EQA for POCT glucose - consequences for patient diagnostics

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Introduction

- Can we use POCT glucose results in primary healthcare to diagnose patients with gestational diabetes and diabetes?
- Benefits
  - Immediately start Oral Glucose Tolerance Test (OGTT)
  - The patients don’t need to come back for another consultation
  - Reduced pre-analytical variables, transport of samples not necessary
- The analytical quality of POCT glucose results is similar to hospital lab results

Introduction

Norwegian Health Authorities

- POCT glucose results can be used to diagnose patients with diabetes and gestational diabetes
  - ➢ if HbA1c cannot be used
  - ➢ if the analytical quality is good enough

- National analytical performance specification (APS)
  - Glucose results within ± 7.5% from true value

How to achieve this? Topic of my talk

- How can the POCT glucose users know if they fulfil the national APS?
  - ➢ Participate in EQA scheme with commutable materials and reference target values

- Is this possible?

Noklus EQA for POCT glucose

- More than 3000 participants
- 26 different POCT glucose instruments
- 2 surveys per year
- 2 control samples in 2 levels

→ are the control materials commutable?

Noklus commutability studies of EDTA whole blood control material for glucose

Bukve et al. Clin Chem 2019; 65:791-7

Compared with Roche Cobas 6000

POCT glucose	Level 7 mmol/L	Level 13 mmol/L	Level 17 mmol/L
Accu-Chek Guide	No	*not tested*	*not tested*
Accu-Chek Performa/Performa Nano/Inform II	No	No	No
Ascensia Contour	Yes	No	No
Contour	Yes	Yes	Yes
Contour XT/next/next ONE	Yes	No	No
FreeStyle Freedom Lite/Lite	Yes	No	No
HemoCue Glucose 201RT/DM RT	Yes	Yes	Yes
HemoCue Glucose 201/201+	No	Yes	Yes
Accu-Chek Aviva/Aviva Nano	*not tested*	*not tested*	*not tested*

The control materials are tested according to CLSI EP14-A3 2014 and Fuller/Gillard

EQA for POCT glucose

- The control material is not commutable for ALL POCT glucose devices
- The control material is not commutable in ALL glucose levels

➢ Therefore, reference target values cannot be used for ALL participants

➢ Therefore, peer group target values must be used

→ *Not possible to evaluate if the POCT glucose measurements is good enough only by EQA*

An alternative approach – two steps

POCT users can diagnose patients if

1. They use a recommended POCT glucose instrument
2. They get “good” performance in relevant glucose level in EQA

both points must be fulfilled

1. The POCT glucose list

Noklus evaluate all POCT glucose instruments and makes a list with

a) Recommended → *commutable*
b) Not recommended → *commutable*
c) Not applicable (neither a or b) → *non-commutable, not possible to evaluate*

- The list is published on the Noklus' web site
- Valid for 1 year

1. The POCT glucose list

NOKLUS
sammen for god kvalitet

How do we make the list?

- The list is based on results from the 3 last EQA surveys (1.5 years period)
- In each EQA survey
  - ✓ Reference target values calculated by using NIST standards in four levels (SRM965b)
  - ✓ Commutable: Each group of POCT glucose system is evaluated against the reference target value
  - ✓ Calculate the systematic deviation from ref. target value
- Mean systematic deviation from 3 surveys, bias ≤ 5%

Example

Contour XT/next

EQA survey	Peer group target value (mmol/L)	Ref.target value (mmol/L)	Deviation (%)
GLU2021.01_1	6.36	6.20	2.58
GLU2021.01_2	5.93	5.90	0.51
GLU2022.01_1	6.54	6.31	3.65
		mean deviation	**2.24**

recommended

Freestyle Freedom Lite/Lite

EQA survey	Peer group target value (mmol/L)	Ref.target value (mmol/L)	Deviation (%)
GLU2021.01_1	5.12	6.20	-17.42
GLU2021.01_2	5.03	5.90	-14.75
GLU2022.01_1	5.30	6.31	-16.01
		mean deviation	**-16.06**

not recommended

Glukoseinstrumenter til diagnostikk av diabetes og svangerskapsdiabetes

PNA-instrumenter som bruker fullblod

Valid from May 2022 to April 2023

Anbefalingene gjelder for perioden mai 2022-april 2023.

Noklus gir her en anbefaling om hvilke glukoseinstrumenter som brukes til pasientnær analysering (PNA) for å stille diagnosen diabetes. Vi gjør oppmerksom på at dette kun er anbefalinger, og at det er den enkelte virksomhet selv som er ansvarlig for de resultater de utgir og hvordan de bruker disse resultatene klinisk. Deltakerne bør i tillegg få «meget god» på riktighetsvurderingene ved utsendelsene.

Følgende instrumenter anbefales: *a) recommended*

- Contour XT/next/next ONE (next ONE er tiltenkt personer med diabetes)
- Ascensia Contour (produseres ikke lengre)
- HemoCue Glucose 201RT *(HemoCue Glucose 201RT er kalibrert for blodprøver med normal Hemoglobin-verdi. Ved Hb <10 g/dl kan HemoCue Glucose 201RT rapportere for høye verdier (ca. 3 %), og resultatene må derfor tolkes med forsiktighet).*

Følgende instrumenter anbefales ikke: *b) not recommended*

- Contour (produseres ikke lengre)
- FreeStyle Freedom Lite/Lite (produseres ikke lengre)

Følgende instrumenter kan Noklus verken anbefale eller ikke anbefale: *neither a) nor b)*

- Accu-Chek Guide
- Accu-Chek Performa Nano/ Accu-Chek Performa/ Accu-Chek Inform II
- Accu-Chek Aviva/Aviva Nano (produseres ikke lengre, erstattes av Accu-Chek Guide)
- HemoCue Glucose201/201+

An alternative approach

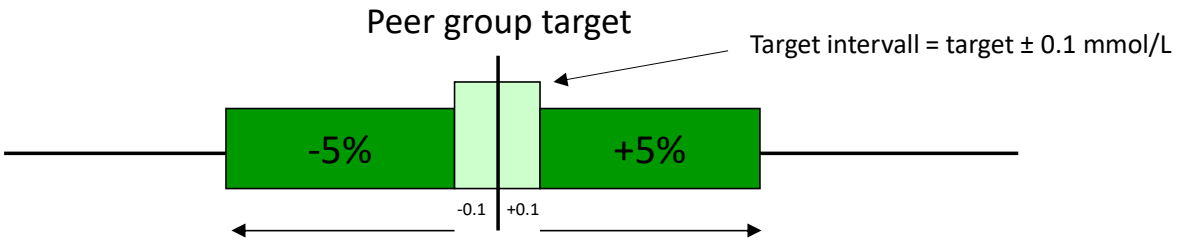
POCT users can diagnose patients if

1. They use a recommended POCT glucose instrument
2. They get “good” performance in relevant level in EQA

both points must be fulfilled

2. Good performance in EQA

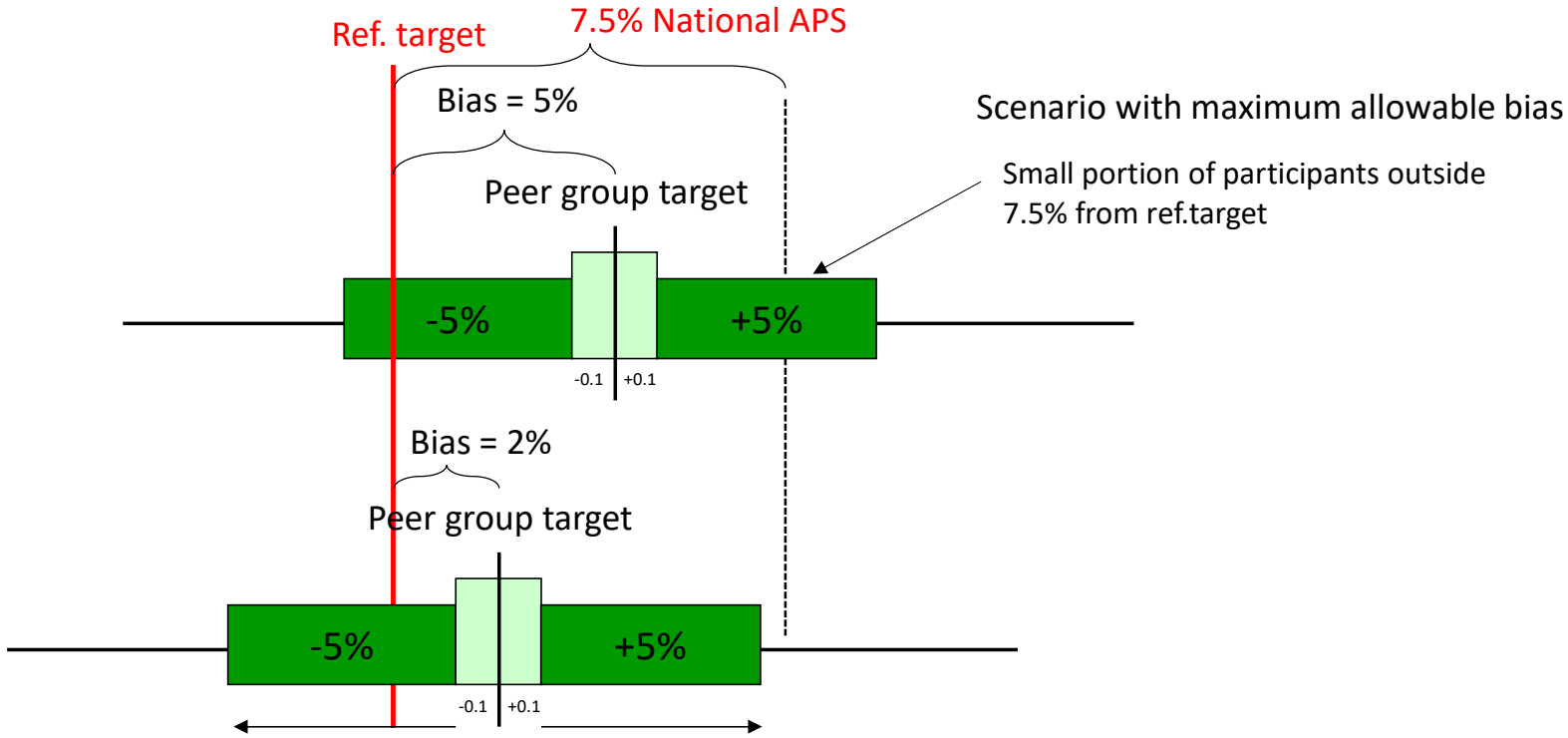
- Each participant must obtain good performance in relevant diagnostic level
- Peer group target value
- Good performance: result within 5% from peer group *target interval*

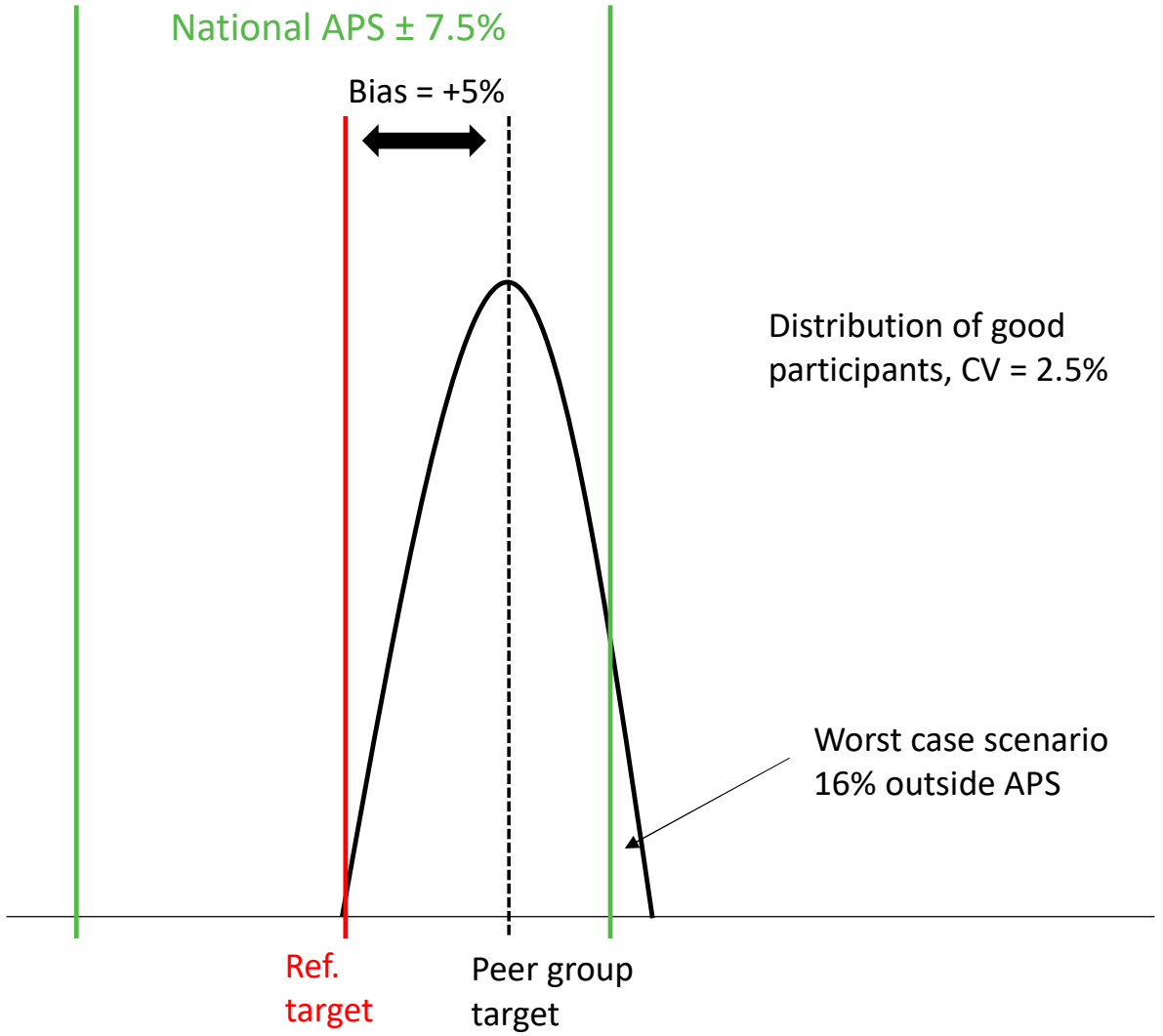


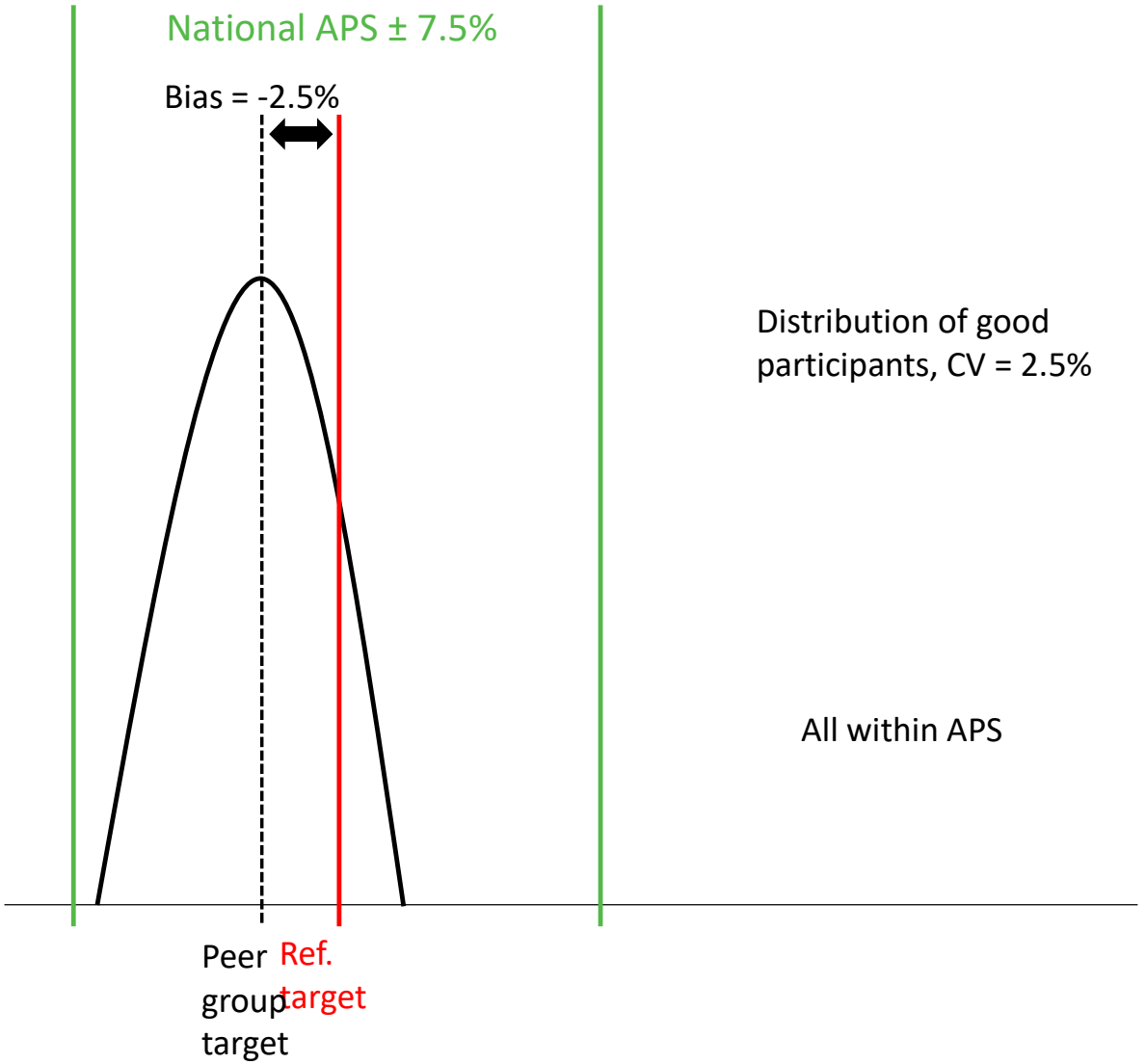
Good performance

5% from target interval

Relation between good EQA performance and the National APS




National APS ± 7.5%
Bias = +5%
Distribution of good participants, CV = 2.5%
Worst case scenario 16% outside APS
Ref. target
Peer group target


National APS ± 7.5%
Bias = -2.5%
Distribution of good participants, CV = 2.5%
All within APS
Peer group target
Ref. target

How well do the participants perform?

EQA survey in 2022 (GLU2022.01)

- 70% (n=1775) of the participants use a recommended POCT glucose instrument
- 87% (n=1538) of these got “good” performance in the EQA scheme

→can use their POCT glucose instruments to diagnose patients

Summary

- The Norwegian Health Authorities recommend that POCT glucose results can be used to diagnose patients with diabetes and gestational diabetes
  - ➢ if they fulfil the analytical requirements

- Noklus have developed a system to evaluate if POCT glucose users fulfil the national requirements
- The POCT glucose users must
  1. use a recommended POCT instrument, AND
  2. get good performance in EQA


Thank you for your attention!