

Critical results reporting in Portuguese hospital laboratories: state-of-the-art

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ABSTRACT

Introduction

This survey aimed to assess the state-of-the-art of current practices on critical results reporting among Portuguese Clinical Pathology Laboratories. The results of the survey will set basis for future standardization and national guideline development.

Materials and methods

The survey was transmitted to 49 Clinical Pathology Laboratories among public hospitals inserted in the Portuguese National Health System. In 27 questions, laboratories were asked about their critical results procedures, critical results list, reporting and further education. Data were analyzed using Microsoft Excel v.2016 and MedCalc Statistical Software version 12.5.0.0 (Ostend, Belgium). Where applicable, the comparison of proportions was used to estimate the level of significance ($P < 0.05$).

Results

The response rate was 44/49 (90%), including 36 participants with a defined critical results reporting proce-

ture. Among them, 31 laboratories defined a critical results list, mainly based on published literature (27/31). There was a statistically significant number of laboratories ($P=0.019$, 24/30) that report different critical results depending on the patient's age, but regardless of disease, ethnicity and location ($P>0.05$). The majority of laboratories (60%) report critical results via telephone within 15 minutes. Critical results are usually reported by clinical pathologists to physicians. Twenty-five laboratories periodically re-evaluate their critical results list.

Conclusion

Despite the fact that most of the Portuguese hospitals have a critical results policy, this survey showed high variability among the hospitals concerning critical results reporting practices and critical results list. This survey points out that nationally established procedures and guidelines are urgent step for critical results standardization.



INTRODUCTION

Critical results of laboratory analyses indicate a high risk of major patient harm or possible death, and require immediate medical intervention and urgent patient treatment (1). These dangerously abnormal laboratory results, also known as “panic” or “alert” values, are first defined by George D. Lundberg and his colleagues in 1972. Currently, the term “panic value” has been abandoned as it represents emotional stress and disables clear communication between laboratory and physicians. However, urgent results need to be distinguished from the critical ones. Urgent results are required by physicians and they need to be processed and reported urgently, nevertheless if they are abnormal or not (2, 3). Management of critical results includes every step between finding out the critical result during laboratory analysis, informing the healthcare

personnel responsible for patient care, as well as their appropriate action. Definition of laboratory parameters and their values that should be considered as critical and life-threatening is complicated due to various recommendations and different expert opinions (4, 5, 6). An appropriate definition of critical results and their compliance is needed to ensure patient safety.

Various practices, different terminologies, parameters included in the critical results list and their values, reporting pathways and communication with physicians and other healthcare personnel affect the quality of critical results management (5, 7). Despite many recommendations, it is evident that many aspects such as lack of standardization and quality indicators are still challenging issues in this area (1, 6).

Furthermore, surveys conducted all over the world discovered a lack of harmonized practices, both internationally and within the same country (7, 8, 9, 10, 11). We hypothesized that a similar situation would be in the Clinical Pathology Departments of the Portuguese Public Health System. According to the Clinical and Laboratory Standards Institute (CLSI) GP47 guideline, each laboratory should develop a certain strategy for critical results management (4). To do so, it is crucial to identify current critical points, possibilities for improvement and set basis for future standardization and guideline development. Therefore, we aimed to assess the state-of-the-art of current practices on critical results reporting among Portuguese Clinical Pathology Laboratories.

MATERIALS AND METHODS

In order to evaluate the status of current practices on critical results reporting, a comprehensive survey was created and transmitted to 49 Clinical Pathology Laboratories among public hospitals inserted in the Portuguese National Health System. A survey was sent to all Laboratory

Directors with a deadline for answer and those who did not respond on time were excluded. The survey was conducted between November and December 2018. Questionnaires were distributed by an e-mail and data were collected using Google Forms.

Survey development

A survey composed of 27 questions (multiple choice questions and yes/no responses) comprised essential topics for the laboratory management of critical results – “Characteristics of Participating Laboratories”, “Characteristics of Critical Result Policies”, “Characteristics Relating to Critical Result Practices”, “Analytes Included on Critical Result List” and “Education” as shown in Tables 1-5. The last section (“Education”) was aimed to establish the attitude of laboratories regarding further improvement on this issue. Confidentiality was assured to all participating laboratories in order to preserve their privacy rights, although the results were never intended

to be presented individually or to reveal the identity of the hospital.

Data analysis

The analysis was carried out using Microsoft Excel v.2016 and MedCalc Statistical Software version 12.5.0.0 (MedCalc Software, Ostend, Belgium). Most data were presented as percentages or ratios when the total number of observations was low. For some proportions, the level of significance has been estimated ($P < 0.05$) using the MedCalc statistical test “comparison of two proportions” (e.g. we estimated if there is statistically significant difference between critical result management between accredited and non-accredited laboratories).

RESULTS

Out of 49 pathology laboratories in Portugal, 44 participated in the survey, thus giving the response rate of remarkably high 89.8%. Among them, 36 reported that they have a certain

Table 1 First part of the survey composed questions about the “Characteristics of participating laboratories”

	Questions	Answers
1.	Is your laboratory accredited?	- Yes - No
2.	Does your laboratory report Critical results?	- Yes - No (end of questionnaire)

Table 2 Second part of the survey referred to the “Characteristics of critical result policies”

	Questions	Answers
1.	Does your laboratory have a defined list of critical results?	- Yes - No

2.	How many critical results are included in the critical results list?	<ul style="list-style-type: none"> - More than 20 - 15 to 20 - 14 to 10 - 9 to 5 - Up to 5
3.	Which was the primary resource for your list of critical results? (more than 1 answer is permitted)	<ul style="list-style-type: none"> - Published literature/textbooks - Consensus with physician - Manufacturer's recommendation - Internal study of healthy individuals
4.	Are there critical results for different age groups?	<ul style="list-style-type: none"> - Yes - No
5.	Are there critical results for different populations based on disease type?	<ul style="list-style-type: none"> - Yes - No
6.	Are there critical results for different populations based on ethnicity?	<ul style="list-style-type: none"> - Yes - No
7.	Are there different critical results for out- and inpatients?	<ul style="list-style-type: none"> - Yes - No

Table 3 Third part of the survey composed questions about "Characteristics relating to critical result practices"

	Questions	Answers
1.	Who is involved in routine notification of critical results to caregivers?	<ul style="list-style-type: none"> - Clinical Pathologist - Superior Laboratory Technician - Laboratory Technician - Others
2.	How are critical results reported to caregivers?	<ul style="list-style-type: none"> - Mobile phone - Department Phone - Electronic communication of critical values
3.	Which is set timeframe of critical results reporting in your laboratory?	<ul style="list-style-type: none"> - Up to 15 minutes - Up to 30 minutes - Up to 1 hour - More than 1 hour

4.	Before reporting critical result, the analysis is repeated?	- Yes - No
5.	Is there an automatic critical result notification system in your laboratory?	- Yes - No
6.	Is the reporting of a critical result documented?	- Yes - No
7.	How is reporting of a critical result documented in your laboratory?	- Comment in the computer system - Written on the result form - Both above
8.	Are the recorded data of a reported critical result easily accessible for all laboratory staff?	- Yes - No
9.	Is the list of critical results periodically evaluated?	- Yes - No
10.	Does your laboratory have the perception of the total number of critical results actually reported?	- Yes - No
11.	Who can receive a critical result?	- Ordering physician - Nurse - On-call physician/resident - Other
12.	Does your laboratory have a “read back” policy implemented?	- Yes - No

Table 4 Fourth part of the survey about Clinical Pathology areas and “Analytes included on critical result list”

	Questions	Answers
1.	For which areas of Clinical Pathology have your laboratory established critical results?	Microbiology - Yes - No Hematology - Yes - No Clinical Chemistry - Yes -No

2.	Which chemistry parameters are included in your critical results list?	<ul style="list-style-type: none"> - Ammonia - Bilirubin - Creatinine - Glucose - Ionized calcium - Lactate - Lipase - Magnesium - Myoglobin - Pancreatic amylase - Phosphate - Potassium - Procalcitonin - Reactive C Protein - Sodium - Therapeutic drugs - Thyroid-stimulating hormone (TSH) - Total calcium - Troponin - Urea
3.	Which hematology parameters are included in your critical results list?	<ul style="list-style-type: none"> - Blasts in peripheral smear - Erythrocyte Sedimentation Rate (ESR) - Hemoglobin - Malaria parasites in peripheral smear - Platelets - Total White blood count - Total Neutrophils count
4.	Which microbiology parameters are included in your critical results list?	<ul style="list-style-type: none"> - Acid-alcohol-resistant bacilli - Carbapenemase-producing Enterobacteriaceae (CPE) positive in screening - Detection of Clostridium difficile - Fungus in blood cultures - Gram negative bacilli in blood culture - Gram positive cocci in two set of blood cultures - Gram positive cocci in one set of blood cultures - Legionella urinary antigen - Methicillin-resistant Staphylococcus aureus (MRSA) - S. pneumococcal urinary antigen - Type A or B Influenza

Table 5 Fifth part of the survey asked about future “Education”

	Questions	Answers
1.	Do you consider that professional qualification on critical results is important in Portugal?	- Yes - No
2.	Do you consider important to implement consensus on reporting critical results in Portugal?	- Yes - No

procedure for critical results reporting. Half of the surveyed laboratories were not accredited (23/44), but there was no statistically significant difference in critical result management despite laboratory accreditation status ($P=0.695$).

The majority of laboratories (31/36, $P<0.0001$) indicated that they have defined a list for critical results reporting. For almost half of these laboratories (13/31), their defined list included more than 20 critical risk results for different analyses. The numbers of Portuguese laboratories which report critical results of particular parameters in each area of clinical pathology – clinical chemistry, hematology and microbiology are shown in Figure 1, Figure 2 and Figure 3. Twenty-six laboratories report critical risk results in all three main areas of clinical pathology. Most reported chemistry parameters are potassium (28/29), sodium (25/29), glucose (27/29) and creatinine (23/29). Regarding hematology parameters, all surveyed laboratories report critical results of hemoglobin (28/28) and most of them report critical results of platelets (25/28). *Acid-alcohol-resistant* bacilli is the most reported parameter in the microbiology area as 23 out of 26 laboratories report its critical result.

Out of 31 laboratories, 28 used only one resource to define their critical results list – previously published literature (24/28) or consensus with physicians (4/28). Remaining three laboratories combined these two resources. Moreover,

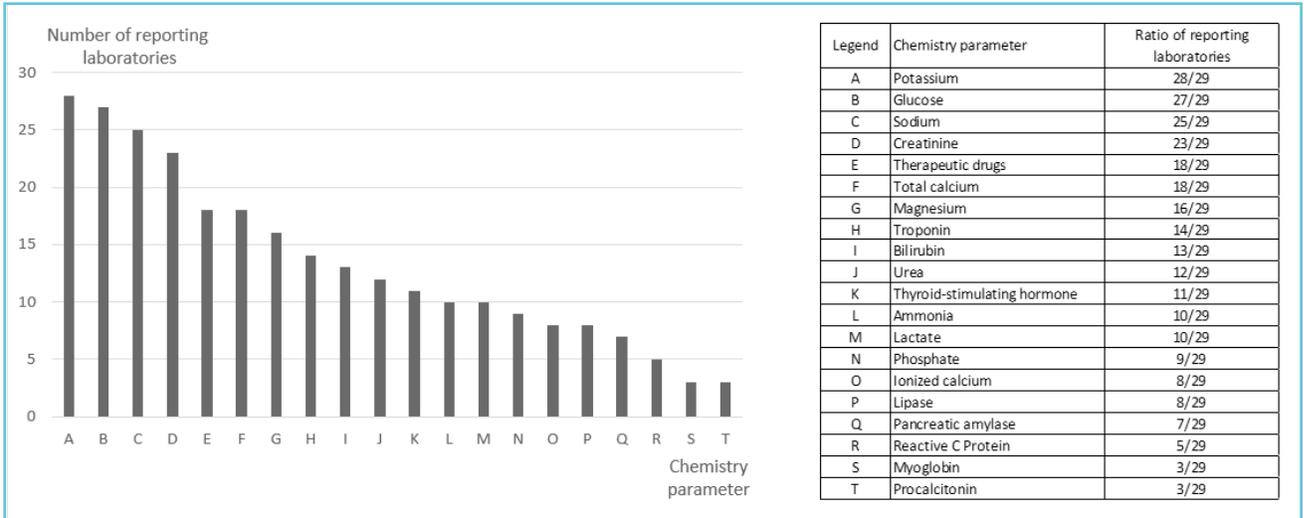
25 out of these 31 laboratories stated that their critical results list is periodically evaluated.

There was a statistically significant difference in the number of laboratories that report different critical results depending on the patient’s age (24/30, $P=0.019$). However, they report the same critical results regardless of disease type (20/30, $P=0.1684$), location (in- and outpatients; 21/30, $P=0.103$) and ethnicity (29/30, $P=0.083$).

In 25 out of 36 laboratories, critical result information is reported by technicians or clinical pathologists, while in other 11 laboratories it is done by clinical pathologists exclusively. Critical risk results are mainly reported via telephone (35/36) to physicians (32/36) or nurses (4/36). Moreover, some laboratories (13/36) implemented a “read back” policy for critical risk results reporting. Only 4 out of 36 hospitals have implemented automated notification systems between laboratory and clinical departments. However, in the majority of laboratories (31/36) reported critical risk result is also documented in the laboratory information system (LIS) and easily accessible for all laboratory staff (31/36).

Half of the surveyed laboratories re-analyze critical results before reporting (19/36, $P=0.785$). Regards to timeframe limits for critical result reporting, 60% of surveyed laboratories have set 15 minutes timeframe, 33% have set 30 minutes, and only 7% of laboratories report critical results within one-hour timeframe. All 44 surveyed

Figure 1 Number of laboratories that report critical results of certain parameters in clinical chemistry*



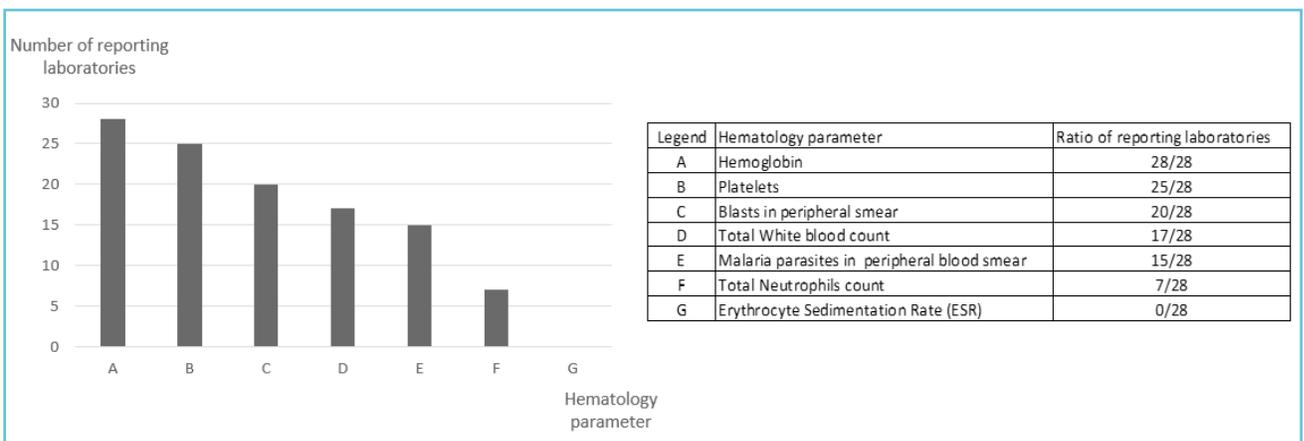
*Total number of reporting laboratories in Portugal is 36;
 Out of them, 29 laboratories report critical results in clinical chemistry area.

laboratories stated that it is important to implement national guidelines concerning reporting critical risk results in Portugal. Moreover, they also indicated that professional qualification on critical risk results is fundamental. Considering that the privacy of survey participants has been assured, all laboratories were consent with this publication.

DISCUSSION

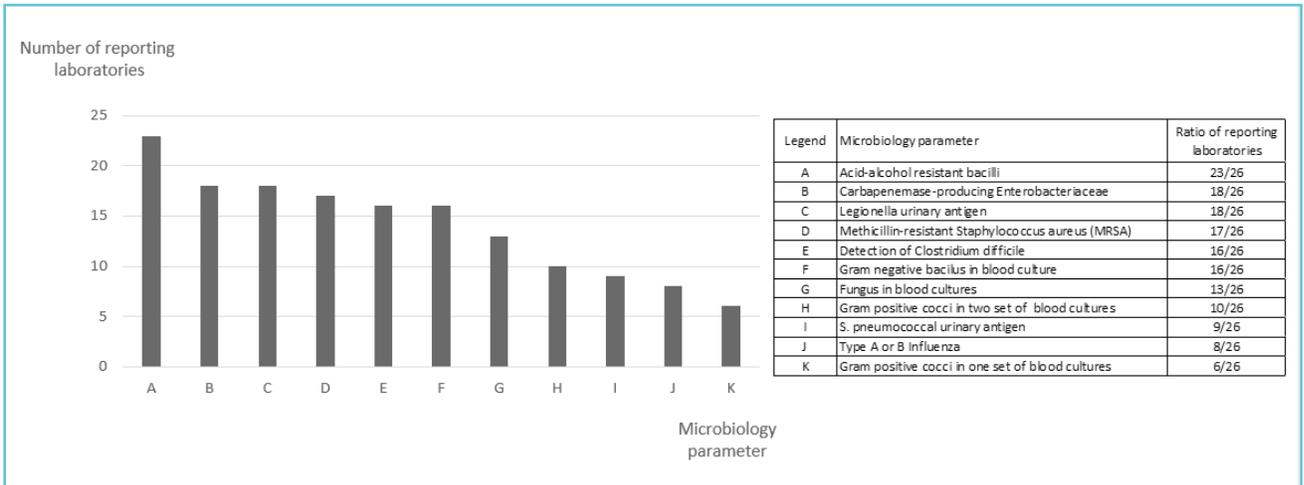
This survey aimed to assess the state-of-the-art of critical results reporting among Portuguese laboratories. Results show that 82% of surveyed laboratories have a certain procedure for critical results reporting. However, they also reveal that practices, timeframes, analytes, and values

Figure 2 Number of laboratories that report critical results of certain parameters in hematology*



*Total number of reporting laboratories in Portugal is 36;
 Out of them, 28 laboratories report critical results in hematology area.

Figure 3 Number of laboratories that report critical results of certain parameters in microbiology*



*Total number of reporting laboratories in Portugal is 36; Out of them, 26 laboratories report critical results in microbiology area.

vary widely among laboratories in Portugal. Considering an impressively high response rate, this survey provides valuable insight into the heterogeneity of critical result laboratory management.

Consistent with some other international surveys, our results show great variability in critical risk results, and even the number of analytes included in predefined lists (8, 9, 10). Half of the participating laboratories include more than 20 critical results of different parameters and different areas of clinical pathology. Wagar et al. described that there are advantages to a relatively limited list of critical results (12). The long and complex list often includes some parameters of which critical results are not necessarily “life-threatening”. These kinds of lists require increased laboratory personnel investment and confuse the importance of critical results. Moreover, we were unable to confirm that laboratory management of critical results depends on the accreditation status of the laboratory as non-accredited laboratories in Portugal have a similar practice in reporting and developing their critical results lists. According to the CLSI

GP47 guideline for critical results management, the critical result list development should reflect professional consensus and sources should always be documented (4). The majority of the laboratories in our survey used previously published literature to develop their critical results list, and only 7 laboratories consulted with physicians. These results reflect those reported previously in Spain and China (10, 11). Lam Q. et al. also emphasized about “published literature” as commonly cited resource for critical results list development, unfortunately that literature is usually not quoted nor further explored (1). Guidelines also recommend that each laboratory should develop customized critical result list suitable for the clinical needs of their patient populations in every healthcare environment (4). Sonjic et al. recently investigated the physicians’ attitudes about unique critical results list in one hospital in Croatia, and stressed out the need for different approaches for each hospital department (13). As reported by Salinas et al., decision making and critical results reporting efficiency are improved if individual patient characteristics are observed.

Unfortunately, Portuguese laboratories only report critical results in accordance with patient's age, but regardless of patient location, disease type or ethnicity. Very similar results are previously reported in a survey conducted by College of American Pathologists (CAP) (14). This survey revealed a gap for the improvement and set the basis for Portuguese laboratories to take action. Laboratories should develop consensus with physicians in order to customize their critical result lists according to groups of patients in different departments and their individual clinical needs.

The fact that most of the surveyed laboratories in Portugal report critical results of potassium, sodium, and glucose broadly reflects on the situation in Europe. The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) also found that these three parameters are included in critical results lists of 90% surveyed laboratories in 30 countries among Europe (1). However, the obvious lack of agreement is present in other parameters and critical result values (9, 13, 15).

Results related to communication practices show that the majority of critical results are reported by clinical pathologists to referring physicians which is previously proved to be the most effective pathway for immediate medical intervention and treatment (10, 11, 16). However, reporting by telephone remains main communication channel which diverts and burden laboratory workload, especially in situation when referring physician can not be contacted (6). Several recent guidelines and accreditation standards require the laboratory to establish critical result communication strategy and reporting protocol (1, 4, 6, 16). The International Council for Standardization in Hematology proposed alternative electronic pathways that will ease laboratory work but still be effective and fast (17). Half of the laboratories in Portugal re-analyze critical results before reporting which

confirms controversy in recent surveys and recommendations. The most recent study conducted in Spain suggest analytical repetition in their notification protocol, while other studies, stated that it contributes to the unnecessary delay of critical results reporting (18, 17, 7). Moreover, CLSI guidelines also emphasized that this repeat examination practice should be carefully evaluated for its usefulness (4). According to CLSI GP47 reporting timeframe classification, all timeframe limits for critical results reporting, set by surveyed laboratories in Portugal, have been "acceptable" (within 60 minutes) (4). Moreover, 60% of Portuguese laboratories report critical results within 15 minutes and thus are classified as "timely". In a survey conducted by the College of American Pathologists, the reporting time for inpatients and outpatients was also within 15 minutes (9, 12, 19), despite that reporting within 30 minutes was also considered acceptable. Interestingly, communication was much faster using computerized options rather than the telephone (12).

Although the majority of surveyed laboratories stated that reported critical results have been documented in LIS, automated notification system and "read-back" policy has been underestimated in Portugal. The implementation of these practices has also been inconsistent in other countries among Europe (1, 17). According to the accreditation norm ISO 15189 (requirement 5.8.2.), the laboratory should keep documentation of critical results for a certain period and continuously monitor reporting performance (6, 16, 17). CLSI also state that entire chain of communication should be well documented in real time (4). Thus, the laboratory can make corrective actions and improvements in reporting and critical results list content. It is noteworthy that 80% of laboratories in Portugal periodically re-evaluate their critical results list. Moreover, all surveyed laboratories stated that further education and

development of national guidelines are substantial in this kind of manner.

This survey also has some limitations. In Portugal most Clinical Pathology Departments do not carry out haemostasis and coagulation studies, which is why INR was not included in this survey. This parameter is performed by Blood and Transfusion Departments. Moreover, laboratory management of critical results highly depends on patient population, therefore these results are not transferable to other countries. Further studies in different healthcare environments are still needed.

To the best of our knowledge, this is the first study on laboratory management of critical results in adults in Portugal. Despite most of the Portuguese hospitals having a critical results policy, this survey shows high variability among the hospitals concerning critical results policies, critical results practices and even critical results list.

Standardization of laboratory management of critical results is a necessary and urgent step, which will improve the diagnostic efficiency and reduce the delay in the identification of patients at risk. Thus, the urgent need for nationally and/or locally established policies and procedures for the management of critical results is evident.

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