Special issue: External Quality Assessment in Laboratory Medicine

Original papers

External quality assessment of medical laboratories in Croatia: preliminary evaluation of post-analytical laboratory testing

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Abstract

Introduction: Proper standardization of laboratory testing requires assessment of performance after the tests are performed, known as the post-analytical phase. A nationwide external quality assessment (EQA) scheme implemented in Croatia in 2014 includes a questionnaire on post-analytical practices, and the present study examined laboratory responses in order to identify current post-analytical phase practices and identify areas for improvement.

Materials and methods: In four EQA exercises between September 2014 and December 2015, 145-174 medical laboratories across Croatia were surveyed using the Module 11 questionnaire on the post-analytical phase of testing. Based on their responses, the laboratories were evaluated on four quality indicators: turnaround time (TAT), critical values, interpretative comments and procedures in the event of abnormal results. Results were presented as absolute numbers and percentages.

Results: Just over half of laboratories (56.3%) monitored TAT. Laboratories varied substantially in how they dealt with critical values. Most laboratories (65-97%) issued interpretative comments with test results. One third of medical laboratories (30.6-33.3%) issued abnormal test results without confirming them in additional testing.

Conclusion: Our results suggest that the nationwide post-analytical EQA scheme launched in 2014 in Croatia has yet to be implemented to the full. To close the gaps between existing recommendations and laboratory practice, laboratory professionals should focus on ensuring that TAT is monitored and lists of critical values are established within laboratories. Professional bodies/institutions should focus on clarify and harmonized rules to standardized practices and applied for adding interpretative comments to laboratory test results and for dealing with abnormal test results.

Key words: post-analytical phase; standardization; external quality assessment; questionnaire

Introduction

Comparability of laboratory test results depends on standardization of all phases of laboratory testing, including pre-analytical, analytical and post-analytical phases. Pre-analytical and analytical phases of laboratory testing aim to generate an accurate test result, while the post-analytical phase - when the clinician receives the test results, interprets them, and uses them to make diagnostic and therapeutic decisions - aims to reduce errors or bias associated with the hand-off from laboratory to clinician. The most frequent errors in the post-analytical phase are erroneous validation of analytical data, failure to report test results to appropriate parties, excessively long turnaround time (TAT), mistakes in data entry, manual transcription errors and failure or delay in reporting critical values (1).

Despite the obvious importance of the post-analytical phase to overall laboratory performance, many providers of external quality assessment (EQA) schemes do not take into account the post-analytical phase (2). In 2009, the Croatian Chamber

of Medical Biochemists (CCMB) and Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) assessed the state of pre- and post-analytical procedures in medical laboratories across the country (3). The results indicated urgent, substantial need for improvement. Therefore, a nationwide EQA scheme covering the post-analytical phase was implemented in 2014, administered by the Croatian Centre for Quality Assessment in Laboratory Medicine (CROQALM) within the CSMBLM. The EQA scheme is implemented modularly three times *per* year. The CCMB made participation in the scheme mandatory for all medical laboratories in Croatia in 2013 (4). In the second EQA exercise of 2014, pilot modules on pre- and post-analytical phases were introduced; in all three EQA exercises of 2015, Module 11 dealing with the post-analytical phase was performed.

The present study was undertaken to evaluate to what extent the recently introduced nationwide EQA scheme for the post-analytical phase of laboratory testing has influenced laboratory practice in Croatia. Since laboratories showed substantial variation in post-analytical practices before the scheme (3), we felt it necessary to evaluate the success of the EQA scheme at this early stage in order to identify the more important issues and implementation gaps and thereby help regulators and laboratory directors focus their energies more efficiently in the coming years. In a separate publication, we will assess pre-analytical procedures using an EQA module for the pre-analytical phase developed by the CSMBLM.

Module 11 is an educational module about the post-analytical phase of laboratory testing, and it contains an optional questionnaire that presents medical laboratories with routine post-analytical scenarios where standardized practices exist under the Croatian EQA scheme or where clear rules are lacking ('grey areas'). The present study retrospectively analysed laboratory responses to this questionnaire in 2014-2015 in order to (a) gain on-the-ground insights into current laboratory practices in Croatia and (b) identify the most urgent areas for improving the standardization of the post-analytical phase in Croatian laboratories.

Materials and methods

Study design

This retrospective, longitudinal study involved analysis of the responses of Croatian medical laboratories to a questionnaire distributed during four national EQA exercises conducted in September 2014 and in May, September and November 2015. During this study period, 194 medical laboratories were registered in the Croatian health care system, comprising 125 (64%) medical laboratories from primary health care facilities (including private medical practices and private laboratories) and 69 (36%) medical laboratories from secondary and tertiary health care centres (clinical hospital centres, clinical hospitals, general hospitals, national hospitals, and special hospitals). Although all medical laboratories were obliged to participate in the national EQA scheme, their responses on the questionnaire were voluntary. Laboratories were told that their responses would not affect their overall assessment from CROQALM. No fees or compensation were involved in completing the questionnaire.

Data from all responding laboratories were used in the present study; no exclusion criteria were applied. When they filled out the questionnaire, laboratories gave consent for the data to be stored and used by CROQALM for group-level analyses. Members of CROQALM signed statements that they would safeguard the confidentiality of EQA data.

Questionnaire

Questionnaires have been proposed as an effective method for assessing the post-analytical phase during EQA exercises (2). The Croatian EQA questionnaire was designed by CROQALM, approved by CSMBLM and CCMB, and distributed to all registered medical laboratories in the country. The responses were analysed by the EQA provider (CROQALM), and one of the authors (JLK) annotated the results in her capacity as EQA/CROQALM Module 11 coordinator. All these steps, from design to final analysis, were conducted via Web interface using inlab2*QALM software, specifically designed in 2011 for quality evaluation of medical laboratory performances (IN2 Group Ltd., Zagreb,

Croatia). Medical laboratories receiving the questionnaire were instructed to ask their laboratory manager or laboratory professionals (or quality control manager) to fill it out.

The questionnaire was part of Module 11, entitled 'Post-analytical phase of laboratory testing', which explained post-analytical practices under the new Croatian EQA scheme. It consisted of closed-type questions covering four indicators of post-analytical quality proposed by the Working Group 'Laboratory Errors and Patient Safety' of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (5). The questions described specific situations or scenarios often encountered in routine practice concerning TAT, critical values, interpretative comments and procedures (repetition or additional testing) in the event of abnormal test results. Participants could choose only one of the offered responses for each question. Responses to 12 questions administered during one or more of the four exercises during the study period were analysed.
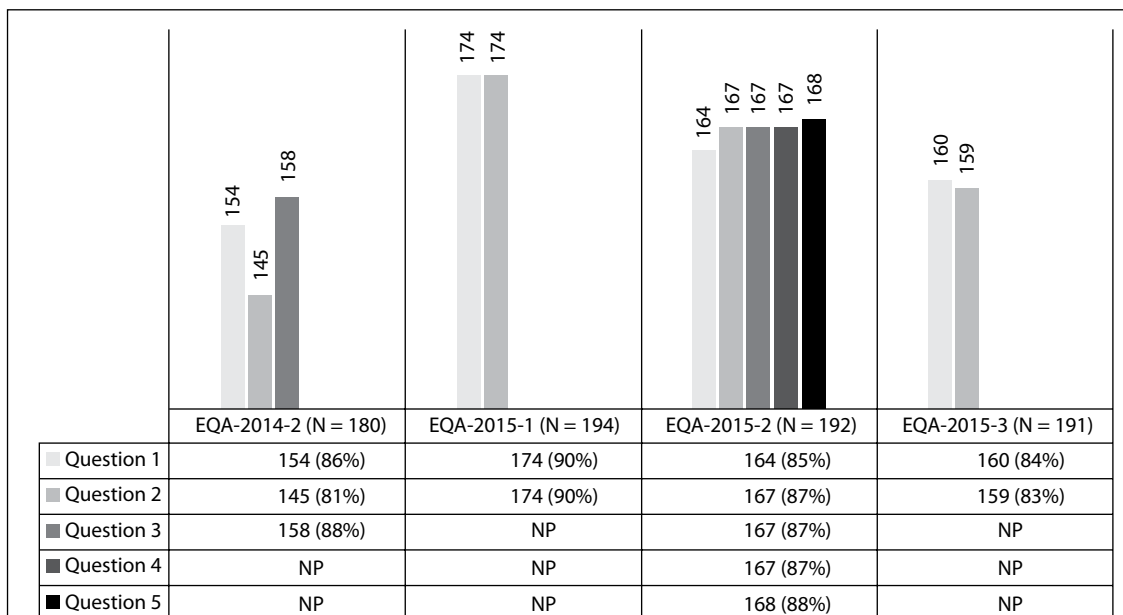
Data analysis

Data were not analysed statistically. Instead, results were reported as absolute numbers and percentages.

Results

The number of medical laboratories participating in each exercise varied, as did the number that filled out the questionnaire; Figure 1 presents a histogram of response rates to questions. The response rate was always more than 80% of laboratories participating in the exercise. Table 1 presents the contents of the questionnaire, which varied with the exercise.

Responses to the questionnaire were analysed to determine to what extent medical laboratories comply with existing rules issued by professional bodies in Croatia, and to identify how medical laboratories are likely to proceed in frequent yet 'grey' situations where no clear rules exist. Frequencies of different responses to all questions are shown in Table 1 where answers that are clearly non-compliant with existing rules are emphasised in question comment. While laboratory respondents showed good knowledge of the definition of TAT, only approximately half of respondents reported that they routinely monitor TAT. Most respondents (85.7%) showed good knowledge of the definition of critical values (reflected in five questions) and of recommendations on how to apply the definition. On the other hand, the laboratories showed sub-

	EQA-2014-2 (N = 180)	EQA-2015-1 (N = 194)	EQA-2015-2 (N = 192)	EQA-2015-3 (N = 191)
Question 1	154 (86%)	174 (90%)	164 (85%)	160 (84%)
Question 2	145 (81%)	174 (90%)	167 (87%)	159 (83%)
Question 3	158 (88%)	NP	167 (87%)	NP
Question 4	NP	NP	167 (87%)	NP
Question 5	NP	NP	168 (88%)	NP

NP: not present in this exercise.

FIGURE 1. Response rates for different questions on the Module 11 questionnaire during the four EQA exercises during the study period.

TABLE 1. Questions and possible responses on the Module 11 questionnaire, by EQA exercise, together with the number (%) of respondent laboratories choosing that response.

Year and EQA exercise	Question type	Question and possible answers	Frequency N (%)
2014, second exercise	Interpretative comments (Case report)	1. The patient (male, 65 years) has a diagnosis of increased heart pressure and cardiac fibrillation and has been on antihypertensive and oral anticoagulant therapy for several months. He comes to the clinic for monthly check of prothrombin time (PT, INR). The patient is in generally good condition and has not altered warfarin dose or antihypertensive therapy in the last month. Target INR for his diagnosis is 2.5 (range 2.0 – 3.0). The measured value of INR is 1.9. In the history of the laboratory test results for this patient, INR values range from 2.3 to 2.8. His blood sample is regular, without any written comments from the pre-analytical phase. The sample was collected properly to the mark, without visible clots, haemolysis or lipemia and there were no notes about patient characteristics. The internal control on that day for PT was the target value of the control sample used. In this situation, you would:	
		a) confirm and issue the laboratory test results without any comments.	22 (14.3)
		b) confirm and issue the laboratory test results without any comments, after repeating the test and obtaining the same value again.	81 (52.6)
		c) contact the patient to find out what might have altered the value of PT, INR and, with the patient's consent, repeat the blood sampling and measurement before issuing laboratory test results.	6 (3.9)
		d) inform the patient's physician about the PV, INR results and, in consultation with him or her, decide on whether to repeat the blood sampling.	33 (21.4)
		e) confirm the test results and issue them with a comment, such as 'Repeat blood sampling if values are not in accordance with the clinical condition of the patient'.	12 (7.8)
2014, second exercise	Critical values (Case report)	2. A male infant with congenital malformation of the abdominal wall (diagnosis: gastroschisis) is admitted to the intensive care unit. Urgent measurements are made of blood gases, acid-base balance, electrolytes and glucose from a capillary blood sample. The concentration of blood glucose is 2.1 mmol/L, and the results for pH, blood gases and ionized electrolytes are within the reference ranges for his age. In this situation, you would:	
		a) telephone the physician immediately after the analysis, inform him or her about glucose concentration (recommended critical value for glucose is < 2.5 mmol/L according CCMB), and record in the appropriate log that the clinician was notified.	51 (35.2)
		b) confirm and release the results immediately after analysis (with no phone contact with the physician), since all measured values are within the reference range for the patient's age.	94 (64.8)
		c) urgently request repeat of blood sampling to confirm the laboratory test results.	0 (0.0)
	Comment:	**Non-compliant answer: c).**	
2014, second exercise	TAT	3. The time required for the issue of laboratory test results (turnaround time, TAT) in your laboratory is:	
		a) clearly defined and monitored for all analyses in the laboratory.	30 (19,0)
		b) defined and monitored only for emergency analysis of first and second category.	59 (37.3)
		c) not monitored, but the laboratory test report displays the time of sample receipt and the time of issue of results.	44 (27.9)

		d) not defined or not monitored at all, with all analyses performed as soon as possible.	15 (9.5)
		e) defined, but not monitored.	10 (6.3)
	Comment:	**Non-compliant answers: d) and e).**	
2015, first exercise	TAT	1. The starting point for measuring TAT is:	
		a) when a physician's request for laboratory tests is received at the laboratory.	5 (2.9)
		b) when the sample is taken.	30 (17.2)
		c) when the sample is received at the laboratory.	91 (52.3)
		d) when the sample enters preparation for analysis.	1 (0.6)
		e) when the sample enters into the analytical procedure.	0 (0.0)
		f) variable and should be defined by each laboratory depending on the type of laboratory and tests performed there (emergency, routine, primary health care or hospital laboratory).	47 (27.0)
	Comment:	**Non-compliant answer: e).**	
2015, first exercise	Interpretative comments	2. Extremely high values are obtained for parameter X using an immunochemical assay. These values are confirmed in repeated measurements and in dilution, yet they are inconsistent with the patient's clinical presentation. Internal quality control values for parameter X are within the acceptable limit. In this situation you would:	
		a) repeat the blood sampling after consulting a physician.	43 (24.7)
		b) verify the laboratory test result without consulting a physician because you have already done everything possible to verify the high values.	5 (2.9)
		c) verify the high values after consulting a physician.	47 (27.0)
		d) measure parameter X using another method (your own or that of another laboratory) before verifying the laboratory test result or consulting a physician.	51 (29.3)
		e) consult a physician and verify the laboratory test result, then measure parameter X using another method (your own or that of another laboratory).	28 (16.1)
		f) Call technical support.	0 (0.0)
	Comment:	**Non-compliant answer: f).**	
2015, second exercise	Interpretative comments (Case report)	1. Measured and re-measured blood glucose from the same blood sample from an outpatient is 11.4 mmol/L. During venepuncture, the patient states that he has been fasting and is not taking any medications. In this situation, you would:	
		a) proceed as if the test result were a critical value and promptly notify the physician.	20 (12.2)
		b) immediately contact the patient and repeat blood sampling, while also requesting more details about 'fasting'.	8 (4.9)
		c) verify the laboratory test results and refer the patient to a specialized facility for diabetes.	2 (1.2)
		d) without verifying the laboratory test result, contact the patient and try to determine possible causes of hyperglycaemia.	3 (1.8)
		e) verify the laboratory test result and include a comment to repeat blood glucose testing using a different sample and to check glucose in urine.	73 (44.5)
		f) verify the laboratory test result without any additional actions.	58 (35.4)
2015, second exercise	Critical values	2. A laboratory test result is a critical value if it:	
		a) falls outside the reference interval.	1 (0.6)
		b) is an abnormal result with medical significance.	7 (4.2)
		c) indicates that a patient's life is in danger and requires immediate notification of a physician or other clinical staff.	159 (95.2)

	Comment:	Non-compliant answers: a) and b).	
2015, second exercise	Critical values	3. Each laboratory should define its own critical values:	
		a) Yes.	78 (46.7)
		b) No.	89 (53.3)
	Comment:	Non-compliant answer b).	
2015, second exercise	Critical values	4. Critical values should be reported:	
		a) after confirmation by additional measurement of the same sample.	42 (25.1)
		b) after confirmation by additional measurement of the same sample and after validation of the results.	89 (53.3)
		c) immediately, since additional measurements would delay reporting.	36 (21.6)
2015, second exercise	Critical values	5. Is a written recommended procedure about critical values available in your laboratory?	
		a) Yes.	144 (85.7)
		b) No.	24 (14.3)
	Comment:	Non-compliant: answer b).	
2015, third exercise	Procedures with abnormal test results (Repetition of testing)	1. Elevated absolute eosinophil count with no clear cause on 5-part differential haematology analyser:	
		a) must be checked using Dunger's method.	0 (0.0)
		b) is sufficiently reliable without checking.	49 (30.6)
		c) must be checked by microscopic examination of a peripheral blood smear.	111 (69.4)
	Comment:	Non-compliant: answer a).	
2015, third exercise	Procedures with abnormal test results (Repetition of testing)	2. Examination of urinary sediment reveals some bacteria (1+) and 0-5 leukocytes in the field of view (magnification, 400X). A urine test strip is positive for nitrite (1+) and leukocytes 500/μL (3+). In this situation you would:	
		a) correct the values of the urinary test strip according to microscopic examination of urinary sediment.	51 (32.1)
		b) issue the laboratory test results without any correction or comment.	53 (33.3)
		c) request a new urine sample without issuing the laboratory test results.	53 (33.3)
		d) correct the values of the urinary sediment microscopic examination based on the urinary test strip results.	0 (0.0)
		e) call technical support.	2 (1.3)
	Comment:	Non-compliant answer d).	

PT – prothrombin time; INR – international normalized ratio; CCMB – Croatian Chamber of Medical Biochemists; TAT – turnaround time.

stantial variation in how they responded to certain questions about critical values; many lacked knowledge about age-dependent critical values and how to establish an intra-laboratory list of critical values.

The questionnaire presented respondents with three scenarios involving interpretative comments in order to understand to what extent medical laboratories in Croatia take an active role in interpreting test results and communicating those interpretations to clinicians orally or in writing. While laboratories varied in their responses to these scenarios, one third selected answers implying an active role in interpretation of test results, either *via* a comment written on the report or contact with the clinician and/or patient. In various situations, up to a third of laboratories issued results without additional activities.

The last group of questions asked laboratories how they proceed in the event of abnormal test results. For example, does the laboratory repeat the test and, if so, does it use the same or a new sample? Is the sample re-analysed using the same test procedure as before or a different procedure? After re-testing, are the initial and/or follow-up test results shown on the final report? Most laboratories reported that they repeat testing to verify abnormal results. Nevertheless, one third reported that they issue results without such verification.

Discussion

Harmonization and standardization of pre- and post-analytical phases of laboratory work are essential for good clinical care. Since 2007, ISO standard 15189 has included assessment of pre- and post-analytical phases of testing as one of the requirements for accreditation of medical laboratories (6). Nevertheless, many providers of EQA schemes do not systematically assess the post-analytical phase (2). Since 2014, all medical laboratories in Croatia are required to participate in a national EQA scheme that includes post-analytical assessment. The present study aimed to assess the current state of laboratory compliance with the EQA scheme, as well as identify areas where clearer rules - or the first set of rules - need to be developed at the national level. This is an urgent problem, because only 11 of 198 (5.5%) registered medical laboratories in Croatia are ISO 15189 - accredited, and most are planning to enter the accreditation process soon (7). In the present study, we retrospectively analysed the responses of medical laboratories to the Module 11 post-analysis questionnaire incorporated in the Croatian EQA exercises since 2014. This questionnaire focused on the four main quality control indicators of the post-analytical phase of testing. Our results indicate substantial heterogeneity in how medical laboratories in Croatia proceed in situations where no clear rules or guidelines exist.

TAT is a frequently used quality indicator: it is easily tracked through the laboratory informatics system, and ISO 15189 mandates that the TAT be established for each type of test, through consulta-

tion between laboratory and clinician (item 5.8.11) (6). One challenge with standardizing TATs across laboratories is that the definition of TAT can vary depending on whether the laboratory is a primary, secondary or tertiary facility and whether the test is routine, emergency or specialized (8,9). Our results indicate that although most respondents know that TAT monitoring is an accreditation requirement, they do not have a monitoring system in place. Nevertheless, most respondents do record when the laboratory sample is received and when validated test results are obtained or reported. This likely reflects the widespread use of laboratory informatics systems.

ISO 15189 requires that laboratories apply standard procedures for recording and reporting critical values (items 5.8.1, 5.9.1 and 5.9.2) (6). Laboratories are also required to generate their own lists of critical values based on the local clinical situation, in consultation with clinicians (6,10,11). Most laboratories in our sample showed an understanding of critical values but not how to define own critical values list, or they neglected to adjust them based on patient age. In January 2015, CCMB published an updated and revised, ISO 15189 - compliant list of critical values (6,12), which includes critical values and reference intervals for neonatal patients (12,13). The recent release of this information at the national level may help to explain the heterogeneity in laboratory responses on our questionnaire. This information may help laboratories define their own lists of critical values and report critical values appropriately. Future work is needed to track laboratory - level implementation of this knowledge around the country.

Most medical laboratories reported that they confirm critical values with additional measurement before reporting, which is consistent with CCMB recommendations. Approximately one fifth indicated that they immediately report critical values without test repetition, which is consistent with practices at accredited laboratories in other countries (10,14,15) and reflects the fact that ISO 15189 - compliant laboratories may choose not to re-test in specific circumstances, such as when national guidelines in their country recommends it or when the use of advanced laboratory technology places

the initial result beyond reasonable doubt. Recent published results of survey on critical results reporting in Croatian medical laboratories found high score for re-analyse critical results before reporting (16). In general, Croatian laboratories are in compliance with valid CCMB recommendation.

While those results based on a carefully designed scoring system are difficult to compare with our preliminary, descriptive results, the two studies may point to the need for more systematic research in this area.

Interpretative comments on the laboratory test report can improve treatment outcomes (17). They are a widely used quality indicator and, since 2007, an obligatory part of ISO 15189 accreditation (6). Although the CCMB has stated since 2004 that 'remarks related to the sample (lipemia, hyperbilirubinemia, haemolysis and others) are a mandatory part of every report of laboratory test results', the type, format and position of the comments on the report are not clearly defined (13), nor do CCMB guidelines indicate which comments necessitate contacting the clinician. Our results indicate that, depending on the situation, 3-35% medical laboratories do not flag abnormal results to the clinician, either in writing or orally. In addition, one third of laboratories neither repeats the test nor performs additional actions in an effort to confirm the abnormal results. Abnormal results may be significant for diagnosis and treatment, and may call into question the reliability of the test results. Including interpretative comments on lab reports can help prevent the release of incorrect or less reliable test reports (18-20). Therefore, our results identify an urgent need to revise and update CCMB recommendations about interpretative comments on test reports, as well as a need for the CCMB and other groups to define when tests or sampling should be repeated or additional tests performed.

A small proportion (12%) of respondent laboratories left open-ended comments to one or more of the questions; nearly all these comments were that their laboratory did not routinely encounter, or had never encountered, the scenario described in the question. This suggests that many laboratories feel they lack sufficient knowledge or experience to deal adequately with many post-analytical problems, despite the implementation of the Croatian EQA scheme. This suggests the need for greater training opportunities for medical laboratories in the country.

The present study presents a preliminary picture of the early stages of post-analytical EQA at the national level in Croatia. It is based on a sampling of medical laboratories from around the country and makes use of a questionnaire tailored to the logistical, clinical, and regulatory situation in Croatia. As with most questionnaire assessments, there is some risk that practices reported on the survey do not reflect actual practices in the respondent laboratory. To reduce this risk, we asked that the questionnaires be filled out by professional laboratory staff responsible for quality control. Another limitation of our study is that the response rate ranged from 81% to 90%, raising the possibility that our sample was biased. For example, perhaps laboratories that felt more confident about their knowledge and practices were more likely to respond to our survey. If this is true, then our study may underestimate the lack of alignment with post-analytical best practices, which only reinforces our conclusion that much more needs to be done to accelerate the harmonization of post-analytical procedures in Croatia. A third limitation is that the survey was not extensive enough to offer comprehensive insights into laboratory practices and attitudes. While this may have helped ensure a high response rate for the preliminary analysis here, future work may wish to look at these issues in greater detail.

In conclusion, assessment of post-analytical quality indicators such as TAT, critical values and interpretative comments are well recognized by both CCMB and ISO 15189, although clear definition of these terms, guidelines compliance and actions to be taken by laboratories are often incomprehensible. The results of Module 11 survey in Croatia highlights major obstacles to harmonization and standardization of post-analytical practices at national level. Future EQA exercises should reinforce the importance of filling out this survey.

Acknowledgments

The authors are grateful to the participating medical laboratories and their employees who filled out the questionnaire.

Potential conflict of interest

None declared.

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