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Implementation, validation and review of a critical values list in a cardiac emergency room

Implantação, validação e revisão da lista de valores críticos em um pronto-socorro cardiológico

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ABSTRACT

Introduction: Laboratory critical values (CV) can indicate threatening conditions that require rapid clinical intervention. The aim of this study was to implement, validate and review a critical values list (CVL) at Pronto-Socorro Cardiológico de Pernambuco-Universidade de Pernambuco (PROCAPE-UPE). **Method:** This study was conducted between 2011 and 2013. To formulate the CVL, laboratory tests performed at PROCAPE were analyzed and compared with those of the Journal of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the College of American Pathologists (CAP). A draft CVL was validated by physicians; staff training and the standard operating procedure were developed covering the entire clinical analysis laboratory, in order to formalize the procedure of critical result reporting. The CVL was updated every six months. **Results:** Changes were made in CV intervals for the measurement of total serum calcium, serum sodium, serum potassium, the international normalized ratio (INR) and total leukocyte count. Thyroid-stimulating hormone (TSH) was also included in the CVL. In the pediatric CVL, dosages of serum sodium and INR were included, and a change in the value of serum potassium was made. Thus, periodic reviews of CVL allowed greater adequacy to the needs of the study population and avoided overloading the notification process. **Conclusion:** Clinical laboratories must be responsible for the implementation, validation and review of their CVL to ensure patients' health.

Key words: implementation; critical values; laboratory tests; cardiology.

INTRODUCTION

Critical values (CV) are abnormal laboratory results that may endanger a patient's life if immediate corrective or therapeutic measures are not taken[30]. First described by Lundeberg in 1972[20], among laboratory procedures, they became a requirement of accreditation agencies, incorporated to standards that watch over patients' safety[1, 26].

Laboratory CV were adopted as a demand by the Clinical Laboratory Improvement Amendments (CLIA 88)[8]. Specifically, the laboratory is committed to immediately alert the patient or the ordering entity about exam results that indicate potentially fatal (panic) values, or CV[8].

CV reporting is an important phase of the clinical laboratory test process, and result notifications outside the target time may indicate ineffectiveness[23]. The lack of CV immediate notification may be as negative as the release of inadequate results[30].

Although CV are widely accepted as extremely important for patient care and safety, there is not yet a world CV list (CVL) because of the great variety of interfering factors, such as clinical demand and patients' population[32]. For this reason, laboratories are required to develop and establish a CV policy according to their institutional

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necessity, that is, specific medical values formulated to meet the clinical needs of each establishment[13]. The chosen parameters and the critical limits depend essentially on the prevailing disease[28], making the construction of a table of critical results a potentially difficult task for an individual clinical laboratory[32].

The College of American Pathologists (CAP)[17], as well as individual institutions, hospitals and health centers[11, 19] publish CVLs. Even with these resources, clinical laboratories may find it difficult to determine the best mechanism for the creation of a list of analytes with CV. Wagar *et al*.[32] assessed CVLs used in 163 institutions and concluded that just 56% of the laboratories in these institutions have a policy for revising the lists, and 27% allow their health professionals to decide whether or not they will accept the use of these CV. The result of this survey serves as an alert for health professionals to be instructed on the importance of creating and using CV for the recovery of patients' health.

All efforts to enhance quality of health services aim at raising the level of patient safety. This demands deep knowledge and monitoring of all the critical processes of a healthcare organization; principally, knowledge of the complexity of the processes and the involved risk factors[4, 14]. Therefore, the objective of this study was to implement, validate and review a CVL for Pronto-Socorro Cardiológico Universitário de Pernambuco (PROCAPE)/Universidade de Pernambuco (UPE), Brazil, emphasizing the importance of continuously updating the list based on the necessity of the studied population.

METHOD

The study was carried out from 2011 to 2013 at PROCAPE, in the city of Recife, PE, Brazil, an institution of UPE, a cardiology referral university hospital. In order to formulate the CVL, the tests conducted at PROCAPE were analyzed and compared with the table published at the Journal of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC)[28] and with the CAP list[17] (**Table 1**). The CVL, after formulation by the clinical laboratory team, was referred to the physicians responsible for the cardiac emergency department and the cardiac intensive care unit for analysis and validation. Results considered critical by physicians were discussed by the group, and each selected analyte had its critical result revised or added.

After CVL validation, trainings and the standard operating procedure (SOP) were developed comprising the entire clinical laboratory of PROCAPE, in order to formalize the procedure of critical result communication. In this context, the printed inpatient reports were analyzed by clinical analysts, and CV cases were highlighted by means of a stamp – critical result –, communicated by telephone to the physicians, and at the same time handed to the physician and/or chief nurse by a trained courier, because clinical laboratory has no technology information system. For the outpatient CV, a telephone call was made and the patient joined a flow to priority service at the hospital emergency department.

The CVL was periodically reassessed by the laboratory staff and cardiologists, at six-month intervals, and value alterations were suggested based on scientific publications in order to adapt the list to the diseases and limit its extension not to overload the laboratory.

RESULTS

CVL

The risk interval adopted in the construction of the CVL was based on the values recommended by the table of critical results made available by IFCC[28] and CAP[17] (Table 1). **Table 2** shows the pediatric and adult CVL, and **Table 3**, a CVL with analytes whose reference values were modified for pediatric patients.

During the implementation of the CVL, updates were provided each six months, then it was possible to suit analytes and critical intervals to the reality at PROCAPE. Table 2 was modified in the values of total serum calcium, serum potassium, international normalized ratio (INR) and total leukocyte count, and had thyroid-stimulating hormone (TSH) testing included. In the CVL modified for pediatric patients (Table 3), the measurements of serum sodium and INR were included, and the values of serum potassium were altered. The analytes that did not suffer modifications in their intervals kept the values defined at the tables of IFCC[28] and CAP[17] (Table 1).

Assessment of the impact of updates on the number of notifications

From November 2012 to August 2013, PROCAPE gave 265 notifications of adult critical results. Among these, 115 (43%) were given for serum potassium, followed by 26 (10%) for INR, 22 (8%) for aminotransferases, 17 and 15 (6%) for serum sodium and platelet count, respectively, and 14 (5%) for serum urea.

Among the 115 critical results for serum potassium, 72 were values above 6 mmol/l; 29 were results higher than 7 mmol/l; and 14 were critical results below 2.6 mmol/l, what demonstrates that the number of critical results for serum potassium will be higher

after its critical result update, in October 2013, from < 2.6 and > 6 to < 3.5 and > 5.5 mmol/l.

DISCUSSION

In order to establish the CVL (Tables 2 and 3), we chose analytes relevant for diagnosis and monitoring of heart diseases, as this is the specialty of PROCAPE. The cardiac markers troponin and creatine kinase (CK) mass were not included in the CVL by the team of the cited hospital, because it was determined they had to be performed within the shortest possible turnaround time (TAT). Arterial blood gas and serum lactate were not included in the CVL for being part of a priority flow at the laboratory, between test performance and results release.

The alterations to the CV of Table 2 (total serum calcium, serum potassium, INR, and total leukocyte count) and Table 3 (serum potassium), as well as the inclusion of TSH, for adults and children, and serum sodium and INR in the CVL exclusive for pediatrics, were made along with the medical team and based on the literature[7, 16, 28].

The critical interval used in the IFCC table for total serum calcium is > 14 mg/dl and < 6.6 mg/dl; for the CVL of PROCAPE, the upper limit value was reduced to > 10 mg/dl. According to Vargas *et al*.[29] and Woods *et al*.[34], from 12 mg/dl patients may present nausea, vomiting and constipation associated to polyuria; total serum calcium levels of 14 mg/dl are related to symptoms of muscle weakness, intense dehydration, hypertension, malignant arrhythmia, bradycardia, renal failure and even coma. For the PROCAPE team, reducing the total calcium upper limit

TABLE 1 – Table of critical values, for adults and children, IFCC and CAP

Analytes	IFCC		CAP	
	High critical value	Low critical value	High critical value	Low critical value
Biochemistry				
Uric acid	> 13 mg/dl	-	-	-
Amylase	-	-	> 200 UI/l	-
Aminotransferases	> 1,000 U/l	-	-	-
Total bilirubin	> 15 mg/dl	-	-	-
Ionized calcium	> 1.6 mmol/l	< 0.78 mmol/l	> 1.6 mmol/l	< 0.8 mmol/l
Total calcium	> 14 mg/dl	< 6.6 mg/dl	> 13 mg/dl	< 6.5 mg/dl
Chloride	> 125 mmol/l	< 75 mmol/l	-	-
Creatinine	> 7.4 mg/dl	-	> 6 mg/dl	-
CK	> 1,000 U/l	-	-	-
Inorganic phosphorus	-	-	-	-
Glucose	-	< 45 mg/dl	> 450 mg/dl	< 45 mg/dl
Lactate	> 45 mg/dl	-	> 30.6 mg/dl	-
Lactate dehydrogenase	> 1,000 U/l	-	-	-
Lipase	> 700 U/l	-	-	-
Magnesium	-	-	> 4.9 mg/dl	< 1 mg/dl
Potassium	> 7.7 mmol/l	< 2.6 mmol/l	> 6.2 mmol/l	< 2.8 mmol/l
Sodium	> 160 mmol/l	< 120 mmol/l	> 160 mmol/l	< 120 mmol/l
TSH	-	-	-	-
Urea	> 240 mg/dl	-	-	-
Hematology				
Leukocyte count	> 50,000 µl	< 2,000 µl	> 40,000 µl	< 2,000 µl
Platelet count	> 1,000,000 µl	< 20,000 µl	> 1,000,000 µl	< 40,000 µl
Hematocrit	> 61%	< 18%	> 60%	< 20%
Hemoglobin	> 19.9 g/dl	< 6.6 g/dl	> 20 g/dl	< 7 g/dl
Bleeding time				
Fibrinogen	-	< 0.8 g/l	> 8 g/l	< 0.9 g/l
PT (INR)	-	-	-	-
apTT	75 s	-	80 s	-

IFCC: International Federation of Clinical Chemistry and Laboratory Medicine; CAP: College of the American Pathologists; CK: creatine kinase; TSH: Thyroid-stimulating hormone; PT: prothrombin time; INR: international normalized ratio; apTT: activated partial thromboplastin time.

TABLE 2 – List of critical values, for adult and pediatric patients, of PROCAPE

Analytes by sector	High critical value	Low critical value
Biochemistry		
Uric acid	> 13 mg/dl	-
Amylase	> 200 UI/l	-
Aminotransferases	> 1,000 UI/l	-
Total bilirubin	> 15 mg/dl	-
Ionized calcium	> 1.6 mmol/l	< 0.38 mmol/l
Total calcium	> 10 mg/dl	< 6.6 mg/dl
Chloride	> 125 mmol/l	< 75 mmol/l
Creatinine	> 7.4 mg/dl	-
CK	> 1,000 UI/l	-
Inorganic phosphorus	> 9 mg/dl	< 1 mg/dl
Glucose	> 450 mg/dl	< 45 mg/dl
Lactate	> 5 mmol/l	-
Lactate dehydrogenase	> 1,000 U/l	-
Lipase	> 700 U/l	-
Magnesium	> 4.9 mg/dl	< 1 mg/dl
Potassium	> 5.5 mmol/l	< 3.5 mmol/l
Sodium	> 160 mmol/l	< 120 mmol/l
TSH	> 10 mUI/l	< 0.01 mUI/l
Urea	> 214 mg/dl	-
Hematology		
Leukocyte differential count	Presence of malaria parasites Sickle cells Suspected aplasia Suspected leukemia Leukemoid reaction	
Leukocyte count	> 50,000 µl	< 3,000 µl
Platelet count	> 1,000,000 µl	< 20,000 µl
Hematocrit	> 61%	< 18%
Hemoglobin	> 19.9 g/dl	< 6.6 g/dl
Bleeding time		
Fibrinogen	-	< 0.8 g/dl
PT (INR)	> 3.5 (INR)	-
apTT	> 75 s	-

PROCAPE: Pronto-Socorro Cardiológico de Pernambuco*; CK: creatine kinase; TSH: thyroid-stimulating hormone; PT: prothrombin time; INR: international normalized ratio; apTT: activated partial thromboplastin time.*

TABLE 3 – List of critical values, modified for pediatric patients, of PROCAPE

Analytes by sector	High critical value	Low critical value
Hematology		
Leukocyte count	> 25,000 µl	< 5,000 µl
Platelet count	-	< 100,000 µl (normal-weight newborn) < 50,000 µl (newborn weighing less than 2.5kg)
Hematocrit	71%	33%
Hemoglobin	> 23 g/dl	< 8.5 g/dl
Biochemistry		
Glucose	> 325 mg/dl	< 30 mg/dl
C-reactive protein	> 5 mg/l	-
Potassium	> 5.5 mmol/l	< 3.5 mmol/l
Sodium	-	< 126 mmol/l
Coagulation		
INR	> 3.5	-

PROCAPE: Pronto-Socorro Cardiológico de Pernambuco*; INR: international normalized ratio.*

was intended to improve patients' safety in corrective measure procedures.

In 2011, when CVLs were established at PROCAPE for children and adults, serum potassium CV were > 7 mmol/l and < 2.6 mmol/l. In its first update, there was a reduction in the upper CV to > 6 mmol/l, and later, an interval of < 3.5 mmol/l and > 5.5 mmol/l. Its monitoring is extremely important for cardiac patients, once hyperkalemia and/or hypokalemia lead to arrhythmias that may cause cardiac arrests[6].

Reduction of potassium upper CV to 5.5 mmol/l and increase of the lower CV to 3.5 mmol/l, for adults and children (Tables 2 and 3), was based on the work by Goyal *et al*.[15], a retrospective cohort study with a data bank including 38,689 individuals with acute myocardial infarction. That study suggested that the optimal interval levels of serum potassium in those patients could range from 3.5 mmol/l to 4.5 mmol/l, and that levels of serum potassium higher than 4.5 mmol/l would be associated with mortality increase. In the study by Ahmed *et al*.[2], with 7,788 patients with chronic cardiac failure, serum potassium up to 5.5 mmol/l seemed to be relatively safe, and values lower than 4 mmol/l were commonly associated with increased mortality and hospitalization[6]. Along with the medical team of PROCAPE, the value of serum potassium was updated to < 3.5 mmol/l and > 5.5 mmol/l.

Another analyte whose value was updated was INR, used to monitor dosage adjustment of warfarin therapy[5], whose function is to prevent thromboembolic events; to do so, it must be kept between 2 and 3.5[10]. INR initial CV was > 4, and it was later reduced to > 3.5. Silva *et al*.[27] analyzed 220 INR tests conducted in patients who used warfarin, in which 72% demonstrated adequate levels of anticoagulation with INR ranging from 2 to 3.5; 17% obtained insufficient anticoagulation in levels < 2, and in 9.7% coagulation was excessive, with INR > 3.5. This justifies the CV reduction of this analyte in the CVL of adults and its inclusion in the pediatric CVL, aiming at reducing the risk of bleeding and ensuring patients' lives.

Total leukocyte count had its lower CV increased from > 2,000 µl to > 3,000 µl. The same value is recommended for patients who use immunosuppressive drugs (antiproliferative agents), according to the II Brazilian Guidelines for Cardiac Transplantation[3]. Platelets play an important role in acute coronary events, in the genesis and evolution of atherosclerotic lesions, and as an indicator of poorer prognosis in critically ill and septic patients, thus justifying the importance of platelets CV for adult and pediatric patients admitted at PROCAPE.

Besides the updates, we added the analyte TSH to the adult and pediatric CVL, with a critical interval of >10 mU/l and < 0.01 mU/l, because some of the most characteristic and common signs and symptoms of the thyroid disease are those that result from the hormone effects on the heart and cardiovascular system[31]. Both hyperthyroidism and hypothyroidism produce changes in cardiac contractility, myocardial oxygen consumption, cardiac output, blood pressure and systemic vascular resistance[26]. Rodondi *et al*.[24] conducted an analysis of 55,287 individual participants in 11 prospective studies; subclinical hypothyroidism was associated with increased risk of coronary events and mortality by coronary cardiac disease in patients with high TSH levels. There was a significant trend of increased risk in participants with TSH levels of 10 mU/l or higher. Subclinical hyperthyroidism, TSH < 0.01 mU/l, is associated with adverse cardiovascular events, including stroke and atrial fibrillation[33].

Sodium is an electrolyte involved in nerve and muscle function, and helps to keep blood pressure control[33]. Hyponatremia, an electrolyte abnormality common among inpatients with cardiac failure, is a marker for increased short- and long-term mortality[25]. Hyponatremic patients with heart failure have poorer prognosis, significantly higher rates of major complications and mortality when compared with normonatremic patients[21].

In the pediatric CV table published by the Clinical Laboratory Reference (CLR)[9], sodium has a lower CV of 121 mmol/l and an upper CV of 156 mmol/l, but values between 110-130 mmol/l also deserve special attention. Based on these data and on the target public of PROCAPE, the medical team adopted the value of < 126 mmol/l as critical, aiming at ensuring a wider margin of safety for pediatric patients.

Thrombocytopenia occurs in less than 1% of all newborns, but is one of the most frequent hematologic problems for inpatients at neonatal intensive care units[13]. In the pediatric CVL, for a normal weight newborn, a result < 100,000/µl must be investigated; and for newborns who weigh less than 2.5 kg, the limit value is 50,000/µl.

In the survey of notifications conducted by PROCAPE, most critical results were generated on serum potassium, the same as verified by Dighe *et al*.[11], and the update of its CV led to a significant increase of notifications (150%), when in comparison with the previous value. This modification caused an overload from notifications in the laboratory, however it permitted corrective actions in due time, always aiming at patients' safety, as in the cases of heart diseases when spironolactone is associated with an inhibitor of enzyme conversor angiotensin (iECA), and according to the Randomized Aldactone Evaluation Study (RALES)[18]. Such

a conduct has caused several patients to develop complications, such as hyperkalemia.

According to what was previously exposed, it is important to highlight that a laboratory CVL must go through careful reviews to determine which tests must be included, and the alterations of critical intervals must be defined together with physicians. The lack of an information technology system at PROCAPE was not an obstacle for the notifications to be conducted in the acceptable length of time of 30 minutes, as recommended by Dighe *et al*.[12] and Park *et al*.[22].

CONCLUSION

Our results demonstrate that clinical laboratories are responsible for the implementation, validation and review of their CVL to ensure patients' health.

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RESUMO

Introdução: *Valores críticos (VC) laboratoriais podem ser indicativos de condições de risco de morte que requerem intervenção clínica rápida. O objetivo deste estudo foi implantar, validar e revisar uma lista de valores críticos (LVC) no Pronto-Socorro Cardiológico Universitário de Pernambuco-Universidade de Pernambuco (PROCAPE-UPE).* ***Método:*** *Este trabalho foi realizado no período de 2011 a 2013. Para elaborar a LVC, os testes laboratoriais realizados no PROCAPE foram analisados e comparados com os dos jornais da Federação Internacional de Química Clínica e Medicina Laboratorial (IFCC) e do Colégio Americano de Patologistas (CAP). Após a elaboração da LVC, ela foi validada por médicos; treinamentos e procedimento operacional padrão foram desenvolvidos abrangendo todo o laboratório de análises clínicas, com o intuito de formalizar o procedimento de comunicação de resultados críticos. A LVC foi revisada a cada seis meses.* ***Resultados****: Foram realizadas modificações nos intervalos de VC na dosagem de cálcio sérico total, sódio sérico, potássio sérico, no índice internacional normalizado (INR) e na contagem total de leucócitos. Também foi incluído na LVC o hormônio estimulante de tireoide (TSH). Na LVC exclusiva da pediatria, foi incluída a dosagem de sódio sérico e o INR, e uma alteração no valor do potássio sérico foi realizada. Assim, uma avaliação periódica da LVC possibilitou maior adequação às necessidades da população de estudo e evitou sobrecarga no processo de notificação.* ***Conclusão:*** *Faz-se necessário que os laboratórios de análises clínicas sejam responsáveis pela implantação, validação e revisão de sua LVC para assegurar a saúde do paciente.*

Unitermos: *implantação; valores críticos; testes laboratoriais; cardiologia.*

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