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Point of care testing, a study at a governmental hospital

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ABSTRACT

Blood glucose testing at bedside is one of the point of care tests. We present a study on the accuracy and reliability of glucose testing at bedside in the medical ward at a governmental hospital and the recommendations for the implementation and management of safe and effective POCT service within a hospital setting.

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1. Introduction

Point-of-care testing (POCT) is medical testing performed at or near the point of patient care. (1,2)

It refers to a laboratory quality assured pathology service employing small analytical devices (including test kits and analyzers), that are provided near to the patient point of care rather than in the traditional environment of a medical laboratory.(3)

Other synonyms of POCT include "near patient testing,"and "bedside testing,".

Personnel performing POCT are referred to as Operators and are usually primary patient care givers (3).

Point of care testing can add a major benefit to the early diagnosis and treatment of patients within a variety of medical and surgical settings,(3) since the test results are received more rapidly and effectively (3).

POCT in a hospital setting includes (3)

Arterial Blood gases, electrolyte analysis, lactate
Rapid Cardiac markers, renal markers, Bilirubin
Cholesterol, triglyceride and HDL, Choleterol screening
Intra-operative PTH measurement
Blood glucose (includes self-testing devices)
Drugs of abuse screening

Urine strips testing

Haemoglobin A1c

Albumin

Anticoagulant therapy monitoring (includes self-testing devices)

Pregnancy testing

Infectious disease testing (Chlamydia, HIV)

Fecal occult blood analysis

POCT has become established worldwide and finds vital roles in public health (5), provided that the result obtained is accurate and reliable (3).

The risks that are encountered in POCT include but are not limited to poor operator competency, failure to adhere to manufacturer's instructions and approved local SOPs in addition to failure to use quality assurance programs.

It should also be emphasized that POCT is not a substitute for the traditional clinical laboratory and that in certain situations where critical management decisions are to be taken, one must confirm the results of POCT by laboratory (3).

2. Materials and methods

This study was conducted at one of our governmental hospitals, The target was the medical ward, since most of the POC tests are usually conducted at the medical ward. The tests that are done there include blood glucose testing and ABGs. POCT is done by nurses at the ward.

We studied blood glucose testing as one of the POC tests and found out that there are 2 different small analyzers that are used

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from 2 different vendors for which, no SOPs for the running of the tests and no special maintenance or instrument validation requirements nor safety regulations are in place.

We analyzed the results of one device compared to the results of the clinical laboratory as a reference method.

The methodology of the blood glucose testing in POCT device is based on Glucose Oxidase, while the methodology of the clinical laboratory is Hexokinase based and the analyzer is fully automated, where internal & external quality programs are in place as well as SOPs in accordance with manufacturer's instructions in addition to regular maintenance and safety regulations.

We started capturing the results of the bedside test and we sent serum samples of same patients to the central lab, A total of 50 patients; 27 males and 23 females were included in the study. The Patients were selected randomly.

Results

No of sample	Reference (LAB)	POC-T	Unit
1	5.7	6.2	mmol/L
2-	9.2	7.1	mmol/L
3-	6.0	7.5	mmol/L
4-	23.6	20.3	mmol/L
5-	5.4	6.5	mmol/L
6-	5.5	7.1	mmol/L
7-	9.1	9.5	mmol/L
8-	11.9	11.3	mmol/L
9-	8.8	9.5	mmol/L
10-	22.7	15.5	mmol/L
11-	5.7	6.0	mmol/L
12-	9.2	7.8	mmol/L
13-	6.0	6.5	mmol/L
14-	23.6	23.0	mmol/L
15-	5.4	5.7	mmol/L
16-	6.6	7.5	mmol/L
17-	8.3	9.3	mmol/L
18-	9.7	10.7	mmol/L
19-	11.6	11.0	mmol/L
20-	11.9	18.0	mmol/L
21-	13.5	15.2	mmol/L
22-	11.0	11.9	mmol/L
23-	5.1	5.9	mmol/L
24-	4.4	5.7	mmol/L
25-	11.1	12.2	mmol/L
26-	5.1	5.9	mmol/L
27-	16.1	17.6	mmol/L
28-	9.3	12.7	mmol/L
29-	4.6	5.1	mmol/L
30-	7.6	8.3	mmol/L

31	19.2	19.8	mmol/L
32-	5.0	6.8	mmol/L
33-	6.0	6.8	mmol/L
34-	16.0	17.3	mmol/L
35-	4.8	5.8	mmol/L
36-	8.8	10.2	mmol/L
37-	1.7	27.7	mmol/L
38-	4.3	5.7	mmol/L
39-	6.0	7.0	mmol/L
40-	3.2	12.1	mmol/L
41-	10.3	11.6	mmol/L
42-	32.4	23.6	mmol/L
43-	5.3	7.4	mmol/L
44-	9.9	11.3	mmol/L
45-	7.4	9.4	mmol/L
46-	12.9	24.8	mmol/L
47-	7.1	11.5	mmol/L
48-	20.3	21.5	mmol/L
49-	5.1	6.4	mmol/L
50-	6.3	6.9	mmol/L

Statistics for both methods are as follows:

Tolerance:

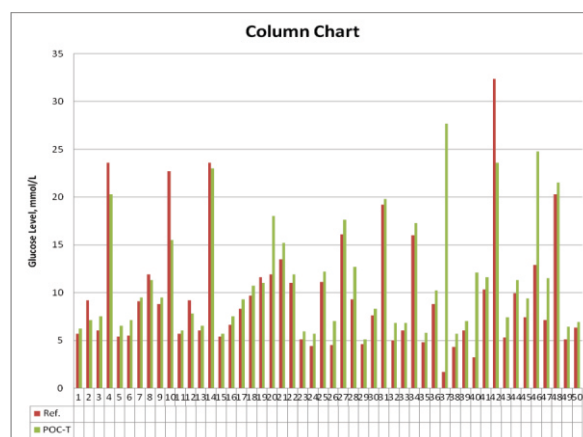
Concentrations	Medical tolerance	Max non equivalence error
Any	10.0%	3.3%

Distribution of concentrations:

Method	Mean	SD	Min	Max	Unit	N
Ref	9.70	6.233	1.7	32.4	mmol/L	50
POC-T	11.22	5.861	5.1	27.7		

Deming regression:

Parameter	Value	Confidence interval (95%)	Unit
Slope	0.917	0.521 to 1.313	mmol/L
Intercept	2.33	-0.72 to 5.38	



Apparently, medical decisions can be harmful in samples 37 & 40, since the results are on the two extremes of the scale.

In samples 20 & 46, both results are high but the values are not comparable.

Discussion

POCT is often done by the use of portable, transportable, and handheld devices and test kits that require a minimal quantity of blood to operate (4).

Within the setting of POCT, the results are provided more rapidly and effectively due to a better turnaround time. However, there are concerns about the accuracy and reliability of results obtained (3,4).

In some situations where critical management decisions are to be taken, it is more appropriate to have testing performed in a clinical laboratory.

Therefore the operation of POCT within a hospital setting should be overseen by a multidisciplinary steering group led by a manager, who is in most cases a lab professional, the steering committee shall have a high level responsibilities by providing clinical governance for POCT services, through the development and implementation of an organization wide policy and shall report to the senior management on all issues of POCT service including future strategies (3).

It also shall assign operational teams to oversee the operation of the POCT service including training of personnel, internal and external quality assurance, stock management, maintenance, infection control measures, development and implementation of applicable SOPs and other issues pertinent for the implementation, monitoring and auditing of the day to day POCT policies and procedures (3,4).

The operational teams shall have the responsibility to do the following:

1. Develop standard operating procedures in compliance with manufacturers' instructions and relevant standards for each POCT device or instrument.
2. Develop a system for training, certification and registration of care givers who do POCT
3. Implement and monitor a quality assurance program, both internal and external for each POCT device and ensure implementation of corrective and preventive actions and that those shall be taken if quality standards are not adhered to.
4. Validate and compare the POCT method with the clinical laboratory method and provide comparative data for review by the Steering Group
5. Ensure that audits are conducted and appropriate corrective actions are implemented where necessary
6. Ensure that the adverse incident reporting policy is in place
7. Establish a procedure for service, calibration, quality control and maintenance of POCT devices in accordance with manufacturers' instructions.

Quality assurance is an essential component of any medical service including POCT service and should include all the necessary measures taken to ensure the reliability and accuracy of the patient result.

It is crucial that all POCT devices are included in a quality assurance program including maintenance and calibration and that this is operational prior to patient testing.

The quality assurance program shall be monitored by the POCT operational team and corrective and preventive actions shall be taken if quality standards are not adhered to.

Conclusion:

Because of the lack of information in relation to evidence-based support for POCT in clinical management and because the test results need to be accurate and reliable in case critical management decisions are to be taken, it is strongly recommended that the users establish their own effective and safe POCT service at a local level.

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