

## Croatian survey on critical results reporting

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### Abstract

**Introduction:** Poor harmonization of critical results management is present in various laboratories and countries, including Croatia. We aimed to investigate procedures used in critical results reporting in Croatian medical biochemistry laboratories (MBLs).

**Materials and methods:** An anonymous questionnaire, consisting of 24 questions/statements, related to critical results reporting procedures, was sent to managers of MBLs in Croatia. Participants were asked to declare the frequency of performing procedures and degree of agreement with statements about critical values reporting using a Likert scale. Total score and mean scores for corresponding separate statements divided according to health care setting were calculated and compared.

**Results:** Responses from 111 Croatian laboratories (48%) were analyzed. General practice laboratories (GPLs) more often re-analyzed the sample before reporting the critical result in comparison with the hospital laboratories (HLs) (score: 4.86 (4.75-4.96) vs. 4.49 (4.25-4.72);  $P = 0.001$ ) and more often reported the critical value exclusively to the responsible physician compared to HLs (4.46 (4.29-4.64) vs. 3.76 (3.48-4.03),  $P < 0.001$ ). High total score (4.69 (4.56-4.82)) was observed for selection of the critical results list issued by the Croatian Chamber of Medical Biochemistry (CCMB) indicating a high harmonization level for this aspect of critical result management. Low total scores were observed for the statements regarding data recording and documentation of critical result notification.

**Conclusions:** Differences in practices about critical results reporting between HLs and GPLs were found. The homogeneity of least favorable responses detected for data recording and documentation of critical results notification reflects the lack of specific national recommendations.

**Key words:** critical results; laboratory testing; quality indicators; survey; post-analytical phase

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### Introduction

In the last few decades, increasing evidence has emerged that the pre- and post-analytical phases of the total testing process are more prone to errors than the highly automated analytical phase. Consequently, the focus of interest of the medical laboratory community shifted to reinforcing the quality of the post-analytical phase as a necessary step in error reduction and patient safety improvement. A key post-analytical issue at the laboratory-clinical interface is the effectiveness of laboratory data communication, i.e. critical test results reporting (1,2).

A critical result is any result that is so extremely abnormal that can be considered life threatening or

could result in significant morbidity and which, therefore, require urgent action, as originally defined by Lundberg over 40 years ago (3,4). Timely release and reporting of critical results is essential for optimal clinical care. The importance of critical results reporting has been recognized by international accreditation and regulatory bodies. The EN ISO 15189:2012 standard and accreditation standards in the UK, USA and Australia, require that laboratories establish documented procedures for the immediate notification of results that fall within established "alert" or "critical" intervals to responsible clinical personnel (5,6). Furthermore, critical results reporting (i.e. notification of

critical values) was included in the consensus list of quality indicators of the International Federation of Clinical Chemistry and Laboratory Medicine Working group on laboratory errors and patients safety's (IFCC LEPS) as a process indicator of first priority for the evaluation and monitoring of post-analytical quality (7,8).

Since accreditation standards give just general guidance and no specific or universally applicable procedure in managing critical results is proposed, practices related to critical results reporting are heterogeneous among laboratories and countries. Accordingly, several national professional organizations carried out surveys to investigate practices and policies of critical result management in their countries in an attempt to formulate specific recommendations and finally harmonize critical result notification (9-13).

In 2006 the Croatian Chamber of Medical Biochemists (CCMB) issued a supplement of good laboratory practice standards currently used in the majority of laboratories in our country. This document was entitled "Critical values", and after a brief definition of the term, it stated that "laboratory should inform the physician about the critical result only after repeating the measurement and after result verification by a competent person who should discuss the obtained result with the physician". Furthermore, a critical results list was compiled comprising threshold values for various analytes, both for adults and children (Table 1) (14). This CCMB document set the foundations for harmonization of critical result reporting in Croatia. Nevertheless, we hypothesized that great variability in policies and procedures for critical results reporting is present in medical biochemistry laboratories (MBLs) in Croatia. This variability particularly refers to: a) responsibilities (competences) for critical results communication (who notifies and to whom), b) channels for critical results communication, c) timeliness of critical values reporting and d) procedures for data recording regarding critical results notification, while a high level of harmonization is achieved in the selection of critical result limits. In addition, we hypothesize that hospitals laboratories, where critical results are expected in higher frequency, are more aware of the

importance of critical results reporting and readily comply with appropriate procedures for this segment of the post-analytical phase.

This survey aims to investigate policies and procedures currently used in critical results reporting in MBLs in Croatia. We attempted to assess the variations in practices and identify critical aspects (i.e. less harmonized procedures) in existing critical results management systems.

## Materials and methods

### Questionnaire

An anonymous questionnaire, consisting of 24 questions / statements related to critical results reporting procedures and attitudes, was sent to a total of 231 MBL manager in Croatia, identified using the Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) database. The participants were surveyed using the online survey platform SurveyMonkey (SurveyMonkey Inc., Palo Alto, USA) during May 2014. Due to poor response rate in the first round (only 18 MBLs responded), during June 2014, the authors contacted each laboratory manager from the database by phone, briefly explaining the aim of the questionnaire and asking if they were willing to participate in the survey. Anonymity was ensured to those who accepted to participate. Those who declared to have participated in the first round were not surveyed in the second round.

The questionnaire was divided in three sections. The first section included questions on type of laboratory (i.e. health care setting), accreditation status, laboratory (LIS) and hospital information system (HIS) availability, reporting responsibilities and preferred communication channels. The second section was designed as statements describing laboratory procedures regarding critical result management. The participants were asked to declare the frequencies of procedures performed in their laboratories on a five grade Likert scale graded as 1 (never), 2 (rarely), 3 (sometimes), 4 (often) and 5 (always). The third section was designed as statements regarding reporting policies and choice of critical result limits. Responses were of-

**TABLE 1.** Adults critical result list of the Croatian Chamber of Medical Biochemists.\*

| Parameter                                    | Value                        | Note   |
|--|------------------------------|--|
| Activated partial thromboplastin time (APTT) | 75 sec                       | Deficiency or inactivity of factor VIII, IX, or XII, with risk of haemorrhage.   |
| AST, ALT                                     | > 1000 U/L                   | Notification depends on the patient population of the clinic or practice in question.  |
| Ammonia                                      | > 59 µmol/L                  | Risk of hepatic encephalopathy.  |
| Anion gap                                    | > 20 mmol/L                  | Indicative of ketoacidosis or lactic acidosis, uraemia, alcohol consumption, salicylate intoxication, poisoning from methanol or ethylene glycol.  |
| Inorganic phosphate                          | < 0.32 mmol/L                | Muscle weakness, muscle pain, central-nervous symptoms such as disorientation, confusion, convulsions, coma, respiratory insufficiency with metabolic acidosis.                                |
|  | > 2.9 mmol/L                 | Occurs in acute tumour lysis syndrome and in terminal renal failure.   |
| Antithrombin (AT)                            | < 0.50                       | There is substantial inhibitor deficiency, which in those with elevated procoagulant activity poses a high risk of thromboembolic complications.   |
| Ethanol                                      | > 3.5 g/L                    | Blood alcohol concentrations of 3-4 g/L can be fatal.  |
| Bilirubin                                    | > 257 mmol/L                 | Hepatobiliary disease caused mainly by hepatotropic viruses and thus of infectious origin with risk of contagion.  |
| Calcium, total<br>ionized calcium            | < 1.65 mmol/L                | Hypocalcaemic tetany   |
|  | < 0.78 mmol/L                |  |
|  | > 3.5 mmol/L<br>> 1.6 mmol/L | Risk of hypercalcaemic crisis, metabolic encephalopathy and gastrointestinal complications   |
| Chloride                                     | < 75 mmol/L                  | Indicative of considerable metabolic alkalosis.  |
|  | > 125 mmol/L                 | Indicative of massive primary metabolic acidosis or pseudohyperchloraemia in the case of bromide intoxication.   |
| Creatinine                                   | > 654 µmol/L                 | Acute renal failure, e.g. in multiple organ failure.   |
| Creatine kinase                              | > 1000 U/L                   | Notification depends on the patient population of the clinic or practice in question.  |
| D-dimers                                     | Positive                     | In disseminated intravascular coagulation (DIC), detection of D-dimers is indicative of phase II (decompensated activation of the haemostasis system) or phase III (full-blown DIC).           |
| Digoxin                                      | > 2.0 µg/L<br>(2.56 nmol/L)  | Non-cardiac symptoms such as tiredness, muscle weakness, nausea, vomiting, lethargy, and headache and cardiac symptoms such as sinus arrhythmia, bradycardia, and various degrees of AV block. |
| Digitoxin                                    | > 40 µg/L<br>(52 nmol/L)     |  |
| Fibrinogen                                   | < 0.8 g/L                    | Risk of haemorrhage.   |
| Fibrin monomers                              | Positive                     | Indicative of consumption coagulopathy in disseminated intravascular coagulation, sepsis, shock, multiple injury, acute pancreatitis, and obstetric complications.                             |
| Glucose                                      | < 2.5 mmol/L                 | Neuroglycopenic symptoms, which can range from impairment of cognitive functions to loss of consciousness.   |
|  | > 27.8 mmol/L                | Diabetic coma due to insulin deficiency. Development of osmotic diuresis with severe exsiccosis and diabetic ketoacidosis (β-hydroxybutyrate > 5 mmol/L, standard bicarbonate < 10 mmol/L).    |
| Haematocrit                                  | < 0.180 L/L                  | Corresponds to hemoglobin concentration of < 60 g/L. Inadequate myocardial oxygen supply.  |
|  | > 0.610 L/L                  | Blood hyperviscosity. Risk of heart failure.   |
| Hemoglobin                                   | < 66 g/L                     | Supply of oxygen to the myocardium inadequate.   |
|  | > 199 g/L                    | Corresponds to haematocrit of 61 % and leads to hyperviscosity syndrome.   |

TABLE 1. Continued.

| Parameter             | Value                          | Note  |
|-----------------------|--------------------------------|---|
| Lactate               | > 5.0 mmol/L                   | Indicator of type A hyperlactataemia, which is caused by an inadequate supply of oxygen to the tissue. Pyruvate is no longer metabolised oxidatively, but reductively.  |
| Lactate dehydrogenase | > 500 U/L                      | Notification depends on the patient population of the clinic or practice in question.   |
| Leukocyte count       | < $2 \times 10^9$ /L           | High risk of infection if the granulocyte count is < $0.5 \times 10^9$ /L.  |
|                       | > $50 \times 10^9$ /L          | Indicative of leukemoid reaction, e.g. in sepsis, or of leukemia.   |
| Lipase                | > 700 U/L                      | Indicative of acute pancreatitis.   |
| Magnesium             | < 0.41 mmol/L                  | Characteristic symptoms are paresthesias, cramp, irritability, and athetoid tetany. The patient often shows cardiac arrhythmia in conjunction with hypokalemia; arrhythmia is intensified by digitalis.   |
|                       | > 5.0 mmol/L                   | Reduction of neuromuscular impulse transmission, resulting in sedation, hypoventilation with respiratory acidosis, muscle weakness, and reduced tendon reflexes.  |
| Myoglobin             | > 110 $\mu$ g/L                | Myocardial infarction should be suspected in patients with angina pectoris.   |
| Sodium                | < 120 mmol/L                   | Tonicity disturbances caused by disorder of the mechanism ADH-thirst, water absorption or the ability of the kidney to concentrate or dilute the urine.   |
|                       | > 160 mmol/L                   | Disturbances in the central nervous system; disorientation and increased neuromuscular excitability   |
| Osmolality            | < 240 mOsm/kg H <sub>2</sub> O | Cellular oedema with an increase in cell volume and development of neurological-psychiatric symptoms.   |
|                       | > 330 mOsm/kg H <sub>2</sub> O | Cellular water loss and intracellular increase in osmotically active substances, which do not permeate the cell membrane. Result: central symptoms and coma.  |
| Osmolar gap           | > 10 mOsm/kg H <sub>2</sub> O  | Indicative of intoxication from non-electrolytes, which increase plasma osmolality, such as ethanol, methanol, ethylene glycol, isopropanol, and dichloromethane.   |
| pCO <sub>2</sub>      | < 2.5 kPa                      | Hyperventilation  |
|                       | > 8.9 kPa                      | Hypoventilation   |
| pH                    | < 7.2                          | Such pH values are characteristic of severely decompensated acidosis or alkalosis. Values < 7.20 and > 7.60 are life-threatening  |
|                       | > 7.6                          |   |
| pO <sub>2</sub>       | < 5.7 kPa                      | Such values correspond to a haemoglobin oxygen saturation of less than 80 % and are to be regarded as life-threatening.   |
| Potassium             | < 2.8 mmol/L                   | Neuromuscular symptoms; weakness of skeletal muscles; paralysis; cardiac arrest. Changes in ECG   |
|                       | > 6.2 mmol/L                   | Arrhythmia; skeletal muscle weakness can lead to paralysis of respiratory muscles   |
| T4, free<br>T3, total | > 45 pmol/L<br>> 46 nmol/L     | Indicative of thyrotoxicosis. Possible causes: Graves' disease, trophoblastic tumour, hyperfunctional adenoma, toxic nodular goitre, and, in rare instances, overproduction of TSH.   |
| Prothrombin time (PT) | > 40 sec (< 0.15)              | Decrease in the vitamin K-dependent factors II, VII, and X or in factor V. Disturbances in liver synthesis. In persons receiving coumarin therapy, there is a risk of haemorrhage if the PT is < 0.15 – which corresponds roughly to an INR of > 4. |
| Platelet count        | < $20 \times 10^9$ /L          | Risk of haemorrhage. Exclude EDTA-induced thrombocytopenia.   |
|                       | > $1000 \times 10^9$ /L        | Risk of thrombosis.   |
| Troponin              | > 0.1 $\mu$ g/L                | Indicative of myocardial infarct or unstable angina pectoris.   |
| Uric acid             | > 773 mmol/L                   | Acute urate nephropathy with tubular blockade and renal failure.  |
| Urea                  | > 35.6 mmol/L                  | Indicative of acute renal failure; unlike pre-renal and post-renal kidney failure, no disproportionate increase in urea compared to creatinine in serum.  |

\*Available at: <http://www.hkmb.hr/povjerenstva/strucna-pitanja.html#1> (14).

ferred as degree of agreement with proposed statements on a five grade Likert scale graded as 1 (completely disagree), 2 (mostly disagree), 3 (neither agree nor disagree), 4 (mostly agree) and 5 (completely agree). Thus, MBLs with the most favorable responses had the highest score, while MBLs with the least favorable responses had the lowest score.

### Statistical analysis

The questionnaire’s internal consistency was determined by calculating Cronbach’s alpha coefficient ( $\alpha$ ). Value of  $\alpha > 0.70$  indicates good survey reliability (15). Demographic characteristics of surveyed laboratories were presented as numbers and percentages (for questions on type of laboratory and critical results reporting policies). Responses to individual statements were presented as mean score with corresponding 95% confidence interval (CI). The mean score was calculated from scores for corresponding separate statements divided according to health care setting. Total score with 95% CI for all statements was calculated as the mean of all individual responses’ score. Since parametric methods are robust enough and can be used on ordinal data, we used a parametric statistical approach for data analysis (16). Differences in obtained scores between two groups were calculated using the Mann-Whitney test for independent samples.  $P < 0.05$  was considered statistically significant. All statistical analyses were performed using MedCalc statistical software version 11.5.1 (MedCalc, Mariakerke, Belgium).

### Results

Cronbach’s alpha coefficient for our survey was  $\alpha = 0.79$ , indicating a good reliability of the obtained test scores. A total of 111 laboratories participated in this survey, which represents 48% of MBLs. The total score of 3.64 (3.57–3.72) (on a scale from 1 to 5) for all statements surveyed was obtained.

The characteristics of the participating laboratories and general critical results policies are presented in Table 2. Hospital laboratories (HLs) com-

**TABLE 2.** Characteristics and general critical results reporting policies of surveyed laboratories in Croatia.

| Parameter   | N   | %    |
|---|-----|------|
| <b>Laboratories by health care setting</b>                      |     |      |
| Hospital laboratories   | 41  | 36.9 |
| General practice laboratories                                   | 70  | 63.1 |
| <b>Accreditation status</b>                                     |     |      |
| Accredited  | 5   | 4.5  |
| Accreditation in process  | 1   | 0.9  |
| Not accredited  | 105 | 94.5 |
| <b>Critical results reporting</b>                               |     |      |
| Yes   | 110 | 99.1 |
| No  | 1   | 0.9  |
| <b>LIS availability</b>   |     |      |
| Yes   | 108 | 98.2 |
| No  | 2   | 1.8  |
| <b>HIS availability</b>   |     |      |
| Yes   | 34  | 30.9 |
| No  | 76  | 69.1 |
| <b>Reporting responsibilities</b>                               |     |      |
| MSc and specialists   | 42  | 38.2 |
| All laboratory personnel (technical staff, MSc and specialists) | 68  | 61.8 |
| <b>Reporting channel</b>  |     |      |
| Phone   | 100 | 90.9 |
| Fax, e-mail, other  | 6   | 5.5  |
| All of the above  | 4   | 3.6  |
| <b>Timeframe of critical results reporting</b>                  |     |      |
| Up to 15 minutes  | 63  | 57.3 |
| Up to 30 minutes  | 28  | 25.5 |
| Up to 1 hour  | 15  | 13.6 |
| More than 1 hour  | 4   | 3.6  |

LIS – laboratory information system; HIS – hospital information system; MSc – master of medical biochemistry; Specialists – specialists in laboratory medicine.

prised laboratories located in special hospitals, general hospitals, clinics, clinical hospitals and clinical hospital centers, while primary care, private laboratories and polyclinic laboratories were designated as general practice laboratories (GPLs). The majority of laboratories who responded to the survey were GPLs compared to HLs (63.1% vs.

36.9%, respectively, analysis not shown) and non-accredited laboratories (94.5%, analysis not shown). Of all laboratories who participated, only one declared not to report critical results, leaving 110 laboratories for further analysis. In the majority of surveyed laboratories (61.8%, P = 0.017; analysis not shown) critical result reporting is the responsibility of all laboratory staff (i.e. managing personnel - master of medical biochemistry and specialists in laboratory medicine, and non-managing personnel – bachelor of science in laboratory diag-

nostics and medical laboratory technicians). The preferred channel for communicating critical results is by phone (90.9%, P < 0.001; analysis not shown). The majority of participants reported to notify critical results in a time frame of up to 15 minutes after re-testing and verification (57.3%, P < 0.001; analysis not shown).

Mean scores for statements regarding critical results reporting procedures of surveyed Croatian laboratories are presented in Table 3. When reporting critical test results, laboratories most often

**TABLE 3.** Comparison of mean scores for critical results reporting procedures of surveyed Croatian laboratories.

| Statement   | Total score (95% CI) | Mean score for hospital laboratories (95% CI) | Mean score for general practice laboratories (95% CI) | P (hospital vs. general practice) |
|---|----------------------|---|---|-----------------------------------|
| When reporting critical test results, the laboratory staff uses the values issued by the CCMB.  | 4.69 (4.56-4.82)     | 4.56 (4.29-4.83)                              | 4.77 (4.63-4.91)                                      | 0.296                             |
| Before reporting critical test result, the analysis is repeated.  | 4.72 (4.61-4.83)     | 4.49 (4.25-4.72)                              | 4.86 (4.75-4.96)                                      | <b>0.001*</b>                     |
| The critical test result is notified exclusively to the responsible physician.  | 4.20 (4.04-4.36)     | 3.76 (3.48-4.03)                              | 4.46 (4.29-4.64)                                      | <b>&lt; 0.001*</b>                |
| When reporting the critical test result, it customary to briefly comment the obtained results with the recipient of the results, in order to eliminate possible preanalytical errors. | 4.15 (3.98-4.33)     | 4.15 (3.88-4.42)                              | 4.16 (3.93-4.39)                                      | 0.727                             |
| When reporting the critical test result, it is customary to ask the recipient of the result to read-back the value notified.  | 3.16 (2.86-3.46)     | 3.41 (2.96-3.87)                              | 3.01 (2.62-3.41)                                      | 0.258                             |
| Reporting of critical test results is systematically recorded.  | 3.86 (3.56-4.17)     | 3.98 (3.47-4.48)                              | 3.80 (3.40-4.19)                                      | 0.555                             |
| The identity of the individual who reported the critical test result is collected within the record.  | 3.43 (3.07-3.79)     | 3.88 (3.34-4.42)                              | 3.16 (2.70-3.62)                                      | <b>0.045*</b>                     |
| The identity of the recipient of the critical test result is collected within the record.   | 3.74 (3.40-4.07)     | 3.98 (3.47-4.48)                              | 3.59 (3.15-4.03)                                      | 0.380                             |
| The record contains the patient's unique identification number.   | 2.65 (2.31-3.00)     | 2.88 (2.29-3.47)                              | 2.52 (2.09-2.96)                                      | 0.312                             |
| The record contains the test value with the unit of measure of the critical test result reported.   | 3.74 (3.39-4.08)     | 3.78 (3.22-4.34)                              | 3.71 (3.27-4.15)                                      | 0.991                             |
| The recorded data pertaining critical test results reporting are easily accessible for periodical evaluation?   | 2.95 (2.60-3.31)     | 3.29 (2.73-3.86)                              | 2.75 (2.30-3.21)                                      | 0.144                             |
| Contact information for critical results reporting (phone number / fax / e-mail) are available on the test request.   | 2.06 (1.78-2.34)     | 2.32 (1.85-2.79)                              | 1.91 (1.56-2.27)                                      | 0.068                             |
| The reporting of critical result is recorded on test report (i.e. as a comment).  | 2.00 (1.70-2.30)     | 2.37 (1.83-2.90)                              | 1.78 (1.43-2.14)                                      | <b>0.033*</b>                     |

CCMB – Croatian Chamber of Medical Biochemists. Total score and mean scores for hospital and general practice laboratories are presented as mean (95% CI). 95% CI – 95% confidence interval. \*Difference between hospital and general practice laboratories mean scores were calculated the Mann-Whitney test for independent samples. P<0.05 was considered statistically significant. \*Statistically significant difference.

used the critical result list issued by CCMB (score (95% CI) = 4.69 (4.56-4.82)). According to the obtained high score, Croatian laboratories in general re-analyze critical results before reporting (4.72 (4.61-4.83)). GPLs more often re-analyzed the sample before reporting the critical result in comparison with HLs (score: 4.86 (4.75-4.96) vs. 4.49 (4.25-4.72);  $P = 0.001$ ). GPLs more often reported the critical result exclusively to the responsible physician (4.46 (4.29-4.64) vs. 3.76 (3.48-4.03),  $P < 0.001$ ). Low mean scores were obtained for statements regarding the recording of critical result notification. HLs more often recorded details about the identity of who reported the critical test result (3.88 (3.34-4.42) vs. 3.16 (2.70-3.62),  $P = 0.045$ , respectively) and more often recorded the critical result notification on the test report (2.37 (1.83-2.90) vs. 1.78 (1.43-2.14),  $P = 0.033$ , respectively).

Table 4 presents mean scores collected from surveyed laboratories for attitudes towards critical results reporting. All the MBLs surveyed acknowledge that timely reporting of critical results influences the patient outcome (4.76 (4.66-4.87)). The agreement with the statement that CCMB list of critical results is complete and does not need revision differed significantly between GPL and HL: the list was more satisfactory for the GPLs, than for HLs (score: 4.58 (4.43-4.72) vs. 4.10 (3.86-4.34);  $P < 0.001$ ).

## Discussion

In this investigation, we surveyed policies and procedures currently used in critical results reporting in Croatia. The total score of 3.64 (on a scale from 1 to 5) for all statements surveyed can be regarded as an indicator of very good practice in critical results reporting in Croatia. However, considerable deviations from desirable procedures for critical result reporting were demonstrated for statements regarding recording and documentation of critical results notification. The homogeneity of least favorable responses (evidenced by lower scores) detected for this segment of critical result reporting procedures reflects the lack of specific and definite recommendations (local and / or national).

Although critical results comprise just up to 2% of all laboratory results, it is the MBL's responsibility to monitor this important part of the post-analytical phase (11,17). Accreditation and patient safety standards require MBLs to have a management system for timely and reliable critical results notification. Key procedures in a critical results management system that require harmonization are: a) definition of the term "critical result", b) compilation of a critical limits list, c) definition of critical result reporting procedures, with special emphasis on timeliness of reporting, and communicating procedures as to who reports, to whom the critical result is reported and how is receipt of the result

**TABLE 4.** Comparison of scores for attitudes towards critical results reporting

| Statement  | Total score (95% CI) | Mean score for hospital laboratories (95% CI) | Mean score for general practice laboratories (95% CI) | P (hospital vs general practice) |
|--|----------------------|---|---|----------------------------------|
| Timely reporting of critical results influences the patient outcome.   | 4.76 (4.66-4.87)     | 4.71 (4.55-4.87)                              | 4.80 (4.65-4.94)                                      | 0.136                            |
| The recommended critical value list issued by the CCMB comprises all the analytes needed in your routine work. | 4.40 (4.27-4.53)     | 4.10 (3.86-4.34)                              | 4.58 (4.43-4.72)                                      | < 0.001*                         |
| The recommended critical value list issued by the CCMB does not need a revision.                               | 3.79 (3.59-4.00)     | 3.41 (3.03-3.80)                              | 4.01 (3.79-4.24)                                      | 0.012*                           |

CCMB – Croatian Chamber of Medical Biochemists; Total score and mean scores for hospital and general practice laboratories are presented as mean (95% CI); 95% CI – 95% confidence interval. Difference between hospital and general practice laboratories mean scores were calculated the Mann-Whitney test for independent samples.  $P < 0.05$  was considered statistically significant. \*Statistically significant difference.

confirmed, d) definition of data that should be recorded, e) establishment of procedures for monitoring and evaluating the performance of critical results management procedures (5,18). This survey was designed to identify variations in these procedures on a national level.

We demonstrated that all MBLs (i.e. HLs and GPLs) in Croatia are almost equally aware of the importance of reporting critical results. All the MBLs surveyed (with one exception) declared the implementation of this valuable post-analytical quality indicator into routine practice. As expected, high level of harmonization is achieved nationally regarding the selection of critical result limits. The favorable total score of 4.69 can be explained by high adherence to the critical results list provided by CCMB. The values provided in the CCMB list are literature derived (19) and MBLs in Croatia mostly agree that it comprises all the analytes necessary for their routine work. Hospital laboratories, however, opine that the CCMB list of critical results needs reviewing and up-dating. The CCMB list of critical values has contributed greatly to the harmonization of this aspect of critical result management, but it must be emphasized that critical result lists should be tailored by each individual laboratory, in consultation with physicians/clinicians, thus implementing data from published literature with professional experience (5,17,20). Expectedly, this aspect of critical results management will hardly ever achieve complete national harmonization.

Since national recommendations for critical results reporting procedures are not available in Croatia, differences in critical results reporting between MBLs surveyed were detected. Our results suggest that critical result reporting is considered a responsibility of all laboratory personnel since the majority of MBLs investigated declared that technical as well as managing staff are involved in critical results communication. This is in contrast with findings from previously published surveys. Results from the majority of similar national surveys indicate that laboratory technicians, who performed the test, were responsible for critical result reporting (10-13,21). However, in Italy laboratory

managers are predominantly involved in critical test result communication (9,22).

A 90.9% of MBLs surveyed in Croatia stated to use the phone as the preferred mechanism for critical result reporting. These results are in accordance with all previously published data (11-13,21,22). However, increasing interest has been demonstrated for alternative channels of communication, based on automation and/or information technology, that are faster and closer to the physician and the patient (13,23-25).

The EN ISO 15189:2012 standard for medical laboratories considers "physicians or other authorized health professionals" suitable recipients of critical results (6). The CCMB document specifies that the physician is the acceptable recipient of critical results (14). Our survey revealed that general practice laboratories in Croatia achieved a higher score, compared to hospital laboratories, regarding notification of critical results exclusively to responsible physicians. This result is very interesting since it has been demonstrated that contacting a physician, especially in an outpatient setting and/or after office hours, is considered the greatest obstacle to timely critical result reporting (9,11,13,17). It can be concluded that general practice laboratories in Croatia seem more determined and prone to comply with local regulations compared to hospital MBLs, although we acknowledge that hospital physicians cannot always be reached by phone because of the tasks' complexity in hospital care.

Re-analyzing of critical results before their notification is standard practice in Croatia (total score 4.72). Hospital laboratories achieved a lower score for re-analyzing before reporting critical result, which suggests lesser frequency of re-analyzing in this clinical setting. Indeed, although the CCMB recommends re-analyzing critical tests to rule out possible erroneous results, recent investigations demonstrated that re-analyzing of critical results adds little to test reliability, and ultimately to patient safety (17). Additionally, repeated verifications necessarily delay critical results notification and increase laboratory costs (26-28).

Timeliness is a crucial aspect of critical result reporting. No recommendations are available, but a



mean "in laboratory" turnaround time (TAT) for critical values of 22 minutes was obtained for a large academic medical centre. Thus the authors set the limit of acceptability of TAT for critical values at 30 minutes (23). In another investigation, notification median time from result verification was found to be 4 minutes and median time from collection to first result was 48 minutes. The authors emphasized the need to establish laboratory timeframes for critical value reporting and proposed that 15-30 minutes after test completion seems a reasonable goal (10). According to our results, 82.8% of surveyed MBLs in Croatia meet this proposed goal (i.e. they notify critical results in a timeframe up to 30 minutes from result verification).

The communication of critical test results directly affects patient outcome, thus erroneous notification of critical test results can be considered a medical error. Read-back of verbally reported critical values is an established way of acknowledging result receipt, although variable practices are present across countries (17,22,29). The obtained score for read-back procedures of critical results in Croatia indicates that this aspect of critical result management could be improved. Efforts should include education of laboratory but also medical staff to raise the awareness of importance of read-back procedures for improving patient safety.

According to the EN ISO 15189:2012 standard, the laboratory should keep records of "actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications" (6). This data recording enables laboratories to monitor and measure their performance in notifying critical results and identify possible improvements (17). Our results indicate that low mean scores, with practically no differences

among hospital and general practice laboratories in Croatia, were observed for statements regarding recording of data and performance evaluation of critical result notification. It must be noted that hospital laboratories obtained slightly better scores for recording the identity of who reported the critical test result and recording the critical result notification on the test report. This extremely important aspect of critical result management calls for urgent improvement in Croatian laboratories.

We have to acknowledge a few limitations of our study. Firstly, the response rate of our nationwide survey was 48%, which means that our results may not be representative of all Croatian MBLs. Furthermore, data from our participants were self-reported and thus could not be independently verified.

In conclusion, our results confirm that considerable deviations from desirable procedures for critical result management are present in Croatia. Thus, the urgent need of nationally and/or locally established policies and procedures for the management of critical results is evident. Variations in practices reported after surveys on critical result reporting procedures have been observed to trigger the formulation of recommendations on critical results reporting (17,30,31). Therefore, we believe that this investigation will contribute to the achievement of this desirable scenario in Croatia as well.

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## Potential conflict of interest

None declared.

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