Original Articles

Current Situation of Assessing Analytical Performance VIA Patient-derived Quality Control

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Background: *A correct test result is essential mean, it provides useful information. To ensure the reliability of test results, not only the internal quality control but also patient-derived quality control is applied. The current situation of assessing analytical performance via patient-derived quality control was thoroughly investigated.* ***Methods:*** *Questionnaires were distributed to 650 Thai clinical laboratories. Data analysis was performed using Chi-square test on Microsoft Excel.* ***Results:*** *Thai clinical laboratory utilizes the patient-derived quality control differently. These 4 items of CVI /CVG, mixed sample, daily patient's mean and test distribution statistic were used less than 15%. The private-hospital laboratory employed the clinical laboratory correlation/test correlation and delta check more often than the government-hospital laboratory ($p<0.01$). The major obstacles of utilizing the patient-derived quality control were knowledge deficiency, time consuming in training and preparing the standard operating procedure, heavy workload and expenditures.* ***Conclusion:*** *Clinical laboratories consider utilizing the patient-derived quality control as a useful tool. It is able to identifying many non-analytical errors.*

Key Words: ● *Patient-derived quality control* ● *Clinical laboratory* ● *Current situation* ● *Analytical performance*

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Introduction

Nowadays, there are many laboratory tests available to the clinician. Only the correct result is essential mean, this may provide useful information. If a test result is incorrect, it is at a best useless and a worst misleading as well as dangerous. Indeed, most clinical laboratories take stringent precautions to control analytical accuracy and precision of test. Quality control plays a vital role in ensuring the reliability of test result. Quality control materials therefore are always run in accompany with other specimens to ensure the correctness of test results. The three phases of laboratory testing process are pre-analytical, analytical and post-analytical. Errors take place in any phase would reduce the effectiveness of test. Generally, the analytical phase always well controlled. Since application of quality control system is sensitive to the analytical component of laboratory error and widely accepted. The pre-analytical as well as post-analytical phases receive less attention. More recently the highly automated analyzer has been used in routine practice especially in laboratory of

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ต้องการสำเนาต้นฉบับติดต่อ พ.อ.โสภณ สิริสาลี ภาควิชาจุลชีววิทยา กองการศึกษา วิทยาลัยแพทยศาสตร์พระมงกุฎเกล้า ถนนราชวิถี เขตราชเทวี กทม. 10400

private hospital. So, the reliable test result always expected. Although the highly automated analyzer, the quality control system of both internal (IQC) and external (EQC) and the ubiquitous use of computer in today's laboratory, errors of testing result are still appeared. It was reported that 46%, 7%, and 47% of errors occurred in the pre-analytical, analytical and post-analytical phases, respectively[1]. Finding of rocket high overall of 93% errors occurred in the non-analytical phase should not overlook.[1,2] It indicates that there is an obscure problem beyond the quality control of analysis. Implementing of quality control material is only useful for monitoring analytical variation; it is usually inefficient in identifying the pre-analytical and post-analytical errors made in the laboratory.[1] Laboratory practitioner should pay a serious attention to these two phases. Pre-analytical phase is concerned primarily with specimen processing. In order to reduce errors of this phase, the automation of specimen processing has been developed.[3]

Reduction of errors of the post-analytical phase is very challenging. This may require other feature. Resultfrom patient sample or so called "the patient-derived data" may serve the need.[2,4,5] Employing the patient-derived data would serve as real time quality control. There are a lot of retrievable data from patients that can act as the control detector. These data can be evaluated on either an individual basis or a group basis; for example, the delta check, limit check, anion gap, duplicated patients' mean, and the average of normal (AON), etc.[4,7] Thai's clinical laboratory also confrontsto the similar problem.

In this study, the real time situation of assessing analytical performance via patient-derived quality control was evaluated. How well they know, implement of the patient-derived data; and what obstacles encounter to has been thoroughly investigated.

Materials and Methods

A questionnaire composed of 3 main categories made up to 50 questions was mailed to 650 Thai clinical laboratories in regard to private and government hospitals. The content validity of this questionnaire had been evaluated by peer group. This survey designed by the authors was used to gather information on utilizing the patients' data of Thai clinical laboratory. Participated laboratories were randomly selected from the members of Thailand External Assessment Scheme. Medical technologists who currently work in these selected laboratories were requested to answer the questionnaire and returned via mail within one month. Data analysis was performed using Chi-square test on Microsoft Excel.

Results

A response rate of 30.6% (199 out of 650 laboratories) was obtained. As shown in Table 1 the hospital size of this study was varied from less than 100 beds to more than 1,000 beds. Majority group participated herein was the small laboratory of both private and government hospitals. Also, they were 2 universities basedhospital with the bed number of over 1,000 beds. Table 2 demonstrates the confronting errors of testing results based on the laboratory testing process which divided into pre-analytical, analytical and post-analytical. Most of testing result's errors occurred in pre-analytical phase of both private and government-laboratories was detected by the performing staff (over 75%). Errors happened in both pre-analytical and analytical phases for both types laboratory were not difference. But testing result's errors happened in the post-analytical phase of private-ones were different from those of government. Private laboratories received more complaints on errors of 43.8% in compared to 38.2% of those of government-ones. There was a various design for operating procedure to

Table 1 Hospitals participated in the study

Hospital Size (Beds)	Numbers of Participated Hospital		
	Government	Private	Total
Less than 100	106 (69.73%)	25 (53.19%)	131
101-500	31 (20.39%)	22 (46.81%)	53
501-1,000	13 (8.55%)	0	13
More than 1,000	2 (1.32%)	0	2
Total	**152**	**47**	**199**

Table 2 Errors detected during laboratory testing process

Laboratory Process	Number	Detected method		
		Performing staff	Complaint	Both
1. Laboratory of government-hospital				
- pre-analytical	75	85.33%	2.67%	12.00%
- analytical	60	71.60%	16.67%	11.67%
- post-analytical	76	44.74%	38.16%	17.10%
2. Laboratory of private-hospital				
- pre-analytical	24	75.00%	20.80%	4.17%
- analytical	23	60.87%	30.43%	8.70%
- post-analytical	32	37.50%	43.75%	18.75%

Table 3 Methods for assuring test result during the pre-analytical phase

Operating Procedures	Types of Hospital (numbers)		Total	P-value
	Government (148)	Private (47)		
Design with the flowchart during specimen registration	135 (90.00%)	41 (87.23%)	176	>0.10
Guideline of specimen rejection	141 (92.76%)	43 (91.49%)	184	>0.10
Guideline of specimen preparation	137 (90.13%)	46 (97.87%)	183	0.08
Guideline of designed person to collect and prepare specimen	121 (79.61%)	42 (89.36%)	163	>0.10
Appraisal and training laboratory staff frequently	106 (69.74%)	41 (87.23%)	147	0.02
Instrument checkup and maintenance regularly	138 (90.79%)	44 (93.62%)	182	>0.10
Proper management of analytical reagents and specimen collection devices	146 (96.05%)	45 (95.74%)	191	>0.10

assure test result quality in the pre-analytical phase as shown in Table 3. In addition, operating procedures on assuring of test results in the pre-analytical phase of both laboratory types was not difference ($p > 0.05$). The only different factor governed for quality assurance was that private laboratory offered more training program as well as the frequent appraisal for performing personnel than the government laboratory ($p < 0.05$). The usages of patient derived data as the qualitycontrol system for laboratory in both government and private-laboratories were investigated. As shown in Table 4, there were various means used for verifying the testing result which laboratories approach to them differently. Our result demonstrated the popularity of verifying means. These following 4 means of CVI/CVG, mixed sample, daily patient's mean and test distribution statistic were used less than 15%. However, there were other 9 means frequently utilized which varied from 50% to above 90%. Moreover, we found no significant difference between private and government laboratories in the utilization of these 9 means ($p > 0.05$). But, the usages of these three means, denoted as doublecheck

Table 4 Current situation of result verification via patient-derived data of various hospital laboratories

Means of result verification	Types of Hospital		Total	P-value
	Government	Private		
Check the QC value from QC chart	118 (77.63%)	37 (78.72%)	155	> 0.10
Check for flag of those run via automated analyzer	132 (86.84%)	40 (85.11%)	172	> 0.10
Check for outlier of reference value	149 (98.03%)	45 (95.74%)	194	> 0.10
For the problem case, check the CVI*, CVG** and index of individuality	17 (11.18%)	6 (12.76%)	23	> 0.10
Critical values (limit value) checking	128 (84.21%)	42 (89.36%)	170	> 0.10
Mixed sample technique checking	20 (13.16%)	7 (14.89%)	27	> 0.10
The anion gap checking	46 (30.26%)	21 (44.68%)	67	0.07
Duplicate patient's mean checking	80 (52.63%)	30 (63.83%)	110	> 0.10
Daily patient's mean checking	19 (12.50%)	4 (8.51%)	23	> 0.10
Test distribution statistics checking	20 (13.16%)	5 (10.64%)	25	> 0.10
After checking, if the result stays unlikely again, does the specimen verification and also check the analytical system	122 (80.26%)	40 (85.11%)	162	> 0.10
Repeating the unlikely results	125 (82.24%)	34 (72.34%)	159	0.07
Double check patient's information with the requisition form or self laboratory system	131 (86.18%)	46 (97.87%)	177	0.02
Clinical correlation and test correlation checking	99 (65.13%)	42 (89.36%)	141	< 0.01
Delta check checking	42 (27.63%)	24 (51.06%)	66	< 0.01

**within-subject biological variation*

***between-subject biological variation*

Table 5 Problems and obstacles of utilizing patient-derived data of the Thai's clinical laboratory

Confronted problems	Numbers of laboratory		
	Government	Private	Total
Insufficiency of knowledge	73 (53.28%)	24 (55.81%)	97 (53.89%)
Time consume in the process of preparation the operating procedure and laboratory staff training	72 (52.17%)	23 (56.10%)	95 (53.07%)
Increasing workload and complexity of routine operation	66 (57.39%)	19 (65.52%)	85 (59.03%)
Increasing expenditures	58 (52.25%)	17 (54.84%)	75 (52.82%)

Table 6 Implementation of patient-derived data to assess testing quality of various laboratory services

Services department	Types of hospital (numbers)		Total
	Government (145)	Private (46)	
Hematology	81 (55.86%)	29 (63.04%)	110 (57.59%)
Microbiology	29 (20.00%)	12 (26.09%)	41 (21.47%)
Urinalysis	44 (30.34%)	19 (41.30%)	63 (32.98%)
Parasitology	22 (15.17%)	7 (15.22%)	29 (15.18%)
Blood bank	30 (20.69%)	17 (36.96%)	47 (24.61%)
Immunology	10 (6.90%)	4 (8.70%)	14 (7.33%)
Cytology	1 (0.69%)	0	1 (0.52%)
Pathology	1 (0.69%)	0	1 (0.52%)
Don't implement to other services	54 (37.24%)	12 (26.09%)	66 (34.55%)

patients' information on the requisition form or inthe information system, the clinical correlationand test correlation checking, and delta check checking in the private laboratories were significantly different ($p < 0.05$) from those of government ones. The private laboratory paid more attention to these means. As demonstrated by the significant different ($p < 0.01$) in employing clinical laboratory correlation/test correlation and delta check between the private- and government-laboratory. The Thai's clinical laboratory perceived problemson utilizingof patient-derived data differently as shown in Table 5. Among several confronted problems, insufficiency on knowledge of patient-derived data was rank as the number one problem. Interestingly, our survey also found that some laboratories not only implemented the patient-derived quality control to clinical chemistry services but also other laboratory services i.e. hematology, microbiology, and urinalysis with 57.6%, 21.5% and 32.9% respectively as presented in Table 6.

Discussion

Problems encountered to the clinical laboratory in

daily practice were investigated with similar problem as other.[1] As shown in table 2, the most frequent errors of testing results took place in the pre-analytical phase. The private-laboratory received more complaints than the government ones. Since patients of the private hospital are always have the high expectation on all kind of services. Table 4 demonstrated that various means had been utilized for verifying testing result. This wide variation might due to the availability of staff knowledge and analyzer system. Problems and obstacles of utilizing patient-derived data were varied from place to place. To overcome them were easily approached. A continuing education either formal or informal one would solve it. So, to be the competent laboratory practitioner, one must attend a training course which an appropriate system.[8] Lastly, we should state that implementing the patient-derived data as a quality control tool must be seriously considered, since these data has already existed during laboratory testing process. It seems to be the free of charge process that require only time and afford to retrieve the information, because today the highly automated analyzer in the clinical laboratories has been available widely. However, a small laboratory without the laboratory automation should not overlook, since this would be the valuable process in assessing the analytical performance with only a little more hard work. But what a laboratory earned is countless. Finally, achieving the quality test result with patient-derived data is worthy.

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สถานการณ์การใช้ patient-derived quality control เพื่อประเมินคุณภาพผลการวิเคราะห์

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ความเป็นมา: *ความพยายามที่จะประกันคุณภาพผลการวิเคราะห์ทางห้องปฏิบัติการให้มีความถูกต้องมากขึ้นจึงมีการนำ patient-derived quality control มาใช้ควบคู่กับการทำ internal quality control ดังนั้นผู้วิจัยมีความประสงค์จะสำรวจการใช้ patient-derived quality control ของห้องปฏิบัติการในประเทศไทย* ***วิธีการศึกษา:*** *ทำการสำรวจการนำ patient-derived quality control มาใช้เพื่อควบคุมคุณภาพผลการวิเคราะห์ในขั้นตอนหลังการวิเคราะห์ (post-analytical phase) โดยการส่งแบบสอบถามไปยังห้องปฏิบัติการทั่วประเทศ 650 แห่ง และได้รับกลับคืน 199 แห่ง (ร้อยละ 30.6) นำข้อมูลมาวิเคราะห์ด้วย Chi-square test โดยใช้โปรแกรม Microsoft Excel* ***ผลการศึกษา:*** *พบว่าห้องปฏิบัติการทั้งภาครัฐและเอกชนมีการนำ patient-derived quality control ทั้ง 9 หัวข้อมาใช้ตรวจสอบผลการวิเคราะห์ทางเคมีคลินิกมากกว่าร้อยละ 80 และหัวข้อที่มีการนำมาใช้น้อยกว่าร้อยละ 15 มี 4 หัวข้อ ได้แก่ วิธีการตรวจสอบ CVI /CVG, วิธี mixed sample, วิธี daily patient's mean, วิธี test distribution statistics และยังพบว่าห้องปฏิบัติการภาคเอกชนมีการนำหัวข้อ clinical/test correlation และหัวข้อ delta check มาใช้มากกว่าภาครัฐ ($p < 0.01$) ส่วนปัญหาและอุปสรรคของการนำ patient-derived quality control มาใช้คือ การขาดความรู้ความเข้าใจ ต้องการเวลาในการอบรมและจัดทำระเบียบปฏิบัติ เป็นการเพิ่มภาระงาน และเพิ่มค่าใช้จ่าย* ***สรุป:*** *ห้องปฏิบัติการเห็นว่าการนำ patient-derived quality control มาใช้ประกอบการควบคุมคุณภาพเป็นสิ่งที่มีประโยชน์ เนื่องจากความผิดพลาดของผลการวิเคราะห์ส่วนใหญ่มีสาเหตุจาก non-analytical error ซึ่งไม่สามารถควบคุมได้ด้วยการใช้ internal quality control*

Key Words: ● *Patient-derived quality control* ● *Clinical laboratory* ● *Current situation* ● *Analytical performance*

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