Interpretative comments and reference ranges in EQA programs as a tool for improving laboratory appropriateness and effectiveness

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Abstract

Introduction: Laboratory information is generated when a meaning is given to certain data. This is usually achieved by comparing a laboratory test result with the reference range/decisional limit (RL), and by providing consultation for the interpretation of data, advice, and follow-up testing. Aim: In this paper, we investigate factors affecting the conversion of data into useful information with regard to biochemical markers of myocardial damage (CK-MB mass, myoglobin, and troponins), in view of their importance in detecting myocardial necrosis. Our aim was to report results obtained in order to verify the consensus between laboratories with reference to interpretative comments and the reference ranges/decisional limits added to clinical reports. Methods: A questionnaire and simulated medical reports on three different patients were distributed to participants (94 laboratories) in the 2001 cycle of the External Quality Assessment (EQA). Moreover, we analysed 113 medical reports sent by laboratories during the most recent EQA cycle 2002, and checked the number of different RLs used, both independent and within the diagnostic system used. We also compared each laboratory result of a control sample, obtained in the 2002 cycle, with declared RL in order to verify the clinical significance of results ("normal" or "pathological") for troponin I and CK-MB. Results: Our findings show that few laboratories regularly add interpretative comments to medical reports. On the contrary, they cooperate with clinicians who require consultation, advice, and information for the appropriate use of biochemical markers. There is a general consensus among participants regarding probable syndromes suggested by the interpretation of the same result and most laboratories also agree on further investigations to be carried out for several diseases. Concerning RL, the data demonstrate that numerous different RLs are used to report the results of the biochemical markers evaluated, both when considered independent of the diagnostic system used and within the diagnostic system used. Discussion and conclusions: The biochemist does not have the opportunity to verify the efficacy of the interpretation that he/she provided. An audit of this activity is therefore required to allow the laboratory to monitor its own performance and to assure good practice. The evaluation of interpretative comments, through specific surveys, should be a prime objective of EQA organisers. Well-designed EQA programs can, moreover, support laboratories in establishing appropriate RL and in verifying the clinical significance of their results with respect to that of other laboratories.

Our survey on interpretative comments and the analysis of the RLs further demonstrate how laboratory medicine can contribute to the objective evaluation of the patients’ health status.

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Keywords: Interpretative comment; Reference range; Biochemical markers of myocardial damage; External Quality Assessment; Laboratory performance assessment; Quality improvement

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1. Introduction

The performances of clinical laboratories play a fundamental role in the quality and effectiveness of health care. Clinical laboratory tests are important in medical practice because laboratory information is essential to the diagnosis and management of patients. Laboratory information is generated when a meaning is given to certain data. This is usually achieved by comparing a laboratory test result with the reference range/decisional limit (RL), and by providing consultation for the interpretation of data, advice, and follow-up testing. The laboratory is thus responsible for ensuring that results and interpretations are reliable. It can, moreover, contribute to the effective utilization of laboratory tests to improve outcomes for both the patients and the health care service.

Assessing the effectiveness of clinical laboratories and their contribution to effective outcomes involves several items, including: turnaround time; sample identification and labelling; correct selection of investigations to be performed; correct collection and transport conditions; accurate recording of laboratory results, which are then reported to the appropriate person for correct interpretation and subsequent action; an extensive system of training for all laboratory staff; and the maintenance of high standards in laboratory techniques. To guarantee the quality of the laboratory information provided, it is therefore of paramount importance to take into account all aspects affecting quality and to establish new evaluation criteria and ways of assessing all items in the total process [1–7].

External Quality Assessment Schemes (EQAS) are an integral part of most laboratories’ overall quality assurance systems. So far, they have mainly considered the achievement of consensus between laboratories, focusing specifically on the analytical phase of the process. Currently, the EQA programs should be used as a tool for quality improvement in the entire laboratory process, and should evolve and extend assessment to other aspects by means of specific surveys [8].

The Center of Biomedical Research (CRB) has managed EQAS in Italy since 1985, promoting trials on specific topics that arise within EQAS [9–12].

In this work, we investigate factors affecting the conversion of data into useful information with regard to biochemical markers of myocardial damage (CK-MB mass, myoglobin, and troponins), in view of their importance in detecting myocardial necrosis [13–21].

Our aim was to report results obtained in order to verify the consensus between laboratories as regards interpretative comments and reference ranges/decisional limits added to clinical reports.

2. Interpretative comment

Adding a brief interpretative comment to the patient’s results report and/or giving advice on any action that should be undertaken represents an essential tool for adding value to laboratory reports. Although the discussion of each result with the requesting clinician should represent the “gold standard,” in the real world, time for this is not always available because numerous reports must be released every day. The addition of brief comments to reports has thus become a valuable indirect means of communication between biochemists and clinicians [22].

Guidelines and standards emphasize the importance of adding appropriate comments to medical reports and their assessment. CPA Accreditation Standards, as well as the ISO 15189 International Standard, stress that the interpretation of results by clinical laboratories is an important aspect of the service they provide [23–25].

As stated by the Clinical Pathology Accreditation (UK)’s Standard for the Medical Laboratory, Version 1 (January 2001):

- G5—“The provision of interpretative comments on reports is an essential role of the laboratory service. The frequency of such comments may vary by specialities.”
- G5.1—“Laboratory management shall ensure that advice on examinations and the interpretation of results is available to meet the needs and requirements of users.”
- G5.2—“Interpretative comments on reports shall be clear, succinct, and unambiguous.”
A survey has been conducted by the CRB to investigate strategies used by laboratories for the provision of interpretative comments for these new tests in laboratory reports.

2.1. Methods

A questionnaire (Fig. 1) and simulated medical reports on three different patients were distributed to participants (94 laboratories) in the 2001 cycle of the Biochemical Markers of Myocardial Damage EQA.

The simulated medical report included:

- age and sex of the patient: a 55-year-old male;
- admission department: first aid ward (emergency department);
- brief clinical notes: chest pain;
- the results of troponin I or T, CK-MB mass, and myoglobin tests, showing different degrees of severity, and related decisional limits (Fig. 2);
- three blank spaces for interpretative comments; and

![EQA Program for Biochemical Markers of Myocardial Damage](image)

**QUESTIONNAIRE**

To communicate cardiac markers results:

- Do you include interpretative comments? YES □ NO □

if so, as a routine, or in particular cases (please specify) ______

- Do the clinicians agree upon the use of these markers? YES □ NO □

if so, how do they use them? □ based on guidelines □ according to the internal protocol □ through verbal agreements

- Do the clinicians require advice from laboratory? YES □ NO □

if so, in which cases (please specify) ______

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Please send completed form to: Centro di Ricerca Biomedica – via Ospedale 18 – 31039 Castelfranco Veneto (TV) Fax 0423 732826

Fig. 1. Questionnaire sent to the participating laboratories.
The reports were relatively simple and therefore amenable to simple comments. Laboratories were asked to make comments that they would have made in routine practice.

2.2. Results

Sixty-six (70.2%) laboratories responded. The answers given in the questionnaire demonstrated that only a few laboratories added comments to medical reports (9%), particularly in the presence of clinical findings or in cases of interpretative doubts. Almost all participants (93.9%) agreed with clinicians on the use of these markers following internal protocol (46.8%), scientific guidelines (29%), and verbal agreements (16.1%). Some laboratories followed two paths: scientific guidelines and internal protocol (4.9%); scientific guidelines and verbal agreements (1.6%); and internal protocol and verbal agreements (1.6%).

Forty-six percent of the clinicians required advice to the laboratory, especially for interpretative doubts (40%), disagreement between laboratory results and clinical–instrumental findings (28.5%), specific requests (14.3%), further investigations (2.9%), and emergency cases (2.9%). A few laboratories (11.4%) provided no comments.

Regarding medical reports, the comments expressed and further investigations proposed reveal a diversity of opinion. Some comments and suggestions for further investigations are shown as follows:

### Report 1: Interpretative comments
- Acute coronary syndrome
- Acute ischemic heart disease
- AMI
- AMI in early phase (since 6–8 h ago)
- Probable AMI if there are clinical findings
- Probable AMI
- Suspicion of AMI since 6 h ago
- If electrocardiogram (ECG) is positive, AMI present for since 6 h ago
- AMI is not ruled out but further serial measurements are needed to confirm diagnosis

### Report 1: Suggestions for further investigations
- Measure CK, CK-MB mass, and troponin I at 3–6–9–12–18–24 h
- Monitor troponin and CK-MB mass after 4 h and then measure only troponin every 4 h
- Repeat troponin T and myoglobin after 3 h
- Measure markers and ECG at serial times
- Measure markers at 2 h and perform ECG
- Measure CK-MB mass at 6 and 12 h

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<table>
<thead>
<tr>
<th>Constituent</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 Results</td>
</tr>
<tr>
<td>Troponin I (μg/L) or Troponin T (μg/L)</td>
<td>0.31</td>
</tr>
<tr>
<td>CK-MB mass (μg/L)</td>
<td>7.2</td>
</tr>
<tr>
<td>Myoglobin (μg/L)</td>
<td>750</td>
</tr>
</tbody>
</table>

Fig. 2. Cardiac marker values of three different hypothetical patients sent to laboratories.
Report 3: Interpretative comments

- Evaluate other diagnostic hypotheses, such as myolysis of the skeletal muscle
- AMI cannot be ruled out, but a traumatic pathology of the skeletal muscle may also be suspected. Consider anamnestic data (time of pain onset, trauma to skeletal muscle, renal insufficiency) and further investigations (total CK, aldolase, creatinine) are required
- Diffuse skeletal muscle injury
- Probable angina—extremocardial
- Probable damage to skeletal muscle
- Probable extracardiac muscular involvement
- Rhabdomyolysis
- Renal insufficiency, myopathy, trauma
- Trauma, myopathy
- Past heart attack and recanalization
- Trauma to skeletal muscle

Report 2: Suggestions for further investigations

- Assess serial measures of CK-MB to estimate extent of the infarction
- Check trend of troponin I and CK-MB mass measures, possibly also during revascularization, with blood collection drawn three times on first day, and once on the following 3 days
- In the presence of angioplasty or thrombolytic therapy, measure myoglobin as indicator of reperfusion status
- Repeat biochemical markers every 6 h to monitor patient’s status
- Repeat biochemical markers once or twice a day to evaluate any complications
- To monitor reperfusion status, measure myoglobin (after 1 h), and to follow-up illness, measure troponin I every 24 h
- Measure, at time 0, troponin I and CK-MB; at 6 h, troponin I and CK-MB; and at 12 h, troponin I and CK-MB

Report 2: Interpretative comments

- AMI
- AMI hyperacute at 8 h since the development, probably thrombotic status-reperfusion required
- AMI since several hours standing
- Strong suspicion of AMI
- Recent AMI present in carrier of unstable angina
- Verify the agreement between ECG recordings and clinical findings by consulting cardiologists for therapeutic decision
- If pain is typical and/or ECG indicates signs of lesion, diagnosis of AMI is probable; conversely, myocardial infarct is suspected but other myocardiopathies or systemic myopathies are to be ruled out

Report 3: Suggestions for further investigations

- After diagnosis of AMI, monitor the extension of necrotic area, measuring the CK-MB peak
- At 2 h, control chest, X-ray, ECG, echocardiography (ECO)
- During revascularization, employ indicative algorithms to assess reperfusion
- If AMI is confirmed, measure troponin I at 4–9–12 h, CK-MB at 4, 8, and 12 h, and then every 12 h for 3 days
- Measure total CK, anamnesis for skeletal muscle damage, STT, LDH, ECG
- Immediate measure creatinine, urea, K, and myoglobin in the urine, and monitor CK and aldolase
- Measure LDH, total CK, AST, ALT, aldolase, GGT
- Measure troponin I at 8–12 h and CK, LDH, and myoglobin in the urine
- Measure total CK, indexes of inflammation, D-dimer, and cardiac markers after 4 h
- Measure troponin I and myoglobin after 1.5–3–6–9–12 h to confirm diagnosis and perform ECO
- Measure troponin I at 4 h to rule out acute ischemic event, and measure AST and CK
- Measure, 4 h after chest pain, troponin I, CK-MB, total CK, and LDH, and evaluate the renal function
- Repeat markers to confirm or rule out cardiac muscle involvement within 6 h, and complete with ECG, ECO, etc.
- Repeat markers to confirm or rule out cardiac muscle involvement within 6 h, and complete with ECG, ECO, etc.
- Serial measurement of the three biochemical markers, hemogram, ECO
- Measure total CK and myoglobin every 4 h

We identified some key phrases in each comment according to the degree of abnormality, summarised them in key groups, and presented them in graphs and tables (Figs. 3–5, Table 1). No indication of appropriateness of comments was given to the participants.

2.3. Discussion and conclusions

Our findings show that few laboratories regularly add interpretative comments to medical reports. They cooperate with clinicians who require consultation, advice, and information for the appropriate use of biochemical markers. Moreover, the advice requested from clinicians has increased since 1999, when only 19.6% of the clinicians applied to the laboratory for consultation (result from a survey carried out in that year by CRB).

There is a general consensus among participants regarding probable syndrome suggested by the interpretation of the results in Reports 1, 2, and 3. Furthermore, most also agree on further investigations to...
be carried out for several diseases. In the presence of musculoskeletal lesions, no particular prevalence was found in the distribution of participants’ answers for the different suggested algorithms. The practice of adding comments to medical reports has been promoted, in recent years, by the introduction of new and complex tests, as well as by the changing perspective on the interpretation of existing tests. Competition between laboratories is an additional factor that promotes the use of interpretative comments to enhance the value of medical reports.

Clinicians require interpretation and/or advice whenever they are not familiar with a test or when test results are not consistent with clinical information. The availability of new tests is forcing laboratories and clinicians to revise and compare diagnostic strategies and different profiles to evaluate whether the new tests are to be used in addition to, or instead of, other traditional tests, in order to follow a cost-effective approach in routine diagnostic setting.

Laboratory staff (with medical or other scientific qualifications) providing interpretative comments must be appropriately qualified and have necessary further formal training for clinical interpretation. The suggestions on results must be highly appropriate; inappropriate or misleading comments have a negative
impact on the patient’s outcome and the health care service.

The biochemist does not have the opportunity to verify the efficacy of the interpretation that she/he provided. An audit of this activity is therefore required to allow the laboratory to monitor its own performance and to assure good practice. The evaluation of interpretative comments, through specific surveys, should be a prime objective of EQA organisers. An efficiency scheme shall be designed to improve the practice, and to be educational and available for teaching and for discussion. It should be directed towards the individual biochemist, identified with a unique code number, rather than the laboratory.

The EQA program shall allow participants to:

- compare their own opinion with that of other colleagues;
- understand whether a misleading comment about an individual case has been made;
- widen their experience of this activity, usually carried out by biochemists in isolation;
- help educate junior clinical biochemists; and
- promote continuous quality improvement.

Table 1
Further investigations: suggestions of the laboratories (in percentage)

<table>
<thead>
<tr>
<th>Algorithm suggested by laboratories</th>
<th>Damage</th>
<th>Myocardial injury (%)</th>
<th>Acute myocardial infarction (%)</th>
<th>Muscle-skeletal lesion (%)</th>
<th>Myocardial injury and muscle-skeletal lesion (%)</th>
<th>No comments (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring of cardiac markers</td>
<td></td>
<td>87.5</td>
<td>78.0</td>
<td>27.8</td>
<td>83.0</td>
<td>25.0</td>
</tr>
<tr>
<td>Monitoring of cardiac and enzymatic markers</td>
<td></td>
<td>0.9</td>
<td>31.0</td>
<td>17.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring of cardiac and enzymatic markers; ECG</td>
<td></td>
<td>1.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring of cardiac markers; ECG</td>
<td></td>
<td>12.5</td>
<td>8.0</td>
<td>10.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring of enzymatic markers</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Monitoring of enzymatic markers; ECG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At clinician’s discretion</td>
<td></td>
<td>2.4</td>
<td></td>
<td></td>
<td></td>
<td>18.8</td>
</tr>
<tr>
<td>No suggestions</td>
<td></td>
<td>9.0</td>
<td>6.9</td>
<td></td>
<td></td>
<td>56.2</td>
</tr>
</tbody>
</table>
As a first step, it is sufficient that the biochemists assess their own comments by comparing them with those of other EQA participants, as a self-audit. Subsequently, when participants are ready to accept an external judgement, it will be useful to classify the participants’ interpretative comments as “acceptable” or “unacceptable.” This calls for the recruitment of a panel of experts, who could be chosen on the basis of their qualifications, their working knowledge, and working experience and training. The experience of well-known authors demonstrates that it is quite difficult to design EQAS for interpretative comments, and to assess their appropriateness. Their scientific papers illustrate that a clear consensus among participants can be achieved, but there is a wide divergence of opinions that cannot be due to simple differences in personal opinion [27–30]. Laboratories therefore need help in controlling the quality of their comments and in making appropriate comments. The most appropriate way of commenting upon patients’ results could be through direct discussion with the clinician responsible for each patient with abnormal test results, and the most useful feedback for a biochemist is the assessment of the patient’s outcome. As it is often difficult to directly contact a general practitioner or hospital clinician, the addition of interpretative comments on medical reports may be the most effective possible way of conveying laboratory information.

Quality assessment of interpretative commenting is an important factor in monitoring the quality of a laboratory service. This experience has given the EQA organisers useful information for organising a program that responds to the needs of laboratories, while being highly educational.

3. Reference ranges/decisional limits

The interpretation of clinical laboratory data involves a comparative decision-making process between the individual laboratory test results and the reference range/decisional limit. RL values are therefore needed for all tests and the provision of reliable intervals is a very important task of clinical laboratories. It has been proven that only with the adoption of an appropriate reference range/decisional limit can we obtain a clinically effective report.

The production of health-associated reference values and the subsequent estimation of the reference interval for a given analyte must be carried out in accordance with a well-defined protocol [31–34]. Otherwise, a paradoxical situation arises in which the results obtained from a same sample in different laboratories, assessed in relation to their own RL, lead to contradictory clinical interpretations, being defined as “normal” by one laboratory and as “pathological” by another laboratory. This state of affairs causes great confusion, affecting both clinicians and patients.

EQA programs can be used to check the validity of RLs used by different laboratories. EQA programs organised by the CRB have been extended to checking the validity of RL used by participating laboratories. In fact, results are required of laboratories in a medical report form. A diagram in which each laboratory’s RL is compared with those used by other participants, and in relation to its own obtained result, is provided by CRB to allow a verification of RL reliability.

In this work, we analysed RL data from the EQA Scheme of Biochemical Markers of Myocardial Damage because of the wide impact that these markers have as indicators for the detection of myocardial necrosis, and following the recent consensus document published by the European Society of Cardiology and the American College of Cardiology, which defined the procedure for determining reference values for cardiac troponins and CK-MB [35].

3.1. Methods

We analysed 113 medical reports sent by laboratories during the most recent EQA cycle 2002, and checked the number of different RLs used for troponins, CK-MB mass, and myoglobin, both independent and within the diagnostic system used. We also compared each laboratory result of a control sample, obtained in the 2002 cycle, with declared RL in order to verify the clinical significance of results (“normal” or “pathological”) for troponin I and CK-MB.

3.2. Results

There are numerous different RLs out of the total RLs provided: 24 of 82 for troponin I; 6 of 26 for troponin T; 29 of 85 for CK-MB mass; and 43 of 98 for myoglobin.
In Table 2, the main diagnostic systems utilised and the corresponding number of different RLs for each constituent are reported; an example of this is given in Table 3, which shows the values of limits for troponin I.

Comparing the laboratory result with RL, we found that the control sample for troponin I was classified as normal by 81% of laboratories and pathological by 19%, and the sample for CK-MB was classified as pathological by 68%, normal by 30%, and borderline by 2%.

### 3.3. Discussion and conclusions

Our findings demonstrate that numerous different RLs are used to report the results of the biochemical markers evaluated, both when considered independent of the diagnostic system used and within the diagnostic system used. The use of different RLs would not cause any problems if the participants classify their result (analysed in the same sample) in the same way: all “normal” or all “pathological.”

Our data show that many laboratories provide different classifications, leading to misleading interpretation. The different diagnostic systems used do not appear to explain these differences: laboratories using the same system declare different RLs. Most laboratories probably use values taken from another laboratory, from literature, or from a package insert of the kit, without any further checking. Internationally accepted recommendations for generating reference values have just been published.

<table>
<thead>
<tr>
<th>Diagnostic system</th>
<th>Troponin I</th>
<th>Troponin T</th>
<th>CK-MB mass</th>
<th>Myoglobin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckman Access 6 (13)</td>
<td>6 (11)</td>
<td>8 (13)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dade/Behring Dimension 15 (35)</td>
<td>11 (31)</td>
<td>18 (30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abbott Assym 7 (18)</td>
<td>9 (15)</td>
<td>5 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dade/Behring Opus 2 (6)</td>
<td>1 (3)</td>
<td>3 (7)</td>
<td></td>
<td></td>
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<tr>
<td>Dade/Behring Stratus CS 2 (4)</td>
<td>3 (3)</td>
<td>2 (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Triage 3 (4)</td>
<td>3 (4)</td>
<td>3 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roche Elecsys 6 (26)</td>
<td>11 (17)</td>
<td>11 (25)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In parentheses are reported the number of laboratories using that diagnostic system.

<table>
<thead>
<tr>
<th>Diagnostic system</th>
<th>Reference range</th>
<th>No. of labs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Assym</td>
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</tr>
<tr>
<td></td>
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<tr>
<td>Beckman Access</td>
<td>0–0.03 1</td>
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<tr>
<td></td>
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</tr>
<tr>
<td>Dade Berhing Stratus CS</td>
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<tr>
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<td>0–0.10 3</td>
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<tr>
<td></td>
<td>0–1.00 2</td>
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</tbody>
</table>

The correct procedures for obtaining RL are complex and this is the main reason why laboratories or diagnostic systems manufacturers have not used them systematically. Therefore, the participants must verify the clinical significance of their results with respect to that of other laboratories and check the accuracy of their analytical results as well as the appropriateness of RL. Any improvement in analytical precision and accuracy might be compromised by an inappropriate use of RL, and could lead to misleading information. The establishment of appropriate RL must be under-
taken by laboratories with support from well-designed EQA programs. Clearly defined RLs will have a positive impact on the quality of laboratory results, and their assessment will therefore fall within the scope of EQA programs.

EQA programs, complied with quality standards, will contribute to achieving the correct use of the RLs of the different laboratories involved [26,36–38].

4. Consideration

The EQA organisers shall feel obliged to actively support quality improvement according to the needs of the laboratories, and to shift the emphasis of the assessment. EQAS could be used to register quality in areas in which improvement is considered particularly important. Our survey on interpretative comments and the analysis of the reference ranges/decisional limits of biochemical markers of myocardial damage further demonstrates how laboratory medicine can contribute to the objective evaluation of the patients’ health status and can be an important part of the clinical decision-making process.

References


[37] ILAC. Guidelines for the requirements for the competence of providers of proficiency schemes. ILAC; ILAC-G13; 2000.

[38] IFCC/EMD/C-AQ. Guidelines for the requirements for the competence of EQAP organizers in medical laboratories, version 3. IFCC; 2002.