Specifics and challenges of EQA in Croatia

Jasna Leniček Krleža, Ph.D.
Presentation content

- Overview:
  - Why are we specific (different?)
  - What are our major problems (challenges)
  - Which activities of CROQALM Team are to be solved main problems in organizing and conducting EQA
  - What are the benefits of national EQA (CROQALM)
Timeline of EQA in Croatia

1953 – first record about conducted EQA in our regia

from 1973 – EQA was conducted continuously through Society of MB

2012 - Committee for EQA gets official name CROQALM

2013 – new composition of CROQALM

2018

CROQALM today

in this composition with minor modifications it still works today

> 50 years

Croatian Centre for Quality Assessment in Laboratory Medicine
**Why are we specific?**

<table>
<thead>
<tr>
<th>CCMB</th>
<th>ML</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ (2005) issued document: Harmonization of laboratory test reports for general, special and high-differentiated medical biochemistry tests – application is mandatory for all ML (refers to recommended methods, units, reference intervals) <strong>ADVANTAGE</strong></td>
<td>Number of registration ML in Croatia vary from 194 to 204 <strong>DISADVANTAGE</strong></td>
</tr>
<tr>
<td>✓ According decision of CCMB (2013), Croqalm EQAS is obligatory for all MLs in Croatia (for each test that ML works and test is part of the CROQALM scheme). <strong>ADVANTAGE/DISADVANTAGE</strong></td>
<td>A large number of different analysers/reagents <strong>DISADVANTAGE</strong></td>
</tr>
<tr>
<td>✓ (2012) issued document: Requests for CROQALM <strong>→ resulting in</strong></td>
<td><strong>→ our challenges</strong></td>
</tr>
<tr>
<td>✓ difficult choice of optimal (commutable) sample for a wide variety of analysers and reagents</td>
<td></td>
</tr>
<tr>
<td>✓ Small and numerous peer groups that can be statistically evaluated</td>
<td></td>
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</tbody>
</table>
Who is responsible to whom...

**Medical laboratories (ML)**

- **Croatian Chamber of Med. Biochemists (CCMB)**: Responsible for licensing and professional supervision.
  - Licenses for work.
  - Annual report for each ML.

- **CROATIAN MINISTRY of HEALTH**: Responsible for accreditation requirements.

- **HAA (Croatian Accreditation Agency)**: Responsible for annual reports and license requirements.

- **CSMBLM Main Board**: Responsible for confidentiality of data.

- **Law on Confidentiality of Data**: overseen by the Main Board.
How are we organized?

Tim/Center/Commission within the CSMBLM

9 members (specialists, trainees)

VOLUNTEERS

According to the working groups for:
- Making and work on web site
- Improving the quality of the sample
- Improving the program for data evaluation
- Education

UNPROFITABLE

Financial strategy

Due to the responsibilities and assessment of MLs - a professional improvement strategy is required

According modules (11 modules):
- 10 analytical modules (schemes) and 1 for extra-analytical phase

Coordinators for modules

organization on two levels
Where are we now?

External quality assessment (EQA) scheme in Croatia

- 10 analytical modules with different number and type of analytes per module
- The control samples distributed three times per year, depending on the participants' application and the module schedule
<table>
<thead>
<tr>
<th>Module</th>
<th>Name of the module</th>
<th>No of round per year</th>
<th>Type of control sample</th>
<th>Number of participants (in 2018)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Biochemistry parameters</td>
<td>3</td>
<td>liquid frozen control sample (pool, WEQAS)</td>
<td>180</td>
</tr>
<tr>
<td>II</td>
<td>Specific proteins, CRP</td>
<td>3</td>
<td>Commercial human based control sample (lyophilized or liquid)</td>
<td>168</td>
</tr>
<tr>
<td>III</td>
<td>Laboratory haematology</td>
<td>3</td>
<td>Stabilized whole blood from blood donor</td>
<td>183</td>
</tr>
<tr>
<td>IV</td>
<td>Laboratory coagulation</td>
<td>3</td>
<td>Commercial control sample (lyophilized plasma sample)</td>
<td>164</td>
</tr>
<tr>
<td>V</td>
<td>Drugs</td>
<td>1</td>
<td>Commercial control sample (lyophilized)</td>
<td>17</td>
</tr>
<tr>
<td>VI</td>
<td>Urinalysis: urine test strip, sediment</td>
<td>3</td>
<td>Commercial human based sample (liquid)</td>
<td>178</td>
</tr>
<tr>
<td>VII</td>
<td>Analysis of pH, blood gases, electrolytes, glucose and lactate</td>
<td>3</td>
<td>Commercial control sample (liquid)</td>
<td>70</td>
</tr>
<tr>
<td>VIII</td>
<td>Hormones, vitamins, tumor and cardiac markers</td>
<td>2</td>
<td>Commercial human based control sample (lyophilized)</td>
<td>94</td>
</tr>
<tr>
<td>IX</td>
<td>Glycosylated hemoglobin A1c (HbA1c)</td>
<td>3</td>
<td>Commercial human based control sample (lyophilized)</td>
<td>151</td>
</tr>
<tr>
<td>X</td>
<td>Extra-analytical phase of laboratory testing</td>
<td>3</td>
<td>Questionnaire design: 1st and 2nd phase: Distributed samples (simulating errors)</td>
<td>168</td>
</tr>
<tr>
<td>XI</td>
<td>Sweat chloride test</td>
<td>3</td>
<td>Liquid control sample (home-made)</td>
<td>8</td>
</tr>
</tbody>
</table>
## Education

### Two levels:

<table>
<thead>
<tr>
<th>Education of CROQALM members</th>
<th>Education of participants (ML)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CROQALM workshop (2015; CSMBLM)</td>
<td>Lectures/Seminar in regional centers</td>
</tr>
<tr>
<td>DEKS (Danish Institute of External Quality Assurance for Laboratories in Health Care) education</td>
<td>E-seminar CSMBLM (sweat test)</td>
</tr>
<tr>
<td>Active participation in EQALM (workgroups of EQALM, posters presentations)</td>
<td>Poster presentations at national and international professional meetings (Sarajevo 2015, Dubrovnik Course 2015 EQALM 2015, 2016, Locus 2016)</td>
</tr>
<tr>
<td><strong>Croatia - host country for EQALM Simposium 2018</strong></td>
<td>Publishing results (BM, CCLM)</td>
</tr>
<tr>
<td></td>
<td>Organizing the Symposium: „National EQA: From sample to judgment”</td>
</tr>
</tbody>
</table>
bilingual (English/Croatian) web site

http://croqalm.hdmblm.hr
Application for participation and results entry/evaluation

is done through a web interface

- using inlab2*QALM software (IN2 Group Ltd., Zagreb, Croatia) as a program for the evaluation of quality in laboratory medicine
Statistical evaluation of quantitative results

- at the end of each exercise
- for each peer group with five or more participants
- after outlier removal (Tukey), mean, standard deviation and coefficient of variation is calculated for each peer group.

- the data are further evaluated according to:
  - predefined allowable limits of performance
  - z-scores with graphical presentation
In 2017 CROQALM defined analytical performance specifications according to:

**Model 1:** Based on the effect of analytical performance on clinical outcomes
- Direct outcome studies
- Indirect outcome studies

**Model 2:** Based on components of biological variation

**Model 3:** Based on state-of-the-art
(only where BV isn’t possible)

**Absolute allowable deviation** from target value at low concentrations

Reports
(at the end of every exercises)

Each laboratory receives:
- Statistical analysis for every analyte
- Summary Report
- Scheme coordinator comments
Annual Report

For:

- Participants (Certificate of participation with an indication of the scheme in which they participated)

- CCMB (report of acceptable results per exercise for each ML – used in professional supervision)
What are benefits of our national EQA?

or why to maintain and improve a small, national EQAS when there are available well-established international EQA providers?

Because:
1. Adapted to our system of professional legality
2. Have an acceptable price for our conditions

This is sustainable because:
• members are volunteers
• each participant (ML) also participates as a professional responsible person
CROQALM members....

all members are:

EuSpLM and work in ML (Hospital or Private ML) and are volunteers for CROQALM and CSMBLM)
THANK YOU!

Have a useful and nice time in Zagreb