

*Meeting Point-of-Care Expectations of the Clinician*

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Anamnesis  
Clinical Findings



Pre-pre  
(test requesting)

Diagnosis  
Treatment  
Monitoring



Post-post (interpretation)



Pre-analytical phase



Post-analytical (report)



**Analysing**



**Anamnesis  
Clinical  
Findings**



Pre-pre  
(test requesting)



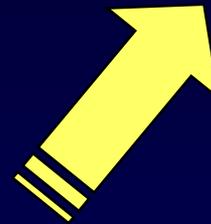
Pre-analytical phase



Analysing



Post-analytical (report)



Post-post (interpretation)

**Diagnosis  
Treatment  
Monitoring**

What do we know

what are clinicians interested in-

Analytical principles

Logistic

Sample handling

Effective laboratory practice

Biochemistry

IT

**NOT INTERESTED**  
*But they have expectations*

# What do we know

-and what are clinicians interested in-

- Analyse test results with precision
- Biological differences
- Probabilities
- Sensitivity / specificity
- Likelihood ratios
- What tests to use?

**INTERESTED**

**But they don't know that we can contribute**

# Clinicians want to use POC tests when a “quick” result is necessary

## Expectations:

Results when needed

Robust and easy to use

Correct result

Cost effective (if they have to pay)

# But

**It is not really expectations, but they take for granted that every POC instrument is:**

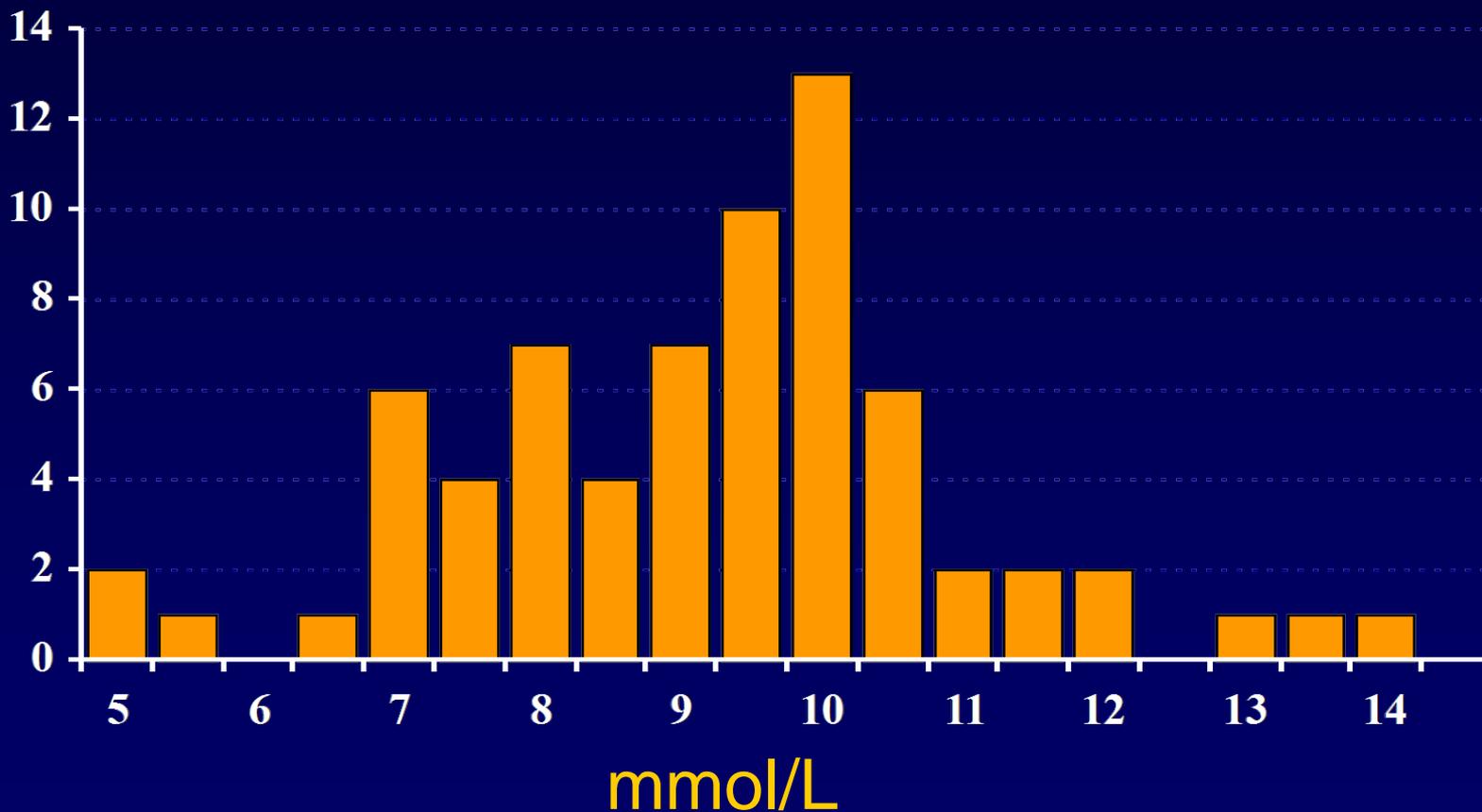
**Robust and easy to use and give a correct result in a short time.**

# And therefore

- They just buy the instrument and use it
- And we have to tell them that they need us
- How?

# Example 1 – B-glucose

# An example: Glucose— in primary care





# U-strips and clinical decision making

*Together with the urine we distributed a case history*

# Urine strips

Mrs. Hansen, 65 years, is consulting you for control of the BP (170/95). She brings an urine sample and tells you about some dysuria the last week. Two years ago she was treated for urinary tract infection.

What is the probability that she has an urinary tract infection? .....

The urine strip shows: nitritis \_\_\_\_\_\*  
and leukocytes \_\_\_\_\_\*

\* to be filled in by co-worker after result from control material

# Urine strips

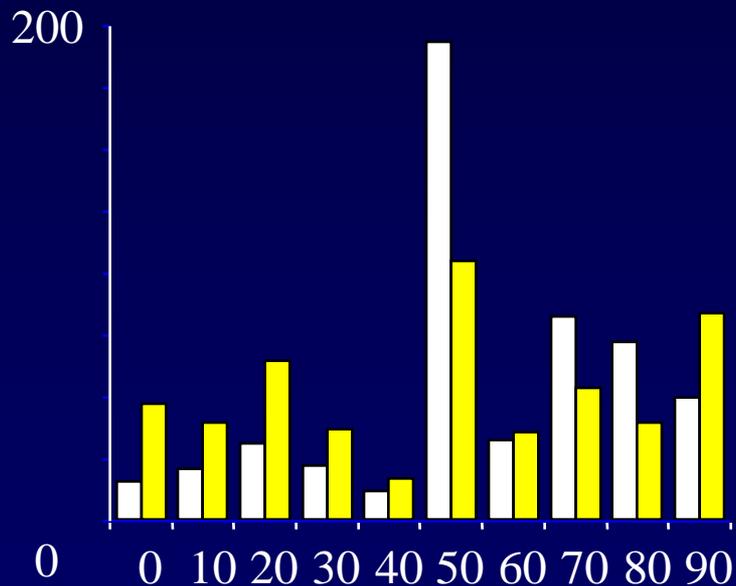
After this result: What is the probability of urinary infection? .....

- and how will you handle the situation?

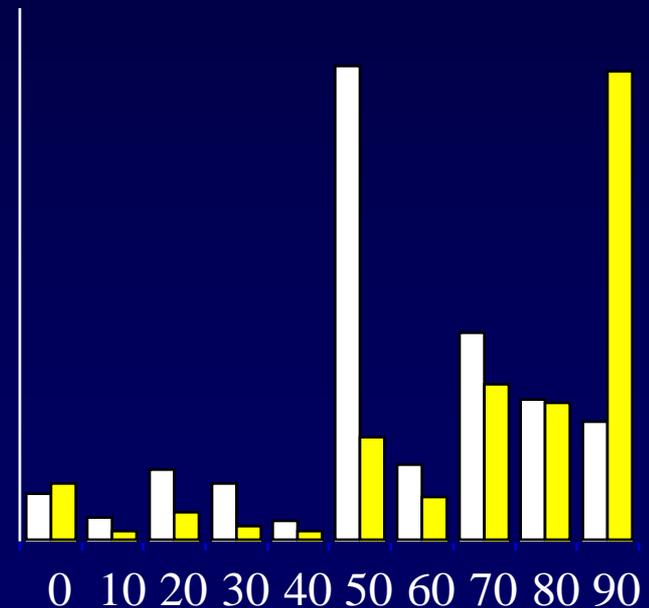
- do nothing
- treat her with .....
- request the following tests.....
- other measures.....

# Urine strips and probability for infection

N- L+



N+ L+



Pre- and **posttest** probability (%)

**All POC instruments do not  
have excellent quality**

**and**

**analytical quality matters in  
relation to clinical decision**

# **Based on such results**

**The Norwegian government established an organisation that should fulfill the expectations of the clinicians in primary health care concerning the laboratory**

**- Noklus**

# What are the needs of the clinicians and the patients?

- Which constituents that shall be requested and where they should be analysed.
- That the results are correct.
- To have someone to consult when something goes wrong.
- Advices about what instruments to buy.
- Correct interpretations of the results.

# **Selection of tests dependent on**

**Need**

**Analytical quality**

**User friendliness**

**Clinical setting**

**Costs**

**Better outcome for patients**

*Start with POC*

?

**Decreased costs  
for society/clinician**

**Increased costs  
for society/clinician**

?

*Do not start with POC*

**Poorer outcome for patients**

# Recommendations

## Basic repertoire at the doctors office

**Hb**

**Glucose**

**CRP**

**ESR**

**Urine strips**

**Blood i faeces**

**HCG**

**Streptocock A-  
antigen**

**Mononucleosis**

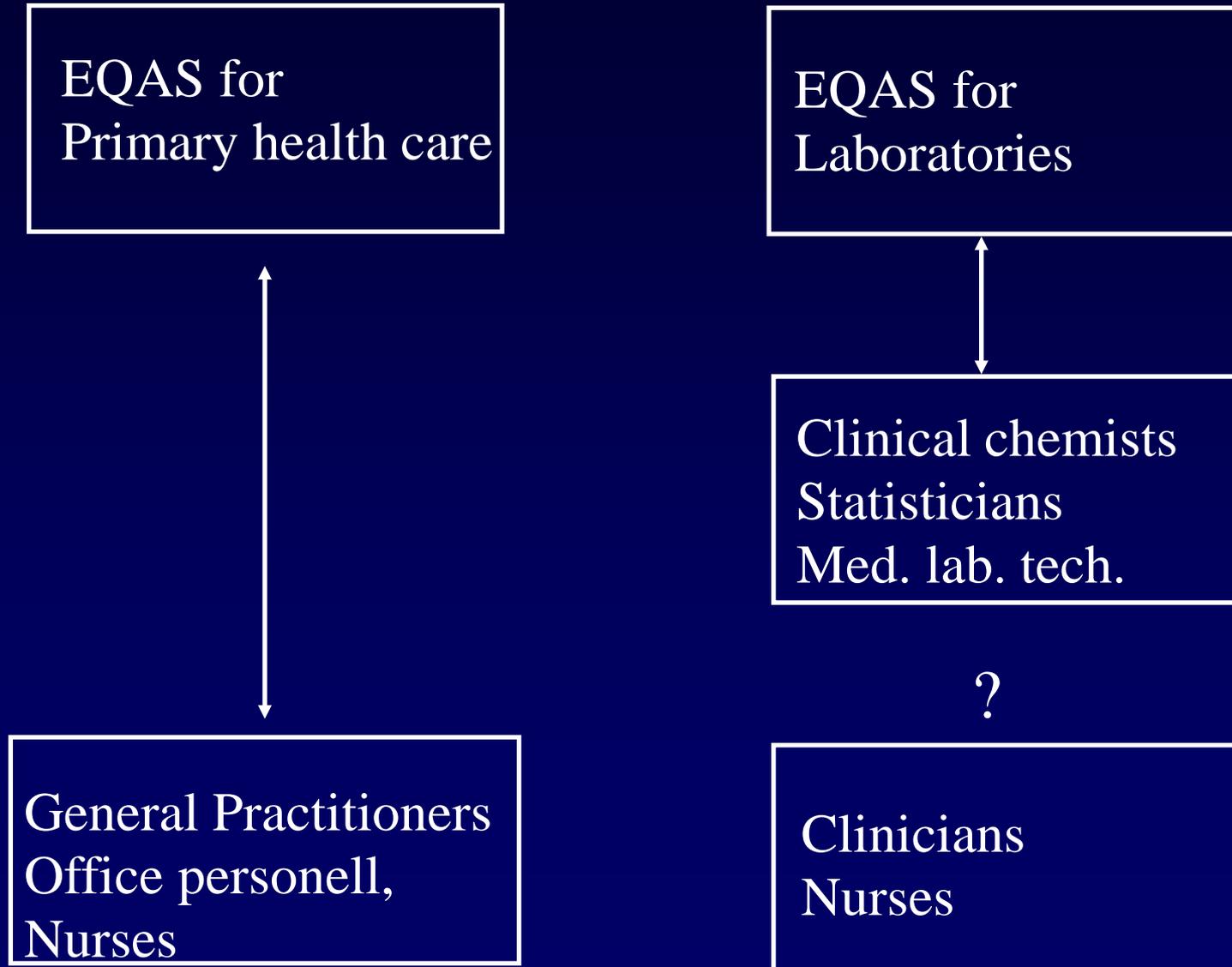
# Reimbursement

**NOKLUS is in dialogue with the Norwegian government and the Norwegian medical association concerning which tests that should be reimbursed**

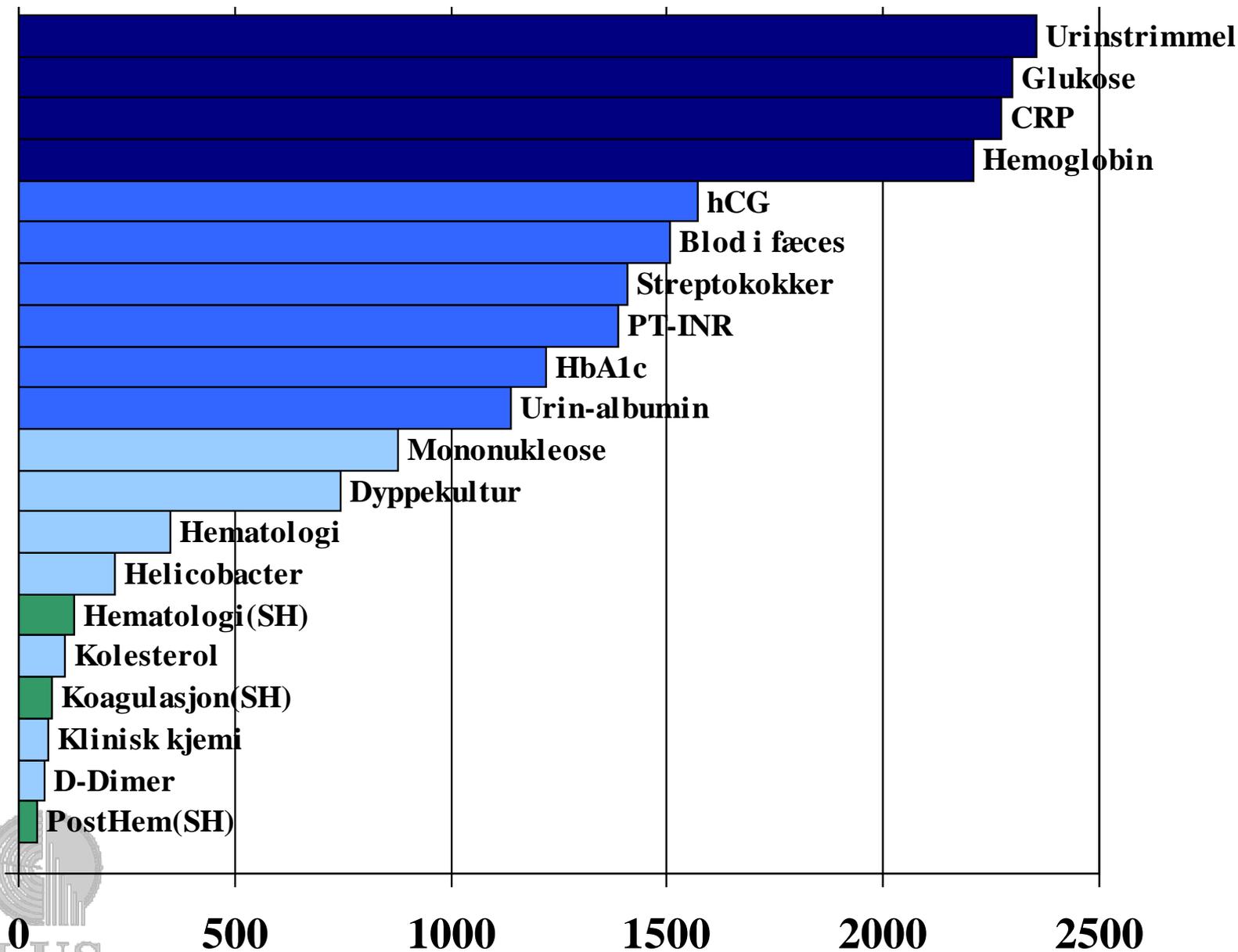
# What are the needs of the physicians and the patients?

- Which constituents that shall be requested and where they should be analysed.
- That the results are correct.
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# EQAS for primary health care and hospital laboratories



# *EQA Schemes for Primary Care*



# **What about internal quality control?**

**It is difficult to convince clinicians that it is important.**

**Is it important?**

# **How correct should the result be?**

**What analytical quality specifications do clinicians expect.**

**They do not know much about trueness and imprecision. If asked directly, they usually expect zero error**

**If asked indirectly, the situation is different.**

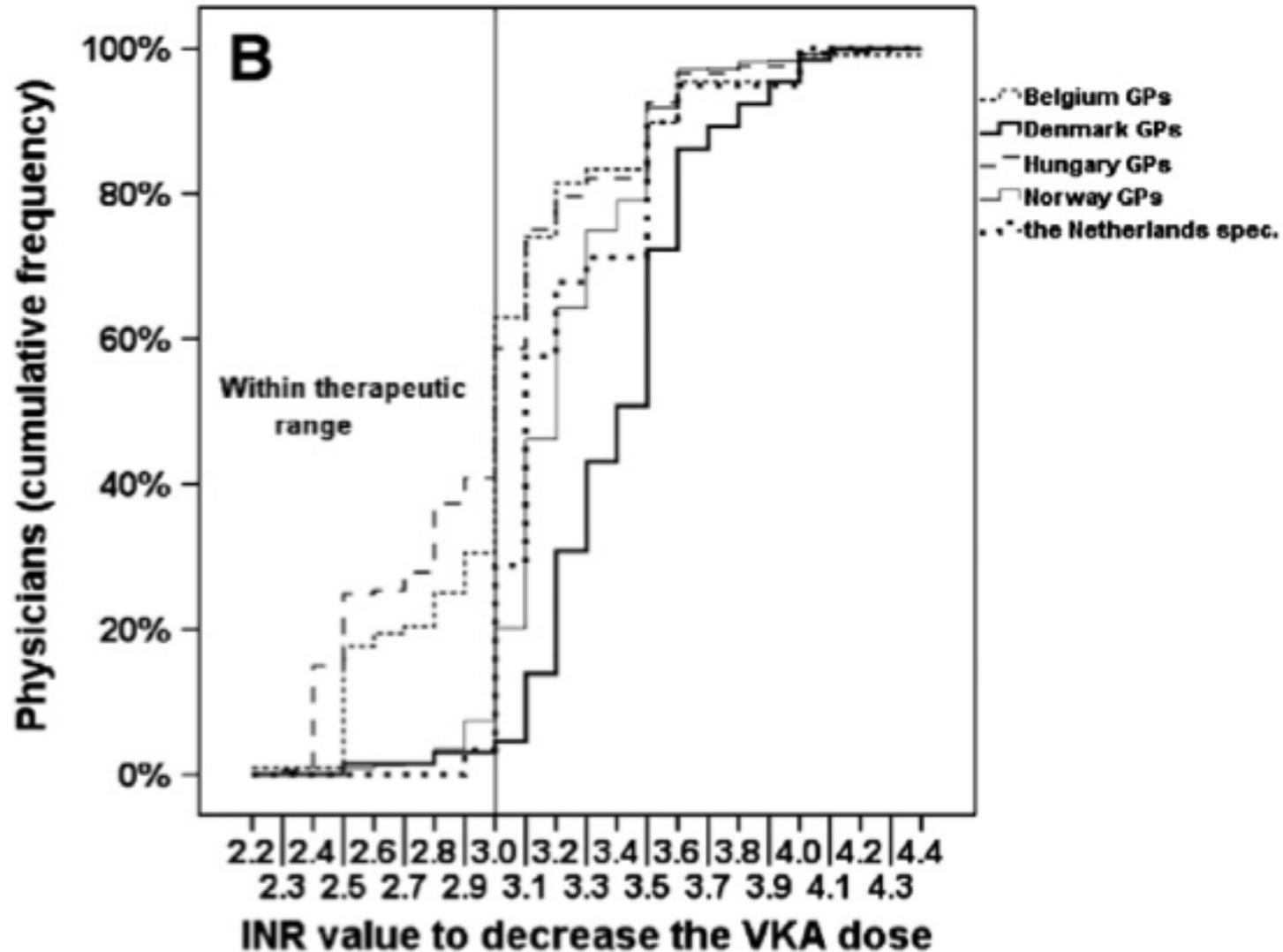
# INR

The patient is a 76-year-old man with permanent atrial fibrillation and hypertension who is treated with warfarin and antihypertensives. The therapeutic interval for this patient is INR 2.0-3.0 (target INR 2.5). He is otherwise healthy and is feeling well at the moment. His INR results have been stable, and have varied between 2.0 and 2.8 during the last months.

His INR today is 2.3, and you decide not to change the warfarin dose.

If you were to decrease his warfarin dose, how high must this next INR value be? \_\_\_\_\_.

# Change from 2.3





# Difference between two results

## Calculations of CD or RCV

$$CD = z \cdot \sqrt{2} \cdot \sqrt{CV_{ws}^2 + CV_a^2}$$

$$CV_a = \sqrt{(CD / z \cdot \sqrt{2})^2 - CV_{ws}^2}$$

**Clinicians react close to a  
decisions limit.**

**When calculated the  
expected CVa for INR POC  
instrument was about 3.4**

# HbA1c

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**A 45 year-old, considerably overweight woman with 5 children. She was diagnosed with type II diabetes 4 years ago and you are her physician. Her diabetes treatment was a total daily dose of 7 mg glibenclamide and 500 mg metformine. She has a tight every-day schedule paying little attention to her diet and without time for exercise.**

# HbA1c

By consultation now the HbA1c is 9.1 % (DCCT value)

You do what you find appropriate.

What do you mean the HbA1c test-result should be at the next consultation for the value to indicate:

- A. *Better diabetes control:*  
HbA1c value must have decreased to at least .....%
- B. *Poorer diabetes control:*  
HbA1c value must have increased to at least .....%



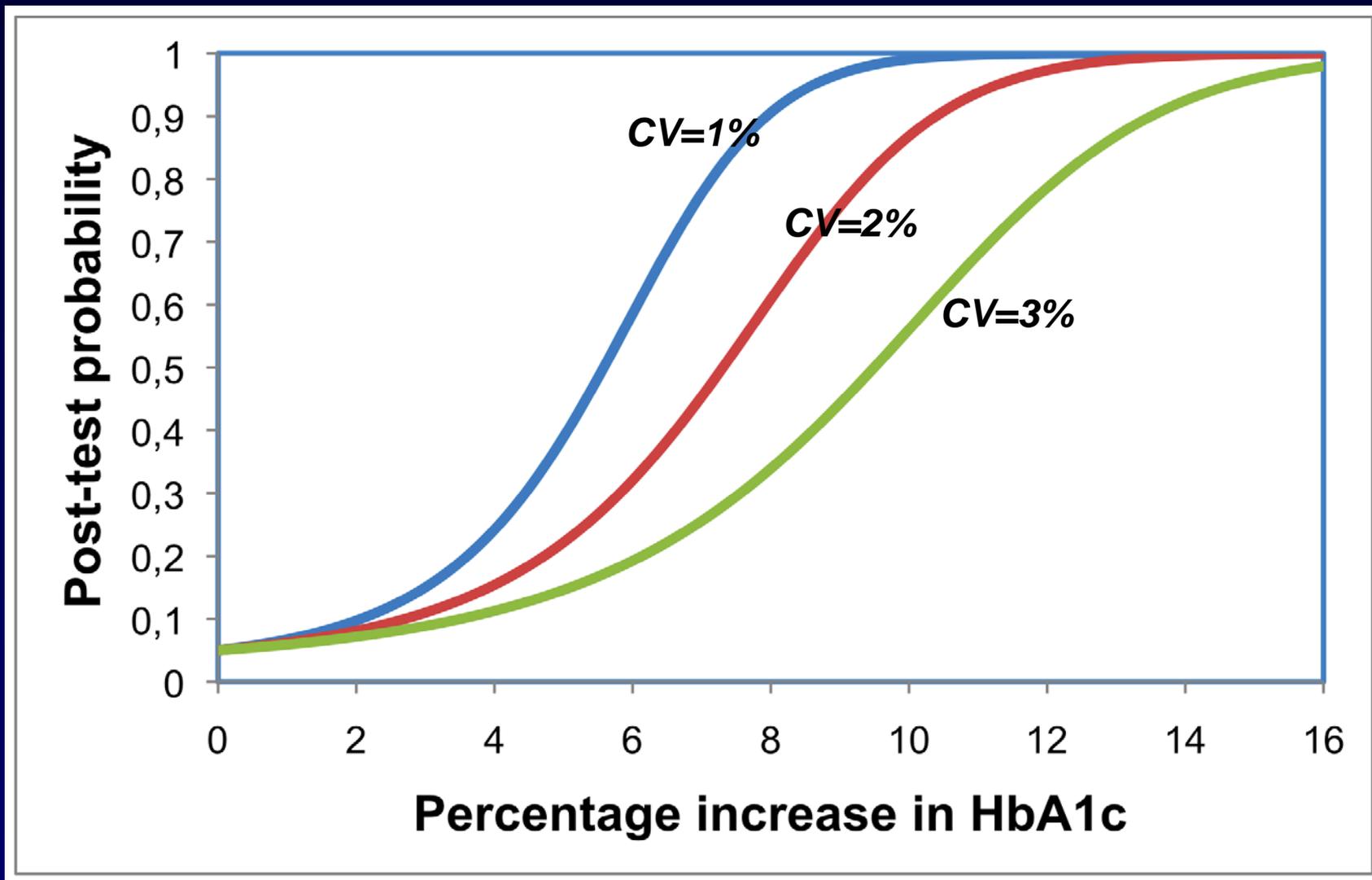
# **HbA1c**

## **– results from 7 countries**

**Median percentage change in HbA1c to indicate poorer or better control was 0.7 % (0.5 – 0.9) which corresponds to a 8% (0.7/9.1) change in HbA1c from 9.1**

**25 % would react on changes of less than 4%**

# HbA1c: Importance of analytical CV (pre-test prob. = 0.05)



# What are the needs of the physicians and the patients?

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- **Advices about what instruments to buy.**
- Correct interpretations of the results.

***Scandinavian evaluation  
of laboratory equipment  
for primary health care***

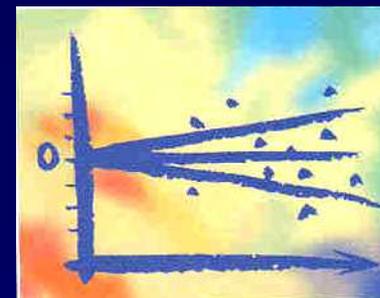
- SKUP provides neutral and independent information about quality and user-friendliness of point of care instruments



- SKUP provides high quality evaluations of instruments for the manufacturers

$$SD = \sqrt{\frac{\sum d^2}{2n}}$$
$$t_{0.05, v} \cdot \frac{SD}{\sqrt{n}}$$

- SKUP distributes the information, regardless of the results of the evaluations ([www.skup.nu](http://www.skup.nu))



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Choose component

## Summaries and Reports

<u>Evaluation #</u>	<u>Instrument/testkit</u>	<u>Summary</u>	<u>Report</u>
SKUP/2009/71	GlucoMen LX		 Download PDF
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Glucomen LX

Diaquick Strep A test



*Thank you*