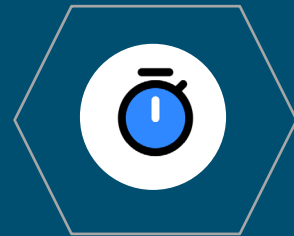


# Value of Point-of-Care Testing in Diabetes



1<sup>st</sup> November 2022



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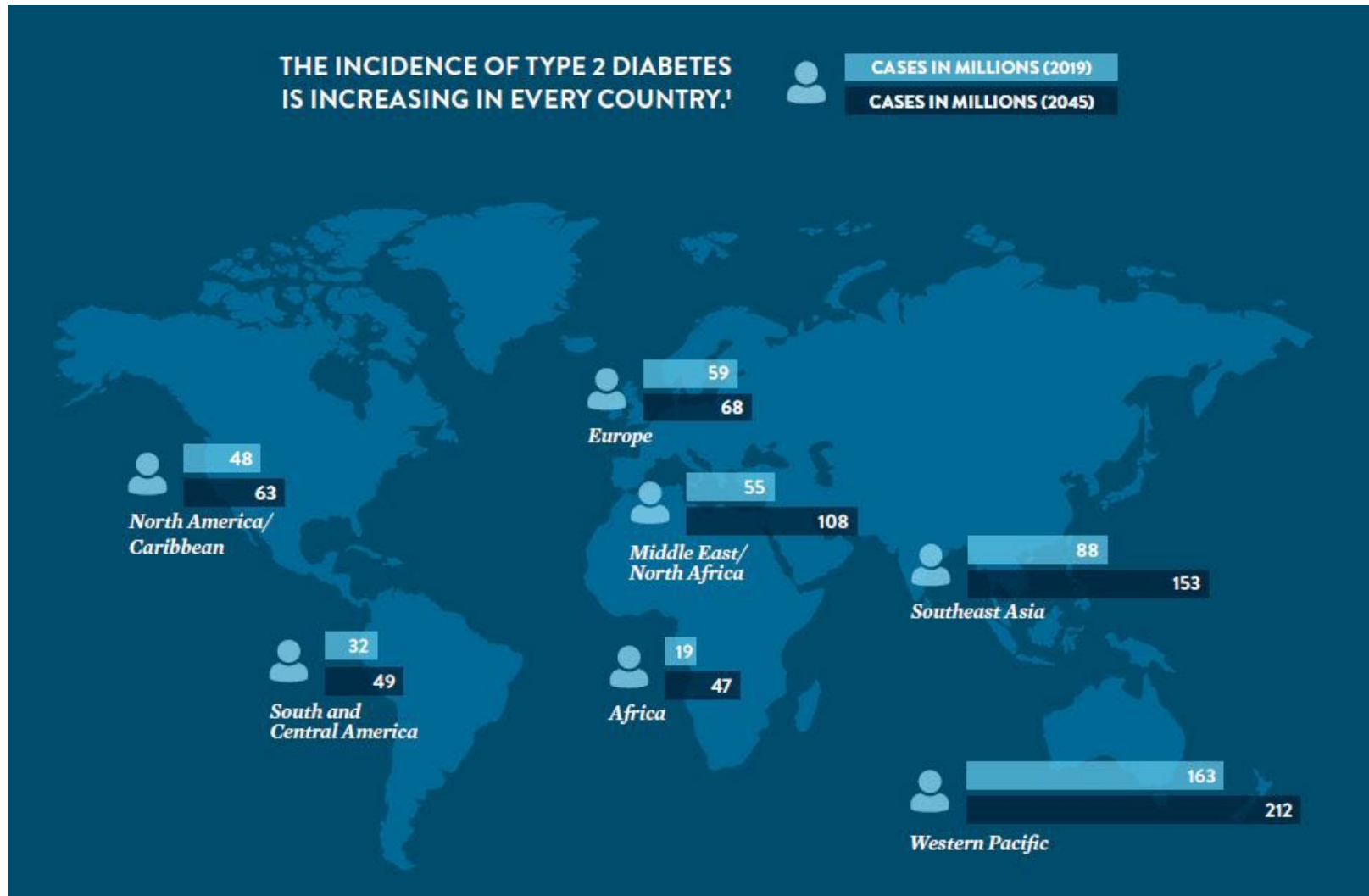
**3** Advantages of Point-of-Care Testing

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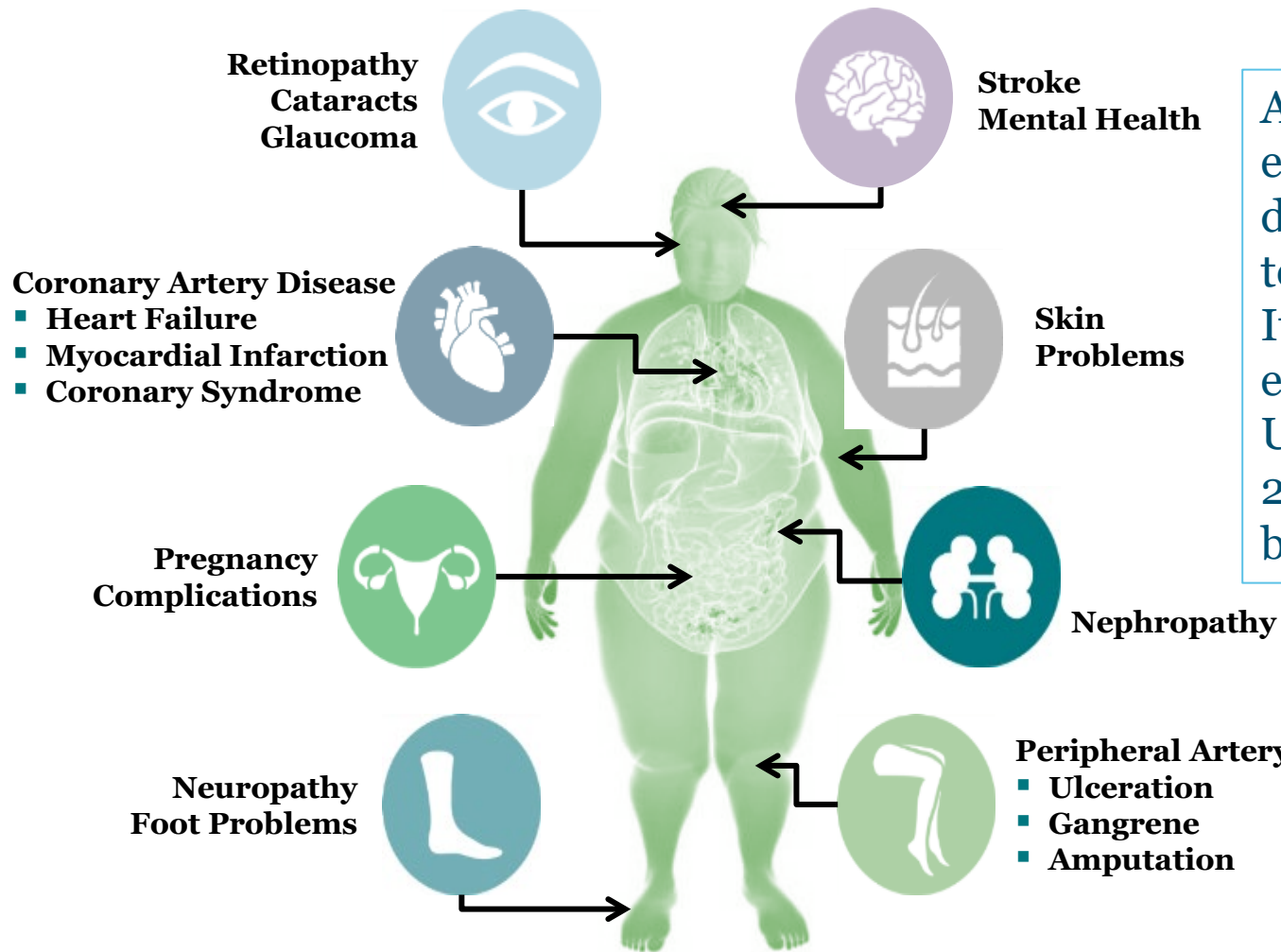
**6** Better Results in Diabetes Care

# Diabetes Incidence in 2017 Estimated Projections for 2045



Adapted from: International Diabetes Federation. *IDF Diabetes Atlas, 9th edn.* 2019. Brussels, Belgium: <http://www.diabetesatlas.org>.

# What Lies Beneath: Complications of Diabetes



Annual global health expenditure on diabetes is estimated to be USD 760 billion. It is projected that expenditure will reach USD 825 billion by 2030 and USD 845 billion by 2045.



# Guidelines & Goals

# What are the Current Guideline Targets for Screening and Diagnosis for Type 2 Diabetes?

	ADA <sup>1</sup>	ESC/EASD <sup>2</sup>	IDF <sup>3</sup>
	<ul style="list-style-type: none"> <li>• Children, adolescents and adults of any age, overweight or obese, plus one or more additional risk factors</li> <li>• Testing should begin at age 45</li> <li>• If test is normal, repeat it at least every 3 years</li> </ul>	<ul style="list-style-type: none"> <li>• General population and people with assumed abnormalities</li> <li>• Start with a risk score (e.g. FINDRISC)</li> <li>• For CVD patients, no diabetes risk score is needed</li> </ul>	<ul style="list-style-type: none"> <li>• Screen high-risk individuals: (&gt;40-45 years, obese, increased circumference, hypertension, family history)</li> <li>• Start with a risk score (e.g. FINDRISK)</li> <li>• If normal, repeat it at least every 3 years; if positive, proceed with diagnostic test</li> </ul>
<b>Tests</b>	<ul style="list-style-type: none"> <li>• FPG</li> <li>• or 2-hr PG after 75-g OGTT criteria</li> <li>• or HbA1c</li> </ul>	<ul style="list-style-type: none"> <li>• OGTT</li> <li>• or combination of HbA1c and FPG</li> </ul>	<ul style="list-style-type: none"> <li>• FPG</li> <li>• or 2-hr PG after 75-g glucose load</li> <li>• or random plasma glucose in symptomatic patient</li> <li>• or HbA1c (a standardized HbA1c test should be available in every primary care clinic)</li> </ul>
<b>Pre-diabetes</b>	HbA1c ≥ 5.7%-6.4% (39-46 mmol/mol)*	refer to WHO and ADA: HbA1c ≥ 6.5% (48 mmol/mol)*	HbA <sub>1c</sub> ≥ 6.5% (48 mmol/mol)*
<b>Diabetes</b>	HbA1c ≥ 6.5% (48 mmol/mol)*	HbA1c ≥ 6.5% (48 mmol/mol)*	HbA1c ≥ 6.5% (48 mmol/mol)*

\*Values not recommended for children and adolescents

<sup>1</sup>ADA. American Diabetes Association. Standards of Medical Care in Diabetes – 2020. Diabetes Care. 2020;43:Supplement 1.-2020

<sup>2</sup>ESC, EASD 2013. Guidelines on diabetes, prediabetes, and CV diseases

<sup>3</sup>IDF 2017. Clinical Practice Recommendations for managing T2D in Primary Care

# What are the Current Guideline Targets for Screening and Diagnosis for Type 2 Diabetes?

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<b>Tests</b>	<ul style="list-style-type: none"> <li>• FPG</li> <li>• or 2-hr PG after 75-g OGTT criteria</li> <li>• or HbA1c</li> </ul>	<ul style="list-style-type: none"> <li>• OGTT</li> <li>• or combination of HbA1c and FPG</li> </ul>	Consider HbA1c as a diagnostic test, particularly in those who are very likely to have the disease, since it will also be necessary to decide treatment and monitor its effectiveness.
<b>Pre-diabetes</b>	HbA1c ≥ 5.7%-6.4% (39-46 mmol/mol)*	refer to WHO and ADA: HbA1c ≥ 6.5% (48 mmol/mol)*	HbA <sub>1c</sub> ≥ 6.5% (48 mmol/mol)*
<b>Diabetes</b>	HbA1c ≥ 6.5% (48 mmol/mol)*	HbA1c ≥ 6.5% (48 mmol/mol)*	HbA1c ≥ 6.5% (48 mmol/mol)*

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<sup>1</sup>ADA. American Diabetes Association. Standards of Medical Care in Diabetes – 2020. Diabetes Care. 2020;43:Supplement 1.-2020

<sup>2</sup>ESC, EASD 2013. Guidelines on diabetes, prediabetes, and CV diseases

<sup>3</sup>IDF 2017. Clinical Practice Recommendations for managing T2D in Primary Care



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

Data sourced from: American Diabetes Association. Standards of Medical Care in Diabetes – 2020. Diabetes Care. 2020;43:Supplement 1.



# What are the Current Guideline Targets for *Monitoring* a Patient With Diabetes?

Test	ADA <sup>1</sup>	ESC/EASD <sup>2,3</sup>	IDF <sup>4</sup>
HbA1c	<ul style="list-style-type: none"> <li>• Point-of-care</li> <li>• 3-6 months</li> <li>• &lt; 7%</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 7% (53 mmol/mol)</li> <li>• Individual &lt; 6.5-6.9% (48-52 mmol/mol)</li> </ul>	<ul style="list-style-type: none"> <li>• Every 2-6 months</li> <li>• &lt; 7% (53 mmol/mol)</li> </ul>
LDL	<ul style="list-style-type: none"> <li>• At diagnosis and annually</li> <li>• &lt; 100 mg/dL</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 100 mg/dL high risk (2.5 mmol/L)</li> <li>• &lt; 70 mg/dL very high risk (1.8 mmol/L)</li> </ul>	<ul style="list-style-type: none"> <li>• At diagnosis and annually</li> <li>• &lt; 70 mg/dL high risk (1.8 mmol/L)</li> </ul>
ACR	<ul style="list-style-type: none"> <li>• At diagnosis and annually</li> <li>• &lt; 30 mg/g</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 30-300 mg/g (&lt; 3.4-34 mg/mmol)</li> </ul>	<ul style="list-style-type: none"> <li>• At diagnosis and every 1-2 years</li> <li>• &lt; 30 mg/g</li> </ul>
BP	<ul style="list-style-type: none"> <li>• Every visit</li> </ul>	<ul style="list-style-type: none"> <li>• &lt; 140 mmHg</li> </ul>	<ul style="list-style-type: none"> <li>• At least annually and every routine visit if patient has CVD or is on associated medication</li> <li>• &lt; 130 to 140/80 mmHg</li> </ul>

<sup>1</sup>ADA. American Diabetes Association. Standards of Medical Care in Diabetes. *Diabetes Care*. 2020;43(Suppl. 1):S66-S76.2016;39(suppl 1):S1-S106

<sup>2</sup>Rydén L, Grant PJ, Anker SD, et al. ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD: the Task Force on diabetes, pre-diabetes, and cardiovascular diseases of the European Society of Cardiology (ESC) and developed in collaboration with the European Association for the Study of Diabetes (EASD). *Eur Heart J*. 2013;34(39):3035-3087.

<sup>3</sup>Mancia G, Fagard R, Narkiewicz K, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension. The Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). *J Hypertens*. 2013;31(7):1281-1357.

<sup>4</sup>IDF Clinical Practice Recommendations for managing Type 2 Diabetes in Primary Care, International Diabetes Federation – 2017. International Diabetes Federation. <https://www.idf.org/e-library/guidelines/128-idf-clinical-practice-recommendations-for-managing-type-2-diabetes-in-primary-care.html>. Accessed January 3, 2020.



# Compliance With Guideline Targets is Poor

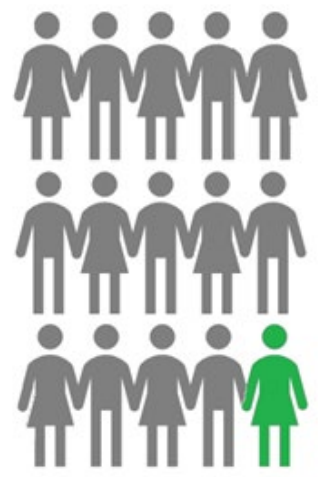
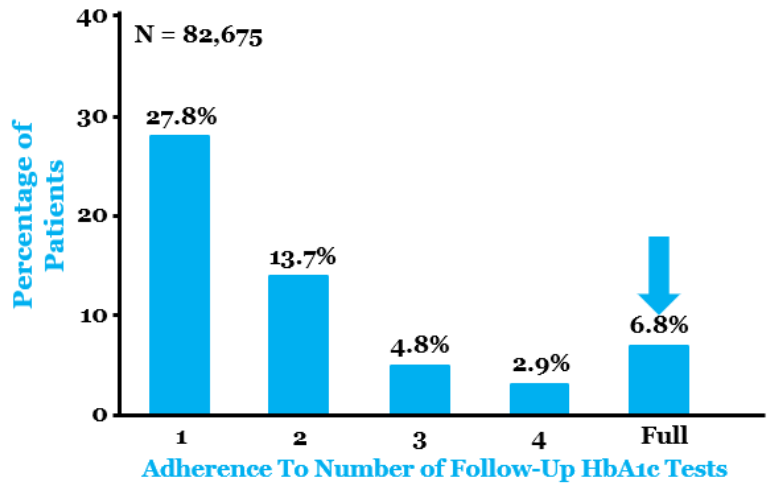
Only 26.7% of patients diagnosed with diabetes meet targets for glycemic, blood pressure, or cholesterol control





# Compliance with recommended frequency of HbA1c testing has been well-studied

- 42,837 patient records in US were retro-spectively evaluated for adherence
- **Less than 7%** were tested at the recommended frequency for HbA1c testing

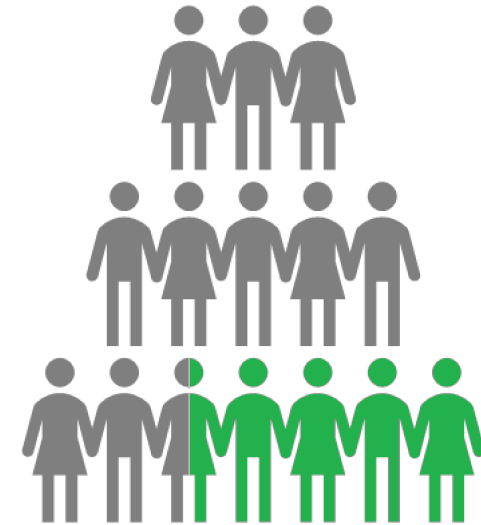


70% of patients tested and treated according to ADA guidelines met HbA1c goals

Lian J, Lang Y. Curr Med Res Opin, 2014. Permission granted through Creative Commons License. (Data from a large US health insurance)



# Testing frequency is important



**70%**

of patients tested and treated according to ADA guidelines met HbA1c goals<sup>1</sup>

only **30%**

met HbA1c goals if they did not meet guidelines for either testing frequency or treatment modification<sup>1</sup>

Lian J, Lang Y. Curr Med Res Opin, 2014. Permission granted through Creative Commons License. (Data from a large US health insurance)



# 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.

# More Time Required Per Patient With Diabetes



## Exam 1

### ADA Diabetes Evaluation

#### Medical history

- Age and characteristics of onset of diabetes, review of treatment, response to therapy, HbA1c and glucose self-monitoring records
- Eating patterns, physical activity habits, nutritional status, weight history, diabetes education history
- Presence of common comorbidities, psychosocial problems, dental disease, other diabetes-related complications
- Hypoglycemic or ketoacidosis episodes

#### Physical examination

- Height, weight, BMI, BP
- Fundoscopic examination, thyroid palpation, skin exam, comprehensive foot exam

#### Laboratory evaluation

- A<sub>1</sub>c, fasting lipid profile, liver function tests, albumin-to-creatinine ratio, serum creatinine and calculated glomerular filtration rate, TSH, as needed

**Medications prescribed/adjusted as needed**

**Referrals as needed**

**Any other reason for appointment**

## Exam 2

### Streptococcal Pharyngitis Evaluation

#### Medical history

- Onset, duration, progression, and severity of the associated symptoms, infection exposure, presence of comorbid conditions

#### Physical examination

- Pharynx exam
- Exam for evidence of fever, rash, cervical adenopathy, coryza, heart murmur.

#### Laboratory testing

- Throat culture, antigen test, monospot test

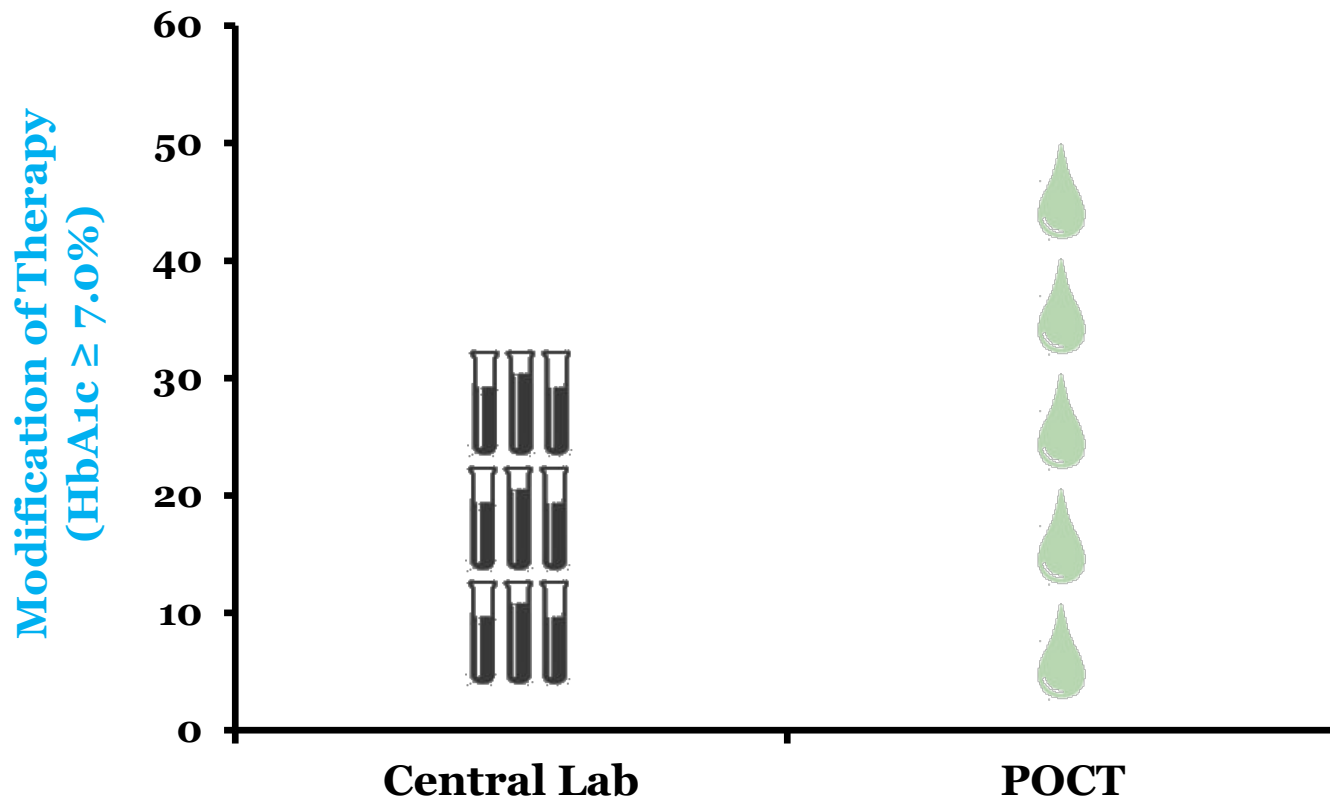
**Medication prescribed as needed**





# 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





# Primary Care Questions Regarding POC Testing

**Q.** Is POC testing the same quality as the lab?

**A.** *Some POCT systems deliver lab quality performance.*

**Q.** What is the turnaround for POC testing results?

**A.** *Results can be available within minutes and in time for the clinical consultation.*

**Q.** Is POC testing expensive?

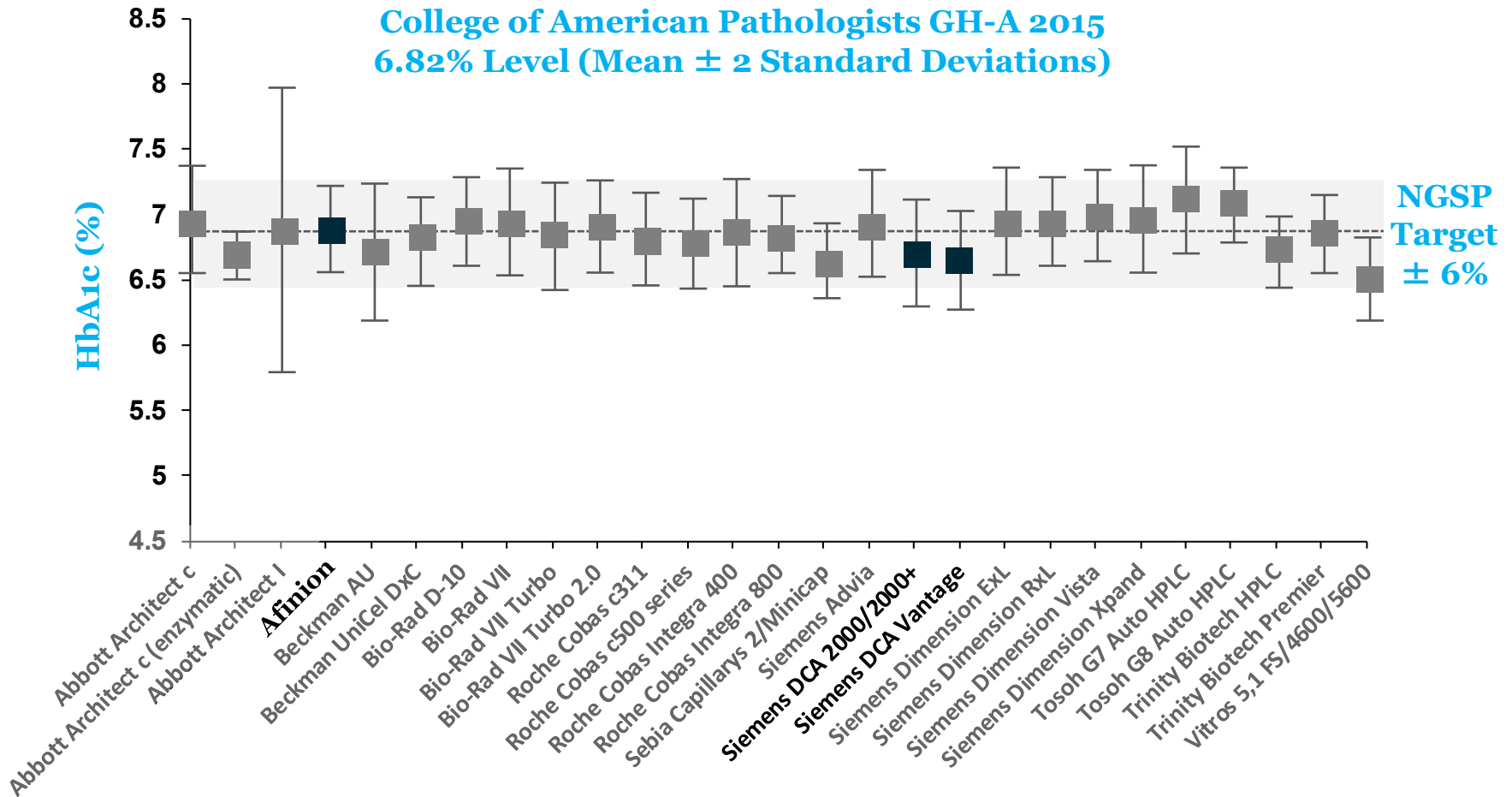
**A.** *POCT can be more expensive on a per-test basis but has been demonstrated to save costs due to improvements in operational efficiencies.*

Sølvik UØ, Røraas T, Christensen NG, Sandberg S. *Clin Chem.* 2013;59(12):1790-801.

Lenters-Westra E, Slingerland RJ. *Clin Chem.* 2014;60(8):1062-72.

Stavelin A, Flesche K, Tollaanes, M, Christensen NG, Sandberg S. *Clin Chem Lab Med.* 2019; Dec [Epub ahead of print].

# Performance Data for Some POC HbA1c Systems: Devices Are Similar to Central Laboratory Standards



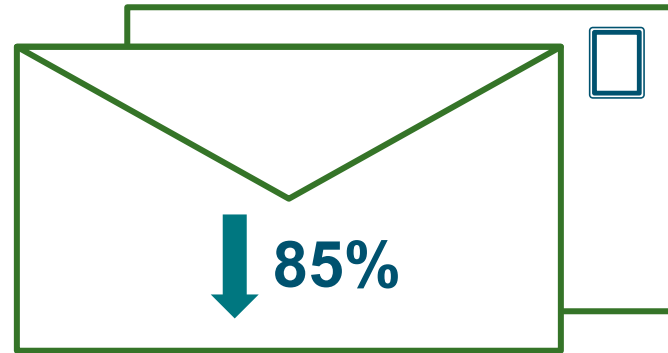
**Afinion, Siemens DCA 2000**  
and **Siemens DCA Vantage** are POC

Permission granted from: NGSP = National Glycohemoglobin Standardization Program

<http://www.ngsp.org/CAP/CAP15a.pdf>. Accessed 09/23/15.



# POC Testing Increases Practice Efficiency and Leads to Cost Reductions



## With POCT

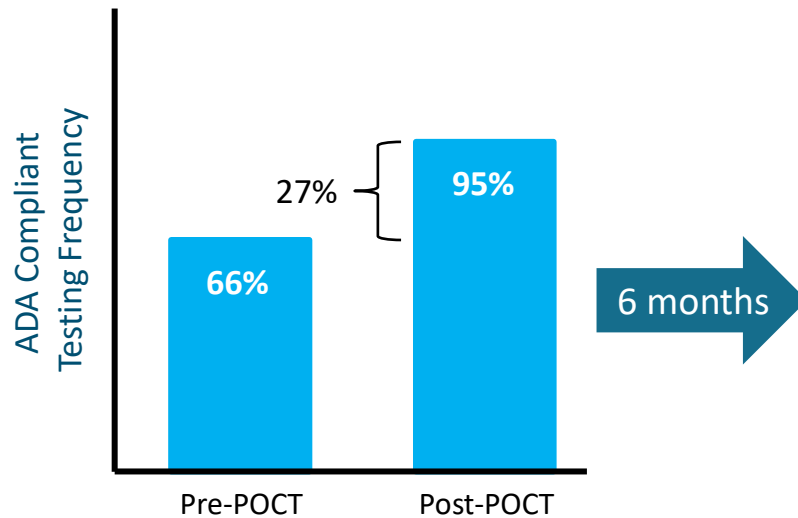
89% fewer follow-up phone calls

85% fewer follow-up letters

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



# POCT: Increased Compliance with Testing Frequency and Reduced HbA1c



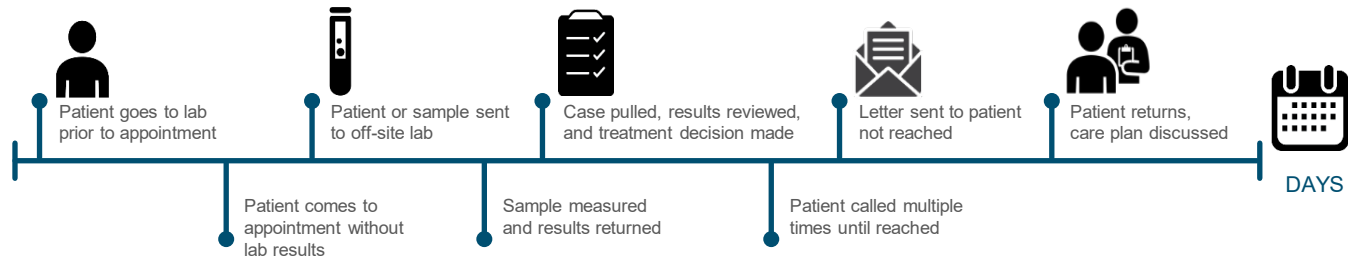
**95%**  
of patient charts  
had guideline compliant  
HbA1c testing with  
significant decreases  
in HbA1c levels  
from mean **8.1%** to **7.7%**

ADA-compliant testing frequency = decreased HbA1c levels<sup>1</sup>

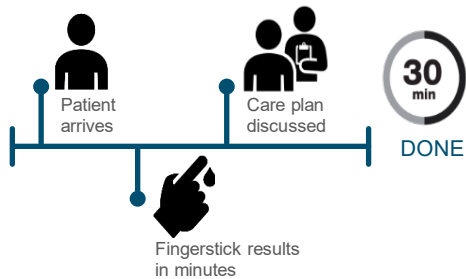
Adapted from: Egbunike V, Gerard S. Diabetes Educator, 2013  
(Study conducted in the US, primary care)

# Workflow: POC Reduces Steps and Inefficiencies

## Central lab



## Point-of-care



Pathways and times are examples for illustrative purposes only

These are just examples for pathways with POCT or testing in the lab and real times may be shorter or longer

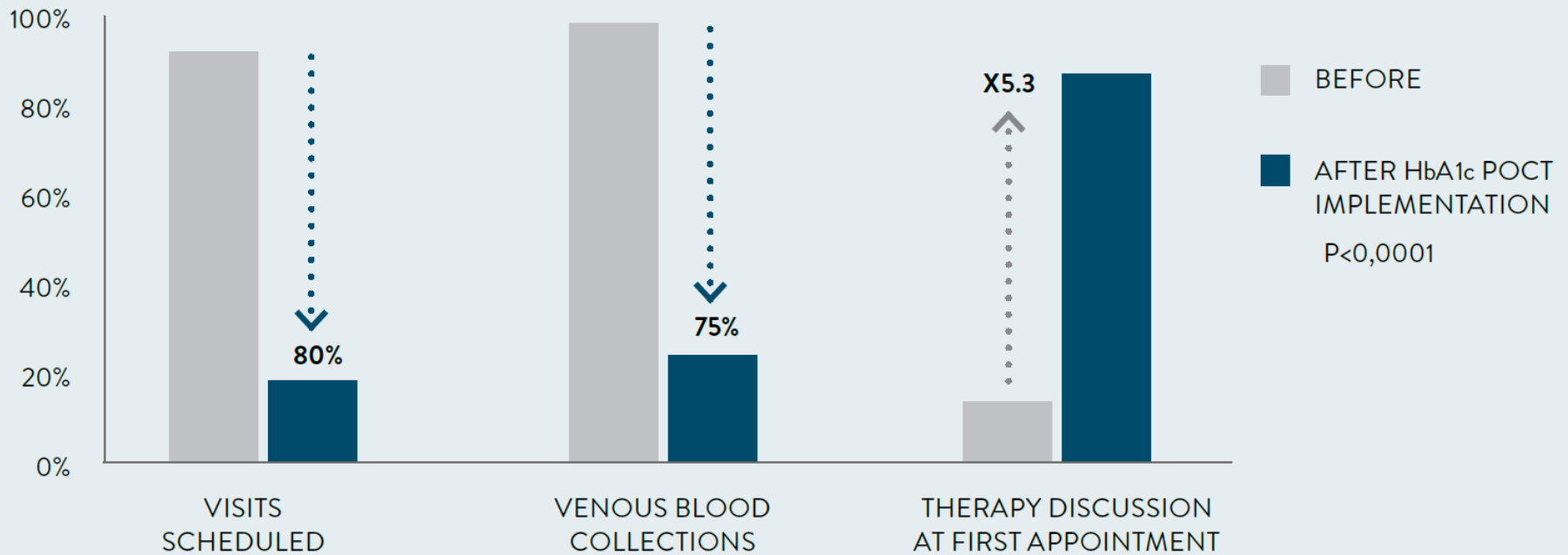
# POCT: Impact on Workflow - Patzer et al. 2018

Original Article  
Journal of Diabetes Science and Technology  
2018, 12(3):687-694  
© 2018 Diabetes Technology Society  
https://doi.org/10.2339/jdst-18-0001  
10.2339/jdst-18-0001

**Implementation of HbA1c Point of Care Testing in 3 German Medical Practices: Impact on Workflow and Physician, Staff, and Patient Satisfaction**

Karl-Heinz Patzer, MA<sup>1</sup>, Payam Ardjomand, MD<sup>2</sup>, Katharina Göhring, MD<sup>3</sup>, Guido Klemptz, MD<sup>4</sup>, Andreas Patzelt, MD<sup>5</sup>, Marius Riedrich, MD<sup>6</sup>, Mathias Zebrowski, MA<sup>7</sup>, Susanne Emmerich, MD<sup>8</sup>, and Oliver Schnell, MD<sup>9</sup>

## Improvement of practice processes



Patzer et al. Journal of Diabetes Science and Technology 2018; 12(3):687-694.  
Schnell et al. IDF congress 2017 poster 345. (Study conducted in Germany, primary care)



# POCT: Impact on Workflow - Patzer et al. 2018

## Time savings

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PRACTICE 1	<b>20 DAYS</b>	<b>95% CI 2-46</b>
------------	----------------	--------------------

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PRACTICE 2	<b>0 DAYS</b>	
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PRACTICE 3	<b>22 DAYS</b>	<b>95% CI 10-44</b>
------------	----------------	---------------------

BASED ON 40-HOUR WORK WEEK;  
CALCULATED FOR 1000 PATIENTS  
HAVING 4 HbA1c MEASUREMENTS  
PER YEAR:

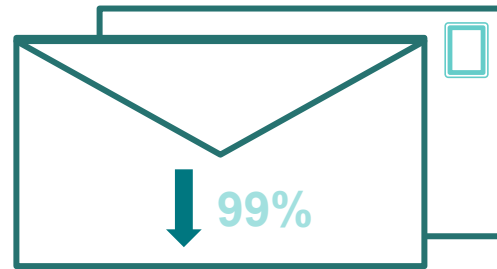
3 CAPILLARY MEASUREMENTS  
WITH POCT, 1 WITH VENOUS  
BLOOD.

Average time saving  
**15 DAYS**

Patzer et al. Journal of Diabetes Science and Technology 2018; 12(3):687-694.  
Schnell et al. IDF congress 2017 poster 345. (Study conducted in Germany, primary care)



# POCT: Impact on Workflow – Lewandrowski et al. 2017



Metrics	Control	POCT	Reduction	P-Value
% Follow-up tests	16 (11-23)	8 (5-14)	<b>50</b>	0.044
% Patient letters	92 (86-96)	1 (0-5)	<b>99</b>	< 0.001
% Patient calls	4 (2-8)	1 (0-5)	<b>75</b>	NS
% Follow-up appointments	13 (8-19)	8 (1-15)	<b>39</b>	NS

Lewandrowski E, Yeh S, Baron J, et al. *Clinica Chimica Acta*. 2017  
(Study conducted in the US, primary care)



# POCT: Impact on Workflow – Lewandrowski et al. 2017

 Net Financial Benefit Per Patient Visit  
\$11.90-\$14.74

Item	\$U.S. per patient
Cost of testing (reagents, consumables, labor)	15.99
Revenue from testing	21.43
Net per patient margin	5.43
Estimated savings from reduction in letters	6.47
<b>Total financial impact</b>	<b>11.90</b>
Savings from efficiencies that were not statistically significant	2.84
<b>Total financial impact</b>	<b>14.74</b>

Lewandrowski E, Yeh S, Baron J, et al. *Clinica Chimica Acta*. 2017  
(Study conducted in the US, primary care)

# POCT: Impact on Satisfaction - Patzer et al. 2018

## Patient satisfaction

**Table 7.** Questionnaire for Patients (Assessment Opinion).

Question	Responses of 298 patients <sup>a</sup>	Mean (n = 298)
1. How did you experience the finger-stick blood collection in comparison to a venous blood collection?	a. Missing response,	3.3%
	b. No difference,	26.5%
	c. More pleasant,	62.1%
	d. Less pleasant.	8.1%
2. Which one would you prefer?	a. Missing response,	3.3%
	b. It doesn't matter,	36.9%
	c. I prefer a finger-stick blood collection,	49.4%
	d. I prefer a venous blood collection.	10.4%
3. Your HbA1c value is being tested directly in your physician's office. Do you see an advantage in this approach?	a. Missing response,	5.7%
	b. Yes, I think this is an advantage,	82.6%
	c. No, I do not see an advantage.	11.7%

<sup>a</sup>100 patients from Bochum and Bonn each and 98 from Bergisch Gladbach.

Patzer et al. Journal of Diabetes Science and Technology 2018; 12(3):687-694.  
Schnell et al. IDF congress 2017 poster 345. (Study conducted in Germany, primary care)

# POCT: Impact on Satisfaction – Laurence et al. 2010

## Patient satisfaction (n=4968)

Areas	Statements	POCT Intervention*	Central Lab Control*	P Value
<b>Collection process</b>	I would rather have blood taken by a finger prick than by needle in my arm	7.8	5.1	< <b>0.001</b>
<b>Confidence in the process</b>	Laboratories have better hygiene than point-of-care testing	4.3	4.6	< <b>0.001</b>
<b>Confidence in the results</b>	I have confidence in the information given by my GP or practice regarding my pathology test result	9.0	8.9	<b>0.010</b>
<b>Convenience</b>	Not having to travel to an outside laboratory would be convenient	8.9	8.7	<b>0.009</b>
<b>Cost</b>	Outside pathology laboratories involves extra time and transport costs	8.5	8.6	<b>0.510</b>
<b>Disease management</b>	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	8.7	<b>0.003</b>
	I am/would be more motivated to look after my condition because of regular point-of-care testing	8.9	8.2	< <b>0.001</b>
	Point-of-care testing strengthened/would strengthen my relationship with my GP	8.3	8.1	<b>0.010</b>

\*median satisfaction score

The score ranges from 0 (completely disagree) to 10 (completely agree) for all statements. The higher the score the higher satisfaction level.

Permission granted through Creative Commons Licence:  
Laurence CO, Gialamas A, Bubner T. Br J Gen Pract. 2010

(Study conducted in Australia, primary care)

# POCT: Impact on Satisfaction - Patzer et al. 2018

## Staff satisfaction

**Table 6.** Questionnaire for Staff Members (Assessment Opinion).

Question	Responses	Total (n = 9), n (%)
1. How did you experience testing with the Alere Afinion ASI00 Analyzer?	a. Easy b. Complicated c. No opinion	9 (100)
2. How do you assess the finger-stick capillary blood collection?	a. Easier than venous b. More difficult c. No significant difference	7 (78)
3. Is there any difference between capillary and venous blood collection in terms of the time needed?	a. Venous is faster b. Capillary is faster c. About the same	2 (22)
4. Did you avoid telephone conversations?	a. Yes b. No c. No change	7 (78)
5. Has the process for scheduling appointments become easier?	a. Yes b. No c. About the same	2 (22)
6. Did you experience a relief of burden for yourself?	a. Yes b. No	8 (89)
		1 (11)
		9 (100)



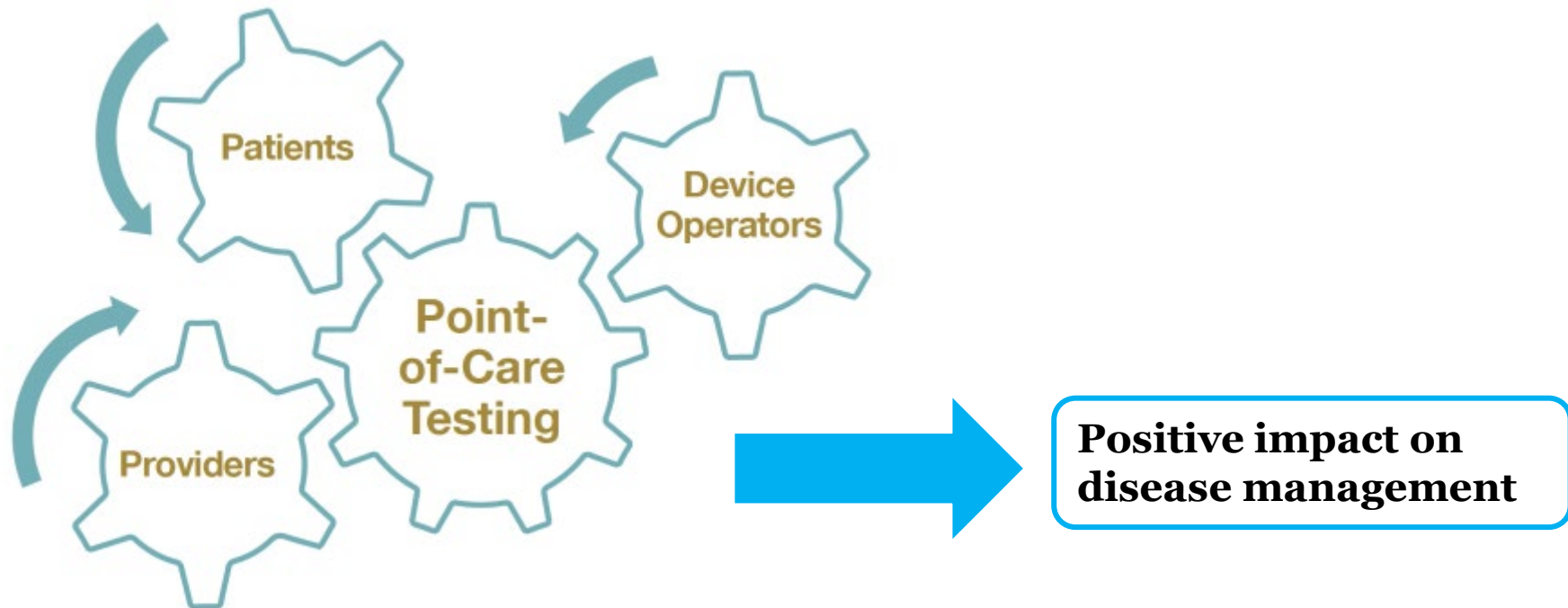
# POCT: Impact on Satisfaction - Patzer et al. 2018

## Physician satisfaction

SCALE		1	2	3	4	5	6	7	8	9	10	MEAN
1 = LOWEST VALUE 10 = HIGHEST VALUE												
1. DID THE IMMEDIATE AVAILABILITY OF HbA1c RESULTS LEAD TO AN IMPROVED PRACTICE WORKFLOW?	YES=5 NO=0								3	2		8,4
2. DID YOU EXPERIENCE A RELIEF OF BURDEN?	YES=5 NO=0							1	2	2		8,2
3. DID THE IMMEDIATE AVAILABILITY OF HbA1c VALUES RESULT IN TREATMENT-IMPROVEMENT?	YES=5 NO=0					1		1	1	1		7,25
4. HOW DO YOU RATE THE IMPLEMENTATION OF HbA1c MEASUREMENT USING POCT OVERALL?	YES=5 NO=0								2	2	1	8,8

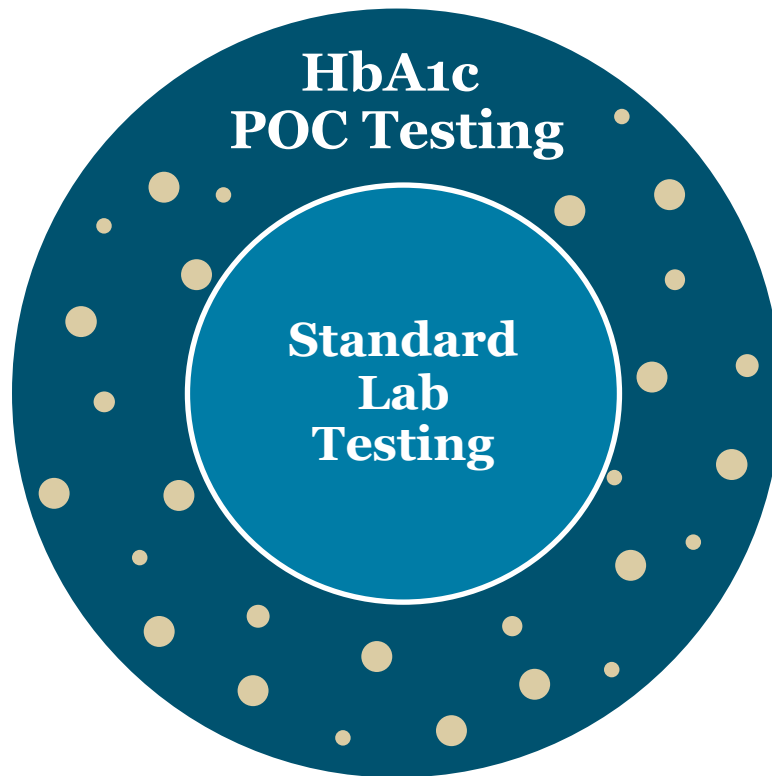
# POC Testing: Increased Overall Satisfaction

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





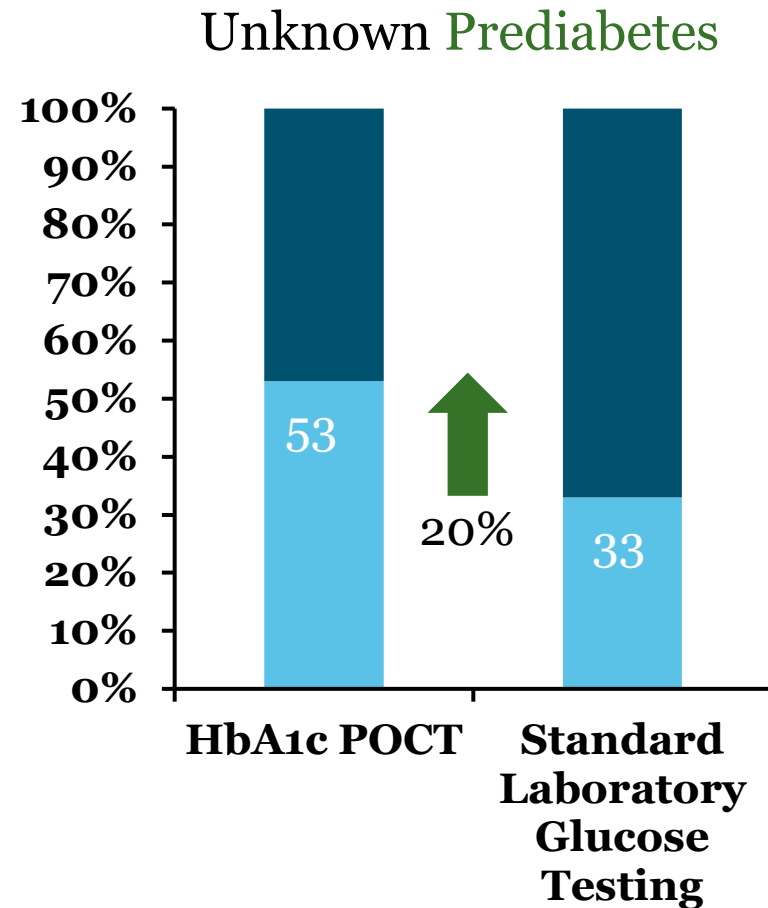
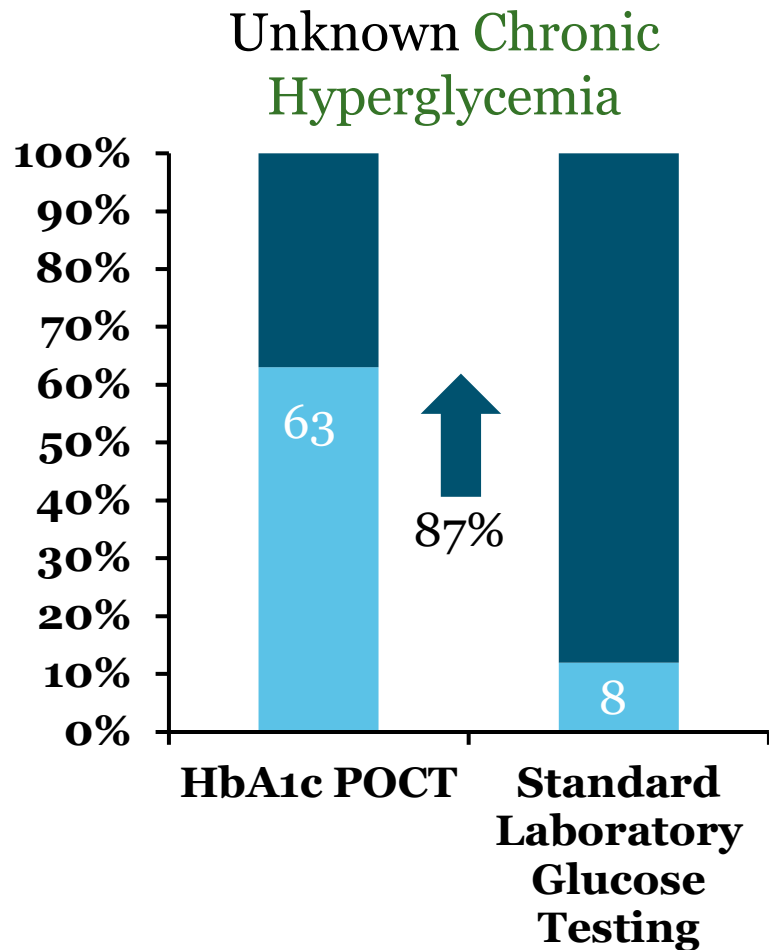
# HbA1c POC Tests Identify More Chronic Hyperglycemic Patients Than Blood Glucose Tests



POC HbA1c tests **increase** the chance for diabetes screening to occur compared to standard practice ( $P = 0.005$ ).

More screening leads to more identification  
and less patients living with unknown uncontrolled diabetes.

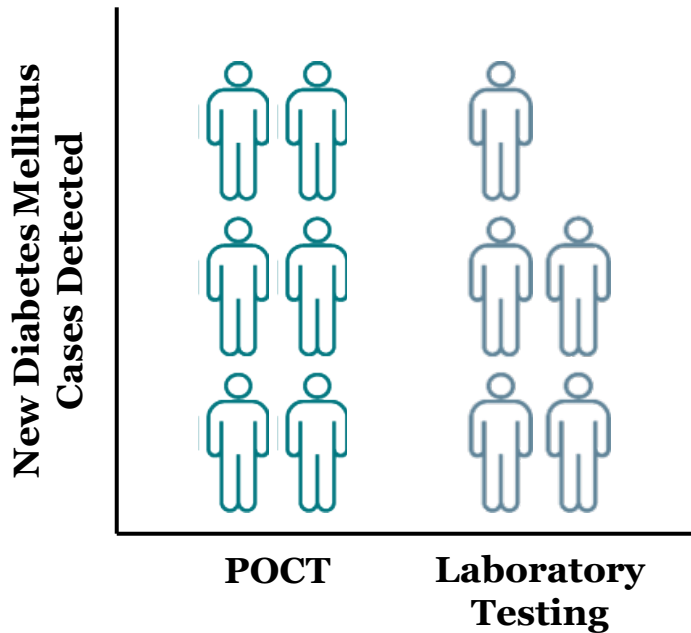
# HbA1c POC Tests Can Identify More Patients With Chronic Hyperglycemia and Prediabetes







# Screening: POC HbA1c Identifies Similar Numbers of New Diabetes Cases as Conventional HbA1c Testing



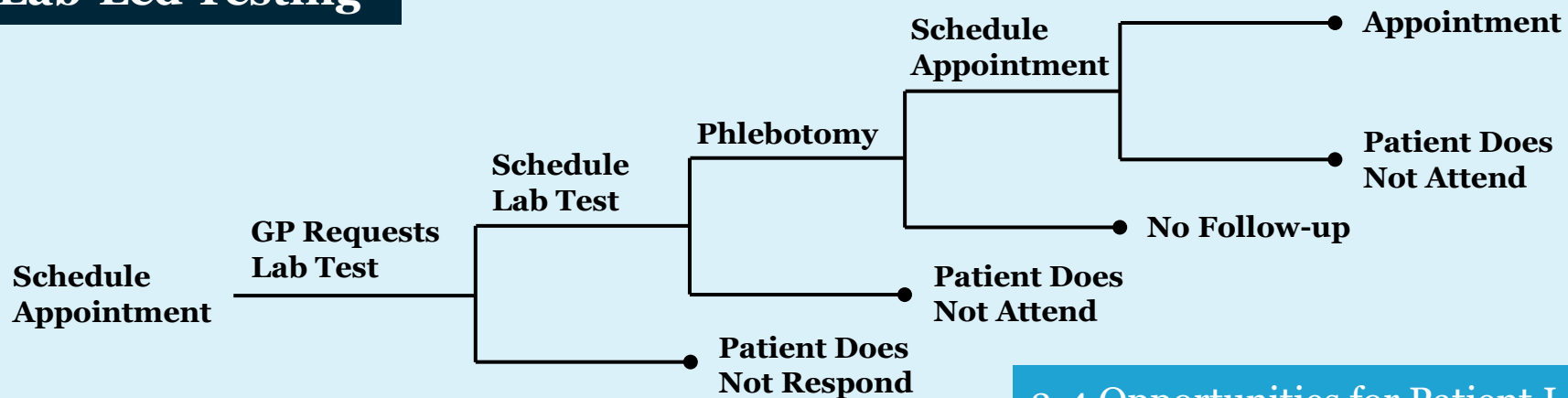
Screening (HbA1c and lipids) was performed at the Hindu Temple in North London.

POCT enables a **‘one stop shop’** approach and **supports better care for under privileged populations.**

**POC HbA1c testing** is **useful for diabetes screening** in the community when confirmed by standard laboratory testing.

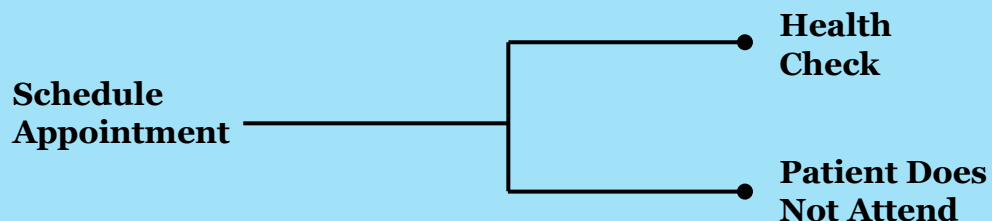
# POC Tests Lead to More Patients Receiving Tests and Results

## Lab-Led Testing



3-4 Opportunities for Patient Loss

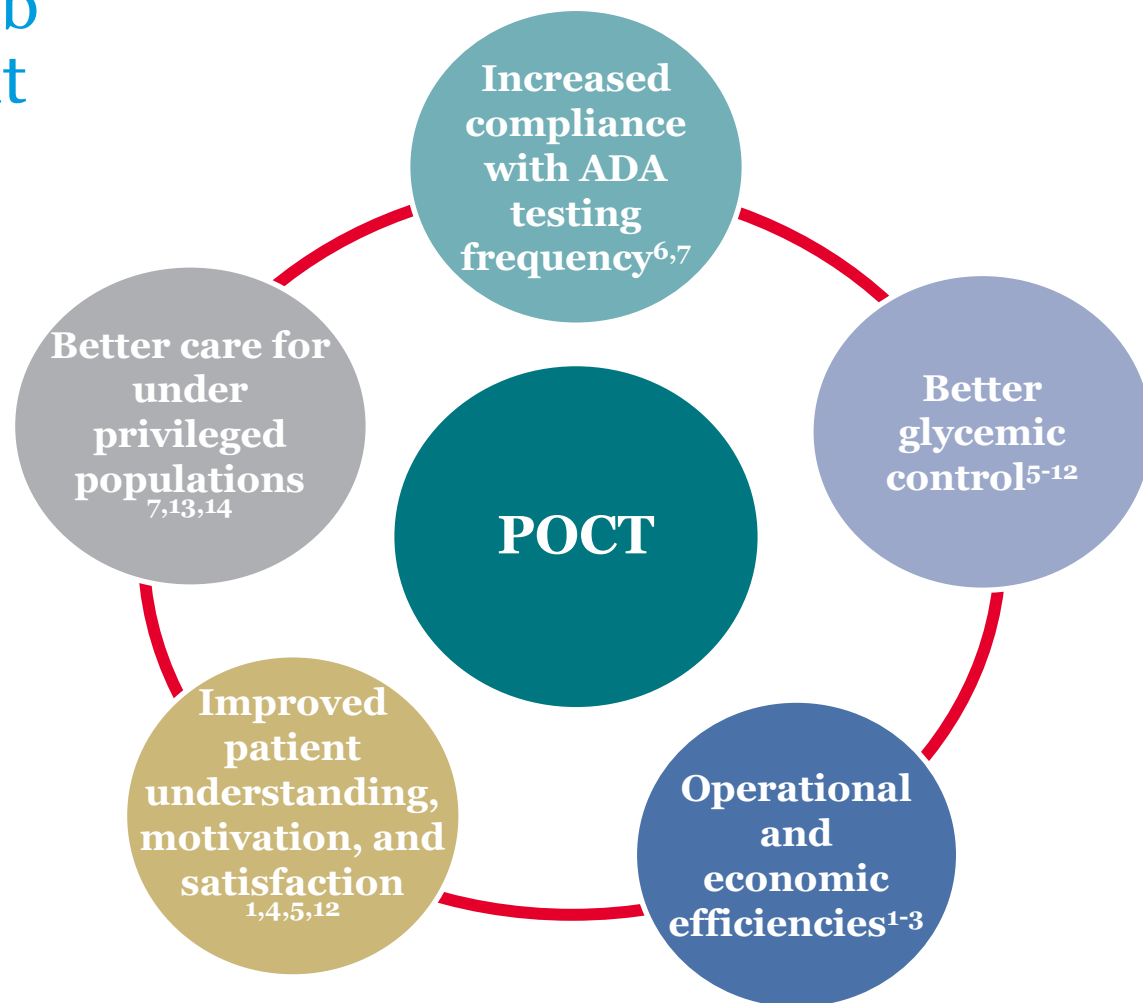
## POC-Led Testing



1 Opportunity for Patient Loss



# Advantages observed with POCT HbA1c vs. Lab for the management of diabetes and comorbidities



Value of Point-of-Care Testing

<sup>1</sup> Patzer KH, Schnell O et al. J Diabetes Sci Technol 2018

<sup>2</sup> Lewandrowski E, Crocker JB et al. Clinica Chimica Acta 2017

<sup>3</sup> Crocker JB, Lee-Lewandrowski E et al. Am J Clin Pathol 2014

<sup>4</sup> Laurence CO, Gialamas A, Bubner T. Br J Gen Pract 2010

<sup>5</sup> Shepard MD. Clin Biochem Rev 2006

<sup>6</sup> Egbunike V, Gerard S. Diabetes Educator 2013

<sup>7</sup> Rust G, Gailor M et al. Int J Healthcare Qual Assurance 2008

<sup>8</sup> Miller CD, Barnes CS, Phillips LS, et al. Diabetes Care 2003

<sup>9</sup> Petersen JR et al. Diabetes Care 2007

<sup>10</sup> Cagliero E et al. Diabetes Care 1999

<sup>11</sup> Pillay S et al. SAMJ 2019

<sup>12</sup> Al Hayek AA et al. Diabetes Ther 2021

<sup>13</sup> Bromley et al. Diabetes & Primary Care 2016

<sup>14</sup> Jain A et al. Ann Clin Biochem 2017

# What is New in POCT and Clinical Practice

**Increasing use of CGM and new metrics for Diabetes**

**Improved Accuracy of CGM**

**Lipid Tests at POC**

**New emphasis on Microalbuminuria screening for CKD in Diabetes**

**Microalbuminuria also available at POC**

**GLUCOSE STATISTICS AND TARGETS**

21 Nov 2018–3 Dec 2018 **13 days**  
 % Time CGM is Active **99.9%**

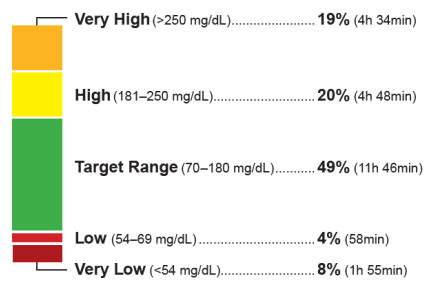
Glucose Ranges	Targets [% of Readings (Time/Day)]
Target Range 70–180 mg/dL	Greater than 70% (16h 48min)
Below 70 mg/dL	Less than 4% (58min)
Below 54 mg/dL	Less than 1% (14min)
Above 180 mg/dL	Less than 25% (6h)
Above 250 mg/dL	Less than 5% (1h 12min)

Each 5% increase in time in range (70–180 mg/dL) is clinically beneficial.

**Average Glucose** **165 mg/dL**  
**Glucose Management Indicator (GMI)** **7.3%**  
**Glucose Variability** **49.4%**

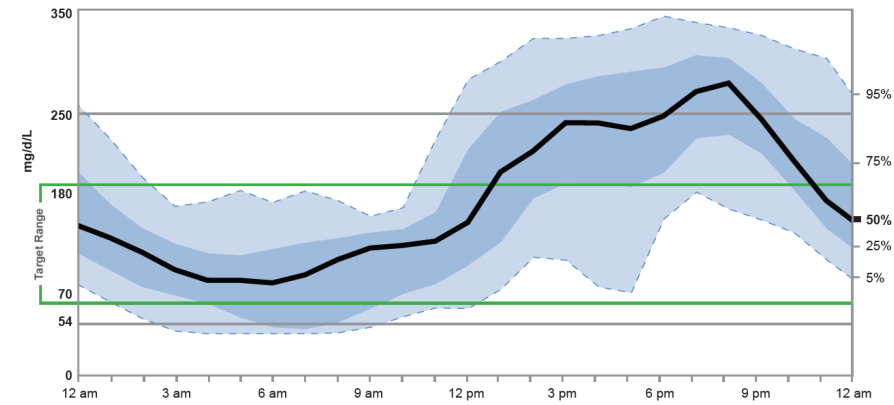
Defined as percent coefficient of variation (%CV): target <36%

**TIME IN RANGES**



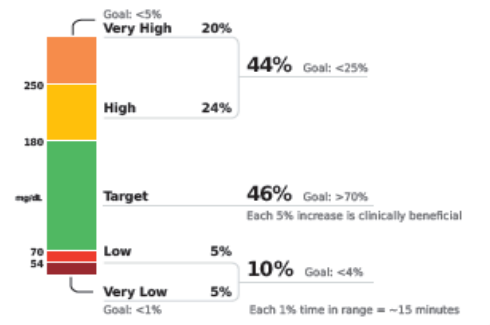
**AMBULATORY GLUCOSE PROFILE (AGP)**

AGP is a summary of glucose values from the report period, with median (50%) and other percentiles shown as if occurring in a single day.



**AGP Report: Continuous Glucose Monitoring**

**Time in Ranges** Goals for Type 1 and Type 2 Diabetes



**Sam Test Patient** DOB: Jan 1, 1970  
**14 Days: August 8–August 21, 2021**  
**Time CGM Active: 100%**

**Glucose Metrics**

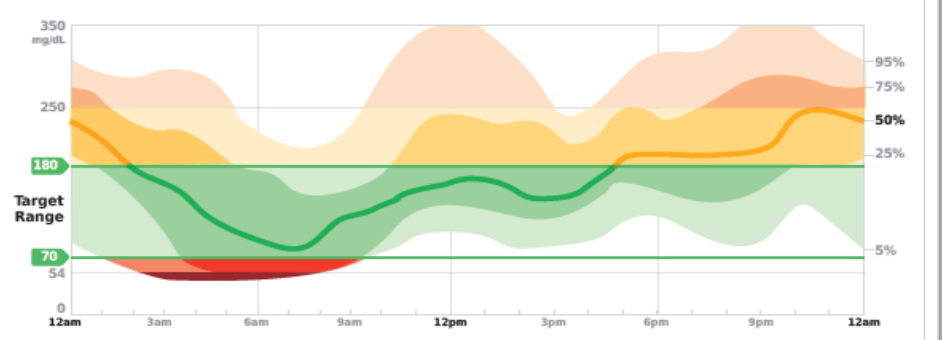
**Average Glucose** ..... **175 mg/dL**  
 Goal: <154 mg/dL

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 Defined as percent coefficient of variation  
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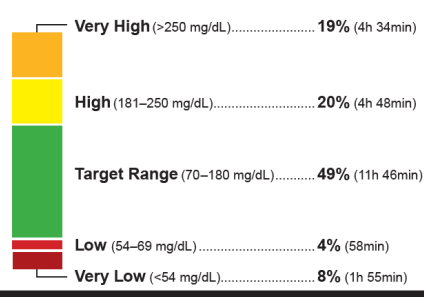
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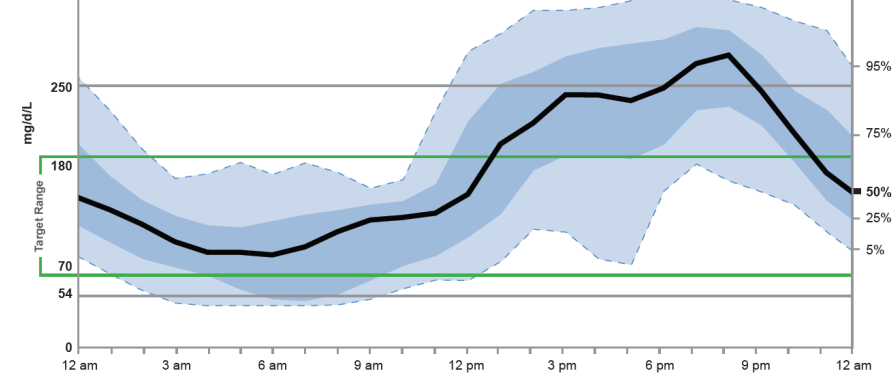
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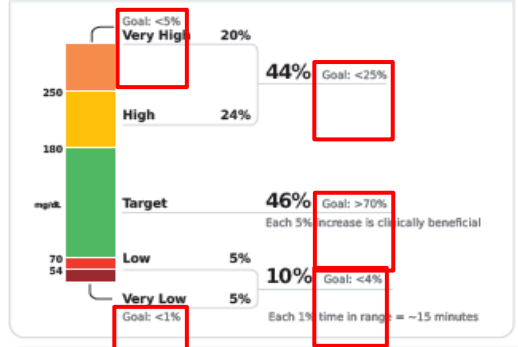
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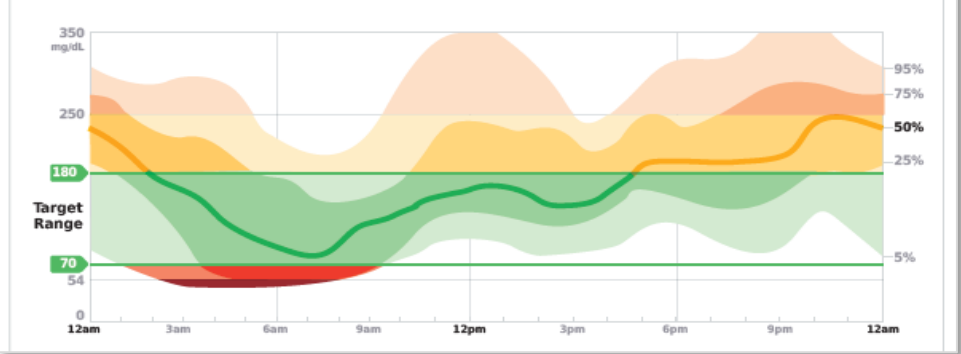
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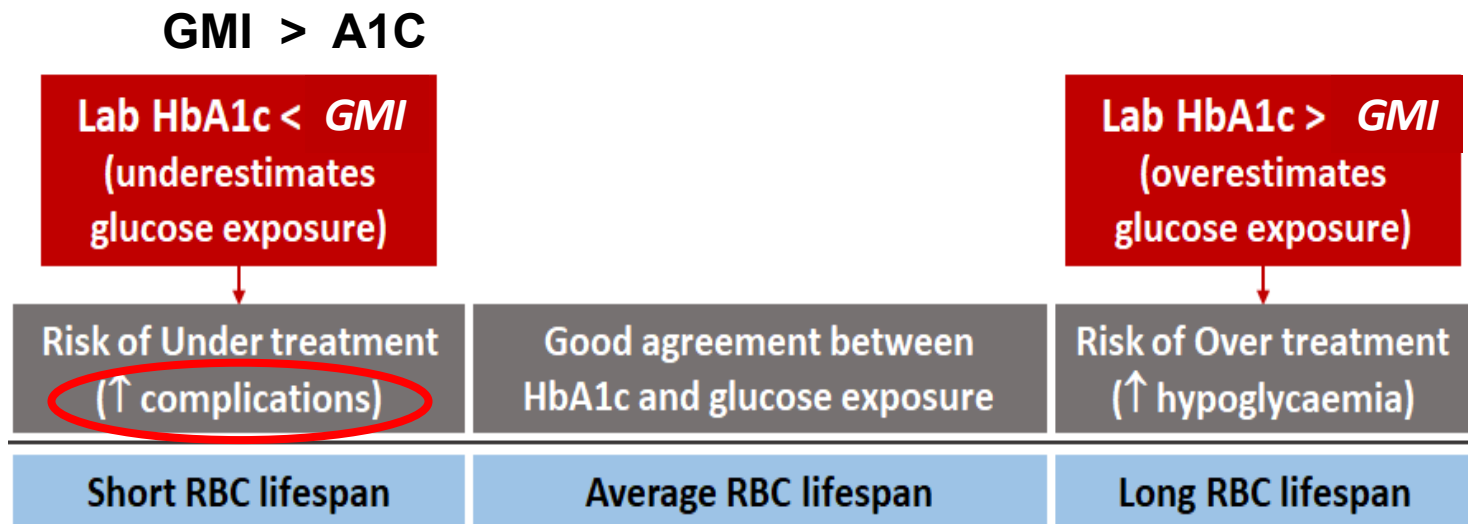
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# Mismatch Between Lab A1C and GMI



R. Bergenstal, R. Beck, K Close et al GMI: New Term for Estimating A1C from CGM. D Care 2018;41:2275-228

Xu Y, Dunn TC, Aijan, RA, Bergenstal RM Addressing shortfalls in Laboratory A1c using a model with RBC lifespan. Elife 2021 Sep 13;10:e69456.



# Screening for Diabetic Kidney Disease

- Early detection is critical
- All patients with T1D should be screened for microalbuminuria beginning 5 yr after diagnosis and annually thereafter
- All patients with T2D should be screened for microalbuminuria at diagnosis with a spot UACR or timed urine collection.
  - If negative, repeat annually thereafter
  - If positive, a spot UACR of 2 out of 3 specimens collected over 3-6 mo (to account for normal variability)
    - Normal range is <30 mg/g
  - Calculation of eGFR
    - eGFR persistently <60 mL/min/1.73 m<sup>2</sup> is considered abnormal



# CKD Diagnosis and Treatment

## Screening and Diagnosis

### Assess

- UACR
- and –
- eGFR

### Diagnose CKD if:

- Persistent UACR  $\geq 30$  mg/g
- and/or –
- Persistent eGFR  $< 60$  mL/min/1.73 m<sup>2</sup>

## Risk Assessment

### CKD associated with:

- ↑ ASCVD (increased risk if UACR  $\geq 30$  mg/g)
- ↑ HF
- ↑ ESKD
- ↑ Hypertension
- ↑ Arrhythmia
- ↑ Hypoglycemia

## Prevention and Treatment

### Goal-directed therapy

- BP control
- Glucose control
- Lipid control

### Lifestyle

- Exercise (150 min/week)
- Nutrition (individualized, no dietary protein restriction)
- Weight loss (if obesity)
- No smoking

### Medications

- Max-tolerated RASi if hypertension + albuminuria
- SGLT2i if eGFR  $\geq 20$  mL/min/1.73 m<sup>2</sup>
- Nonsteroidal MRA (finerenone) if T2D + albuminuria<sup>a</sup>
- Consider GLP1-RA if T2D

<sup>a</sup> Outcomes evidence only available for finerenone. Albuminuria = UACR  $\geq 30$  mg/g.


ASCVD = atherosclerotic cardiovascular disease; BP= blood pressure; CKD = chronic kidney disease; eGFR = estimated glomerular filtration rate; GLP1-RA = glucagon like peptide 1 receptor agonist; HF = heart failure; MRA = mineralcorticoid receptor agonist; RASi = renin angiotensin system inhibitor; SGLT2i = sodium glucose cotransporter 2 inhibitor; T2D = type 2 diabetes; UACR = urine albumin-creatinine ratio.



# Screening: POC Testing Provides Same Lipid Concentrations as Laboratory Methods

Analyte Mean $\pm$ SD (mmol/L) (N = 232)	Cholestech LDX (POCT)	Afinion AS100 (POCT)	Roche (Laboratory Method)
TC	4.0 $\pm$ 0.96	4.2 $\pm$ 0.90	4.2 $\pm$ 1.0
HDL-C	1.1 $\pm$ 0.32	1.2 $\pm$ 0.34	1.2 $\pm$ 0.32
TG	1.8 $\pm$ 1.1	1.9 $\pm$ 1.2	1.9 $\pm$ 1.1

TC: total cholesterol; HDL-C: high-density lipoprotein cholesterol; TG: triglycerides;  
POCT: point-of-care testing.

 **POC lipid testing performance** is similar to standard laboratory testing.

**THANKS FOR YOUR ATTENTION !**



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