Hospital Authority Point-of-Care Testing Policy

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Table of Contents

1. INTRODUCTION	
1.1	Point-of-Care Testing (POCT) is laboratory testing performed in the clinical setting by non-laboratory healthcare professionals. Its complexity ranges from simple dipstick test to sophisticated analyzer test.
1.2	POCT has both advantages and disadvantages as compared with conventional laboratory testing. A faster turnaround time (TAT) can be invaluable in the management of critically ill patients in whom a treatment decision is urgently needed but the clinician cannot make up his mind without resorting to certain laboratory tests. On the other hand, the perceived benefit can only be realized, and potential harm avoided, if accuracy and reliability are being upheld.
1.3	Crucial considerations of POCT are: How reliable is it? What happens when it goes wrong? More fundamentally, what are the added values on top of the existing laboratory service, and does it really improve patient outcomes? Lastly, does the advantage, after weighing risk and benefit, justify the efforts and resources needed?
1.4	POCT is an evolving field which does not fit neatly into an existing regulatory framework. Nonetheless, care providers are under legal obligation to provide up-to-standard care to patients, who are entitled to quality test results regardless of who performs the tests or where they are performed. While HA is ultimately liable under the doctrine of vicarious liability, service director permitting POCT and healthcare staff performing POCT are part of the chain linking to the duty of care.
1.5	POCT requires a quality system and trained operators to ensure a good standard of performance.
2. HA POLICY	
2.1	Laboratory tests should be performed in the laboratory whenever possible. The use of POCT should be limited to situations where it provides a clear advantage in patient management, and is supported by appropriate technology, trained staff and sufficient quality assurance (QA) measures. POCT should not be used to replace routine non-urgent tests, and all POCT programs must not fall below the quality system standards prevailing in the HA.

2.2	The scope of POC testing under this Policy covers all medical testing that is performed close to or near the patients, examines materials derived from patients, such as blood, urine and expired gases and excludes patient self-testing or testing for research purpose.
3. GOVERNANCE STRUCTURE	
3.1	The HA POCT Committee, a task force under the COC in Pathology, was set up in 2007.
	Terms of Reference The HA POCT Committee will report to COC in Pathology and (i) Advice on the POCT service in HA, including • Scope of POCT • Quality standards for POCT service • Competency requirement of POCT operators (ii) Monitor the practice of POCT in HA
3.2	The Hospital/Cluster POCT Coordinating Committee, represented by clinical services, laboratory and hospital management shall coordinate and monitor POCT development in respective hospitals/clusters with POCT activities. Its roles are: (i) Establishing needs for POCT in the respective hospitals/clusters. With the support of Hospital/Cluster POCT Coordinating committee, seeking the HA POCT committee for approval in the adoption of new POCT technologies or tests. (ii) Ensuring compliance to HA policy and decision on POCT including procurement matters and establishing a procedure with hospital/cluster procurement department to seek endorsement from hospital/cluster laboratory department before processing purchase requisitions of POCT devices. (iii) Establish a hospital/cluster registry of the location and type of POCT devices.

	(iv) Keeping track of training activities for POCT operators. (v) Overseeing performance and standards of POCT in the respective hospitals/clusters. (vi) Sharing POCT incidents and quality issues to Hospital/Cluster Quality & Safety Committee to enhance risk communication as appropriate.
3.3	Site Supervisor: Clinical department where POCT is being practiced has the overall responsibility of the service. Each clinical site shall have a designated Site Supervisor to liaise with the pathology department and the Hospital/Cluster POCT Coordinating Committee on matters relating to POCT, and to report problems. Site Supervisor shall implement this Policy at department level.
4. GOOD POCT PRACTICE	
	(The stringency required should correspond to the perceived risk. As such, they may not apply to simple dipstick test.)
4.1	**ACQUISITION OF POCT**
4.1.1	The decision to adopt POCT should be agreed between clinical and laboratory departments and fall in line with the HA policy (section 2.) Priority should be given to explore the existing laboratory services to see if it could be enhanced to meet the clinical needs without using POCT.
4.1.2	POCT/ Devices should be evaluated for: (i) Needs and alternatives. (ii) Balance between benefits (to the extent achievable and sustainable in the real service setting) and risks (all potential risks, including negligent liability, that are possible within the healthcare system as a result of the POCT.) (iii) Performance in terms of reliable methodology, accuracy, precision, and study of correlation with the existing laboratory test. (iv) Availability of external quality assurance programmes, and if not, any possible alternatives

	(v) Logistics such as ease of operation, space and service requirements, mode of entry of unique patient's identifiers (preferably by 2D barcode scanning), IT interface assessment and environmental assessment. (vi) Sustainability, for which all costs including direct ones (e.g. capital investment, environmental refurbishment, running cost including reagents, calibrators, QC materials, maintenance cost and external QA programmes) and indirect ones (e.g. staff cost in operating the POCT and required in training, maintenance, trouble-shooting and QA, etc.) must be considered. (vii) Support by the manufacturer in instrument evaluation, provision of training before the initiation of service and technical support in the event of instrumental failure. (viii) Costs and benefits.
4.2	**STANDARD OPERATION PROCEDURE (SOP)**
4.2.1	The operation of POCT should be clearly laid out in simple written instructions, which must be formally approved by the respective department or the Hospital/Cluster POCT Coordinating Committee.
4.2.2	The SOP should be reviewed and revised regularly, and uniquely identified with an effective date. All operators must have ready access to the latest revision of the SOP (refer to Annex I for Operator requirement).
4.3	**TRAINING AND COMPETENCE VALIDATION**
4.3.1	All staff operating a POCT device must receive training, supported by written materials (ideally traceable to an up-to-date manual). When nursing and medical students undertaking training in HA operate a POCT devices, appropriate supervision by trained staff should be provided.
4.3.2	Under the train-the-trainer approach, the POCT Coordinating Committee shall designate appropriate personnel to organize training for trainers, who are then responsible for training field staff on-site. The participation of the manufacturer in the training of trainers is highly recommended. Trainers are expected to draw from grades like doctor, nurse, technologist, scientific officer

	(medical) and other specialist.
4.3.3	The competency of a trained staff shall be documented before she/he is allowed to operate the POCT device. All training activities and competence validation records should be documented and readily traceable.
4.3.4	POCT operators, including trainers, should be revalidated at an interval of not more than three years.
4.3.5	The POCT Site Supervisor shall ensure that training and competence validation is in place for the respective clinical sites.
4.4	**QUALITY ASSURANCE (QA)**
4.4.1	POCT shall have comparable QA as other tests provided by hospital laboratory. Because results from POCT and laboratory are used concurrently in the same setting, an overriding concern is to ensure local comparability of results, which requires correlation studies and regular QA.
4.4.2	<u>Internal Quality Control (QC)</u> Measurement of QC materials at regular intervals is used to ensure that a device is meeting the clinical and technical specifications required for a particular test. This is an essential requirement for all devices that are generating results on which a clinical decision may be made. The following are QC requirements for a POCT device:
4.4.2.1	For multiple-use bench top and cartridge-based device like blood gas analyzer requiring calibration at regular intervals, QC samples must be analyzed at intervals recommended by manufacturer or according to local pathology laboratory practice.
4.4.2.2	For single-use or handheld POCT device with onboard control (OBC) or internal control, i.e. incorporated multiple channels for low and high controls and calibration check to be run simultaneously with patient test, the manufacturer's instruction should be followed.
4.4.2.3	For single-use or handheld POCT device without OBC or internal control: (i) Two levels of QC samples must be run with every new shipment of consumables.

	(ii) Two levels of QC samples must be run on a day when patient sample is tested (before or along with running of patient specimen). (iii) The two QC materials should cover both normal and abnormal levels. For qualitative tests, these may be positive and negative controls.
4.4.2.4	All QC results shall be recorded and kept for at least three years.
4.4.2.5	Corrective actions for out-of-control results and other QC nonconformances shall be documented and kept for at least three years.
4.4.3	<u>External Quality Assessment (EQA)</u> External Quality Assessment involves the measurement of samples supplied by a third party and comparison of the results obtained with other participants. EQA is useful to reassure POCT users about result comparability with other users and to promote good QA practices.
4.4.3.1	Participation in an EQA scheme is highly recommended especially for high complexity tests like coagulation, blood gases and electrolytes.
4.4.3.2	In the absence of an EQA scheme, one should establish an alternate quality assessment scheme involving the circulating of samples for analysis or replication of the test within the laboratory.
4.4.3.3	All EQA/alternate QA scheme results should be recorded and kept for at least three years.
4.4.3.4	Corrective actions for all nonconformances of EQA/alternate QA scheme results shall be documented and kept for at least three years.
4.4.4	<u>Audit</u> An annual internal audit on POCT service including quality assurance should be conducted to review the local processes and identify weak points in the system where errors could occur. The audit records shall be kept for at least three years.
4.4.5	The Hospital/Cluster POCT Coordinating Committee shall function to coordinate the audit and oversee the quality of the POCT program.

4.5	**DOCUMENTATION AND REPORTING**
4.5.1	The standard of reporting for POCT is similar to that of laboratory testing, in essence:
	(i) POCT results shall be reported with sufficient detail.
	(ii) POCT results shall be permanently recorded in patient's medical record.
	(iii) The record shall distinguish between POCT results and those from the central laboratory or its satellites.
	(iv) Data recorded should include or be traceable to patient demographics for identification purpose, specimen type, date and time of specimen collection and analysis, result(s) obtained, identity of device used and identity of operator.
	(v) Connectivity with the Laboratory Information System (LIS) to facilitate data capture and result documentation is recommended in the acquisition of new or replacement of POCT devices of high test volume or performing multi-parameter analysis.
4.5.2	Clusters should establish a mechanism for timely user account maintenance and the annual user account review of POCT devices with connectivity to LIS.
4.6	**MAINTENANCE**
4.6.1	The POCT Site Supervisor shall ensure that a maintenance program is in place for the respective clinical sites, in that: (i) the parties responsible for maintenance are identified, (ii) the staff involved had received the necessary training to perform maintenance required and that the device is being serviced according to schedule, (iii) each device should have a log book to keep track of maintenance, faults, repairs and corrective action taken.
4.7	**SAFETY**

4.7.1	Staff operating POCT devices must be aware of the biohazards of patient samples, the chemical hazards of reagents and the physical or electrical hazards of operating the device and potential harm to patients as a result of the aforementioned risks. Proper infection control measures should be practiced.
4.7.2	Appropriate personal protective equipment such as gloves, gowns, face shields or masks, and eye protection should be provided and used accordingly.

5. REFERENCES

5.1	Kost GJ, Ehrmeyer SS, Chernow B, et al. The laboratory-clinical interface: point-of-care testing. Chest 1999;115(4):1140-54.
5.2	Kane B. Point-of-care testing: instant gratification? Ann Intern Med 1999;130(10):870-2.
5.3	Hospital Authority Point-of-Care Testing Guidelines, 1st Revision, ed. 1.1, 10 October 2001.
5.4	CSLI. Essential Tools for Implementation and Management of a Point-of Care Testing Program. 3rd ed. CLSI Guideline POCT04. Wayne, PA: Clinical and Laboratory Standards Institute, 2016.
5.5	Price CP et al. (ed). Point-of-Care Testing, Second Edition, AACC Press, 2004, p. 36 and Chapter 13, p. 137 – 145.

Annex I

Classification of Complexity of Testing for POCT/ Devices#

Complexity of Testing*	Level I	Level II
Description	Low complexity of testing	Moderate to high complexity of testing
Type of POCT/ Devices	1. Glucometers, e.g. Bayer Contour® TS system, Roche Accu-Chek® Performa system. 2. Haemoglobinometers, e.g. HemoCue® Haemoglobin system. 3. Blood ketone 4. Breath carbon monoxide and alcohol tests 5. Urinalysis	All types of POCT/ devices NOT classified as Level I.
POCT Operator Requirement	Well-trained hospital staff, including supporting staff.	Well-trained professional staff (doctors, nurses, medical technologists, other specialists).

Urine dipstick tests which are simple to perform with little potential for adverse medical consequence are exempted from compliancy to this Policy. However it should be noted that performance of these tests should adhere to the manufacturer's instructions. Exempted tests include urine test strips for glucose, protein, ketone, red blood cells, pH, bilirubin and urobilinogen.

* Factors considered include complexity of testing methodology, potential analytical interference, clinical importance, medical-legal implications, availability of positive patient identification, etc.

Annex II

Guidelines for Performing Point-of-Care Urine Pregnancy Test

1. It should be noted that the result of urine pregnancy test (UPT) bears significant indications on subsequent medical procedures on the patient.

2. The brands of test strips for UPT should be selected after rigorous testing and scrutiny and approved for use by the cluster POCT committee.

3. The site supervisor of the clinical area offering UPT must ensure that the test strips are kept under conditions stipulated by the manufacturer.

4. Should there be any doubt on possible deterioration of test strips due to improper storage condition, the entire box/batch of test strips must be removed and discarded.

5. All operators for the test must receive thorough training on how the test is performed and must understand how to interpret the test result which is mainly through visual inspection on change in colour or appearance of the test strip.

6. The competency of the operators should be revalidated at an interval of not more than three years. Assistance may be sought from the hospital's clinical laboratory or an accredited clinical laboratory in this respect, as well as providing technical advice on the test procedures.

7. Technical requirements for UPT are given below:

   (i) It is desirable to collect the first morning urine sample for the test

   (ii) For test kits that **do not** include a procedural/built-in internal control, positive and negative controls must be run on days when patient testing is performed.

   (iii) For test kits that include a procedural/built-in internal control, positive and negative urine controls must be run for each new lot number or shipment of test materials. On each day of testing, it is also advisable to include both a positive and a negative control urine for verifying the test strips' performance.

   (iv) All test and QC results must be clearly documented either electronically or manually in a log book that may be inspected by the site supervisor or the cluster POCT coordinator.

(v) Should there be any doubt on interpreting test results, the test must be abandoned and another sample should be sent to an accredited clinical laboratory for confirmation. Test result obtained under this situation should be reported as “interference”.

8. It is desirable that an external quality assurance program be in place for all clinical areas performing UPT as to ascertain testing quality and operator competency. The cluster POCT committee shall consider this requirement with respect to the cluster’s situation and need.

9. A Checklist for Point-of-Care Urine Pregnancy Testing is included as an addendum to this guideline.

Addendum to Guidelines for Performing Point-of-Care Urine Pregnancy Test

Checklist for Point-of-Care Urine Pregnancy Testing

Item		Yes	No	Remarks
1.	Test Kit Inventory Record			
2.	User Guide / Package Insert			
3.	Standard Operation Procedure			
4.	Training Materials/ Handouts			
5.	Trainer Training Record			
6.	Trainer Assessment Record			
7.	Qualified Trainer Name List			
8.	Operator Training Record			
9.	Operator Assessment Record			
10.	Qualified Operator Name List			
11.	Site Supervisor List			
12.	Internal Quality Control Record			
13.	Internal Quality Control Failure Report			
14.	External Quality Assurance Record			
15.	External Quality Assurance Failure Record			
16.	Patient Result Record			

Addendum to HA POCT Policy

University POCT Devices and Devices Used in Clinical Studies

It is common practice for university clinical departments to have their POCT devices housed in HA institutions. These devices may serve dual purposes: teaching and clinical. POCT devices are also frequently employed in clinical studies conducted within HA.

If such devices generate test result or data that are used for disease diagnosis or management of HA patients, then the quality requirements for operation of such devices must follow guidelines and policy set by the HA POCT Committee and the respective Cluster POCT Committee.