Accuratezza e precisione dei dati sul compenso glicemico

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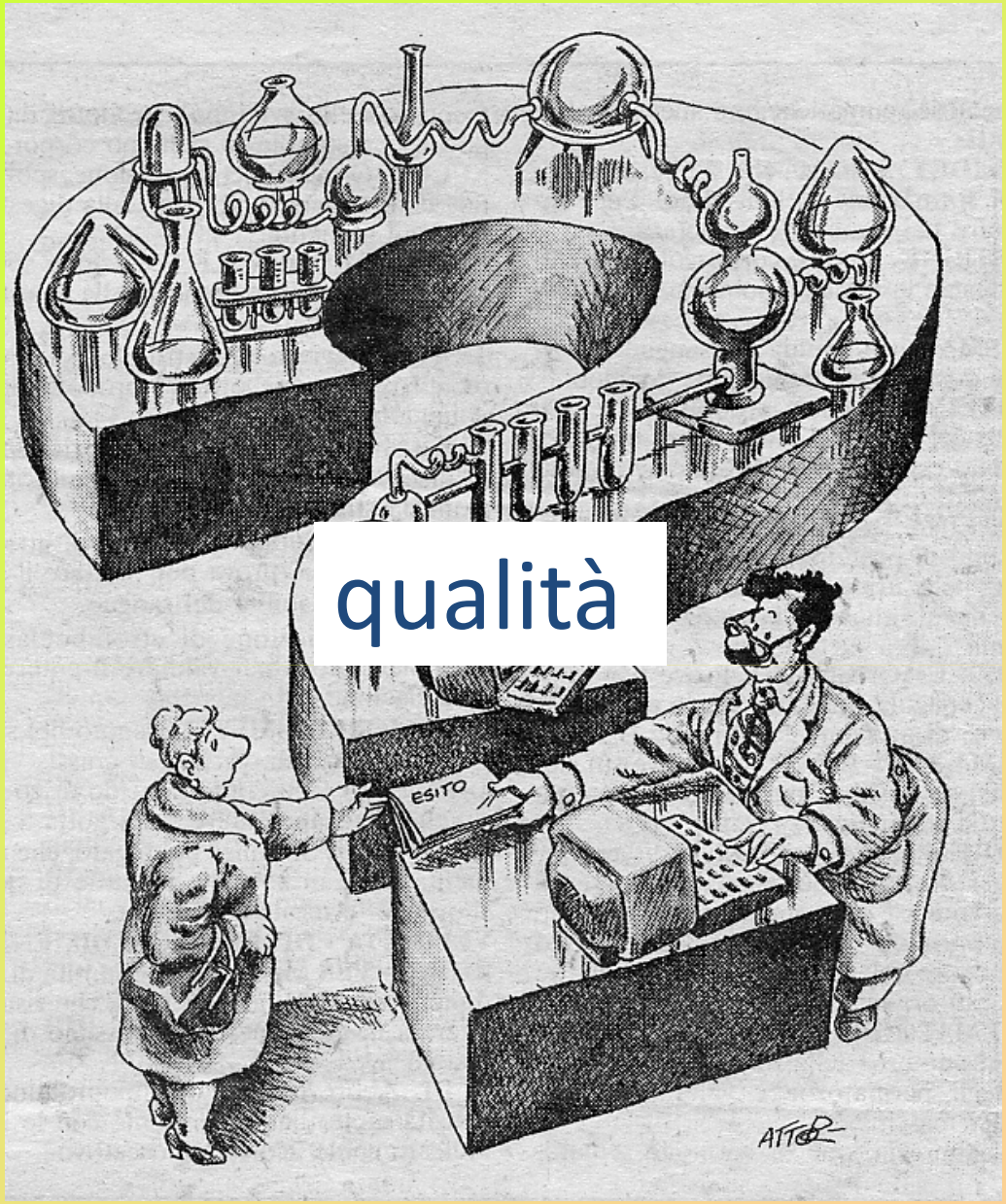
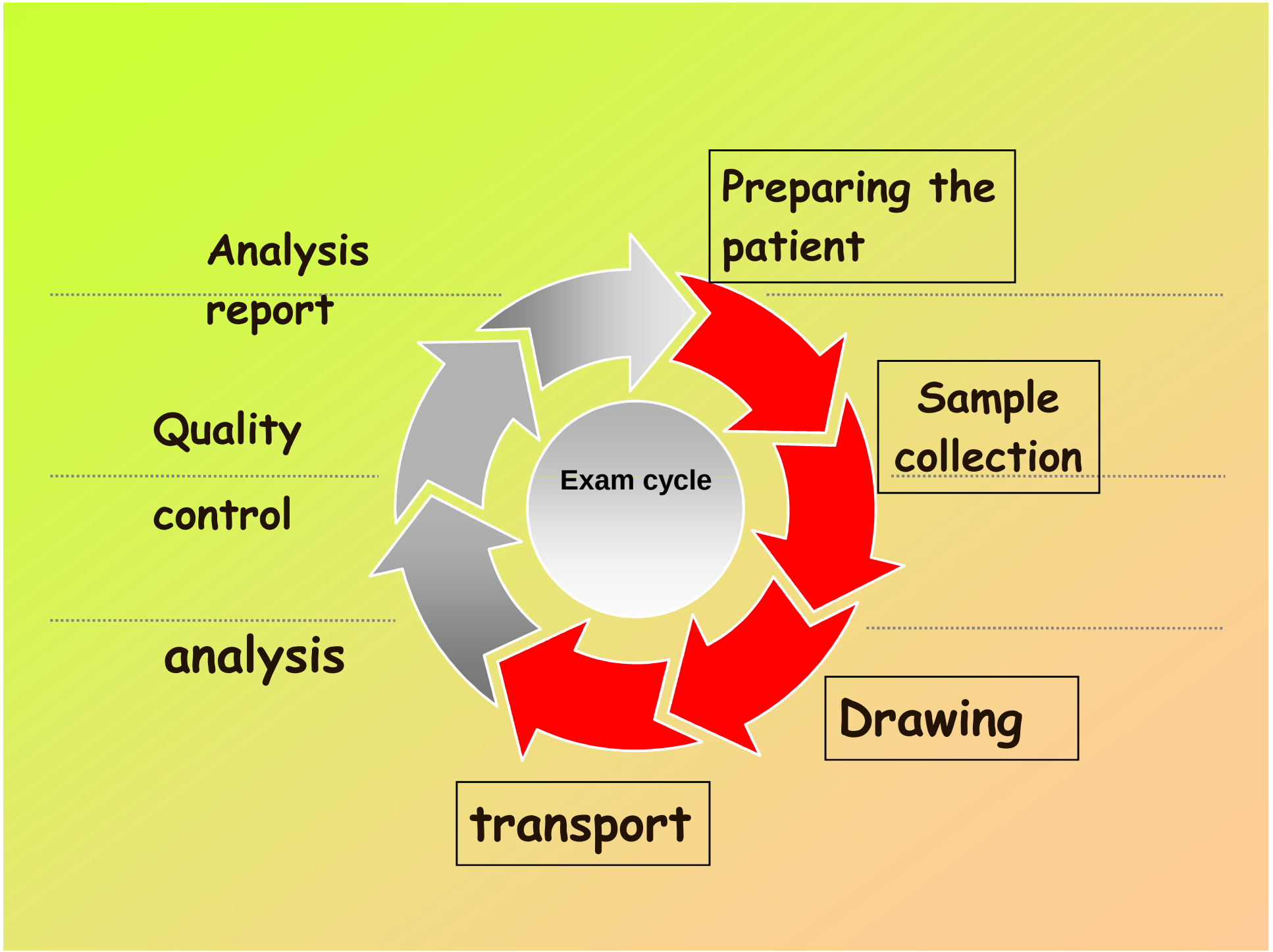
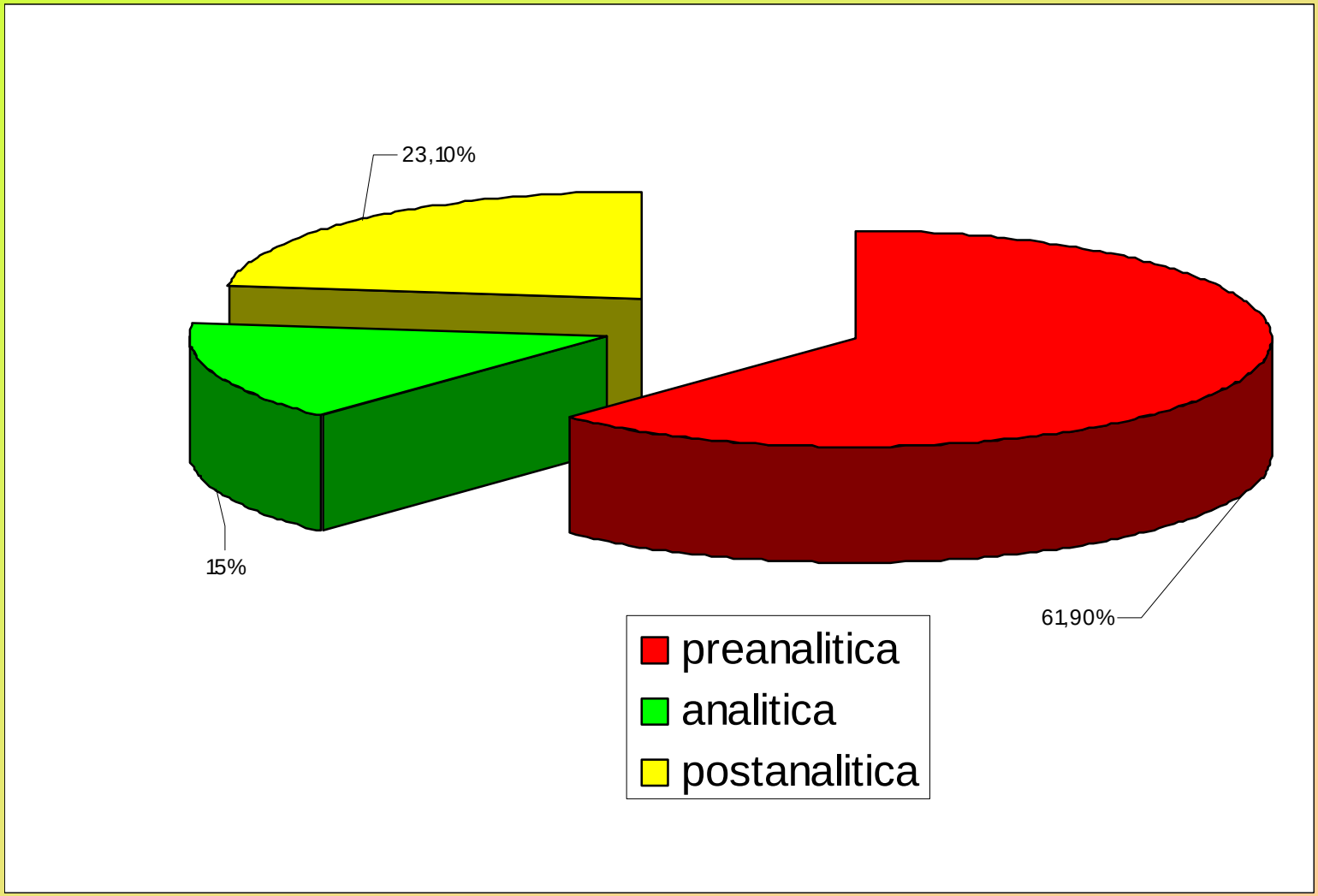
Università Politecnica delle Marche

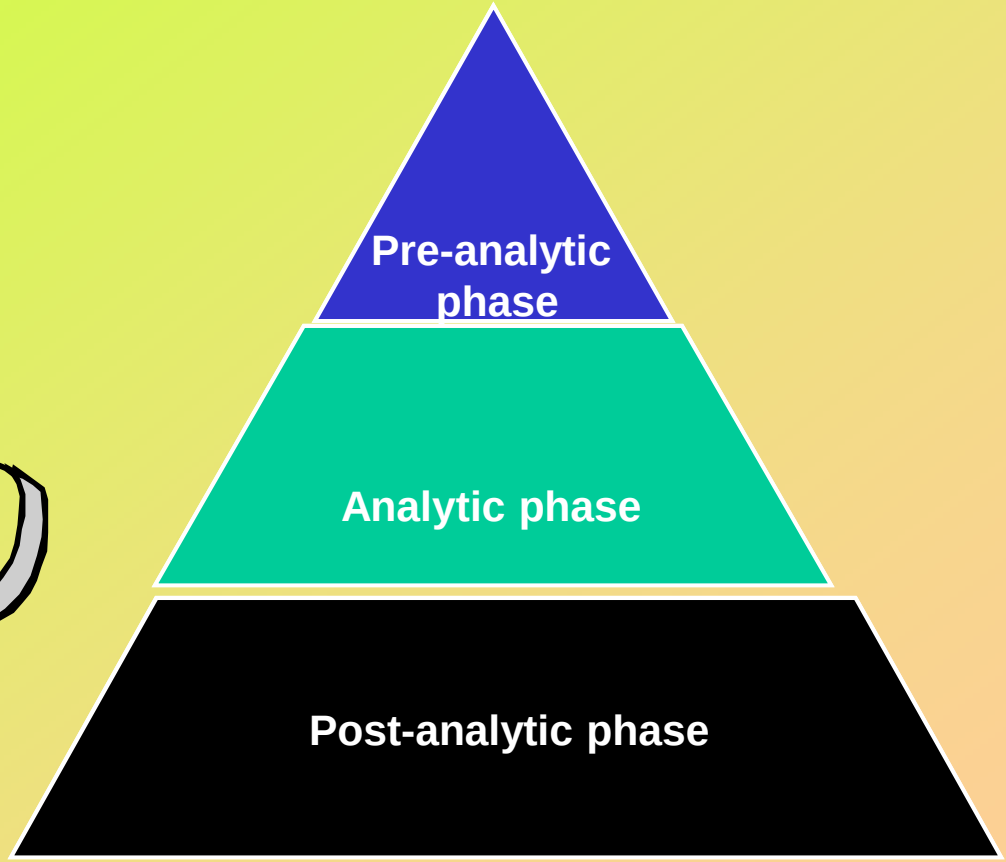

qualità
ESITO


Preparing the patient
Sample collection
Drawing
transport
analysis
Quality control
Analysis report
Exam cycle

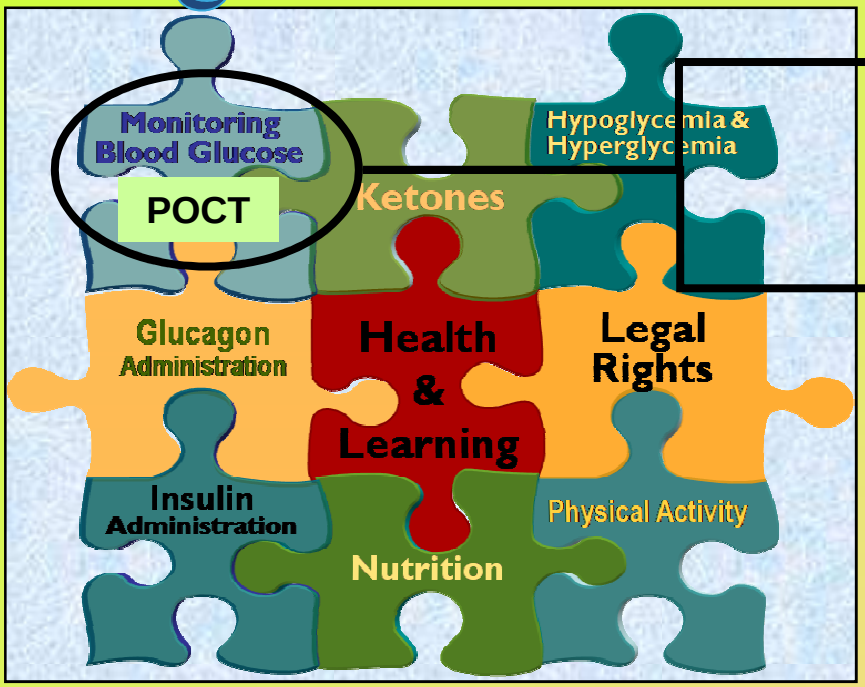
Carraro, Plebani, 2007: gli errori in laboratorio



Reliable result



Background



"SMBG is a vital piece of a comprehensive management plan (LdE:A)"
American Diabetes Association

L'autocontrollo quotidiano (almeno 3-4 controlli/die) è indispensabile per la persona con diabete tipo 1 in terapia insulinica intensiva. (**Livello della prova II, Forza della raccomandazione** A)

L'autocontrollo glicemico continuativo, con frequenza e modalità diverse, è utile per la persona con diabete tipo 2 insulino-trattato. (**Livello della prova II, Forza della raccomandazione** B)

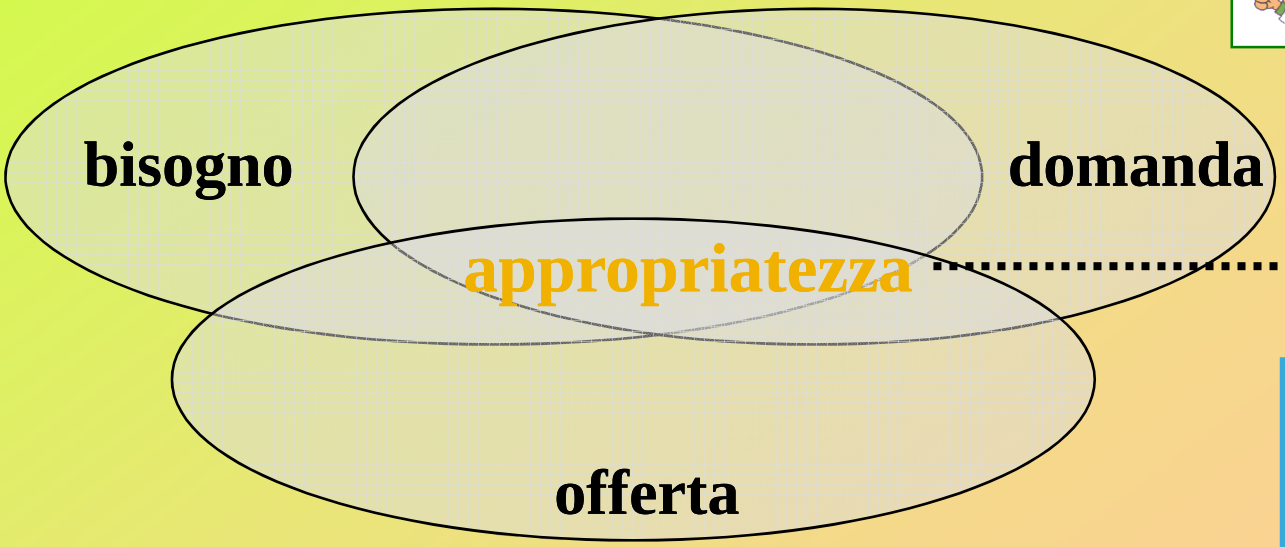
L'autocontrollo glicemico non continuativo è potenzialmente utile per la persona con diabete tipo 2 in terapia orale o dietetica, ma non sono disponibili chiare evidenze di efficacia sul controllo glicemico. (**Livello della prova VI, Forza della raccomandazione** C)

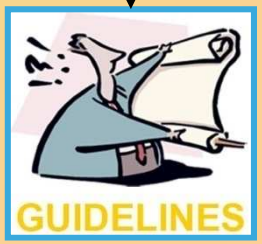
AMD 1974 ANNO DI FONDAZIONE ASSOCIAZIONE MEDICI DIABETOLOGI

SID SOCIETÀ ITALIANA DI DIABETOLOGIA

….anche per i POCT

Monitoraggio del numero e della tipologia degli esami effettuati (appropriatezza richieste)





ADA, SID, AMD..

Is Self-Monitoring of Blood Glucose Appropriate for All Type 2 Diabetic Patients?

The Fremantle Diabetes Study

Oggi: misurazione della glicemia


BONGARD


109
mg/dL

POCT

Documenti di riferimento

Documenti normativi di riferimento:

- UNI EN ISO 22870:2006 Point of care testing (POCT) - Particular Requirements for Quality and Competence.
- UNI EN ISO 15189:2007 Medical Laboratories-Particular Requirements for Quality and Competence.
- Additional Standards for Point-of-Care Testing (POCT) facilities. (Clinical Pathology Accred
- Linee
- Risk
- Racco

Linee guida professionali di riferimento:

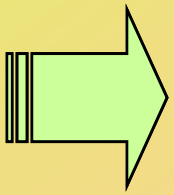
- Management and Use of IVD Point of Care Test (Medical Devices Agency/MDA, Department of Health, UK, 2002). *http://www.dhsspsni.gov.uk/hea-db%28ni%292002-03.pdf*
- Plebani M, Carraro P, Cremaschi A, et al. Il governo clinico del Point of Care Testing: un documento aperto alla discussione. (Biochim Clin 2004;28:594-7).
- Guidelines of Point-of-Care Testing (Roya *http://www.rcpath.org/resources/pdf/poin*
- Evidence-Based Practice for Point-of-Car Biochemistry/NACB, 2007). *http://www.aacc.org/members/nacb/LMP octpdf.aspx*
- Guidelines for Safe and Effective Manage (Association of Clinical Biochemists, Irel *http://www.acbi.ie/Downloads/Guideline*
- POCT1-A2, Point Of Care Connectivity; Standards Institute/CLSI - Second Edition

- POCT4-A02, Point of Care In Vitro Diagnostic (IVD) Testing; Approved Guideline (Clinical and Laboratory Standards Institute/CLSI - Second Edition, 2006).
- POCT02-A, Implementation Guide of POCT01 for Health Care Providers; Approved Guideline (Clinical and Laboratory Standards Institute/CLSI - First Edition, 2008).
- EP18-A2, Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline (Clinical and Laboratory Standards Institute/CLSI - Second Edition, 2009).
- POCT07-A, Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline (Clinical and Laboratory Standards Institute/CLSI - First Edition, 2010).
- POCT09-A, Selection Criteria for Point Of Care Testing Devices; Approved Guideline (Clinical and Laboratory Standards Institute/CLSI - First Edition, 2010).
- Management and Use of IVD Point of Care Test Devices (Medicines and Healthcare Products Regulatory Agency/MHRA, Department of Health, UK, 2010). *http://www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON071082*
- Point-of-Care Testing: Needs, Opportunity, and Innovation, 3rd Edition (American Association for Clinical Chemistry/AACC, 2010). *http://direct.aacc.org/ProductCatalog/Product.aspx?ID=6117*

The last decade has seen the forced implementation in POCT of programs for quality assurance and management, based on ISO 22870 point-of-care (POCT) requirements for quality and competence [18]. This requires:

- Internal and external quality control
- Training programs for end-users
- Certification and re-certification of end-users
- Evaluation of new or alternative POCT instruments and systems by professionals in laboratory medicine
- Evaluation and approval of proposals and protocols that are strongly directed at the end-user
- Maintenance of consumable supplies and reagents

International Organization of Standardization (2006) Point-of-care testing (POCT): requirements for quality and competence (ISO 22870:2006). ISO, Geneva



Qualità
Educazione
Certificazione
Efficienza
Tracciabilità
Connettività

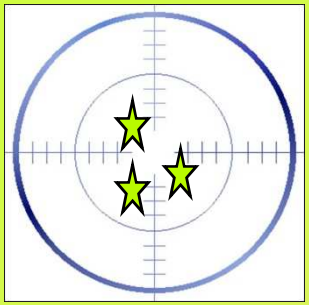
DIN EN ISO 15197. *In vitro* Diagnostic Test Systems-Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus (ISO 15197:2003). European Committee for Standardization, Brussels, 2003

ISO 15197:2003 specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples and procedures for the verification and the validation of performance by the intended users. These systems are intended for self-testing by laypersons for management of diabetes mellitus.

ISO 15197:2003 is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

ISO 15197:2003 does not provide a comprehensive evaluation of all possible factors that could affect the performance of these systems; does not pertain to glucose concentration measurement for the purpose of *diagnosing* diabetes mellitus; does not address the medical aspects of diabetes mellitus management; does not apply to measurement procedures with results on an ordinal scale (e.g. visual, semiquantitative test methods).

Accuratezza (coincidenza tra valore misurato e valore vero)

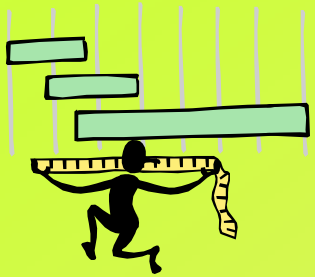


Esattezza (trueness)

David B. Sacks
Blood Glucose Meters
public Meeting
16th March, 2010

Analytical Goals for Glucose Meters

Source	Year	Goal
ADA	1986	TE <10% for 100% of the time
ADA	1996	±5% total analytical error
CLIA '88	1988	±10% or ±6 mg/dL 80% of time
NCCLS/CLSI	1994	>100 mg/dL ± 20% ≤100 mg/dL ± 15 mg/dL
FDA	1998	<100 mg/dL ± 20 mg/dL
ISO/TC212	2003	≥75 mg/dL ± 20% for 95% of time ≤ 75 mg/dL ± 15 mg/dL



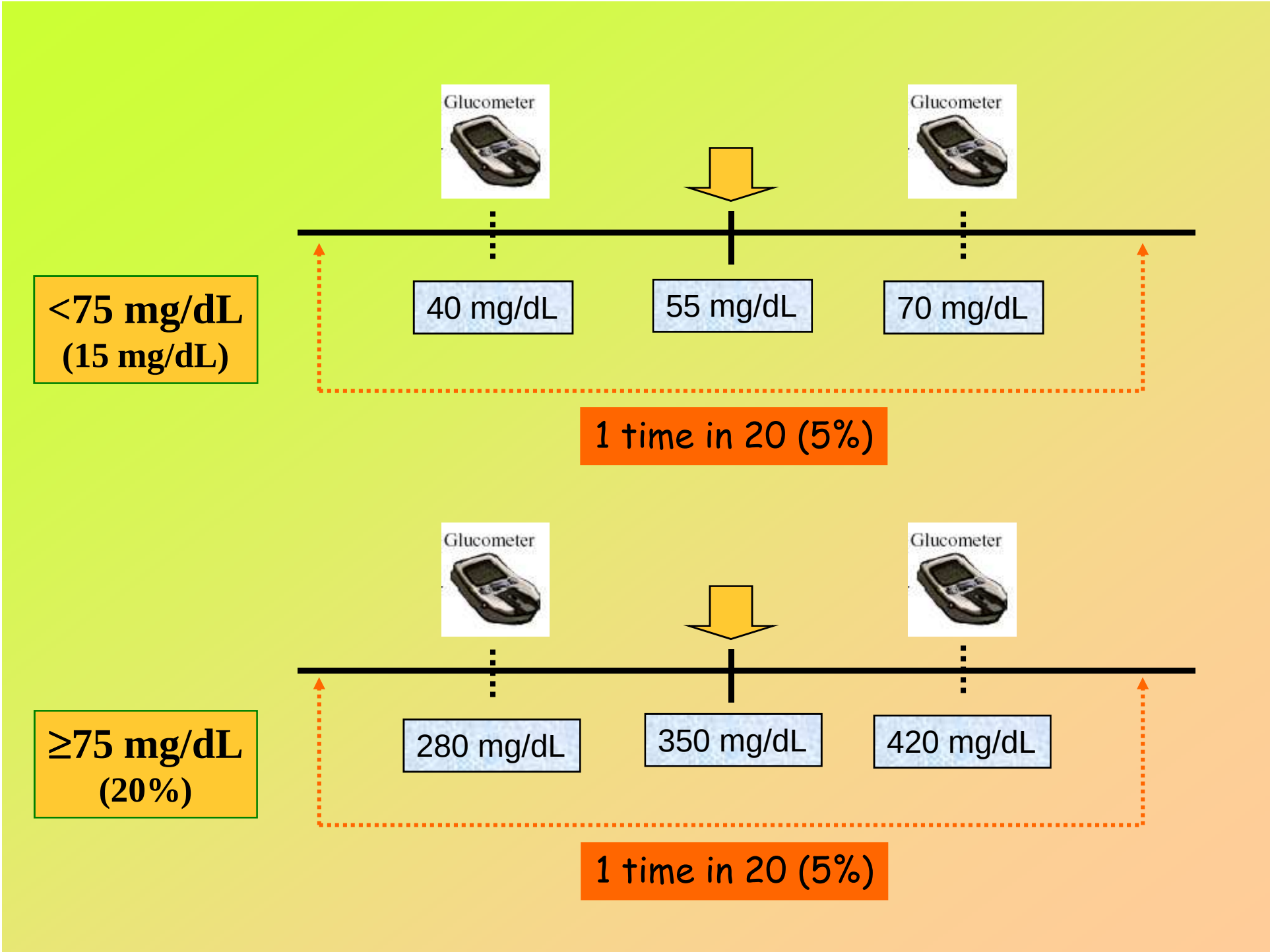
Requisiti minimi di accuratezza

A few years ago, the International Standards Organization (ISO), in conjunction with international regulatory authorities, health care providers, and device manufacturers in many countries, established a standard for evaluating the accuracy of blood glucose meters. Called ISO 15197, the standard calls for a minimum accuracy. Ninety five percent of all measured values should fall within

- 20% of glucose values above 75 mg/dl
- 15 mg of glucose values below 75 mg/dl.[3]

CLSI (C30A) & ISO

International Organization for Standardization. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus. Reference number ISO 15197:2003 (E). Geneva: International Organization for Standardization; 2003.


Glucometer
Glucometer
<75 mg/dL
(15 mg/dL)
40 mg/dL
55 mg/dL
70 mg/dL
1 time in 20 (5%)
Glucometer
Glucometer
≥75 mg/dL
(20%)
280 mg/dL
350 mg/dL
420 mg/dL
1 time in 20 (5%)

Diabetes Technol Ther. 2010 Mar;12(3):221-31.

System accuracy evaluation of 27 blood glucose monitoring systems according to DIN EN ISO 15197.

Freckmann G, Baumstark A, Jendrike N, Zschornack E, Kocher S, Tshiananga J, Heister F, Haug C.

University of Ulm, Germany.

) monitoring systems enable diabetes patients to effectively control and adjust their
n a Conformité Européenne (CE) label should meet the standard DIN EN ISO
esults shall fall within +/-15 mg/dL of the reference method at BG concentrations <75
centrations > or =75 mg/dL. We intended to verify if BG monitoring systems with a CE
requirements.

onitoring systems from 18 manufacturers for system accuracy according to DIN EN ISO
ere compared with the glucose oxidase reaction (YSI 2300 glucose analyzer [YSI Life
three systems with the hexokinase reaction (Hitachi 917 [Roche Diagnostics GmbH,
easurements of 100 blood samples with a defined distribution of BG concentrations
or =100 subjects were included in the evaluation.

nitoring systems fulfilled the minimum accuracy requirements of the standard, i.e., > or
nimum acceptable accuracy. Overall, the mean percenta f results showing the
95.2 +/- 5.2%, ranging from 80.0% to 100.0%.

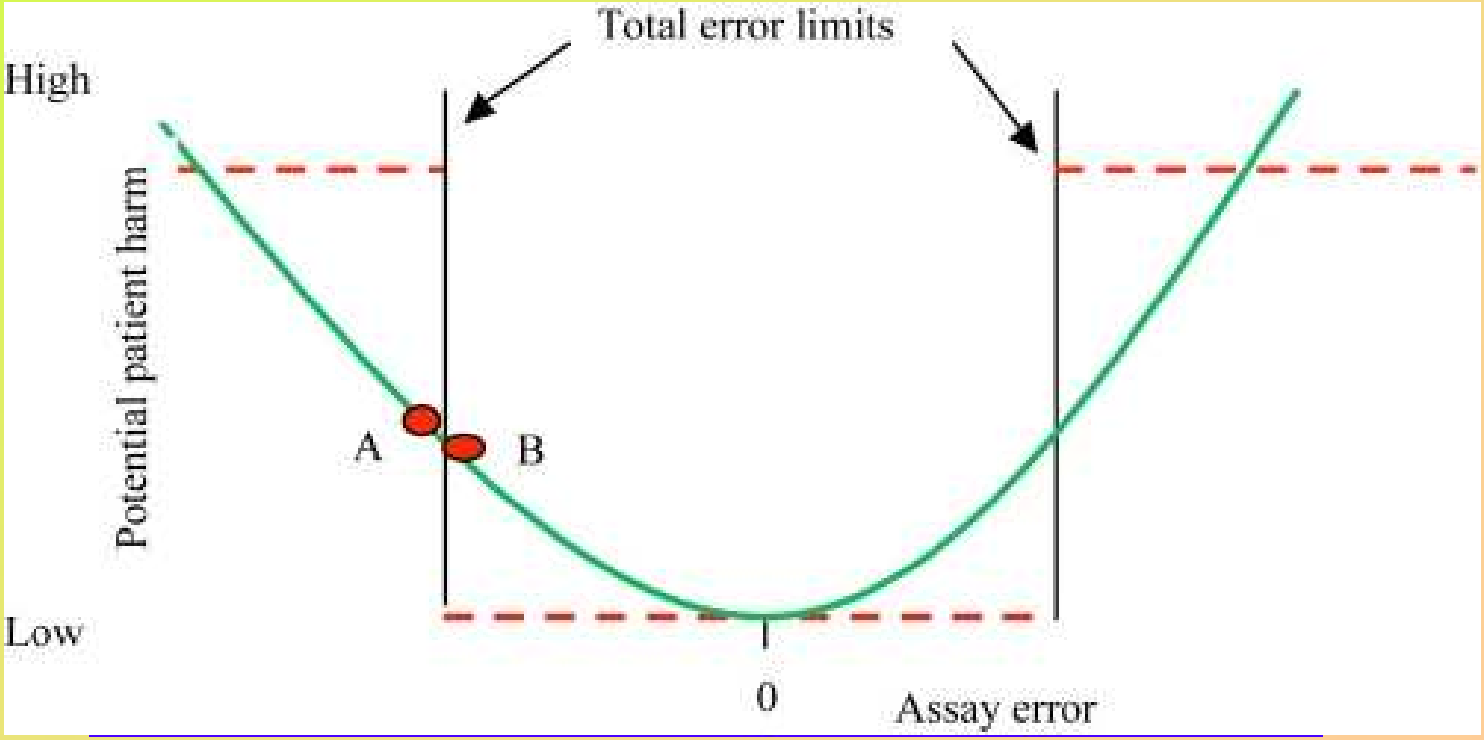
the evaluated BG monitoring systems did not fulfill the minimum accuracy requirements
urate BG monitoring systems bear the risk of false treatment decisions by the diabetes patient and subsequent possible severe health injury, manufacturers should regularly and effectively check the quality of BG meters and BG test strips.

11/27 (40%)

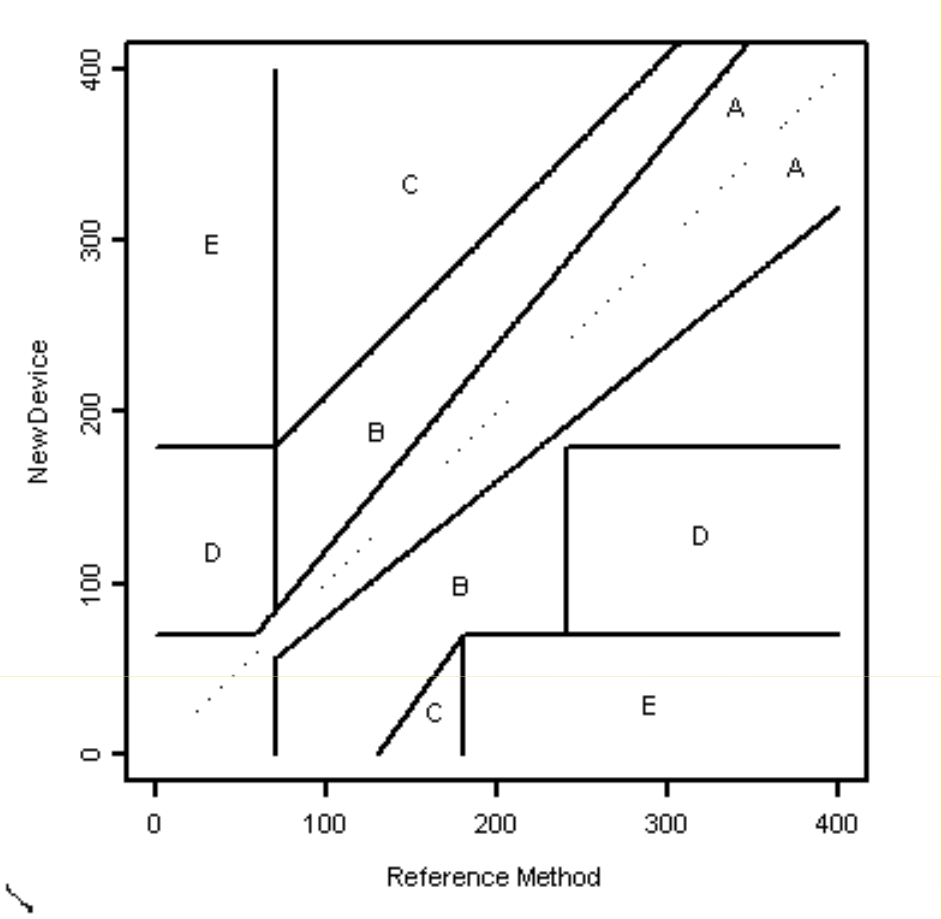
Another problem can be inferred from details in the ISO protocol, which suggest that the ISO total error specification is for the *analytical* subset of total error.

Krouwer JS et al. J Diabetes Sci Technol 2010;4:75-83.

…and other errors are cumulative…



The Clarke Error Grid Analysis (EGA) was developed in 1987 to quantify clinical accuracy of patient estimates of their current blood glucose as compared to the blood glucose value obtained in their meter.[1] It was then used to quantify the clinical accuracy of blood glucose estimates generated by meters as compared to a reference value. A description of the EGA appeared in Diabetes Care in 1987.[2] Eventually, the EGA became accepted as one of the “gold standards” for determining the accuracy of blood glucose meters.



Region A are those values within 20% of the reference sensor,
Region B contains points that are outside of 20% but would not lead to inappropriate treatment,
Region C are those points leading to unnecessary treatment,
Region D are those points indicating a potentially dangerous failure to detect hypoglycemia or hyperglycemia, and
Region E are those points that would confuse treatment of hypoglycemia] for hyperglycemia and vice-versa.

’70-’80

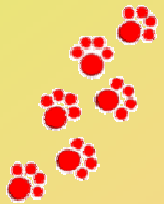
"Results from glucose meters are not as <u>accurate</u> as those from laboratory methods…"
Saudek CD, et al. JAMA 2006;295:1688-97.

American Diabetes Association buyer's guide. Diabetes Forecast 2001;54:46–110.

…anche per i POCT

Controllo del processo: organizzazione e gestione dell'attività tale da garantire che nulla venga lasciato all'improvvisazione

- **Attribuzione responsabilità**
- **Formazione personale e pazienti**
- **Registrazione e tracciabilità**



Controllo della qualità analitica:

- **calibrazione**
- **CQ interno ed esterno**
- **manutenzioni**
- **monitoraggio scorte**

Formazione del personale e dei pazienti

- È necessario istruire il paziente all'autocontrollo glicemico, valutare periodicamente la correttezza dell'utilizzo del glucometro e la capacità di modificare la terapia sulla base dei valori misurati, eventualmente facendo uso di un algoritmo condiviso. **(Livello della prova VI, Forza della raccomandazione B)**

- L'istruzione all'autocontrollo glicemico deve inserirsi in un programma educativo condotto e controllato a medio-lungo termine da personale sanitario del team diabetologico. **(Livello della prova VI, Forza della raccomandazione B)**

STANDARD ITALIANI PER LA CURA DEL DIABETE MELLITO

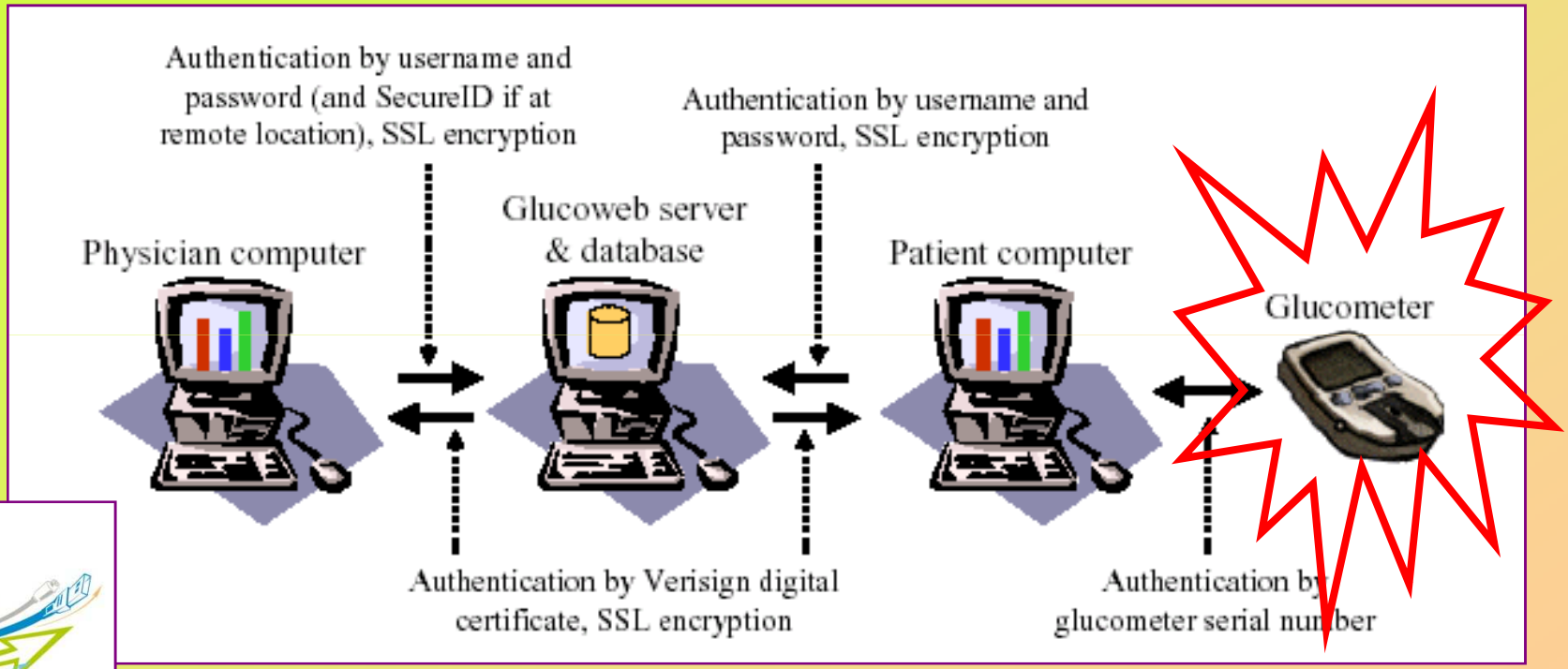
2009-2010

AMD ASSOCIAZIONE MEDICI DIABETOLOGI 1974

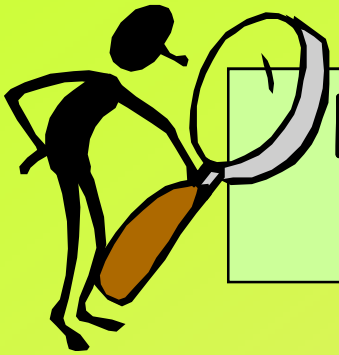
SID SOCIETÀ ITALIANA DI DIABETOLOGIA

Registrazione e tracciabilità

Connettività

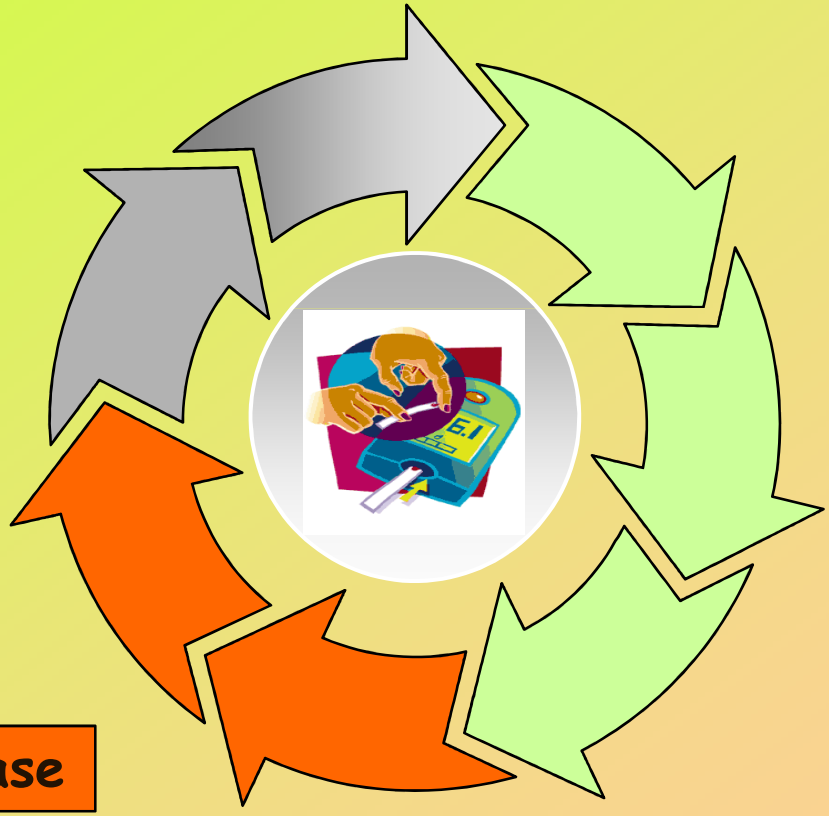


Factors that affect Accuracy



Factors that affect Accuracy

Post-analytical phase



Pre-analytical phase:

- Patient
- Strip
- Lancet

Analytical phase

1. Strip factors

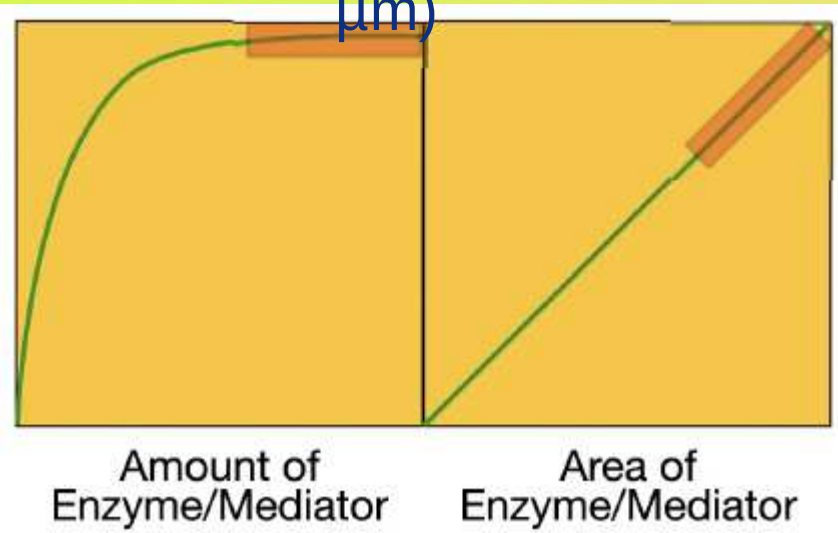
- Check expiration date on each new vial of strips
- Avoid exposure to air, heat, cold, humidity (consider temperature during shipping)
- Preserve original container
- Recap immediately

Factors Affecting Blood Glucose Monitoring: Sources of Errors in Measurement

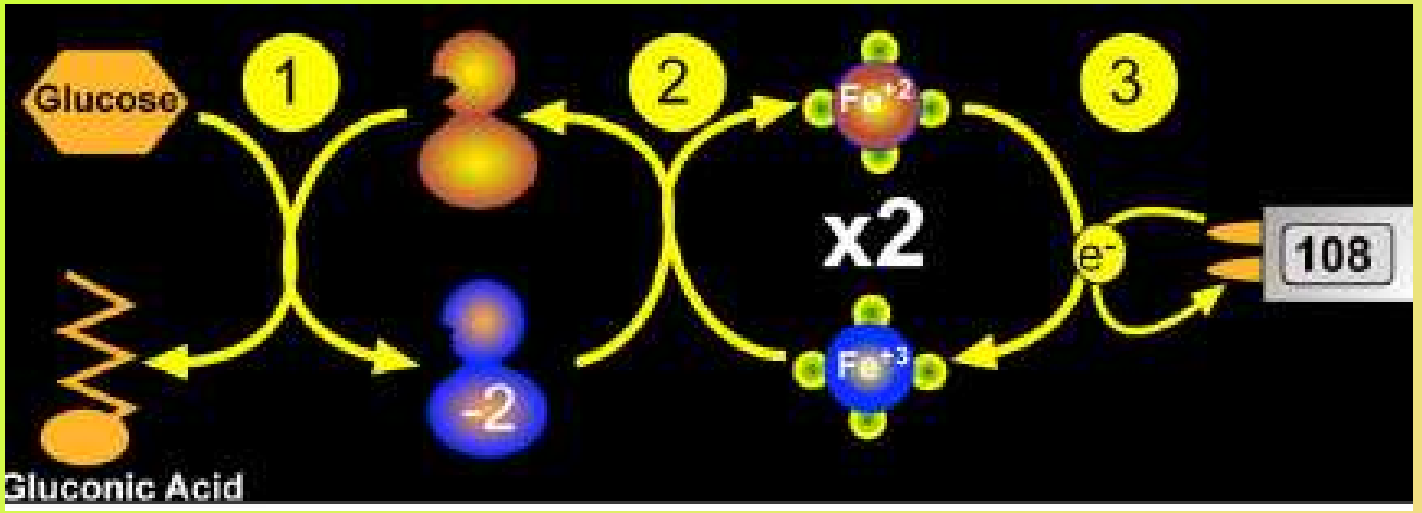
Journal of Diabetes Science and Technology Volume 3, Issue 4, July 2009

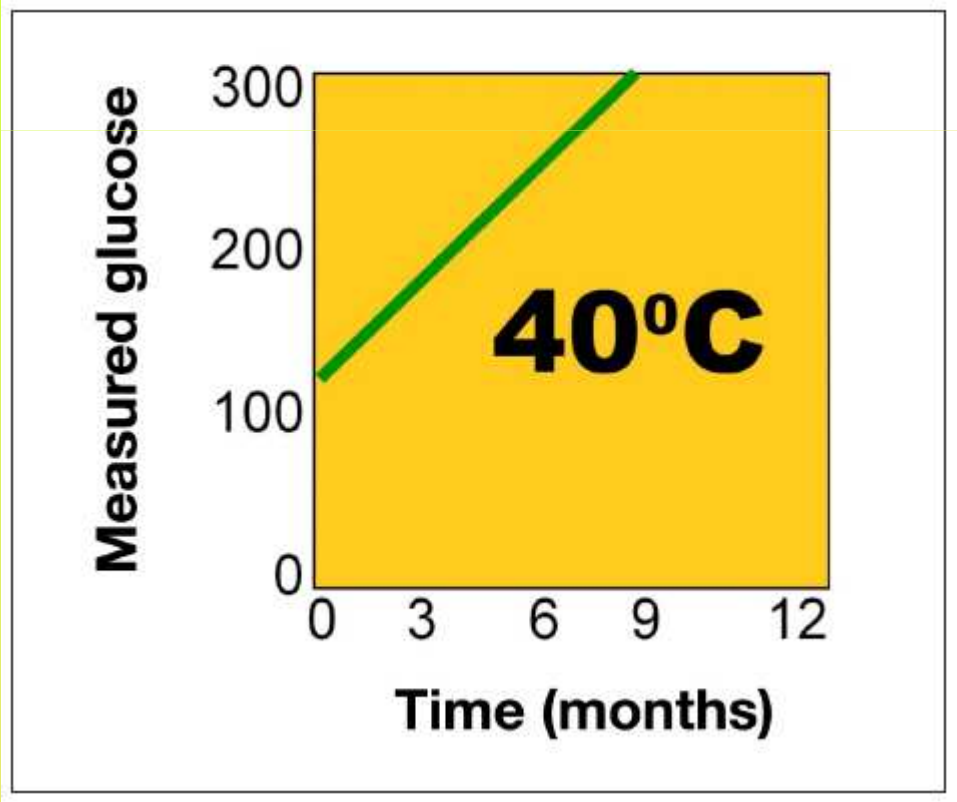
Barry H. Ginsberg, M.D., Ph.D.

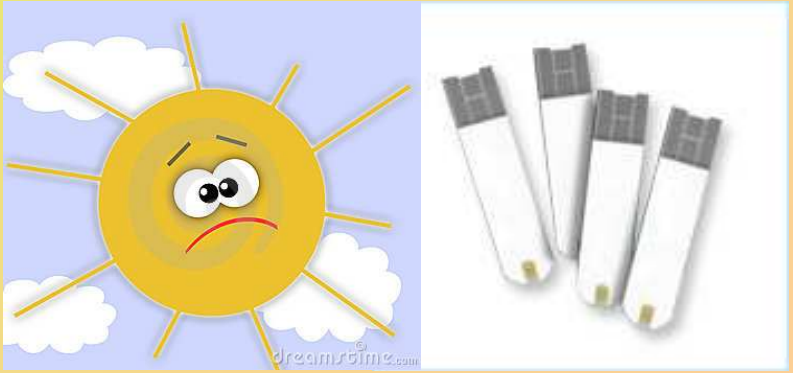
- Well-size variation (~50 µm)



Changes in enzyme coverage may also influence accuracy. Generally, excess enzyme is used in strips, thus small decreases in enzyme amount do not alter glucose values (**Figure 5, left**). On the other hand, changes in the proportion of the well covered by enzyme directly correlates with the reading (**Figure 5, right**). Thus, a thinning of the enzyme will not cause an error, but loss of enzyme coverage, with bare spots, will lead to underestimation of the glucose values.







110 mg/dL → 300 mg/dL

Effect of Ambient Temperature on Analytical Performance of Self-Monitoring Blood Glucose Systems

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 13, Number 9, 2011

Kari Nerhus, M.S.,[1] Pål Rustad, M.S.,[2] and Sverre Sandberg, M.D., Ph.D.[1,3]

Background: The analytical quality of self-monitoring of blood glucose (SMBG) can be affected by environmental conditions such as temperature. The objective of this study was to determine the influence of (1) a shift in the ambient temperature immediately before measurement and (2) taking measurements in the lower and upper part of the operating temperature range.

Methods: Nine different SMBG systems on the Norwegian market were tested with heparinized venous blood (4.8 and 19.0 mmol/L). To test the shift in ambient temperature effect, the glucometer and strips were equilibrated for 1 h at 5°C or 1 h at 30°C before the meter and strips were moved to room temperature, and measurements were performed after 0, 5, 10, 15, and 30 min. To test the lower and upper temperature range, measurements were performed at 10°C and at 39°C after 1 h for temperature equilibration of the glucometer and strips. All these measurements were compared with measurements performed simultaneously on a meter and strips kept at room temperature the whole time.

Results: Six of nine SMBG systems overestimated and/or underestimated the results by more than 5% after moving meters and strips from 5°C or 30°C to room temperature immediately before the measurements. Two systems underestimated the results at 10°C. One system overestimated and another underestimated the results by more than 5% at 39°C.

Conclusions: The effect on analytical performance was most pronounced after a rapid shift in the ambient temperature. Therefore patients need to wait at least 15 min for temperature equilibration of affected meters and strips before measuring blood glucose.

2. Physical factors

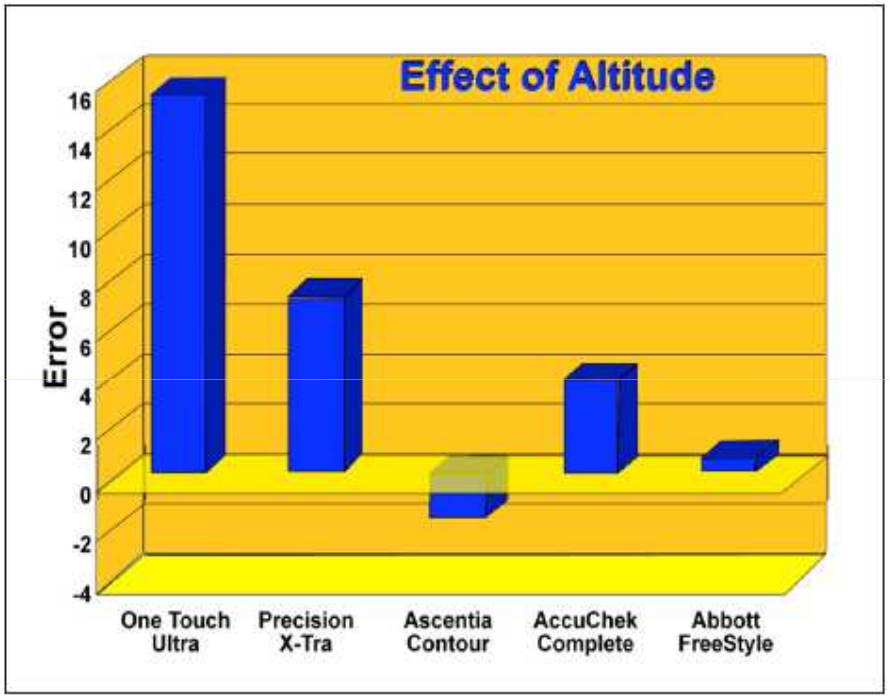


Figure 8. A group of mountain climbers tested blood glucose systems atop a 3000 m mountain to measure the effect of altitude and temperature (**Figure 9**). The glucose-oxidase-based meters overestimated the glucose by 6–15%. The glucose-dehydrogenase-based meters were more accurate at high altitude.

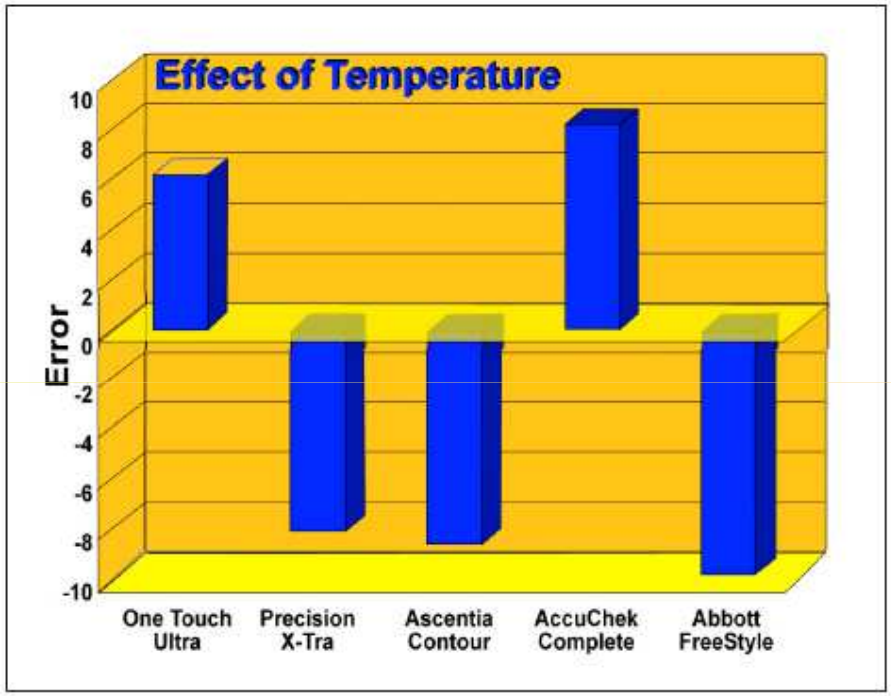


Figure 9. The same group of mountain climbers measured the effect of the ambient temperature of 8 °C on accuracy, reported here.

The influence of temperature is less predictable. Most meters have a temperature sensor and will report errors at extreme temperatures. The same mountain climbers also tested the influence of temperature, measuring glucose at 8 °C (**Figure 9**). The results were brand specific, not technology dependent. The errors were 5–7% but could be either positive or negative.

3. Patient factors

- **Low Battery**
- **Damage (scratches) to optic window of meter**
- **Dirty meter**
  - Clean outer surface with gentle disinfectant
  - Don't use alcohol, cleaners with ammonia, glass cleaners or abrasive cleaners

- Pay attention to calibration failures
- Methods
  - Code chip
  - Check strip
  - Enter code on box of strips into meter
- Encourage client to get in habit of calibrating meter with each new box/bottle of strips.
- Some newer meters automatically calibrate meter.

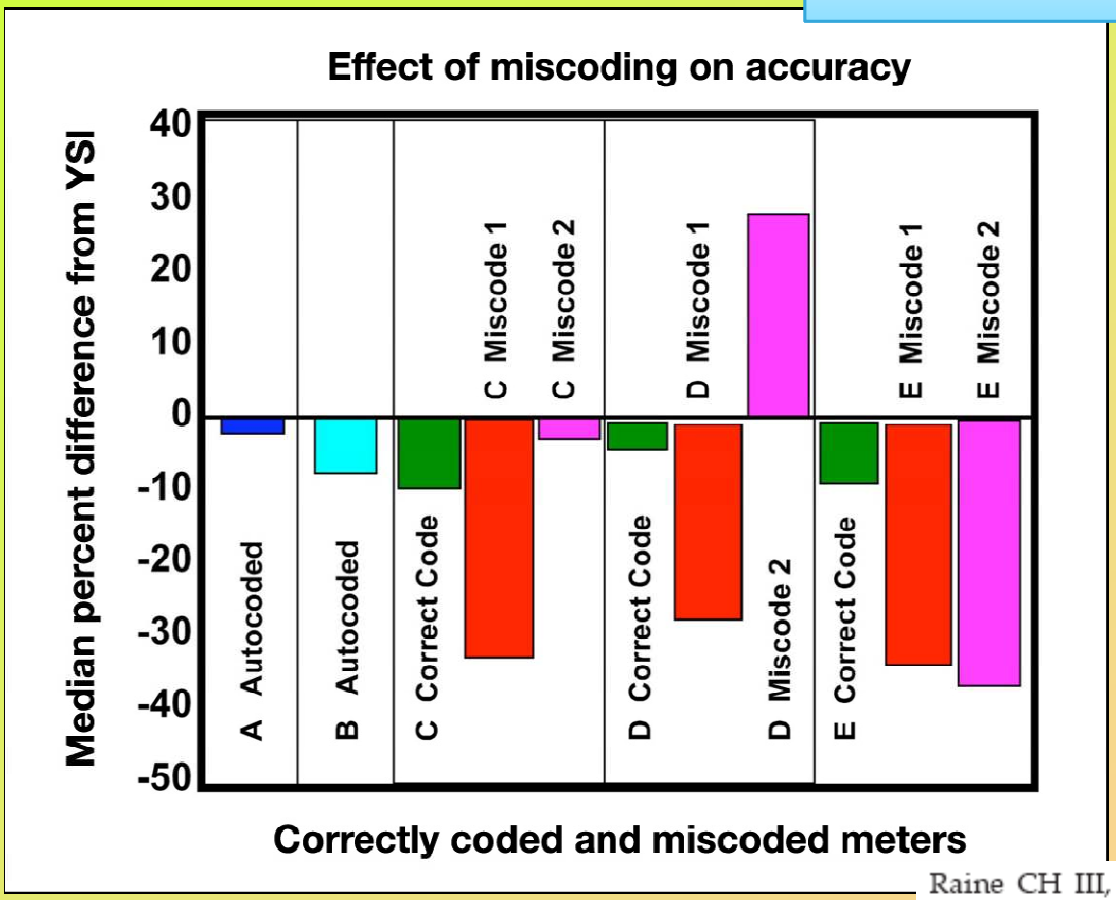
Calibration
Coding determines the relationship between the electrical signal produced by the strip and the reported blood glucose

Clin Chim Acta. 2001 May;307(1-2):61-7.

Error detection and measurement in glucose monitors.

Johnson RN, Baker JR.

"Patient failure to calibrate the glucose meter regularly is a common cause of error"



Raine CH III, Schrock LE, Edelman SV, Mudaliar SRD, Zhong W, Proud LJ, Parkes JL. Significant insulin dose errors may occur if blood glucose results are obtained from miscoded meters. J Diabetes Sci Technol. 2007;1(2):205–10.

Controllo di qualità

laboratories [46,47].

Invited critical review

Clinica Chimica Acta 402 (2009) 7–13

Overview on self-monitoring of blood glucose

Martina Montagnana [a], Marco Caputo [b], Davide Giavarina [c], Giuseppe Lippi [a,*]

Diabetes Care. 2011 Feb 2. [Epub ahead of print]

Self-Monitoring of Blood Glucose: The Use of the First or the Second Drop of Blood.

Hortensius J, Slingerland RJ, Kleefstra N, Logtenberg SJ, Groenier KH, Houweling ST, Bilo HJ.

Diabetes Centre, Isala Clinics, Zwolle, the Netherlands.

RESULTS—Not washing hands led to a difference in glucose concentration of ≥10% in the first and in the second drops of blood in 11% and 4% of the participants, respectively. In fruit-exposed fingers, these differences were found in 88% and 11% of the participants, respectively. Different external pressures led to ≥10% differences in glucose concentrations in 5–13% of the participants.

CONCLUSIONS—We recommend washing the hands with soap and water, drying them, and using the first drop of blood for self-monitoring of blood glucose. If washing hands is not possible, and they are not visibly soiled or exposed to a sugar-containing product, it is acceptable to use the second drop of blood after wiping away the first drop. External pressure may lead to unreliable readings.

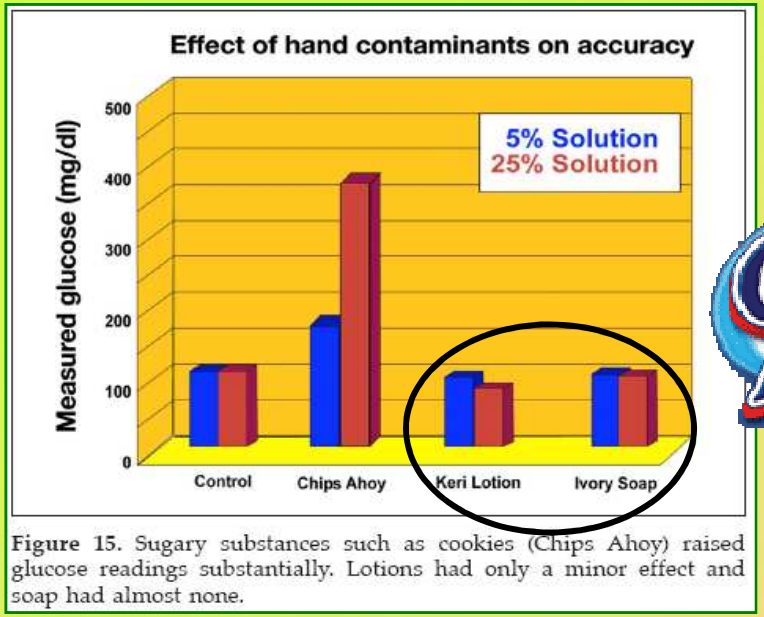


Figure 15. Sugary substances such as cookies (Chips Ahoy) raised glucose readings substantially. Lotions had only a minor effect and soap had almost none.

Diabetes Care. 2011 Jan 31. [Epub ahead of print]

Glucose Monitoring After Fruit Peeling: Pseudohyperglycemia When Neglecti Hand Washing Before Fingertip Blood Sampling: Wash your hands with tap wa before you check blood glucose level.

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Abstract

OBJECTIVE To examine whether hand contamination with fruit results in a false blood glucose (BG) reading using capillary fingertip blood sample. RESEARCH DESIGN AND METHODS The study subjects were healthy volunteers with normal glucose tolerance test. Capillary BG samples were collected from the fingertip after peeling orange, grape, or kiwi fruit, followed by no action, washing hands with tap water, or rubbing the fingertip with an alcohol swab, then analyzed with glucose monitors. RESULTS The BG levels measured after peeling any of the fruits, followed by washing hands, were similar to the control subjects (no fruit handling), but the levels after fruit peeling, followed by no washing, were abnormally and significantly high, even when the fingertip was cleaned once or five times with an alcohol swab before blood sampling. CONCLUSIONS To avoid overestimation of blood glucose using portable monitors the hands should be washed before monitoring capillary BG, especially after fruit has been handled.

Table 1.
Confounding Variables in Glucose Measurement[a]

Variable	Methodology affected[b]	
	GO	GD
Hematocrit		
Anemia	↑	↑
Polycythemia	↓	↓
Oxygen concentration		
Hypoxia	↑	–
Oxygen therapy	↓	–
pH (6.8–7.55)		
Low pH	– / ↓	–
High pH	– / ↑	–
Hypothermia	↑	↓ / ↑
Hypotension	↑	↓ / ↑
Drugs		
Ascorbic acid	↓	↓ / –
Acetaminophen	↓	↑
Dopamine	–	↓
Icodextrin	–	↑
Mannitol	↑	

Challenges to Glycemic Measurement in the Perioperative and Critically Ill Patient: A Review

Journal of Diabetes Science and Technology Volume 3, Issue 6, November 2009

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Hematocrit levels

- ↑ hematocrit (i.e. dehydration) will give false low reading

- ↓ hematocrit (i.e. anemia) can give false high reading (lower erythrocyte mass)

- Each meter lists a range of hematocrits for which it is accurate

⇒ Important when monitoring pregnant women or newborn.

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A low hematocrit increases SMBG results[18] because of the lower erythrocyte mass. Erythrocytes are relatively glucopenic, so the whole blood applied to strips normally has about 15% less glucose than plasma glucose, the difference lessened with anemia. Most meters today are calibrated to provide plasma glucose equivalent readings[19] and assume a normal hematocrit.

JAMA. 2006;295:1688-1697

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2

creased number of erythrocytes in the whole-blood sample may mechanically impede diffusion of plasma into the reagent layer,[14] block the "holes" in the mesh membrane,[12] or decrease the volume of plasma available to diffuse.

(Tang et al. Arch Pathol Lab Med 2000;124:1135-40).

Plasma capillare
11.88 mmol/L

+ 9.6%

Plasma venoso
10.84 mmol/L

+ 13.1%

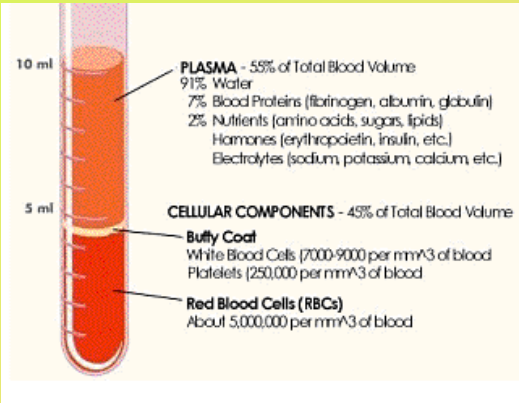
- 3.2%

Sangue intero capillare
10.50 mmol/L

+ 13.1%

Sangue intero venoso
9.58 mmol/L

+ 9.6%



In USA:	**plasma equivalente (AACC, ADA)**
In GB:	**preferenza tradizionale per sangue** **obbligo di etichetta evidente**
In Italia:	**massima confusione**

Confronto degli schemi enzimatici di rivelazione dei glucometri elettrochimici in termini di errore dovuto a sostanze endogene ed esogene

Centonze D et al, G It Diabetol Metab 2006

Sostanza interferente	Schema enzimatico di rivelazione[a]				Condizioni cliniche
	PQQ-GDH	GOD/HRP	GOD	1-GDH	
Acido ascorbico	Sovrastima	Sottostima	Sovrastima	Sovrastima	• Abuso nell'ingestione di vitamina C • Tutte le patologie che provocano aumento del valore ematico
Acido urico	Sovrastima	Sovrastima/ sottostima	Sovrastima	Sovrastima	• Gotta e tutte le patologie che provocano aumento del valore ematico
Bilirubina	Sovrastima	Sovrastima/ sottostima	Sovrastima	Sovrastima	• Anemia emolitica, itteri ostruttivi e tutte le patologie che provocano aumento del valore ematico
Colesterolo	Sovrastima	Sovrastima/ sottostima	Sovrastima	Sovrastima	• Tutte le patologie che provocano aumento del valore ematico
Galattosio	Sovrastima	[b]	-	Sovrastima	• Galattosemia
Icodestrina	Sovrastima	-	-	Sovrastima	• Trattamento con soluzioni per dialisi peritoneale (per es., Extraneal)
Maltoso	Sovrastima	-	-	Sovrastima	• Trattamento con soluzioni per dialisi peritoneale (per es., Extraneal) • Trattamento con preparati immunoglobulinici umani (per es., Octagam)
Ossigeno	-	Sovrastima/ sottostima	Sovrastima/ sottostima	-	• Ipossiemia, anemia, policitemia • Particolari condizioni di vita (per es., soggiorno in altitudine)
Paracetamolo	Sovrastima/ sottostima	Sovrastima/ sottostima	Sovrastima/ sottostima	Sovrastima/ sottostima	• Trattamento con farmaci che contengono il principio attivo
Triglicerídi	Sovrastima	Sovrastima/ sottostima	Sovrastima	Sovrastima	• Tutte le patologie che provocano aumento del valore ematico
Xilosio	Sovrastima	-	-	Sovrastima	• Test orale di malassorbimento alle xilosio

TABLE 3. MALTOSE-CONTAINING OR MALTOSE-GENERATING DRUGS

Drug trade name	*Approved indications*	*Estimated units sold in the United States (inpatient)*	*Estimated patient population (inpatient)*	*Delivery*	*Alternate medication option available*
Extraneal® (contains icodextrin)	End-stage renal disease	Unknown	26,082 peritoneal dialysis patients (United States, 2006)[4]	Solution used for peritoneal dialysis[5]	Yes
Octagam® 5%	Intravenous immunoglobulin solution for treating primary and secondary immunodeficiency diseases[6]	154,000[a]	30,800 (5 units/patient)	Slow infusion with professional oversight	Yes
WinRho® SDF liquid	Specific intravenous immunoglobulin for treatment of ITP and Rh transfusion reactions[7]	61,000[a]	20,333 (3 units/patient)	Liquid or lyophilized formulation administered intravenously or intramuscularly	Yes
Orencia® (abatacept)	Selective intravenous immunosuppressant drug for the treatment of rheumatoid arthritis[8]	3,000[b]	3,000 (1 unit/patient)	Intravenous solution	No therapeutic equivalents[9]
Adept® adhesion reduction solution (4% icodextrin)	Separate and protect tissues and decrease the number of new adhesions after surgery[10]	New to market 2006[11]	No data	Fluid used during or after laparoscopic gynecological surgery	Unknown
HepaGam B®	Acute exposure to blood containing HBsAg, exposure to HBsAg-positive persons or persons with acute HBV infections[12]	5,000[a]	5,000 (1 unit/patient)	Intravenous immunoglobulin	Unknown
Bexxar®	Treatment of non-Hodgkin's lymphoma[13]	2,000[a]	2,000 (1 unit/patient)	Radioimmunotherapy	No therapeutic equivalents[9]

Es. maltosio

A patient treated with intravenous immunoglobulin preparations containing maltose was found to have capillary glucose readings of 167 and 439 mg/dl using a GDH-PQQ meter but simultaneous lab-measured venous plasma glucose levels of 41 and 187 mg/dl, respectively. On its website, the U.S. Food and Drug Administration (FDA) draws attention to this hazard by listing the following items as being potential "interfering products" with GDH-PQQ strips: Extraneal (icodextrin) peritoneal dialysis solution; some immunoglobulins, including Octagam 5%, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human), and HepaGamB; Orencia (abatacept); Adept adhesion reduction solution (4% icodextrin); and BEXXAR radioimmunotherapy agent (9). Additionally, the FDA warns that any product containing or metabolized into maltose, galactose, or xylose could be a potential hazard in this respect.

41 mg/dL → 167 mg/dL

187 mg/dL → 439 mg/dL

U.S. Food and Drug Administration. FDA public health notification: potentially fatal errors with GDH-PDD glucose monitoring technology [Internet], 2009. Available from http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm. Accessed 13 January 2010

Sostanze e prodotti interferenti

Finger-Stick Glucose Monitoring

Issues of accuracy and specificity

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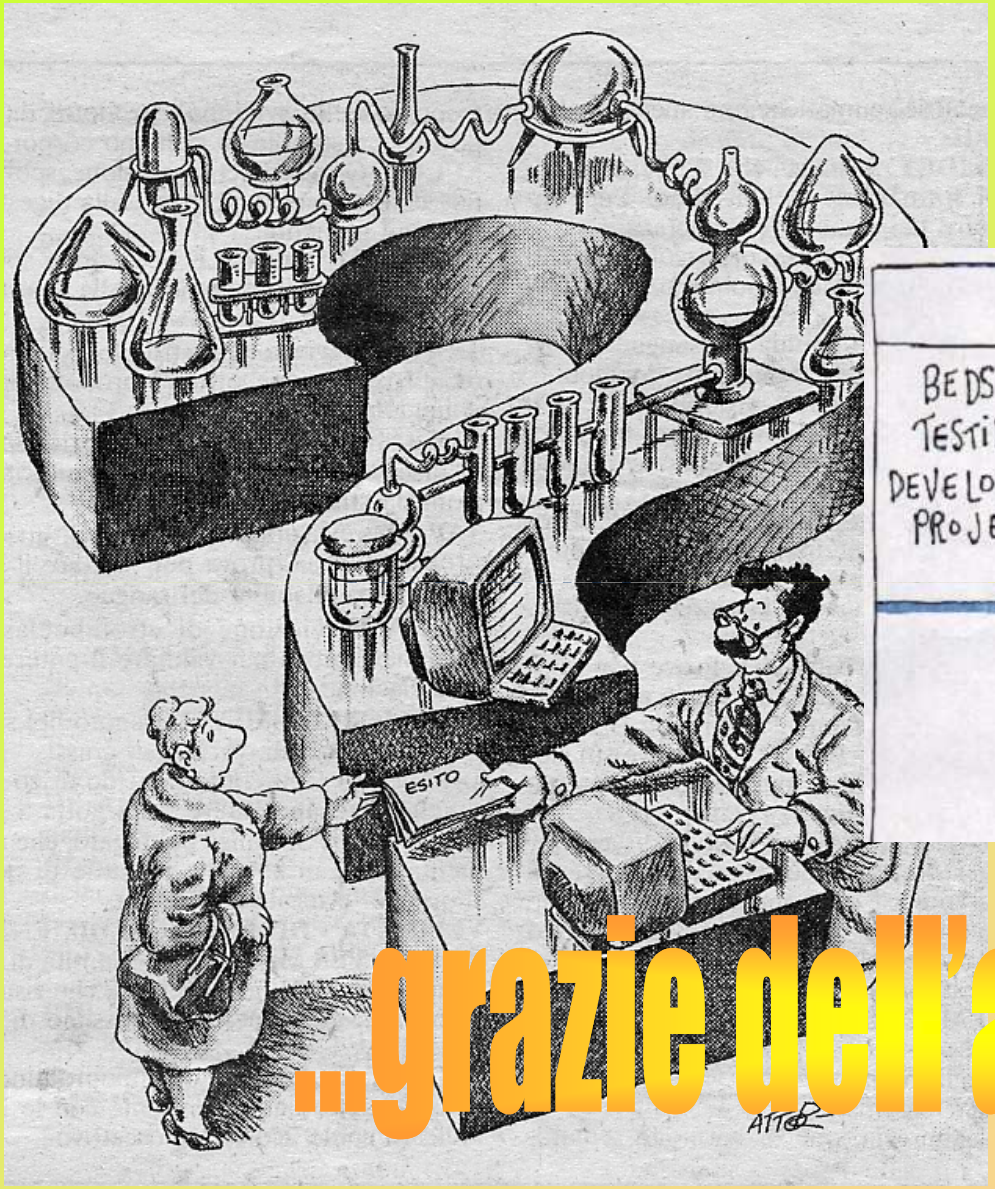
DIABETES CARE, VOLUME 33, NUMBER 4, APRIL 2010

? Soluzioni ?

Source of inaccuracy	Solutions
Physical variation in strips	QC[a], WaveSense Technology
Enzyme failure	Destroy outdated strips. store properly, code chip
Enzyme coverage	QC[a], solubilize enzyme
Mediator reduction	Destroy outdated strips. Store properly
Coding	No-code meters
Hematocrit	WaveSense technology, AC[a] signal
Hand washing	Education
Technique	Education
Interfering substance	Coatings, education

[a] QC, quality control; AC, alternating current.

1. Scelta della strumentazione
2. Formazione pazienti e operatori
3. Controllo di qualità periodico
4. ….supervisione del laboratorio



...grazie dell'attenzione!!