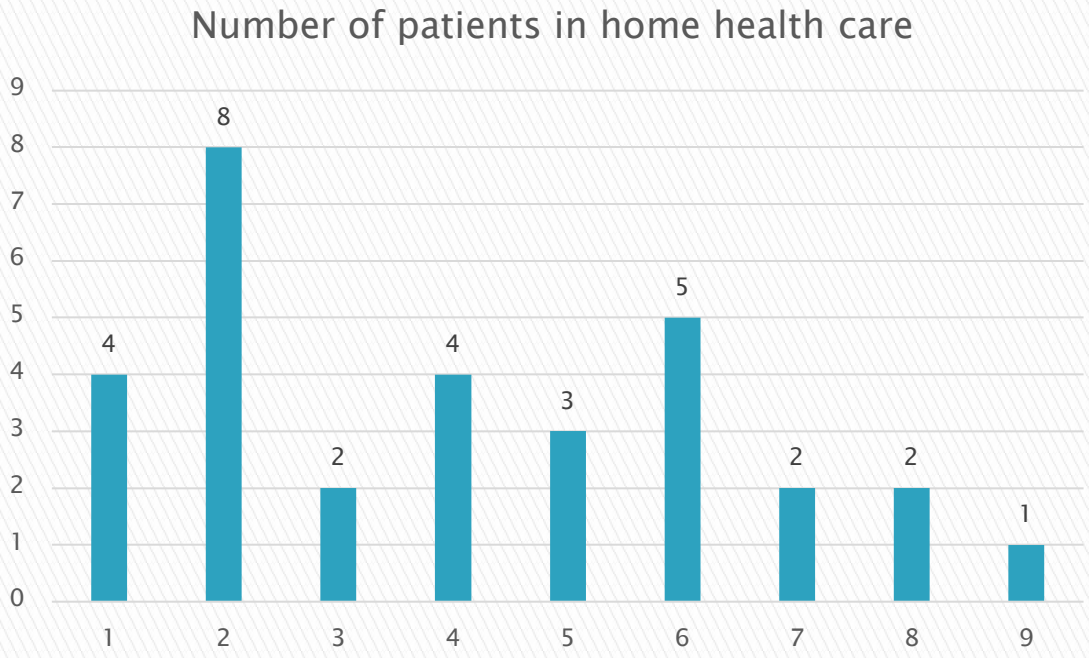
Reductions in steroid dose followed by lower BG, resulting in reduced insulin dose

Case Study 2
Most recent month

Hospital Admissions



Home Health Utilization



Overall results of all patients in pilot

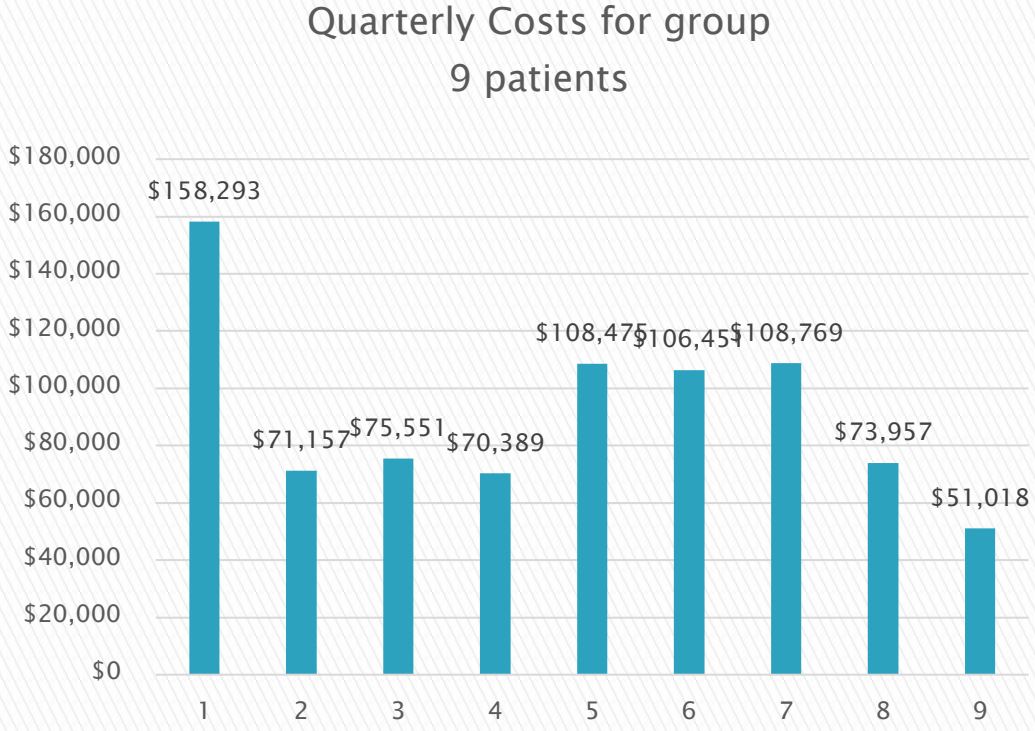


TABLE 1.

Changes in Total Costs, Hospital Expenses, and Home Health Agency Costs from 6 Months Before to 6 Months After the QIP Intervention ($n = 9$)

	6 Months Before QIP	6 Months After QIP	Change
Total	$215,325	$115,099	–$100,226
Total hospital costs	$86,121	$15,111	–$71,010
Non-ER hospital admissions	$36,738	$0	–$36,738
ER visits with hospital admissions	$49,383	$15,111	–$34,272
ER visits with no hospital admissions	$4,880	$4,638	–$242
Hospital outpatient services	$41,045	$31,933	–$9,112
Skilled nursing facilities	$1,047	$0	–$1,047
Home health agencies	$25,103	$17,754	–$7,349
Other Medicare Part B costs	$38,986	$28,080	–$10,906
Medicare Part D costs	$9,136	$14,294	$5,158
Durable medical equipment	$6,738	$3,292	–$3,446

Our ACO mHealth 2.0 Background

> The Diabetes Health Partnership (DHP) is a telephonic coaching program designed to extend the impact of diabetes patients' care team between office visits. All coaches are certified diabetes educators.

> The DHP program us the Patient Activation Measure® (PAM) to guide the content and frequency of coaching.

> The Patient Activation Measure (PAM) is a validated, 100-item questionnaire that assesses patient activation (scored: 0=low, 100=high) and reveals four levels of activation relevant to diabetes self-management: [1,2]

- > Level 1 - disengaged and overwhelmed
- > Level 2 - becoming aware but still struggling
- > Level 3 - taking action and gaining control
- > Level 4 - maintaining behaviors and pushing forward

1. Chrvala CA, et al. Patient Educ Couns 2016;99(6):926-943; 2. Garcia-Perez LE, et al. Diabetes Ther 2013;4(2):175-194; 3. Downing J, et al. J Med Internet Res 2017;19(7):e234; Castro Sweet CM, et al. J Aging Health 2018;18(5):692-710

Study Overview

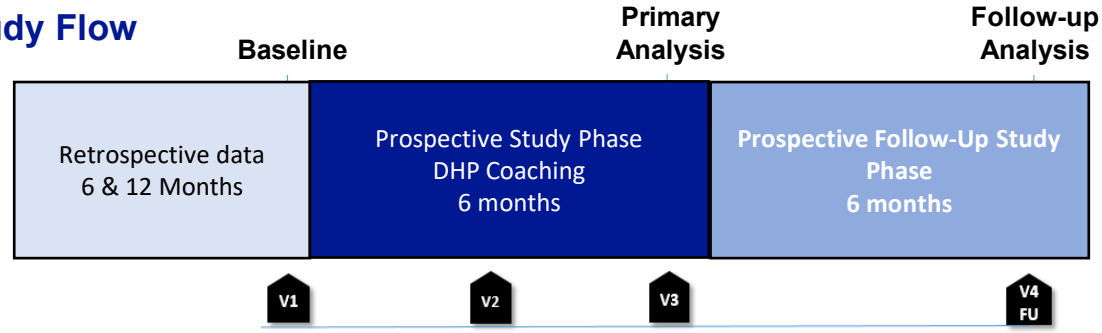
- **Study Design:**
  - 12-month, observational, self-controlled, multi-site study.
  - Combined retrospective and prospective data.
- **Outcomes:**
  - *Primary:*
    - Change in A1C from baseline at 6 months (Full Cohort)
    - Responder (≥0.5% reduction) vs. Non-Responder (<0.5% reduction)
  - *Secondary:*
    - Medical Costs
    - PAM Activation Measures
    - Patient Satisfaction
    - Medication Adherence
    - Coaching Utilization
    - Health Metrics

Study Overview

> Inclusion Criteria

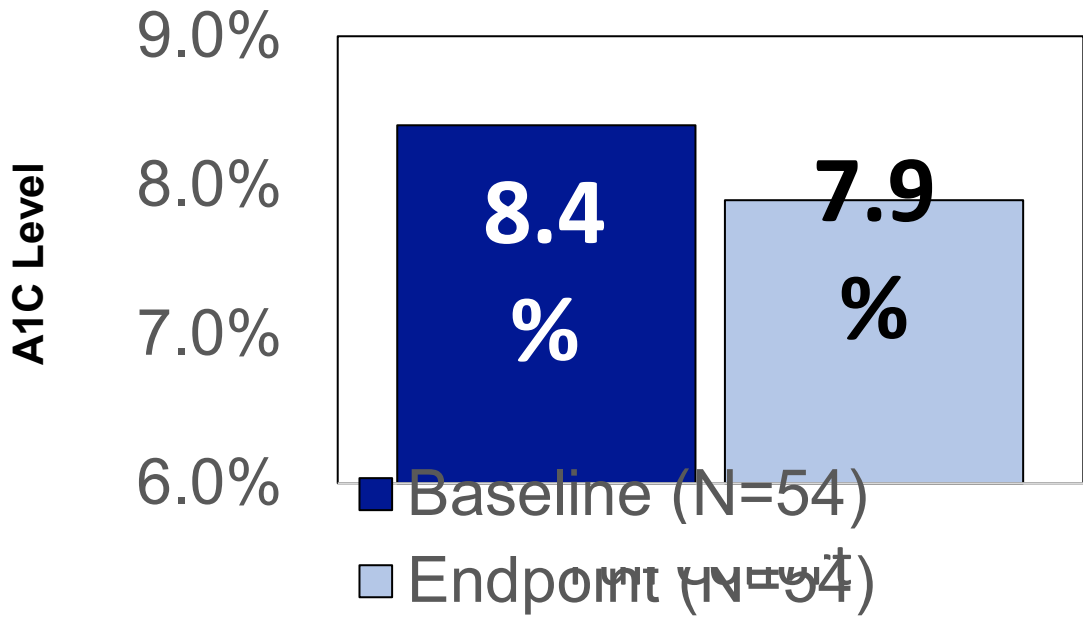
- ≥18 years
- T1D/T2D
- ≥7.5% A1C
- Medicare Fee-for-Service attributed in MSSP to ACO
- Top 50% cost category

> Study Flow



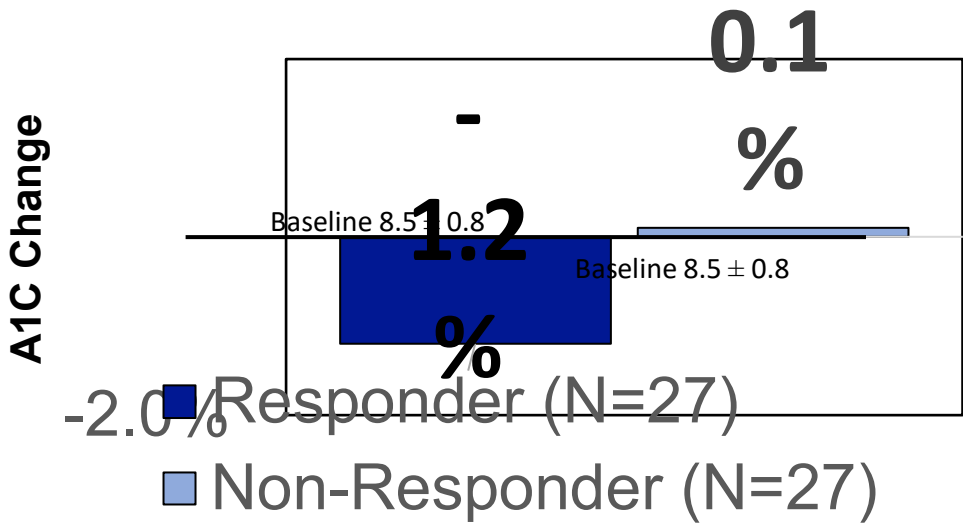
Results: A1C Change

Full Cohort



Results: *A1C Change*

Responders vs. Non-Responders



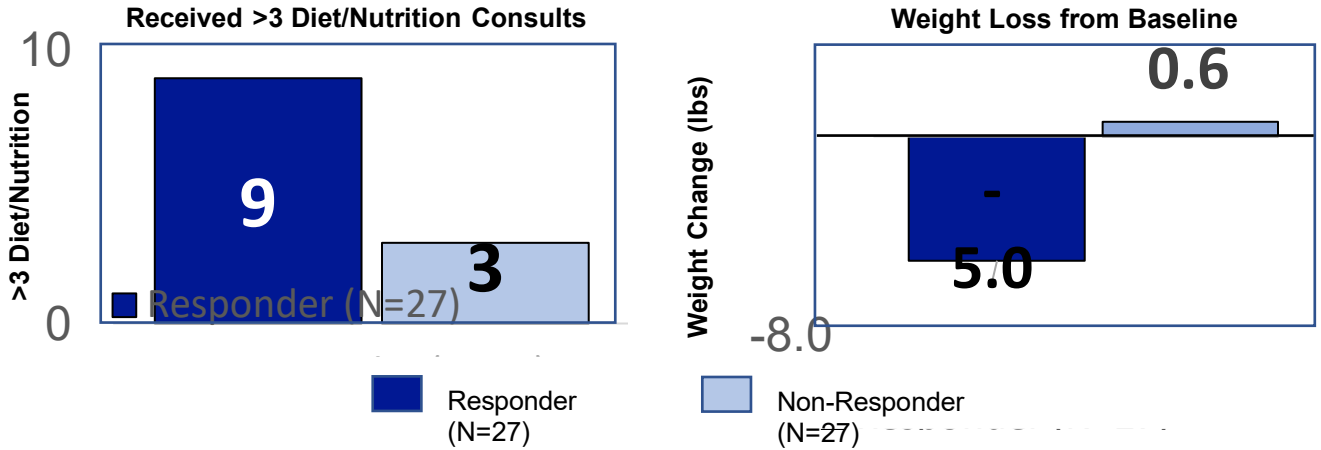
Results: *Other Metrics of Interest*

Responders vs. Non-Responders

> No change in medication adherence.

> Only between-group difference in medication changes was insulin.

> Notable between-differences in Diet/Nutrition consults and weight loss.



Summary

Properly designed remote patient monitoring :

- is an effective tool for treatment of health conditions such as diabetes

- Results in
  - Lower ER utilization
  - Lower hospitalization rates
  - Lower HHA and SNF utilization
  - Improved drug adherence
  - Lower overall costs

- When Care Coordination and Education/Coaching is included
  - Improved HbA1c measurements
  - Weight loss
  - Lower costs

Publications for more information

- Optimizing mHealth Technologies in Real-World Clinical Practices
  - Clinical Diabetes
  - 2019 Jul;37(3):269-275. https://doi.org/10.2337/cd18-0081
- Telephonic Coaching Is Associated with Improved Patient Activation in Diabetes Self-Management
  - Diabetes
  - https://doi.org/10.2337/db20-760-P
- Telephonic Coaching Is Associated with Improved Glycemic Control in Many Individuals with Type 1 and Type 2 Diabetes
  - Diabetes
  - https://doi.org/10.2337/db20-759-P

William C Biggs, MD FACE
william@amarilloaco.com

DIGITAL DIAGNOSTICS

AI the right way.

Transforming Healthcare through Automation

NAACOS

National Association of ACOs

Michelle Havinga (Director Population Health & ACO Ops UIHC)

- “COVID-19 had resulted in a diabetic eye exam backlog of approximately 200+ patients
- thanks to autonomous AI we were able to get all these patients seen within 6 weeks
- with IDx-DR we stayed on top of closing care gaps even during a pandemic
- Access to diabetic eye exam is not a problem anymore because of the highly scalable capacity”

DIGITAL DIAGNOSTICS

The long road from ML science to autonomous AI in patient care

1989: Brain simulation using artificial neural networks
2000: First publication on diabetic retinopathy AI
2018: First FDA "approval" for autonomous AI

CAN NEURAL NETWORKS EXPLAIN DYSFLUENT SPEECH?

Maikl Abramoff, Ton Coolen, George Wieneke and Peggy Janssen

This pilot study is based on the assumption that stuttering is a disorder of s
motor control. Parameters of a neural network were varied in order to pr
simulations resembling stuttering behavior. A Hopfield network with ten
delays was used and a sequence of ten patterns was learned. These pa
were supposed to represent the control of muscles for an articulatory move
The following parameters of the network were varied systematically: noise
simulated neurons and the ratio (v) between the delay in the neural conn
and the duration during which the patterns were realized in the network
learning phase. Moreover the similarity between the patterns was v
Abnormalities in the network output were found for certain combinatio
parameter values. However, these abnormalities showed no clear resemblar
stuttering behavior. Noise had only a very moderate effect. When the subse
patterns were correlated, an increase in the value of the parameter v resul
increased temporal variability and increased duration of the production of a
of ten patterns.

Recently, artificial neural networks have received a great deal of
from various disciplines (Amit, 1989). This study illustrates the use o
network for simulating the temporal organization of speech in r
stuttering. More specifically, it addresses the question, whether the ne
be influenced in such a way that behavior resembling stuttering will
modification of the original Hopfield type neural network was chosen t
the temporal aspects of motor systems. By introducing delay
connections between the neurons, sequences of patterns can be st
reproduced at a later time (Coolen & Gielen, 1988). It is assumed
pattern in a sequence represents the information necessary for
articulatory movements from one phoneme to the next (Braamhof, 198

Neural network

Generally a neuronal network consists of a collection of neurons,
interconnected by axons ending in synapses on dendrites. In the Hop
network these parts are all represented rather simply (Hopfield, 1982)
are discrete on/off threshold units. That is to say, a neuron only fi
summation of all of its inputs is higher than some threshold. All neuron

15 ABSTRACTS

LOW LEVEL SCREENING OF EXSUDATES AND HAEMORRAGHES IN BACKGROUND DIABETIC RETINOPATHY

M.D. Abramoff[1,2,3], MD MSc, J.J. Staal[2,3], MSc, M.S. Suttorp[1], MD PhD, B.C.P. Polak, MD PhD, M.A. Viergever, PhD

Dept. of Ophthalmology and Diabetes Cer
University Hospital, Amsterdam, Netherla
Image Sciences Institute, University Hosp
I2 Engineering, Amstelveen, Netherlands

Purpose: to develop a fast and reliable m
images on exsudates and haemorraghes
retinopathy
Methods: a differential topology based, s
operator was used to obtain geometrical f
images (Canon non-mydriatic fundus cam
JPEG decompressed). Using this operato
Hessian and the structure tensor were ma
multidimensional probability measure

$$f_i = prob(\Gamma(H_\sigma(\lambda_i \ldots \lambda_n$$

The operator is constructed in such a way
yellowish ellipsoid structures (20-520μm)
Results: 500 images were used for optim
were found to correspond closely to the e

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FDA NEWS RELEASE

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

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For Immediate Release: April 11, 2018

Español

The U.S. Food and Drug Administration today permitted marketing of the first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

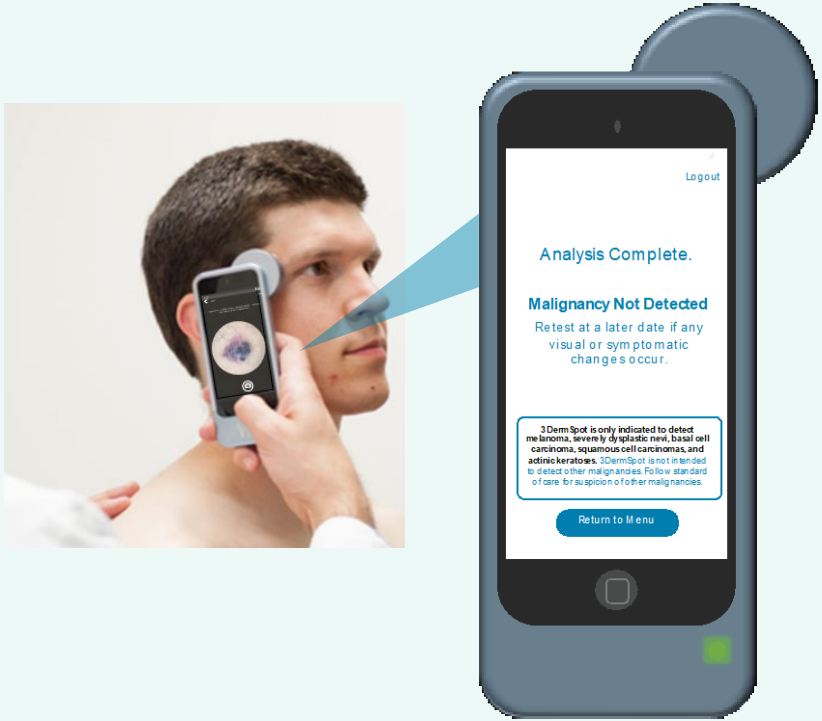
DIGITAL DIAGNOSTICS

Abramoff MD. Spatiotemporal correlation and the cerebellum. In: KOHONEN T, MÄKISARA K, SIMULA O, Jari KANGAS, editors. Artificial Neural Networks. II. North-Holland: IEEE - INNS International joint conference on neural networks; 1991. p. 1739-42.
Abramoff et al, Proc. CAFIA 2000, Copenhagen, Denmark, 2000,, pp15

Company Overview

- **Company Name:** Digital Diagnostics Inc.
- **Headquarters:** Coralville, Iowa, U.S.
- **Founded:** 2010
- **Mission:** To transform the affordability, accessibility and quality of healthcare through the automation of medical diagnosis and treatment
- **Founder and Executive Chairman:** Michael D. Abramof, MD,PhD
- **CEO:** John Bertrand
- **President and COO:** Seth Rainford

Digital Diagnostics Autonomous AI Platform for early diagnosis & care gap closure



3DermSpot: Skin cancers

IDx-DR: Diabetic Retinopathy and macular edema

DIGITAL DIAGNOSTICS

Artificial Intelligence: Autonomous vs Assistive

Autonomous

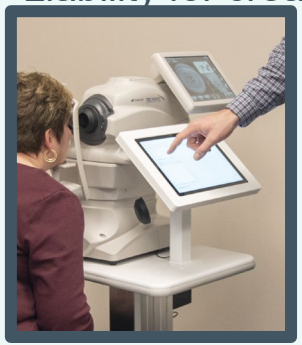
Medical decision by AI

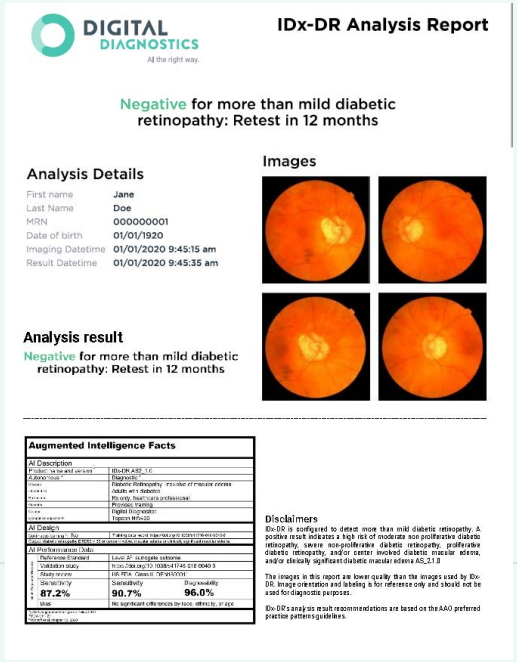
No human oversight

Instantaneous

Point of Care

Liability for creator





DIGITAL DIAGNOSTICS

All the right way.

IDx-DR Analysis Report

Negative for more than mild diabetic retinopathy: Retest in 12 months

Analysis Details

First name	Jane
Last Name	Doe
MRN	000000001
Date of birth	01/01/1920
Imaging Datetime	01/01/2020 9:45:15 am
Result Datetime	01/01/2020 9:45:35 am

Images

Analysis result

Negative for more than mild diabetic retinopathy: Retest in 12 months

Augmented Intelligence Facts

AI Description

AI Design

AI Performance Data

Reference Standard	Level A* outregate outcome	
Validation study		
Study scope		
Sensitivity	Sensitivity	Specificity
87.2%	90.7%	96.0%
Bias	No significant differences by race, ethnicity, or age	

Disclaimers

IDx-DR is configured to detect more than mild diabetic retinopathy. A positive result indicates a high risk of moderate non proliferative diabetic retinopathy, severe non-proliferative diabetic retinopathy, proliferative diabetic retinopathy, and/or center involved diabetic macular edema, and/or clinically significant diabetic macular edema AS_2.1.0

The images in this report are lower quality than the images used by IDx-DR. Image orientation and labeling is for reference only and should not be used for diagnostic purposes.

IDx-DR's analysis result recommendations are based on the AAO preferred practice patterns guidelines.

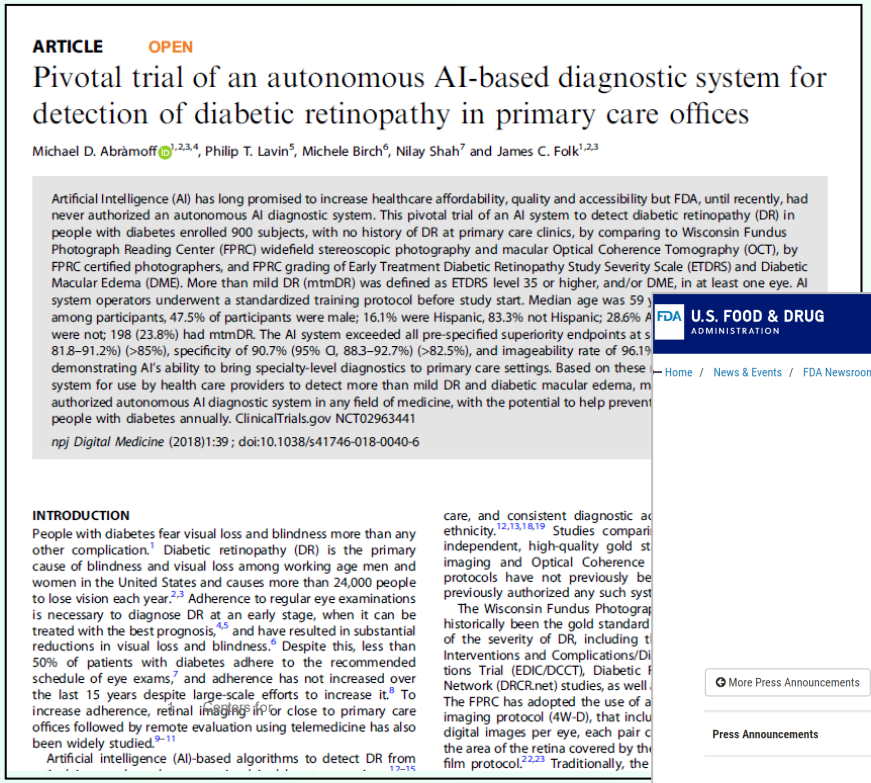
Assistive

Clinician needed

Medical decision by clinician

Liability for clinician

2017: First Preregistered Trial for autonomous AI
2018: First De Novo Authorization for Autonomous AI



ARTICLE OPEN

Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices

Michael D. Abràmoff[1,2,3,4], Philip T. Lavin[5], Michele Birch[6], Nilay Shah[7] and James C. Folk[1,2,3]

Artificial Intelligence (AI) has long promised to increase healthcare affordability, quality and accessibility but FDA, until recently, had never authorized an autonomous AI diagnostic system. This pivotal trial of an AI system to detect diabetic retinopathy (DR) in people with diabetes enrolled 900 subjects, with no history of DR at primary care clinics, by comparing to Wisconsin Fundus Photograph Reading Center (FPRC) widefield stereoscopic photography and macular Optical Coherence Tomography (OCT), by FPRC certified photographers, and FPRC grading of Early Treatment Diabetic Retinopathy Study Severity Scale (ETDRS) and Diabetic Macular Edema (DME). 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. Median age was 59 y among participants, 47.5% of participants were male; 16.1% were Hispanic, 83.3% not Hispanic; 28.6% A were not; 198 (23.8%) had mtmDR. The AI system exceeded all pre-specified superiority endpoints at s 81.8–91.2%) (>85%), specificity of 90.7% (95% CI, 88.3–92.7%) (>82.5%), and imageability rate of 96.1 demonstrating AI's ability to bring specialty-level diagnostics to primary care settings. Based on these system for use by health care providers to detect more than mild DR and diabetic macular edema, m authorized autonomous AI diagnostic system in any field of medicine, with the potential to help prevent people with diabetes annually. ClinicalTrials.gov NCT02963441

npj Digital Medicine (2018)1:39 ; doi:10.1038/s41746-018-0040-6

INTRODUCTION

People with diabetes fear visual loss and blindness more than any other complication.[1] Diabetic retinopathy (DR) is the primary cause of blindness and visual loss among working age men and women in the United States and causes more than 24,000 people to lose vision each year.[2,3] Adherence to regular eye examinations is necessary to diagnose DR at an early stage, when it can be treated with the best prognosis,[4,5] and have resulted in substantial reductions in visual loss and blindness.[6] Despite this, less than 50% of patients with diabetes adhere to the recommended schedule of eye exams,[7] and adherence has not increased over the last 15 years despite large-scale efforts to increase it.[8] To increase adherence, retinal imaging in or close to primary care offices followed by remote evaluation using telemedicine has also been widely studied.[9–11]

Artificial intelligence (AI)-based algorithms to detect DR from

care, and consistent diagnostic a ethnicity.[12,13,18,19] Studies compari independent, high-quality gold st imaging and Optical Coherence protocols have not previously be previously authorized any such syst

The Wisconsin Fundus Photograp historically been the gold standard of the severity of DR, including t Interventions and Complications/Di tions Trial (EDIC/DCCT), Diabetic F Network (DRCR.net) studies, as well The FPRC has adopted the use of a imaging protocol (4W-D), that inclu digital images per eye, each pair c the area of the retina covered by th film protocol.[22,23] Traditionally, the

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Español

The U.S. Food and Drug Administration today permitted marketing of the first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

Intention to Diagnose cohort study.

A Randomized Clinical Trial would have been unethical (requires leaving one arm untreated)

Abràmoff MD, Lavin PT, Birch M, Shah N, Folk JC. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. Nature Digit Med 2018;1:39off Lavin PT, Birch M, Shah N, Folk JC. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. Nature Digit Med 2018;1:39,

2020: Autonomous AI in Standard of Diabetes Care

American Diabetes Association. Diabetes Care

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Position Statements

11. Microvascular Complications and Foot Care: *Standards of Medical Care in Diabetes–2020*

American Diabetes Association
Diabetes Care 2020 Jan; 43(Supplement 1): S135-S151.
https://doi.org/10.2337/dc20-S011

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Abstract

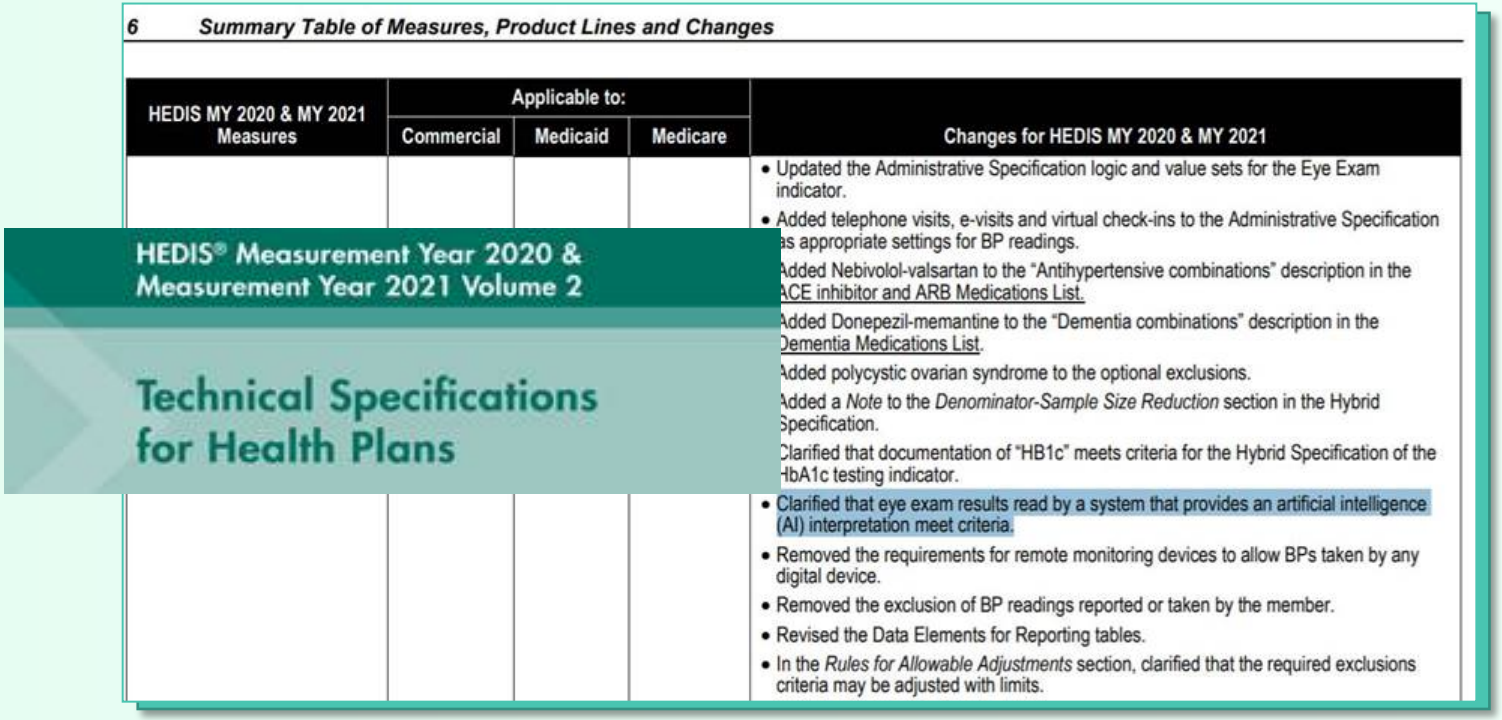
The American Diabetes Association (ADA) "Standards of Medical Care in Diabetes" includes the ADA's current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care. Members of the ADA Professional Practice Committee, a multidisciplinary expert committee

11.17 […] Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches

115. Abràmoff MD, Lavin PT, Birch M, Shah N, Folk JC. Pivotal trial of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. NPJ Digit Med 2018;1:39

American Diabetes Association. 11. Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes − 2020. Diabetes Care; 43(Supplement 1): S135-S151, 2020. https://care.diabetesjournals.org/content/43/Supplement_1/S135

2020: Autonomous AI closes HEDIS/MIPS care gaps



6 *Summary Table of Measures, Product Lines and Changes*

HEDIS MY 2020 & MY 2021 Measures	Applicable to: Commercial	Medicaid	Medicare	Changes for HEDIS MY 2020 & MY 2021
				• Updated the Administrative Specification logic and value sets for the Eye Exam indicator. • Added telephone visits, e-visits and virtual check-ins to the Administrative Specification as appropriate settings for BP readings. • Added Nebivolol-valsartan to the "Antihypertensive combinations" description in the ACE inhibitor and ARB Medications List. • Added Donepezil-memantine to the "Dementia combinations" description in the Dementia Medications List. • Added polycystic ovarian syndrome to the optional exclusions. • Added a *Note* to the *Denominator-Sample Size Reduction* section in the Hybrid Specification. • Clarified that documentation of "HB1c" meets criteria for the Hybrid Specification of the HbA1c testing indicator. • Clarified that eye exam results read by a system that provides an artificial intelligence (AI) interpretation meet criteria. • Removed the requirements for remote monitoring devices to allow BPs taken by any digital device. • Removed the exclusion of BP readings reported or taken by the member. • Revised the Data Elements for Reporting tables. • In the *Rules for Allowable Adjustments* section, clarified that the required exclusions criteria may be adjusted with limits.

HEDIS® Measurement Year 2020 & Measurement Year 2021 Volume 2

Technical Specifications for Health Plans

https://www.ncqa.org/wp-content/uploads/2020/07/20200701_Summary_Table_of_Measures_Product_Lines_and_Changes.pdf

2020: CMS will cover and pay for autonomous AI

Proposed CMS Rule for OPPS and PFS Will Allow First-Ever Reimbursement of Autonomous AI in a Healthcare Setting, for the diabetic eye exam

The AMA CPT Editorial Panel also created CPT code 9225X (Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral) for point-of-care automated analysis that uses innovative artificial intelligence technology to perform the interpretation of the eye exam, without requiring that an ophthalmologist interpret the results.

CPT code 9225X can be used at a primary care practice site and the artificial intelligence technology interprets the test instead of a remotely located ophthalmologist. Because no physician is involved, this service is PE only. We are considering CPT code 9225X to be a diagnostic service under the PFS and are creating separate payment for it. (page 271ff)

https://www.cms.gov/files/document/cms-1734-p-pdf.pdf

Autonomous AI's bio-ethical foundation: from *principles*…

Ethical principles

- Non-maleficence
- Autonomy
- Justice

Legal principle

- Accountability

Abramoff MD, Tobey D, Char DS. Lessons Learned About Autonomous AI: Finding a Safe, Efficacious, and Ethical Path Through the Development Process. *Am J Ophthalmol.* 2020 [in press]

… to autonomous AI *requirements*

- **Improve** patient outcome shown by direct evidence or linked clinical literature; aligned with evidence based clinical standards of care/practice patterns, while accounting for **safety, efficacy and equity**

- **Design** so operations are maximally reducible to characteristics aligned with scientific knowledge of human clinician cognition

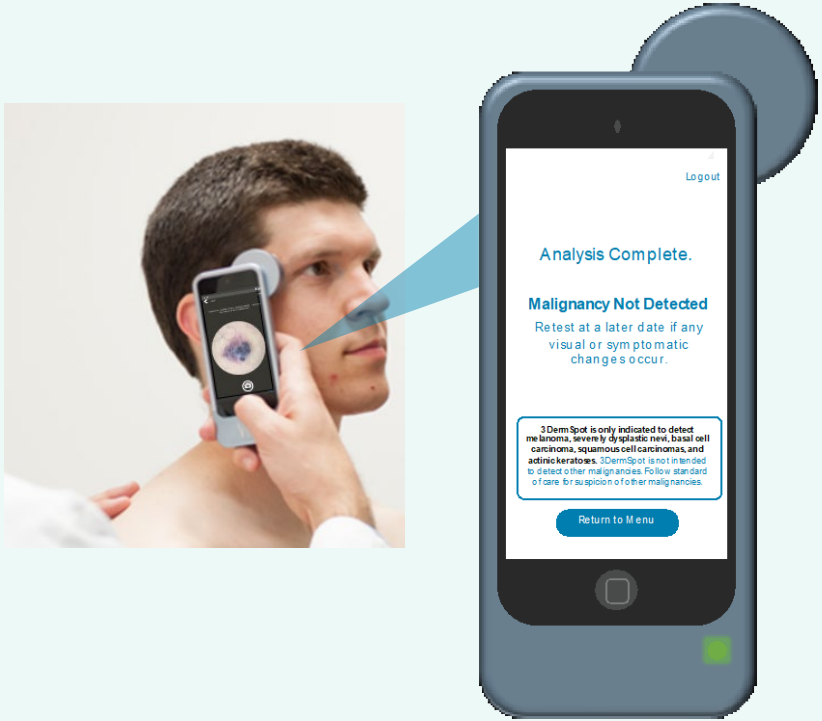
- **Maximize** traceability of patient derived data, and commensurate data stewardship

- **Validate rigorously** for safety, efficacy and equity, using preregistered clinical studies, comparing the AI against clinical outcome, in the intended clinical workflow and usage

- **Align** liability or other protections commensurate with indications for use and autonomy

Abramoff MD, Tobey D, Char DS. Lessons Learned About Autonomous AI: Finding a Safe, Efficacious, and Ethical Path Through the Development Process. *Am J Ophthalmol.* 2020 [in press]

Digital Diagnostics Autonomous AI Platform for early diagnosis & care gap closure



3DermSpot: Skin cancers

IDx-DR: Diabetic Retinopathy and macular edema

DIGITAL DIAGNOSTICS

Platform of instantaneous intake diagnostics enabled by autonomous AI

Autonomous

Instantaneous

- Point of care diagnoses / triages
- In-network cascade of high value episodes

High program integrity

- Instantaneous CPT coding and claims
- Instantaneous care gap closure
- Instantaneous RAF/HCC increases

Infinitely scalable

- Minimally trained operators
- Less staff for f/u scheduling / result chasing etc

High quality of care

- FDA approval / validation in clinical trials for safety, efficacy and equity
- Minimize patient copays for referrals

Telemedicine

24-72 hours delay for each diagnostic

- Many non-billable extra episodes
- Involvement of out-of-network providers
- Patients incur extra copays

Problematic program integrity

- Care gap closure dependent on coding by clinician
- CPT coding and claims dependent on clinician

Minimally scalable

- hard-to-get clinicians
- Extra staff for f/u scheduling / result chasing

Unknown quality of care

- Unknown equity / disparities
- Never validated

DIGITAL DIAGNOSTICS

Diabetes is a large and growing problem in the US.[1,2]

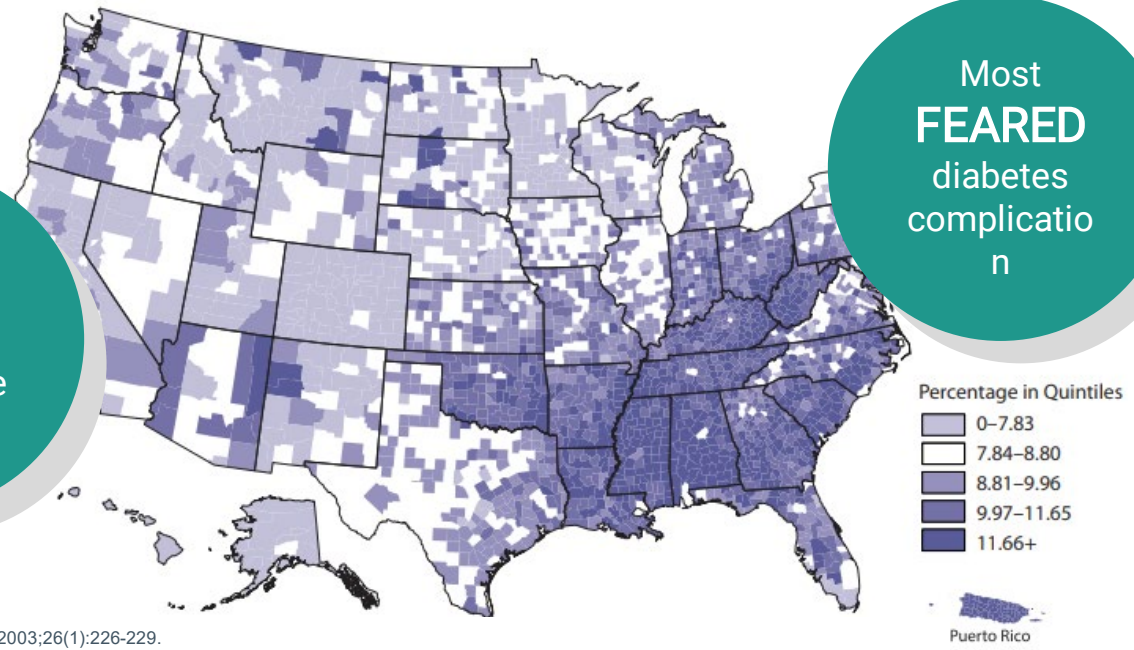
Blindness from diabetes is preventable.

60,000 Americans blind every year

34.2 million people have diabetes [3,4]

Most **FEARED** diabetes complication

Diagnosed Diabetes Prevalence among US Adults [3]



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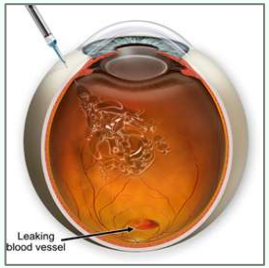
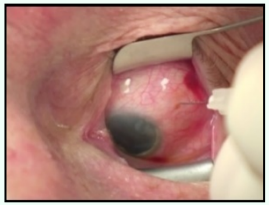
Centers for Disease Control and Prevention. *Diabetes Report Card 2012.* Atlanta, GA: U.S. Department of Health and Human Services;2012
The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med.* 1993;329(14):977-986.
Vision Health Initiative | Economic Studies." U.S. Centers for Disease Control level distribution of diagnosed diabetes among US adults aged 20 or older, 2013.
https://www.cdc.gov/diabetes/pdfs/library/diabetesreportcard2017-508.pdf. Accessed June 18, 2020.
Image from: CDC Infographics. A Snapshot: Diabetes in the United States. https://www.cdc.gov/diabetes/library/socialmedia/infographics/diabetes.html Accessed June 18, 2020

Diabetic Eye Exams Improve Visual Outcome

- Regular eye examinations are necessary to diagnose DR at an early stage, when it can be treated with the best prognosis and therefore the best outcome.[1,2]
- Population based eye exams, with compliance > 70%, result in substantial reductions in visual loss and blindness from diabetes and improves vision outcomes at the population level.[3,4]
- Diabetic eye exams are the most cost-effective intervention for diabetes complications.[5-7]
- The cost-effectiveness of all treatments for diabetic macular edema are high, starting at $7000 per QALY.[8]





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7. Lairson DR, Pugh JA, Kapadia AS, Lorimor RJ, Jacobson J, Velez R. Cost-effectiveness of alternative methods for diabetic retinopathy screening. *Diabetes Care*. 1992;15(10):1369-1377.
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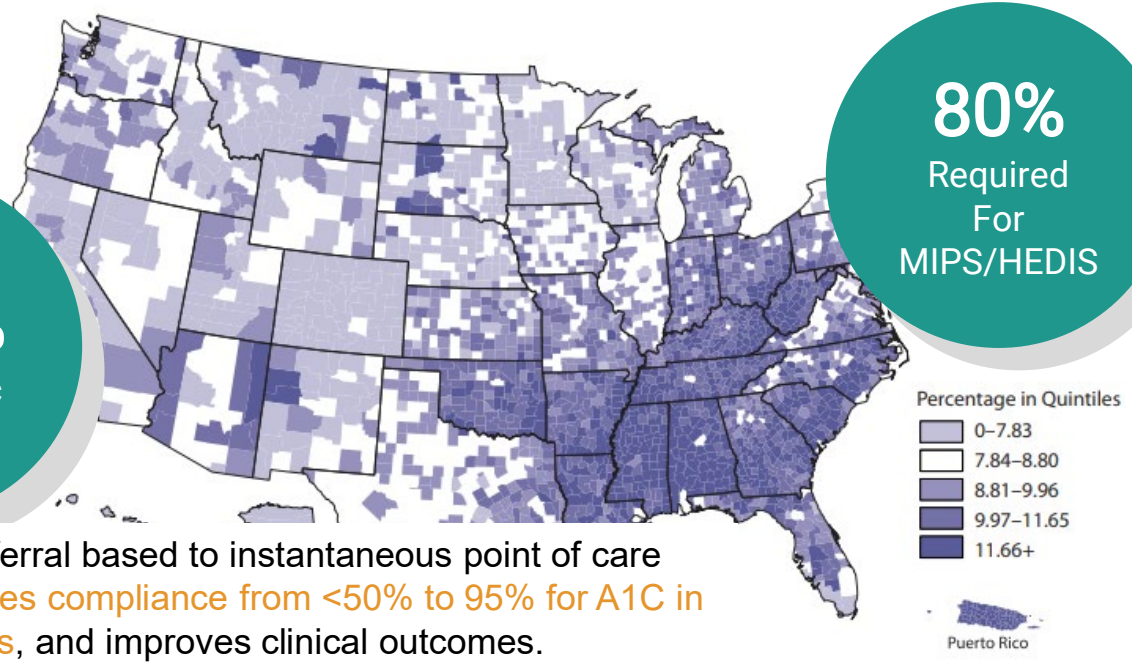
DIGITAL DIAGNOSTICS

DIGITAL DIAGNOSTICS

Diabetic Eye Exam remains ‘most difficult to close HEDIS/MIPS gap’

60,000
Americans blind every year

Only **15.3%** get diabetic eye exam



80%
Required For MIPS/HEDIS

- Shifting from lab referral based to instantaneous point of care A1C testing increases compliance from <50% to 95% for A1C in people with diabetes, and improves clinical outcomes.

1. Benoit SR, Swenor B, Geiss LS, Gregg EW, Saaddine JB. Eye Care Utilization Among Insured People With Diabetes in the U.S., 2010-2014. Diabetes Care. 2019;42(3):427-433.
2. Hatef, Vanderver, Fagan, Albert, Alexander. Annual Diabetic Eye Examinations in a Managed Care Medicaid Population. American Journal of Managed Care, 2015
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4. Lian J, Liang Y. Diabetes management in the real world and the impact of adherence to guideline recommendations. *Curr Med Res Opin.* 2014;30(11):2233-2240.
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Large Health Inequities in Diabetic Retinopathy

Affects groups differentially, and large differences in:

- Diabetes incidence and prevalence
- Diabetic retinopathy incidence
- Compliance w/ eye exams
- Visual loss from diabetic retinopathy

Trifecta of vulnerability:

- *Higher risk for getting diabetes*
- *More severe diabetic retinopathy*
- *Less diabetic eye exams*

Some examples:

- In Black Americans, diabetes prevalence 20.4% (95% CI, 18.8%-22.1%), almost twice of that of white Americans
- Diabetes prevalence U.S. Hisps 22.1% (95% CI, 19.6%-24.7%)
- Black Americans 2.5x risk of developing DR at equal A1C
- Compliance among the Black American population to have diabetic eye exams is less than of all other groups

1. Cheng YJ, Kanaya AM, Araneta MRG, Saydah SH, Kahn HS, Gregg EW, et al. Prevalence of Diabetes by Race and Ethnicity in the United States, 2011-2016. JAMA. 2019;322(24):2389-98.
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DIGITAL DIAGNOSTICS

The IDx-DR Point-of-Care Diagnostic System is the first ever FDA cleared fully autonomous AI system for the diagnosis of DR[1]

Fully autonomous AI

- ✓ Diagnoses diabetic retinopathy & macular edema
- ✓ Instantaneous point-of-care diagnostic result, takes 5-10 min
- ✓ No specialist overread or reading network required
- ✓ Fully integrated with Electronic Medical Records (EMRs)

Designed for mini-mally trained operator

- ✓ Assistive AI for operator for image quality and field—easy to use
- ✓ Robotic retinal camera
- ✓ 88% diagnosability without dilation
- ✓ Scalable across the Organization

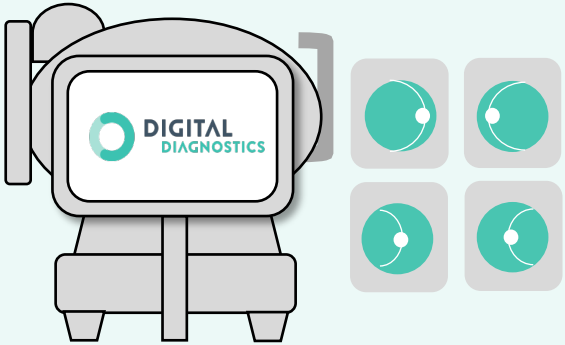
Bring DR Testing to ACO members where they get their diabetes care

Primary Care | Retail Health Centers | Pharmacies

1 Abramoff et al. Pivotal trail of an autonomous AI-based diagnostic system for detection of diabetic retinopathy in primary care offices. Npj Digital Medine. (2018)1:39; doi:10.1038/s41746-018-0040-6.

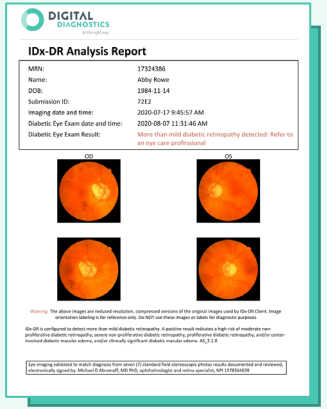
Digital Diagnostics' Platform with IDx-DR increases access to streamline referrals and close care gaps

Image Capture (eyes) → Diagnostic Evaluation → Results & Triage



Negative :
Re-test in 12 months

Diabetic retinopathy or macular edema: Refer to eye care provider


DIGITAL DIAGNOSTICS

IDx-DR Analysis Report

MRN:	17324386
Name:	Abby Rowe
DOB:	1984-11-14
Submission ID:	72E2
Imaging date and time:	2020-07-17 9:45:57 AM
Diabetic Eye Exam date and time:	2020-08-07 11:31:46 AM
Diabetic Eye Exam Result:	More than mild diabetic retinopathy detected: Refer to an eye care professional

OD OS

Using the robotic fundus camera, the minimally-trained operator captures two images per eye of an eligible* patient during vitals or rooming

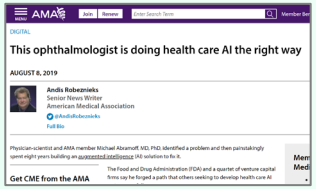
FDA-de novo cleared IDx-DR AI diagnoses patient. Results available in 30 seconds and sent directly to EHR. No specialist over-read required

- ✓ PDF/EHR Report with easy to read results
- ✓ Patient referral care based on results
- ✓ Provider bills as indicated including quality measure capture

DIGITAL DIAGNOSTICS

* IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy (mtmDR) in adults (22 years of age or older) diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400. Read the full indications for use.

IDx-DR Stakeholder Support

American Diabetes Association.	AMERICAN TELEMEDICINE ASSOCIATION	AMA	AMERICAN ACADEMY OF OPHTHALMOLOGY®	NCQA
ADA includes FDA-authorized AI in 2020 Standards of Medical Care in Diabetes 11.17 […] Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches (115).	"With the urgent need to provide high-quality, cost-effective screening to prevent avoidable blindness from diabetes, and the recent introduction of FDA-cleared fully autonomous diagnostics, the ATA expanded its ocular telehealth guidelines to provide a more comprehensive best practices around the use of AI."	AMA CPT ® Editorial Panel created first ever CPT® category 1 code for autonomous AI, on May 15, 2019 "This ophthalmologist is doing health care AI the right way"  AMA DIGITAL This ophthalmologist is doing health care AI the right way AUGUST 8, 2019 Andis Robeznieks Senior News Writer American Medical Association @AndisRobeznieks Full Bio Physician-scientist and AMA member Michael Abramoff, MD, PhD, identified a problem and then painstakingly spent eight years building an augmented intelligence (AI) solution to fix it. Get CME from the AMA The Food and Drug Administration (FDA) and a quartet of venture capital firms say he forged a path that others seeking to develop health care AI	"An IDx-DR exam can alert a patient that they have signs of diabetic retinopathy, making it far more likely they will enter the care of an ophthalmologist before it's too late."	HEDIS/MIPS CDC eye exam measure 2020 update to allow autonomous AI to close the care gap

American Diabetes Association. 11. Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes − 2020. Diabetes Care; 43(Supplement 1): S135-S151, 2020.
https://care.diabetesjournals.org/content/43/Supplement_1/S135
https://www.ncqa.org/wp-content/uploads/2020/07/20200701_Summary_Table_of_Measures_Product_Lines_and_Changes.pdf
https://www.ama-assn.org/practice-management/digital/ophthalmologist-doing-health-care-ai-right-way

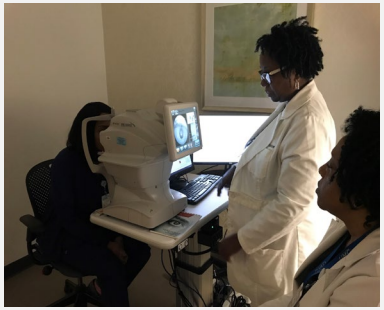
ACO Case Study: UMC in New Orleans

UMC participates in LHP ACO and is part of the LCMC Health System in New Orleans.
Community-based PCP facility with high rates of diabetes;most patients covered by Medicare and Medicaid.

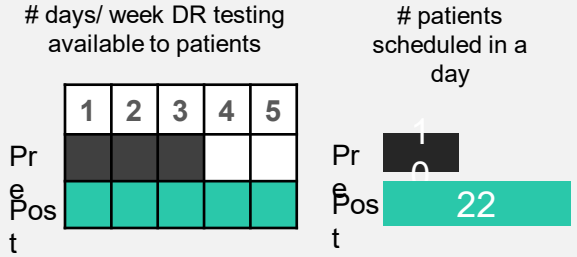
Background Situation

- Lack of ophthalmologists
- 4-month appointment wait time; frequent no shows

IDx DR System Implemented

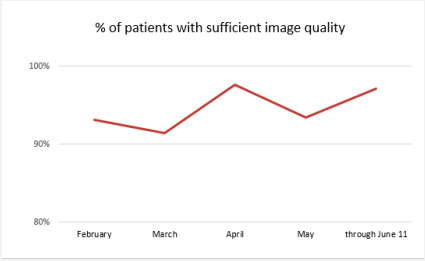


Impact on Backlog (Pre/ Post IDx)



High Diagnosability

Over 90% of images sufficient quality



Results after 9 months

- **Eliminated 4 month wait time**
- Same day appointments
- 25% patients informed they had a potentially blinding disease, providing opportunities for timely treatment.
- Reduced backlog for 805+ previously undiagnosed patients who were able to complete annual DR exam
- Moving an underserved population to served!

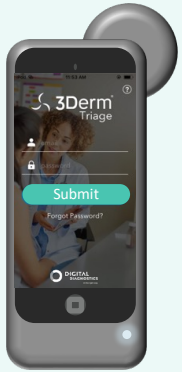
Provider Feedback

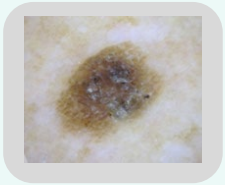
"We feel more confident about the referrals we are making because we can rely on IDx DR's results."

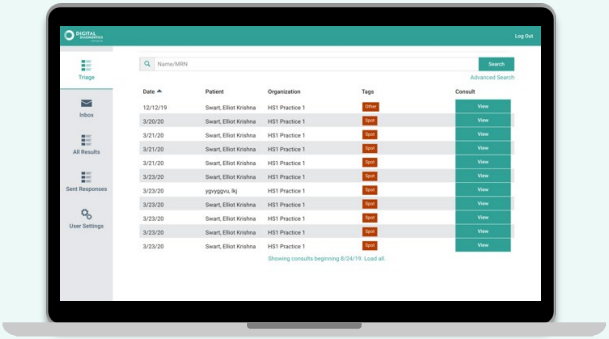
"It's a better and more efficient system that allows us to do more exams."

Digital Diagnostics' Platform with 3DermTriage™ streamlines referrals to dermatology preparation for fully autonomous AI (3DermSpot)

High quality Imaging (skin) → **Diagnostic Evaluation** → **Diagnosis and referral**







Using the robotic camera, the minimally-trained operator captures the lesion image during a PCP visit.

The PCP submits the exam through secure 3DermTriage software. The dermatologist remotely triages the skin concern and submits an e-signed consult report within 24 hours.

- consult report,
- easy to read diagnostic results
- management recommendation (including urgency)

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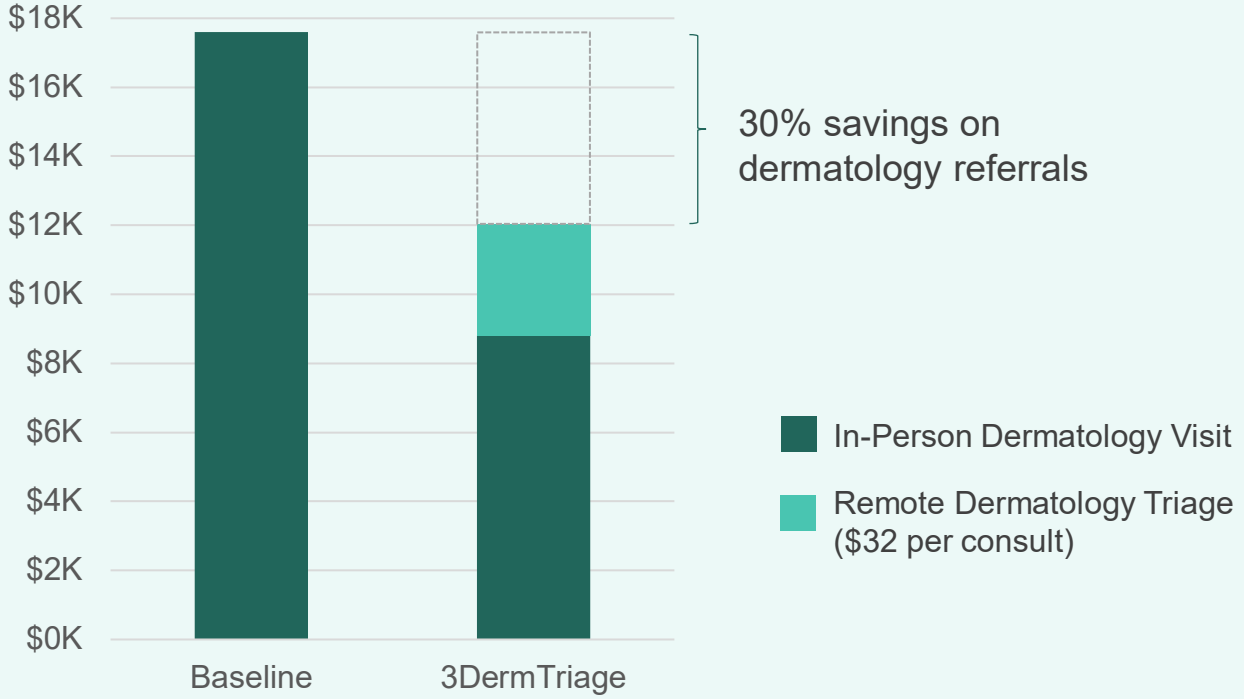
Utilizing 3DermTriage improves outcomes while reducing overall spend

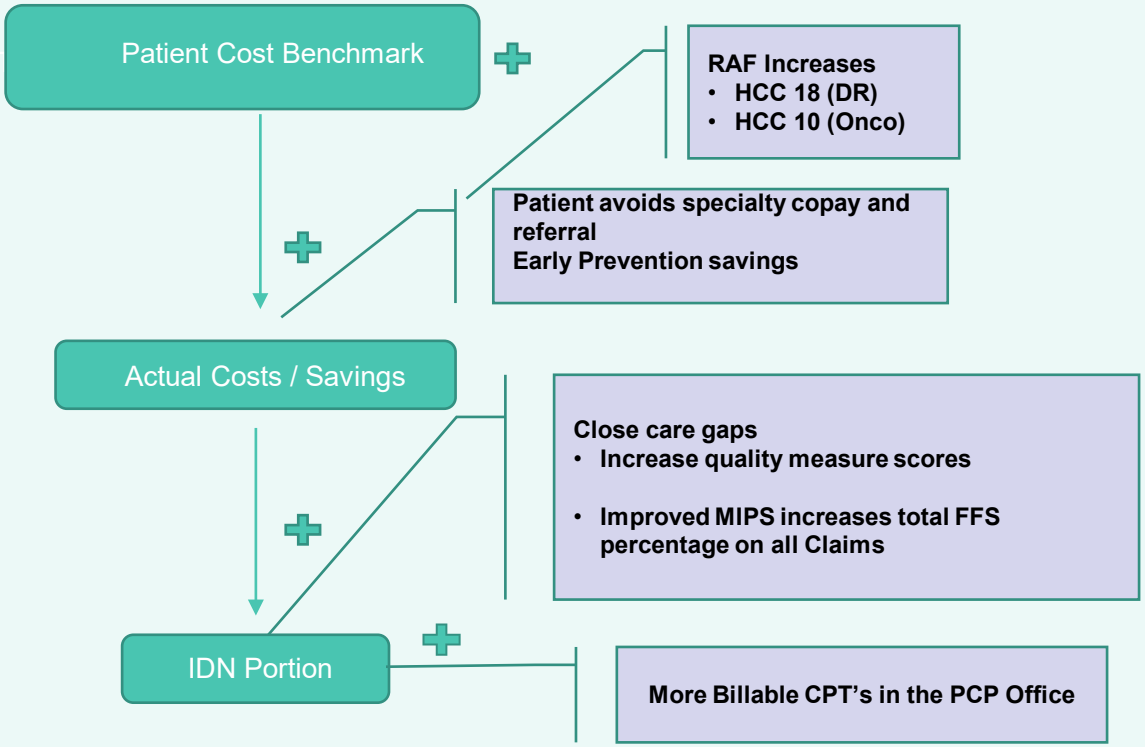
Spending on 100 dermatology referrals before and after implementing 3DermTriage[1]



Paradise, RK., Bettano, C., McGuire, T. (2019, January 3). A Teledermatology Initiative to Increase Access for Community Health Center Patients. *NEJM Catalyst*. Retrieved from: https://catalyst.nejm.org/teledermatology-access-community-health/

Value based care Autonomous AI Platform

Support	IDx-DR
NCQA supported	YES
HEDIS met	YES
HCC / RAF Credit	YES
Fully Integrated	YES



Wolf RM, Channa R, Abramoff MD, Lehmann HP. Cost-effectiveness of Autonomous Point-of-Care Diabetic Retinopathy Screening for Pediatric Patients With Diabetes. JAMA Ophthalmol. 2020..

Everyone Wins with Digital Diagnostics

Patients
- Convenience – at least one less doctor appointment
- Increased diagnostic access
- Patient avoids extra copay
- Validated safety, efficiency, equity

Front-Line Care Providers
- Immediate results allow for more comprehensive care
- Increased compliance with quality metrics
- New revenue streams
- Program integrity and consistent billing

Specialists
- More actionable referrals of treatable disease
- More time for higher yield procedures

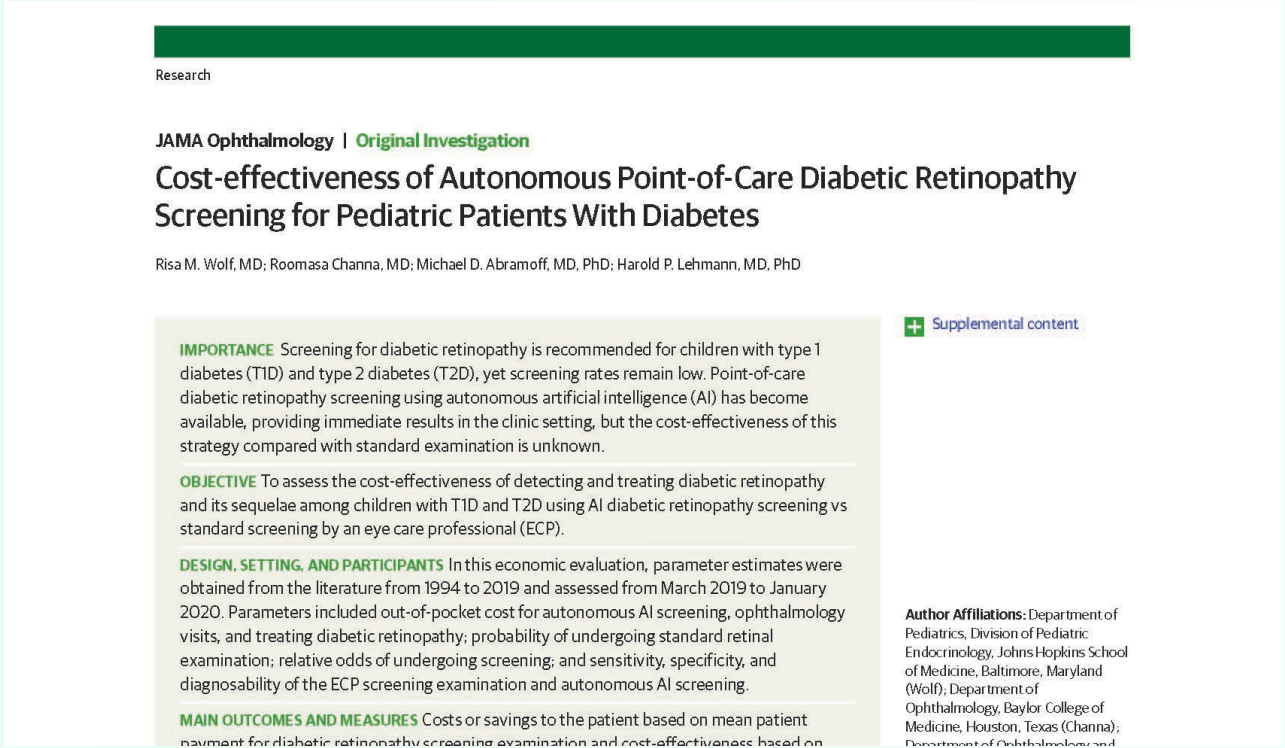
ACO
- Potential cost savings over the life-time of care
- Higher Quality Scores
- Proper Patient Risk Stratification
- Scalable Autonomous AI Platform

DIGITAL DIAGNOSTICS

DIGITAL DIAGNOSTICS

Live Customers

Cost-effective analysis (w J Hopkins)



Research

JAMA Ophthalmology | Original Investigation

Cost-effectiveness of Autonomous Point-of-Care Diabetic Retinopathy Screening for Pediatric Patients With Diabetes

Risa M. Wolf, MD; Roomasa Channa, MD; Michael D. Abramoff, MD, PhD; Harold P. Lehmann, MD, PhD

IMPORTANCE Screening for diabetic retinopathy is recommended for children with type 1 diabetes (T1D) and type 2 diabetes (T2D), yet screening rates remain low. Point-of-care diabetic retinopathy screening using autonomous artificial intelligence (AI) has become available, providing immediate results in the clinic setting, but the cost-effectiveness of this strategy compared with standard examination is unknown.

OBJECTIVE To assess the cost-effectiveness of detecting and treating diabetic retinopathy and its sequelae among children with T1D and T2D using AI diabetic retinopathy screening vs standard screening by an eye care professional (ECP).

DESIGN, SETTING, AND PARTICIPANTS In this economic evaluation, parameter estimates were obtained from the literature from 1994 to 2019 and assessed from March 2019 to January 2020. Parameters included out-of-pocket cost for autonomous AI screening, ophthalmology visits, and treating diabetic retinopathy; probability of undergoing standard retinal examination; relative odds of undergoing screening; and sensitivity, specificity, and diagnosability of the ECP screening examination and autonomous AI screening.

MAIN OUTCOMES AND MEASURES Costs or savings to the patient based on mean patient payment for diabetic retinopathy screening examination and cost-effectiveness based on

Supplemental content

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Wolf RM, Channa R, Abramoff MD, Lehmann HP. Cost-effectiveness of Autonomous Point-of-Care Diabetic Retinopathy Screening for Pediatric Patients With Diabetes. *JAMA Ophthalmol.* Published online September 03, 2020

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Questions