BLOOD GLUCOSE MONITORING: CLINICAL NEED AND TECHNOLOGY

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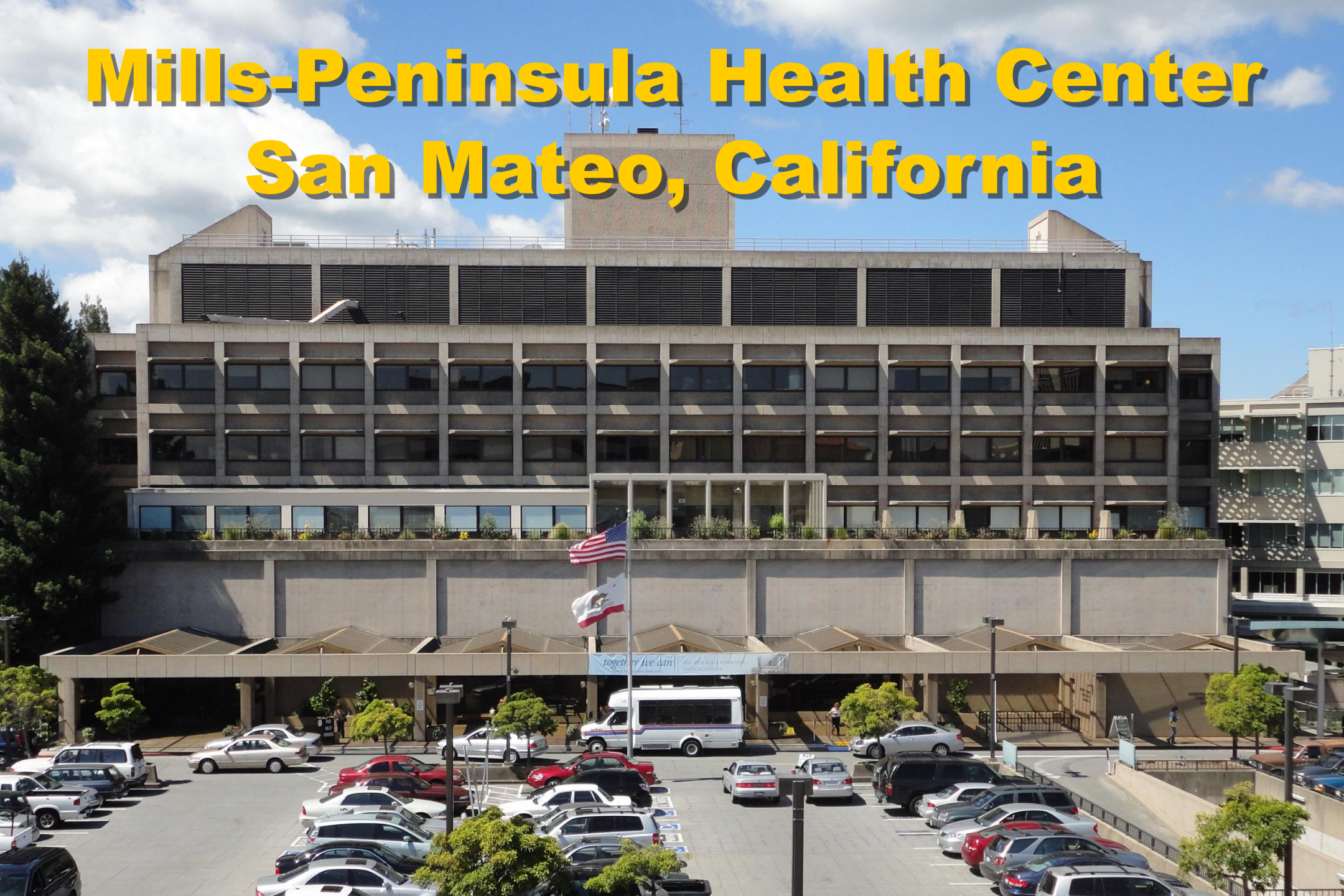

SMBG - AN ESTABLISHED AND EVOLVING INTERVENTION TO IMPROVE OUTCOMES

CURRENT STATUS

- Safety to pts/non-pts is under scrutiny
- Accuracy requirements are in flux and industry must now improve accuracy
- Clinical indications are established for insulin Rx but controversial in NIT T2
- New barriers & opportunities ensure that SMBG has an unknown future

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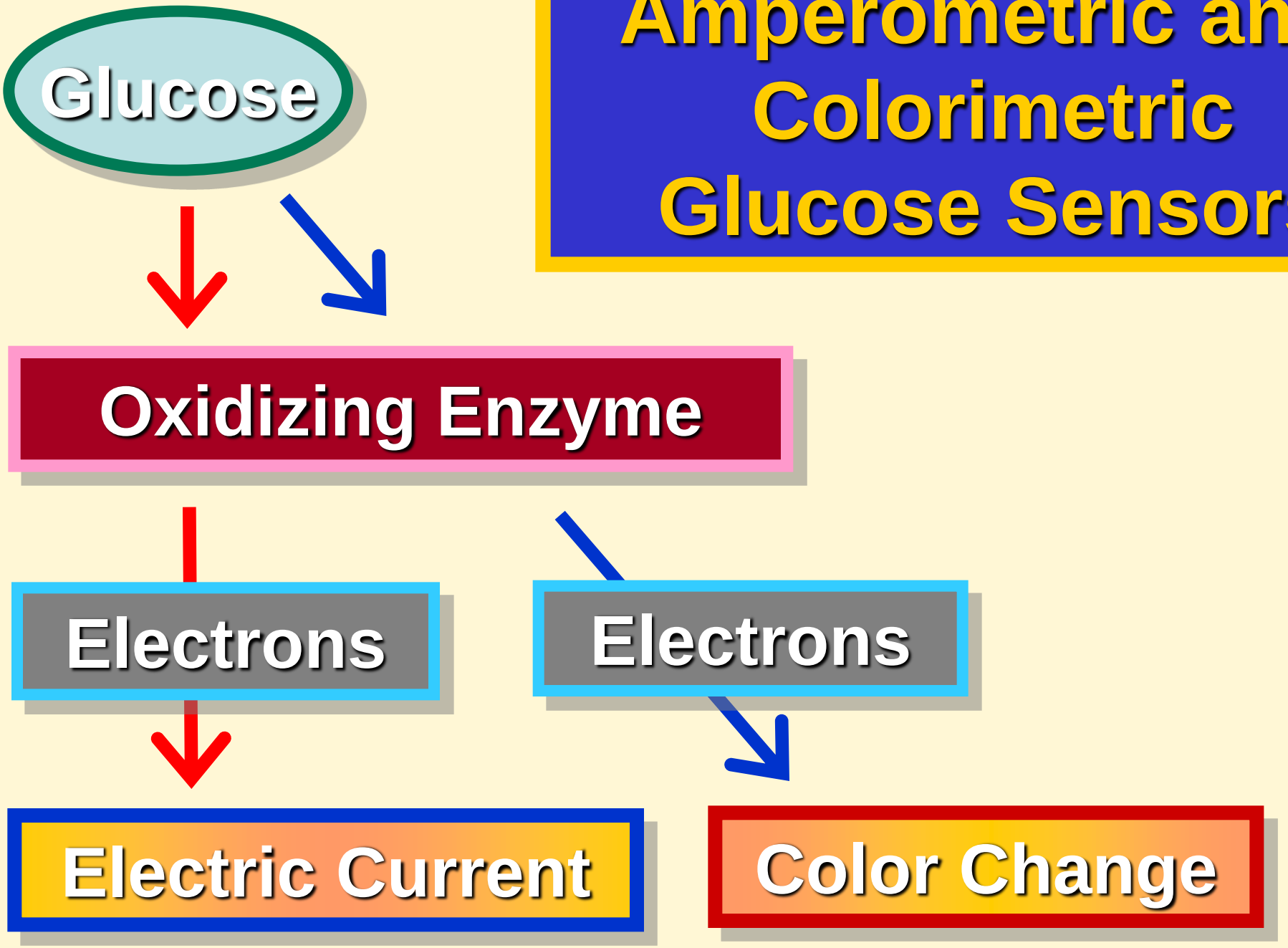
FUTURE DIRECTIONS IN BLOOD GLUCOSE MONITORING

- Technology
- Safety
- Accuracy
- Clinical Indications
- Barriers and Opportunities

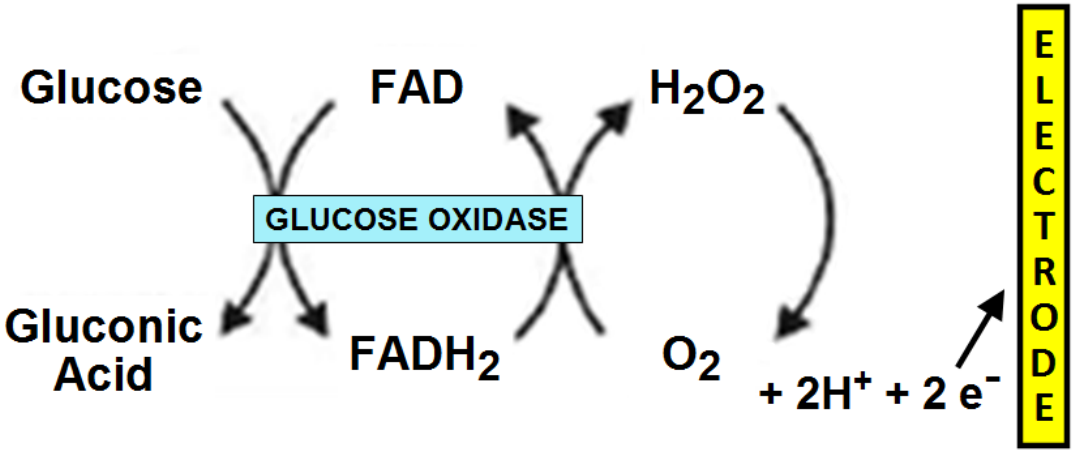
TECHNOLOGY

Amperometric and Colorimetric Glucose Sensors

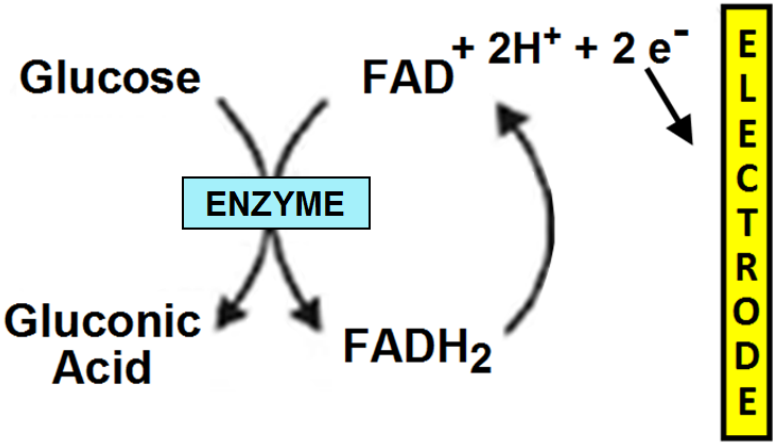


FOUR GENERATIONS OF GLUCOSE BIOSENSORS

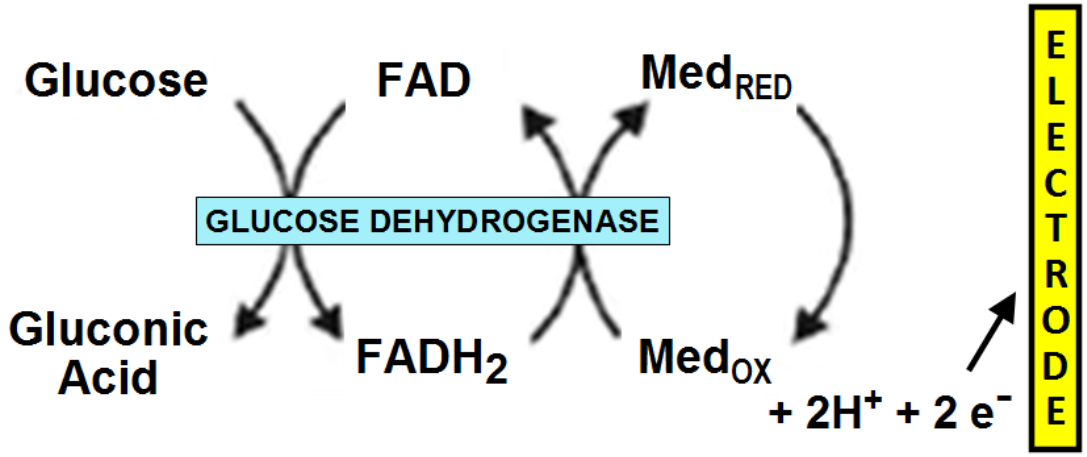
FIRST GENERATION BIOSENSOR



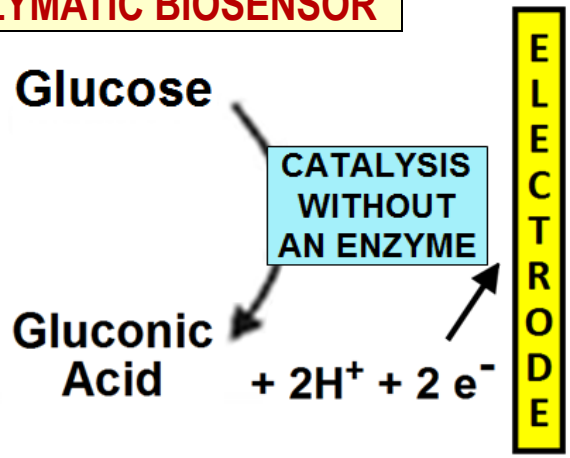
THIRD GENERATION ENZYMATIC BIOSENSOR



SECOND GENERATION BIOSENSOR



FOURTH GENERATION NON-ENZYMATIC BIOSENSOR



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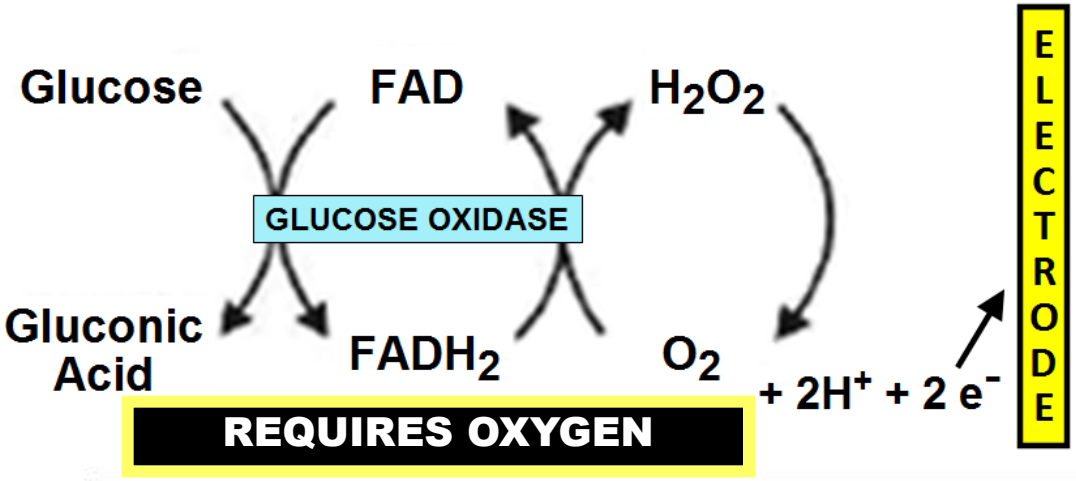

REQUIRES OXYGEN

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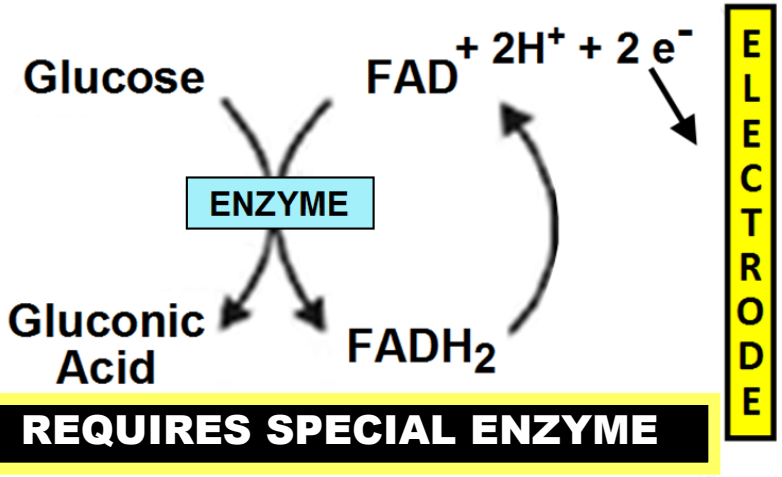
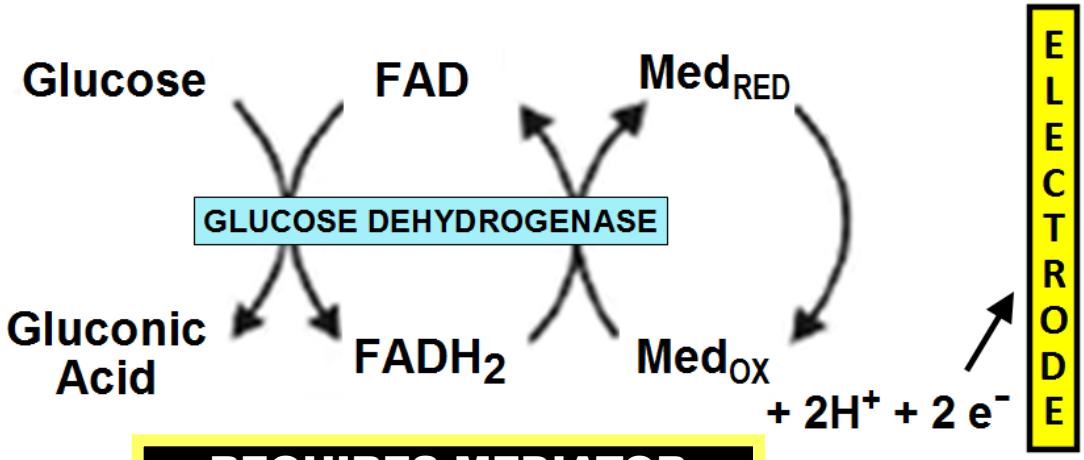


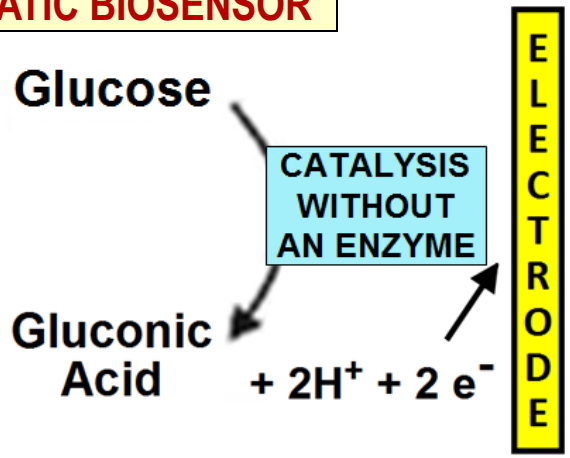
REQUIRES SPECIAL ENZYME

SECOND GENERATION BIOSENSOR



REQUIRES MEDIATOR

FOURTH GENERATION NON-ENZYMATIC BIOSENSOR



REQUIRES SPECIAL ELECTRODE

SAFETY

SAFETY OF SMBG: WHAT ARE THE RISKS?

- Transmission of bloodborne viral pathogens from patient to patient
- Community exposure to sharps and other medical waste
- Finger trauma due to lancing

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Journal of Diabetes Science and Technology
Volume 3, Issue 2, March 2009

ORIGINAL ARTICLES

Eliminating the Blood: Ongoing Outbreaks of Hepatitis B Virus Infection and the Need for Innovative Glucose Monitoring Technologies

Nicola D. Thompson, Ph.D., M.S.,[1] and Joseph F. Perz, Dr.P.H., M.A.[2]

Abstract

Background:

As part of routine diabetes care, capillary blood is typically sampled using a finger-stick device and then tested using a handheld blood glucose meter. In settings where multiple persons require assistance with blood glucose monitoring, opportunities for bloodborne pathogen transmission may exist.

Methods:

Reports of hepatitis B virus (HBV) infection outbreaks in the United States that have been attributed to blood glucose monitoring practices were reviewed and summarized.

Results:

Since 1990, state and local health departments investigated 18 HBV infection outbreaks, 15 (83%) in the past 10 years, that were associated with the improper use of blood glucose monitoring equipment. At least 147 persons acquired HBV infection during these outbreaks, 6 (4.1%) of whom died from complications of acute HBV infection. Outbreaks appear to have become more frequent in the past decade, primarily affecting long-term care residents with diabetes. Each outbreak was attributed to glucose monitoring practices that exposed HBV-susceptible persons to blood-contaminated equipment that was previously used on HBV-infected persons. The predominant unsafe practices were the use of spring-loaded finger-stick devices on multiple persons and the sharing of blood glucose testing meters without cleaning and disinfection between uses.

Conclusion:

Hepatitis B virus infection outbreaks associated with blood glucose monitoring have occurred with increasing regularity in the United States and may represent a growing but under-recognized problem. Advances in technology, such as the development of blood glucose testing meters that can withstand frequent disinfection and noninvasive glucose monitoring methods, will likely prove useful in improving patient safety.

J Diabetes Sci Technol 2009;3(2):283-288

Author Affiliations: [1]Epidemiology and Surveillance Branch, Division of Viral Hepatitis, Centers for Disease Control and Prevention, Atlanta, Georgia; and [2]Prevention and Response Branch, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia

Abbreviations: (CDC) Centers for Disease Control and Prevention, (HBV) hepatitis B virus, (HCV) hepatitis C virus, (HIV) human immunodeficiency virus, (LTC) long-term care

Keywords: bloodborne virus, blood glucose monitoring, diabetes, hepatitis B virus, prevention, transmission

Corresponding Author: Nicola D. Thompson, Ph.D., M.S., 1600 Clifton Road, MS G-37, Atlanta, GA 30333; email address ndthompson@cdc.gov

TYPES OF UNSAFE BLOOD GLUCOSE MONITORING PRACTICES ASSOCIATED WITH HEPATITIS B

- Vectors of transmission were typically spring loaded lancets for individual use
- No outbreaks were due to reused lancets
- Disposable endcaps for lancets were reused or stored with unused endcaps
- In all cases BG meters were shared and not cleaned between measurements

Journal of Diabetes Science and Technology
Volume 4, Issue 5, September 2010

EDITORIAL

Assisted Monitoring of Blood Glucose: Special Safety Needs for a New Paradigm in Testing Glucose

David C. Klonoff, M.D., FACP,[1] and Joseph F. Perz, Dr.P.H.[2]

A New Paradigm

The term "assisted monitoring of blood glucose" (AMBG) is a new paradigm in blood glucose testing and is introduced in this editorial. Assisted monitoring of blood glucose is similar to self-monitoring of blood glucose (SMBG), but unlike SMBG for which patients perform the monitoring, AMBG is performed for a patient with diabetes by a health care provider or other caregiver. Assisted and self-monitoring both have had long traditions in practice, but it is important that AMBG be recognized more broadly as a distinct concept in order to address safety concerns. In many instances, the equipment and processes that are appropriate for an individual performing SMBG are not appropriate in an AMBG setting. The primary reason for this is the ever-present risk of transmitting bloodborne viruses between individuals who are having capillary blood sampled and tested. This risk is heightened when finger-stick lancing devices, blood glucose meters, or other equipment are used for multiple patients.

Self-Monitoring of Blood Glucose

The practice of SMBG is a basic intervention for all patients with diabetes and generally is considered very safe. Patients with diabetes stick themselves routinely with a lancet to obtain a blood sample with which to perform SMBG. Basic diabetes education programs teach and promote this practice, and have emphasized safe disposal of sharp paraphernalia as a means to avoid contaminating others with blood waste. To transmit a bloodborne virus, a susceptible patient must come in contact with blood from another person. If a diabetes patient never shares equipment, supplies, or insulin with anyone else and safe waste disposal practices are followed, then there should be no risk of transmission from one person to another.

Most blood glucose monitoring equipment has been designed for self-use. In the context of personal use for SMBG, device design emphasizes features such as comfort, convenience, and portability. However, an important, growing, but inadequately studied setting for blood glucose monitoring is the environment where patients are not monitoring themselves, but rather receiving assistance with their monitoring from a caregiver or health care provider (i.e., AMBG). Types of settings [e.g., assisted living facilities (ALFs)] where patients receive assistance with blood glucose monitoring are shown in **Table 1**.

Author Affiliations: [1]Mills-Peninsula Health Services, San Mateo, California; and [2]Centers for Disease Control and Prevention, Atlanta, Georgia

Abbreviations: (ALF) assisted living facility, (AMBG) assisted monitoring of blood glucose, (CDC) Centers for Disease Control and Prevention, (HBV) hepatitis B virus, (SMBG) self-monitoring of blood glucose

Keywords: assisted monitoring of blood glucose, bloodborne infection, diabetes, glucose, hepatitis, monitor, self monitoring of blood glucose

Corresponding Author: David C. Klonoff, M.D., FACP, Mills-Peninsula Health Services, 100 South San Mateo Dr., Room 5147, San Mateo, CA 94401; email address dklonoff@yahoo.com

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David C. Klonoff, M.D., FACP,[1] and Joseph F. Perz, Dr.P.H.[2]

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J Diabetes Sci Technol 2010;4(5):1027-1031

RECOMMENDED PRACTICES FOR PREVENTING BLOODBORNE PATHOGEN TRANSMISSION DURING AMBG IN HEALTH CARE SETTINGS

BLOOD GLUCOSE MONITORING
Finger-stick devices
• Restrict use of finger-stick devices to individual persons. They should *never* be used for more than one person. Select single-use lancets that permanently retract upon puncture. This adds an extra layer of safety for the patient and the provider.
• Dispose of used lancets at the point of use in an approved sharps container. Never reuse lancets.
Blood glucose meters
• Whenever possible, blood glucose meters should be assigned to an individual person and not be shared.
• If blood glucose meters must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions, to prevent carry-over of blood and infectious agents. If the manufacturer does not specify how the device should be clean and disinfected, then it should not be shared.

Klonoff and Perz J Diab Sci Technol 2010; 4:1027

RECOMMENDED PRACTICES FOR PREVENTING BLOODBORNE PATHOGEN TRANSMISSION DURING AMBG IN HEALTH CARE SETTINGS

BLOOD GLUCOSE MONITORING

Finger-stick devices

- Restrict use of finger-stick devices to individual persons. They should *never* be used for more

Do not share lancets and use retractable single use ones

an

extra layer of safety for the patient and the provider.

Dispose of lancets in approved sharps containers

lancets.

Blood glucose meters

Each patients must have their own BGM whenever possible

be

shared.

- If blood glucose meters must be shared, the device should be cleaned and disinfected after

Shared BGMs: clean/disinfect after each use per mfr's instructions

nts.

If the manufacturer does not specify how the device should be clean and disinfected, then it should not be shared.

Klonoff and Perz J Diab Sci Technol 2010; 4:1027

RECENT REPORTS OF VIRAL OUTBREAKS AND RISKY EXPOSURES DUE TO UNSAFE AMBG PRACTICES

SAFETY OF SMBG: WHAT ARE THE RISKS?

- Transmission of bloodborne viral pathogens from patient to patient
- Community exposure to sharps and other medical waste
- Finger trauma due to lancing

CURRENTLY IN THE US USED NEEDLES, SYRINGES, AND LANCETS ARE COMMONLY INCERATED OR TREATED AND DISPOSED OF IN LANDFILLS

THE IMPACT OF LANCET, NEEDLE, AND SYRINGE DISPOSAL IN THE US

- 26 M with DM in US; 26% use 1-4 insulin injects/d = 13 M needles & syringes/d
- Lancets and strips are used similarly
- 1 in 12 households in US use a syringe and needle for a medical condition
- Total needle and syringe use in the US is estimated to be 7.5 Billion per year

CDC ADVICE FOR SHARPS DISPOSAL

- Place used sharps in an FDA-cleared sharps disposal container
- Or else a heavy-duty plastic household container: leak-resistant, upright, tight fitting, puncture-resistant lid
- Local trash or Public Health Depts have sharps disposal programs
- No sharps in trash, toilet, or recycling bin

SAFETY OF SMBG: WHAT ARE THE RISKS?

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LANCING THE FINGERTIP TO PERFORM SMBG

- Little published research on safe lancing
- AST decreases pain but introduces lag
- Laser lancets poorly received and all-in-one devices do not decrease pain
- Pain from lancing can be mitigated by optimizing the lancet & lancing process
- Controlled lancing can avoid trapped blood (“black dots”) / callus / ↓ sensation

ACCURACY

SETTINGS FOR MEASURING BLOOD GLUCOSE MONITOR PERFORMANCE

- Analytical
- Clinical
- Simulation

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NEW STANDARDS FOR BLOOD GLUCOSE MONITOR ACCUCACY

- Revised ISO 15107 (“Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus”) for outpatient monitors 2003
- CLSI POCT12-A3: Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition 2013
- FDA Draft Guidances for OTC and Rx POC Blood Glucose Monitors (2014)

MINIMUM ACCURACY CRITERIA FOR BLOOD GLUCOSE MONITORS FROM THE 2003 ISO 15197 STANDARD

95% of glucose results must be:

- For glucose < 75 mg/dl – within 15 mg/dl of reference
- For glucose ≥ 75 mg/dl – within 20% of reference

MINIMUM ACCURACY CRITERIA FOR BLOOD GLUCOSE MONITORS FROM THE 2013 ISO 15197 STANDARD

95% of glucose results must be:

For glucose < 100 mg/dl – within 15 mg/dl of reference

For glucose ≥ 100 mg/dl – within 15 % of reference

99% of glucose results must be:

Within the Parkes (Consensus) Error Grid Zone A or B

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: January 7, 2014

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Patricia Bernhardt at patricia.bernhardt@fda.hhs.gov, or at 301-796-6136.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

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U.S. Department of Health and Human Services
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Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

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MINIMUM ACCURACY CRITERIA FOR OTC BLOOD GLUCOSE MONITORS FROM THE 2014 DRAFT FDA GUIDANCE

95% of glucose results must be within 15% of reference

99% of glucose results must be within 20% of reference

ACROSS THE RANGE

Within +/- 5 mg/dL	Within +/- 7 mg/dL	Within +/- 10 mg/dL	Within +/- 15 mg/dL
X/Y (%)	X/Y (%)	X/Y (%)	X/Y (%)

MINIMUM ACCURACY CRITERIA FOR PRESCRIPTION POINT-OF-CARE BLOOD GLUCOSE MONITORS FROM THE 2014 DRAFT FDA GUIDANCE

99% of glucose results must be:

For glucose < 70 mg/dl – within 7 mg/dl of reference

For Glucose ≥ 70 mg/dl – within 10% of reference

And 100% of glucose results must be:

For glucose < 75 mg/dl – within 15 mg/dl of reference

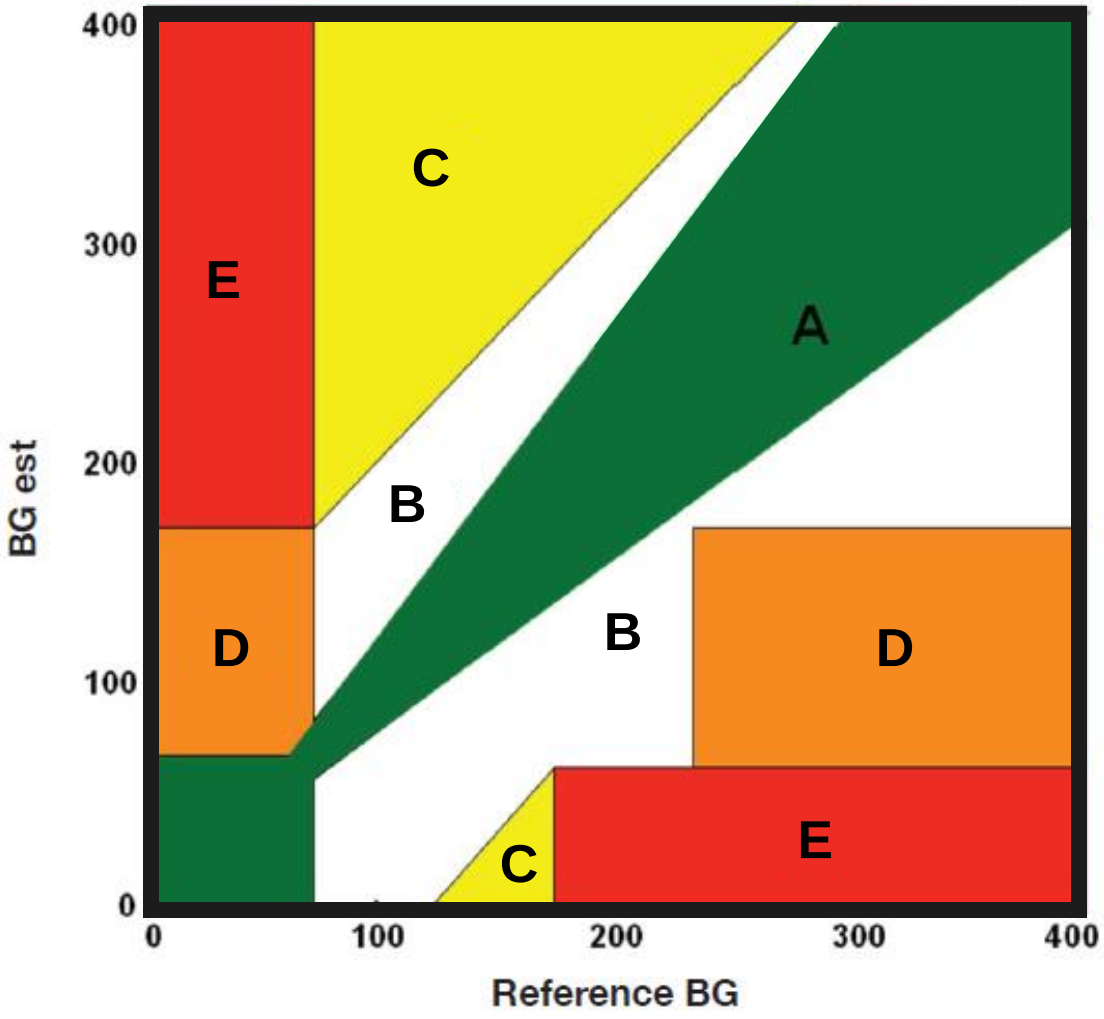
For Glucose ≥ 75 mg/dl – within 20 % of reference

SETTINGS FOR MEASURING BLOOD GLUCOSE MONITOR PERFORMANCE

- Analytical
- Clinical
- Simulation

ALL BLOOD GLUCOSE ERRORS OF A PARTICULAR PERCENTAGE FROM THE REFERENCE METHOD DO NOT HAVE EQUAL CLINICAL SIGNIFICANCE

CLARKE ERROR GRID REPORTED IN 1987



Zone A – No effect on clinical action

Zone B – No effect on treatment or benign effect on treatment

Zone C – Altered clinical action likely to affect clinical outcome

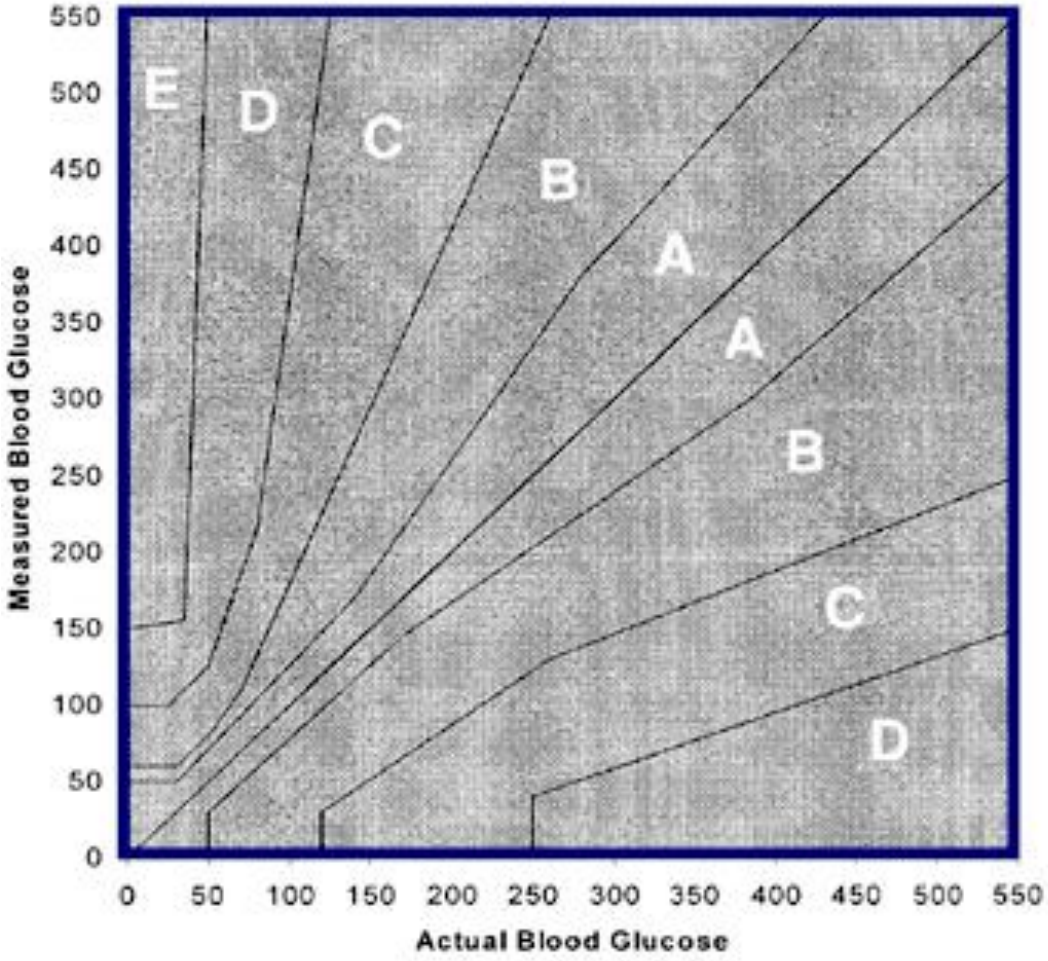
Zone D – Altered clinical action – could have significant medical risk

Zone E – Altered clinical action – could have dangerous consequences

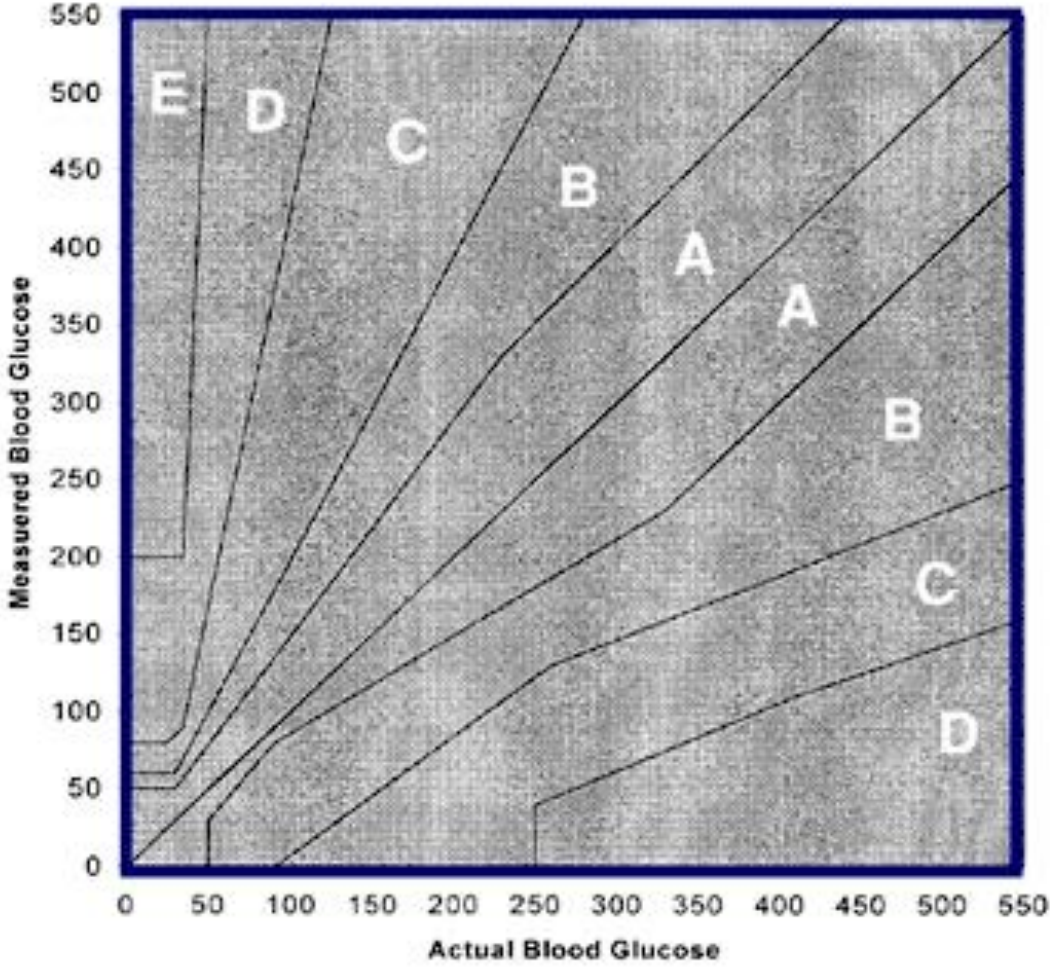
Clarke D Care 1987; 10:622

PARKES CONSENSUS ERROR GRID DEVELOPED IN 1994 FOR T1DM AND T2DM

Type 1



Type 2



Parkes D Care 2000; 23:1143

LIMITATIONS OF THE TWO ERROR GRIDS THAT ARE WIDELY USED CURRENTLY

- Diabetes management has changed since 1987 (Clarke) and 1994 (Parkes)
- DCCT results were one year old when the more modern ERG was developed
- Analog insulin was unavailable when the EGs were developed
- Analytical accuracy standards used to be looser when the EGs were developed

SETTINGS FOR MEASURING BLOOD GLUCOSE MONITOR PERFORMANCE

- Analytical
- Clinical
- Simulation

Journal of Diabetes Science and Technology
Volume 4, Issue 3, May 2010

ORIGINAL ARTICLES

Impact of Blood Glucose Self-Monitoring Errors on Glucose Variability, Risk for Hypoglycemia, and Average Glucose Control in Type 1 Diabetes: An *In Silico* Study

Marc D. Breton, Ph.D., and Boris P. Kovatchev, Ph.D.

Abstract

Background:

Clinical trials assessing the impact of errors in self-monitoring of blood glucose (SMBG) on the quality of glycemic control in diabetes are inherently difficult to execute. Consequently, the objectives of this study were to employ realistic computer simulation based on a validated model of the human metabolic system and to provide potentially valuable information about the relationships among SMBG errors, risk for hypoglycemia, glucose variability, and long-term glycemic control.

Methods:

Sixteen thousand computer simulation trials were conducted using 100 simulated adults with type 1 diabetes. Each simulated subject was used in four simulation experiments aiming to assess the impact of SMBG errors on detection of hypoglycemia (experiment 1), risk for hypoglycemia (experiment 2), glucose variability (experiment 3), and long-term average glucose control, i.e., estimated hemoglobin A1c (HbA1c)(experiment 4). Each experiment was repeated 10 times at each of four increasing levels of SMBG errors: 5, 10, 15, and 20% deviation from the true blood glucose value.

Results:

When the permitted SMBG error increased from 0 to 5–10% to 15–20%—the current level allowed by International Organization for Standardization 15197—(1) the probability for missing blood glucose readings of 60 mg/dl increased from 0 to 0–1% to 3.5–10%; (2) the incidence of hypoglycemia, defined as reference blood glucose ≤70 mg/dl, changed from 0 to 0–0% to 0.1–5.5%; (3) glucose variability increased as well, as indicated by control variability grid analysis; and (4) the incidence of hypoglycemia increased from 15.0 to 15.2–18.8% to 22–25.6%. When compensating for this increase, glycemic control deteriorated with HbA1c increasing gradually from 7.00 to 7.01–7.12% to 7.26–7.40%.

Conclusions:

A number of parameters of glycemic control deteriorated substantially with the increase of permitted SMBG errors, as revealed by a series of computer simulations (e.g., *in silico*) experiments. A threshold effect apparent between 10 and 15% permitted SMBG error for most parameters, except for HbA1c, which appeared to be increasing relatively linearly with increasing SMBG error above 10%.

J Diabetes Sci Technol 2010;4(3):562-570

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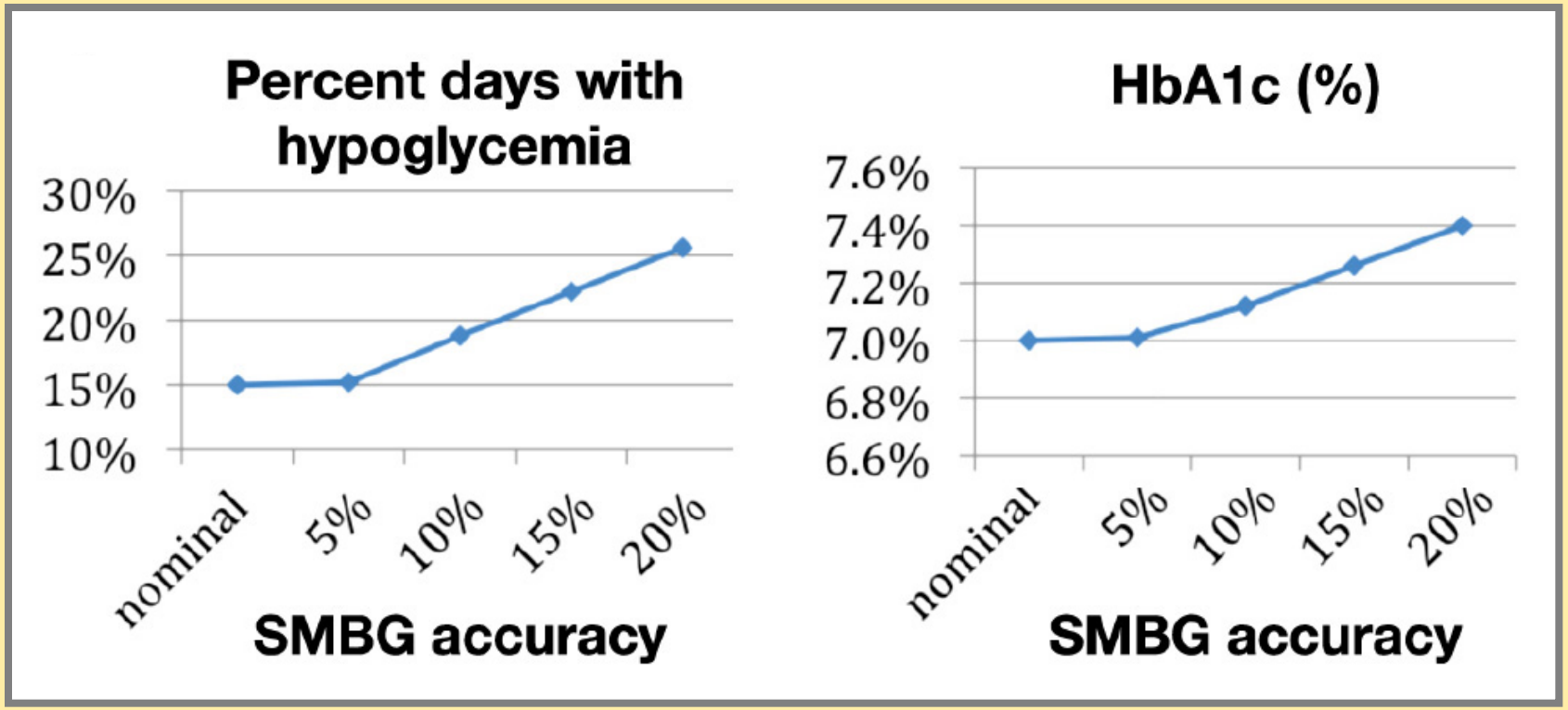


SOURCES OF ERROR IN BLOOD GLUCOSE MONITORING

FACTORS WHICH ADVERSELY AFFECT PERFORMANCE OF BG MONITORS

- Preanalytical – related to specimen procurement and handling prior to performing the measurement
- Analytical – related to performance of the measurement
- Postanalytical – related to how data is delivered, interpreted, and acted upon

OBTAINING A BLOOD GLUCOSE MONITOR TEST RESULT IS LIKE ORDERING A PIZZA

PREANALYTICAL FACTORS WHICH ADVERSELY AFFECT BG MONITORING

- Patient performance (e.g. hand washing, site selection, proper lancing, sampling a hanging drop etc.)
- Strip factors (use past expiration date, exposure to heat and humidity, product imprecision due to lot-to-lot variability)

ANALYTICAL FACTORS WHICH ADVERSELY AFFECT BG MONITORING

- Physical environment (high altitude, heat, cold – if vasoconstriction occurs)
- Physiology (O_2, TG, galactose, uric acid, hematocrit)
- Medications (acetaminophen, C, L-dopa, tolazamide, icodextrin/maltose, D-xylose)
- System (strip/parts quality, outlier data)
- Patient performance (following all mfrs instructions, cleaning meter, strip filling)

ANALYTICAL FACTORS WHICH ADVERSELY AFFECT BG MONITORING

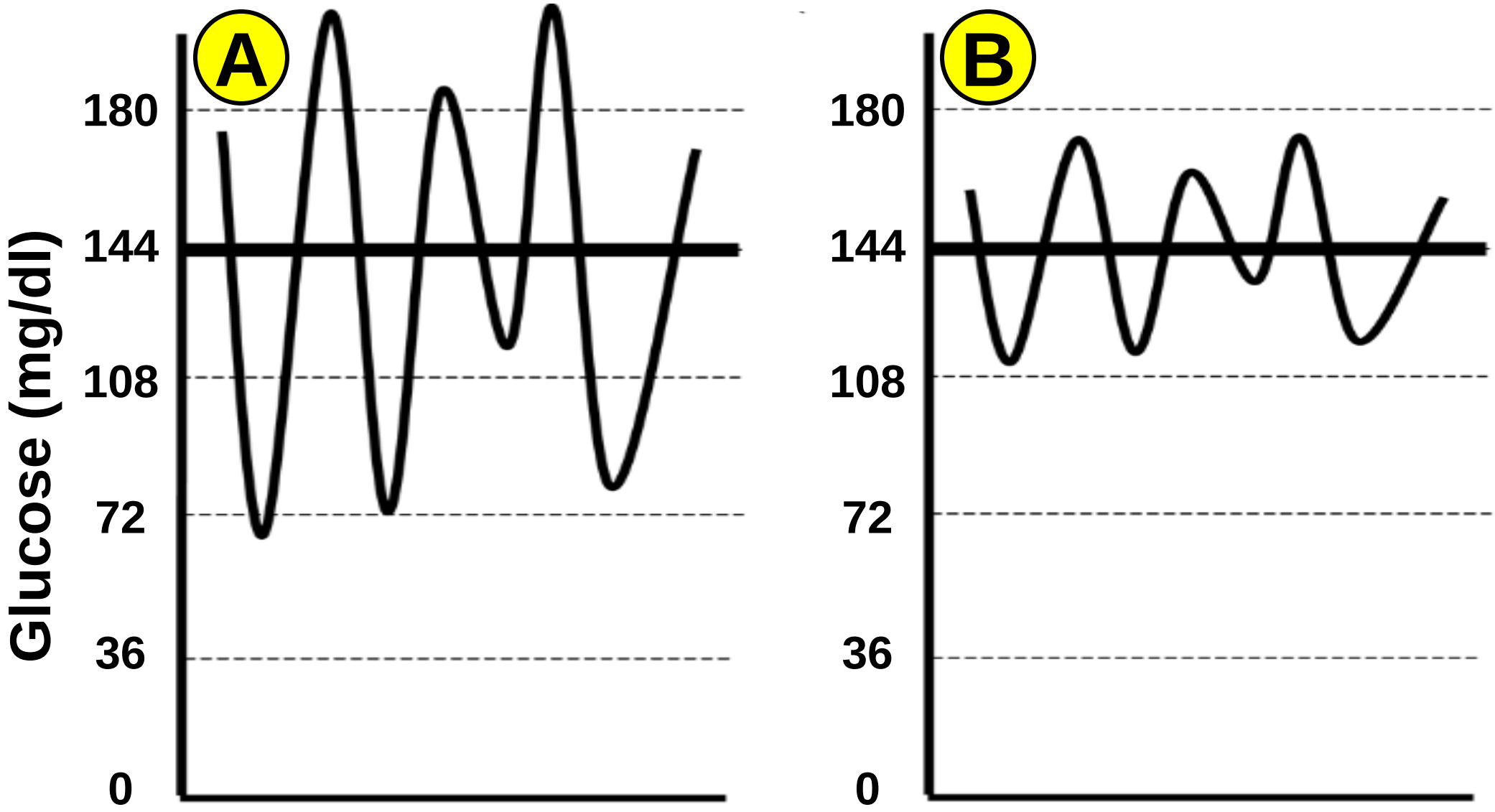
- Physical environment
- Physiology
- Medications

ENVIRONMENTAL, PHYSIOLOGICAL, AND PHARMACOLOGICAL FACTORS WHICH AFFECT BG MONITOR PERFORMANCE ARE KNOWN AS INTERFERING SUBSTANCES

POSTANALYTICAL FACTORS WHICH ADVERSELY AFFECT BG MONITORING

- Incorrect units of glucose are presented
- Data is not recorded or uploaded
- Data is transmitted incorrectly
- A misleading message is presented
- Monitor shuts off if BG is very high

AND NOW A WORD ABOUT GLYCEMIC VARIABILITY



THE SIGNIFICANCE AND MEASUREMENT OF GLYCEMIC VARIABILITY

- Patients with the same A1C can have different patterns of fluctuations
- GV provides an integrated picture of PP-hypers and episodes of hypos
- GV triggers endothelial dysfunction and promotes oxidative stress, but the link to clinical outcomes is unproven
- Aim for SD to be < 0.5 x mean [BG]

CLINICAL INDICATIONS

CURRENT STATUS OF SMBG AS AN INTERVENTION TO IMPROVE OUTCOMES

- A tool for patients which empowers improved day-to-day self-care
- Established to improve BG control in T1DM and insulin-treated T2DM
- Proper use in non-insulin Rx'd T2DM is evolving with use of structured protocols
- Works best when patients and MDs use the information to make Rx decisions

THE OLDER MEDICAL LITERATURE PRIOR TO 2008

MOST OLDER TRIALS OF SMBG IN NIT T2DM HAVE HAD LITTLE VALUE BECAUSE OF SERIOUS METHOD FLAWS

- Not randomized or poorly randomized
- Low baseline A1C
- Intervention subjects did not necessarily practice any study intervention
- Study intervention did not include a structured educational program and a therapeutic response to the BG data

THE NEWER MEDICAL LITERATURE SINCE 2008

NEWER TRIALS OF SMBG IN NIT T2DM SINCE 2008 HAVE AVOIDED THE EARLIER METHOD FLAWS

- Randomized or even cluster randomized
- Sufficiently high baseline A1C
- Intervention subjects have practiced the study SMBG intervention
- Study interventions have included a structured educational program and a therapeutic response to the BG data

NEWER TRIALS OF SMBG IN NIT T2DM SINCE 2008 HAVE AVOIDED THE EARLIER METHOD FLAWS

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MODERN RCTs OF SMBG IN NIT T2DM HAVE USED STRUCTURED SMBG INTERVENTIONS

TWO QUESTIONS ABOUT HOW TO USE SMBG

WHAT ARE THE APPROPRIATE BLOOD GLUCOSE TARGETS?

HOW CAN TREATMENT BE ADJUSTED TO REACH TARGET BG LEVELS USING SMBG?

WHAT ARE THE APPROPRIATE BLOOD GLUCOSE TARGETS?

BLOOD GLUCOSE GOALS PER MAJOR ORGANIZATION GUIDELINES ARE FASTING 70-130 MG/DL AND AFTER MEALS UP TO 140-180 MG/DL

	ADA (1)	AACE (2)	IDF-Europe type 1 (3)	IDF type 2 (4)
HbA_{1c}, % (mmol/mol)	<7 (<53)	≤6.5 (≤48)	6.2–7.5 (44–58)	<7 (53)
Premeal, mg/dL	70–130	<110	91–120	<115
Postmeal, mg/dL	<180	<140	136–160	<160
Before bedtime, mg/dL			110–135	

MEAN BLOOD GLUCOSE LEVELS FOR BINS OF HEMOGLOBIN A1C LEVELS

Blood Glucose (mg/dl with 95% CI)	Hemoglobin A1c (%)				
	5.5 - 6.49	**6.5 - 6.99**	**7.0 - 7.49**	**7.5 - 7.99**	**8.0 - 8.5**
	n = 119	*n* = 91	*n* = 74	*n* = 61	*n* = 33
Mean fasting	**122** (117-127)	**142** (135-150)	**152** (143-162)	**167** (157-177)	**178** (164-192)
Mean premeal	**118** (115-121)	**139** (134-144)	**152** (147-157)	**155** (148-161)	**179** (167-191)
Mean postmeal	**144** (139-148)	**164** (159-169)	**176** (170-183)	**189** (180-197)	**206** (195-217)
Mean bedtime	**136** (131-141)	**153** (145-161)	**177** (166-188)	**175** (163-188)	**222** (197-248)

DIFFERENCE BETWEEN PREMEAL AND POSTMEAL GLUCOSE LEVELS FOR SPECIFIED HBA1C LEVELS

Blood Glucose (mg/dl with 95% CI)	Hemoglobin A1c (%)				
	5.5 - 6.49	6.5 - 6.99	7.0 - 7.49	7.5 - 7.99	8.0 - 8.5
	n = 119	*n* = 91	*n* = 74	*n* = 61	*n* = 33
Mean fasting	**122** (117-127)	**142** (135-150)	**152** (143-162)	**167** (157-177)	**178** (164-192)
Mean premeal	**118** (115-121)	**139** (134-144)	**152** (147-157)	**155** (148-161)	**179** (167-191)
Δ	**26**	**25**	**24**	**35**	**27**
Mean postmeal	**144** (139-148)	**164** (159-169)	**176** (170-183)	**189** (180-197)	**206** (195-217)
Mean bedtime	**136** (131-141)	**153** (145-161)	**177** (166-188)	**175** (163-188)	**222** (197-248)

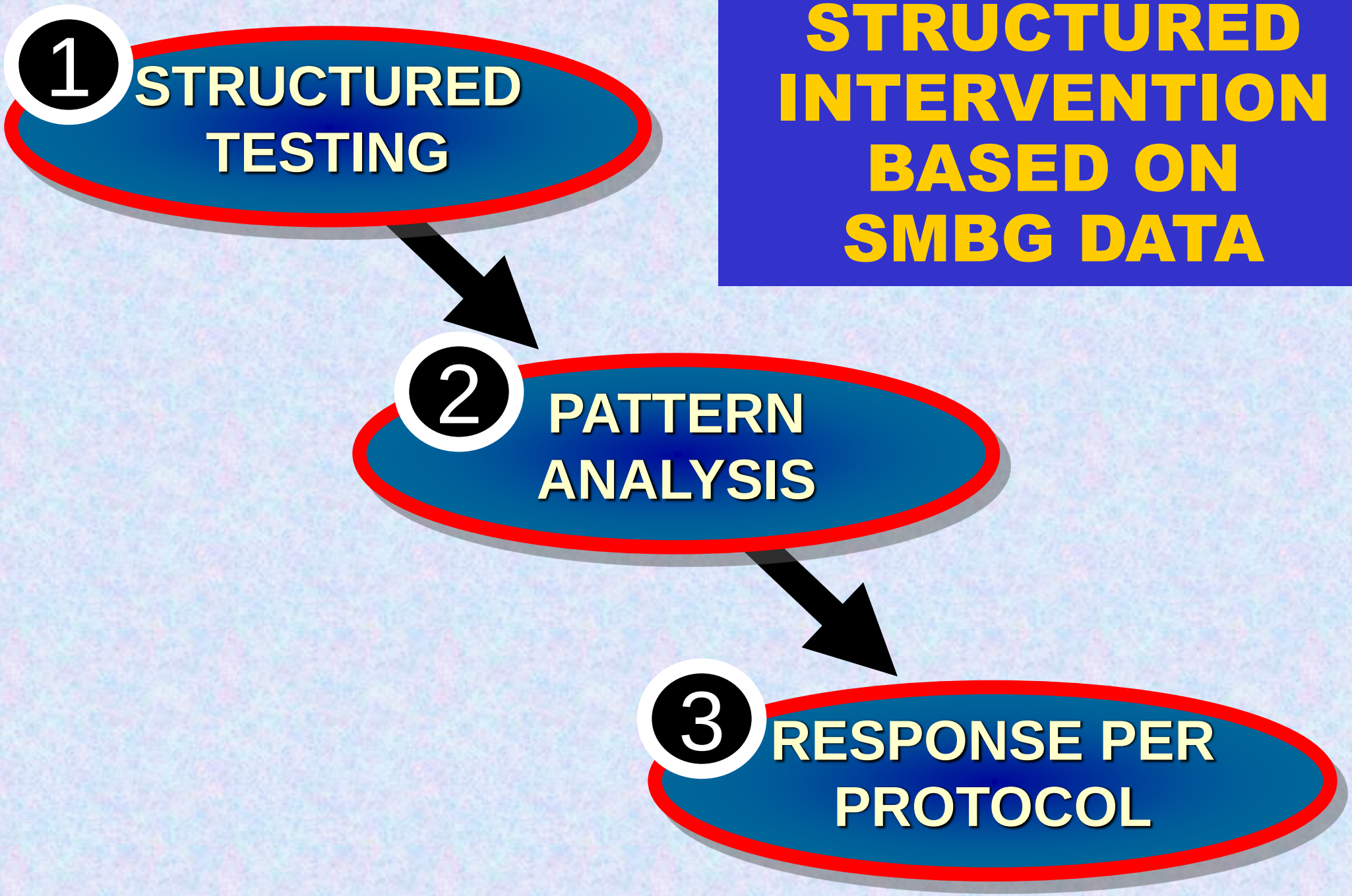
HOW CAN TREATMENT BE ADJUSTED TO TO REACH TARGET BLOOD GLUCOSE LEVELS USING SMBG?

STRUCTURED SMBG INTERVENTION

1) PATIENT MUST PERFORM SMBG AT A FIXED TIME AND FREQUENCY

2) PATIENT OR HEALTHCARE PROFESSIONAL MUST ANALYZE AND RESPOND TO THE BG DATA PATTERN ACCORDING TO A PROTOCOL

STRUCTURED INTERVENTION BASED ON SMBG DATA



STRUCTURED TESTING

PATTERN ANALYSIS

PATTERN ANALYSIS APPROACH TO SMBG

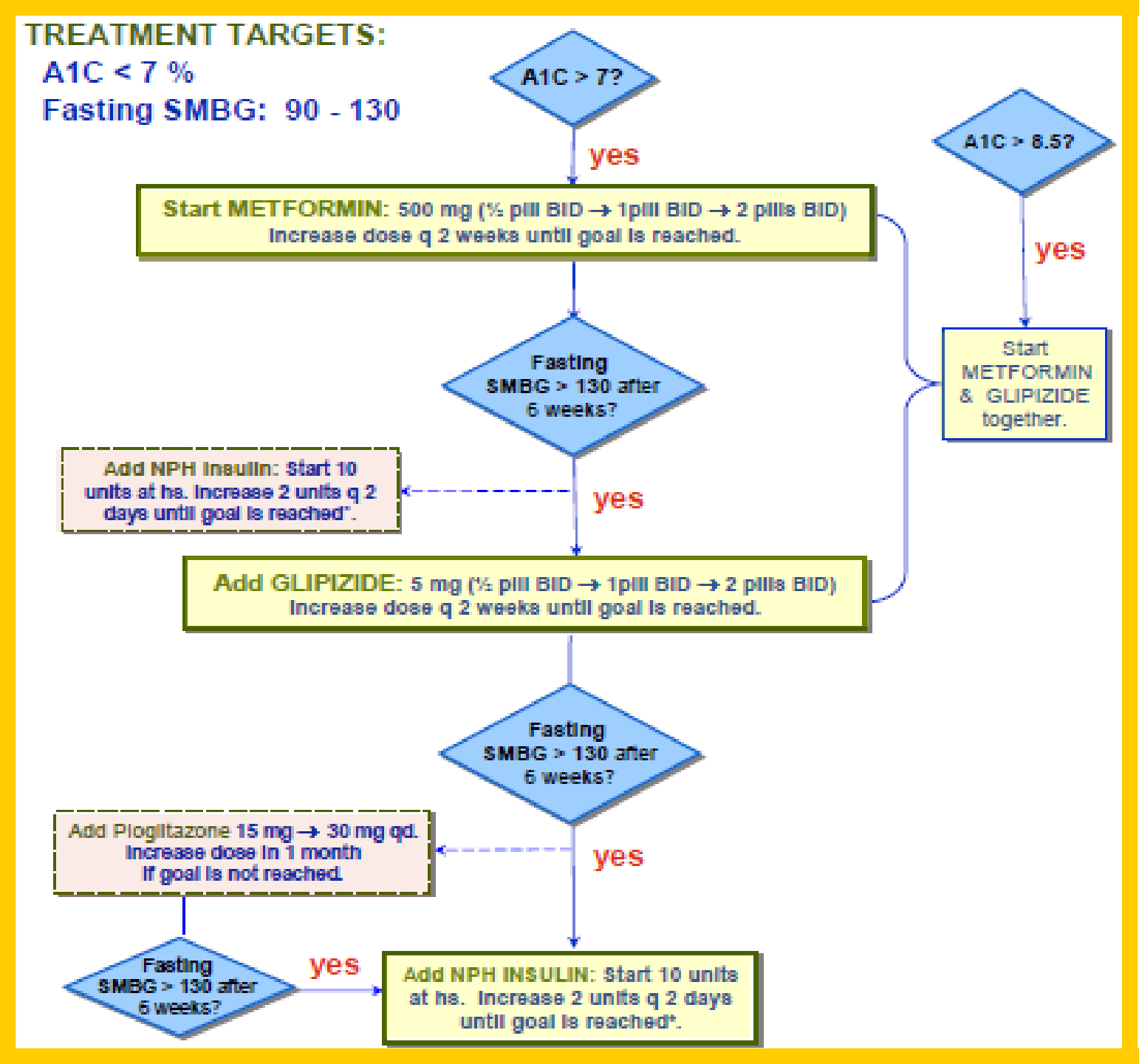
EMPHASIS ON BEHAVIOR AND MEDICATIONS

- Identify the **glycemic abnormality**
- Determine the **timing and frequency** of occurrence
- Investigate potential **causes,** including behavior (eating/activity/stress) & meds
- Take **action** to adjust behavior or meds

RESPONSES PER PROTOCOL

STRUCTURED RESPONSES TO SMBG FOR INSULIN TREATED PATIENTS

- Adjust long acting insulin with a treat-to-target regimen based on fasting BG
- Adjust out-of-range pre-prandial BG (lunch/dinner/bed) by adjusting the sliding scale dose or the carb:insulin ratio at the preceding meal
- Adjust out-of-range post-prandial BG by adjusting the sliding scale dose or the carb:insulin ratio at the preceding meal



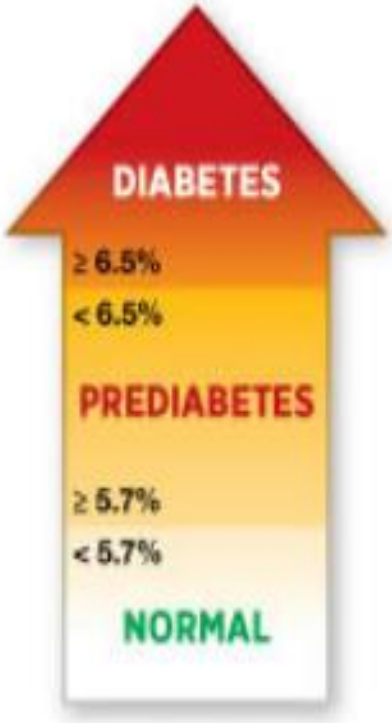
THE KAISER PERMANENTE ALGORITHM FOR ADJUSTING MEDICATIONS FOR NIT T2DM USING A PATTERN ANALYSIS APPROACH

FUTURE BARRIERS AND OPPORTUNITIES FOR BLOOD GLUCOSE MONITORING

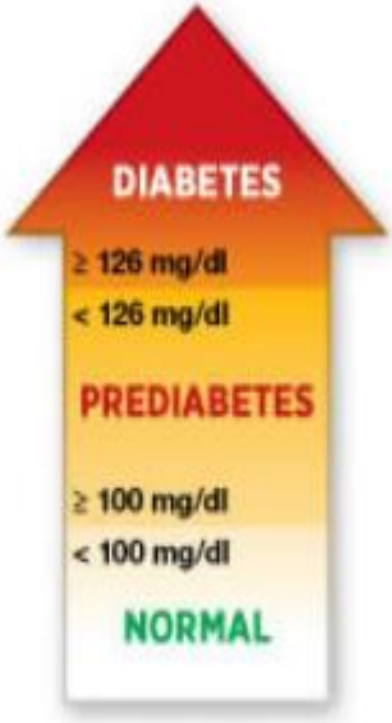
FUTURE BARRIERS AND OPPORTUNITIES FOR BLOOD GLUCOSE MONITORING

Barriers to BG Monitoring	Opportunities for BG Monitoring
Accuracy of generic monitors?	Advances in Accuracy
Accuracy of generic strips?	Advances in Human Factors
Counterfeit Strips	Advances in Data presentation
Cutbacks in Coverage	Decision Support Software / Mobile applications
Fixed Pricing and ?Stifled Innovation	FGS for Better Hypoglycemia Detection

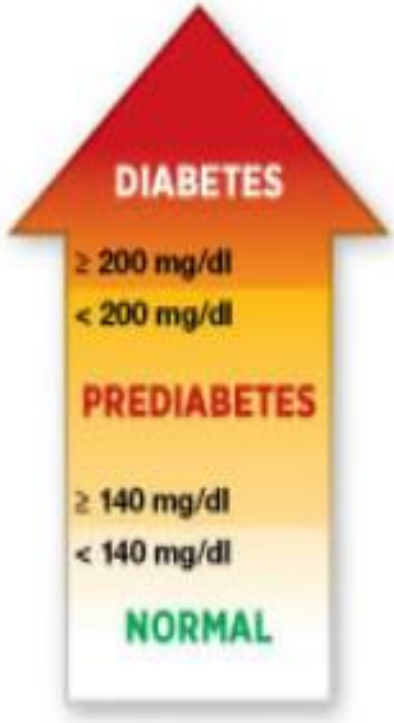
DIAGNOSIS OF ASYMPTOMATIC DIABETES AND PREDIABETES USING A1C, FASTING PLASMA GLUCOSE, AND A 2-HOUR GLUCOSE TOLERANCE TEST



A1C



FPG



2-HOUR GTT PG

BLOOD GLUCOSE MONITORING: PAST, PRESENT, AND FUTURE

CONCLUSIONS

- Safe practices avoid blood transmission, sharps exposure, and finger trauma
- Accuracy can mean analytical, clinical, and modeling performance metrics
- SMBG is for any DM patient, including NIT T2DM patients on structured testing
- Barriers and technology opportunities will clash and determine future of SMBG