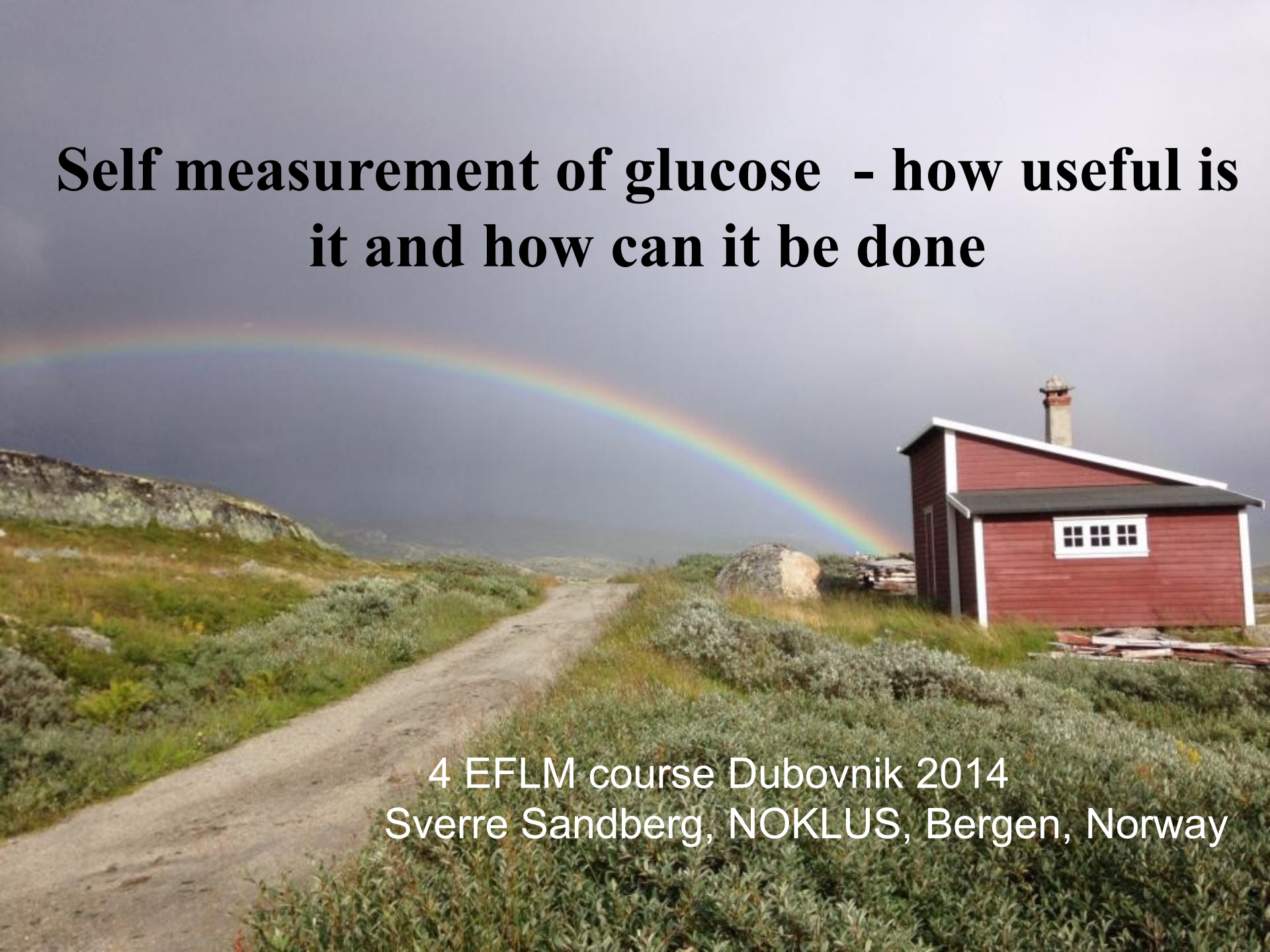
Self measurement of glucose - how useful is it and how can it be done



4 EFLM course Dubovnik 2014
Sverre Sandberg, NOKLUS, Bergen, Norway

Self measurement of glucose - how useful is it and how can it be done

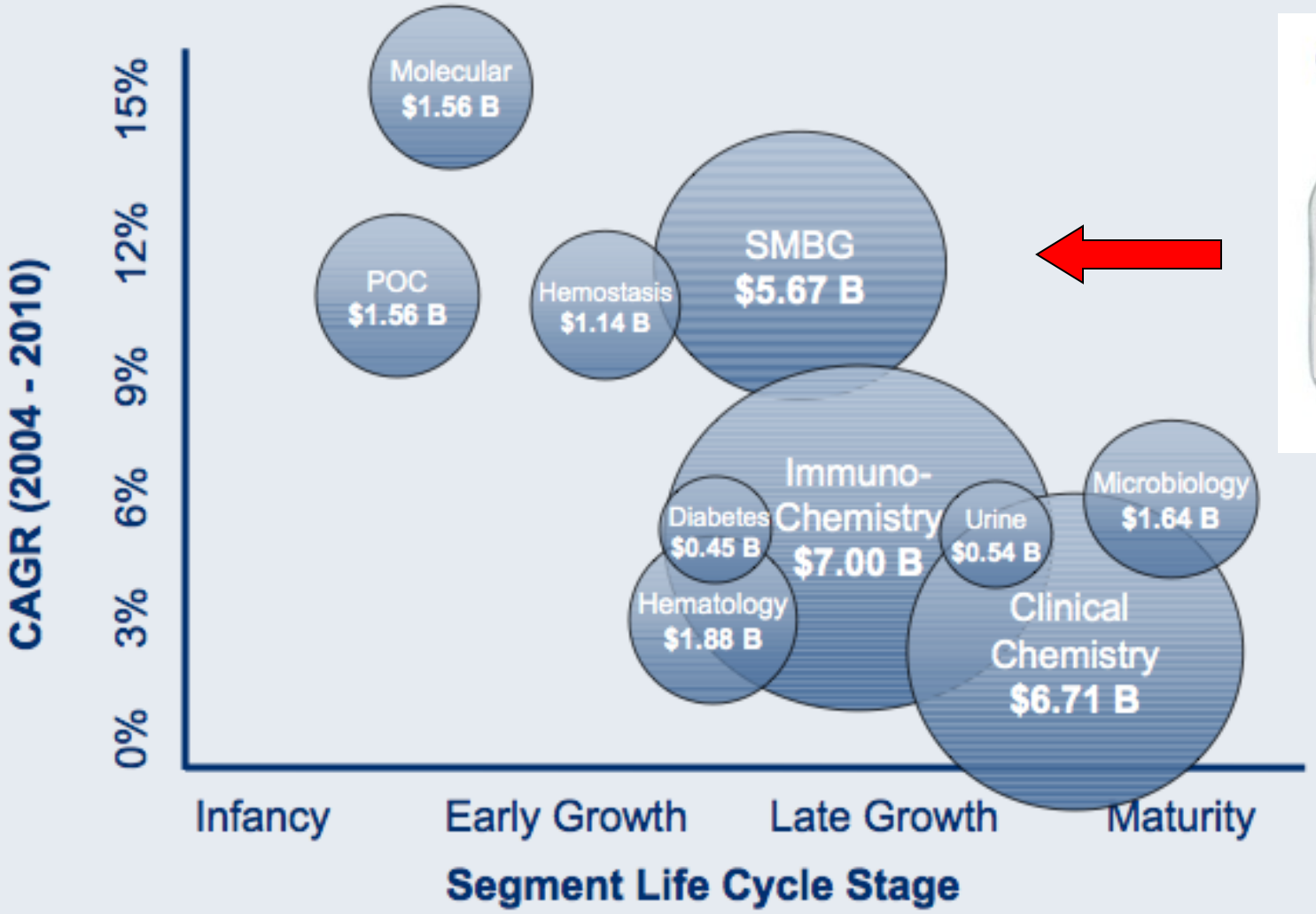
What I will talk about

- ✓ Economy and use
- ✓ Evaluations
- ✓ Who should use SMBG

DIABETES ELLITUS

Small - cheap - but many….

Market Revenue & Growth Forecast by Segment



About 12% of lab. market worldwide - 27% in USA

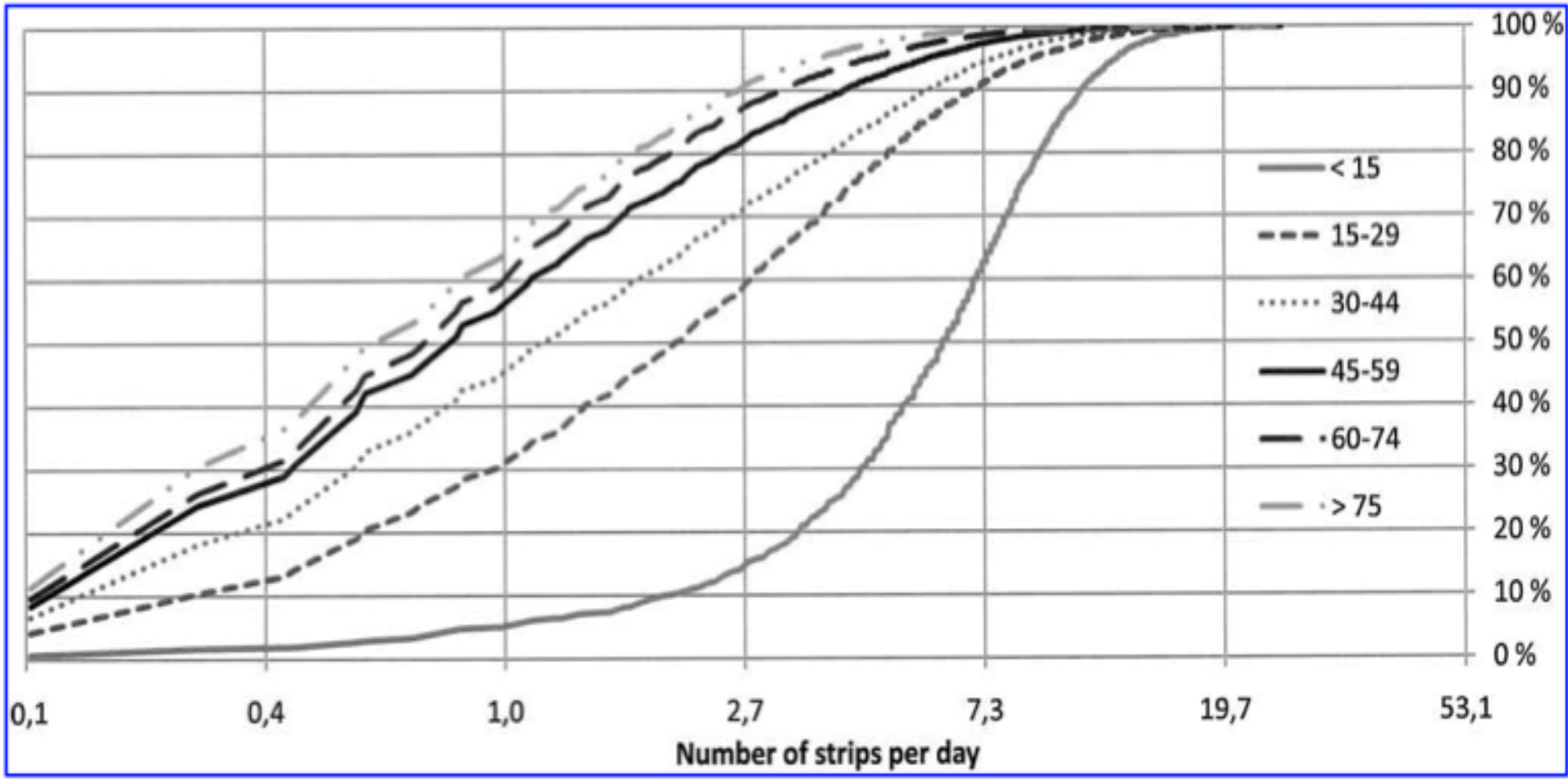
How many strips are sold – are they used in a rational and economic way?

Table 3. Use of Different Types of Self-Monitoring of Blood Glucose Strips by Number of Patients and Mean Number of Strips Used per Day

Number of different types of strips	*Number of patients (%)*	*Mean number of strips per day*
1	79,837 (82)	1.4
2	14,571 (15)	2.8
3	2,171 (2.2)	4.5
4	343 (0.4)	6.4
5	62 (0.1)	7.2
6	14 (0.0)	9.5
7	1 (0.0)	7.0

Kjome RL, et al. The Prevalence of Self-Monitoring of Blood Glucose and Costs of Glucometer Strips in a Nationwide Cohort. Diabetes Technol Ther. 2010, Aug 6;

Cumulative numbers of persons buying strips in each age group by number of strips per persons per day.



“Over-use”

Approximately 270 patients purchased more than 5,000 strips in 1 year, equivalent to 100 packages, i.e., 14 strips per day. One cannot exclude that these patients may share strips with others or sell them nationally or internationally. While we assume that this is not common, the costs for these 270 patients add up to almost 1.3 million euros for one year, or roughly 4,800 euros per person, 10 times the average costs per person.

Presuppositions for SMBG

(a) Instruments should have good enough quality.

(b) Patients should be able to use the instruments (education).

(c) Patients should interpret the results and take actions when necessary.

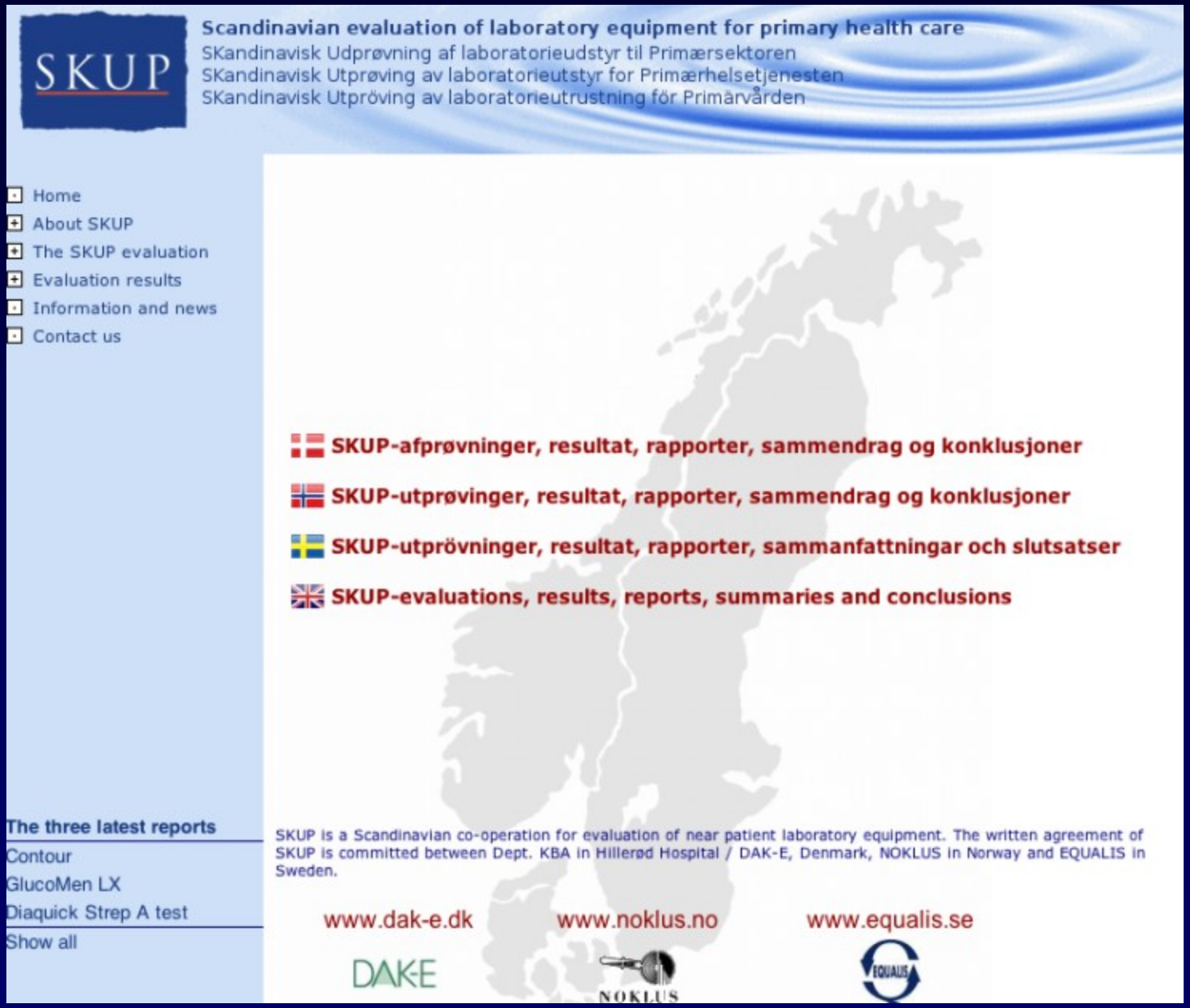
Quality specifications

- Based on the actual use of instrument (asking the clinicians) ± 13%
- Biological variation ± 2% or ±25%
- Consensus among manufacturers and professional people (ISO 15197) ±20% and from 2013, 15%
- Patient organisation (ADA, IDF) ±10%

Scandinavian evaluation of POC instruments www.skup.nu

- Reports in English (and Scandinavian) for more than 70 POC instruments and many instruments for self monitoring.
- From 2009: Translated into Italian through CIRME in Milano (Andrea Mosca)

www.skup.nu


SKUP
Scandinavian evaluation of laboratory equipment for primary health care
SKandinavisk Udprøvning af laboratorieudstyr til Primærsektoren
SKandinavisk Utprøving av laboratorieutstyr for Primærhelsetjenesten
SKandinavisk Utpröving av laboratorieutrustning för Primärvården
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The three latest reports
Contour
GlucoMen LX
Diaquick Strep A test
Show all
SKUP is a Scandinavian co-operation for evaluation of near patient laboratory equipment. The written agreement of SKUP is committed between Dept. KBA in Hillerød Hospital / DAK-E, Denmark, NOKLUS in Norway and EQUALIS in Sweden.
www.dak-e.dk
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SKUP

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SKandinavisk Udprøvning af laboratorieudstyr til Primærsektoren
SKandinavisk Utprøving av laboratorieutstyr for Primærhelsetjenesten
SKandinavisk Utpröving av laboratorieutrustning för Primärvården

Choose component: Glucose

Summaries and Reports

Evaluation #	Instrument/testkit	Summary	Report
SKUP/2009/75	Contour		Download PDF
SKUP/2009/71	GlucoMen LX		Download PDF
SKUP/2008/66	DANA DiabeCare IISG		Download PDF
SKUP/2007/64	Freestyle Lite		Download PDF
SKUP/2007/59	Ascensia BREEZE2		Download PDF
SKUP/2005/51*	FreeStyle		Download PDF
SKUP/2006/50	Glucocard X-meter		Download PDF
SKUP/2006/49	Precision Xtra Plus		Download PDF
SKUP/2006/48	Accu-Chek Sensor		Download PDF
SKUP/2006/45	HemoCue Monitor		Download PDF
SKUP/2005/44	Accu-Chek Aviva		Download PDF
SKUP/2005/43	Accu-Chek Compact Plus		Download PDF
SKUP/2005/40	GlucoTouch		Download PDF
SKUP/2005/39	OneTouch Ultra		Download PDF

The three latest reports
Contour
GlucoMen LX
Diaquick Strep A test
Show all

Is it necessary to test the instruments among the users?

Poor correlation between patient results and MLT results

Clin Chem 2002; 48: 994-1003

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 10, Number 6, 2008

DOI: 10.1089/dia.2008.0034

Standardized Evaluation of Nine Instruments for Self-Monitoring of Blood Glucose

Gunn B.B. Kristensen, M.S.,[1] Grete Monsen, B.S.,[1]
Svein Skeie, M.D., Ph.D.,[1,2] and Sverre Sandberg, M.D., Ph.D.[1,3]

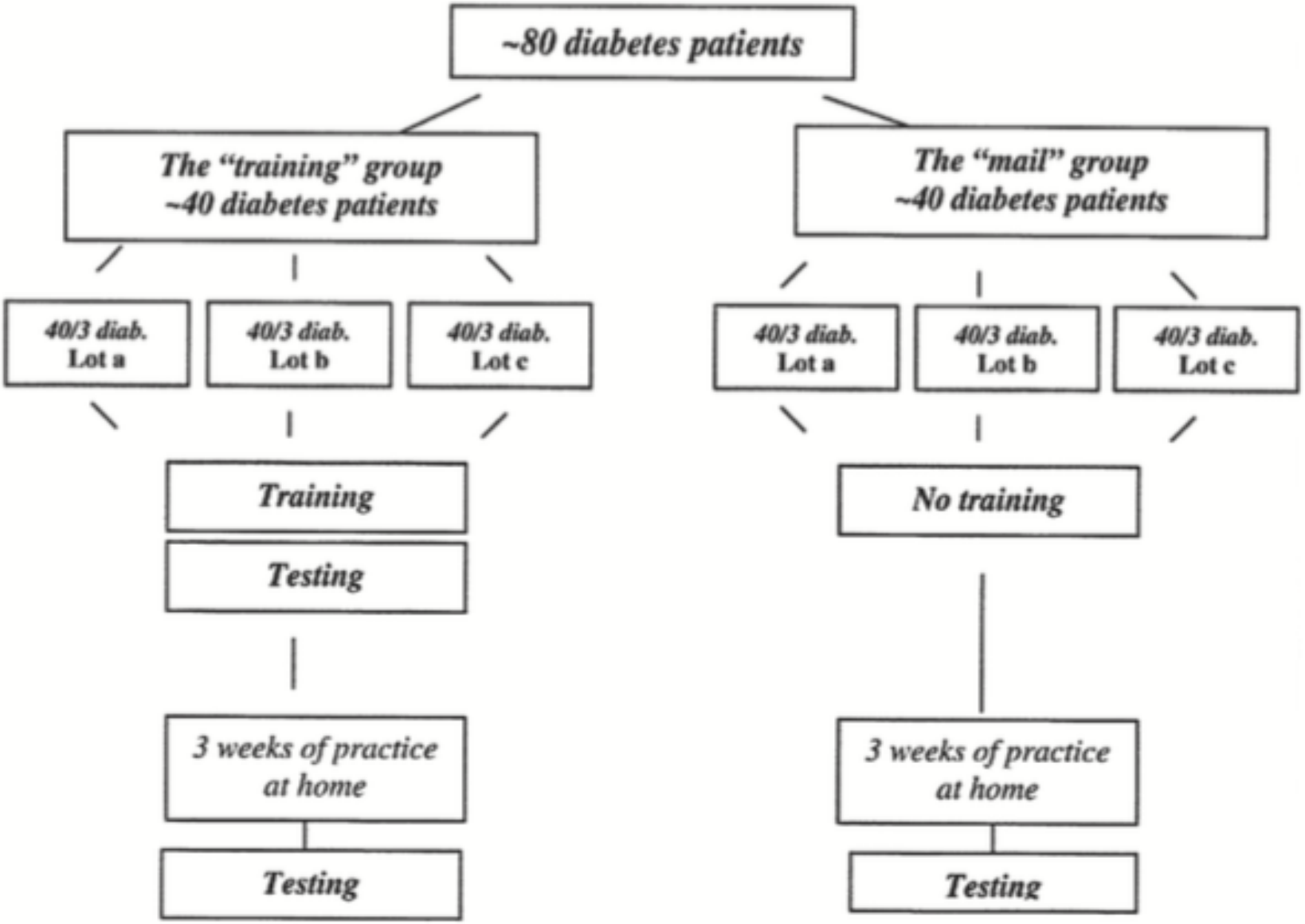
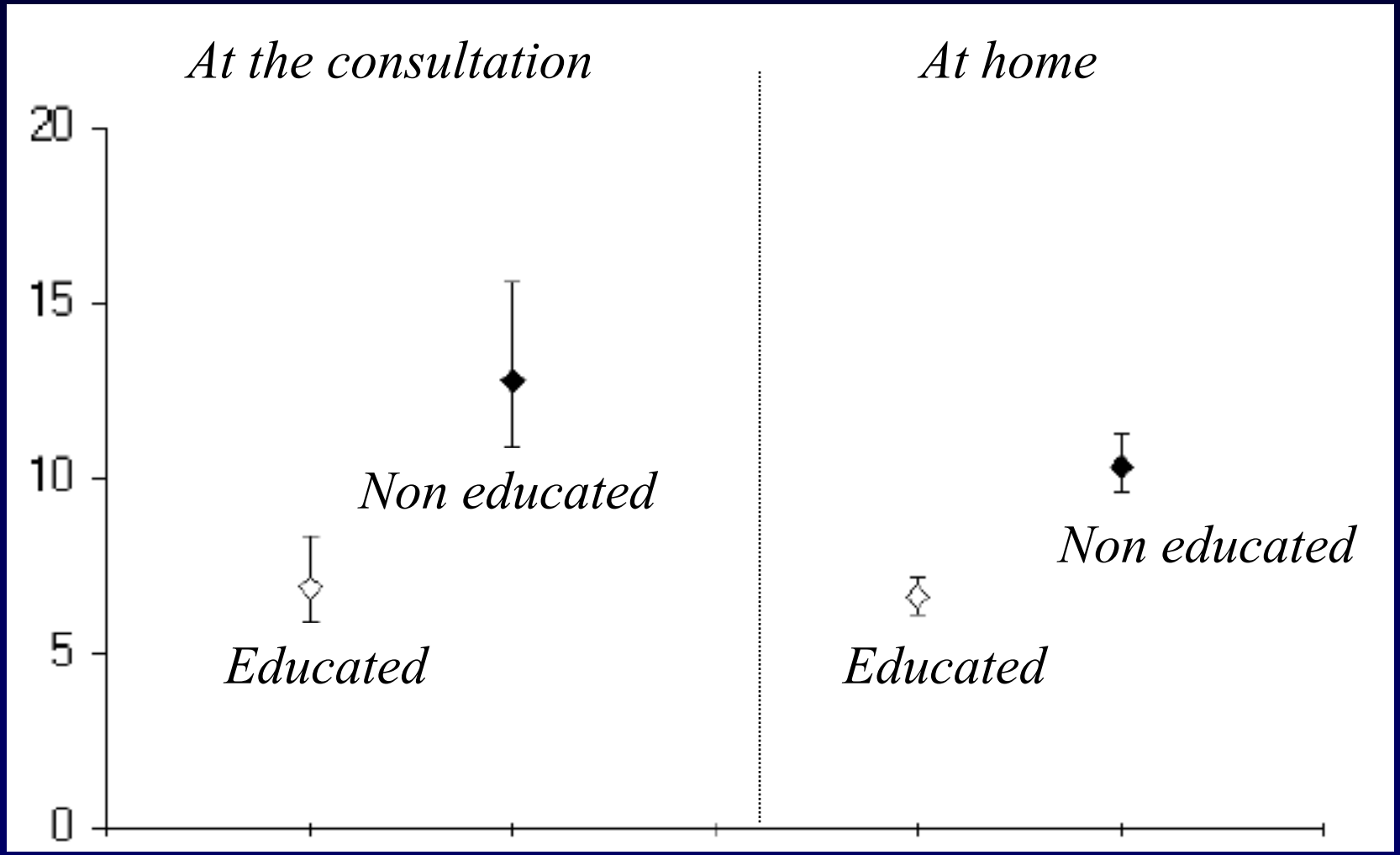


FIG. 1. Design of the user evaluation.

Effect of education on imprecision (CV)



Kristensen et al. Clin Chem 2004;50:1068-71.

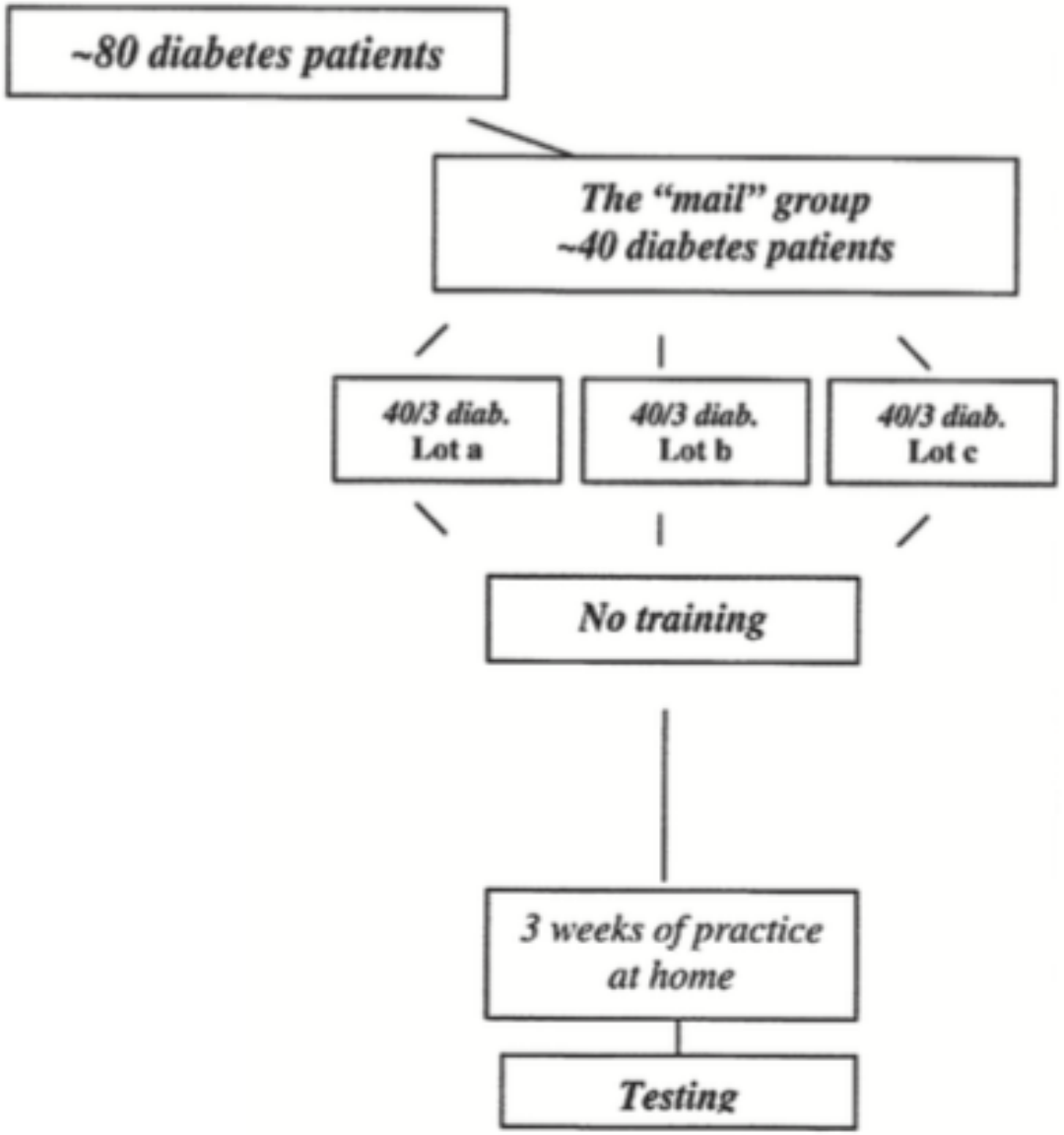
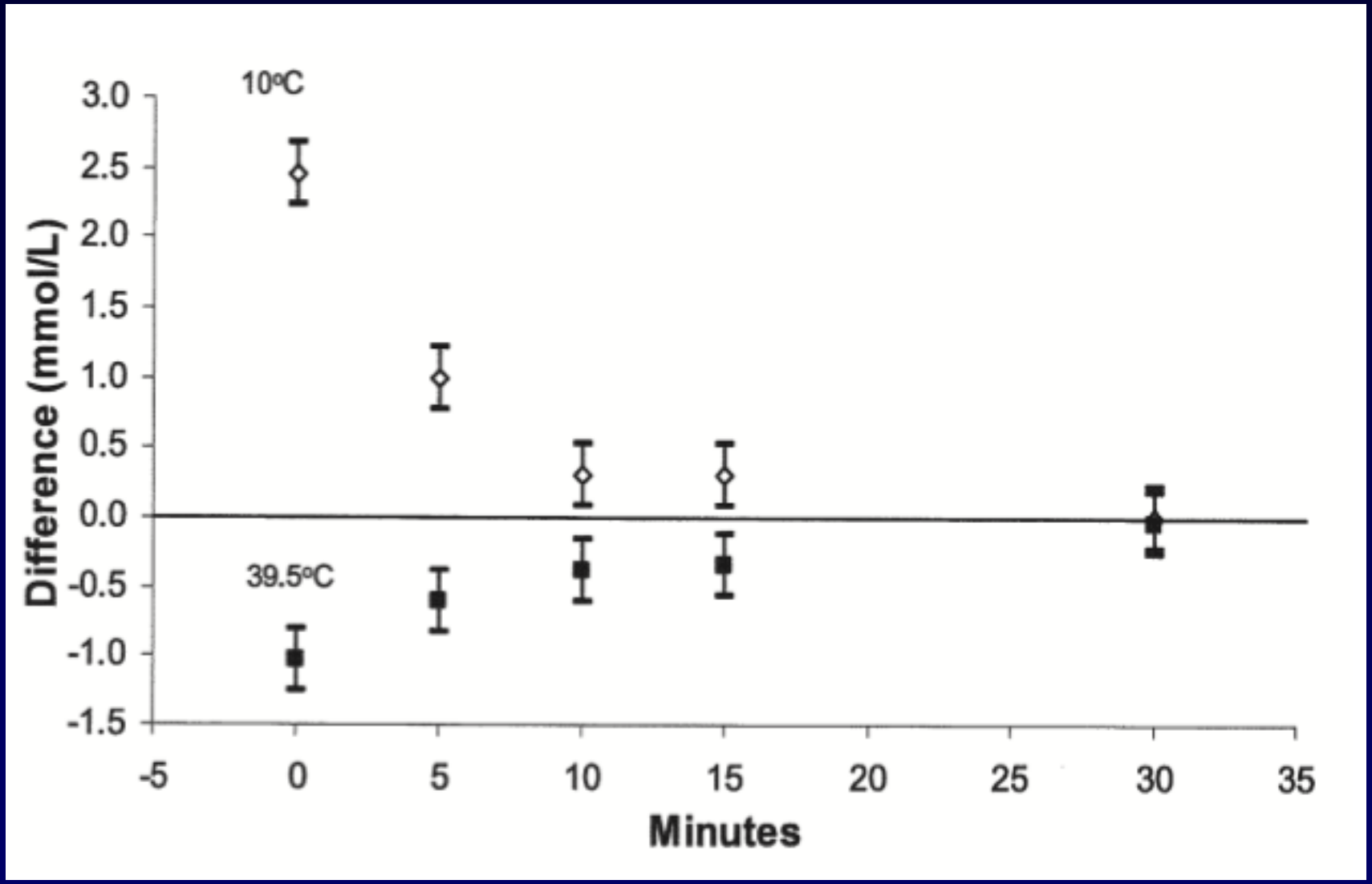


FIG. 1. Design of the user evaluation.

Temperature effect



Kristensen GB, Monsen G, Skeie S, Sandberg S. Diabetes Technol Ther. 2008;10:467-477.

No reimbursement from government if quality is not proven - and especially the quality in the hands of the patients.

This has reduced the number of instruments that are sold in Norway considerably

How should patients control their performance and the instruments?

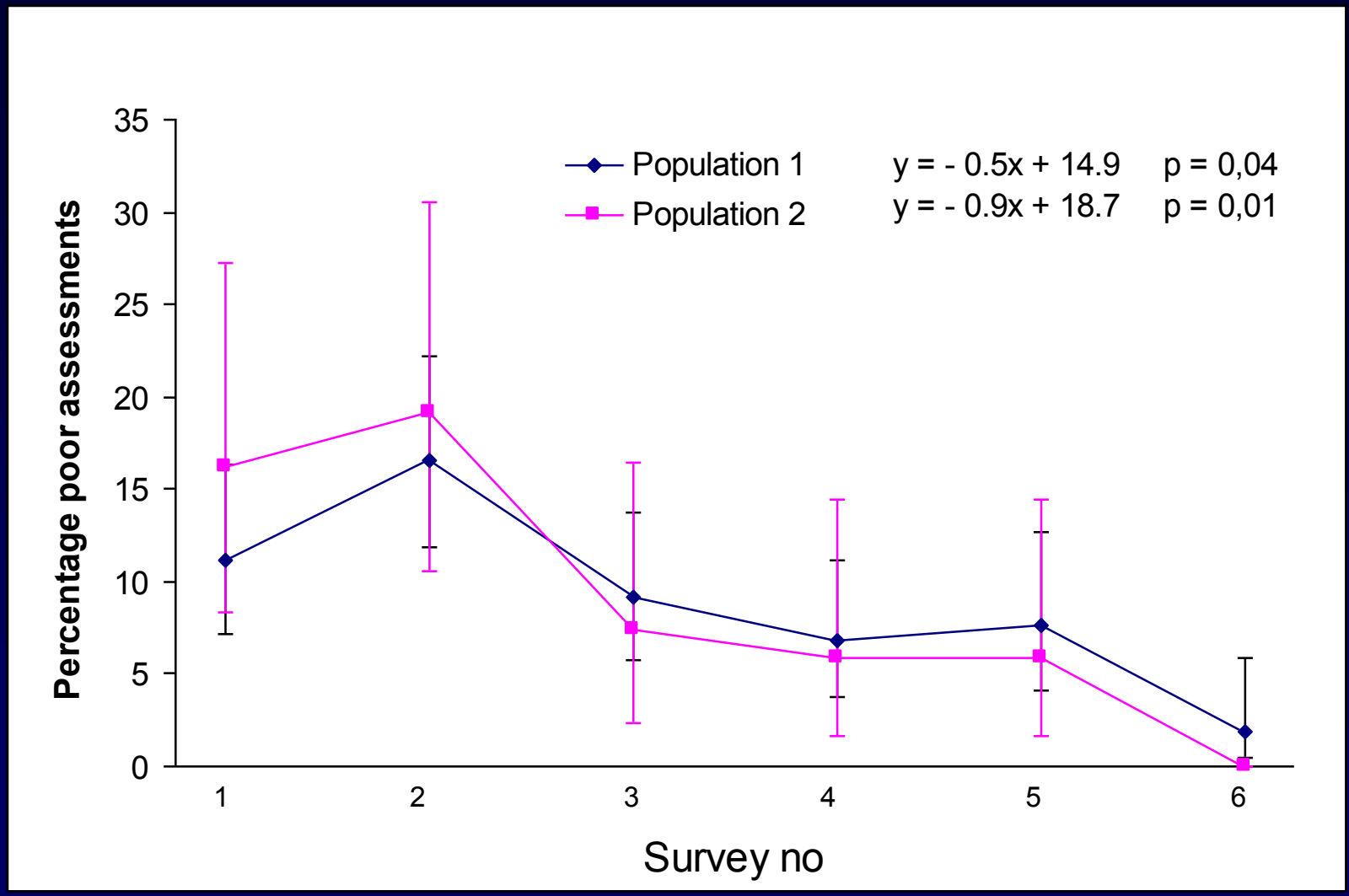
- External quality control?
- User assessment at the physicians office?
- User assessment at the pharmacy?

Aim of the EQA-study

- Participating in an EQAS twice a year for three years. Follow up of patients with “poor” results.

- Did the analytical quality improve?

Poor results (bias > |0.1mmol +10%|



Kristensen GB, Nerhus K, Thue G, Sandberg S.. Clin Chem. 2006;52:1311-1317.

Conclusion

Implementing a traditional EQA-program for glucose for diabetes patients improved the analytical quality of SMBG over time

(Clin Chem. 2006;52:1311-1317)

Split sample at the physicians office/pharmacy. A similar improvement can be shown

(*Point of Care. 2006;5:100-104*)

Who should use SMBG?

Recommendations
Type I DM – and type II with insulin use

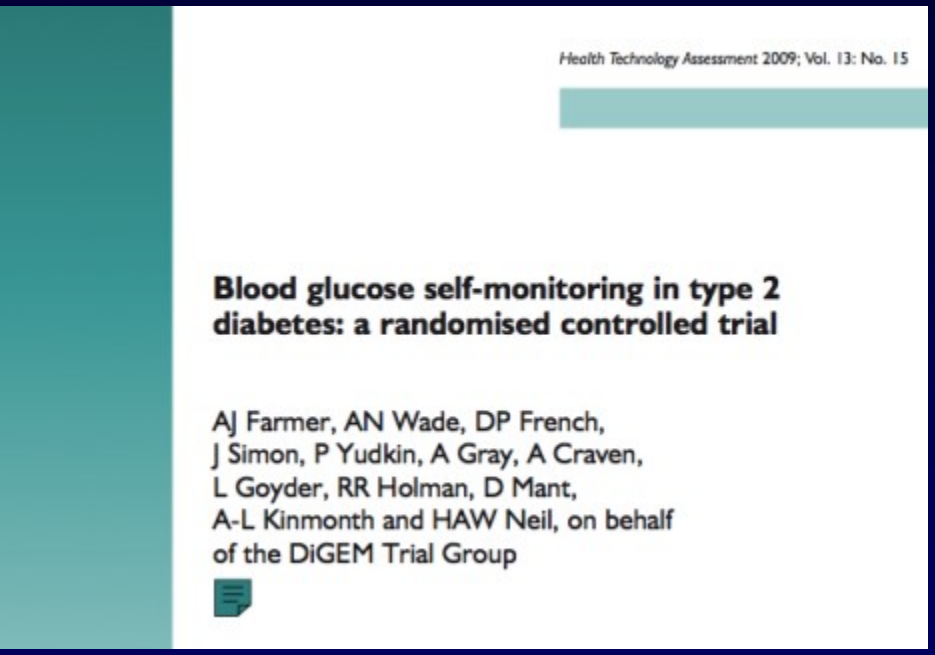
The evidence is poor and based on old studies.

Comments:

*The consensus agreement among experts is very strong (e.g. ADA, IDF), and it is difficult to advice against SMBG.

*The balance between benefits and costs must be evaluated in each single environment.

Recommendations type II DM, not insulin treated



We have found no convincing evidence to recommend routine use of SMBG by reasonably well-controlled, non-insulin-treated patients with type 2 diabetes.

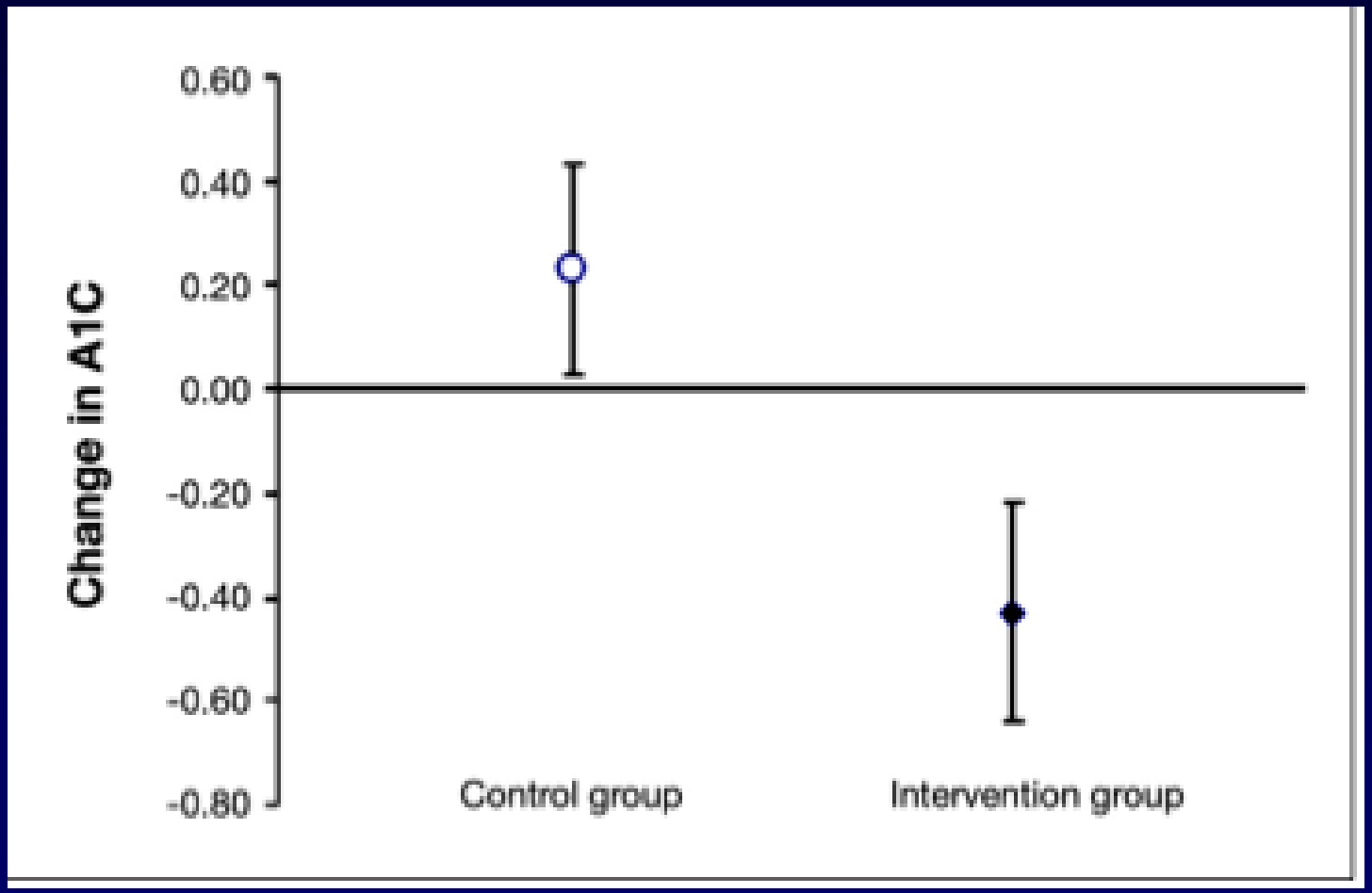
General limitations of studies

- Very few studies address instrument quality / different instruments.
- Some studies address the education of the patients.
- Some studies address if the patients have got information on what to do with the results.
- Many studies examine SMBG together with other procedures

Effect of high quality instrument and focused education in SMBG

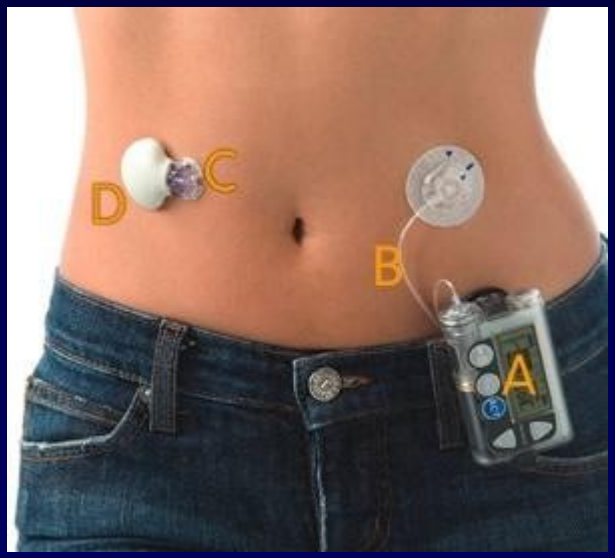
One hundred fifty-nine outpatients with type 1 diabetes on multiple injection therapy with insulin and A1C ≥8% were recruited and randomized to one group receiving a focused, structured 9-month SMBG intervention and another group receiving regular care based on guidelines.

Effect of education and a high quality instrument



Skeie, Kristensen, Carlsen, Sandberg. J Diabet Sci Techn. 2009;3:83-88.

The future which is present: Continuous glucose monitoring



Paradigm Real-time

Continuous Glucose Monitoring systems (CGM)

- CGM systems provide information about the direction, magnitude, duration, frequency, and causes of fluctuations in blood glucose levels.
- Currently, there are no standards or guides regarding how the analytical quality of CGM system should be evaluated or described.

Self measurement of glucose - how useful is it and how can it be done

What I ~~will~~ hope I have talked about

- ✓ Economy and use the use is not under complete control
- ✓ Evaluations – should be performed in the hands of the users
- ✓ Who should use SMBG especially insulin treated diabetic patients

Thank you