Pre and post analytical PT

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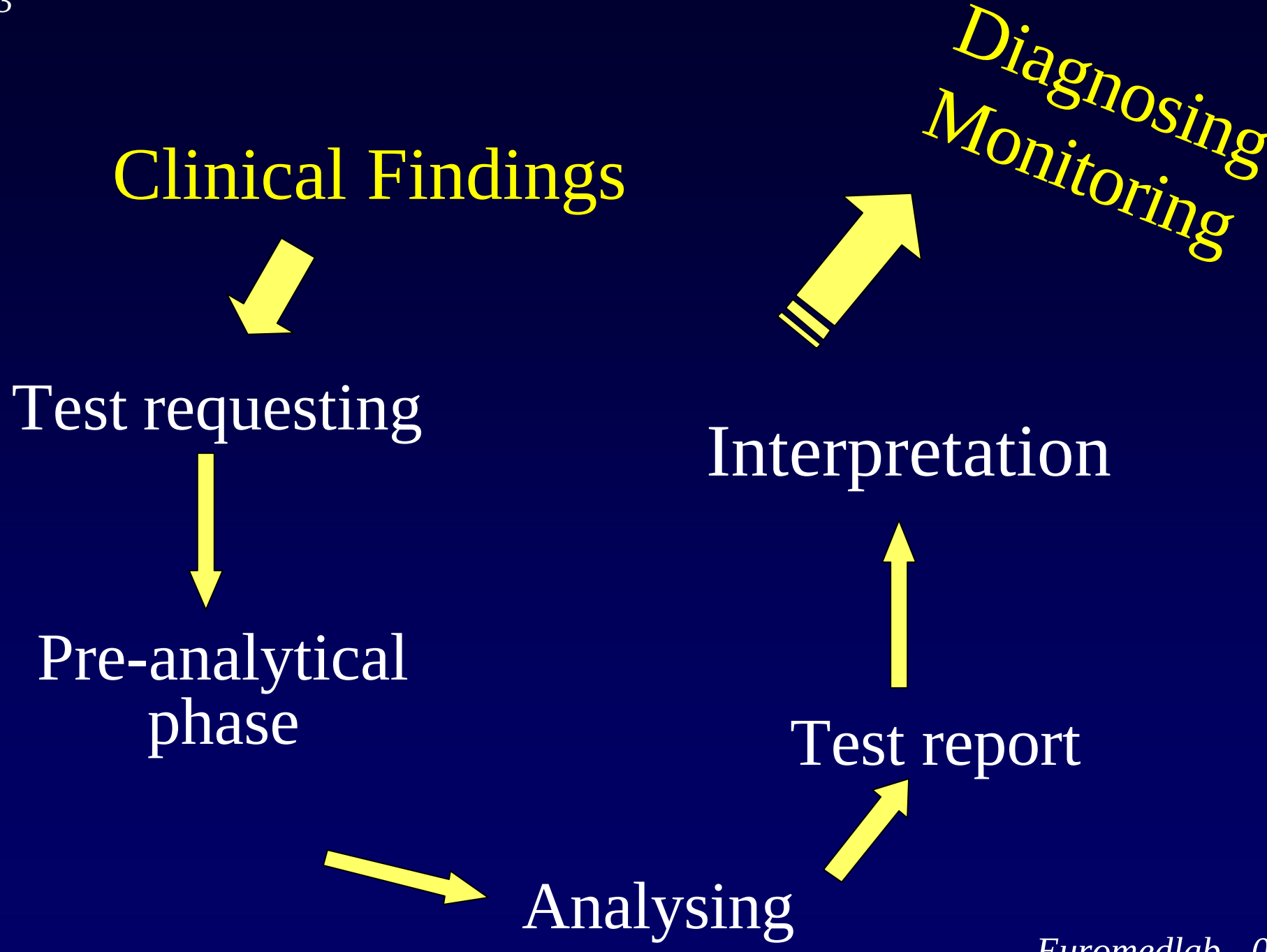
WHAT shall we look for?

Only analytical quality?

OR ALSO

What happens before and after the analytical phase?

Cartoon by courtesy of Amanda Burls


Clinical Findings
Test requesting
Pre-analytical phase
Analysing
Test report
Interpretation
Diagnosing
Monitoring

QuickTime™ og en
TIFF (LZW)-dekomprimerer

External quality assessment programmes should, as far as possible provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre- ad post-examination procedures

Pre-analytical quality assurance

Test requesting

- correct constituents to correct clinical problem

Sample taking

- who and how

Sample treatment

- centrifugation / extraction

Sample sending - exchange

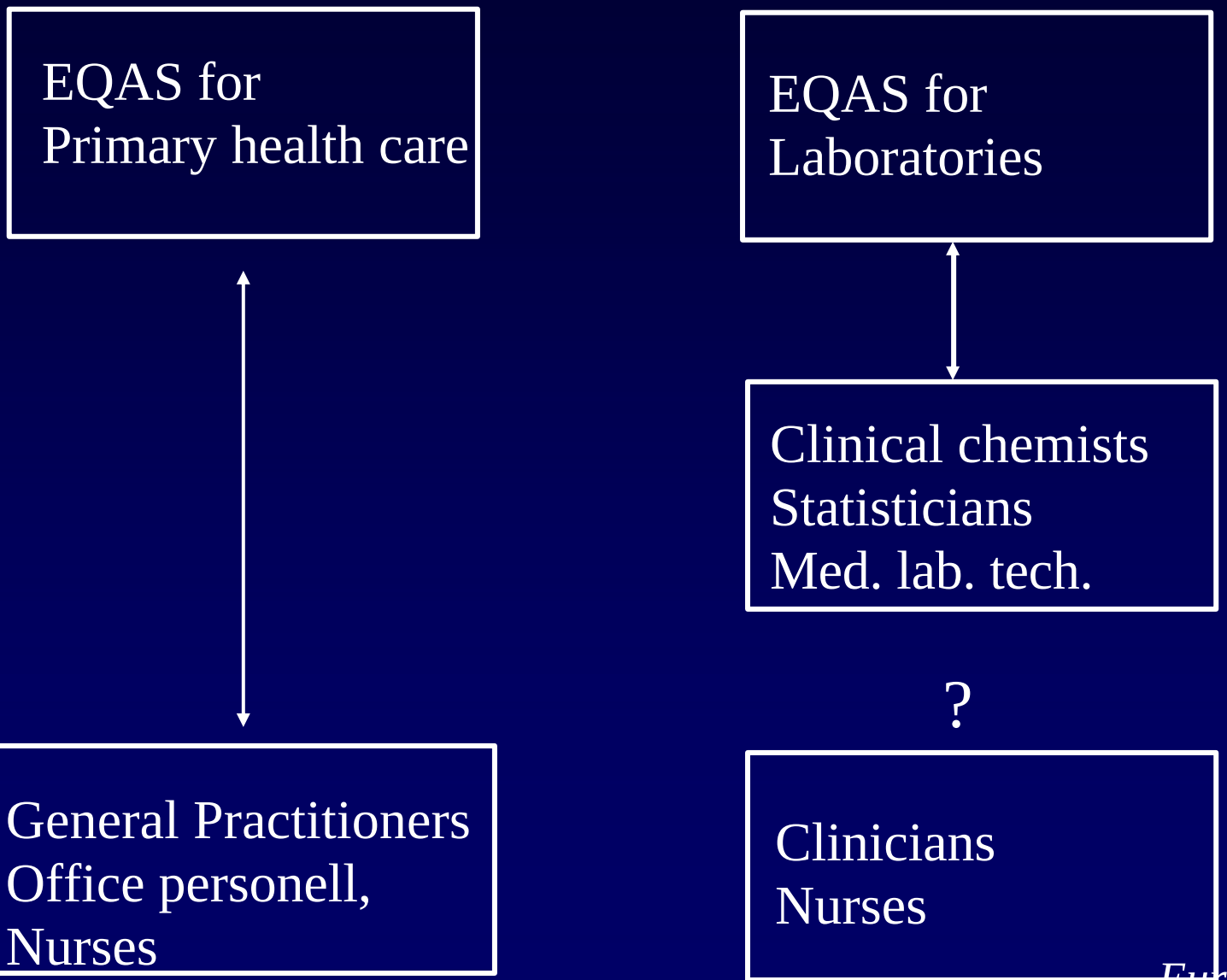
Post analytical quality assurance

How is the tests interpreted?

What do they do with the results?

Will it change the outcome of the patient?

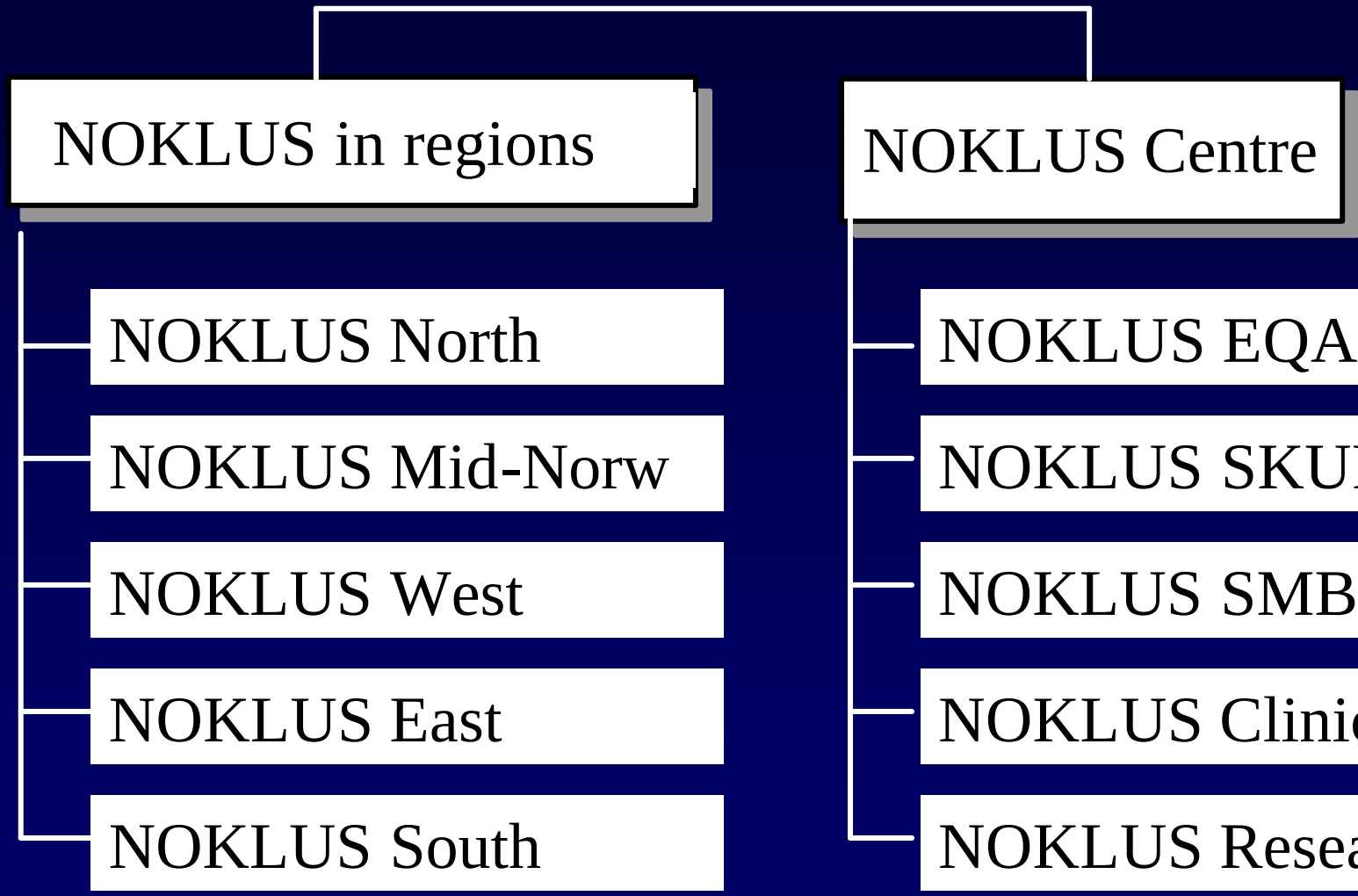
EQAS for primary health care and hospital laboratories



Development of Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS)

- EQA organisation
- Establishment of a consultant organisation
- Establishment of pre- and post-analytical EQAS

NOKLUS


NOKLUS in regions
NOKLUS North
NOKLUS Mid-Norw
NOKLUS West
NOKLUS East
NOKLUS South
NOKLUS Centre
NOKLUS EQA
NOKLUS SKUP
NOKLUS SMBG.
NOKLUS Clinic
NOKLUS Research

Post-analytical - P-EQAS

Primary health care

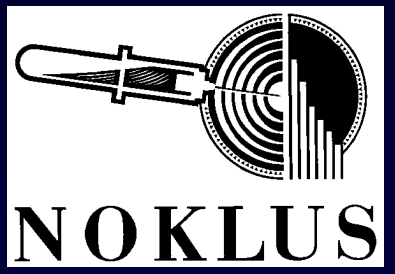
Urine strips

HbA1c

Hospitals laboratories

Automated haematology

Norwegian Centre for Quality Improvement
of Primary Care Laboratories



EQAS for analytes

P-EQAS for test interpretation

About 2000 doctors offices

About 4000 physicians

Design of P-EQAS of test interpretation

Together with the analytical control material, we routinely distribute 1-2 case stories typical for general practice in which the result from the analytical EQAS shall be used.

Urine strips

Mrs. Hansen, 65 years, is consulting you for control of the BP. She brings an urine sample and tells you about some pain during urination 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 WBC ____ *

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

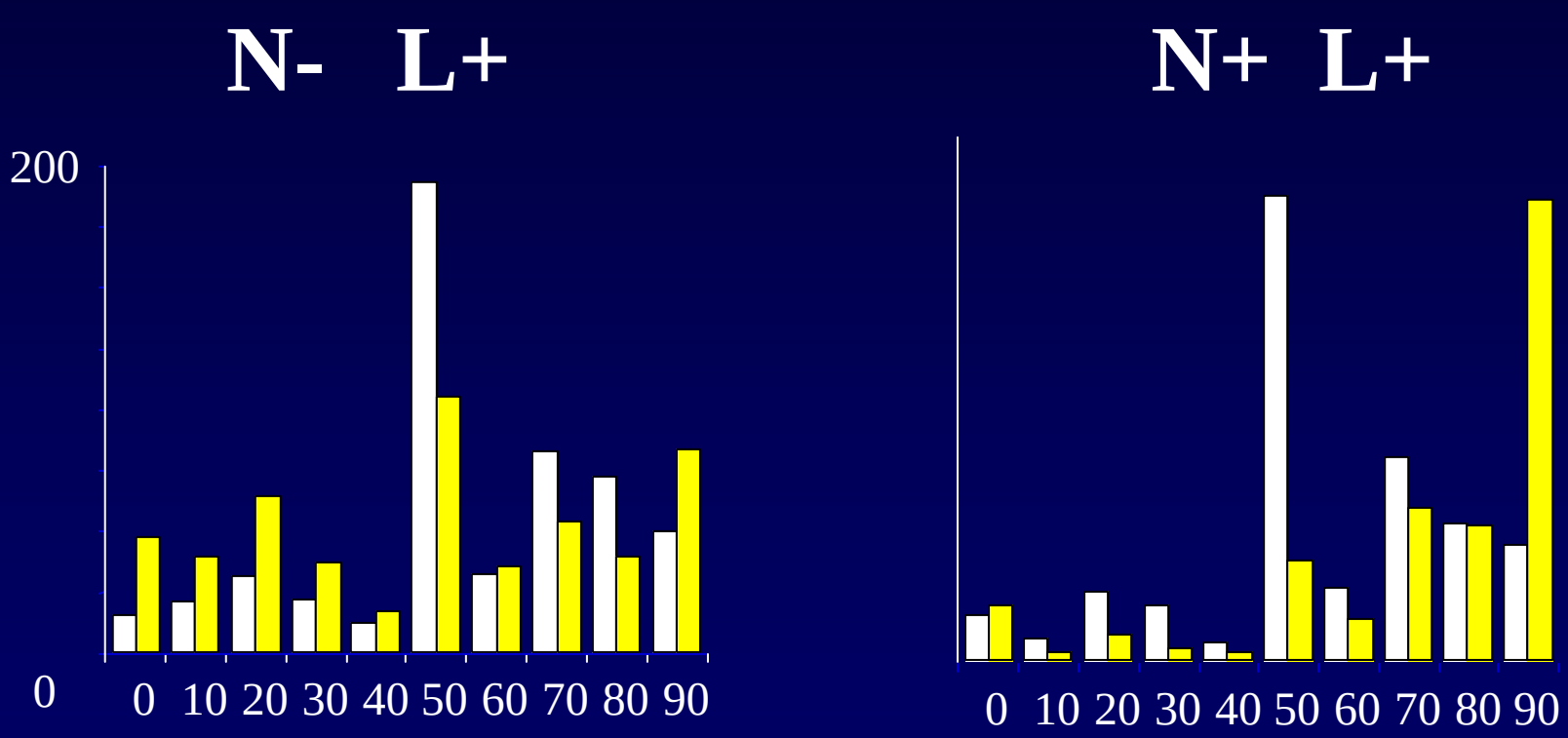
Urine strips

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



Pre- and posttest probability (%)

What were the consequences for the patient?

- High probability : More treatment of patients
- Probability around 50: Expect / more tests
- Low probability: do nothing

- BUT THERE WAS A LARGE VARIATION

Feedback report to the participants within 4 weeks. ONE page
- small group activity -

- *Information on*
  - Own results compared to others both analytically and ”clinically”
  - About urine test strips
  - About probabilities
  - Synopsis of guidelines for diagnosing urinary tract infection

Advantages of P-EQAS in general practice

Analytical performance can be directly linked to clinical actions.

It is possible to implement clinical guidelines in the feed-back reports.

Clinical Chemistry 51:7
1145–1153 (2005)

Evidence-Based
Laboratory Medicine
and Test Utilization

Postanalytical External Quality Assessment of Blood Glucose and Hemoglobin A_{1c}: An International Survey

Svein Skeie,[1*] Carmen Perich,[2] Carmen Ricos,[2] Agnes Araczki,[3] Andrea R. Horvath,[3] Wytze P. Oosterhuis,[4] Tanya Bubner,[5] Gunnar Nordin,[6] Rhena Delport,[7] Geir Thue,[1] and Sverre Sandberg[1]

Case stories distributed in:

- Hungary
- Norway
- Sweden
- The Netherlands
- Australia
- Spain
- South-Africa

HbA1c (”long-term blood sugar”)

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. She is taking tablets for her diabetes. She has a tight every-day schedule paying little attention to her diet and without time for exercise.

HbA1c

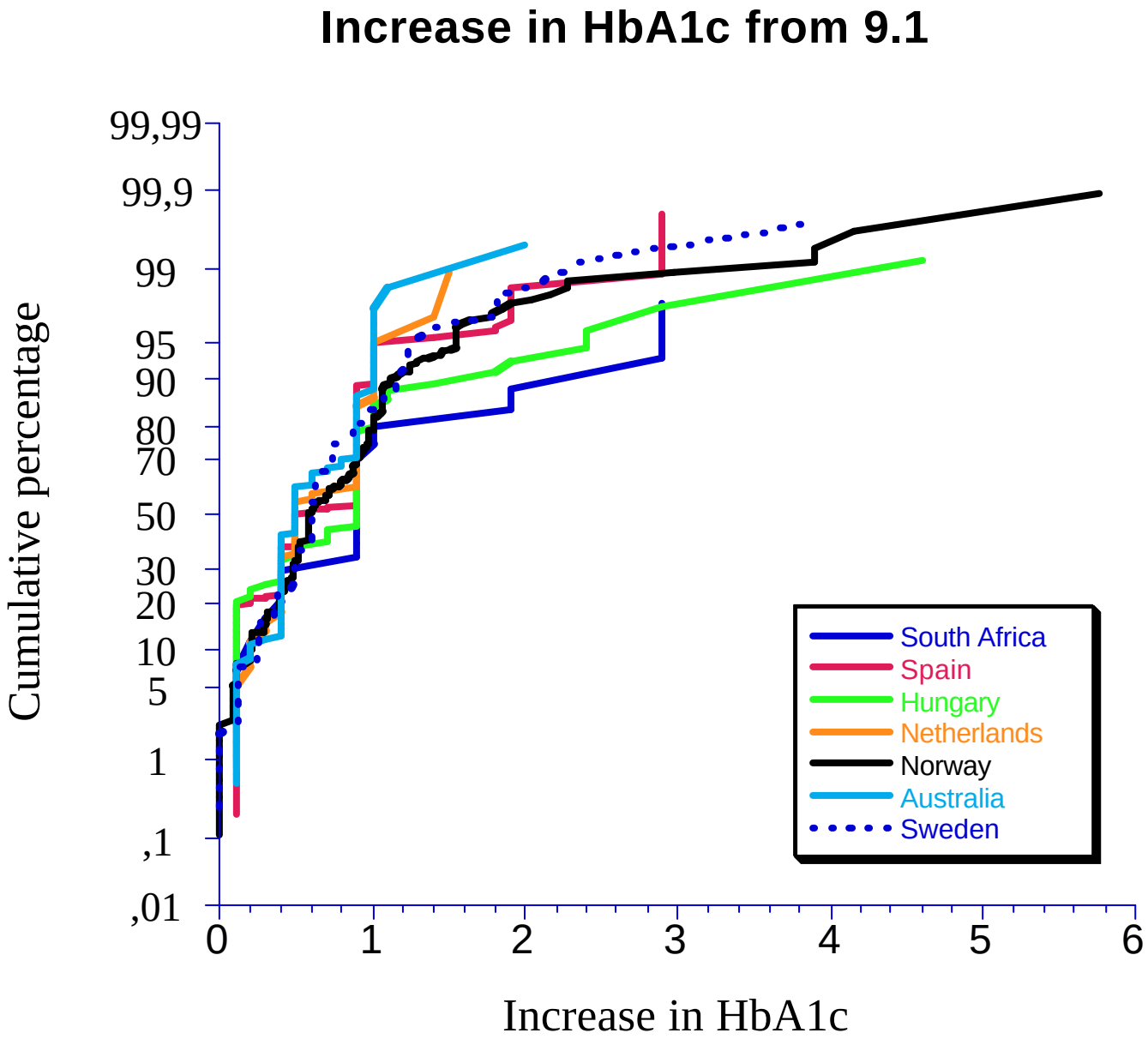
By consultation now the HbA1c is 9.1 %

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 …….%


Increase in HbA1c from 9.1
Cumulative percentage
99,99
99,9
99
95
90
80
70
50
30
20
10
5
1
,1
,01
0
1
2
3
4
5
6
Increase in HbA1c
South Africa
Spain
Hungary
Netherlands
Norway
Australia
Sweden

Feedback report to the participants

- Information on
  - Own results compared to others
  - Corresponding analytical quality
  - What differences that can be explained by analytical and biological variation
  - Interpretation of laboratory tests

P-EQAS for hospital laboratories
NKK / EQUALIS / NOKLUS

Example: Automated haematology

P-EQAS in Automated Haematology in Norway and Sweden

- Survey has been carried out two times
- (1) - 58 laboratories participated
- (2) - Most laboratories in Norway and Sweden

PLOT 1

Software Version: R8-1: Analyzer S/N: 32106AB

CELL-DYN 4000 Laboratory Worksheet 30/06/99 10:55

Sequence #: 905 Autoloader r03t03
Patient/Human
Specimen ID: 20192701
Name:

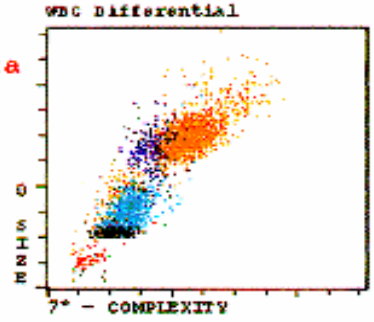
Test Selection: CBC+RETC+R
Param Set(Chart Page): 1
Limit Set: 2
Run Date/Time: 29/06/99 09:57

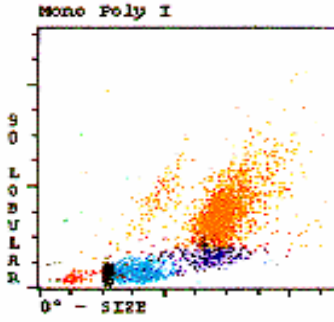
X-B	WBC	RBC	PLT	RETC
In	In	-	-	-
				*InvalidData

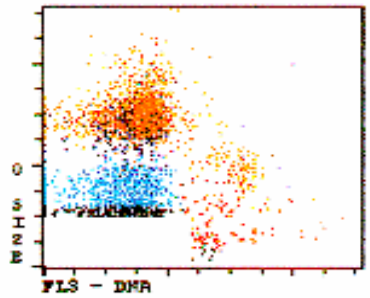
WBC	6.46 10e9/l	WVF	.953		
SEG	4.35	%S	67.3		
BAND	0.00	%BD	0.00		
IG	0.00	%IG	0.00		
BLST	.007	%BL	.101	BLAST	.52
MONe	.633	%Me	9.80		
EOS	.015	%E	.235		
BASO	.004	%B	.067		
LYMe	1.46	%Le	22.5		
[illegible]RL	0.00	%VL	0.00		

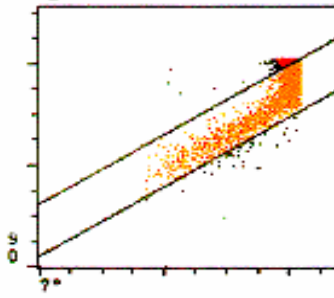
RBC	3.37*10e12/l	RBCo	2.78*
HGB	9.19 g/dl		
HCT	.284*L/l		
MCV	84.2*fL		
MCH	27.2*pg		
MCHC	32.4*g/dl		
RDW	29.4*%		
RETC	102.*10e9/l	%R	3.01*
IRF	.373*		IR
NRBC	.187 10e9/l	NR/W	2.89

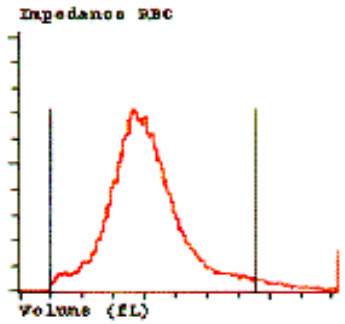
PLTo	764.*10e9/L	PLTi	103.*
MPV	15.9*fL		
PDW	22.8*10(GSD)		
PCT	12.1*mL/l		

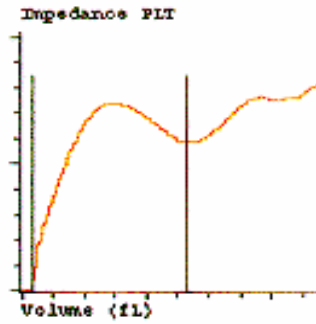












Lower, Upper, or Lower and Upper Region Interference in PLT Histogram
PIC/POC Delta
RIC/ROC Delta

Plot 3.
Infectious mononucleosis
”kissing disease”

16 year old girl hospitalized in the ear-nose-throat dept. with fever and swollen glands. The results are from the first bloodsample taken.

White blood cells and haemoglobin were requested.

RESULTS

WBC:	14,5	10^9/l
Hb:	13,7	g/dl
PLT:	110	10^9/l

DIFF:

Neutro %:	23	%
Lymfo %:	72	%
Mono %:	5	%
Eos % :	0	%
Baso %:	0	%

Variant/atyp lymph, Blasts

LUC(H*2): 15 %

Before reporting the results-would you obtain more clinical information?

13% of the labs would have obtained more information.

What would you have reported?
(WBC and Hb were requested)

All laboratories would report the WBC and Hb from the instruments.

Additional parameters reported from 39 lab (50%):

PLT:	17 lab.
DIFF.:	16 lab
CBC:	3 lab
Blast flag	1 lab.

Examples of some text comments reported

Technical comments : ”PLT validated by manual count in microscope”

Printouts will be sendt to the ward with the result from the examination of the film

Diagnostic comments: ” Lymphocytosis with activated /reactive lymphocytes, scatterplot and smear is compatible with MNI or other viral infection.

P-EQAS haematology

Most of the participants were positive to the P-EQAS. ..”this might be the first step to standardise the way we should answer and make the answers as equal as possible... ”

There are large differencies between the laboratories concerning what results they report and what actions they take before reporting them (although they have similar and excellent analytical quality).

Conclusions

As the analytical quality now is improving and under control, more and more focus should be given to the pre- and postanalytical phase.

Quality assurance of the postanalytical phase can be implemented in the usual external quality assurance EQAS as P-EQAS.

EU water directive

Trueness = 10%

Precison = 10% (acceptable precision = 20%)

What are the conclusions for the laboratories?

What are the consequences?

Are the labs closed?

Is the water supply stopped?

The way forward…

We have established an excellent communication system.

Why not use it for establishing systems for better communication with the users, to assess that test results are used correct and to implement guidelines?

ifcc
International Federation
of Clinical Chemistry