PoCT Supporting Management of Diabetic Patients

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CEO of the Center Specialized in Diabetes, Obesity and Prevention of Cardiovascular Diseases S.C.
People with diabetes (6.4-14 million adults)*

Reversible changes
People with impaired glucose tolerance.
(20-25 million)*

Reversible changes
Population without diabetes, exposed to risk factors
(35-45 million)

Inflammatory endotelial process since birth.

*ENEC, 1993, ENSANUT 2012
Top 10 Causes of Death are Diabetes and Its' Complications

<table>
<thead>
<tr>
<th>No.</th>
<th>Clave CIE 10a. Rev.</th>
<th>Descripción</th>
<th>Defunciones</th>
<th>Tasa 1)</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>E10-E14</td>
<td>Diabetes mellitus</td>
<td>29,554</td>
<td>42.6</td>
<td>14.6</td>
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<tr>
<td>2</td>
<td>K70, K72.1, K73, K74, K75</td>
<td>Cirrosis y otras enfermedades crónicas del hígado</td>
<td>18,006</td>
<td>26.1</td>
<td>8.9</td>
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<tr>
<td>3</td>
<td>I20-I25</td>
<td>Enfermedades isquémicas del corazón</td>
<td>14,968</td>
<td>21.6</td>
<td>7.4</td>
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<tr>
<td>4</td>
<td>X34-X90, Y37.1</td>
<td>Accidentes de tráfico de vehículo de motor</td>
<td>13,314</td>
<td>19.2</td>
<td>6.6</td>
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<tr>
<td>5</td>
<td>I85-I89</td>
<td>Enfermedad cerebrovascular</td>
<td>7,054</td>
<td>10.2</td>
<td>3.5</td>
</tr>
<tr>
<td>6</td>
<td>B20-B24</td>
<td>VIH/SIDA</td>
<td>4,661</td>
<td>7.2</td>
<td>2.4</td>
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<tr>
<td>7</td>
<td>N00-N19</td>
<td>Neftis y nefrosis</td>
<td>4,749</td>
<td>6.8</td>
<td>2.3</td>
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<tr>
<td>8</td>
<td>X60-X64, Y87.0</td>
<td>Lesiones autoinfligidas intencionalmente (suicidios)</td>
<td>4,089</td>
<td>5.9</td>
<td>2.0</td>
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<tr>
<td>9</td>
<td>I10-I15</td>
<td>Enfermedades hipertensivas</td>
<td>3,363</td>
<td>4.8</td>
<td>1.7</td>
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<tr>
<td>10</td>
<td>C50</td>
<td>Tumor maligno de la mama</td>
<td>3,275</td>
<td>4.7</td>
<td>1.6</td>
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<tr>
<td>11</td>
<td>J00-J18, J20-J22</td>
<td>Infecciones respiratorias agudas bajas</td>
<td>2,969</td>
<td>4.3</td>
<td>1.5</td>
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<tr>
<td>12</td>
<td>C53</td>
<td>Tumor maligno del cuello del útero</td>
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<td>1.2</td>
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<td>13</td>
<td>C16</td>
<td>Tumor maligno del estómago</td>
<td>2,371</td>
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<td>1.2</td>
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<td>14</td>
<td>J40-J44, J47</td>
<td>Enfermedad pulmonar obstructiva crónica</td>
<td>2,146</td>
<td>3.1</td>
<td>1.1</td>
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<td>15</td>
<td>F10, G31.2</td>
<td>Uso de alcohol</td>
<td>2,095</td>
<td>3.0</td>
<td>1.0</td>
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<td>16</td>
<td>C91-C95</td>
<td>Tumor maligno de tráquea, bronquios y pulmón</td>
<td>2,007</td>
<td>2.9</td>
<td>1.0</td>
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<tr>
<td>17</td>
<td>C01-C90</td>
<td>Tumor maligno del sistema nervioso</td>
<td>1,822</td>
<td>2.6</td>
<td>0.9</td>
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<tr>
<td>18</td>
<td>W65-W74</td>
<td>Tumor maligno del sistema endocrino</td>
<td>1,773</td>
<td>2.6</td>
<td>0.9</td>
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<tr>
<td>19</td>
<td>R00-R99</td>
<td>Total</td>
<td>65,210</td>
<td>94.0</td>
<td>32.2</td>
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</tbody>
</table>

1) Tasa por 100,000 habitantes
### Table 4 Major diabetes complications and their direct costs in Mexico

<table>
<thead>
<tr>
<th>Complication</th>
<th>Direct costs attributable to diabetes complications in US dollars*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinopathy</td>
<td>4,968,491</td>
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<tr>
<td>Cardiovascular disease</td>
<td>4,516,810</td>
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<tr>
<td>Nephropathy</td>
<td><strong>32,972,722</strong></td>
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<tr>
<td>Neuropathy</td>
<td>1,626,050</td>
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<tr>
<td>Peripheral vascular disease</td>
<td>1,084,033</td>
</tr>
</tbody>
</table>

* 2005 estimates were for the three main public institutions of the Mexican health care system; 2010 estimates included private costs and private insurances.
ECONOMIC IMPACT OF METABOLIC SYNDROME, IMSS.

2006

Cardiovascular Disease

GLUCOSE INTOLERANCE

Diabetes Mellitus

Obesity

Sedentarism

Systemic Arterial Hypertension

More than 25% of the budget

Bad Nutrition Habits

Tabacco and Alcohol

Insulin Resistance

Hiperinsulinism

Bad Stress Management

Cerebrovascular Disease (Stroke)

METABOLIC SYNDROME

- in 6.9 years,
- n=360 (10%) died,
- n=209 (5.8%) died of cardiovascular disease.

Cardiovascular (CV) mortality ↑12% vs 2.2% (p<0.001)

Microalbuminuria showed the highest risk of CV disease mortality (RR 2.8; p=0.002)

Risk of Coronary Artery disease and Stroke ↑3 times (p<0.001)

Total Mortality rate 18% vs. 4.6% (p<0.001)

PATHOPHYSIOLOGY OF THE
METABOLIC SYNDROME

Insulin Resistance

Manifestations

Hyperinsulinemia
Obesity
H.T.N
Dyslipidemia
Hyperuricemia
Fibrinolysis Alt.
P.C.O.S

β Cell Failure

IGT

DM 2

Endothelial Dysfunction
Accelerated Atherosclerosis

Cardiovascular Disease

# PATHOPHYSIOLOGY OF TYPE 2 DIABETES

**Normoglycemia**

- Impaired glucose tolerance

**Type 2 Diabetes**

- **PANCREATIC RESERVE**
  - 0-5y
  - 6-15y
  - >15y

**Diet + Systematic Exercise**

- **Oral Hypoglycemic agents**

**Insulin**

- Systematic Exercise
- Diet + Systematic Exercise
- +Insulin or Oral Hypoglycemic agents (with reserve)

**Microalbuminurinuria > 30 mg**

- Alb/Creat Ratio > 300mg/g

**CLINICAL**

- **HbA1c <6.5%**
- **HbA1c >6.5%**
- Insulin Reserve slowly decreases, addition persistent high levels of glucose.
- Insulin deficiency and waisting.

**PREVENTION**

- Low Costs

**Diabetes**

- Insulin Resistance appears 15-20 before DM onset.
- To compensate there is a metabolic state of hyperinsulinemia.
- Dyslipidemia and HTN.
- Insulin deficiency and waisting.

**Diabetes Prevention**

- Islet inhibitors
- Insulin sensitizers
- Lipid lowering agents
- Blood pressure control

**TREATMENT**

- Insulin

- Some diabetic patients develop close to complete loss of insulin secretion.
  - These patients are usually malnourished with metabolic discontrol.
Diabetic Nephropathy is not adequately treated in the Comprehensive treatment of Diabetes.

In USA most of the comorbidities remain low in the last 20 years.

Diabetic Nephropathy remains the same for the last 20 years.

Studies and intents to treat are limited.

→The REASON may be lack of work regarding comprehensive treatment with an Endocrine-Nephrologist approach.
EVERY PATIENT IS DIFFERENT: PERSONALIZED TREATMENT!

BEGINNING: Patient with an early diagnosis of T2DM

Mechanisms of Diabetic Nephropathy Progression are Unknown

- Final Result:
  Renal Replacement Treatment

OBVIOUS NEED FOR: CUTTING-EDGE INVESTIGATION

Study the mechanisms responsible for the progression of renal disease in diabetic patients.
1) Improved prognosis.
2) Treatment of evidence-based medicine.
Growing Obesity and T2DM epidemic.

- High treatment related health costs, which are not sustainable.
- Lack of adequate Prevention models.
- Neglect of vulnerable populations in Mexico.

- It's cheaper to prevent than cover expensive health costs related to complications according to the natural course of the disease!!
KEY TREATMENT

Prevention and Primary care
Loss of 30% Visceral Fat

- Helps lower blood pressure levels
- Improves lipid profiles
- Increases insulin sensitivity
- Lowers risk of thrombosis
- Lowers inflammatory markers

- Lowers risk of Cardiovascular Disease.
Food portions and plate size increase over time

Include physical activity, and share good food, and great moments.

Baron RB en: Papadakis MA et al. Current Medical... 2013
National Programs to promote the use of bicycles

Mexico City and 86 other Mexican cities promote the massive use of bikes:

- Promote a greater use of bicycles in Mexico,
- Fight obesity and climate change (global warming).
- Strengthen family ties and building happier and healthier cities.
Control parameters and Diagnostic Tools
Increased pressure to improve patient’s follow-up and results

Diabetes is a growing epidemic all around the world!

- Identify pre-diabetics to reduce risk of progression
- Find undiagnosed patients as soon as possible
- Ensure glycemic control and renal function.
→ It serves as a marker for estimating average glucose levels over the previous 8-12 weeks.

→ It has been validated to use for diagnosis of DM and for follow-up patients.
Better glycemic control equals less complications

- Microvascular complications (nephropathy, blindness)*: 37%
- Amputation or peripheral artery disease*: 43%
- Deaths related to DM*: 21%
- Acute MI*: 14%
- Stroke**: 12%

* p<0.0001
** p=0.035

Glucometers suggest good glycemic control

Capillary Glucometer

- Glucose sensor
- Glucose average

Glucose (mg/dL)

A1C = 8.0%

Courtesy of CEDOPEC
HbA1c suggests the need to adjust treatment and safe therapeutic intervention

Cortesía CEDOPEC
INDIVIDUALIZED TREATMENT

INDIVIDUALIZE GOALS

**A1c ≤ 6.5%**
For patients without concurrent serious illness and at low hypoglycemic risk

**A1c > 6.5%**
For patients with concurrent serious illness and at risk for hypoglycemia
• Reproducibility: coefficient of variation = 3.39%

• Linearity, correlation coefficient = 0.9955
HbA1c measurement during a doctor’s visit shows improvement in care efficiency and patient results.

Immediate HbA1c results during the visit has demonstrated a better glycemic control in patients with type 1 and type 2 diabetes. ¹,²
Convenient, Cost-effective Testing Procedure

- No phlebotomy; only 1 μL of fingerstick blood needed
- No requirement for patient fasting, dietary changes, or glucose beverage ingestion before testing
- No sample or reagent preparation
- Simple, four-step test process does not require a lab technician
- No need for expensive external laboratory tests

Advantages of in-clinic DCA HbA1c testing
Fast and Flexible Results Reporting

- HbA1c results are available to Diabeter physicians in just 6 minutes
- Dual HbA1c reporting in mmol/mol and % HbA1c
- DCA HbA1c test is NGSP certified, traceable to IFCC reference materials and test methods and is CLIA-waived in the US
Certificate

Traceability of Manufacturers to the IFCC Reference Measurement Procedure for HbA1c

This certifies that Siemens Healthcare Diagnostics using DCA Vantage, participates in the Monitoring Programme to demonstrate traceability. In the Monitoring Programme of 2014 the following performance was seen:

- Deviation from IFCC-target at 30 mmol HbA1c/mol Hb: 2.1
- at 60 mmol HbA1c/mol Hb: 2.6
- at 90 mmol HbA1c/mol Hb: 3.0

Reproducibility, coefficient of variation: 3.39%

Linearity, correlation coefficient: 0.9955

Date of issue: 10 December 2014

Certification expires: 31 December 2015

IFCC Network Coordinator

[Signature]
Certificate of Traceability

Manufacturer Certification

This certifies that **Siemens Healthcare Diagnostics**, using **DCA Vantage** has participated in and successfully completed the NGSP certification for manufacturers and is traceable to the **Diabetes Control and Complications Trial** Reference method. The comparison was performed with: **University of Missouri SRL#9**

The system evaluated was:

<table>
<thead>
<tr>
<th>Instrument:</th>
<th><strong>DCA Vantage</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent Lot:</td>
<td><strong>0912035</strong></td>
</tr>
</tbody>
</table>

Date of Certification: **June 1, 2015**  
Certification Expires: **June 1, 2016**

**David Jacobs**  
NGSP Steering Committee Chair

**Lindie R. Little PhD.**  
NGSP Network Coordinator

**Sheri Arnold**  
SRL director/supervisor
Effective Patient Management

- Actionable results at the time of the Diabeter patient visit
- Clinical studies show that face-to-face testing along with direct physician-to-patient guidance significantly improves patient compliance.
- DCA Vantage Analyzer HbA1c patient-trending graphs can be used to track a patient’s progression.

Advantages of in-clinic DCA HbA1c testing
MOST COMMON CAUSES OF INACCURACY

• Low erythrocyte half-life

• Acute blood loss

• Renal insufficiency, pregnancy and anemia.
Advantages of in-clinic DCA HbA1c testing

HbA1c testing on the DCA Vantage Analyzer is integral to the success of the Diabetes care program, which is helping people with diabetes to:

• Reduce and stabilize their long-term blood glucose levels

• Lower their risk of long-term complications

• Minimize the frequency and duration of their visits to hospital

• Self-monitor their condition with support via cost-effective e-communication
## HbA1c Comparison

<table>
<thead>
<tr>
<th>Gender</th>
<th>DCA VANTAGE</th>
<th>COVANCE USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>MASCULIN</td>
<td>9.90%</td>
<td>8.80%</td>
</tr>
<tr>
<td>MASCULIN</td>
<td>10.40%</td>
<td>9.70%</td>
</tr>
<tr>
<td>FEMENIN</td>
<td>8.30%</td>
<td>8.70%</td>
</tr>
<tr>
<td>MASCULIN</td>
<td>7.10%</td>
<td>6.80%</td>
</tr>
<tr>
<td>MASCULIN</td>
<td>9.20%</td>
<td>9.40%</td>
</tr>
<tr>
<td>FEMENIN</td>
<td>7.70%</td>
<td>7.90%</td>
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# HbA1c Comparison

<table>
<thead>
<tr>
<th>Gender</th>
<th>DCA VANTAGE</th>
<th>QUINTILES USA</th>
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<tbody>
<tr>
<td>Masculino</td>
<td>9.20%</td>
<td>9%</td>
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<tr>
<td>Masculino</td>
<td>10.80%</td>
<td>10.60%</td>
</tr>
<tr>
<td>Masculino</td>
<td>7.10%</td>
<td>7.50%</td>
</tr>
<tr>
<td>Masculino</td>
<td>7.70%</td>
<td>7.90%</td>
</tr>
<tr>
<td>Femenino</td>
<td>7.10%</td>
<td>7.20%</td>
</tr>
<tr>
<td>Femenino</td>
<td>8.90%</td>
<td>9.10%</td>
</tr>
<tr>
<td>Femenino</td>
<td>8.90%</td>
<td>9.20%</td>
</tr>
<tr>
<td>Femenino</td>
<td>6.80%</td>
<td>8%</td>
</tr>
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</table>
New Solutions Should Improve These Pressures

- Identify pre-diabetics to reduce risk of progression
- Find undiagnosed patients as soon as possible
- Ensure glycemic control to avoid complications

- Easy to Use
- Precise results which are on time to adjust treatment regimens
- Simple and convenient tests can improve diagnosis
- We need precise results to monitor levels of HbA1c

High Quality Lab
POOR GLYCEMIC CONTROL

-Great predictor of mortality and CV events

If the GFR < 30 ml/min/1.73 m², there is a greater risk of death.

7.3% of patients have microalbuminuria when diagnosed with DM.

Alb/Creat Ratio
Chronic Renal Disease avoids the adequate kidney function, it presents secondary to diseases like Diabetes and Hypertension, representing 60% of patients with chronic dialysis.

**Monitoring Frequency (Numb. times/year) according to GFR and albuminuria category**

<table>
<thead>
<tr>
<th>G1</th>
<th>G2</th>
<th>G3a</th>
<th>G3b</th>
<th>G4</th>
<th>G5</th>
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</thead>
<tbody>
<tr>
<td>≥90</td>
<td>60-89</td>
<td>45-59</td>
<td>30-44</td>
<td>15-29</td>
<td>&lt;15</td>
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<table>
<thead>
<tr>
<th>Description</th>
<th>Range</th>
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<tbody>
<tr>
<td>Normal to mildly decreased</td>
<td>A1</td>
</tr>
<tr>
<td>Moderately increased</td>
<td>1 if CKD</td>
</tr>
<tr>
<td>Severely increased</td>
<td>2</td>
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**Pesistant Albuminuriria Category. Description and Range**

<table>
<thead>
<tr>
<th>A1</th>
<th>A2</th>
<th>A3</th>
</tr>
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<tbody>
<tr>
<td>&lt;30 mg/g</td>
<td>&lt;3 mg/mmol</td>
<td>&gt;300 mg/g</td>
</tr>
<tr>
<td>&lt;30-300 mg/g</td>
<td>&lt;3-30 mg/mmol</td>
<td>&gt;30 mg/mmol</td>
</tr>
</tbody>
</table>

ADA has stated a preference for the A/C ratio for screening EKD.

AACE/ACE Diabetes Guidelines, *Endocr Pract.*, 2015;21(Suppl 1)
Unidades de Atención a Diabéticos (UAD)

Las Unidades de Atención a Diabéticos del Estado de México son unidades médicas especializadas en la detección y tratamiento de pacientes con diabetes tipo 2, hipertensión y síndrome metabólico.

NEED TO EMPHASIZE ON RENAL PREVENTION!!!
CONCLUSIONS

• PoCT is a practical tool used in the clinician’s office, to assess diabetic patient’s glycemic control, side by side with patient, explain the best therapeutic approach and adjust the treatment regimen.

• PoCT has been found to have a positive impact on the process of care in the patients with diabetes.

• Studies have also described an improvement in patient satisfaction and glycemic control as a result of the immediate feedback of PoCT.
Diabetes is a growing epidemic worldwide. Our Mision in CEDOPEC S,c,.: PREVENTION

“Hospitals are the most expensive hotels in the world. Fewer and shorter hospital visits help make the care we provide significantly more cost-effective”

Dr. Henk-Jank Asnstoot

Ensure glycemic control with HbA1c
Thank you for your attention!

Dr. Melchor Alpízar Salazar
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