

Establishing a Hospital POCT Program

Policies & Procedures

07 November 2016

SKMC Case Study

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Are you ready?



POCT

What is Point of Care Testing?

From Wikipedia, the free encyclopedia

- **Point-of-care testing** (POCT), or **bed-side testing** is defined as medical testing at or near the site of [patient](#) care. These are simple medical [blood tests](#) which can be performed at the bedside. Simple tests such as those found in [medical examinations](#), [urine test strips](#) and even simple imaging such as with a portable [ultrasound device](#). As well as regular observations such as [ECG's](#), [O2 saturation](#) and [heart rate](#).
- The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient, physician, and care team will receive the results quicker, which allows for immediate clinical management decisions to be made. POCT includes: blood glucose testing, blood gas and electrolytes analysis, rapid coagulation testing, rapid cardiac markers diagnostics, drugs of abuse screening, urine strips testing, pregnancy testing, fecal occult blood analysis, food pathogens screening, hemoglobin diagnostics, infectious disease testing and cholesterol screening.
- POCT is often accomplished through the use of transportable, portable, and handheld instruments (e.g., [blood glucose meter](#), [nerve conduction study](#) device) and test kits (e.g., CRP, HBA1C, Homocystein, HIV salivary assay, etc.). Small bench analyzers or fixed equipment can also be used when a handheld device is not available—the goal is to collect the specimen and obtain the results in a very short period of time at or near the location of the patient so that the treatment plan can be adjusted as necessary before the patient leaves. Cheaper, smaller, faster, and smarter POCT devices have increased the use of POCT approaches by making it cost-effective for many diseases, such as [diabetes](#), [carpal tunnel syndrome](#) (CTS) and [acute coronary syndrome](#).

Defined as those analytical patient-testing activities provided within the facility, but performed outside the physical facilities of the laboratory medicine department.

WHY

- Why set up a POCT program?
 - Accreditation
 - Local level (MOH / HAAD)
 - International level (JCIA / CAP / ISO)
 - Major benefits are obtained when the output of a POCT device is made available immediately within an electronic medical record.
 - Results can be shared instantaneously with all members of the medical team through the software interface enhancing communication by decreasing turn around time (TAT).
 - A reduction in morbidity and mortality has been associated with goal-directed therapy (GDT) techniques when used in conjunction with POCT and the electronic medical record.

Getting started

- **Approval**
 - Getting approval from CEO / Management shows the importance of the project.
 - Allows for a more fluid transition for the project.
- **Policies and Procedures**
 - **Tests**
 - What test menu is of clinical relevance is going to be implemented
 - Urgent Care setting
 - Emergency Room setting
 - Radiology setting
 - Outpatient
- **Validation studies**
 - Choosing instruments based on test menu
- **Training**

Policies

Point of Care Policy

All analytical testing conducted outside the main laboratory at SKMC Hospital including of blood gas analysis shall be overseen by the Point of Care Testing (POCT) Committee chaired by the Chair of Laboratory Medicine.

Policies and Procedures shall cover, but not be restricted to the following areas:

- The POCT Committee Terms of Reference
- Responsibilities of individuals responsible for oversight & coordination
- Personnel issues including training and competency assessment
- Test ordering
- Specimen identification
- Collection of specimens
- Result reporting including reporting of critical values and recording of results
- Equipment handling and maintenance
- Procedure manual & Quality Control
 - IQCP eligible (Individualized Quality Control Plan)
- Reagent requirements and handling
- Evaluation & Validation of methods for POCT
- Health and Safety matters
- Performance indicators

POCT Instrument Requisition and Approval Policy

Any request for POCT tests at SKMC Hospital must be submitted to the POCT Committee for evaluation and approval prior to the procurement of the device or reagents. (form)

- Several questions need to be asked:
 - 1) Clinically relevant test
 - 2) Estimated test numbers
 - 3) Cost implications (Reimbursement)
 - 4) Connectivity

POCT Critical Result Notification Policy

Defined as a test result with a critical value as determined by the Laboratory Consultants and Clinical Chairs to be critical to the patient's subsequent treatment decision and may be potentially life threatening. Critical values determined by the POCT committee & the laboratory Medicine Department are as follows:

Glucose measuring POCT devices

	<u>Upper Limit</u>	<u>Lower Limit</u>	<u>Unit</u>
Glucose, Adult	> 14	< 2.9	mmol/L
Glucose, Neonate (0 - 28 days)	> 18.0	< 1.7	mmol/L

POCT Management and Responsibility Policy

Task / Responsibility	POCT Coordinator	Pathologist	Nurse Educator	Nurse and Other Department Supervisors	Biomed	Lab Supervisory Staff	Representative from IT	POCT Committee
Method selection	X	X		X		X		
Method, validation, and setup						X		
Selection of personnel to perform testing			X	X				
Personnel training	X		X	X				
Ongoing competency assessment	X		X	X				
Review of daily Quality control (QC)	X			X				
Review of monthly QC and other data	X					X		
Review of reports from POCT coordinator		X						X
Instrument function checks and maintenance					X			
Approval of new method request		X		X				X
Collation and review of performance improvement (PI) information	X							
Decisions - PI data	X	X		X				X
Instrument connectivity	X						X	

What is out there ?



Organizing the Policies and Procedures

- Policies
- Quality Manual
- Safety Program
- Data Management Manual
- Procedures
 - Based on instruments in place

Quality Manual

In order to ensure patient safety and results of the highest quality possible, the Chair of the Department of Pathology and Laboratory Medicine and the POCT Coordinator will ensure that all aspects of near patient testing are well controlled specifically pre-analytical, analytical and post analytical phases.

Safety Program

The purpose of this program is to provide guidelines and codes of general practice for the protection of the employees performing the Point of Care Testing and for the safety of the involved patients.

Information gathered based on Corporate Standards of the facility

Data Management Manual

To standardize the Point of Care Data Management at Sheikh Khalifa Medical City (SKMC) and its associated satellite areas using a robust POCT data management system.

- Monitors the following:
 - Materials
 - Operators
 - Competencies
 - Quality Controls
 - QC acceptance / rejection
 - Linearity
 - LJ charts
 - Statistics

Procedures

- Each procedure will contain the following when applicable;
 - Purpose
 - Definitions
 - Introduction
 - Test Principle
 - Target Audience
 - Quality Assurance
 - Safety
 - Specimen Source
 - Supplies
 - - Required for testing
 - - Storage requirements
 - Procedure
 - - Equipment Maintenance
 - - Equipment calibration
 - - Quality Controls
 - - Specimen Collection
 - - Pre-preparation of patient if applicable
 - - Specimen requirements
 - - Specimen Identification
 - - Patient testing
 - - Errors
 - Results
 - - Limitations
 - - Interpretation
 - - Normal Ranges
 - - Critical Results
 - Protocol for reporting imminently life-threatening (critical) results where applicable
 - Performance Evaluations
 - Proficiency Testing
 - Competency
 - Trouble Shooting Responsibilities
 - References
- **Controlled Copy Binder**
 - Relevant procedures for each ward / clinic

<u>Policy / Procedure Name</u>	<u>Policy Manager Number</u>	<u>Ver</u>	<u>Revised Date</u>	<u>Complexity CLIA</u>	<u>Comp</u>	<u>QC Log</u>	<u>Patient Log</u>	<u>SDS</u>	<u>CPT</u>	<u>CAP Survey</u>	<u>FDA / CE</u>
Point of Care Testing Policy	D-MD-LAB-01-020	v1	Feb 11	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Instrument Requisition and Approval Policy	D-MD-LAB-01-021	v1	Feb 11	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Critical Result Notification Policy	D-MD-LAB-01-022	v1	Feb 11	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Management and Responsibility Policy	D-MD-LAB-01-023	v1	Feb 11	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Quality Manual	D-MD-LAB-15-001	v4	May 14	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Safety Program	D-MD-LAB-15-002	v1	Jan 11	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Data Management Procedure	D-MD-LAB-15-003		Jul 14	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
POCT Glucose Procedure	D-MD-LAB-15-004	v3	May 14	Waived	√	√	n/a	13, 14, 15	82962	WB2, LN17	K121679
POCT Urinalysis Procedure	D-MD-LAB-15-005	v3	May 14	Waived	√	√	n/a	28, 29, 30	81002(m) 81003(a)	CMP	K033548
POCT Strep A antigen	D-MD-LAB-15-006	v2	May 14	Waived	√	√	√	6	87880	D9	K010582
POCT Hemoglobin A1c Procedure	D-MD-LAB-15-007	v2	May 14	Waived	√	√	n/a	31, 32	83036	GH2, LN15	K071466
POCT Fecal Occult Blood Procedure	D-MD-LAB-15-008		Mar 11	Waived	√	n/a	n/a	5	82270	OCB	CE
POCT Prothrombin-INR Procedure	D-MD-LAB-15-009		Apr 11	Waived	√	√	√	21, 22	85610	WP10	K021190
POCT NT-proBNP Procedure	D-MD-LAB-15-010		Apr 11	Waived	√	n/a	n/a	25, 26, 27	83880	BNP	CE
POCT BHCG Procedure	D-MD-LAB-15-012	v2	May 14	Waived	√	n/a	n/a	n/a	81025	CMP	CE
POCT i-STAT Procedure	D-MD-LAB-15-014		May 11	Waived	√	√	n/a	1, 2, 3	80047	AQ4	K053110
POCT Hemoglobin Procedure	D-MD-LAB-15-015		Jun 11	Waived	√	√	n/a	5	85018	HCC	K041234
POCT H.pylori detection (CLOtest)	D-MD-LAB-15-016		Jun 11	Waived	√	√	√	4		RUR	K882199
POCT Troponin T Procedure	D-MS-LAB-15-017		Mar 12	Waived	√	n/a	n/a	26, 27	84484	TNT	CE
POCT Activated Clotting Time Procedure	D-MS-LAB-15-018		Jul 11	Non-waived	√	√	n/a	7 - 10	85347	CT2, CT3	K050016
POCT Influenza A & B Procedure	D-MS-LAB-15-019		Jul 11	Waived	√	√	√	11	87804	VR4	K031899
POCT RSV Procedure	D-MS-LAB-15-020		Aug 11	Waived	√	√	√	12	87807	VR4	K070747
POCT TEG Procedure	D-MS-LAB-15-021		Aug 11	Non-waived	√	n/a	n/a	33 – 41		TEG	K993678
POCT Ketone (urine)	D-MD-LAB-15-022		May 12	Non-waived	√	√	n/a	n/a	82009	KET	CE
POCT Urea Breath Test	D-MD-LAB-15-023		Oct11	Non-waived	√	n/a	√	n/a	78267, 78268, 83014	n/a	CE
POCT Cholesterol Procedure	D-MD-LAB-15-024		May 12	Waived	√	√	√			LCW	CE
POCT Blood Analyzer Procedure (cobas b221)	D-MD-LAB-15-025		Jan 12	Non-waived	√	n/a	n/a	16, 17, 18, 19, 20	80051, 83605, 84520, 82947	AQ2	K032311

Summary

- The purpose of utilizing Point of Care testing as part of a process improvement program is to provide accurate results in the shortest period of time to medical staff at the patient's bedside which is then actioned upon.
 - Improving Patient Encounter TAT
 - Improving Clinical TAT
 - Improving Order TAT
 - Improving Laboratory TAT
 - Improving Sample TAT
- Positive effects of POCT
 - Potential gain when using a POCT system can:
 - “Lean” the current system by removing several steps
 - Physician decision time can be improved significantly
 - Patient LOS in ED improved (decreased stay length)

References

- Dreamstime.com, (2014). Chaos Clip Art, Chaos Vector Images, Chaos Illustrations - Dreamstime. [online] Available at: <http://www.dreamstime.com/illustration/chaos.html> [Accessed 10 May. 2014].
- Wikipedia, (2014). Point-of-care testing. [online] Available at: http://en.wikipedia.org/wiki/Point-of-care_testing [Accessed 11 May. 2014].

Thank You

Questions