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Assessment of critical values policies in Italian institutions: comparison with the US situation

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Abstract

Background: Critical value reporting is considered an essential tool to ensure the quality of medical laboratory services. Important issues include defining cut-off values, assessing responsibility for communication and adopting information technology solutions to improve notification. Here, we report the state of critical value reporting in a large cohort of Italian laboratories and comparison with Q-Probes surveys from the College of American Pathologists as representatives of the US situation.
Methods: To compare critical value policies and procedures, formulation of critical values list with critical values limits and monitoring tools, a web-based questionnaire was formulated for 389 institutions participating in the External Quality Assessment Schemes of Veneto Region, in Italy.
Results: A total of 90 clinical laboratories submitted data. Accredited laboratories represented 82.2% of participants, but written procedures for reporting were indicated by 70.5% of participants. Relevant differences between US and Italian policies have been observed, particularly regarding who provides the notification and on the formulation of the cut-off threshold for critical values.
Conclusions: Accreditation according to international standards can decrease differences regarding the management of critical values across laboratories of different countries. However, the issues concerning critical limits should be debated and a consensus critical values list should be considered. Automated systems could offer improvements regarding some issues, such as who makes the notification, reducing the time spent in notification of critical values. Surveys for comparing and improving existing policies regarding critical values should be promoted at an international level.
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Introduction

Critical values, formerly known as panic values, are test results that fall significantly outside the normal range and represent a life-threatening condition (1). Since the Lundberg concept of critical values was adopted, laboratories have been responsible for notifying physicians of critical values so that clinical interventions can be made in an appropriate time frame. To provide better care to patients, accreditation standards such as those contained within the Clinical Laboratory Improvement Amendments (CLIA), or supported by the Joint Commission (JC) and College of American Pathologists (CAP) have attempted to assess the quality of critical value result reporting (2–4). Since 2005, the JC has stated that the effective reporting of laboratory critical values has become a National Patient Safety Goal. Also in the US, the Massachusetts Coalition for the Prevention of Medical Errors has developed strategies for communicating critical test results in a timely and reliable way to clinicians so that they can take immediate action (5). Internationally, the most widely accepted standard is the ISO EN 15189:2007, which includes (in clause 5.8.7) the immediate notification of a critical value as a special requisite (6). In the UK, the Clinical Pathology Accreditation (CPA) has defined critical value reporting as essential to ensure the quality of diagnostic laboratory services (7). The failure to notify caregivers of a critical value is considered to be a medical error. Laboratories must seek ways to reduce these errors by changing organizational culture, educating professionals, and developing and adopting reliable notification processes. New issues concerning critical values are arising. These include defining cut-off values, assessing responsibility for communicating critical values, identifying indicators to monitor process improvement, and using the most up-to-date information technology (IT) in the notification process. Using a web-based questionnaire on institutional critical value practices and policies, data from 90 clinical laboratories were evaluated. The current state of critical value reporting in Italy and a comparison with Q-Probes surveys from the CAP is presented in this report.

Materials and methods

Study design

This study was conducted to develop an understanding of the policies and management surrounding critical values in a large cohort

of Italian clinical laboratories. A total of 389 institutions that subscribed in 2009 to the External Quality Assessment Schemes of Center of Biomedical Research (CBR), Castelfranco Veneto, Treviso, Italy, were invited to participate in this survey. Participants were asked to provide demographic information concerning the bed number, occupancy, institution location, institution type, and accreditation/certification status. The respondents' rate to the survey was 23% which included all responders that answered all the questions. The questionnaire was web-formulated and questions were multiple choice or yes/no. Participants could introduce comments, depending on the question. The questionnaire was designed to investigate the issues below.

1. Institutional policies and practices of the laboratories for reporting critical values;
2. Policies regarding the notification of health care providers of critical values, in particular a) the selection of critical values, and the process for reviewing and updating this list; b) procedures for notification of critical values for inpatients and outpatients; c) the laboratory professionals who were authorized to communicate critical values; d) the healthcare providers authorized to accept the notification from the laboratory; e) the major difficulties in the notification process;
3. Participants were asked to provide their high and low critical values for the following laboratory assays: potassium, sodium, magnesium, calcium, neutrophil count, hemoglobin, platelet count, prothrombin time (PT) and activated partial thromboplastin time (aPTT);
4. Participants were asked about the criteria used to formulate the critical value list;
5. Participants were asked about the monitoring system in their institution to determine the effectiveness of the reporting process for critical values.

The critical values list submitted by each participant was also assessed in this study to evaluate the variability in the critical value lists among participating institutions. In general, most institutions tested serum rather than plasma.

Statistical analysis

Laboratories reported data using the units of the test results they commonly used, and these were converted to SI units by applying established conversion factors. The participants' answers were compared to the most recent Q-Probes surveys of the CAP. Frequency distribution of lows and highs for critical values were evaluated. Critical values submitted were ranked according to the 2007 Q-Probes percentile rankings, with the 5th percentile corresponding to the lowest critical values, the 95th percentile corresponding to the highest, and the 50th percentile corresponding to median values (8).

Results

Specific characteristics of the institutions participating in the study

A total of 90 institutions submitted data for this study. Of these, 48.9% (44) were public hospitals, while the remaining 53.1% (46) were for profit and not for profit private institutions. A total of 52.3% of participating institutions had $<$150 beds; 21.6% had 150–300 beds; 17% had more than 300 beds and some of these were hospitals with pathologists in training. Accredited or certificated laboratories represented 82.2% of participants. Certification had been earned according to ISO standards at 57.8% of the institutions, to regional (local) norms at 22.2% of the institutions, and 2.2% according to CPA or Canadian Council standards. Participating laboratories operating without accreditation or certification represented 17.8% of responders.

Reporting procedures

The percentage of participants that indicated that written procedures were in place in their institutions for critical value identification and reporting was 72.2%; 90% of these participants indicated that they assessed the timeliness of reporting the results, but 10% did not report the turnaround time for reporting of critical values. Survey responses regarding the review of critical values showed that only 63.3% of laboratories regularly update their procedures. The reporting of critical values from the laboratory to caregivers was made mainly by telephone (81.1%). Less commonly used means of communication included computer (10%), fax (1.1%) or all tools indicated (7.8%). No laboratories used call centers for notification of critical values. In addition, no participants performed notification using wireless technology. In this study, 64.4% of the respondents affirmed that critical values are easily identified by the laboratory information system (LIS) in use at their institution. The notification was made principally by laboratory managers, i.e., pathologists, biologists, doctors on call (83.3%) rather than by laboratory technologists, who provided the notification in only 11.1% of the institutions. A comparison with the 2008 CAP survey is shown in Figure 1. For inpatients, the critical values were communicated to physicians ordering the test (37.3%), nurses (29.4%), any physician on call (17.9%), any people working on the ward (11.9%), and clerks (3%). A comparison to the survey proposed by the CAP in 2008 is shown in Figure 2. For outpatients, the communication of critical values was made to general practitioner (GP, 80%), directly to patients (12.2%), GP's secretary (3.3%), nurses (1.1%), GP's relatives (1.1%), or anyone answering the telephone (2.2%). Comparison to CAP surveys is shown in Figure 3.

Monitoring critical value reporting process

Survey responses regarding institutional policies for monitoring of critical values are presented in Table 1. In the present survey, many laboratories require the read-back of critical values as proposed by the JC, and established a policy requiring communication within a certain timeframe. Nevertheless, 81.1% of respondents indicated that they did not document this time. A total of 7.8% of respondents could establish errors in the process of communication in their institution.

The main difficulties in the notification process

Participants were asked to identify the major challenges in their notification process of critical values. For inpatients, the respondents indicated that the main difficulties were

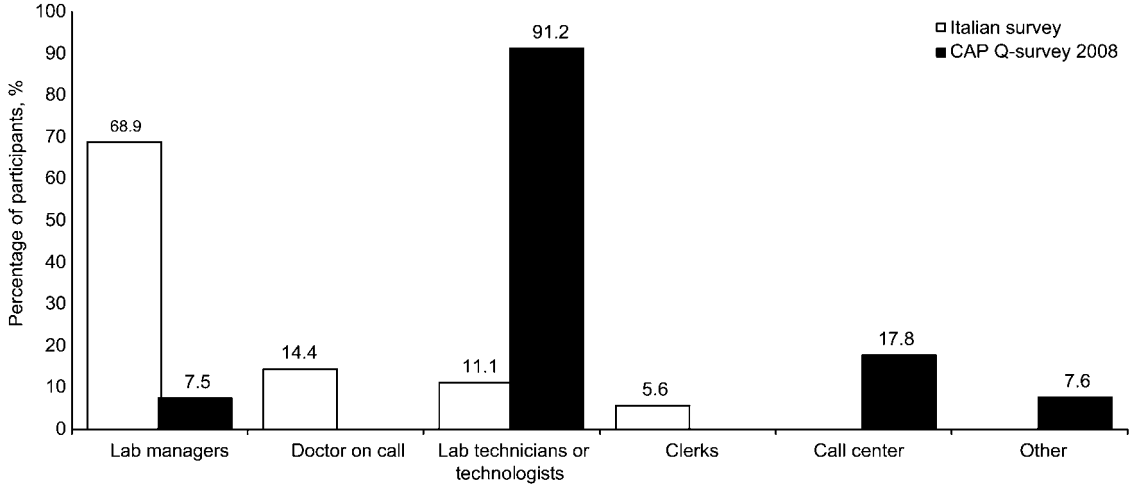

Figure 1 Characteristics related to critical values notification and comparison to the 2008 CAP surveys.
Comparison shows that in the US notification is made by laboratory technicians or technologists more than 80% of the time, while in Italy the percentage of technologists who make phone calls is only 11.1%. Usually, the majority of notifications are made by laboratory managers (medical doctors, doctors on call, other medical graduates).

reporting critical values to the actual physician assigned to care of the patient (55.6%), knowing the name of the assigned physician (17.8%), and promptly identifying the person who was calling to accept the results (17.8%). No difficulties were noted by 8.9%. For outpatients, 51.1% of participants indicated that the main cause of unsuccessful notification was a) the lack of availability of the telephone numbers of the GP, b) the lack of reaching the GP after office hours (24.4%). A total of 4.4% of participants indicated difficulties in identifying GPs from their prescriptions written to order the laboratory tests, 20% of participants reported no difficulties.

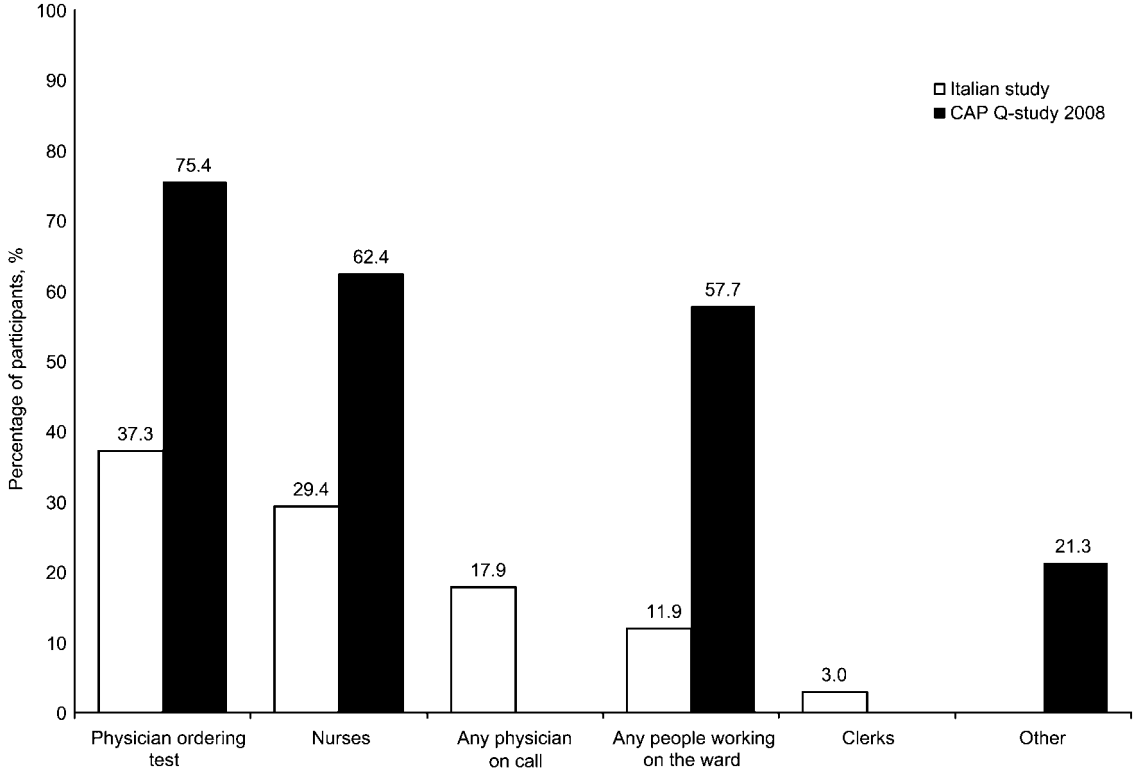

Figure 2 Characteristics of the health care provider who receives the notification for inpatients.
In the US as well in Italy, critical values were reported to physicians and nurses.

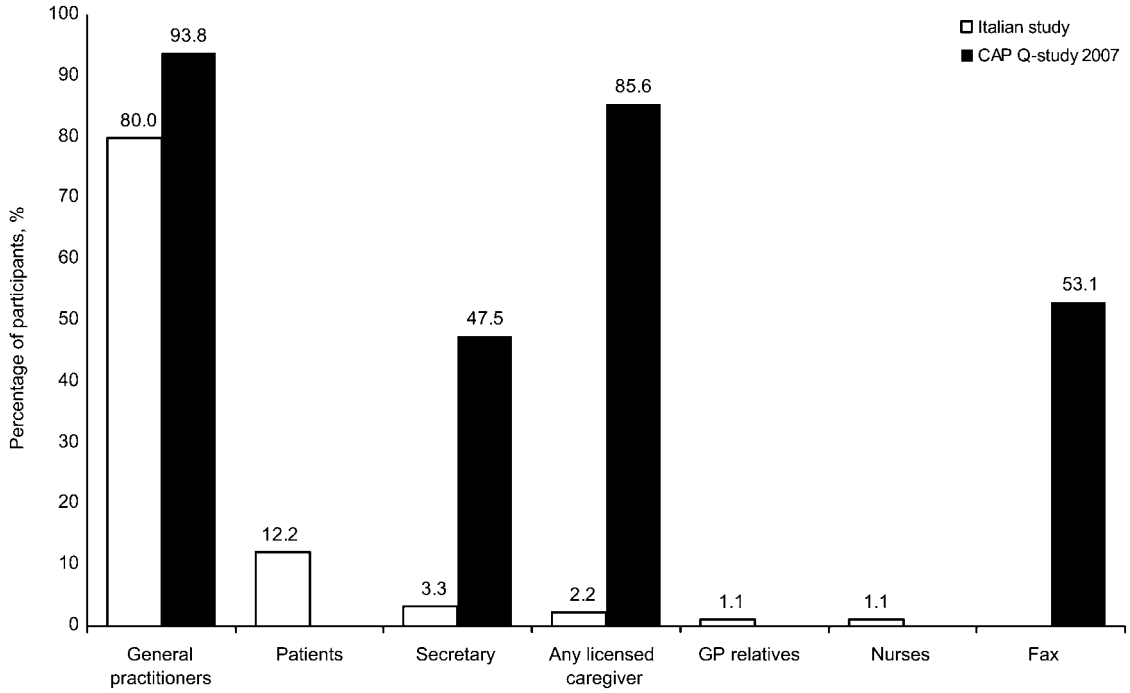

Figure 3 Characteristics of individuals receiving the notification for outpatients.
For outpatients, notifications are made principally to general practitioners and nurses. In the US more options are employed compared with Italy.

Formulation of the critical value list

Among responders, 58.9% of laboratories confirmed that they were aware of the recommendations promulgated by the Laboratory Medicine Societies, SIBioC (Società Italiana di Biochimica Clinica) and SIMeL (Società Italiana di Medicina di Laboratorio), about critical values. However, only 36.7% employed these recommendations. Nevertheless, 56.7% of participants claimed to have assessed critical value lists using data from the literature; 21.1% stated that their list of critical values was based on the opinions of clinicians' at their institution; 15.6% developed their critical value list on the recommendations of related medical societies, and only 6.7% on informal laboratory peer reviews.

Critical values limits

Table 2 shows the medians for adult critical values and the 5th and 95th (10th and 90th for sodium) percentiles for the reported analytes. These include total calcium, hemoglobin, potassium, magnesium, sodium, platelet count, and aPTT. Data from the survey of Italian laboratories were compared to those of Q-Probe survey from US laboratories published in 2007 (8). The comparison shows differences mainly for potassium, magnesium and platelet count, while median and percentile results were very similar for sodium and total calcium.

Analytes included by participants in descending order of frequency are: platelets, hemoglobin, potassium, sodium, calcium, PT or INR, aPTT, neutrophils, white blood cell count and magnesium. Of these, sodium, magnesium, calcium and white blood cell count were reported by all participants with low and high critical cut-offs. INR and aPTT were presented with a single high cut-off value by all participants. The low and the high cut-offs for the other analytes were established in different ways by participants. To determine the inter-laboratory variability for potassium values, the relative frequencies for both low and high cut-offs are presented in Figure 4A,B.

Discussion

Since 1988, the use of critical values reporting has been adopted in the US as a requirement of CLIA. National health care accreditation agencies, such as the JC, have established standards which make critical values reporting an important part of health care excellence. Hence, the development of a critical values policy has become a national issue for patient health and safety (5). More recently in Italy, many laboratories adopting accreditation or certification systems have introduced policies and procedures for reporting critical values. Responses from the survey indicate that the majority of participants belong to accredited laboratories that have written procedures for critical values. A small percentage of laboratories (about 10%) do not have any written procedures, probably because local or regional regulations do not require the reporting of critical values. The present survey highlights some important differences between US and Italian labora-

Table 1 Response of participants to questions regarding the critical value reporting process.

Questions	Response	Percentage of participants
Written policy for establishing, revising or updating critical values policy	Yes	63.3
Establishes timeless for notification	Yes	90.0
The laboratory policy requires read-back	Yes	62.2
Recording of the communications	Yes	57.8
There is an indicator of the communication process	Yes	18.9
There are mistakes in the communication	Yes	7.8
I don't know		21.1

tories regarding the management of critical values. With respect to updating and revision of written policies, only 56% of Italian participants regularly revise and update their policies, and the same situation seems to exist in the US, according to a report on Critical Values Comparisons prepared by the CAP in 2007. This could be problematic because critical values policies continue to evolve and to improve.

It is also important that the reporting policy specifies who is responsible for communicating critical values and who should receive them in the case of inpatients or outpatients. A number of CAP surveys, particularly the one published in 2008, showed that in the US, professionals involved in communicating critical values were usually the laboratory technicians or technologists who performed the tests. In recent times, laboratories have created call centers in order to centralize the reporting of critical values, particularly for callback. In Italy, our survey showed that it is usually doctors or other graduates who communicate critical values to clinicians. While this reflects national differences regarding the professional profiles of technologists, it should be stressed that the communication of critical values needs to become a service in interpretive laboratory medicine. In some clinical cases, especially where outpatients are concerned, clinicians need to interpret the critical value and any additional relevant information should be provided to better communicate the patients' status. Thus, interpretive advice can help clinicians take the appropriate steps in caring for patients. As far as inpatients are concerned, the people receiving the calls both in Italy and in the US are physicians and nurses for a fairly high percentage of cases. In the US, the number of clerical personnel receiving calls has decreased significantly. It seems that in order to meet JC requirements clinical laboratories should ensure that the ''responsible, licensed caregiver'' is contacted (4). The vast majority of notifications for inpatients and outpatients are still made by telephone. To avoid misunderstandings during the communication of critical values, the JC and CAP require a read-back policy. A documented read-back procedure was indicated by 90.7% of respondents in the 2008 CAP survey, but only by 62.2% of participants in the present survey. Although the percentage is significantly lower than in the CAP survey, this is, however, a significant improvement compared to just 2 years ago where a previous Italian cohort study found that no laboratories acknowledged a read-back policy to avoid errors (9).

One of the most important challenges for critical value reporting is to improve communication tools. This is an area in which several opportunities exist, especially if IT appli-

Table 2 Comparison of the distribution of critical values. Critical values are ranked according to the 2007 Q-Probes percentile rankings, with the 5th percentile corresponding to the lowest critical values, the 95th percentile corresponding to the highest, and the 50th percentile corresponding to median values.

Critical value	Italian survey			CAP Q-Probes survey		
	5th	50th (median)	95th	5th	50th (median)	95th
Calcium high, mmol/L	2.7	3.2	3.5	3	3.3	3.5
Calcium low, mmol/L	1.4	1.7	2.1	1.5	1.5	1.8
Hemoglobin high, g/L	171	199	200	180	200	230
Hemoglobin low, g/L	50	66	84	50	70	80
Potassium high, mmol/L	5.5	6.2	7.1	5.9	6	6.5
Potassium low, mmol/L	2.0	2.8	3	2.5	2.9	3.1
Magnesium high, mmol/L	0.93	2	2.9	1.25	2.05	2.9
Magnesium low, mmol/L	0.41	0.5	0.8	0.35	0.4	0.55
Sodium high, mmol/L	150	160	160	150	160	170
Sodium low, mmol/L	110	120	130	110	120	125
Platelet count high, $\times 10^9$/L	449	900	1500	700	999	1000
Platelet count low, $\times 10^9$/L	10	30	85	20	31	70
Activated partial prothrombin time, s	41	85	180	42	80	150

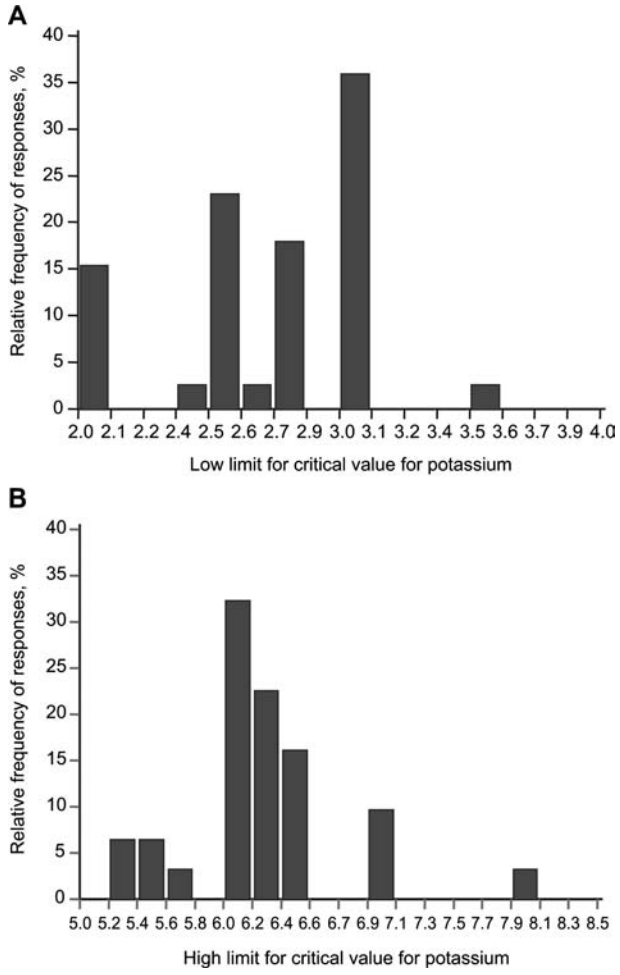

Figure 4 Relative frequencies of responses for (A) the low critical value limit for potassium and (B) the high critical value limit for potassium.
Large intervals show much inter-laboratory variability.

cations become widely available. Additionally, IT can help laboratory professionals to eliminate potential errors in communication, now reduced by the call-back policy which has led to substantial improvements in patient safety. Creating an effective reporting policy requires the coordinated effort of laboratory professionals and the IT team. Despite the promotion of better solutions supported by professional organizations, in 2008 the survey made by the CAP showed that only 8.6% of 623 institutions communicate critical values using wireless technologies. At our hospital in Padua with the help of the IT department, we have implemented a computerized notification system which has led to more timely notifications, an improvement in the rate of successful notifications, and delivering critical values to the responsible clinician (10). In the US for the management of critical test results, new software has been released (as Vocada Veriphy™), but wireless technologies for automated notification are still not widely used in the US or in Italy (11, 12). In the near future, alert reporting software should be applied everywhere, especially for reporting outpatient critical values, which the 2008 CAP survey indicated to be the major obstacle to successful notifications (13). At our hospital, the automated notification system adopted to reach GPs appears to be adequate. Despite the regulatory requirements pertaining to critical value notification, little attention has been devoted to finding which indicators can be assessed. The large number of critical results, the failure to deliver notifications within the target time, and the time required for phone calls, may be considered indicators of the efficiency in the critical value reporting process (14). More than 80% of Italian participants have not established any indicators for the communication process, although they have established a time-frame for notification. The lack of indicators of the critical value process may mean that some important aspects are not revealed. The rate of unsuccessful notifications should be documented in order to monitor the efficiency of the process. In the 2008 CAP survey, failure in the notification process was reported by 9.7% of respondents who indicated that some or all outpatient critical values were reported the following day (13). Also, in the present survey, a common difficulty was that of reaching GPs because of the unavailability of their phone number. Strategies should be put in place to rectify this situation. Finally, the selection of analytes and their critical limits deserves some consideration. Since 1990, several surveys have been conducted in the US and a number of publications have described critical value lists used by a number of institutions (15–17). In Europe, few studies have been conducted to compare critical value limits (9, 18). In a previous Italian survey, 80% of participants did not have a comprehensive list of critical values. In this survey, 70.5% of respondents have declared that they have a critical values list. As far as the list of analytes with critical values is concerned, the CAP survey of 2007 and this found the following analytes to be listed by all participants laboratories: potassium, sodium, calcium, platelets, hemoglobin, aPTT, white blood cell count, and PT. However, comparing the critical limits reported by the CAP with those provided by participants' laboratories revealed some relevant differences focused on two specific issues. First, the critical value analyte list is usually determined by individual institutions and variability exists among the choice of ''critical'' analytes. Second, significant inter-laboratory variability exists in establishing the actual critical limits. In comparison to the 2007 CAP survey, poor harmonization exists for high potassium limits, low calcium limits and for magnesium. For example, potassium represents one of the most frequent critical values and hyperkalemia occurs in both the outpatient setting and in hospitalized patients at a frequency ranging between 1% and 10% (13, 19). Among patients with end-stage renal-disease (ESRD) undergoing hemodialysis, 24% normally require emergency hemodialysis at some time for treatment of hyperkalemia; the mortality rate in these patients, due to hyperkalemia, has been estimated at 3.1 per 1000 patient years in the USA (20). Usually, critical limits are compared or adopted by laboratories that consider the published literature, the advice of other laboratories, and the

recommendations and advice of clinicians. More recently, in a Canadian study on how laboratory critical values were perceived by clinicians, 61% suggested 6.0 mmol/L as the clinical decision-making high potassium concentration. The CAP 2007 survey proposed the median high critical value of 6.0 mEq/L, which was indicated by 73% of institutions that utilized the literature and recommendations of non-laboratory medical staff as the primary source. In the present survey more than 52% of the participants reported a higher critical level, showing a wide distribution of high potassium critical value limits. Excellent harmonization seems to have been achieved for sodium. The median for both critical sodium values proposed by the Q-Probes surveys are the same as those obtained with that present study, also showing a good agreement with the opinions of clinicians (21, 22). Poor harmonization exists for critical values for hematological analytes. It could legitimately be asked if a hemoglobin concentration greater than 180 g/L or a platelet count more than 900×10^9/L represent a life-threatening condition. According to hematologists, these cut-offs do not reflect a true critical situation and these values could be communicated as ''courtesy'' call. Critical values should be limited to parameters where there is clear evidence of a life-threatening situation, or where a clinical decision is needed. Similar comments can be made about the decision (of a small number of Italian participants) to have a low critical value for aPTT (also reported in 2007 CAP survey), while the different high values can be related to differences in reagent lots. Thus, Italian guidelines, such as those recently proposed by national scientific societies (SIBioC and SIMeL) should be a reference for reducing inter-laboratory variability (23).

Among institutions, different critical limits denote different levels of patient safety. Hence, the comparison of critical values for the most common analytes should be considered essential in order to achieve consensus. Surveys for critical value comparisons, such as those performed by the CAP, should be proposed for all countries. The present survey shows that Italian laboratories, although not representative of western Europe, are beginning to show a greater awareness of the importance of critical values.

Conflict of interest statement

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