Critical Value of the Clinical Laboratory Test in Thailand

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Background: *The critical values are the values of laboratory testing results which required attention or action by the physicians. It is an essential component of good laboratory practice and widely used throughout the world. The present study examined the current situation on implementing of critical value list (CVL) of Thai clinical laboratory and what factors were involved in their consideration.*

Material and Method: *A questionnaire composed of 3 main categories made up of 34 questions was mailed to 450 Thai clinical laboratories. These participated laboratories were randomly selected from both private-and government-hospitals. Participated ones were requested to answer the questionnaire and return via mail within two months. Data were analyzed by Chi-square test on Microsoft Excel.*

Results: *The results showed that there were only 48.9% of Thai laboratories implemented the CVL. It was found that there were many factors which governed the implementation of critical values. These factors were significantly different between those who implement the critical values and those did not ($p < 0.01$). In regard to private- and government-hospital laboratories, implementation of CVL was not significant difference ($p > 0.1$). However, it was found that assigned persons who responded to notify and act on the critical value was significantly different ($p < 0.01$). Moreover, there were no significant differences on laboratory policy, communication method as well as standard operating procedures on critical values between the private- and government-hospital laboratories ($p > 0.1$). There were only 20.2% of those who implemented the CVL and considered this action as a non-troublesome matter. But, a large group of 95.7% considered this matter as an extra-ordinary tool for quality control of result reporting system.*

Conclusion*: Thai laboratories perceived the implementation of critical values list differently. There were some factors beyond their consideration. However, utilizing of CVL would be an extra-ordinary tool for assuring test results.*

Keywords: *Clinical laboratory, Critical value, Current situation, Implementation*

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The concept of critical values was first introduced in 1972[1]. Critical values are also referred as alert values or panic values or vital laboratory values. They are the values of a laboratory testing results that are regarded as an unexpected finding, which would require medical intervention of an urgent nature, or which require immediate attention or action by the physician[2]. The American Society of Clinical Pathologists (ASCP) defines critical value as "a pathological state at such variance with normal as to be immediately life-threatening unless something is done promptly and for which some corrective action must be taken[3]". The medical technologist who performs the test must immediately verify its accuracy and report to the appropriate individuals either by telephoning to wards or to clinicians. Nowadays critical value is also accepted as a component of the good laboratory practice and widely used throughout the world. Each laboratory needs to set it's acutely important critical values.

To be a world class laboratory, Thai clinical laboratories need to follow this universal rule. Recently, most of Thai clinical laboratories have begun gearing to enter into the accredited system, especially the external accrediting body of Department of Medical Science, Ministry of Public Health. The critical value is also a required component stated in the ISO 15189

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guideline[4]. Therefore, Thai clinical laboratories must consider the necessity of establishing the critical value list (CVL) of laboratory measurements.

The purpose of the present study was to determine how frequently Thai clinical laboratory implement CVL and what factors are involved in their considerations.

Material and Method

Subjects were Thai clinical laboratories. These participated laboratories were randomly selected from both private-and government-hospitals all over Thailand. A questionnaire composed of 3 main categories as follows; the first category was general laboratory information *e.g.* type of hospital, number of beds, number of daily specimens, number of laboratory staff, number of medical technologists etc, the second category was critical value information *e.g.* basic knowledge of critical value, have or don't have critical value list, etc, and the third category was the most important information on critical value *e.g.* critical value of clinical laboratory test list, critical value guideline, authorized person as well as method of reporting critical value, problem shooting on critical value, etc. These three categories made up of 34 questions were mailed to 450 Thai clinical laboratories. The content validation of this questionnaire had been evaluated by a peer group. A survey designed by the authors was used to gather information on critical values of Thai clinical laboratories. The Questionnaire was answered by a medical technologist who was in charge of the laboratory and returned via mail within two months. Data analysis was performed using mean, standard deviation (SD), frequency with percent and Chi-square test on Microsoft Excel. Statistical significance was set at $p < 0.05$.

Results

A response rate of 53.8% was obtained and 97.1% (235 out of 242 questionnaires) was completly filled out. Despite widespread and long-standing use of critical value[1,2], the Thai clinical laboratory has had limited use. Table 1 shows that there were only 48.9% of Thai laboratories which implemented the CVL in the daily practice. It seems that laboratories of government hospital payed more intention to this usage than those privately-owned. It was also found that those accredited laboratories significantly ($p < 0.01$) implemented the critical value lists more than the non-accredited ones. This indicated that to become an accredited laboratory, a critical value list was considered to be one importance component[3]. In regard to private- and government-hospital laboratories, implementation of CVL was not significantly different ($p > 0.1$, data was not shown). Factors leading to implementation of CVL are identified. Despite many factors which governed the implementation of critical values *i.e.* number of daily specimens, basic knowledge on critical values of laboratory staff, and being an accredited laboratory. These mentioned factors were significantly different between those which implemented the critical values and those that did not ($p < 0.01$). The majority of laboratories with CVL implementation have 101-300 specimens daily. With this remarkable number of samples, an automated analyzer solved the problem with a pre-set checking system (so called the flag down) for critical value of testing results. Then a warning signal would show to remind the performer. For that small laboratory with a manual type analyzer, one who performs the test must check the testing results manually. So, some laboratories concerned it as a workload burden. This might be one of the reasons for not implementing the CVL. It was also considered as an economic burden. Since implementing of critical value is a costly practice[5]. The present study found that one of the obstacles of the CVL usage was the lack of basic knowledge. In terms of procedures for handling CVL, who should be the one to report the finding and to whom should it be reported, as well as the means of reporting. Table 2 demonstrates the understanding on

Table 1. Usages of critical value list (CVL) of the Thai clinical laboratory

Type of Hospital	Numbers of Laboratory		Total
	Have CVL	Don't have CVL	
Government	86 (36.60%)	87 (37.02%)	173
Private	27 (11.49%)	33 (14.04%)	60
Others	2 (0.85%)	0	2
Total	115 (48.94%)	120 (51.06%)	235

CVL of laboratory staff. There was a significant difference ($p < 0.01$) of having basic knowledge of critical value between those with and without implement of CVL. Most laboratories have a list of tests with critical values, and a process to follow in reporting these values. Each laboratory should prepare, in cooperation with its medical staff. The CVL of routine chemistry tests in the present study is summarized in Table 3. Critical values of testing were varied from laboratory to laboratory. Each laboratory must work up the CVL with appropriateness to itself. However, transforming of these values into the SI unit was comparable to the universal one[2,3,6]. The person who is in charge of reporting the finding of any test which exceeded critical value was varied from place to place as shown in Table 4. A significant finding was found ($p < 0.01$). Regarding the private hospital laboratory, the medical technologist who performs that test was the solely authorized person. In contrast to the government hospital laboratory, either a medical technologist, or the chief medical technologist or a clinical laboratory technician or others was the one who reported. In the present study, several communication methods of reporting the critical value was used as shown in Table 5. It was found that a phone call is the most common reporting mechanism similar to a previous study by McDowell[5]. However, the reporting method must be re-considered on the basis of in-patient and out-patient. Since the urgency in diagnosis and therapeutic management was different among these groups. In addition, patient identification must be seriously concerned, to comply with patient safety the person making the call must read back the patient's name, the hospital number and all laboratory results. For those having the LIS (Laboratory Information System) or HIS (Hospital Information System), things go easier, since this system may be particularly convenient because it can capture most of the required information automatically[2]. Achieving the successful implementing of the CVL, not only the list but also policy and handling procedure is the important matter. Therefore, laboratory policy as well as standard operating procedure of reporting

Table 2. Understanding of laboratory staff on basic knowledge of critical value

Knowledge of CVL	Implementing CV		Total	p-value
	Yes	No		
Yes	97 (42.73%)	47 (20.70%)	144	< 0.01
No	14 (6.17%)	69 (30.40%)	83	
Total	111 (48.90%)	116 (51.10%)	227	

Table 3. Summarization of critical value list (CVL) being used in the Thai clinical laboratory

Test	Lower limits (Mean ± SD)	Upper limits (Mean ± SD)	Unit
Glucose	46.91 ± 8.64	430.62 ± 103.62	mg/dL
Calcium	6.35 ± 0.50	13.15 ± 1.46	mg/dL
Magnesium	1.13 ± 0.53	5.14 ± 1.28	mg/dL
Potassium	2.58 ± 0.4	6.37 ± 1.03	mmol/L (mEq/L)
Sodium	120.53 ± 7.34	157.72 ± 11.31	mmol/L (mEq/L)
Chloride	80.02 ± 8.51	120.59 ± 10.16	mmol/L (mEq/L)
Phosphorus	1.17 ± 0.39	8.69 ± 1.74	mg/dL
pH	7.44 ± 1.41	7.60 ± 0.09	pH unit
PCO_2	20.17 ± 6.06	68.93 ± 27.31	mmHg
PO_2	44.14 ± 12.49	92.67 ± 20.03	mmHg
Bilirubin	0.12 ± 0.13	15.43 ± 4.62	mg/dL
Bicarbonate	11.19 ± 3.03	39.43 ± 1.74	mg/dL
BUN	11.08 ± 15.94	87.74 ± 37.32	mg/dL
Creatinine	0.18 ± 0.1	7.58 ± 4.60	mg/dL

Table 4. Authorized persons of reporting finding on the critical value

Authorized persons	Numbers of Laboratory			Total
	Government	Private	others	
Person performing test :				
- Medical technologist	73 (84.88%)	27 (100%)	2 (100%)	102
- Clinical laboratory technician	49 (56.98%)	0	0	49
Chief of clinical service	4 (4.65%)	1 (3.70%)	0	5
Others (Physician/nurse)	1 (1.16%)	0	0	1

Table 5. Communication methods of reporting finding on the critical value

Critical values reporting procedure	Numbers of Laboratory			Total
	Government	Private	Others	
Sending test-report to ward	18 (20.93%)	3 (11.11%)	0	21
Phone call	81 (94.19%)	24 (88.89%)	2 (100%)	107
Facsimile	1 (1.16%)	1 (3.70%)	0	2
On-line computer	17 (19.77%)	8 (29.63%)	1 (50.00%)	26
Direct contact to meet and talk to the end user	1 (1.16%)	2 (7.41%)	0	3
Others	4 (4.65%)	3 (11.11%)	0	7

the critical values was also studied. There were no significant differences on laboratory policy, communication method as well as standard operating procedures on critical values between the private- and government-hospital laboratories ($p > 0.1$). Table 6 shows the standard operating procedure on handling the critical values. In order to properly manage the findings of critical value, various procedures had been used. The authors found that 100% of both types of laboratories (government based as well as privately based) did a repeating test before reporting the finding of critical value as the first choice, since every laboratory has to ascertain this finding was not due to the analytical incorrectness. Besides, a laboratory must be very careful in reporting by phone, personnel involved in a critical call would have to use a "read-back" system to ensure the correctness[5,7]. Moreover, our surveys have shown that there were only 20.2% of those who implemented the CVL considered this action as a non-troublesome matter. Others considered it as time consuming and a costly process (Details of data are not shown). However, a large group of 95.7% had different perceptions; they considered the implementing of CVL as an extra-ordinary tool for quality control of the result reporting system.

Finally, it should be stated herein that the outcome of the present study was adding value to the medical service society; this could be divided into three aspects as follows:

1. The patient, any critical value would lead to an urgent attention and immediate action to the patient which is a great concern on patient safety.

2. The laboratory staff, a great chance for them to play an essential role in patient care as well as becoming an all time learner, ensuring confidence and becoming a competent laboratory personnel.

3. The healthcare system, laboratory service is transforming to a knowledge-based service.

Discussion

The present study suggests that there are some limitations on the utility of the critical values. Factors leading to an implementation of critical value lists are identified. Several factors are found *e.g.* number of daily specimens, background knowledge of laboratory staff as well as other healthcare personnel, type of hospital and also type of analytical instruments. It seems to be that the larger laboratory may have a

Table 6. The standard operating procedure (SOP) for handled the finding on critical values of Thai clinical laboratory

SOP for handled the finding	Numbers of Laboratory		
	Government	Private	Others
Test must be repeated to ascertain the correctness of analytical process.	74 (100%)	26 (100%)	2 (100%)
If repeated test result stays as critical value, phone call to nurse to ascertain the proper specimen collection.	61 (82.43%)	20 (86.92%)	2 (100%)
In emergency cases, phone call to nurse to ascertain the correctness of specimen collection.	67 (90.54%)	22 (87.62%)	2 (100%)
A new specimen for confirmation test is requested directly from the nurse who takes care the patient.	51 (68.92%)	18 (69.93%)	2 (100%)
Upon requested a new specimen, the nurse must document critical value notification and report back to laboratory to confirm the correctness of specimen collection	25 (33.78%)	10 (38.46%)	2 (100%)
If the test result stays as critical value again, laboratory should report it immediately to the ward, and nurse who in charge will contact the physician for consultation.	60 (81.08%)	22 (84.62%)	2 (100%)
Laboratory reports the finding on critical value immediately and directly to the physician.	36 (48.65%)	17 (65.38%)	2 (100%)
Laboratory must record every report on critical value finding that reported to physician or nurse.	55 (74.32%)	17 (65.38%)	2 (100%)
Reporting the critical value via phone to only physician or nurse who look after this patient.	63 (85.14%)	24 (92.31%)	2 (100%)
The respondent to call of critical values must be physician or special-train nurse.	39 (52.70%)	10 (38.46%)	1 (50%)
Reporting of critical value on the phone must be a “read-back” system	53 (71.62%)	21 (80.77%)	2 (100%)

convenient trail of implementing the critical value list through an automated analyzer. But the smaller laboratory may have to put a great effort on working out manually. It leads to a performing burden of the laboratory in terms of manpower as well as economics. This is one of the obstacles on utilization of the critical value list. The inadequacy on knowledge of the critical value can be easily solved. Currently, the availability of continuing education program and refresher courses are nation wide. In addition, several courses are freely provided by the non profit group incorporation with private sectors. Finally, the authors should state herein that in Thailand, implementing of CVL is not required by laws, but having the CVL must be a valuable tool for ensuring patient safety. In order to fulfill the advantages of implementing a critical value list, each laboratory has to develop such a list of critical test results and the reporting procedure with medical staff. As well as training laboratory staff in appropriate verification and reporting procedures when test results exceed critical values.

Conclusion

The implementation of critical values of clinical laboratory test varied widely from laboratory to laboratory. There were various factors beyond the consideration. But, having a critical value list would direct to many benefits *i.e.* patient safety, laboratory staff’s confidence and creating a knowledge based laboratory service.

Thai laboratories perceived the implementation of critical values list differently. There were some factors beyond their consideration. But, utilizing of CVL would be an extra-ordinary tool for assuring test results.

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การรายงานค่าวิกฤติของห้องปฏิบัติการเวชศาสตร์ชันสูตรในประเทศไทย

กุลนารี สิริสาลี, สุดารัตน์ มโนเชี่ยวพินิจ, ไพโรจน์ ลีฬหกุล, วราภรณ์ เรืองไร, อัปสร สัตยาคม, โสภณ สิริสาลี

***ภูมิหลัง**: ค่าวิกฤติ (critical value) เป็นค่าของผลการวิเคราะห์ทางห้องปฏิบัติการที่ผิดปกติมากจนจะทำให้เกิดอันตรายต่อผู้ป่วยหากไม่ได้รับการดูแลจากแพทย์อย่างทันเวลา และมีการกำหนดให้ค่าวิกฤติเป็นหัวข้อหนึ่งของการปฏิบัติที่ดีของห้องปฏิบัติการ (good laboratory practice) ดังนั้นการวิจัยนี้จึงมีวัตถุประสงค์เพื่อศึกษาสถานการณ์ของการนำค่าวิกฤติมาใช้ และปัจจัยที่เกี่ยวข้องกับการนำค่าวิกฤติมาใช้*

***วัสดุและวิธีการ**: ศึกษาการนำค่า critical value มาใช้ของห้องปฏิบัติการในประเทศไทยโดยใช้แบบสอบถามจำนวน 34 ข้อ เป็นเครื่องมือในการเก็บข้อมูลจากห้องปฏิบัติการ 450 แห่ง โดยการสุ่มตัวอย่างห้องปฏิบัติการทั้งจากโรงพยาบาลภาครัฐและเอกชน โดยให้ส่งแบบสอบถามกลับคืนทางไปรษณีย์ วิเคราะห์ข้อมูลด้วย Chi-square test*

***ผลการศึกษา**: พบว่าห้องปฏิบัติการเวชศาสตร์ชันสูตรมีการนำค่าวิกฤติมาใช้เพียงร้อยละ 48.9 และปัจจัยที่เกี่ยวข้องกับการนำค่าวิกฤติมาใช้มีหลายปัจจัย ซึ่งปัจจัยเหล่านี้เป็นสาเหตุของการนำค่าวิกฤติมาใช้หรือไม่นำมาใช้ ($p < 0.01$) การนำค่าวิกฤติมาใช้ไม่มีความแตกต่างกันระหว่างห้องปฏิบัติการภาครัฐและเอกชน ($p > 0.1$) อย่างไรก็ตามพบว่า การมอบหมายผู้รับผิดชอบเกี่ยวกับการรายงานค่าวิกฤติมีความแตกต่างกันระหว่างห้องปฏิบัติการของภาครัฐและเอกชน ($p < 0.01$) นอกจากนั้นยังพบว่านโยบาย, วิธีการรายงานผล และระเบียบปฏิบัติของการรายงานค่าวิกฤติไม่มีความแตกต่างกันระหว่างห้องปฏิบัติการภาครัฐและเอกชน ($p > 0.1$) ห้องปฏิบัติการที่มีการรายงานผลค่าวิกฤติร้อยละ 20.2 เห็นว่าการรายงานผลค่าวิกฤติไม่เป็นปัญหาแต่ห้องปฏิบัติการร้อยละ 95.7 เห็นว่าการนำค่าวิกฤติมาใช้มีส่วนช่วยในการควบคุมคุณภาพการรายงายผลการวิเคราะห์ทางห้องปฏิบัติการ*

***สรุป**: ห้องปฏิบัติการเวชศาสตร์ชันสูตรในประเทศไทย มีความเห็นเกี่ยวกับการนำค่าวิกฤติมาประกอบการรายงานผลการวิเคราะห์ที่แตกต่างกัน เนื่องจากมีปัจจัยที่เกี่ยวข้องจากภายนอกห้องปฏิบัติการ แต่ยังเห็นว่าการค่าวิกฤติมาใช้มีส่วนช่วยประกันคุณภาพการรายงานผลการวิเคราะห์ทางห้องปฏิบัติการ*