



V Convegno Nazionale  
Centro Studi e Ricerche Fondazione AMD - onlus



FIRENZE  
18 - 20  
novembre  
2010

# Un problema emergente: la falsificazione del dato

Giorgio Grassi  
SCDU Endocrinologia,  
Diabetologia e Metabolismo  
Az. Ospedaliero-Universitaria  
San Giovanni Battista Torino  
“Le Molinette”

Centro Studi e Ricerche  
Fondazione AMD  
Firenze 18-19 novembre  
2010

# Il contesto

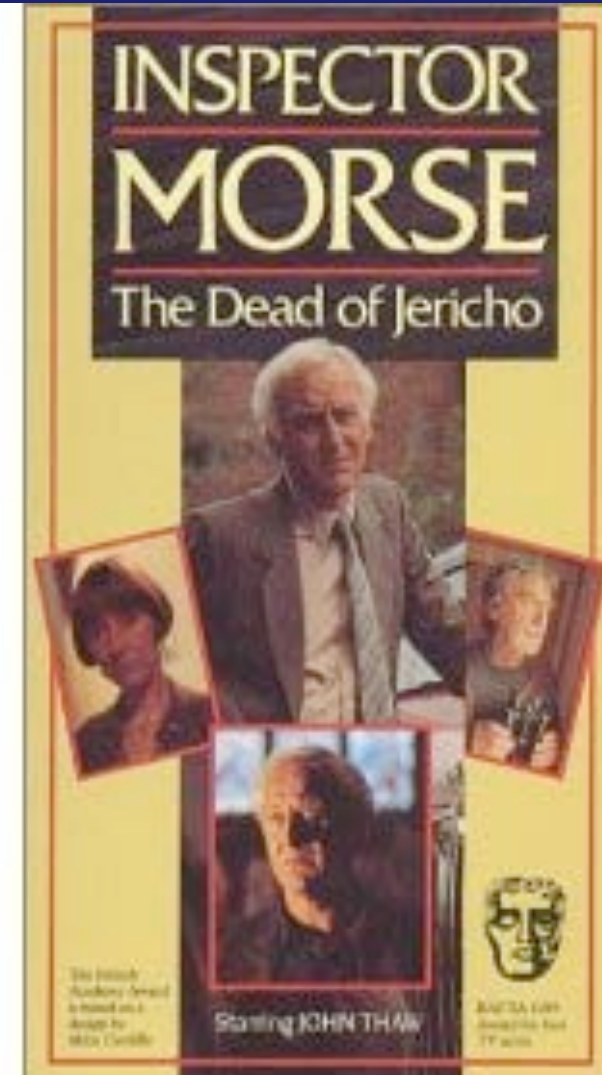
- “La falsificazione”
  - Definizione
  - Dimensione del problema
- E’ un vero problema ?
- come giocarlo a favore dei nostri pazienti



# Autocontrollo glicemico: condizioni indispensabili per l'efficacia

- 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**)

# Colin Dexter, un autore contemporaneo inglese del Poliziesco classico





# Diabetes Stories

Personal tales of diabetes through the decades

## People with Diabetes

Click to change to [Family Members](#) or [Professionals](#)

[Home](#)

[Interviews](#)

[Research](#)

[Who are we?](#)

[Publications](#)

[Help](#)

[Contact Us](#)

Colin Dexter around time of diagnosis, with actor John Thaw, who played Inspector Morse



### Interview 50 Colin Dexter

[< Previous page](#)

**Person with diabetes**  
**Born in Stamford, Lincs in 1930.**  
**Diagnosed Type 2 in Oxford in 1987**

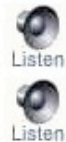
[< Back](#) | [Forward >](#)

**Overview:** Colin Dexter was diagnosed in the same year that his Inspector Morse novels began to be shown on TV, after his wife recognised his symptoms and urged him to see his GP. He was admitted to hospital immediately and put on an insulin drip. He sometimes finds it a bother to take all his insulin and blood-testing equipment with him on his travels, but doesn't otherwise allow diabetes to dominate his life. He continued to be a 'very big drinker indeed' until 2004, when he gave up alcohol altogether.

*Please note that Overview relates to date of recording 09 June 2005*

#### Short samples

- 1 He has always been careful about his injections, but in the past used to fabricate his blood test results – until modern technology made it more difficult to do so. [ 60 secs ]
- 2 In his later years, Inspector Morse also developed diabetes, after leading a lifestyle that bore a strong resemblance to that of his creator. [ 58 secs ]



## Colin Dexter's Inspector Morse Mysteries

A Return to the 'Golden Age' of Detective Stories

Celebrities & Personalities

## **Inspector Morse Creator Colin Dexter Launches Unique New National Centre for UK's 2 Million Diabetics & Reveals that Diabetes is What finally Kills Morse...**

Inspector Morse's creator Colin Dexter will launch a unique new national centre - Warwick Diabetes Care on 15th November 2000. Mr Dexter, himself a diabetic, will explain how Inspector Morse dies as a result of complications relating to diabetes, and how a Centre such as Warwick Diabetes Care will make a real difference to the treatment options available to the UK's Diabetics.

Warwick Diabetes Care, based in the University of Warwick will be launched on 15th November 2000. Warwick Diabetes Care will spearhead significant improvements in the care and treatment of the UK's 2 million diabetics and will deliver a range of courses and degree programmes for health care professionals (over 1,000 professionals in diabetes care have already signed up for courses with the centre).

---

## Self monitoring of glucose by people with diabetes: evidence based practice

Marilyn Gallichan

- As well as technical inaccuracies, deliberate falsification of results is common across all age groups and social classes. By asking patients to use blood glucose meters with a hidden memory, researchers showed that the results recorded in home monitoring diaries were often lower than the actual readings.....

---

# Self monitoring of glucose by people with diabetes: evidence based practice

Marilyn Gallichan

- Patients frequently omitted to record high readings and made up extra results so that it appeared that they had tested more frequently than they had in reality.





---

## Self monitoring of glucose by people with diabetes: evidence based practice

Marilyn Gallichan

- Colin Dexter, the writer who created Inspector Morse, admits to making a New Year's resolution for 1996 not to invent quite so many satisfactory blood sugar readings when he goes for his diabetic check ups.

# Studi anni 80-90

- I primi studi con soggetti ignari della memoria del glucometro (DMT1) mostravano frequenti e statisticamente significative manipolazioni con omissioni dei valori e falsificazioni (Am J med 1984; 77:211)
- Quando il soggetto era a conoscenza della memoria del glucometro e partecipava alla lettura dei dati l'affidabilità aumentava sensibilmente (Diabetes care 1985;8(3):207)

# Studi anni 80-90

- Non venivano individuate caratteristiche particolari del soggetti
- Non chiaro legame tra affidabilità del diario glicemico e controllo metabolico
  - Mazze R., Am J med 1984; 77
  - Mazze R.,Diabetes care 1985;8(3)

## Studi anni 80-90

- Studio di soggetti in CSII (Diabetes Care 1989;12 (3):1989)
  - Pazienti ignari del download dati
  - 5 dei 14 pz. Avevano un autocontrollo che rendeva inaffidabile la loro gestione della terapia
  - Relazione significativa tra emoglobina glicata bassa e affidabilità del Diario



- 2. Mazze RS, Shamoon H, Pasmantier R, et al. Reliability of blood glucose monitoring by patients with diabetes mellitus. *Am J Med.* 1984;77:211-217 = **74% accuratezza**
- 3. Zeigler O, Kolopp M, Got I, et al. Reliability of self-monitoring of blood glucose by CSII-treated patients with type 1 diabetes. *Diabetes Care.* 1989;12:184-188. = **77% accuratezza**
- 4. Hoskins PL, Alford JB, Handelsman DJ, et al. Comparison of different models of diabetes care on compliance with self-monitoring of blood glucose by memory glucometer. *Diabetes Care.* 1988;11:719-724. = **63% accuratezza**

# Punti di domanda

- Esiste oggi un criticità nell'accuratezza e affidabilità di gestione da parte del paziente dell'automonitoraggio glicemico ?
- Studi sul DMT2 ?
- E' diverso il comportamento della persona con DMT1 o T2 (Predittori del comportamento) ?
- Come gestire nel rapporto team curante/persona con diabete questo problema ?

# Accuracy and Reliability of Reporting Self-monitoring of Blood Glucose Results in Adults With Type 1 and Type 2 Diabetes

Maria Kalergis<sup>1</sup> PhD RD CDE, Julie Nadeau<sup>1</sup> MSc PDt, Danièle Pacaud<sup>2</sup> MD, Zeina Yared<sup>1</sup> MD,  
Jean-François Yale<sup>1</sup> MD

- Adults with type 1 diabetes (15 pz) participated in a 12 month trial to compare 3 treatment strategies used in intensive management
- Adults with type 2 (45 pz.) diabetes participated in an 8 month nutrition-education trial to assess the impact of teaching them how to incorporate added sugar choices or sweets into their daily meal plan

# Accuracy and Reliability of Reporting Self-monitoring of Blood Glucose Results in Adults With Type 1 and Type 2 Diabetes

Maria Kalergis<sup>1</sup> PhD RD CDE, Julie Nadeau<sup>1</sup> MSc PDt, Danièle Pacaud<sup>2</sup> MD, Zeina Yared<sup>1</sup> MD, Jean-François Yale<sup>1</sup> MD

- Participants with type 1 diabetes were asked to perform SMBG at least 4 times per day.
- Participants with type 2 diabetes were asked to perform SMBG at least 4 times in the same day once a week (before meals and at bedtime) and 7 times in the same day once per month (before meals, 1 hour after meals and at bedtime).



# Accuracy and Reliability of Reporting Self-monitoring of Blood Glucose Results in Adults With Type 1 and Type 2 Diabetes

Maria Kalergis<sup>1</sup> PhD RD CDE, Julie Nadeau<sup>1</sup> MSc PDt, Danièle Pacaud<sup>2</sup> MD, Zeina Yared<sup>1</sup> MD, Jean-François Yale<sup>1</sup> MD

- Although participants were aware that BG results would be downloaded from the meters.
- discrepancies between self-reported logbook and meter-downloaded results were not discussed between patients and healthcare professionals

# DMT1

	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Glicemie Meter n	1597	1419
Frequenza dei controlli media $\pm$ ES	2.1 $\pm$ 0,2/die *	3.4 $\pm$ 0,2/die
Glicemie sul Diario	1613	1337
Frequenza dei controlli media $\pm$ ES	2.2 $\pm$ 0,2/die*	3.4 $\pm$ 0,2/die

# DMT2

	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Glicemie Meter n	1330	1061
Frequenza dei controlli media $\pm$ ES	3.7 $\pm$ 0,3/week	2.9 $\pm$ 0,3/week
Glicemie sul Diario	1674	1412
Frequenza dei controlli media $\pm$ ES	4.7 $\pm$ 0,3/week	3.9 $\pm$ 0,3/week

# DMT1

<b>Accuratezza del diario %</b>	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Diario accurato (diff. < 15% tra meter e diario)	49*	93
Glicemie modificate	6*	2
Glicemie Fantasma	44*	5
Glicemie Omesse	45*	8

# DMT2

<b>Accuratezza del diario %</b>	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Diario accurato (diff. < 15% tra meter e diario)	76	72
Glicemie modificate	3	3
Glicemie Fantasma	21	25
Glicemie Omesse	N/A <sup>^</sup>	N/A

<sup>^</sup> non calcolate le glicemia omesse dato che i pz. DMT2 non erano istruiti a registrare le glicemia extra



# DMT1

<b>Affidabilità diario %</b>	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Affidabile	67	53
Moderatamente affidabile	20	33
Non affidabile	13	13

# DMT2

<b>Affidabilità diario %</b>	<b>PERIODO 1 (Inizio Studio)</b>	<b>PERIODO 2 (Fine Studio)</b>
Affidabile	51	59
Moderatamente affidabile	31	17
Non affidabile	18	24

\*  $p < 0.001$  (periodo 1 vs periodo 2)

**Affidabilità= glicemie modificate+fantasma+omesse**

# Relazione affidabilità Diario e frequenza automonitoraggio

- Sia per il T1 che per il T2, i soggetti che riportavano un diario affidabile o moderatamente affidabile avevano una frequenza di controlli glicemici superiore.
- DMT1  $3.0 \pm 0.2$  times/day vs  $1.1 \pm 0.3$  times/day (p=0.001)
- DMT2  $7.1 \pm 0.6$  times/week vs  $3.3 \pm 0.6$  times/week (p=0.003).

# Relazione frequenza autocontrollo e qualità del controllo metabolico

- Non vi era una relazione significativa tra frequenza del controllo glicemico e qualità del controllo metabolico.
- DMT1: I soggetti con diario affidabile (n=10) o moderatamente affidabile (n=3) presentavano una A1c inferiore rispetto ai soggetti con diario non affidabile (n=2).
- DMT2: nessuna relazione tra frequenza automonitoraggio e qualità del controllo metabolico

# Qualità di vita e affidabilità del diario glicemico

- DMT1: la maggior affidabilità del diario si associa ad una miglior qualità di vita e maggior fiducia nella autogestione-
- DMT2: I soggetti con diario non affidabile presentano una minor qualità di vita: more diabetes-related worries (ma non significativa la differenza)



# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

- This was a cross-sectional study of adults with type 2 diabetes.
- We collected copies of SMBG diaries and downloaded data from their glucose meters if patients brought them to their clinic appointment. Trained interviewers used standard tests to assess literacy, depression, and cognitive function.

# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

- The patients were instructed to monitor blood glucose daily, alternate testing time (once a day either before breakfast, lunch, dinner, or bedtime\*), and record results in a glucose diary table with the date and time of testing. All patients were asked to bring both their glucose diary and meter to each diabetes clinic visit
  - \*Quale valore informativo per il paziente e per il medico ?

There were two primary outcomes:  
adequacy and accuracy of glucose  
self-monitoring.

- Glucose self-monitoring was considered **adequate** if either the glucose diary was accurate or if only a meter was brought to clinic, the meter contained at least 10 readings within the previous 60 days.

There were two primary outcomes:  
adequacy and accuracy of glucose  
self-monitoring.

- The **accuracy** of the diary was assessed by comparing recorded values to the last 20 readings in glucose meter memory (meter-verified accuracy) or, if the meter was not available, to the A1c value (tested within 2 weeks of index visit).

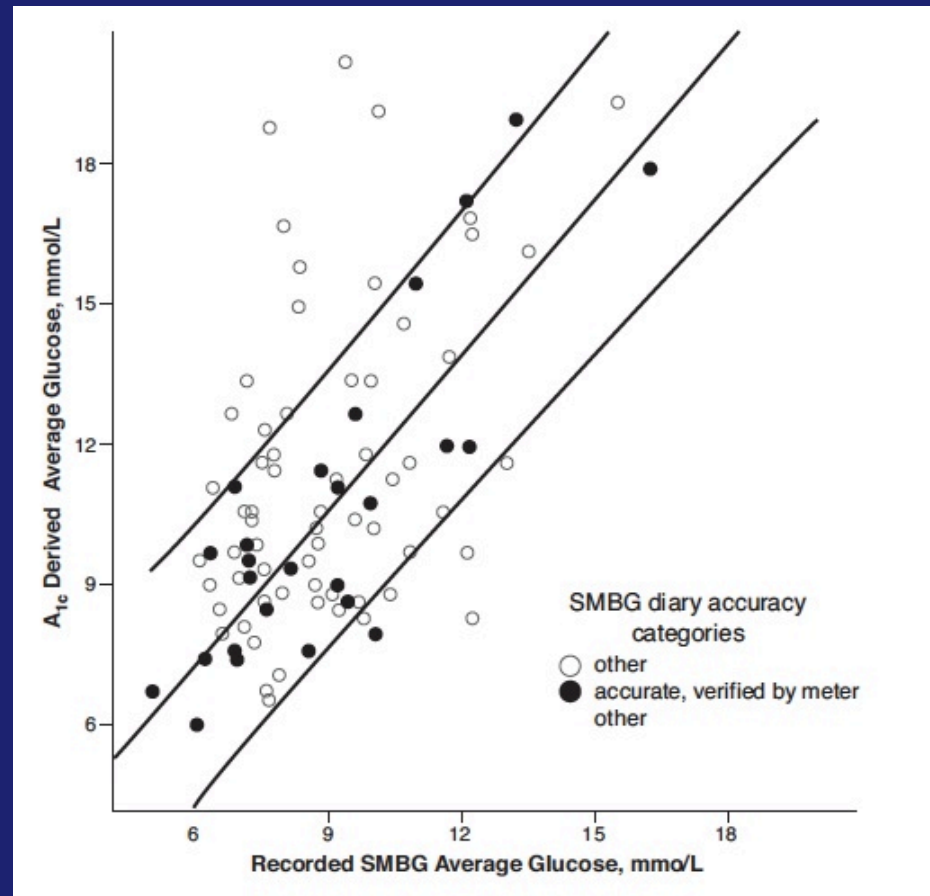
## diary inaccurate if there were:

- Two or more recorded values in the diary without evidence for testing in the meter memory (**phantom glucose entries**)
- Two or more glucose values recorded in the meter memory but not reported in the diary (**errors of omission**)
- Two or more exaggerated values (more than 50 mg/dL difference between diary value and meter values at the corresponding Time)

## diary inaccurate if there were:

- When a meter was not available.....
- comparing the average glucose from values recorded in the SMBG diary with the average glucose derived from the patient's A1c value.
- The predicted average glucose was calculated using the International ADAG Study equation.

# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

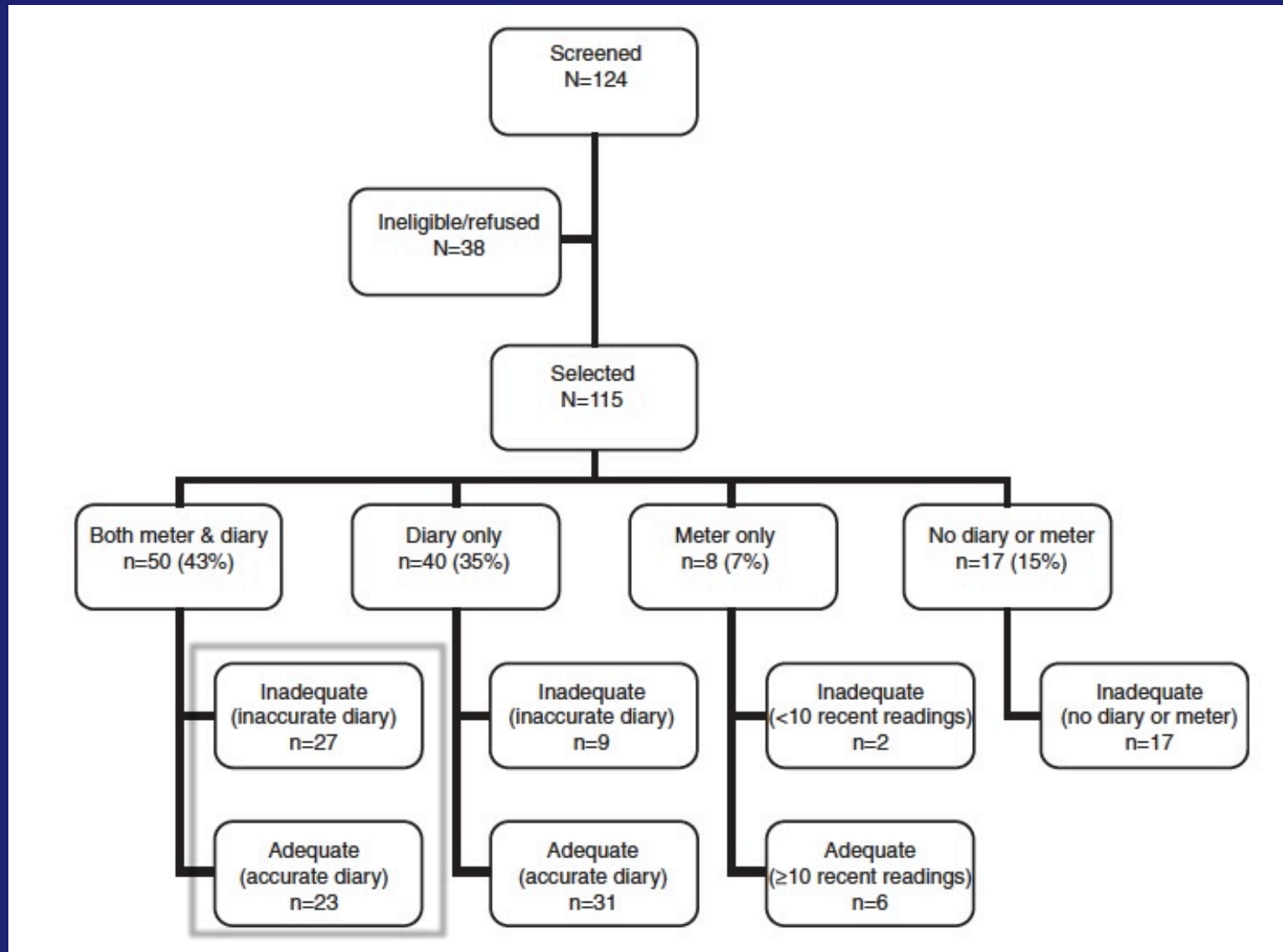




# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

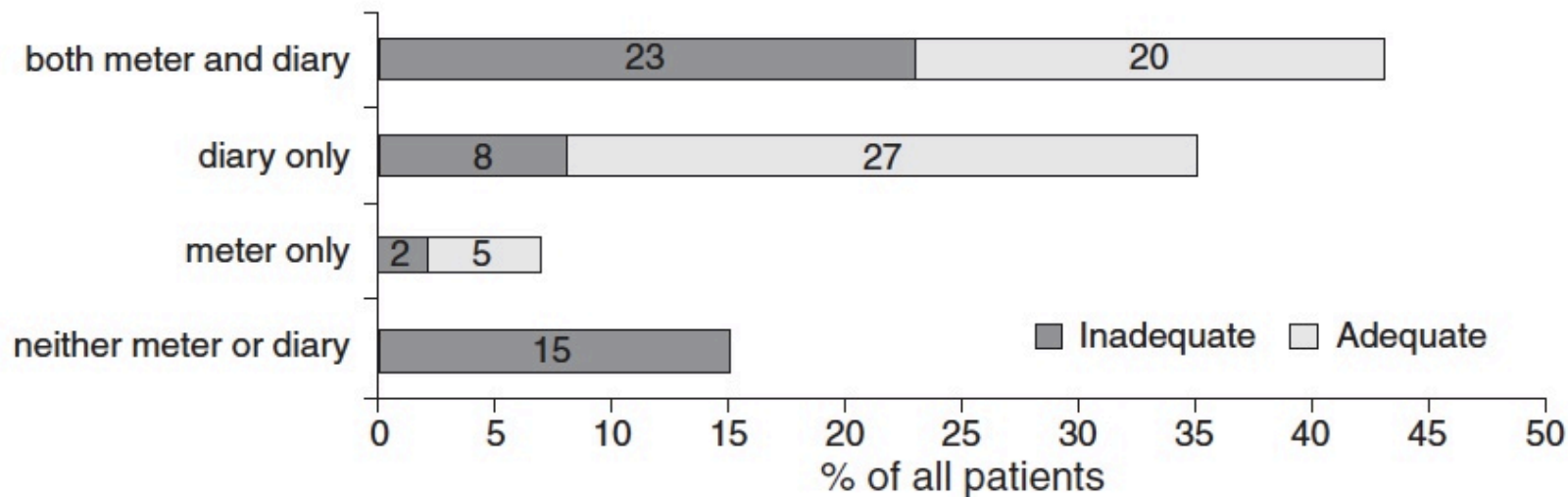
- Only 58 of 115 patients (50%) brought their glucose meter to the office visit.
- The patients taking insulin were three times as likely to bring their meter compared to non-insulin-treated patients.

# SMBG was inadequate for 55 of 115 subjects 48%



SMBG was inadequate for 55 of 115 subjects 48%  
(95% confidence interval, 38% to 57%).

Available at index visit:



# Predictor of Inadequate Reporting

TABLE 2. PREDICTORS OF INADEQUATE REPORTING

<i>Variable</i>	<i>OR</i>	<i>P value</i>
Diabetes' duration <10 years	3.3	0.003
Uncontrolled blood pressure (>130/80 mm Hg)	0.3	0.003
Dyslipidemia (LDL-cholesterol >2.6 or triglycerides >1.7 mmol/L)	2.9	0.007
Age <55 years	2.2	0.04
>5 medications per day	0.6	0.12
Literacy Assessment of Diabetes >9 <sup>th</sup> grade	1.5	0.46
Body mass index >30 kg/m <sup>2</sup>	1.3	0.53
Male gender	1.2	0.58
Insulin therapy	1.3	0.62
Self-reported hypoglycemia	0.8	0.63
Speed of information processing (Trail making A), below average	1.2	0.68
Education, last grade completed [ <i>n</i> (%)]		0.76
Less than high school graduate	1.0	
High school graduate	1.0	
More than high school graduate	0.7	
Digit Symbol Coding below average	1.1	0.78
Ethnic group		0.88
African American	1.0	
Hispanic/Latino	0.9	
Other	0.8	
Depression symptoms, moderate-severe (BDI-FS score 10–21)	1.1	0.90
RAVLT below average	1.0	0.94
Executive function (Trail Making B) below average	1.0	0.98

# Predictor of Inadequate Reporting

TABLE 3. MULTIVARIABLE LOGISTIC REGRESSION TO PREDICT INADEQUATE REPORTING IN ALL PATIENTS AND IN THE SUBGROUP OF PATIENTS WITH SMBG DIARIES, VERIFIED BY GLUCOSE METER

<i>Variables in the model</i>	<i>Inadequate reporting (all patients)<sup>a</sup></i>		<i>Inaccurate reporting (patients with meter-verified SMBG diary)<sup>b</sup></i>	
	<i>OR</i>	<i>P value</i>	<i>OR</i>	<i>P value</i>
Diabetes' duration less than 10 years	3.3	0.009	—	—
Blood pressure at goal	3.2	0.01	5.5	0.02
Uncontrolled dyslipidemia	2.8	0.02	—	—
Digit Symbol Coding (for every 2 points lower score)	1.2	0.41	2.2	0.02

<sup>a</sup>Area under the curve = 0.75 (95% confidence interval, 0.66–0.89).

<sup>b</sup>Area under the curve = 0.77 (95% confidence interval, 0.64–0.89).

# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

## Conclusion:

- we found no association between the accuracy SMBG and education, literacy, depression, or any neuropsychological variable except performance on the Digit Symbol Coding test.
- This finding suggests that, at least in some patients, impaired cognitive performances slowed information processing and disrupted fine motor performance affects the accuracy of written glucose diaries.

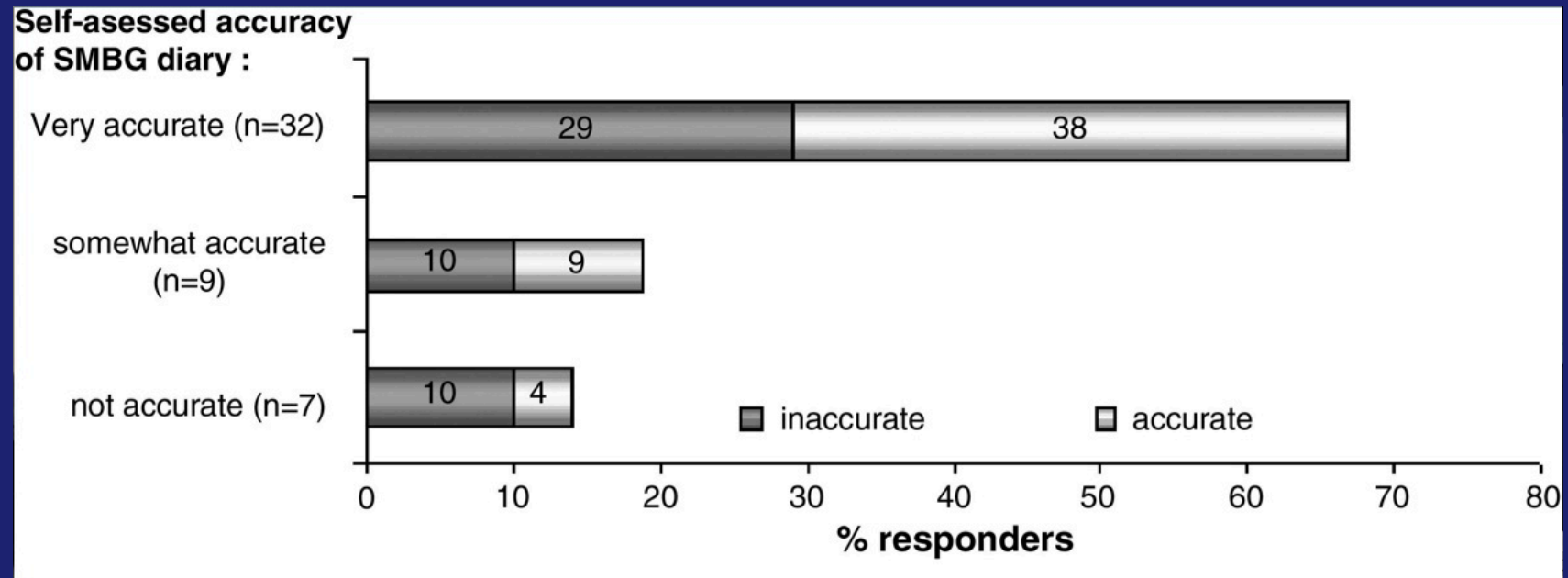
# Accuracy of Self-Monitored Blood Glucose in Type 2 Diabetes

## Conclusion:

- Our findings are analogous to the high rates (29–59%) of medication nonadherence in chronic disease.
- Just as medication nonadherence affects health outcomes, inaccurate glucose diaries may explain the reported ineffectiveness of glucose self-monitoring to improve diabetes outcomes.
- is likely that inaccurate diaries lead to inappropriate therapeutic decisions and clinical inertia.

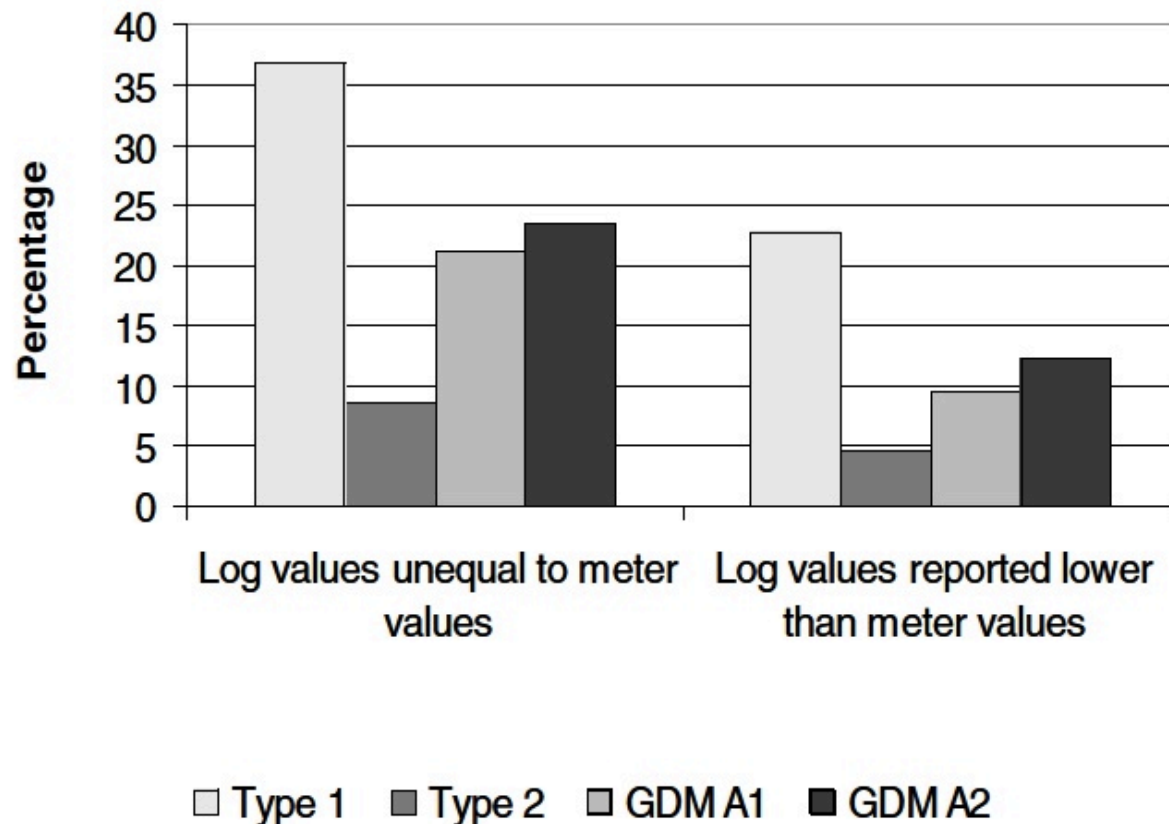


# Self-assessed accuracy of SMBG diary



# Reliability of Reporting of Self-Monitoring of Blood Glucose in Pregnant Women

Jo M. Kendrick, Candy Wilson, Robert F. Elder, and Cary Springer Smith



**Setting and Participants:** A convenience sample of 85 pregnant women with pregestational and gestational diabetes enrolled in a perinatal diabetes program in an urban teaching hospital.

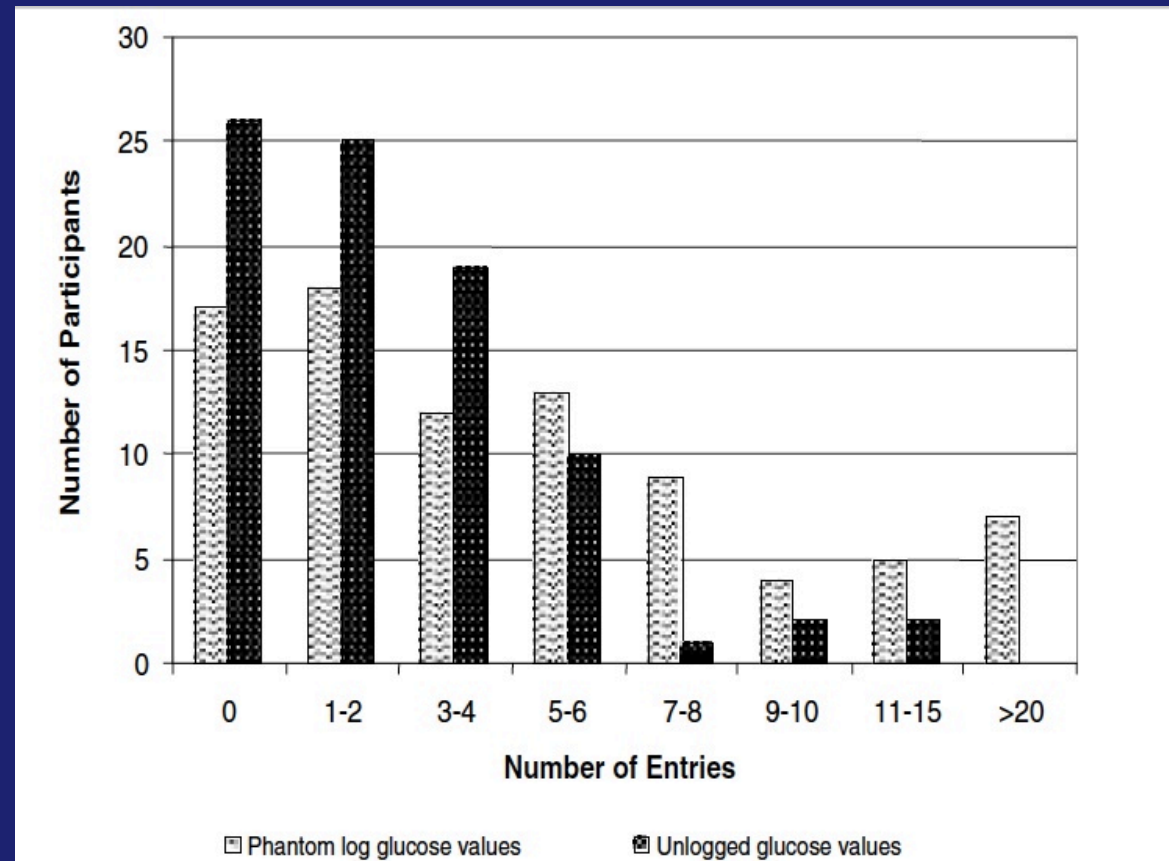
FIGURE 1

Women's log glucose values compared to glucometer memory values by type of diabetes.

Note. GDMA<sub>1</sub> = gestational diabetes mellitus, diet controlled; GDMA<sub>2</sub> = gestational diabetes mellitus, insulin controlled.

# Reliability of Reporting of Self-Monitoring of Blood Glucose in Pregnant Women

Jo M. Kendrick, Candy Wilson, Robert F. Elder, and Cary Springer Smith



**FIGURE 2**

Frequency of logged phantom and unlogged values.

# *Reliability of Reporting of Self-Monitoring of Blood Glucose in Pregnant Women*

*Jo M. Kendrick, Candy Wilson, Robert F. Elder, and Cary Springer Smith*

- Inaccurate reporting by women was found to be:
- Type 1 36.7% (22.7% values lower)
- type 2 8.5% (4.5% values lower)
- GDMA1 21.2% (9.4% values lower)
- GDMA2 (ins.) 23.4% (12.1% values lower).



# *Reliability of Reporting of Self-Monitoring of Blood Glucose in Pregnant Women*

*Jo M. Kendrick, Candy Wilson, Robert F. Elder, and Cary Springer Smith*

- SI:
- As age increases, accuracy significantly increases
- Accuracy significantly differed in women of different economic backgrounds (MEDICAID lower)

*JOGNN, 34, 329-334; 2005.*

# *Reliability of Reporting of Self-Monitoring of Blood Glucose in Pregnant Women*

*Jo M. Kendrick, Candy Wilson, Robert F. Elder, and Cary Springer Smith*

- NO:
- duration of diabetes.
- gestational age
- married versus single
- Educational status of women

*JOGNN, 34, 329-334; 2005.*

# La Falsificazione del diario

- Esiste per le due forme di diabete, frequenza differente ma misurabile
- In alcuni studi si associa ad una riduzione della qualità di vita



# La Falsificazione del diario

- La correlazione con la qualità del controllo metabolico negli studi disponibili è debole e osservata in particolare per il DMT1, sebbene il percepito comune dei diabetologi sia invece di un legame tra falsificazione e qualità del controllo

- La manipolazione, l'omissione, la dimenticanza del diario glicemico rappresentano un aspetto della più generale criticità dell'automonitoraggio domiciliare della glicemia:

Metanalisi di McAndrew, 2007

Very few studies examined potential mediators or moderators of SMBG on HbA1c levels:

- know how to take a reading;
- Understand when the reading is above (or below) target values;
- See the connection between deviant readings and prior behavior;
- Have and implement an action plan to Control;

Metanalisi di McAndrew, 2007

Very few studies examined potential mediators or moderators of SMBG on HbA1c levels:

- Rely more heavily on SMBG readings and give less weight to subjective feelings (?: Blood Glucose Awareness Training – BGAT)
- Create simple action plans that will allow the patient to integrate them into his or her ongoing life patterns
- Evaluate glucose readings in a nonjudgmental framework

## Consensus Recommendations for Improving SMBG Accuracy, Utilization, and Research

- I risultati dei Lavori specifici restano molto variabili soprattutto nei pz. Non insulino trattati. Questo perché gli studi non considerano:
  - Le reali condizioni di utilizzo degli strumenti
  - Quando, per cosa e come i pz. sono stati educati all'utilizzo dell'autocontrollo ed all'interpretazione del dato al fine di una corretta azione
  - **L'insieme di circostanze (fisiologiche, di comportamento e sociali) all'interno delle quali l'autocontrollo viene realizzato.**

## Consensus Recommendations for Improving SMBG Accuracy, Utilization, and Research

- Sono necessari sforzi per ampliare gli orizzonti ed il focus della ricerca sull'autocontrollo. **Bisogna passare da risultati legati a confronti numerici ad una dimensione più pratica, più umana e di comportamento.**

# DMT2

- Nel DMT2 sicuramente la scarsità di evidenze sulla utilità dell'automonitoraggio deriva anche da problematiche più ampie di “Self-Care Behaviors” e tra queste ha un posto l'affidabilità del Diario Glicemico



# EMPOWERMENT LEGITTIMARE

Risultato di un processo che porta il paziente ad acquisire la padronanza delle sue competenze e comportamenti, rendendolo autonomo.

“...potenziamento; condivisione; delega e trasferimento del potere;  
apertura a nuovi mondi possibili; responsabilizzazione;  
aumento di capacità; sviluppo di potenzialità” C. Piccardo

Nicoletta Musacchio

## Una nuova sfida ...

- ... sarà quella di andare a vagliare l'efficacia dell'autocontrollo scegliendo indicatori coerenti con la natura di strumento **per** la cura e non **di** cura (Nicoletta Musacchio)
- Studi mirati a valutare il processo educativo più che il confronto autocontrollo si/no

- “la falsificazione è una delle diverse modalità di negoziazione con la malattia, individuarla può essere una risorsa per aumentare il grado di adesione alla cura”

# Riflessioni di una Pedagogista

- “Falsificare un dato è come dire le bugie, solitamente queste persone attraversano un periodo di fragilità e di insicurezza. Solo un operatore davvero preparato può rendersi conto che è una fase passeggera e che il paziente necessita ancora di più di aiuto.”
- M.T. mail ottobre 2010

Grazie per l'attenzione !



Dall'ambulatorio..



Diabetimetro Bottini, per l'autocontrollo domiciliare della glicosuria.  
(Fonte *TELEDIAB Magazine*, Ottobre 1993)

Il Museo del Diabete



A cura di:

ASSOCIAZIONE  
CENTRO DI DIABETOLOGIA  
KAREN BRUNI BØCHER

# The Diabetes Educator

<http://tde.sagepub.com/>

## Accuracy

### Identifying Variables Associated With Inaccurate Self-Monitoring of Blood Glucose: Proposed Guidelines to Improve Accuracy

Richard Bergenstal, Jan Pearson, George S. Cembrowski, Dawn Bina, Janet Davidson and Sue List  
*The Diabetes Educator* 2000 26: 981

*Of the 280 participants, 19% had blood glucose test results greater than the 15% limit for meter accuracy. After reeducation, 69% of those who had initially failed achieved acceptable results. The most significant problems were lack of periodic meter technique evaluation, difficulty using wipe meters, incorrect use of control solutions, lack of hand washing even when observed, and unclean meters.*

# Modello kaiser autogestione