Practical aspects of common reference intervals including external quality assessment

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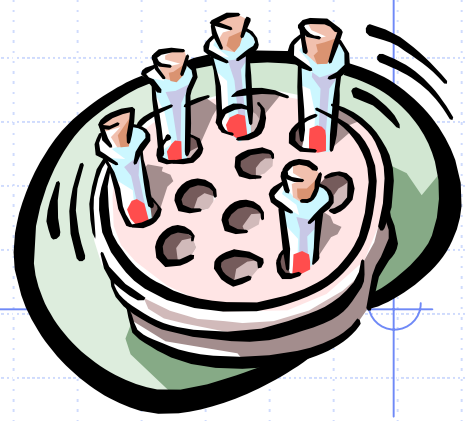

The NORIP project has

- **… done a very good job!**
- …done the work for which the manufacturers should be responsible….
- …used CAL and X to calibrate the measurements while waiting for reliable calibrators from the manufacturers

The reference value a part of an vitro medical device!

Annex 1 ESSENTIAL REQUIREMENTS

8.7. Where appropriate, the instructions for use must contain the following particulars:

- (l) the reference intervals for the quantities being determined, including a description of the appropriate reference population;

Different types of traceability to NORIP…

- Participating laboratories still using the same methods as during the data collection –
- Participating laboratories using new methods
- Not participating laboratories using the same methods as have been evaluated in NORIP
- Not participating laboratories using methods which not yet have been evaluated in NORIP

The practical aspects of NORIP

- We need simple rules to introduce and use NORIP
  - Conservative categorisation of data
  - Easy to follow
    - validation procedures for new methods and calibrators with the use of X, CAL, P and HK02
    - validation procedures for new participants

Suggestions

- All laboratories in the Nordic countries should be recommended by NFKK and the national societies to implement NORIP reference intervals
  - Reasonable time table - during 2003?
- Information material from NFKK and the national societies concerning information about NORIP to be presented for
  - Laboratories and clinicians
  - Patients and other end users
  - Professional journals
  - Professional meetings

Some items still open for discussion…..

- Common reference limits for serum and heparin plasma?
  - Not potassium
- Correction for preanalytical dilution of samples for hematology
- And the enzymes
  (we will listen to Heidi Stensland)

The role of EQA

- To monitor and report on method bias and calibration bias
- To collect specific information in order to evaluate calibrators in use
- A yearly Nordic survey specially designed to follow up the use of NORIP

”NQLM trueness project” 2002

- See EQAnews 13(1) 2002, pp 7-9
- Links from IMEP-17 sera to Materials “CAL”, “HK02” and “X”
- 136 participants
  - DK (55), FI (12), IS (1), NO (50), SE (18)
- Samples run in parallel March/April 2002
- Results reported on Excel sheets via national EQAS organiser

NQLM trueness project 2002 Status report

- IMEP-17 reference method values will be final in August-02
- Participants' results (IMEP-17 and NQLM project) will be extracted/compiled August-02 by EQUALIS
- Information needed for evaluation in NORIP can at best be transferred from EQUALIS September-02. Further responsibility needs to be agreed on

What will happen after the introduction of NORIP?

- Discrepancies will be discovered
  - Between different calibrators
  - Between data from the manufactures on biological reference interval and NORIP reference interval?

We need a continued NORIP project in cooperation with the industries to discuss and solve these problems.