



CHCANYS DEFINING NEW DIRECTIONS
Community Health Care Association of New York State

CHCANYS NYS-Health Center Controlled Network:
**Diabetes Management
at the Point of Care**

April 24th 1:00 pm



About CHCANYS

- Represent over 75 member CHCs in New York State
- Provide training and technical assistance to support health center quality improvement and transformation, alongside other focus areas including:
 - Advocacy
 - Workforce development
 - Training & Education
 - Promotion of clinical quality initiatives and health IT
 - Champion adoption and use of Azara CPCI

- **Cole Unger**, Clinical Quality Improvement Project Manager, *CHCANYS*
- **Dan Jorgensen**, Sr. Marketing Manager, *Abbott*
- **Amy Walters**, Chief Financial Officer, *The Chautauqua Center*
- **Dr. Sara Palomino**, DNP, Director of Nursing and **Dr. Angel Ruiz**, MD, Adult Medicine Provider, *Urban Health Plan*

Objectives

- Learn the fundamentals of HbA1c testing at the point of care and current market solutions
- Understand the clinical, operational, and economic benefits of A1c POC testing
- Hear health center experiences from financial and care team perspectives implementing A1c testing at the point of care

Why Point-of-Care Testing?

- Demonstrating Value
 - POCT critical to transformation, quality, and outcomes
- Priority of Diabetes Management
 - A1c control a major target area for payers, state, and federal agencies
 - Diabetes complications a significant risk factor for repeat hospitalizations

Quality Measure Alignment

Measure	<u>NCQA PCMH 2017</u>	<u>MU CQM</u>	<u>MIPS*</u>	<u>UDS 2019</u>	<u>APC NYS PCMH</u>	<u>TCGP/ IPC</u>	<u>QARR / HEDIS*</u>	<u>DSRIP *</u>
Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9.0%)	1	1	1	1	1	1	1	1
Diabetes: Eye Exam (retinal) performed	1	1	1		1	1	1	1
Diabetes: Medical Attention for Nephropathy	1	1	1		1	1	1	1
Diabetes: Foot Exam	1	1	1		1	1		
Diabetes: Hemoglobin A1c (HbA1c) testing performed					1	1	1	1
Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications						1	1	1
Comprehensive Diabetes Care (All Three Tests)						1	1	1
Statin Therapy for Patients with Diabetes						1	1	
Monitoring for People with Diabetes & Schizophrenia							1	1
Diabetes: Hemoglobin A1c (HbA1c) Control (<8.0%)						1		



Diabetes Action Plan

- Starting in 2018, HRSA operational site visits include action planning relating to UDS diabetes measure performance
- Health centers must further submit quarterly progress updates on designated steps outlined in Diabetes Action Plan at OSV

Diabetes: A Challenging Epidemic - The Shape of Things to Come

Agenda

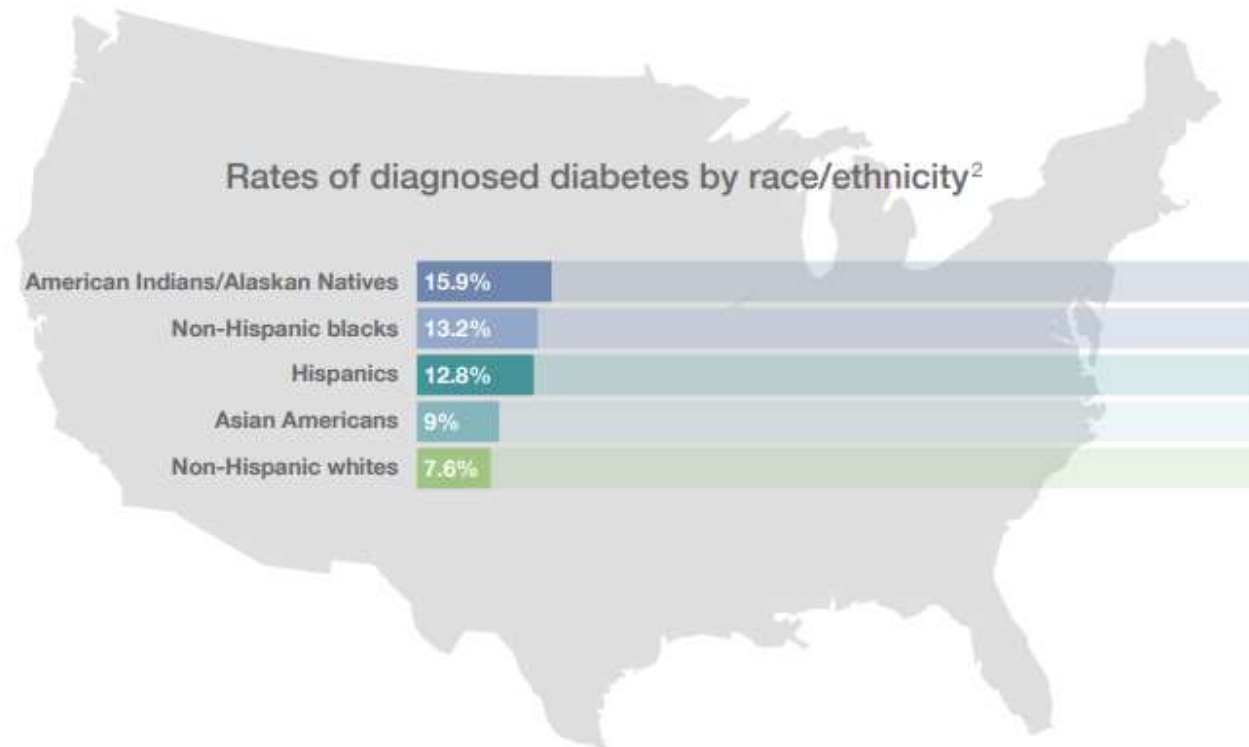
1. Diabetes
2. POC HbA1c Benefits – Clinical, Operational, Economic
3. Better Diabetes Care with POC Testing – RGV ACO
4. POC HbA1c Testing Option

Diabetes Incidence in 2015 Estimated Projections for 2040



Adapted from: International Diabetes Federation. *IDF Diabetes Atlas, 7th edn.*
Brussels, Belgium: International Diabetes Federation, 2015. <http://www.diabetesatlas.org>.

1 in 3 adults in the US will have diabetes by 2050, if present trends continue.¹



1.4 million Americans are diagnosed with diabetes every year.¹
One every 23 seconds.

29.1 million Americans or 9.3% of the US population is living with diabetes.¹

1. ADA fast facts 2015, https://professional.diabetes.org/sites/professional.diabetes.org/files/media/fast_facts_12-2015a.pdf

2. National Center for Chronic Disease Prevention, National Diabetes Statistics Report 2014

Diabetes Costs Are Dramatically Increasing

Global health costs to treat diabetes reached over \$673 billion USD in 2015.

Rank	Country/ Territory	2015 Diabetes- Related Health Expenditure*
1	United States	320 billion
2	China	51 billion
3	Germany	35 billion

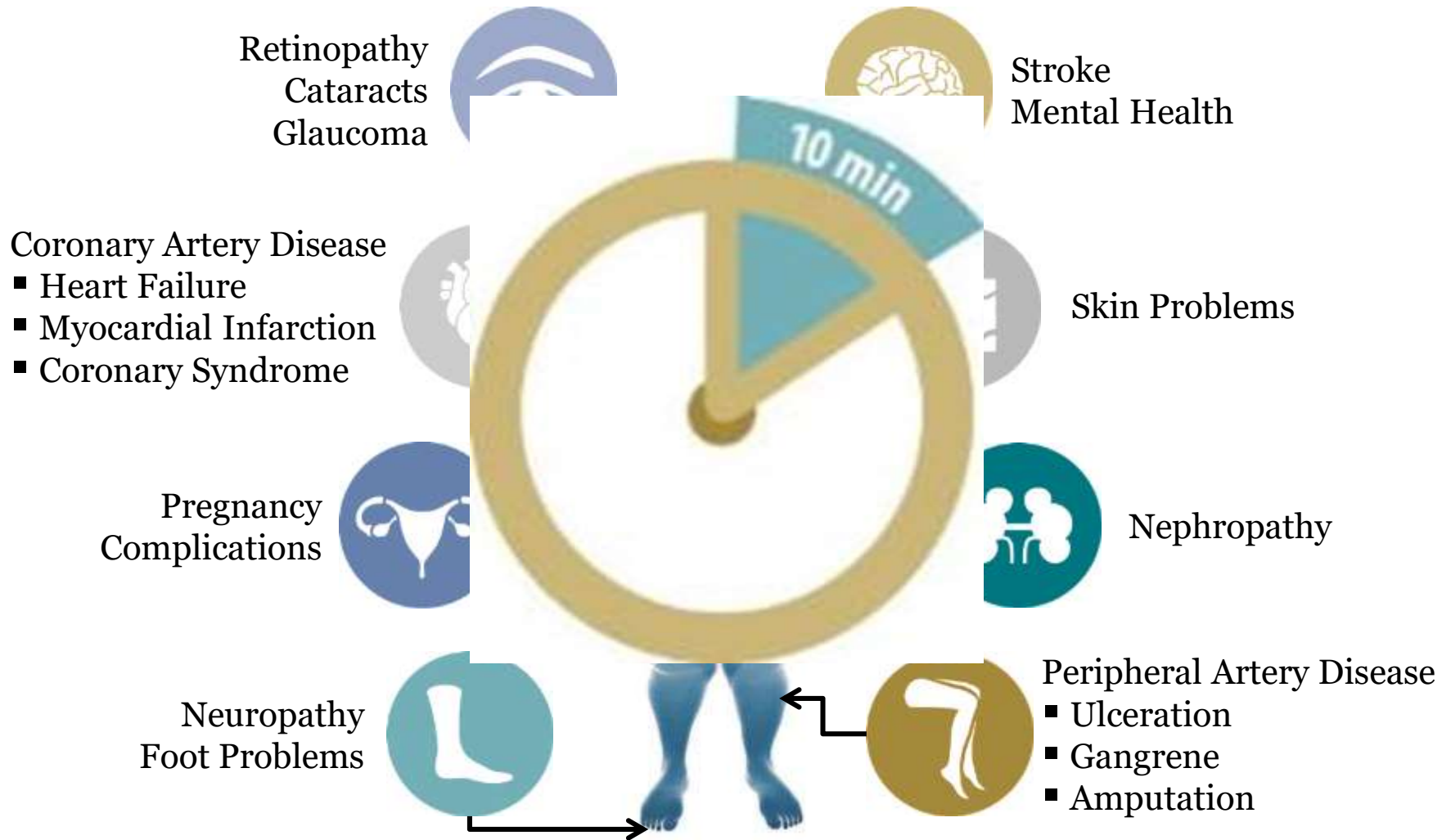
\$673,000,000,000

Rank	Country/ Territory	2040 Diabetes- Related Health Expenditure*
1	United States	349 billion
2	China	72 billion
3	Germany	36 billion

Permission granted from: International Diabetes Federation. IDF Diabetes Atlas, 7th ed. Brussels, Belgium: International Diabetes Federation, 2015. <http://www.diabetesatlas.org>.

* U.S. dollars

What Lies Beneath: Complications of Diabetes



Data sourced from: American Diabetes Association. Living With Diabetes: Complications. 2015.
Fowler MJ. *Clin Diabetes*. 2008;26:77-82.

Diabetes Management is Complex



Guidelines & Goals

What are the Current Guidelines for Testing Frequency in a *Comprehensive* Diabetes Evaluation?

American Diabetes Association:

Hemoglobin A1c (HbA1c)	<ul style="list-style-type: none">▪ 2-3 times per year in stable glycemic control▪ Quarterly in patients who have recently changed medications or who are not meeting glycemic goals▪ Use of point-of-care testing (POCT) for HbA1c provides the opportunity for more timely treatment changes
Albumin: creatinine ratio	<ul style="list-style-type: none">▪ > 1 time/year, 3 in 6 months to confirm, more for monitoring changes in therapy
Fasting lipid panel	<ul style="list-style-type: none">▪ At diagnosis, to monitor therapy adherence, and annually
Liver function tests	<ul style="list-style-type: none">▪ At diagnosis and annually
Serum creatinine and calculated glomerular filtration rate	<ul style="list-style-type: none">▪ At diagnosis
Blood pressure (BP)	<ul style="list-style-type: none">▪ Every routine visit

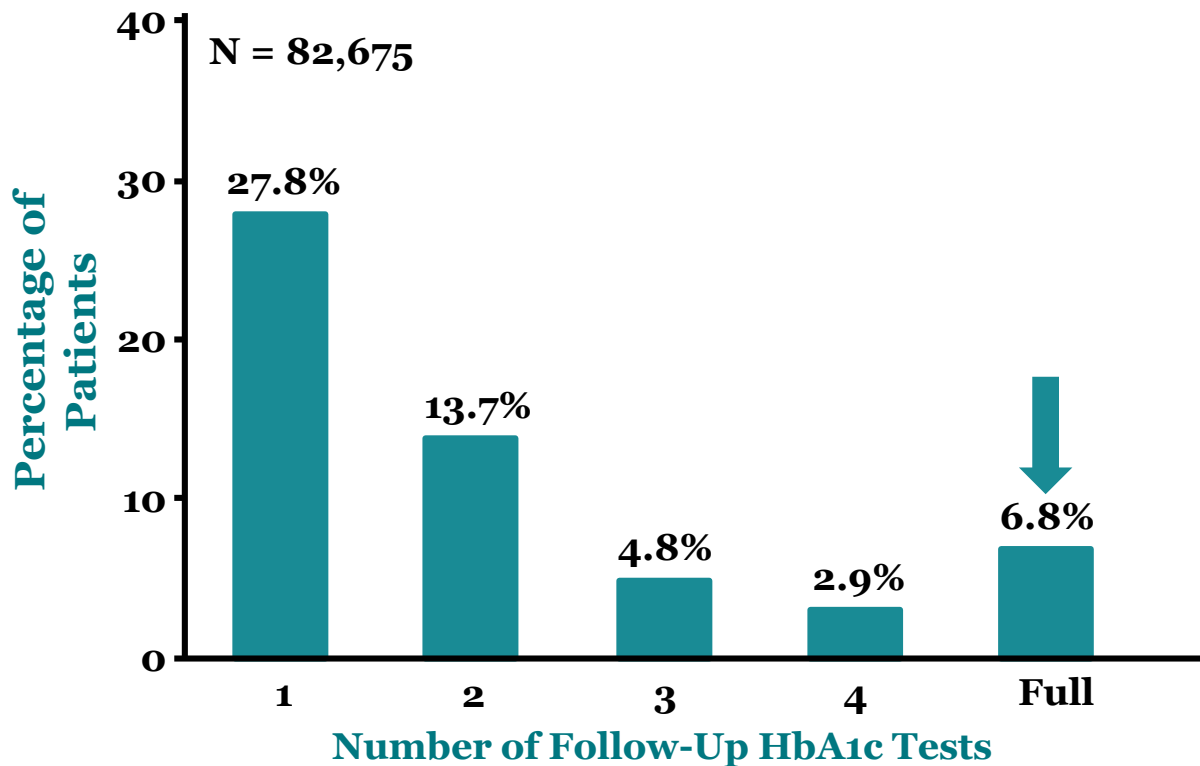
Compliance With Guideline Targets is Poor

Only 26.7% of patients diagnosed with diabetes meet targets for glycemic, blood pressure, or cholesterol control



Less than 7% Are Tested at the Guideline Recommended Frequency for HbA1c

Patients managed in compliance with guidelines were **5.29 times more likely to achieve HbA1c < 7%** than those who were not ($P < 0.0001$).



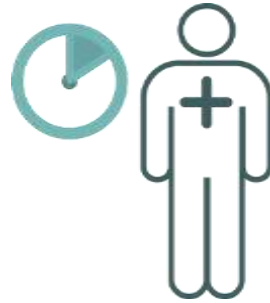
Only 3% of Patients Are Tested and Treated According to Guidelines

3% of patients meet guidelines for HbA1c testing frequency AND guideline recommended antidiabetic treatment modification

- 70% of patients tested and treated according to ADA guidelines met HbA1c goals
 - Only 30% met HbA1c goals if they did not meet guidelines for either testing frequency or treatment modification

Outcome	Did Not Meet Either Guideline (N = 1,297)	Met Both Guidelines (N = 40)	Total (N = 1,337)
Did not achieve target HbA1c, n (%)	900 (69.4)	12 (30.0)	912 (68.2)
Achieved target HbA1c, n (%)	397 (30.6)	28 (70.0)	425 (31.8)

Why is Testing Compliance Poor?



Provider Time Constraints



Lost to Lab

Poor Testing Compliance



Lower Socioeconomic Status



Cultural Issues

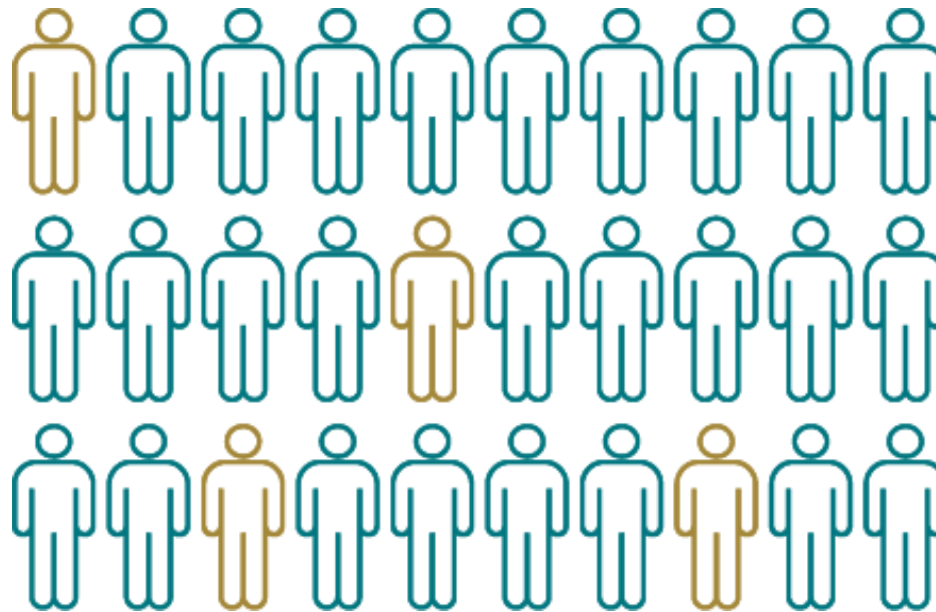
Currie CJ, Peyrot M, Morgan CLL, et al. *Diabetes Care*. 2012;35:1279–84.

García-Pérez LE, Alvarez M, Dilla T, Gil-Guillén V, Orozco-Beltrán D. *Diabetes Ther*. 2013;4(2):175–94.

How Many Patients Are Lost to Labs?

14% of patients don't report for an HbA1c lab test within 6 months of provider referral

Mean time to lab is **28 days**

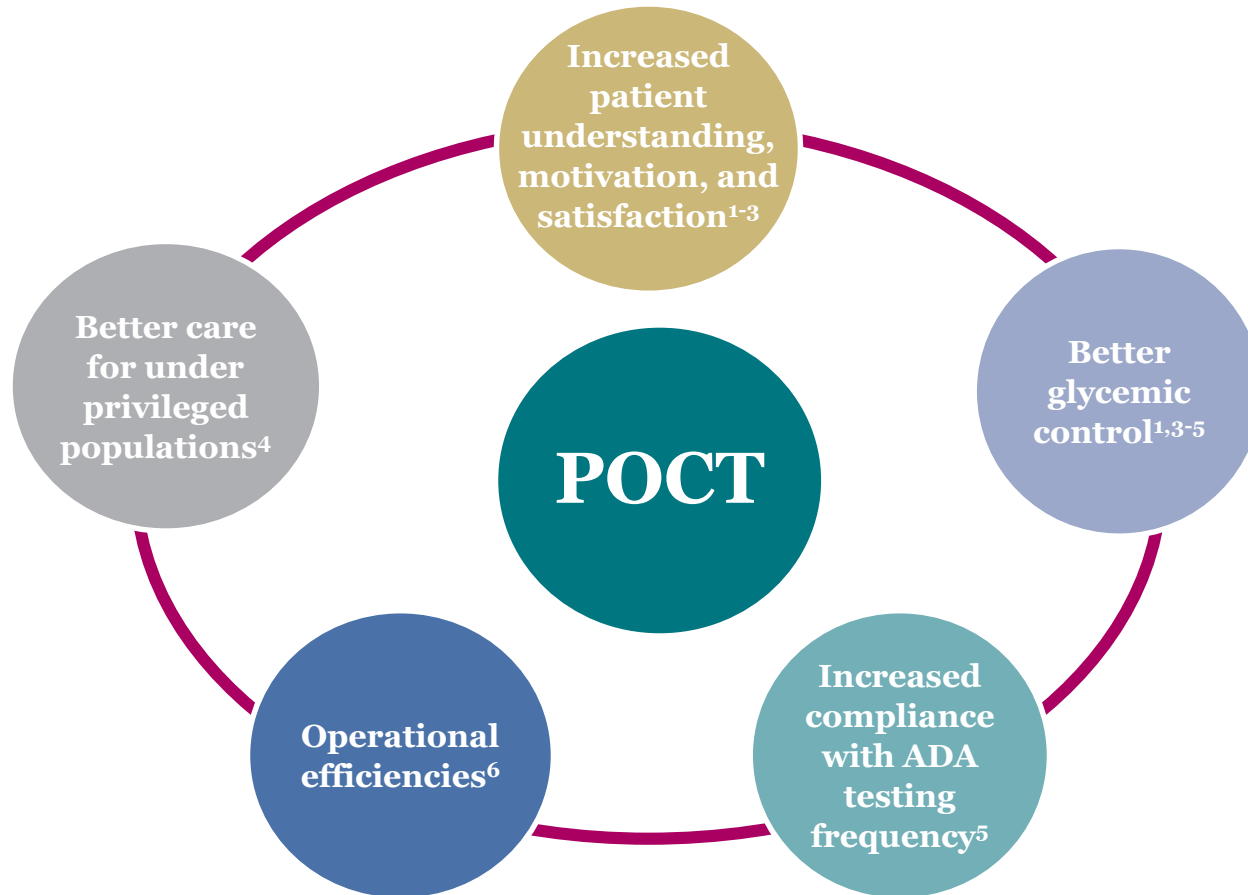


Less HbA1c control = higher mortality

Advantages of Point-of-Care Testing

Can POC Testing Help?

Advantages Observed With POCT HbA1c vs. Lab for Monitoring Diabetes



¹Shepard MD. *Clin Biochem Rev.* 2006;27(3):161-70.

²Laurence CO, Gialamas A, Bubner T. *Br J Gen Pract.* 2010;60(572):e98-e104.

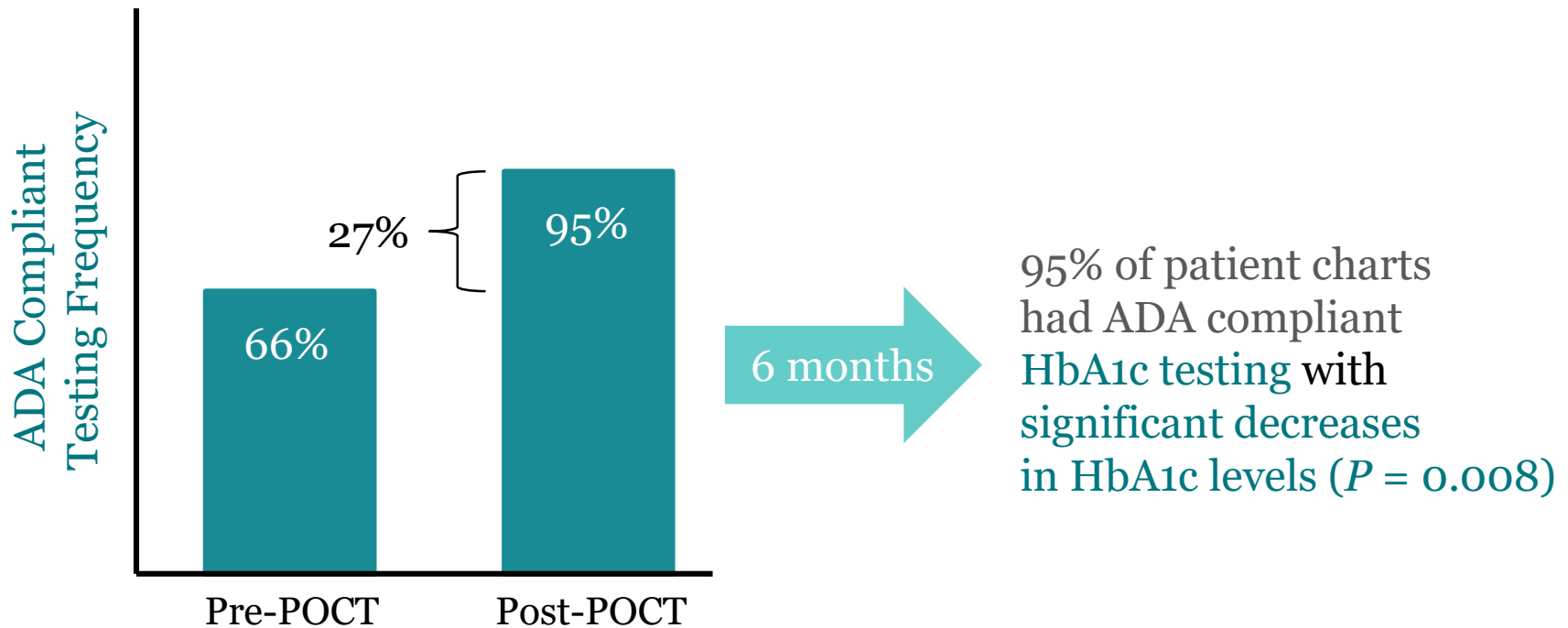
³Miller CD, Barnes CS, Phillips LS, et al. *Diabetes Care.* 2003;26(4):1158-63.

⁴Rust G, Gailor M, Daniels E, et al. *Int J Healthcare Qual Assurance.* 2008;21(3):325-35.

⁵Egbunike V, Gerard S. *Diabetes Educator.* 2013;39:66-73.

⁶Crocker JB, Lee-Lewandrowski E, Lewandrowski N, et al. *Am J Clin Pathol.* 2014;142:640-6.

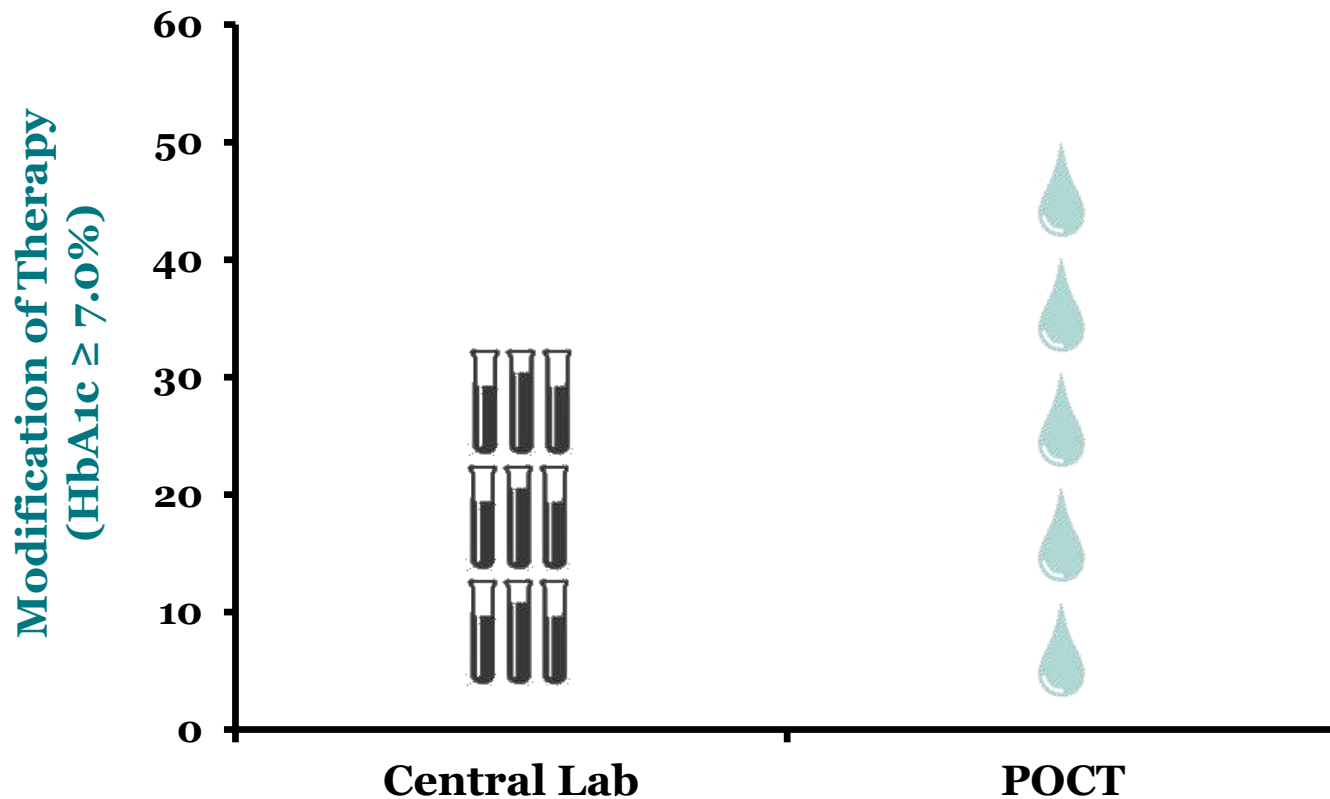
POC Testing: Increased Compliance With Testing Frequency and Reduced HbA1c



ADA-compliant testing frequency = decreased HbA1c levels.

POC Testing: Increased Compliance With Testing Frequency and Reduced HbA1c





POCT HbA1c resulted in more frequent modification of therapy when HbA1c was $\geq 7.0\%$ compared to central lab (N = 597, P = 0.01)



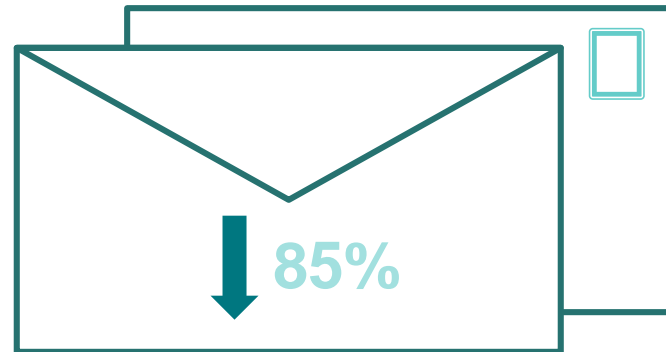
Adapted from: Miller CD, Barnes CS, Phillips LS, et al. *Diabetes Care*. 2003;26(4):1158-63.

POC Testing: Increased Compliance With Testing Frequency and Reduced HbA1c

- HbA1c dropped significantly in the POCT group in follow-up (N = 275, P = 0.04)
- Follow-up appointment at 4 months

	Initial HbA1c	Follow-up HbA1c	P Value
POCT	8.4 	8.1 	0.04
Central Lab	8.1 	8.0 	0.31

POC Testing Increases Practice Efficiency and Leads to Cost Reductions



With POCT

89% fewer follow-up phone calls

85% fewer follow-up letters

Cost savings from improved efficiency: **\$24.64 per patient**

Data sourced from: Crocker JB, Lee-Lewandrowski E, Lewandroski N, et al. Am J Clin Pathol. 2014;142:640-6.

POC Testing Improves Patient Satisfaction

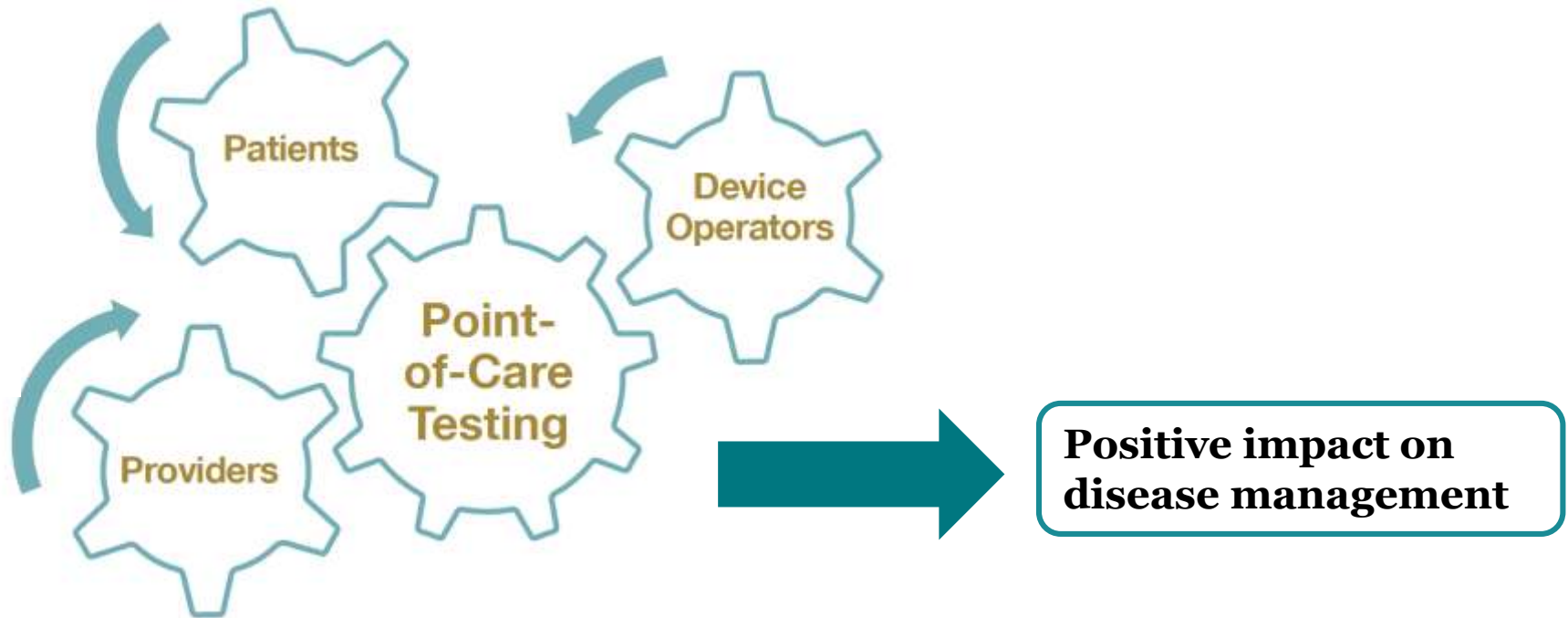
Areas	Statements	POCT Intervention*	Central Lab Control*	P Value
Collection process	I would rather have blood taken by a finger prick than by needle in my arm	7.8 (0.92)	5.1 (1.64)	< 0.001
Confidence in the process	Laboratories have better hygiene than point-of-care testing	4.3 (1.65)	4.6 (2.07)	< 0.001
Confidence in the results	I have confidence in the information given by my GP or practice regarding my pathology test result	9.0 (0.06)	8.9 (0.18)	0.010
Convenience	Not having to travel to an outside laboratory would be convenient	8.9 (0.17)	8.7 (0.36)	0.009
Cost	Outside pathology laboratories involves extra time and transport costs	8.5 (0.44)	8.6 (0.39)	0.510
Disease management	Having immediate feedback of the test result for my condition was important as it allowed/would allow me to discuss the management of my condition with my GP	9.0 (0.12)	8.7 (0.30)	0.003
	I am/would be more motivated to look after my condition because of regular point-of-care testing	8.9 (0.29)	8.2 (0.64)	< 0.001
	Point-of-care testing strengthened/would strengthen my relationship with my GP	8.3 (0.52)	8.1 (0.72)	0.010

A lower transformed score indicates a higher level of agreement

*median satisfaction score (mean transformed satisfaction score)

POC Testing: Increased Overall Satisfaction

Patients, practitioners, and device operators all agreed that POCT increased satisfaction over central laboratory practices and results



Adapted from: Point-of-Care Testing in General Practice Final Report Jan 2009. Laurence CO, Gialamas A, Bubner T. Br J Gen Pract. 2010;60(572): e98–e104.

HbA1c POCT Improves Glycemic Control, Appropriate Management, and Operational Efficiencies

Study	Findings
Rust et al. ¹	<ul style="list-style-type: none"> • HbA1c testing frequency increased post-POCT implementation • HbA1c levels decreased post-POCT implementation • Interventions increased significantly in post-POCT implementation period
Thaler et al. ²	<ul style="list-style-type: none"> • POCT HbA1c resulted in more appropriate management
Grieve et al. ³	<ul style="list-style-type: none"> • POCT HbA1c resulted in more appropriate management • Patients were more satisfied with POCT HbA1c compared to conventional testing • Patients were more likely to remember HbA1c levels if provided from POCT • HbA1c levels were lower in POCT group than conventional lab group • Patients tested with POCT had lower costs and number of visits
Shephard et al. ⁴	<ul style="list-style-type: none"> • HbA1c contributed positively to patient care, improved the doctor-patient relationship and improved compliance and self-motivation • Post-POCT implementation — HbA1c levels decreased, there were fewer patients with poor control and a higher number achieved target HbA1c levels
Egbunike et al. ⁵	<ul style="list-style-type: none"> • POCT HbA1c improved operational efficiencies • HbA1c testing frequency increased post-POCT implementation • HbA1c levels decreased post-POCT implementation.
Miller et al. ⁶	<ul style="list-style-type: none"> • POCT HbA1c resulted in more appropriate management • HbA1c levels decreased with POCT

Data sourced from:

¹Rust G, Gailor M, Daniels E. *Int J Health Care Qual Assur.* 2008;21:325-35.

²Thaler LM, Dunbar VG, Ziemer DC, et al. *Diabetes Care.* 1999;22:1415-21.

³Grieve R, Beech R, Vincent J, Mazurkiewicz. *Health Technol Assess.* 1999;3:1281-357.

⁴Shephard MDS. *Health Technol Assess.* 1999;3:1281-357.

⁵Egbunike V, Gerard S. *Diabetes Educator.* 2013;39:66-73.

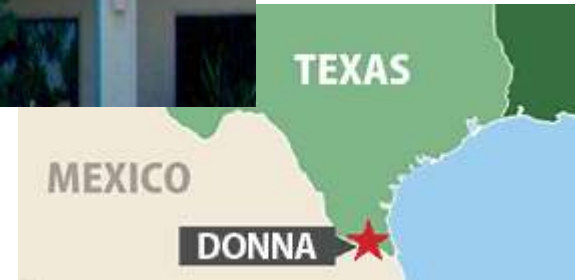
⁶Miller CD, Barnes CS, Phillips LS, et al. *Diabetes Care.* 2003;26(4):1158-63.

Better Results in Diabetes Care

Rio Grande Valley ACO: A Case Study



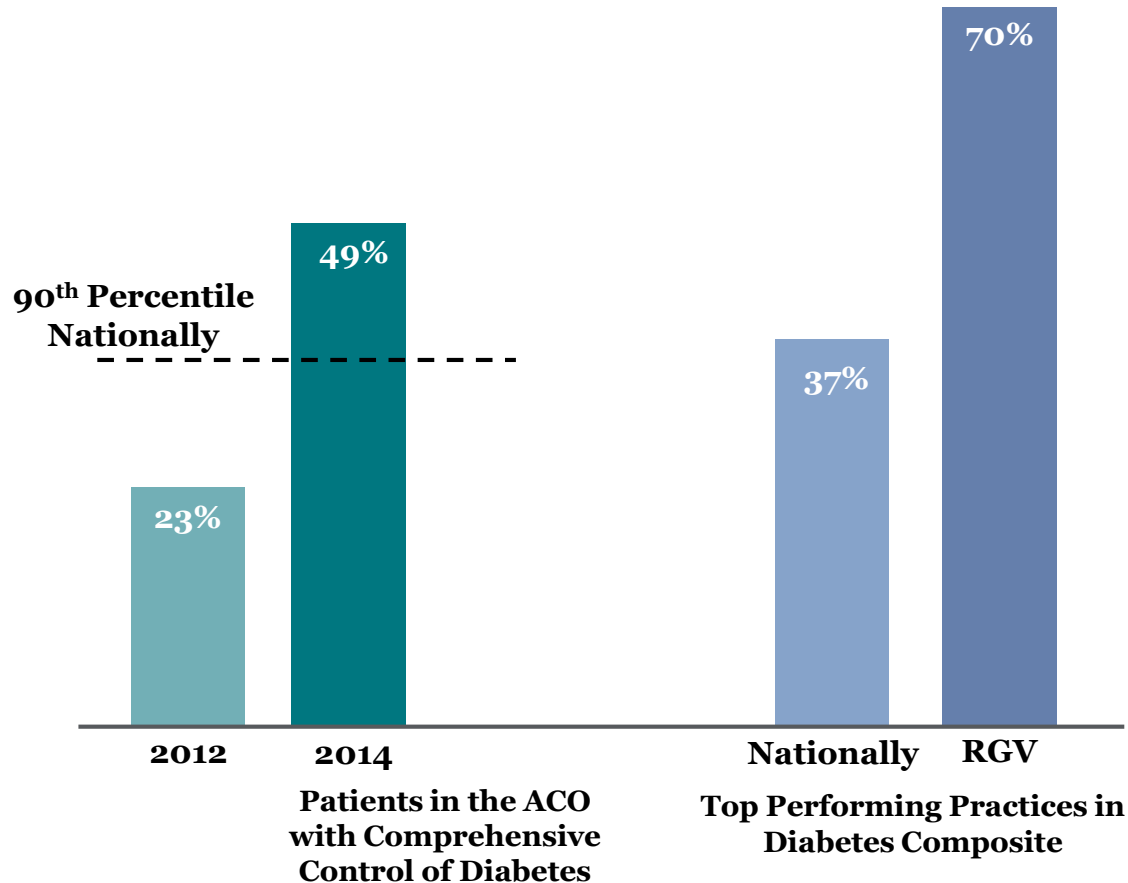
Jose F. Pena, MD
Chief Executive Officer
Chief Medical Officer
Rio Grande Valley ACO



- 8,500 patients
- 45% with type 2 diabetes
- Primarily elderly, Hispanic, Spanish speaking
- Lacking in health literacy
- Low socioeconomic status

Clinical Outcomes: RGV ACO vs. National Average

After implementation of POC testing as part of a comprehensive diabetes program, 75% of patients are < 8% HbA1c and only 14% remain uncontrolled > 9% HbA1c



McClellan MB, Pena JF, eds. *Enhancing diabetes care through personalized, high-touch case management*. Rio Grande Valley Accountable Care Organization. Center for Health Policy at Brookings. Accessed 6 April 2015.

RGV ACO: Economic Benefits of POCT

RGV ACO decreased Medicare patient per capita costs by 14% after implementation of their comprehensive diabetes program including POC testing

- Decreased hospital admission
- Decreased readmissions

Centers for Medicare and Medicaid Services determined RGV ACO's reduced healthcare expenditures were **\$20.2 million** for 2014

Medicare shared savings program accountable care organizations performance year 1 results. <https://data.cms.gov/ACO/Medicare-Shared-Savings-Program-Accountable-Care-O/yuq5-65xt>. Accessed 22 December 2015.

Medicare shared savings program quality measures: 2014. <https://www.pulsepilot.com/directory/RGV-ACO-Health-Providers,-LLC>. Accessed 19 February 2016.

POC A1C Testing Options

POC A1C Testing Options

Currently there are 3 POC A1C tests that have been cleared for use by the FDA for managing metabolic control in patients with diabetes

- HbA1c test on the Abbott Afinion™ 2 Analyzer
- HbA1c test on the Siemens DCA Vantage™ Analyzer
- HbA1c testing with the PTS A1CNow®+ test

All three tests are CLIA Waived and provide quantitative results

Afinion™ Analyzer

Features

- Multi-assay analyzer system
- 3-minute HbA1c test – waived
- 5-minute Albumin/Creatinine Ratio (ACR) test - moderate complexity
- Short test time provides the opportunity for more timely treatment changes
- Easy sample collection and operation – minimal training required
- Reliable, lab-quality results
- First POC A1C test to achieve FDA clearance for diagnosis*

*Launching in June (moderate complexity at launch)



Abbott Afinion™ HbA1c Assay

Test for quantitative determination of glycated Hemoglobin (HbA1c) in human whole blood, used to monitor metabolic control in patients with diabetes.

Simple. Fast. Reliable.

- 3 minutes test time
- Excellent precision (< 3% CV)
- No interference from Hb variants
- NGSP and IFCC certified
- CLIA waived



The 3-minute Afinion™ test fits perfectly within the workflow

"Immediate feedback motivates patients to make the necessary treatment changes."

Cagliero E et. al. Diabetes Care 1999;22:1785-1789.

"Use of point-of-care testing for HbA1c allows for timely decisions on therapy changes, when needed."

ADA, 2011. Diabetes Care 2011;34(supl 1):s11-s61.

Siemens DCA Vantage™ Analyzer and A1C Test

- 6-minute HbA1c test
- 1 μ L sample volume
- 2.5-14% HbA1c
- Onboard printer
- Stores 4000 test results
- User lock out
- QC lock out
- Adjustable correlation to reference methods
- Patient trending graphs
- Ethernet compatible



PTS A1CNow[®]+ Test Device

- Results in 5 minutes
- Small (5 μ L) blood sample
- Portable - use in multiple exam rooms
- Easy to use - minimal training required
- Available in multiple test count configurations
- No maintenance





Questions

dan.jorgensen@alere.com

HGB A1C

ARE YOU GETTING REIMBURSED FOR YOUR WORK?



CLIA WAIVER

CLIA WAIVER

**IS THE A1C LISTED ON
YOUR CLIA WAIVER?**

CERTIFICATE

**A1C IS CLASSIFIED AS A CLIA WAIVED TEST
BY THE FDA.**

**A CLIA CERTIFICATE IS REQUIRED ANY TIME A
CLINICAL LABORATORY TEST IS PERFORMED;
HOWEVER, PERFORMANCE OF WAIVED
CATEGORY TESTS REQUIRES ONLY A CLIA
CERTIFICATE OF WAIVER.**

**CERTIFICATE OF WAIVER LABS MUST
REGISTER WITH MEDICARE, PAY A FEE EVERY
TWO YEARS, AND AGREE TO FOLLOW
MANUFACTURER'S INSTRUCTIONS IN
PERFORMING CLINICAL LAB TESTS.**

TO APPLY IF NEEDED

***GO TO WWW.CMS.HHS.GOV/CLIA,
DOWNLOAD CLIA APPLICATION***

***FOLLOW THE INSTRUCTIONS PROVIDED,
AND SEND IT TO THE APPROPRIATE
STATE AGENCY. A LIST OF STATE AGENCY
ADDRESSES IS ALSO AVAILABLE ON THE
INTERNET AT WWW.CMS.HHS.GOV/CLIA***

CLAIMS DELAYS

**“CLINIC DAYS” (E & M CODE 99211)
IF A PATIENT SEES A NURSE OR OTHER NON-
PHYSICIAN HEALTH CARE PROFESSIONAL FOR
THE PURPOSE OF
HBA1C TEST (FOR EXAMPLE, TO MONITOR
INSULIN THERAPY) AND THE NURSE TAKES
VITAL SIGNS, COMPARES THE
RESULTS WITH THE HBA1C TEST TO
PREDETERMINED GUIDELINES, AND ADVISES
THE PATIENT ACCORDINGLY,
E & M CODE 99211 MAY BE BILLED.**



ICD-10 CODE

**NOT USUALLY PAYABLE FOR
SCREENING CODES**

- **AN APPROPRIATE DIAGNOSIS (ICD-10-CM) CODE (OR NARRATIVE DESCRIPTION) MUST BE IDENTIFIED IN THE PATIENT'S MEDICAL RECORD AND REPORTED ON THE CLAIM FORM TO THE PATIENT'S INSURER, FOR EACH SERVICE OR SUPPLY BILLED UNDER MEDICARE PART B. WHEN A PATIENT PRESENTS WITH AN ILLNESS, THE PROVIDER SELECTS THE ICD-10-CM CODE OR CODES BY THE "SIGNS AND SYMPTOMS" THAT MOST ACCURATELY DESCRIBE THE PATIENT'S CONDITION.**

IN HOUSE EXPENSE

COST OF MACHINE/SUPPLIES

**MACHINE: INITIAL COST COULD BE
\$2600-\$3200 PER MACHINE
DESK TOP ANALYZER, OTHER
MACHINES CHEAPER
COST PER TEST \$8.87 DESK TOP**

REIMBURSEMENT

**REIMBURSEMENT IS ROUGHLY \$8-
12 DEPENDING PER INS CARRIER.**

VALUE ADD

**YOU HAVE THE RESULTS AT HAND
AT TIME OF PATIENT ENCOUNTER.
YOU CAN UPDATE ANY MEDS AT
THAT POINT IN TIME AND LEARN
OF ANY BARRIERS FOR
UNCONTROLLED ISSUES TO
RESOLVE.**

BILLING

CPT CODES

83036 OR 83037

**83036-A1C TEST WITH DESK TOP
ANALYZER**

**83037- HOME DEVICE USED IN
OFFICE(CHECK WITH PAYORS)**

PLUS: ADD CPT II CODE TO CLAIM:

3044F A1C <7%

3045F A1C 7-9%

3046F A1C >9%

DX CODES

**DIABETES ICD-10: E08.42, E09.42,
E10.42,, E11.42, E13.42,,
E11.319, E11.359,, E11.329,
E11.339,, E11.349, E11.311. –
E11.311, E08.36,,**

SIGNS AND SYMPTOMS

MODIFIERS

QW

**USUALLY DIABETIC PATIENTS ARE
SEEN EVERY 3 MONTHS,
THEREFORE, 83036 IS USUALLY
PAYABLE FROM 4-8 TIMES PER
YEAR. CHECK WITH INDIVIDUAL
PAYORS.**

QUESTIONS?

A silver stethoscope is positioned in the top right corner of the slide, partially overlapping the dark blue background.

Point of Care Hemoglobin A1c Testing

Sara Palomino, DNP
Director of Nursing
Dr. Angel Ruiz, MD
Adult Medicine Provider
Urban Health Plan

Urban Health Plan, Inc.

- Founded by Dr. Richard Izquierdo in 1974
- Network of FQHCs
 - 10 sites: 8 in Bronx; 1 Queens; 1 Harlem
 - 12 School-based Health Centers
 - 3 administrative sites
- 2018: more than 88,000 patients served; over to 486,000 visits
- 1000 employees and providers
- Joint Commission accredited
- NCQA Patient Center Medical Home



Strategies to Improve Diabetes Care



- Implementation of a Performance Improvement Project
- Use of QI Models
 - PDSA cycles
- Best Practices Committee
 - At point of care A1c
 - Microalbumin screening
 - Fundus photography
- Care Management
- Share data with the Team
- Integrate data in sites dashboards
- Use of multi-disciplinary Team Based Approach
 - Case conferences of patients whose diabetes is not improving
 - Identify SDOH and link patients to support services

Implementation into Practice

- Establish protocols specifying when to perform HgA1c on patients.
- Assure that each departments is equipped with the respective number of HgA1c machines. Number must be based on needs.
- Assure that all medical assistants/RNs/LPNs are competent in performing the HgA1c.



Implementation into Practice



- Assure that each department obtains the necessary supplies and proper storage.
- Location of HgA1c machine must be determined based on the needs of the department.
- Keep quality control logs.
- Assure documentation of results in patients' record.

Point of Care A1c Testing



Advantages:

1. A1c is performed at point of care every 3 months.
2. A1c results can be tracked by MR #
3. Results only take 3 minutes and 20 seconds
4. Quality Controls are done every time a new lot number and/or new shipment is opened and then monthly
5. Analyzer performs self QC during clinic off hours.
6. Used test cartridge can be discarded in regular garbage

Provider Statement

In our community, our patients are not always able to perform glucose monitoring at home given multiple issues from being underinsured to having orthopedic issues (i.e. arthritis) preventing them from measuring their sugar at home regularly. The results are available within less than 5 minutes and is easily done in office as all it requires is a pin prick, and is done at the same time as the finger stick. This in turn allows us to make better clinical decisions as to how we should adjust their regimen.

