Standards of SMBG

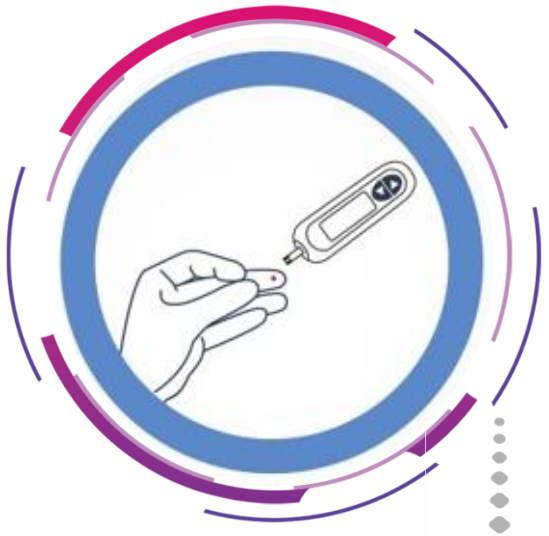
Sima Abbasi

Diabetes Educator

Gabric Diabetes Education Association

Renovating Diabetes Education

2023



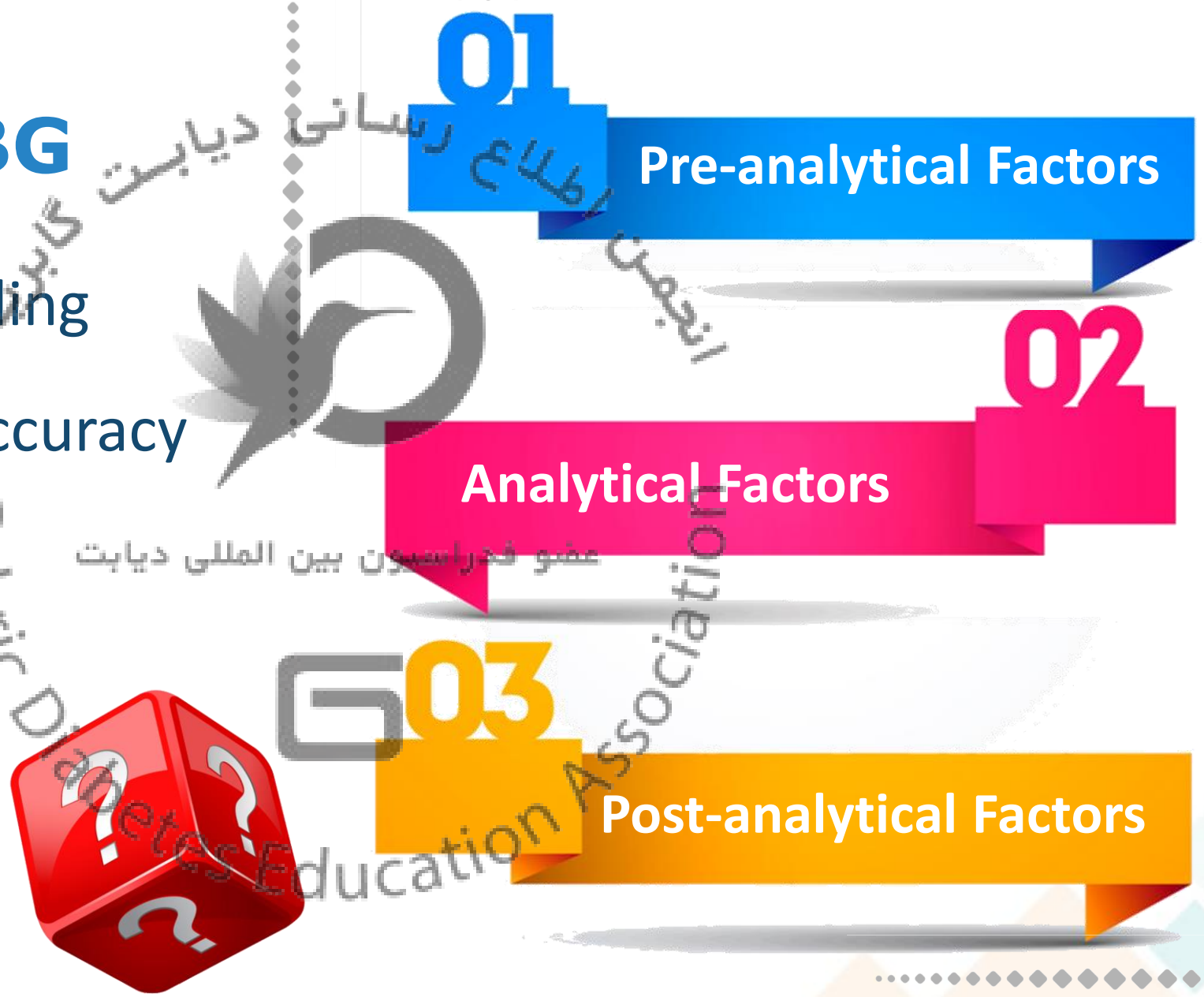
SMBG roles

- Treatment decisions
- Critical event detection
- CGM double check
- Closed-loop system calibration

Weinstock RS, et al. The Role of Blood Glucose Monitoring in Diabetes Management. ADA *Publication, 2020*

Accurate SMBG

- Holistic Understanding
- Factors Affecting Accuracy



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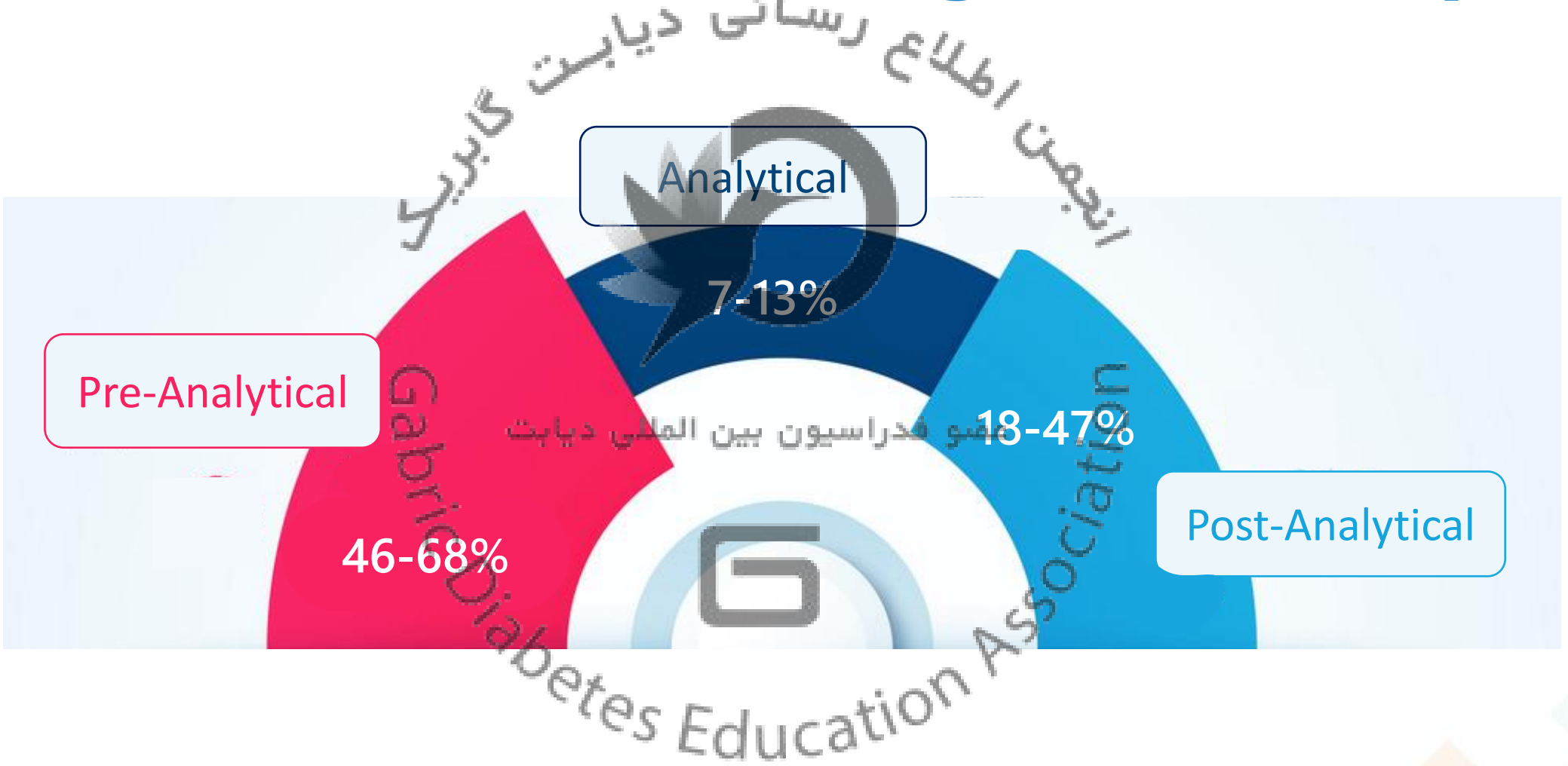
Holistic Understanding of Accuracy



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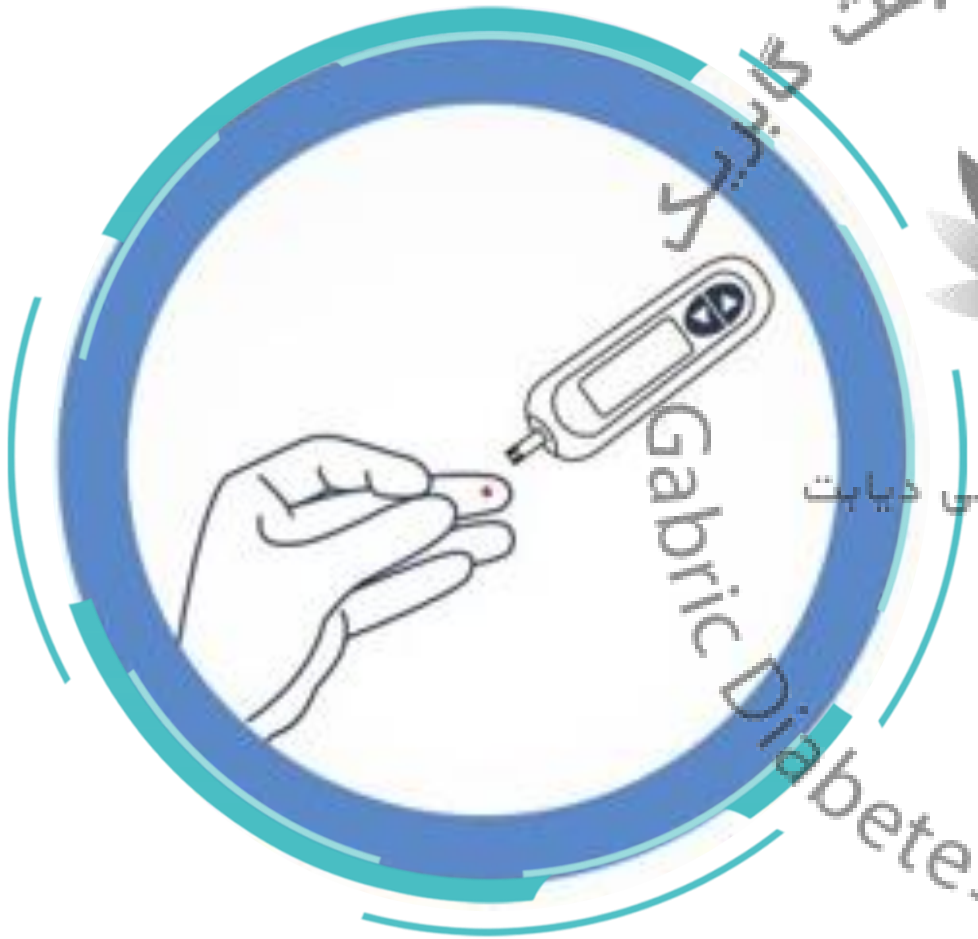
Pre-Analytical Factors

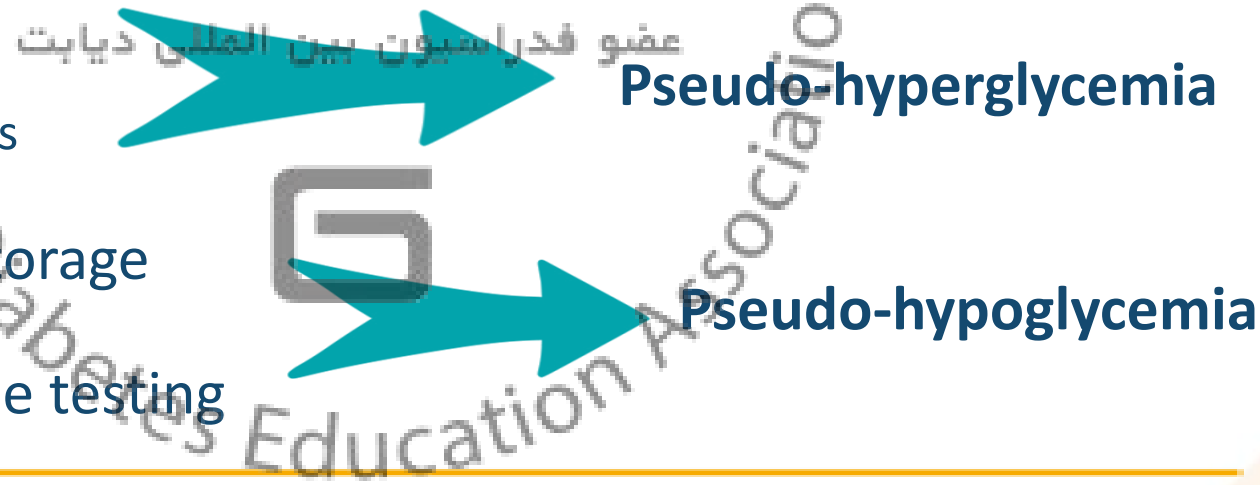


Any factor that can affect the reliability of a test result occurring before the sample is analyzed.

Weinstock RS, et al. The Role of Blood Glucose Monitoring in Diabetes Management. ADA *Publication, 2020*

Pre-Analytical Factors

- Lot Specific Coding
- Test Strip Underfilling or Overfilling
- Poor Surface Cleansing:
  - Fruit handling
  - Use of Specific Lotions
- Inappropriate Strip Storage
- Extraneous fluid at the testing



Weinstock RS, et al. The Role of Blood Glucose Monitoring in Diabetes Management. ADA *Publication, 2020*

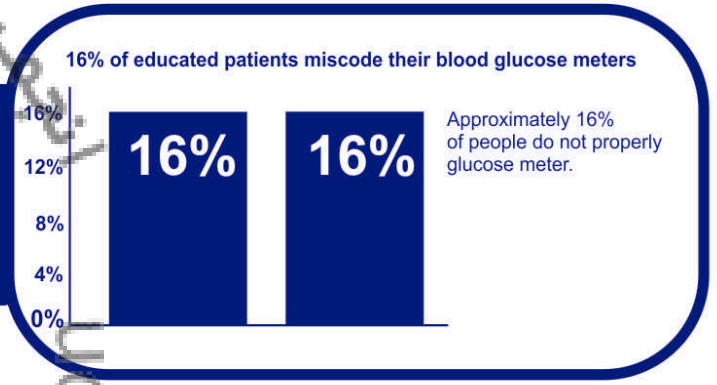
Coding: A Source of Error

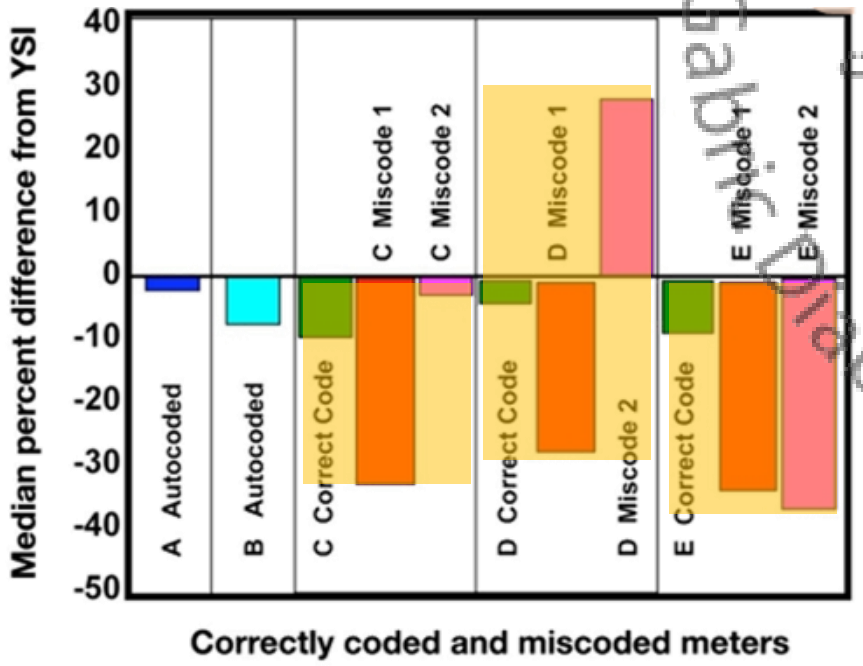
Coding determines the relationship between the electrical signal produced by the strip and the reported blood glucose.

IMPORTANT

Approximately **16% of EDUCATED patients** miscode their meters.

16%
Miscode Meters[1,2]



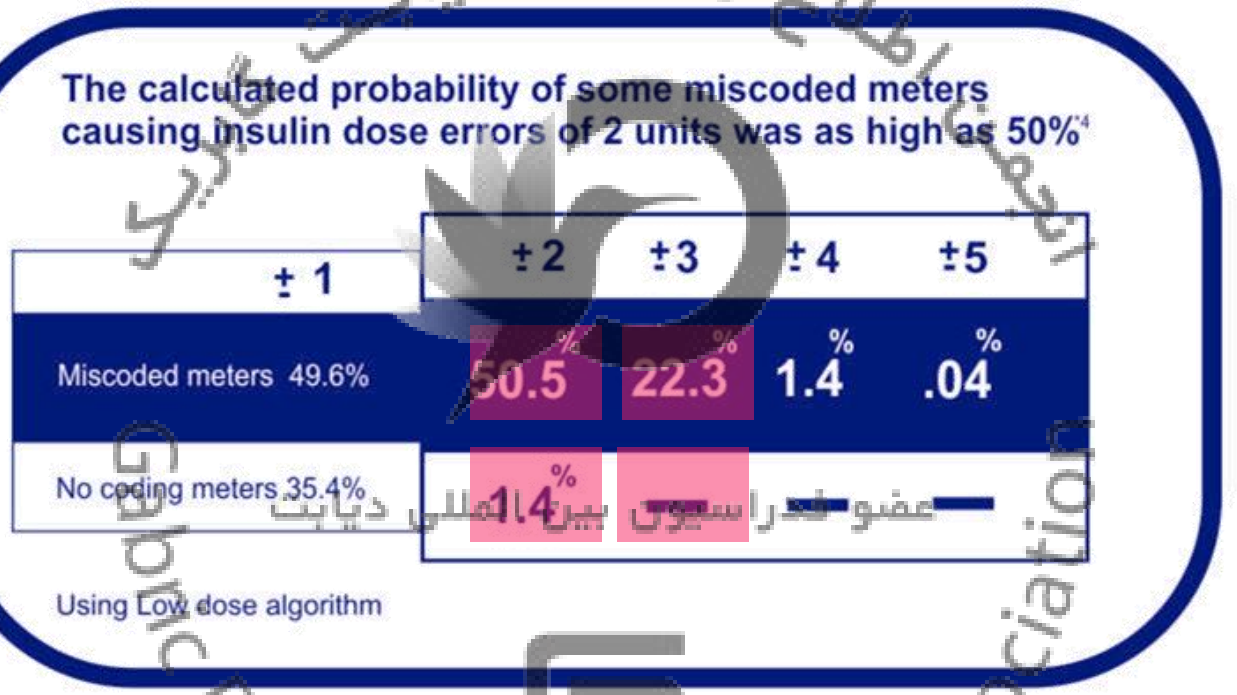


Incorrect coding may lead to measurement errors of ±30% or more.

Erbach, M. et al. (2016), *J Dia Sci Technol*, 10(5), pp. 1161–1168.

Miscoding Causes Insulin Dose Errors

Insulin dose errors may occur[4]



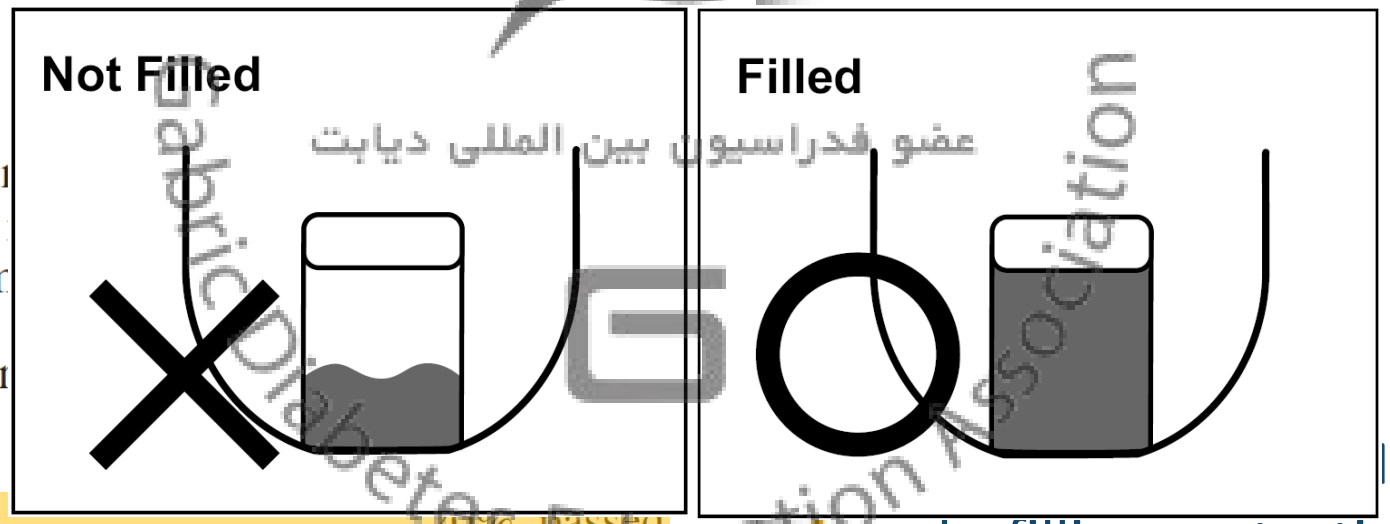
No Coding or **Auto coding** meters avoid this error.

Charles H, et al. (2007).*J Dia Sci Technol, 1*(2), 205-210.

Under Filling Protection

Test performed	Results based on TNO criteria
Accuracy (max. 15% deviation from hexokinase-method)	60% passed
Reproducibility (max. CV 10%)	83% passed
Haematocrit dependency (range 0.35 - 0.50 L/L) (max CV 10% at maximu values < 6.5 mmol/L or 1 for glucose values < 6.5 m	
Haematocrit dependency r by manufacturers	
Underfilling protection (max 10% from result at minimal volume or error mark)	20% passed

t strips results in



systems had underfilling protection

Ned Tijdschr, Klin Chem Labgeneesk 2007; 32: 202-204

William E Winter et al, *J Clinical Chemistry*, 2004

Alto WA, et al. J Am Board Fam Pract. 2002

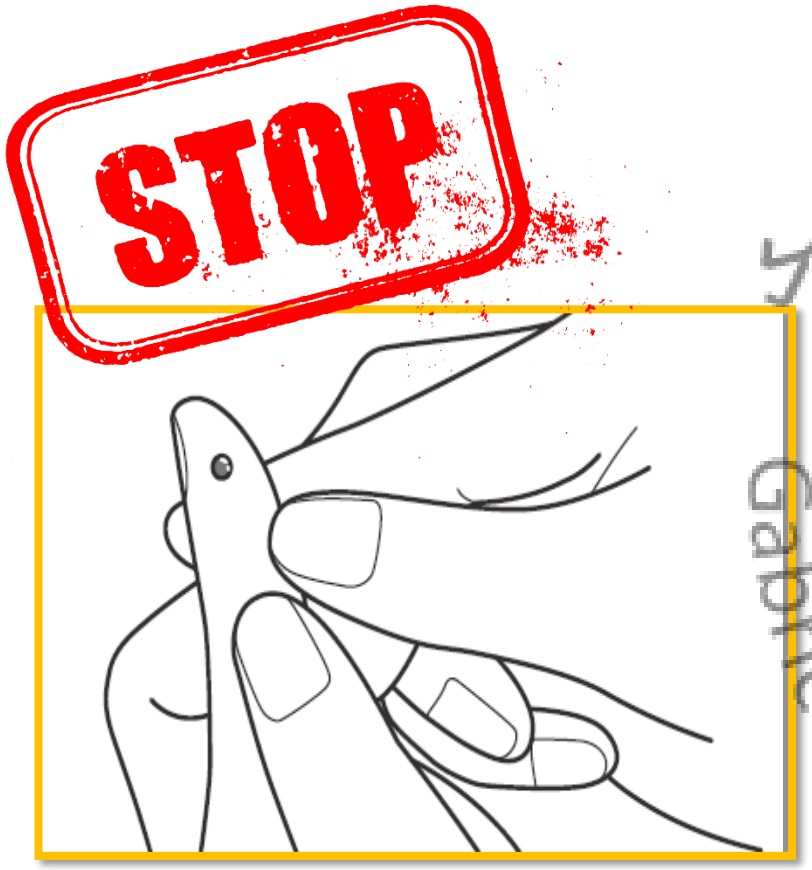
Under Filling Protection

20% of people have difficulties in filling test strips results in inaccurate result and painful pricking.

1) Minimal blood sample
2) Blood Volume Control (BVC) or Underfilling detection
3) Second chance Sampling: the possibility of re-sampling

William E Winter et al, *J Clinical Chemistry*, 2004

External pressure may lead to unreliable readings



Different external pressures led to **≥10% differences** in glucose concentrations in 5%–13% of the participants.

On average, blood sugar readings were **lower** when people put pressure on the finger.

Hortensius, J., et al (2011), *Diabetes care, 34*(3), 556-560.

Hand washing has always been a problem!

With a sample of 0.3 µl, **1 µg of glucose (the weight of a dust particle)** will increase the blood glucose by **300 mg/dl.**

DO'S

DONT'S

Ginsberg, B. H. (2009). *J Diabetes Sci Technol, 3*(4), 903-913.

Ferretti, J., & Martin, K. (2008).. *JCOM-WAYNE PA-, 15*(4), 179

Pre-Analytical Factors

- The impact of these factors has increased because of the smaller sample volume required by newer meters.
- Technological advances have addressed many of the pre-analytical sources of reduced accuracy.
- Comprehensive patient education remains important to address remaining pre-analytical issues.

Education is a MUST!

Patient demonstration of SMBG to the diabetes educator or health care provider is critical.

Table 3.
Tips for Successful Self-Monitoring of Blood Glucose Teaching

Use simple and specific steps at the patient's level of comprehension.
Be sure the patient can demonstrate the steps for SMBG.
Give your patient written recommendations for frequency and times of testing and desired results.
Observe SMBG procedure at follow-up visits.
Ask the patient to assess the relationship of SMBG with exercise, food, medications, and stress.
Specify which SMBG values are most problematic (especially low blood glucose) and discuss solutions with the patient.
Acknowledge the patient for goals achieved with SMBG.

Kirk, Julienne K et al, *J Diabetes Sci Technol,* 4.2 (2010): 435-439.

Analytical Factors

Analytical Factors

- Hematocrit
- Peripheral blood perfusion
- Partial pressure of oxygen (pO2)
- Triglycerides
- Bilirubin
- Uric acid

- Temperature
- Humidity
- Altitude

- Ascorbic acid
- Acetaminophen
- Maltose

- Proper storage and distribution
- Quality control process
- Degraded manufacturing quality

All devices must include results of these tests in their labeling.

Erbach, M. et al. (2016), *J Dia Sci Technol*, 10(5), pp. 1161–1168.

ISO 15197:2013 and FDA blood glucose meter accuracy standards

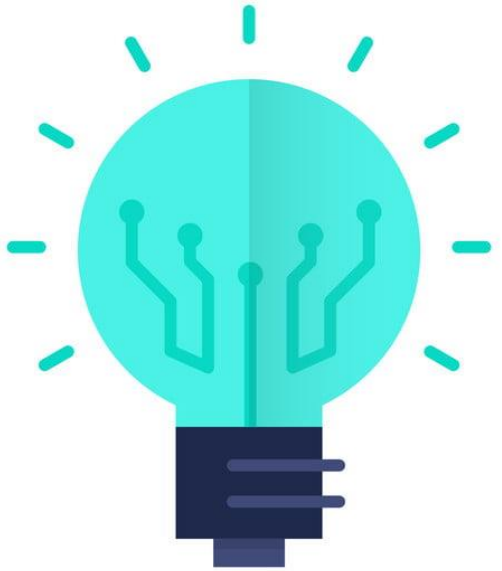
Table 7.1—Comparison of ISO 15197:2013 and FDA blood glucose meter accuracy standards

Setting	FDA (248,254)	ISO 15197:2013 (255)
Home use	95% within 15% for all BG in the usable BG range† 99% within 20% for all BG in the usable BG range†	95% within 15% for BG ≥100 mg/dL 95% within 15 mg/dL for BG <100 mg/dL 99% in A or B region of consensus error grid‡
Hospital use	95% within 12% for BG ≥75 mg/dL 95% within 12 mg/dL for BG <75 mg/dL 98% within 15% for BG ≥75 mg/dL 98% within 15 mg/dL for BG <75 mg/dL	

BG, blood glucose; FDA, U.S. Food and Drug Administration; ISO, International Organization for Standardization. To convert mg/dL to mmol/L, see endmemo.com/medical/unitconvert/Glucose.php. †The range of blood glucose values for which the meter has been proven accurate and will provide readings (other than low, high, or error). ‡Values outside of the "clinically acceptable" A and B regions are considered "outlier" readings and may be dangerous to use for therapeutic decisions (256).

Post-Analytical Factors

Post-Analytical Factors



- Poor User Numeracy
- Misleading Unit Conversion
- Misleading Manual Log
- Software Processing Errors

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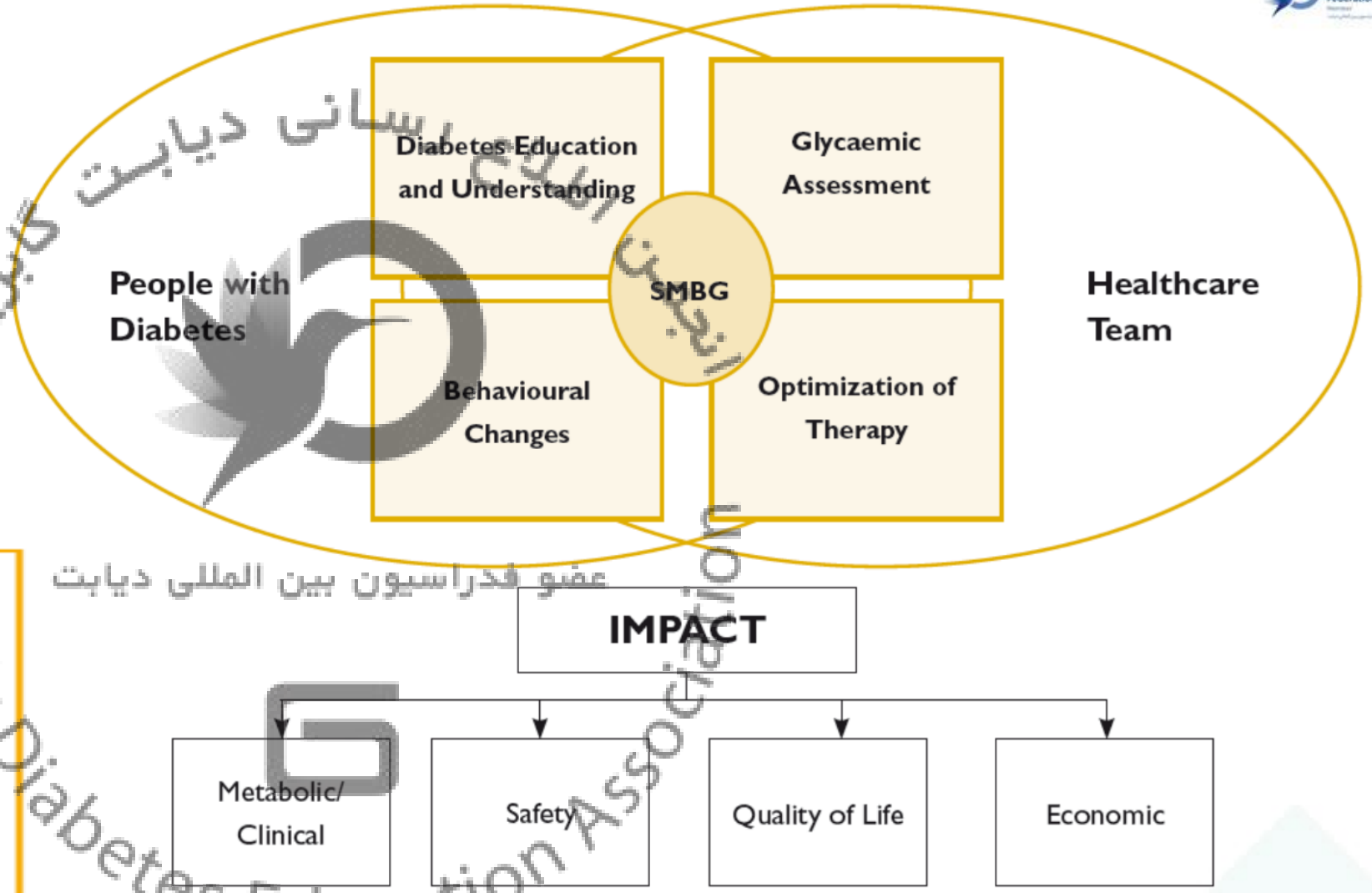
SMBG: Component of the Education/Treatment Programme



Self-Monitoring of Blood Glucose in non-insulin treated type 2 diabetes, (2009), IDF Publication, accessed via https://www.idf.org/e-library/guidelines

Holistic Approach

Take Home messages

- Inaccurate SMBG has both clinical and economical consequences.
- Technological advancements is necessary but not sufficient.
- Communicate with patients about accurate SMBG.
- Patient education is a MUST!