THE NEW PARADIGM OF CRITICAL LABORATORY MEDICINE: SHIFTING FROM LABORATORY BASED TO PATIENT BASED

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ABSTRACT

The use POCTs have been very rapid. The availability of POCT device with acceptable performance did lead the shift of laboratory testing from the laboratory to patient based. The shift to bedside testing must be taken seriously by the laboratory professionals. Since the clinical pathologist in charge of the laboratory service must be responsible to the results of POCT in all area of responsibility. Not only economic and technical considerations, the ethical consideration and law enforcement must all be carefully followed. Several laboratory tests are more beneficial if provided bedside while several other tests are better stay in the laboratory. Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management is certainly required in order to maximally use the fast TAT results for the benefit of patient management. Quality laboratory results is important as well as timely results. Quality control is required may applied to every phase: pre-analytical, analytical, post-analytical. The laboratory need to set up quality management in the POCT usage where training is a compulsory. Routine evaluation is also needed, and the correct action be implemented and documented. The medical team must also understand the pitfalls and avoid errors in POCT diagnostic testing.

Keywords: Point of care testing, critical care

Introduction

The history of medicine showed that the early laboratory tests were performed in bedside. Further the tests become more complicated and specialized so that the laboratory tests were performed in the laboratory.[1]

Along with the availability of point of care testing (POCT) devices, the laboratory testing are shifting back to the patient's side. Although it is very clear that not all the laboratory tests will be economically or technically better be performed at the bedside, it is very clear also that several laboratory tests are providing more benefits to the critical care when the tests are available bedside. The shift to bedside testing of course must be taken seriously by the laboratory professionals. Since

the clinical pathologist in charge of the laboratory service must be responsible to the results of POCT in all area of responsibility. Not only economic and technical considerations, the ethical consideration and law enforcement must all be carefully followed.[2, 3]

The clinical needs of current critical practice had been changed and often stated that currently need of fast and reliable results, simple devices, be performed near patient with a simple interpretation of results. There many aspects, though, that must be taken into consideration in order to provide a better service to the patients of the critical unit.[4] This brief review will discuss some aspects of the shifting of practice in the critical laboratory testing including the POCT devices, non-technical aspects (e.g. POCT management team), and the technical aspects (e.g. pitfalls, quality control).

The agent of change: POCT device availability

The current rapid change had been supported by the availability of point of care testing (POCT) devices.[5] POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (selftesting). POCT refers to any testing performed outside of the traditional, core or central laboratory."[6]

Many studies showed that the use of POCT device did improve the turn around time (TAT) of several laboratory tests e.g. glucose, blood gases, which in turn may cause faster clinical decision and therapy. The actual change of quality of patient management may vary since the matter is not only regarding TAT but there are other factors that are important i.e the people, medical facilities and the system or process of critical care. For example, a study by Lee-Lewandrowski et.al[7] in the setting of a large academic hospital, showed that the presence of POCT satellite laboratory decreased test TAT and decreased emergency department (ED) length of stay (LOS). There was also excellent satisfaction with test accuracy and TAT of blood glucose, urine human chorionic gonadotropin, urine dipstick, creatine kinase–MB, and troponin tests that were performed in the ED POCT laboratory. Test TAT declined an average of 87% after the institution of POCT (Table 1). The ED LOS decreased for patients who received pregnancy testing, urine dipstick, and cardiac markers (Table 2). Clinician satisfaction surveys documented equivalent satisfaction with test accuracy between the central laboratory and the POCT laboratory (Table 3).[4, 7]

Table 1. In-labotoraty TAT for urinalysis, pregnancy testing, glucose and cardiac markers (Lee-Lewandrowski, 2003)[7]

Test	Turnaround Time Before POCT, min	Turnaround Time During POCT, min	Change in Turnaround Time After Initiation of POCT, min†
Urinalysis	40 (n = 37)	4 (n = 106)	−36 (90%)
Pregnancy testing	78 (n = 44)	5 (n = 54)	−73 (94%)
Glucose	10 (n = 128)	6 (n = 28)	−4 (60%)
Cardiac markers	110 (n = 62)	17 (n = 128)	−93 (84.5%)
Mean	59.5	8	−51.5 (86.6%)

* The decrease in lab turnaround time for all tests combined was significant with $P = .02$. POCT indicates point-of-care testing.
† A minus sign indicates faster turnaround time.

Table 2. ED length of stay for patients receiving urinalysis, pregnancy testing, glucose or cardiac markers (Lee-Lewandrowski, 2003)[7]

Test	ED Length of Stay Before POCT, min	ED Length of Stay During POCT, min	Change in ED Length of Stay After Initiation of POCT†
Urinalysis	395 (n = 37)	358 (n = 106)	37 ($P = .25$)
Pregnancy testing	386 (n = 44)	346 (n = 54)	40 ($P = .22$)
Glucose	380 (n = 128)	404 (n = 56)	−24 (P = none: see text)
Cardiac markers	386 (n = 62)	338 (n = 128)	47 ($P = .06$)
Mean‡	389	347	41 ($P = .006$)

* ED indicates emergency department; POCT, point-of-care testing.
† Positive number indicates shorter length of stay.
‡ Glucose data excluded (see text).

Table 3. Clinician satisfaction with TAT (Lee-Lewandrowski, 2003)[7]

Test	Before POCT (15 RNs, 36 MDs)	During POCT Program (13 RNs, 17 MDs)	Difference (During − Before)
Urinalysis	1.8	4.5	2.7
Pregnancy testing	1.5	4.4	2.9
Glucose	2.4	4.3	1.9
Cardiac markers	2.1	4.0	1.9
Mean	1.95	4.3	2.35 ($P < .001$)

* Scale: 1–5, with 1 = least satisfied, and 5 = most satisfied. POCT indicates point-of-care testing; RNs, registered nurses; and MDs, medical doctors.

Non-technical aspects

Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. For certain laboratory, typically in a large hospitals, there may be a need to provide satellite critical lab, whereas in other laboratory, faster transport system and connected information system will benefit more to the critical unit. Further, systematic changes in patient management is certainly required in order to maximally use the fast TAT results for the benefit of patient management.[8]

Short TAT not necessary always mean better patient care. Parvin et.al[9] prospectively investigated whether routine use of a point-of-care testing (POCT) device by nonlaboratory operators in the emergency department (ED) for all patients requiring the available tests could shorten patient

length of stay (LOS) in the ED. ED patient LOS was examined during a 5-week experimental period in which ED personnel used a hand-held POCT device to perform Na, K, Cl, glucose (Gluc), and blood urea nitrogen (BUN) testing. However, no decrease in ED LOS was observed in the tested patients during the experimental period. Median LOS during the experimental period was 209 min vs 201 min for the combined control periods. Stratifying patients by presenting condition (chest pain, trauma, etc.), discharge/admit status, or presence/absence of other central laboratory tests did not reveal a decrease in patient LOS for any patient subgroup during the experimental period. From these observations, Parvin et.al concluded that it is unlikely that routine use of a hand-held POCT device in a large ED such as theirs is sufficient by itself to impact ED patient LOS.[9]

The critical care area and the laboratory need to improve the efficiency wherever possible and at the same time maintaining or improving quality of testing. Good POCT practice can accomplish both of those objectives. The trend toward providing POCT will continue, particularly in the critical care units where TAT of the most important STAT tests is of the utmost importance in providing the best possible patient care. To support that trend, critical care clinicians need to closely work with experts in laboratory medicine to bring the expertise of the laboratory to the patient's bedside, where quick and accurate results are needed. By working together, critical care clinicians and the laboratory can create quality POCT programs in the critical care unit, which can meet the needs of the critically ill patients.[10]

Management of POCT service

The management of POCT service in critical unit can consist of building a POCT team / working group, planning: costs, equipments, supporting network and staffing, defining the needs, detailing the specifications needed, assess the performance of equipment, procurement and installation, training, internal quality control (IQC), external quality assurance (EQA), audit, continuous quality monitoring and improvement. In the Indonesian hospital accreditation settings which adopt Joint Commission International (JCI) standards, a program that manage and evaluate laboratory testing in all site of the hospital is required by Komite Akreditasi Rumah Sakit (KARS), meaning that POCT in the critical unit must be included int laboratory program.[11]

Training for the best practice is mandatory. The management should considers several materials to be included in the training module such as awareness of preanalytical factors, how to obtain the correct specimen, the importance of clinical contraindications, sample handling, stability of sample, stability of reagents, test devices, operation, calibration, and routine maintenance, analytical limitation of the instrument or test system, recognize instrument malfunction and able to do simple trouble shooting techniques, internal QC & external QA, cleaning, decontamination, and disposal procedures. Training to ensure correct action is taken when the test result is obtained can also include the actions to be taken if result is outside the limits of the test system, the actions to be taken if the result is within or outside preprescribed action, critical or alert limits. For the certification of training

/ competence and posttraining surveillance several aspects may be considered i.e the use of multiple assessment techniques, techniques for assessing competence, self assessment, multiple-choice questionnaire, peer comparison, written examination, observation, certificate with unique identifying number, expiry date, name of the trainee, areas of competence (tests and equipments), signed by the trainer and supervisor, and lastly continuous review process.[12, 13]

Technical aspects

Regulatory requirements is in place to ensure quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test is performed. CLIA 2003 takes a quality systems approach like ISO documents where the quality requirements follow the route of the specimen including pre-analytical, analytical, and post-analytical aspects.[14]

Quality Control and Quality Assurance

The laboratory must build internal quality control program which is performed by testing personnel. Since QC activities must be part of everyday laboratory workload, QC activities must be practicable and workable. Results of QC must be documented. Patient results not reported unless QC performed and acceptable. In the event of out of range result corrective actions must be documented. The QC results must be reviewed at least monthly. External quality assurance programs should also implemented to compare results with other laboratory (peer group).[15]

Understanding pitfalls of the POCT devices

In order to correctly interpret the results, medical personnel should understand factors that can cause variations in the POCT device as well as the pitfalls. In glucose measurement, several studies showed that in critical patients where hematocrit (HCT) may at the extreme level, the results of glucose measurement may vary between glucosemeters (Figure 1). Difference of glucose results in the presence of vitamin C also reported (Figure 2).[16]

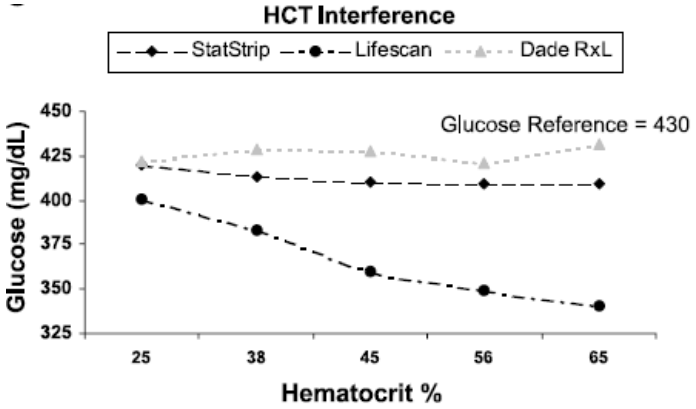

Figure 1. The effect of hematocrit to POCT glucose may vary according to device (Holtzinger C,et.al)[17]

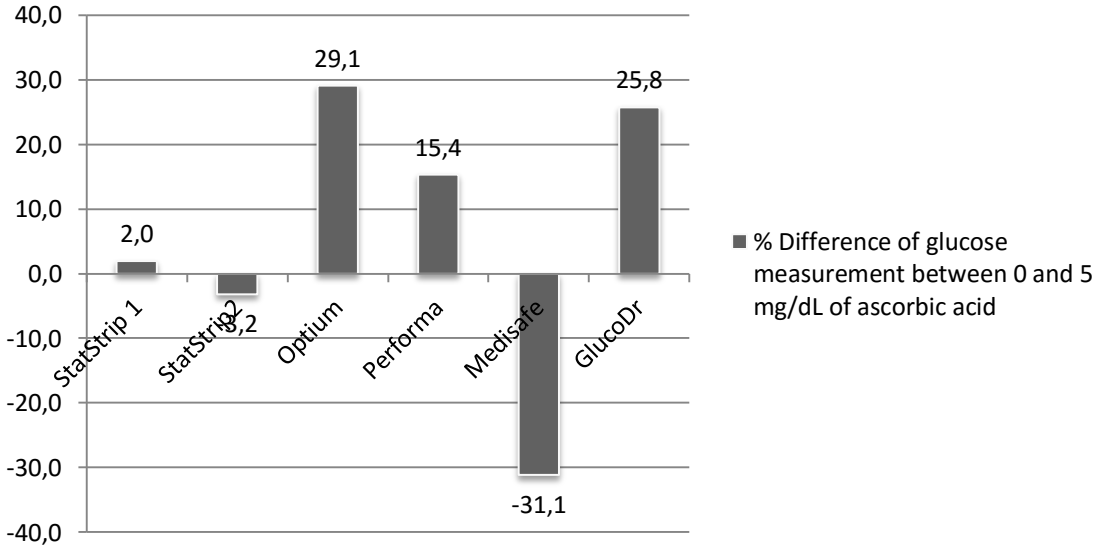

Figure 2. The effects of vitamin C may vary according to device[16]

In electrolyte testing, a study by Jain et.al[18] showed that there was no significant difference between the potassium values measured by the blood gas machine and the auto-analyzer. However, the difference between the measured sodium was found to be significant therefore need to be taken in consideration.

Errors in POCT diagnostic testing

Errors may happen in the pre-analytical, analytical and post-analytical phase of measurement. The laboratorian must ensure the manufacturers guide is followed by conducting package insert investigation, device specific aspects, and electronic QC better be confirmed with routine comparison to the standard clinical laboratory method.

Pre-analytical errors may happen such as unsuitable indication for the performance of the test, lack of preparation of the patient (e.g., fasting before functional tests), inappropriate sampling times, lack of information about the patient's condition (for example, drug history, body temperature), inappropriate sampling technique (for example, sample diluted by compression during collection of capillary blood), wrong or missing additives to blood, unsuitable test material, inappropriate sample handling (e.g. inadequate mixing of sample with additives). Analytical errors may include faulty calibration, or malfunctional device. Post-analytical errors may include inadequate technical validation, POCT results not designated in cumulative findings, abnormal results not marked, erroneous assignment of the results or other errors in data storage.[2]

Summary

The use POCTs have been very rapid. Several laboratory tests are more beneficial if provided bedside while several other tests are better stay in the laboratory. Quality laboratory results is important as well as timely results. Quality control is required may applied to every phase: pre-analytical, analytical, post-analytical. The laboratory need to set up quality management in the POCT usage where training is a compulsory. Routine evaluation is also needed, and the correct action be implemented and documented. The medical team must also understand the pitfalls and avoid errors in POCT diagnostic testing.

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