



CGM – does 70% Time in Range mean the same thing on all systems?

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Disclosures

- Payments for Speaking and Advisory boards
 - Abbott Diabetes Care, Dexcom, Insulet, Lilly Diabetes, Medtronic, Menarini, Novo Nordisk, Sanofi
- Institutional Research Support
 - Abbott Diabetes Care, Novo Nordisk
- Positions held
 - Chair, Diabetes Technology Network-UK
 - Member of EXTOD executive



Plan

- Why is understanding CGM accuracy important? How might it impact your day to day practice?
- The importance of assessing CGM accuracy
 - CE marking
 - MARD
 - Consensus error grids
 - Study design
- The importance of benchmarking/calibration



Why is understanding CGM accuracy important?

Scenario



- Bill comes to see you in clinic to discuss his diabetes management
- He has bought a CGM device that was advertised to him online, and tells you that he finds it really helpful
- The device has a CE mark, MARD is reported as 9.1%
- He checks the readings it gives him against fingerprick readings, and in his experience they are usually pretty close.
- The device is cheaper to buy than Freestyle Libre 2, so Bill suggests that the NHS could save money by switching to this device and says that you should make it available to your population
- What do you do?

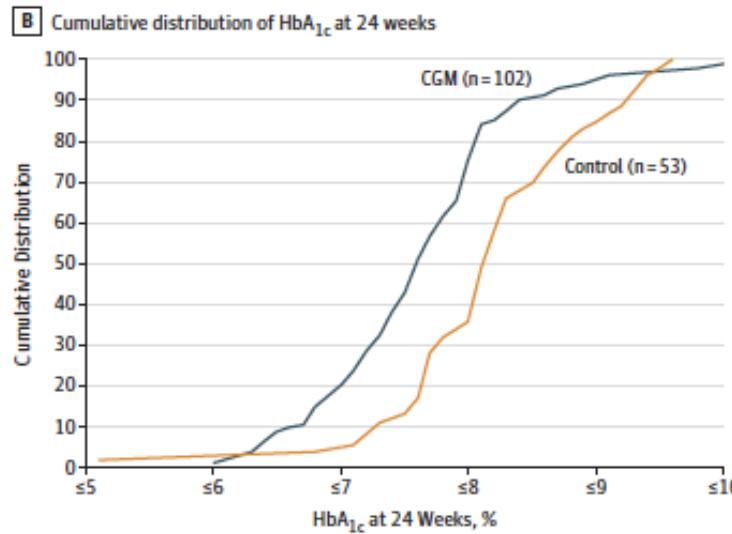


Benefits of CGM

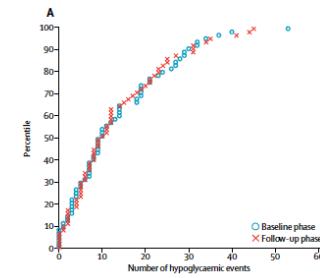
Type 1 diabetes is challenging to manage



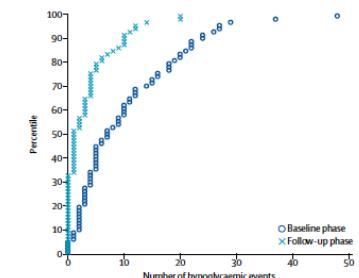
CGM benefits HbA1c and hypoglycaemia



Control group



CGM group



	Control group n/N	rtCGM group n/N	IRR (95% CI)	p value
All severe hypoglycaemia events				
Requiring third-party assistance	39/66	24/75	0.36 (0.15-0.88)	0.0247
Requiring third-party assistance, but no medical intervention	36/66	19/75	0.26 (0.10-0.69)	0.0071
Requiring third-party assistance, with medical intervention	3/66	5/75	1.60 (0.30-8.49)	0.59

Reduced risk in rtCGM group Increased risk in rtCGM group

JAMA 2017;317(4):371-378

Lancet 2018;391:1367-1377

Works both for MDI and those using pumps

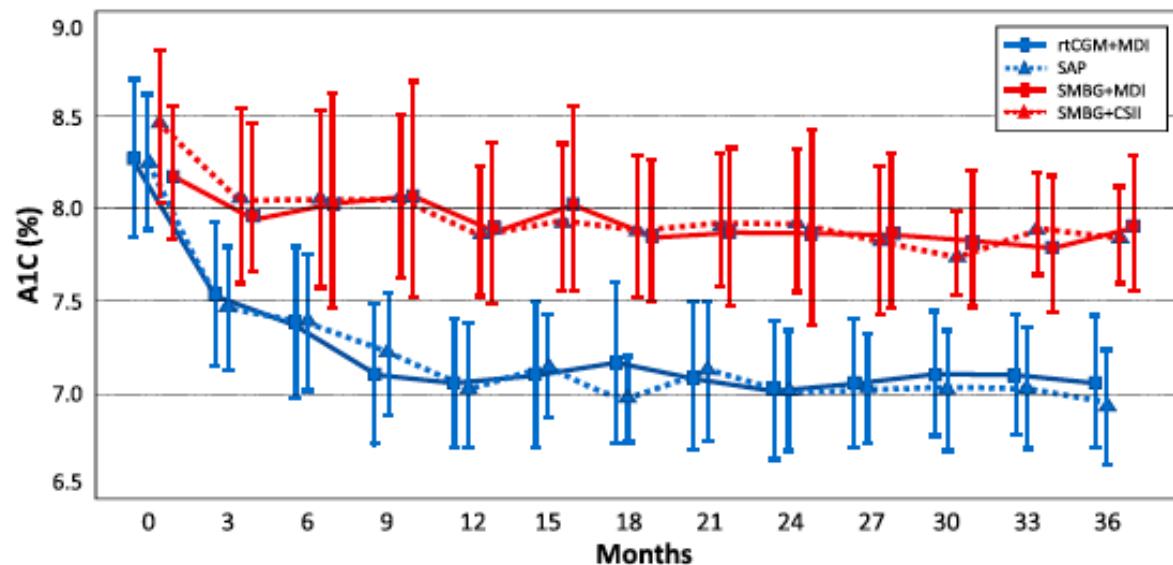


Figure 1—Change in A1C from baseline by study group. SAP, sensor-augmented pump.

Improvements in both TIR and TBR

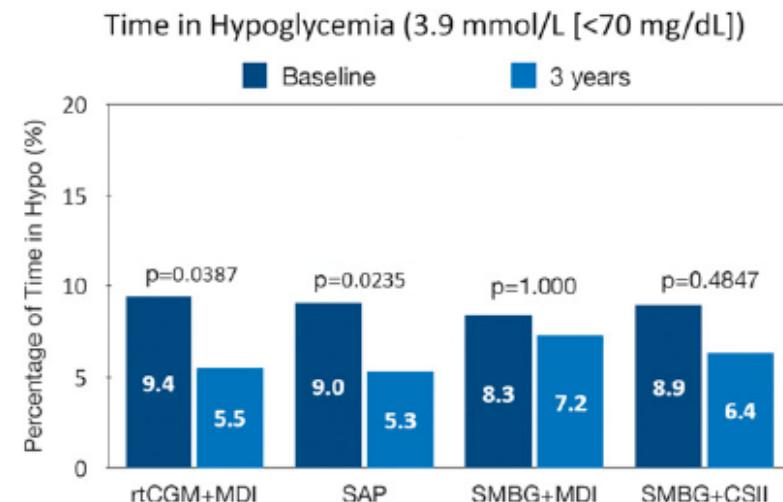
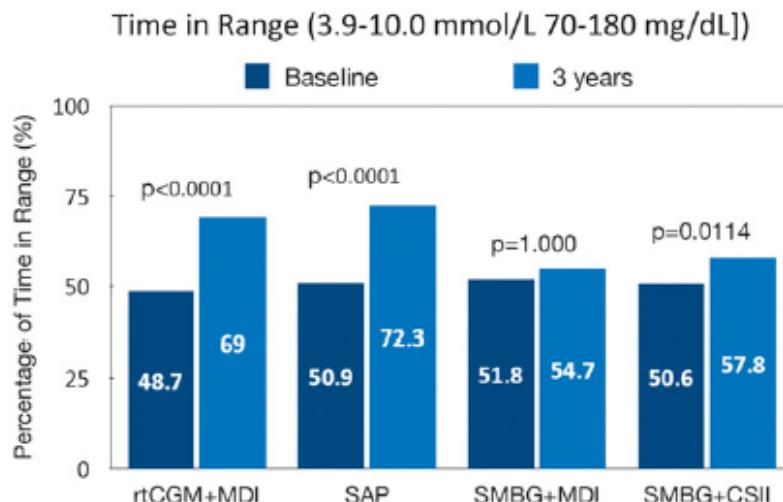
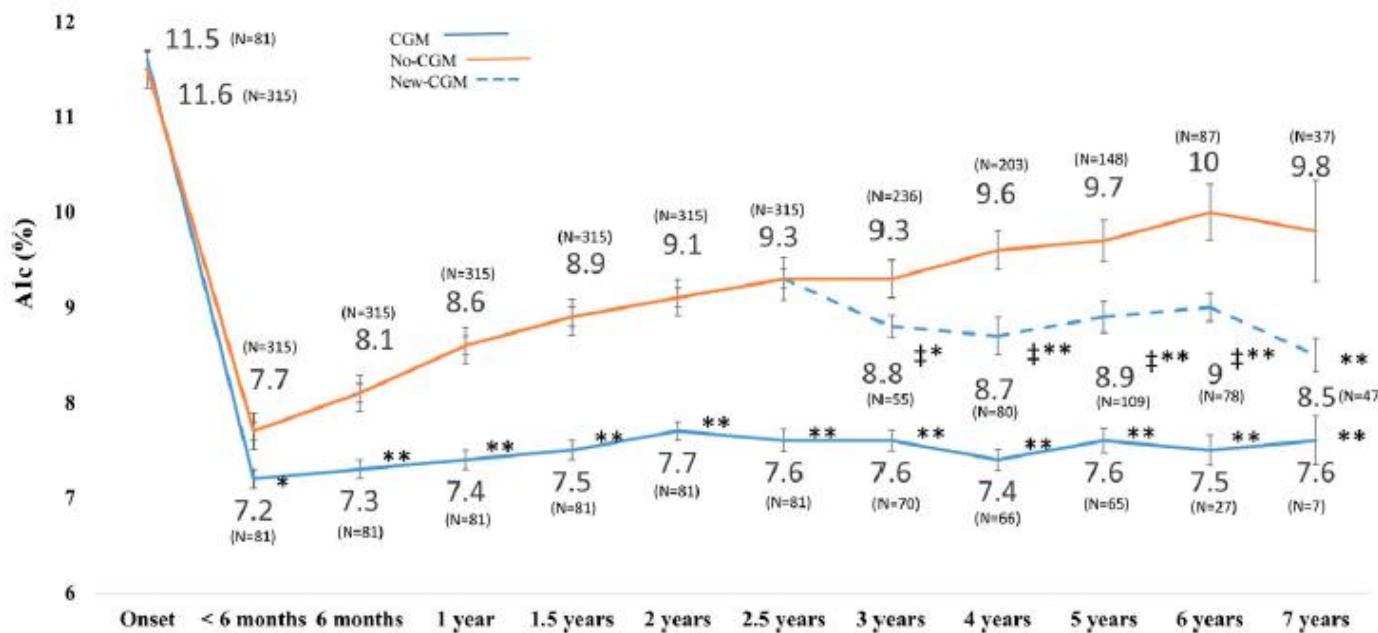


Figure 2—Changes in percentage of time in range and time in hypoglycemia. SAP, sensor-augmented pump.

Benefit of CGM from diagnosis





**So we want people to have access
to CGM devices.**

**How can we know if a device is
any good?**

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REVIEW ARTICLE

WILEY

International clinical opinion on transparency, standardisation, and calibration alignment in the performance evaluation of systems for continuous glucose monitoring

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Katharine Barnard-Kelly PhD⁴ | Tadej Battelino MD^{5,6}  | Thomas Danne MD⁷  |
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Martin Tauschmann MD^{25,26} | Amanda Williams MSc²⁷ | Emma G. Wilmot MD^{28,29} |
Dessi P. Zaharieva PhD^{13,14}  | Othmar Moser MD^{30,31}

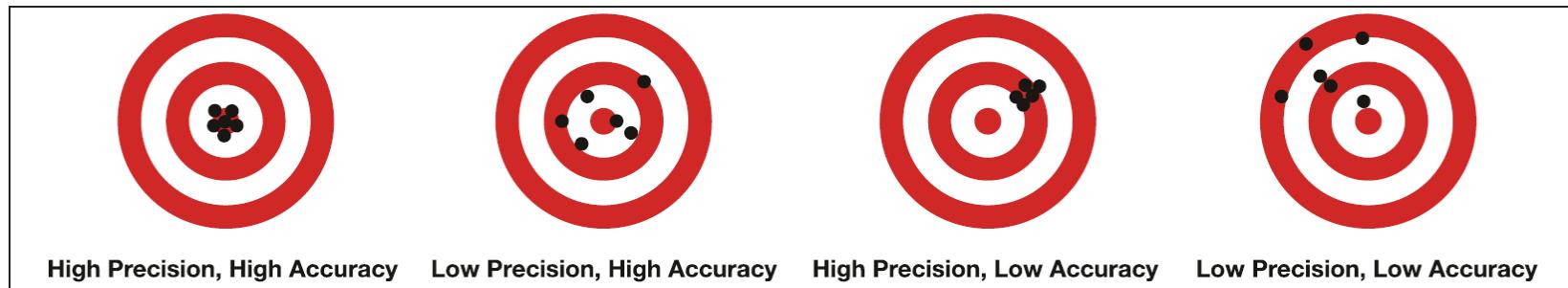


What about CE marking?

- Any device with a CE mark can be marketed in the UK and Europe
- What are the issues with CE marking?
- There does not need to be **transparency** about the data used to assess a submission
 - Data *may* be publicly available but this is not a requirement
 - If data are not publicly available then they cannot be independently assessed, which means that **CE marking alone is not sufficient to guarantee accuracy**

What about MARD?

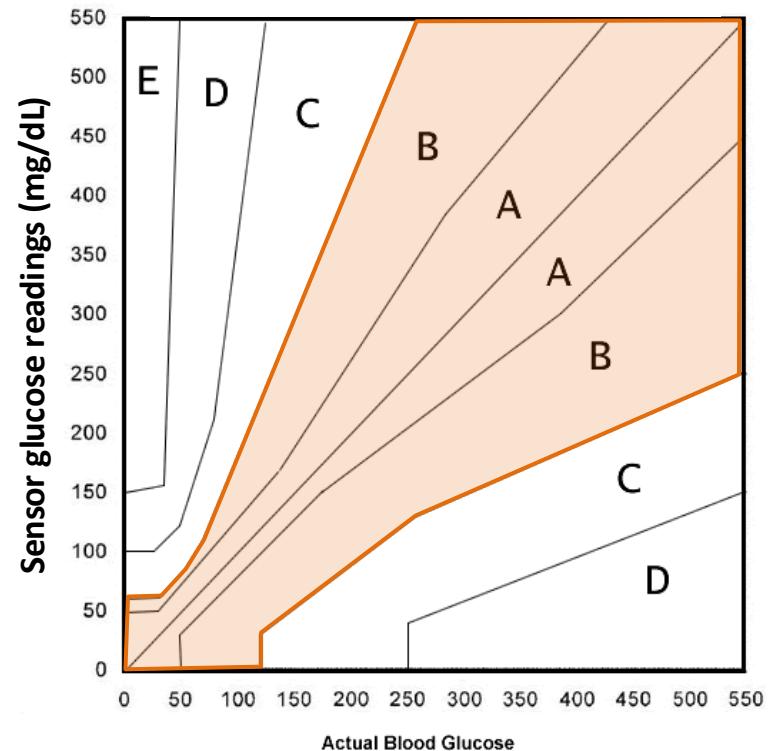
- **Accuracy** – how close is the reading to the reference standard?
- **Precision** – how close are sensor readings to each other?



- **MARD** – measures average accuracy but not precision
- A consensus error grid allows visualization of precision as well

Consensus error grid

- 5 zones which reflect clinical relevance:
- **Zone A:** no effect on clinical action
- **Zone B:** altered clinical action but little/no effect on clinical outcome
- **Zone C:** altered action, likely to affect outcome
- **Zone D:** significant medical risk
- **Zone E:** erroneous treatment, could have dangerous consequences



Limitations of MARD

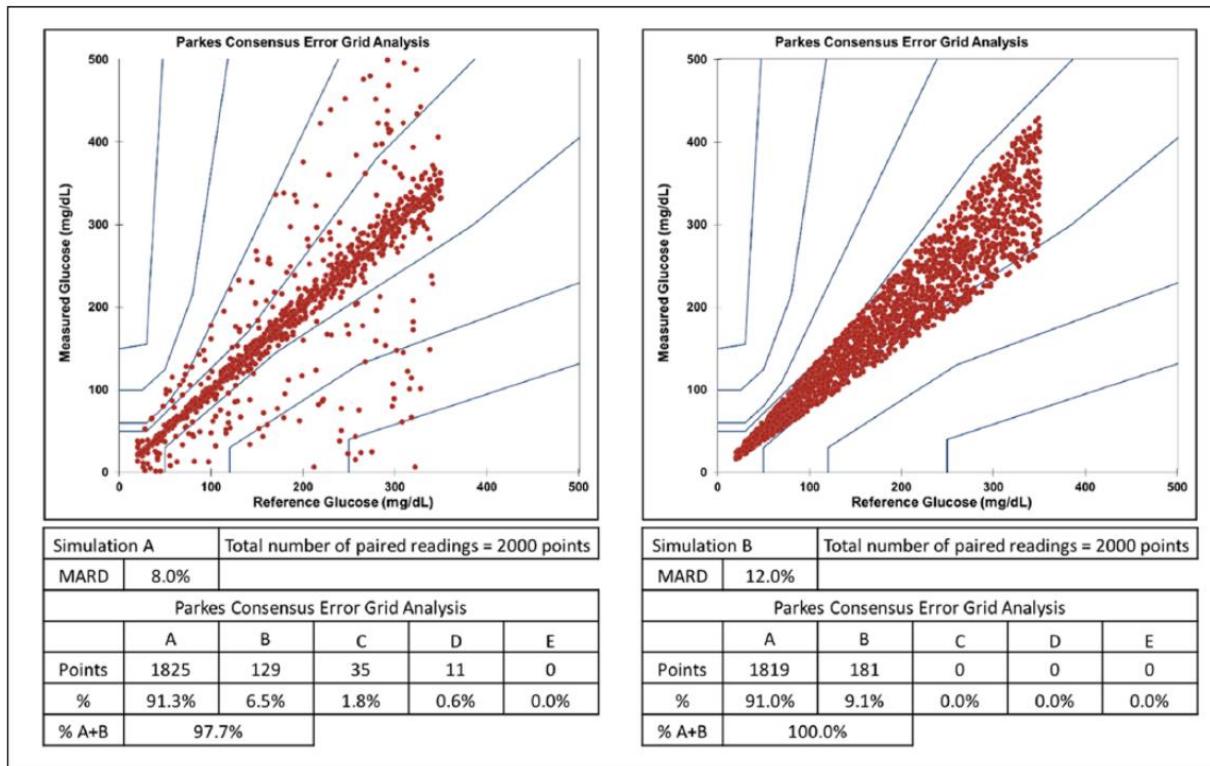
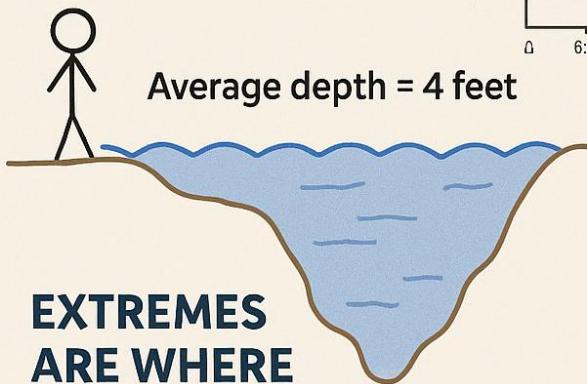


Figure 5. Comparisons of simulated test and reference glucose samples. The MARD and CEG plots of 2000 paired readings can be modelled to illustrate that different methods of analysis may generate different assessments of 'accuracy'.

LIMITATIONS OF MARD

MARD does not account for risks at extreme glucose levels.

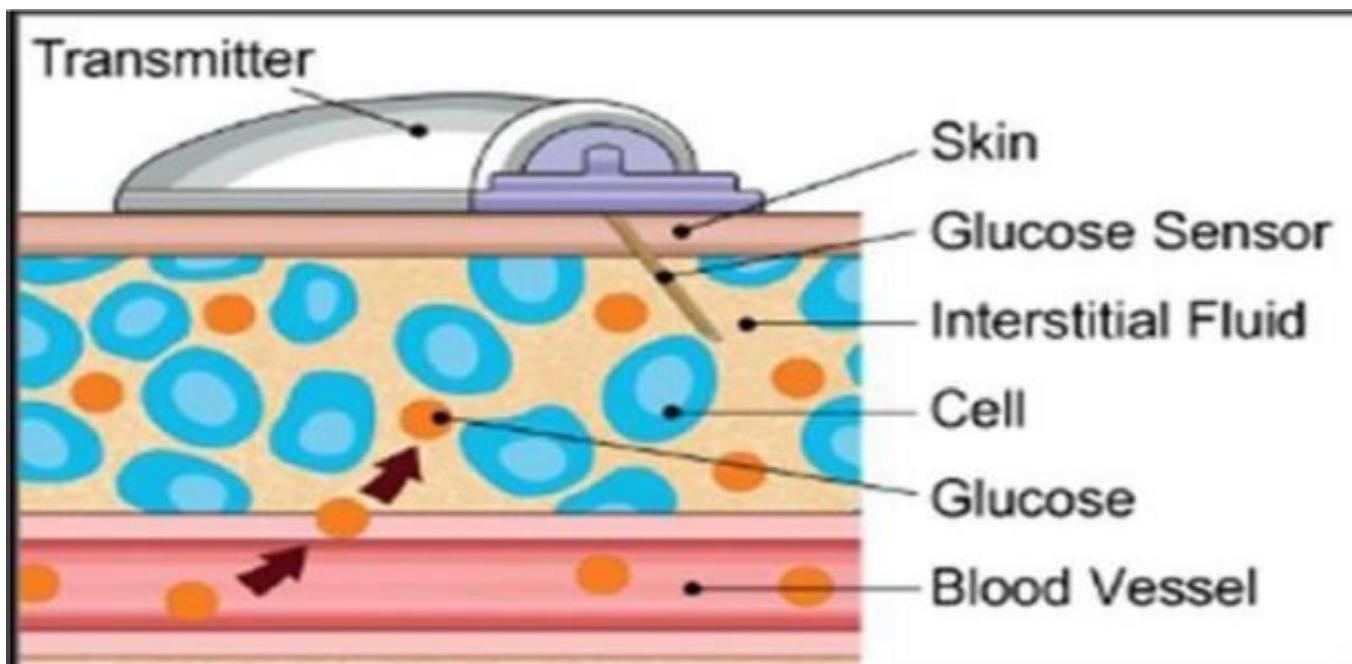
“Would you cross a river if its average depth were 4 feet even if you couldn’t swim?

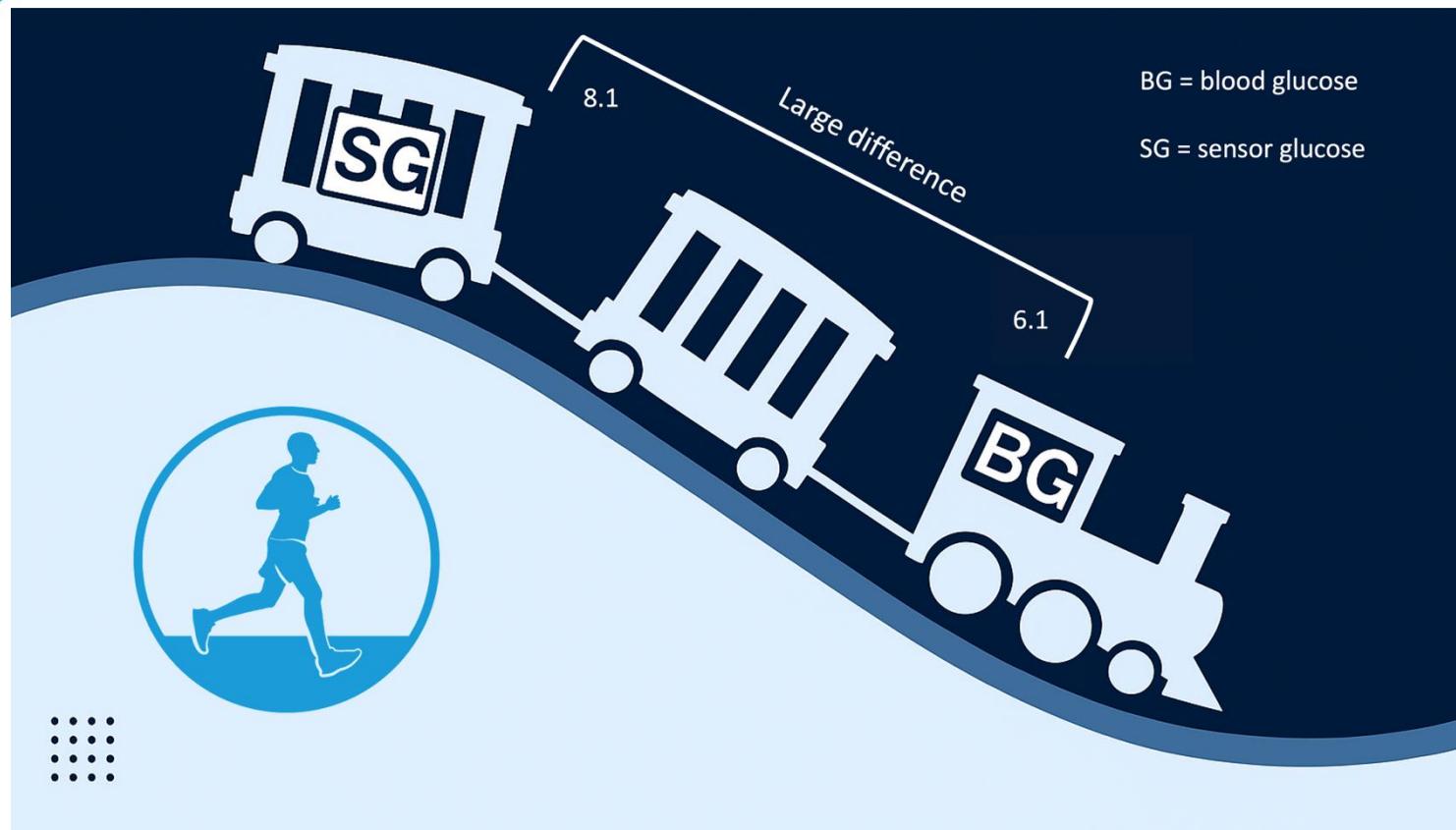


**EXTREMES
ARE WHERE
CRITICAL DECISIONS
OCCUR!**



CGM measures interstitial glucose







Studies to assess accuracy

Received: 24 October 2024

Revised: 9 December 2024

Accepted: 12 December 2024

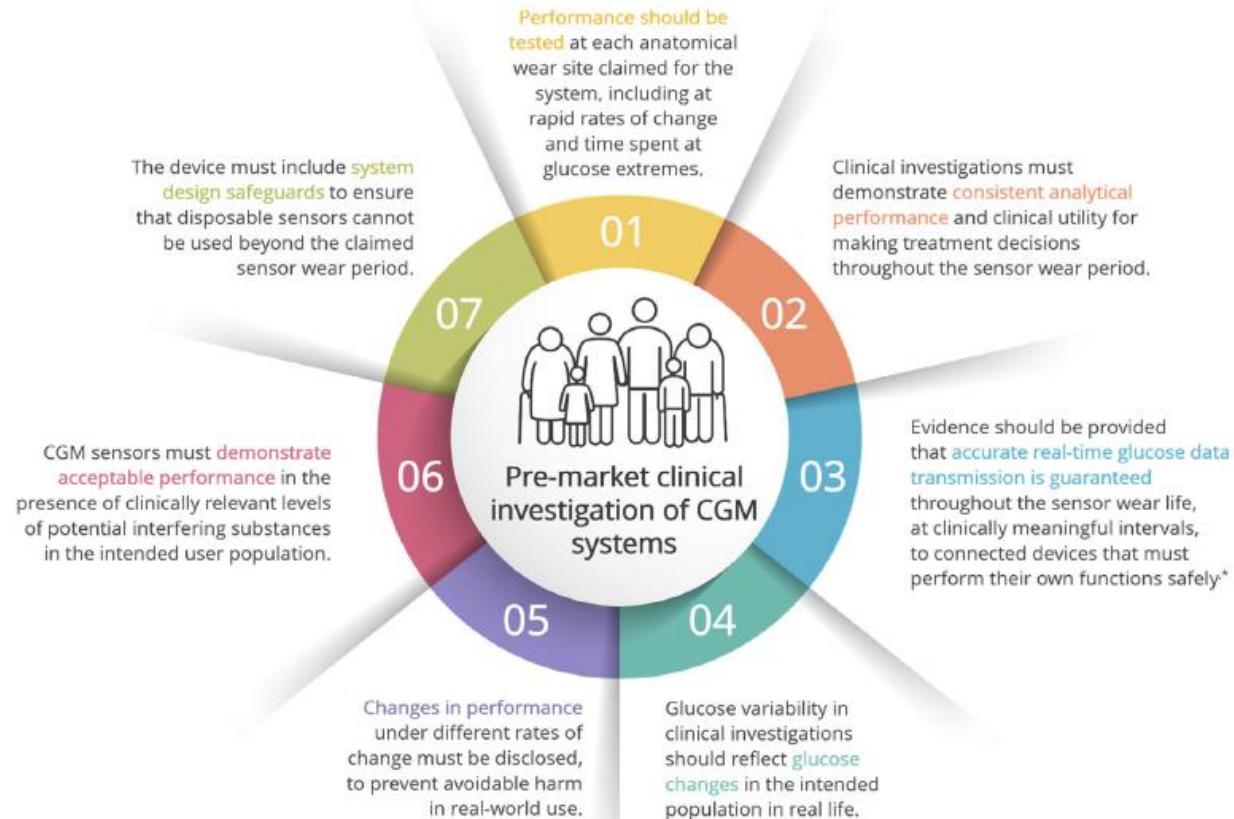
DOI: 10.1111/dom.16153

COMMENTARY

WILEY

Minimum expectations for market authorization of continuous glucose monitoring devices in Europe—‘eCGM’ compliance status

Chantal Mathieu MD ¹  | Concetta Irace MD ²  | Emma G. Wilmot MD ^{3,4} |
Bassil Akra PhD ⁵ | Stefano Del Prato MD ⁶ | Martin Cuesta MD ⁷ |
Peter Adolfsson MD ^{8,9} | Tomasz Klupa MD ¹⁰ | Eric Renard MD ¹¹  |
Tadej Battelino MD ^{12,13} 

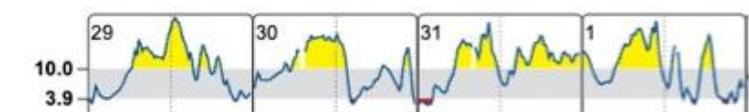
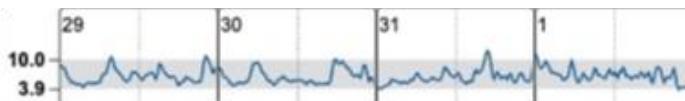




Key study criteria

- Should include at least 100 people, at least 70% with type 1 diabetes
- Tested throughout the sensor wear period
- Each anatomical site should be included
- At least 3 sensor lots
- Should include meal and insulin challenges
- At least 8% of readings less than 4.4 mmol/l
- At least 5% of readings over 16.7 mmol/l
- Data should be disclosed publicly for each intended population
- Minimum number of paired readings for each anatomical site
 - 2500 younger children
 - 10000 adults

Type 2 v type 1



Multicenter Evaluation Study Comparing a New Factory-Calibrated Real-Time Continuous Glucose Monitoring System to Existing Flash Glucose Monitoring System

Journal of Diabetes Science and Technology
2023, Vol. 17(1) 208–213
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DOI: 10.1177/1932296821103799
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An example

- MARD reported as 9.08%
- Multicentre study with 120 participants
- **However:**
 - Only 14 people (11.3%) included with type 1 diabetes
 - Only 57 people (49.6%) using insulin
 - No sensor day 1 readings evaluated
 - No meal or insulin challenge



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Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/cca



Clinical assessment and acceptance criteria for continuous glucose monitoring (CGM) system performance: A proposed guideline by the IFCC Working Group on CGM



Stefan Pleus ^{a,b,*}, Manuel Eichenlaub ^b, Pradeep Kumar Dabla ^{a,c}, Peter Diem ^{a,d},
Elisabet Eriksson Boija ^{a,e}, Marion Fokkert ^{a,f}, Rolf Hinzmann ^{a,g}, Johan Jendle ^{a,h},
David C. Klonoff ^{a,i}, Jingyi Lu ^{a,j}, Konstantinos Makris ^{a,k}, Viswanathan Mohan ^{a,l},
James H. Nichols ^{a,m}, John S. Pemberton ^{a,n}, Elizabeth Selvin ^{a,o}, Robbert J. Slingerland ^{a,f},
Andreas Thomas ^{a,p}, Nam K. Tran ^{a,q}, Lilian Witthauer ^{a,r,s}, Guido Freckmann ^{a,b}, on
behalf of the Working Group on Continuous Glucose Monitoring of the IFCC Scientific Division

Study design and procedures

- **≥100 participants** with insulin-treated diabetes, **≥80% with type 1**
- One sensor per anatomical wear site
- Capillary **comparator** measurements every 15 minutes during in-clinic sessions scheduled **throughout the sensor life**, using a device with **minimal bias** to higher-order method/material
- Pairing of comparator measurements with CGM readings recorded closest in time.

Distribution of comparator data

7.5% of data in each **dynamic glucose region** reflecting clinically relevant scenarios



„BG Low“
(Hypoglycemia)



„Alert Low“
(Hypoglycemia imminent)



„Alert High“
(Hyperglycemia imminent)



„BG High“
(Hyperglycemia)

Proposed IFCC Guideline on CGM System Performance

Minimum accuracy

- **7 point accuracy requirements** to ensure adequate agreement overall and in each dynamic glucose region
- **3 trend accuracy requirements** to ensure minimal trend arrows with wrong or misleading direction
- **2 sensor-specific accuracy requirements** to ensure a minimal number of sensors with poor accuracy

Characterization of performance

- Point accuracy
- Trend accuracy
- Sensor-specific accuracy
- Clinical accuracy
- Stability
- Alert reliability
- Technical reliability
- Safety

Publication of CGM performance reports



Key criteria – distilled down

1. Is the data publicly available?
2. Is the data sufficient?
 - a. Are there sufficient participants?
 - b. Do at least 70% have type 1 diabetes?
 - c. Are there enough paired data points?
3. Does the study include meal and insulin challenges?
4. Are there sufficient low glucose data points?
5. Are there sufficient high glucose data points?

Use the DSN forum comparison chart!

Study Design, Clinical Accuracy, and Regulatory Approval Status of CGM Systems Available in the UK

Diabetes Specialist
NHS Forum UK

CGM Systems (Distributor in the UK)	Study Design Assessment and Score							Accuracy Data & Regulatory Status									
	Peer-reviewed ^a	≥70% T1D	Meal & insulin challenge	28% of readings <4.4 mmol/L (80 mg/dL)	≥5% of readings >16.7 mmol/L (300 mg/dL)	Study design score ^b	Age range tested	N = adults	Adult 20/20 ^c	Adult 40/40 ^c	N = Paed	Paed 20/20 ^c	Paed 40/40 ^c	CE marking for non-adjunctive ^d (age indication)	iCGM for HCl ^e	GP via FP10	NHS Supply Chain
Non-adjunctive use:																	
Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide [®] (ROCHE) ¹	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	d	d	d	✓ ^f (18yrs)	x	✓	x
ALLYcgm (AgaMatex) ⁹	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	d	d	d	✓ ^f (18yrs)	x	x	x
CareSens Air [®] (Spirit Healthcare) ⁹	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	d	d	d	✓ ^f (18yrs)	x	✓	x
Dexcom G6 [™] (Dexcom) ²⁻³	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ ^f (≥2yrs)	✓ ^g	x	✓
Dexcom G7 [™] (Dexcom) ⁴⁻⁵	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ ^f (≥2yrs)	✓ ^g	x	✓
Dexcom One [™] (Dexcom) ²⁻³	✓	✓	✓	✓	✓	5	≥2yrs	159	93%	>99.5%	165	92%	>99.5%	✓ ^f (≥2yrs)	x	✓	x
Dexcom One+ [™] (Dexcom) ⁴⁻⁵	✓	✓	✓	✓	✓	5	≥2yrs	316	95%	>99.5%	127	95%	>99.5%	✓ ^f (≥2yrs)	x	✓	x
FreeStyle Libre [®] 2 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ ^f (≥2yrs)	✓ ^g	✓	✓
FreeStyle Libre [®] 3 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ ^f (≥2yrs)	✓ ^g	✓	✓
Simplera/Simplera Sync [™] (Medtronic) ⁸	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	d	138	88%	d	✓ ^f (≥2yrs)	x	x	✓
GlucoMen iCan (A. Menarini Diagnostics) ⁹	x	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ ^f (≥2yrs)	x	✓	x
Guardian [™] 4 Sensor and Guardian [™] 4 Link Transmitter (Medtronic) ⁴	x	✓	✓	✓	✓	4	≥2yrs	153	88%	d	108	83%	d	✓ ^f (≥2yrs)	x	x	✓
TouchCare [®] Nano A8 (Medtronic) ⁴	x	x	✓	d	d	1	≥14yrs	63	89%	99%	d	d	d	✓ ^f (≥2yrs)	x	x	✓
Linx (Microtech) ⁴	x	d	d	d	d	0	≥18yrs	91	>90%	99%	d	d	d	✓ ^f (≥18yrs)	x	x	x
Adjuactive use:																	
Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Glucovano [®] (Infinovo) ¹⁰	✓	x	x	x	x	1	≥18yrs	78	90%	99%	d	d	d	x (2yrs)	x	x	x
GlucoRx Aidx [™] (GlucoRx) ¹¹	✓	x	x	x	x	1	≥18yrs	114	96%	>99.5%	d	d	d	x (≥14yrs)	x	✓	x
Yuwell Anytime CT3 (Urathon) ⁴	x	d	d	d	d	0	≥18yrs	72	93%	d	d	d	x (≥14yrs)	x	x	✓	
Sysi Tag (Sysi Health Technology) ⁴	x	d	d	d	d	0	≥18yrs	72	93%	d	d	d	x (≥18yrs)	x	x	x	

Study design score

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Non-adjunctive use: Licensed for clinical decision-making including insulin dosing. Finger-prick blood glucose confirmation is not required for treatment decisions, unless symptoms do not match the CGM reading or the value and/or trend arrow is unavailable.																	
Accu-Chek SmartGuide® (ROCHE) ¹	✓	✓	✓	✓	✓	5	≥18yrs	48	91%	99%	d	d	d	✓ ^f (18yrs)	x	✓	x
ALLYcgm (AgaMatrix) ⁹	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	d	d	d	✓ ^f (18yrs)	x	x	x
CareSens Air® (Spirit Healthcare) ⁹	✓	✓	✓	✓	✓	5	≥18yrs	30	94%	>99.5%	d	d	d	✓ ^f (18yrs)	x	✓	x
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Guardian™ 4 Sensor and Guardian™ 4 Link Transmitter (Medtronic) ⁴	x	✓	✓	✓	✓	4	≥2yrs	153	88%	d	108	83%	d	✓ ^f (≥2yrs)	x	x	✓
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Yuwell Anytime CT3 (Urathon) ⁹	x	d	d	d	0	≥18yrs	72	93%	d	d	d	d	x (≥14yrs)	x	x	✓	
Sysi Tag (Sysi Health Technology) ⁹	x	d	d	d	0	≥18yrs	72	93%	d	d	d	d	x (≥18yrs)	x	x	x	



Fingerprick readings

- Fingerprick glucose is advised:
 - To confirm hypoglycaemia (and hyperglycaemia)
 - When sensor glucose does not match symptoms
- For some systems, fingerprick glucose is also *required* to support decisions about insulin dosing. Where this is **not** required, the device has a “non-adjunctive indication”

Study design score

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FreeStyle Libre [®] 2 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ ^g (≥2yrs)	✓	✓	✓
FreeStyle Libre [®] 3 Plus (Abbott) ^{6,7}	✓	✓	✓	✓	✓	5	≥2yrs	148	94%	>99.5%	127	94%	>99.5%	✓ ^g (≥2yrs)	✓	✓	✓
Simplera/Simplera Sync [™] (Medtronic) ⁸	✓	✓	✓	✓	✓	5	≥2yrs	160	89%	d	138	88%	d	✓ ^g (≥2yrs)	x	x	✓
GlucoMen iCan (A. Menarini Diagnostics) ⁹	x	✓	✓	✓	✓	4	≥2yrs	35	96%	>99.5%	60	95%	>99.5%	✓ ^g (≥2yrs)	x	✓	x
Guardian [™] 4 Sensor and Guardian [™] 4 Link Transmitter (Medtronic) ⁴	x	✓	✓	✓	✓	4	≥2yrs	153	88%	d	108	83%	d	✓ ^g (≥2yrs)	x	x	✓
TouchCare [®] Nano A8 (Medtronic) ⁹	x	x	✓	d	d	1	≥14yrs	63	89%	99%	d	d	d	✓ ^g (≥2yrs)	x	x	✓
Linx (Microtech) ⁹	x	d	d	d	d	0	≥18yrs	91	>90%	99%	d	d	d	✓ ^g (≥18yrs)	x	x	x
Adjuactive use: Not licensed for clinical decision-making. All clinical decisions must be confirmed with a finger-prick blood glucose test																	
Glucanovo [®] (Infinovo) ¹⁰	✓	x	x	x	x	1	≥18yrs	78	90%	99%	d	d	d	x (2yrs)	x	x	x
GlucoRx Aidx [™] (GlucoRx) ¹¹	✓	x	x	x	x	1	≥18yrs	114	96%	>99.5%	d	d	d	x (≥14yrs)	x	✓	x
Yuwell Anytime CT3 (Urathon) ⁹	x	d	d	d	d	0	≥18yrs	72	93%	d	d	d	x (≥14yrs)	x	x	✓	
Sysi Tag (Sysi Health Technology) ⁹	x	d	d	d	d	0	≥18yrs	72	93%	d	d	d	x (≥18yrs)	x	x	x	



The importance of benchmarking



Time in range

- Time in range (3.9–10.0 mmol/l) is an increasingly important measure
- It is often used to assess glycaemia (and therefore diabetes management) both by people with diabetes and clinicians
- HbA1c is standardized and machines are calibrated
- Is TIR comparable between CGM systems?



Comparing different systems



Diabetes Care®



A Comparative Analysis of Glycemic Metrics Derived From Three Continuous Glucose Monitoring Systems

Guido Freckmann, Stephanie Wehrstedt, Manuel Eichenlaub, Stefan Pleus, Manuela Link, Nina Jendrike, Sükrü Öter, Derek Brandt, Cornelia Haug, and Delia Waldenmaier

Diabetes Care 2025;48(7):1213–1217 | <https://doi.org/10.2337/dc25-0129>

Comparing different systems

Objective

To analyze the **differences in continuous glucose monitoring (CGM)-derived metrics** among three current-generation systems and evaluate their impact on **therapeutic decision-making**.

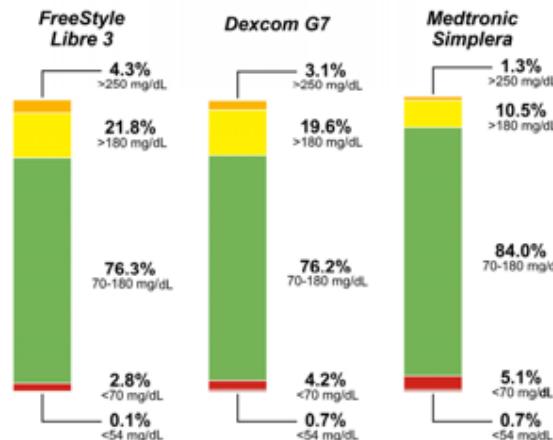
Research Design & Methods



23 adult participants, 14 days
FreeStyle Libre 3
Dexcom G7
Medtronic Simplera

CGM metrics calculated for each participant and CGM system separately

Results



Median percentage of time in different glucose ranges across all study participants according to the different CGM systems.

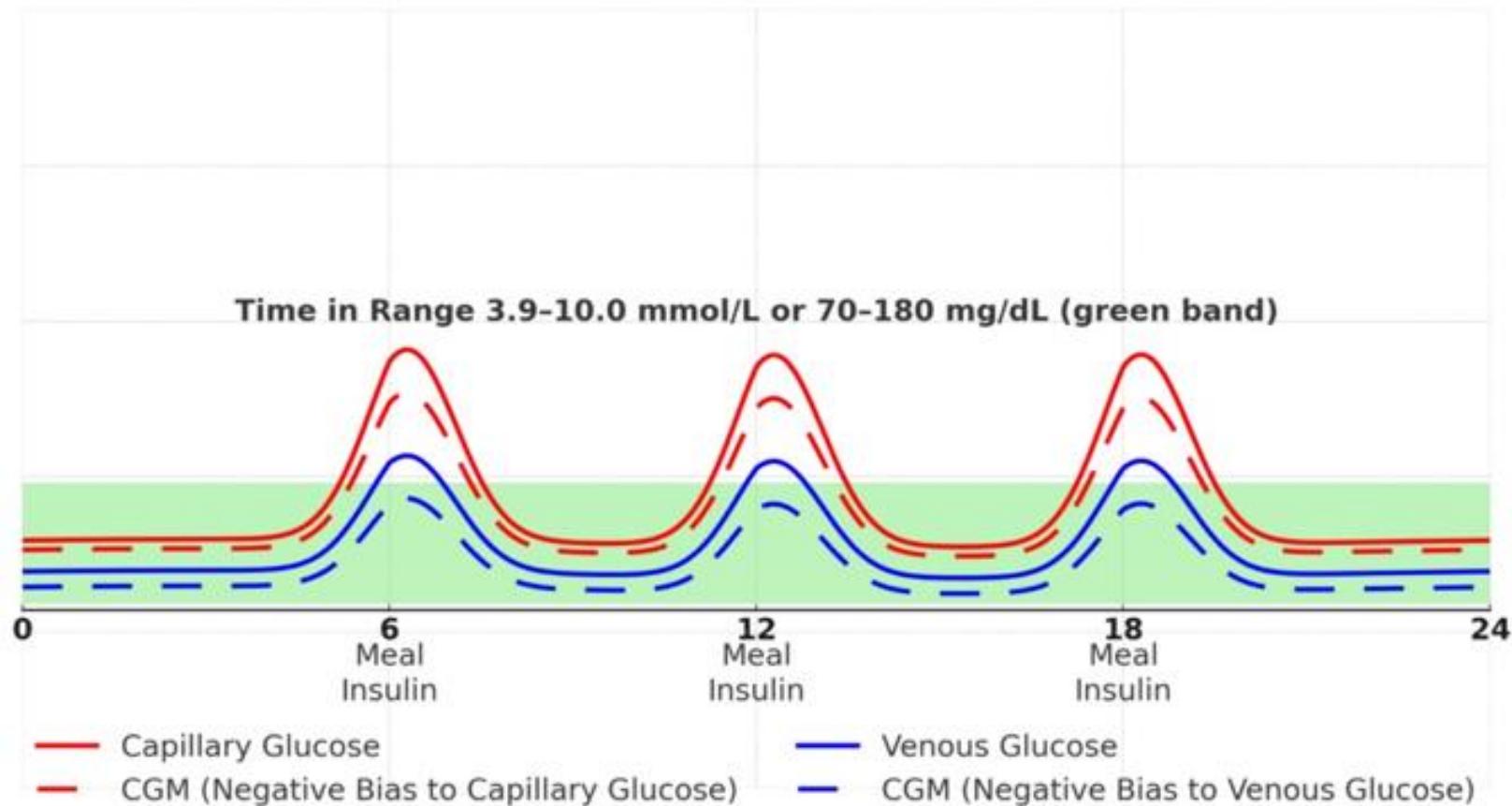
➤ Differences in glucose profiles, resulting in **substantially different glycemic metrics** among the three systems.

➤ Marked intra-participant discrepancies that would have resulted in **different therapeutic recommendations**.

Conclusions

The CGM systems indicated discordant glycemic metrics that should be considered in diabetes therapy. Different CGM systems should provide the same glucose readings and CGM-derived metrics when used by the same person.

Comparator is important



So, back to the beginning...



What are you going to say?



- Bill comes to see you in clinic to discuss his diabetes management
- He has bought a CGM device that was advertised to him online, and tells you that he finds it really helpful
- The device has a CE mark
- He checks the readings it gives him with his fingerprick readings, and in his experience they are usually pretty close.
- The device is cheaper to buy than Freestyle Libre 2, so Bill suggests that the NHS could save money by switching to this device and says that you should make it available to your population
- What do you do?



Summary

- Why is understanding CGM accuracy important? How might it impact your day to day practice?
- The importance of assessing CGM accuracy
 - CE marking
 - MARD
 - Consensus error grids
 - Study design
- The importance of benchmarking/calibration



**Thanks for your attention
Any questions?**