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Organization of the POCT unit

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ABSTRACT

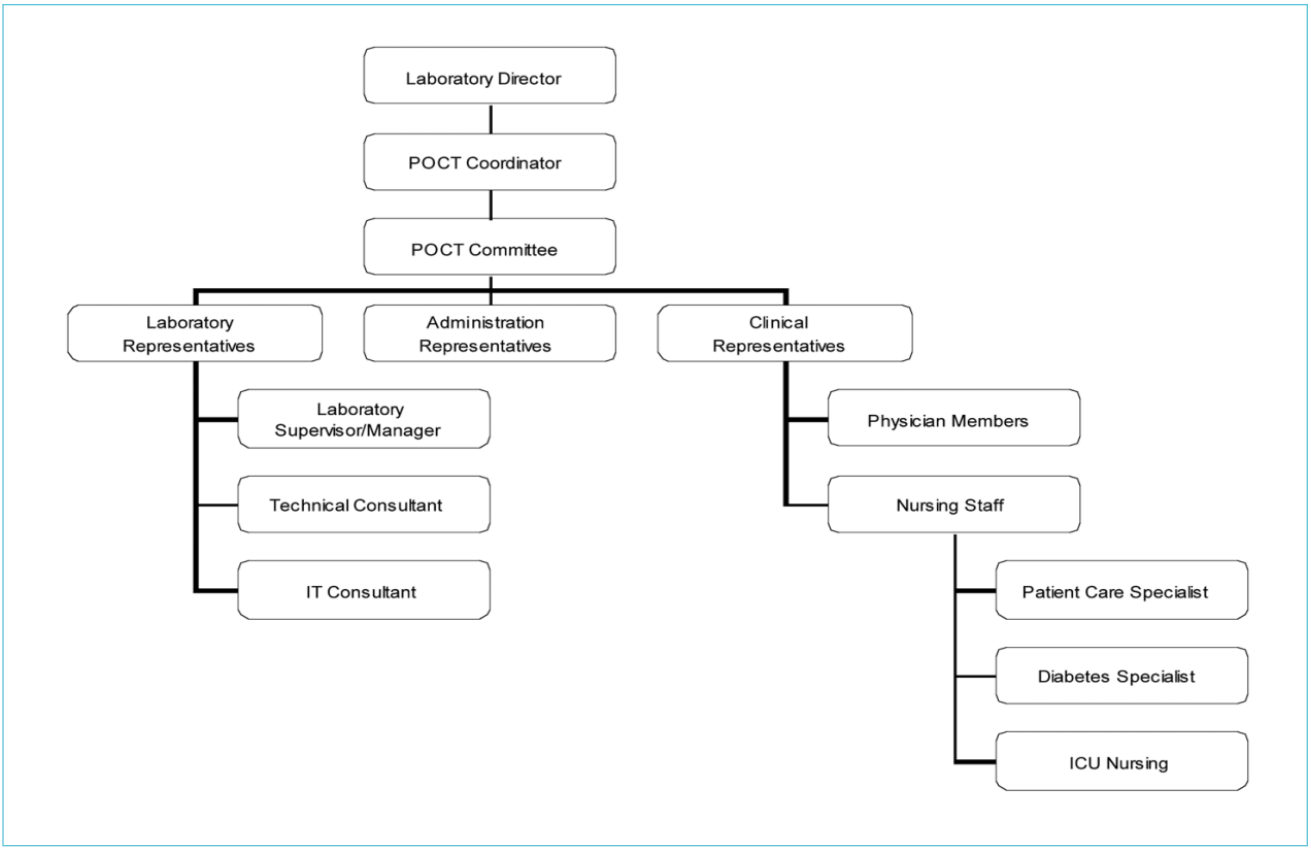
Point-of-care testing (POCT) has evolved as an important part of laboratory medicine by virtue of its compactness, portability, and the feasibility of operation by nonlaboratory personnel, where fast and accurate testing methods are a primary concern and, as a result, improving the patient care. To successfully achieve POCT quality in networks, a multidisciplinary organizational approach is required. A clearly defined organizational structure should be put in place for proper functioning and optimum utilization of each POCT unit. The POCT unit must include designated authority, responsibility, and accountability.

ORGANIZATION OF THE POCT UNIT

Point-of-care testing is also known as extra-laboratory, alternate site, or near-patient testing. It typically refers to the performance of a diagnostic laboratory test outside of a traditional central laboratory and near the site of patient care, whether it is inpatient settings or outpatient clinics. The worldwide volume is rapidly expanding, with a 12% to 15% annual growth rate. The point-of-care testing (POCT) has evolved as an important part of laboratory medicine by virtue of its compactness, portability, and the feasibility of operation by nonlaboratory personnel, where fast and accurate testing methods are a primary concern and, as a result, improving the patient care.(1) The reasons for performing tests in this setting include convenience to the clinicians, a faster turnaround time (TAT), and advantage to the hospital administration in terms of cost savings. Concerns that have arisen with the POCT include problems with ensuring quality, potential conflicts of interest, and an uncertainty of the responsibility.(2) In larger networks, testing may be performed at locations ranging from the emergency room (ER), the operating room (OR), or intensive care units (ICUs) in the hospital to satellite outpatient clinics. The large majority of clinical staff members involved in POCT are focused primarily on clinical care and are much more variable in their familiarity with the testing process and quality control requirements. Training and ongoing competency maintenance of the staff performing POCT can be overwhelming to manage. POCT implementation requires a systematic approach, which involves all stakeholders.

An example of an organizational chart for a POCT network is shown in Figure 1.

Figure 1 Organizational chart for a POCT network



Traditionally, POCT was unregulated and little effort was made by hospitals to establish an approach to managing these technologies. Predictably, issues concerning the quality of test results became apparent, resulting in the establishment of regulatory requirements that have been enforced by hospital accreditation organizations. Failure to comply with regulatory mandates may have major consequences. The need to address regulatory requirements combined with rapid expansion of POCT technologies has resulted in a concerted effort by institutions to manage POCT as a formal hospital program. The first step in developing a strategy to manage POCT involves setting up an interdisciplinary POC management team, including the laboratory, physicians, and nurses.

Tasks and responsibilities can be moved across traditional territories. By identifying where the process crosses territories, opportunities for cooperating and adopting a total system perspective can lead to powerful new solutions to common problems. Typically, the cross-territory concept occurs in three areas of the hospital, i.e. the clinical user unit, the laboratory and the information technology department (ITD). (3) In order to improve the utilization of POCT and the quality of patient care, and to ensure that results are integrated into and being networked with the laboratory information system, the establishment of new relationships among the laboratory, clinicians and the ITD people is needed.(4)

POCT STAKEHOLDERS PLANNING PROCESS

Prior to purchase of POCT equipment, it is recommended that all those with involvement in POCT, namely the POCT stakeholders, are part of the planning process. This group (in a hospital or clinic setting) might include, in addition to a POCT specialist, or specialist in the area under consideration for testing, representatives from the following groups:

- End Users (to state their needs and wants);
- Biomedical engineering (information on analyser design issues);

Table 1 Organizational structure for small set up (5)

POCT performed on Hospital Campus	Lab Director
	Technical Consultant
	On-Site Supervisor
	Testing Personnel
POCT in Physician Offices and Clinics	Lab Director
	Clinical Consultant
	Technical Consultant
	On-Site Supervisor
	Testing Personnel

- Information Technology staff (advice on software interfaces and functionality);
- Organisational Quality staff (registration, certification requirements);
- Purchasing / contracts officer (optional, depending on local practice);
- Representative from local pathology laboratory.

Lab director

All POCT to be put under the direction, authority, jurisdiction and responsibility of the Chief of Pathology and Laboratory Medicine.

Responsibilities of the Director of the Clinical Laboratory:

- Responsible for all POCT activities on the SFGH campus;
- Ensures compliance with all applicable regulations, rules and standards;
- Provides expert advice and information to the POCT Committee, including identifying alternatives to various POCT methods and devices, determining criteria for medical necessity, and identifying procedures for adopting and implementing the tests.

Director of the clinical laboratory or an authorized representative (6)

a. Screens, recommends and approves all instruments, devices, procedures, reagents, materials and kits used in POCT, including new lots of previously approved reagents, and supplies, and new versions of any established POCT.

b. Establishes and regularly reviews procedures for all approved POCT, including guidelines appropriate quality assessment processes.

c. Collaborates with the Medical Staff, Nursing Services, and the Department of Education and Training, in the training of individuals designated as trainers and supervisors of the personnel selected to perform POCT.

d. Conducts periodic reviews of POCT performance by monitoring for compliance to established guidelines and providing, as required, proficiency test specimens to each site authorized by the Clinical Laboratory to perform POCT.

e. Conducts periodic inspection of the POCT sites for compliance with regulatory mandates.

f. Periodically reports on the status and performance of POCT as requested by SFGH oversight committees, including, but not limited to PIPS and MEC.

g. Monitors utilization of all POCT, communicates with each POCT site, and recommends methods to improve efficiency to the unit performing the tests and to the POCT Committee.

h. Maintains a current master list of all POCT sites and the types of tests performed at each site.

POCT coordinators as leaders (7)

POCT should be introduced in a systematic process which is inclusive of all stakeholders. Ad hoc approaches are potentially expensive and dangerous in terms of patient safety. To avoid this situation, a POCT Coordinator should be employed.

The POCT Coordinator should be an experienced medical technologist/scientist from a hospital, laboratory or specialist POCT service provider background. The responsibilities of the POCT Coordinator includes overall supervision and management of the POCT activity, ensuring compliance with the policies and quality standards required by the program particularly in relation to selection and evaluation

of instruments, staff training and competency assessment, surveillance of the entire testing process, quality control and quality assurance procedures and resolving technical problems. The POCT Coordinator provides invaluable leadership in collaboration with nurses and physicians. Institutions should set up POCT committees to oversee the POCT service. The committee should be responsible for evaluating and prioritizing new tests and balancing use of limited resources. With numerous tests available for PCT and each year, needs arising for more the POCT committee carefully determines clinical indications, test clusters, and valid applications before approving near-patient or bedside testing.

There will be many people involved in the creation, implementation and management of a POCT service. It is vital that an appropriate senior professional is identified to act as a 'POCT co-ordinator' and given the authority and overall responsibility for the service at the beginning of the development process. This individual will have responsibility for both the results that are generated and the correct use of the devices that generate those results. Managers of POCT should also be aware of their responsibility for clinical governance and of the medico-legal implications of an erroneous result. Liability under the Consumer Protection Act will only remain with the manufacturer or supplier if the user can demonstrate that the equipment has been used in strict accordance with the manufacturer's instructions.

Responsibilities of the POCT coordinator (8)

- Ensuring that all POCT is performed to the same standard as would be expected from regular laboratory testing.

Table 2 Role of the POCT coordinator (8)

Identifying suitable POCT equipment for evaluation
Performing an evaluation
Installing POCT equipment
Writing procedures
Training staff
Preparing worksheets, log books, etc.
Maintenance schedules
QC programs
Trouble shooting
Monitoring and review of procedures
Competency reviews

- Identifing the types and locations of all POCT equipment within the CDHB. An electronic record of all equipment is maintained.
- Ensuring that all of the CDHB staff performing POCT have current competency training and documentation, including an awareness of health and safety issues pertaining to samples and equipment.
- Ensuring regular Quality Assurance is maintained and Quality Control (QC) samples are analysed on POCT devices, with up-to-date documentation and history.
- Troubleshooting of POCT devices, with up-to-date documentation and history.

Role of the local hospital pathology laboratory

The local hospital pathology laboratory should play a key role in the development and management of a POCT service. This is particularly true for secondary care and may also be useful for some primary care services. The pathology laboratory can provide advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, quality assessment and health and safety. There should therefore be close liaison between users and the local hospital pathology laboratory on all issues relating to POCT. Wherever possible this liaison should be formally defined e.g. by a service level agreement specifying the range of products, services, operational details and the responsibilities of the central laboratory and the POCT user

Establishment of a POCT committee (7)

In addition to the appointment of a POCT co-ordinator, the establishment of a multidisciplinary POCT committee to oversee POCT whether in the hospital setting or in some elements of primary care is recommended as good practice. All stakeholders should be represented in a POCT committee e.g. laboratory staff, clinicians, nursing staff, specialist nurses, pharmacists, IT and finance. POCT in the community requires similar stakeholder representation; input from a clinical scientist or a biomedical scientist may be helpful.

The role of the POCT committee may include the following:

- Determining if POCT is justified at a particular location. This would include a clear demonstration of increased clinical effectiveness
- Establishing a system for the continuing audit and assessment of POCT
- Ensuring that no POCT device is used unless it has been looked at by the POCT committee
- Setting up a quality hierarchy to ensure that there is a direct link between the person performing the analysis and the POCT committee
- Establishing the presence of a link nurse or other healthcare professional at the point of service delivery
- Including representatives from primary care and the community where necessary
- Ensuring that users have documented training in the use of POCT devices and that they are fully aware of all contra-indications and limitations
- Ensuring that internal quality control (IQC) and external quality assessment (EQA) schemes are applied to POCT in the same way as they would be for the established laboratory service.

Clinical consultant

Physicians and Nurse Practitioners within the office or clinic serve as a liaison between the laboratory and its clients in reporting and interpreting results.

Technical consultant

Hospital Laboratory is responsible for technical and scientific oversight of the POCT.

Pharmacy and materials management

a. Notifies the Clinical Laboratory upon the arrival of new lots of specified POCT reagents, devices, kits and supplies (e.g., occult blood cards, glucose strips, urine dipsticks, urine pregnancy test kits, etc).

b. Notifies the Clinical Laboratory upon receipt of any shipment of specified POCT materials, supplies or devices.

c. Provides periodic information on utilization and consumption to the Director of the Clinical Laboratory or authorized representative.

On-site supervisor

Nurse Directors, Nurse Managers, and Administrative Clinical Leaders qualify as supervisors based on their education. They will be responsible for the day-to-day supervision or oversight of personnel performing POCT and reporting test results. A supervisor must be accessible to testing personnel at all times testing is being performed.

Responsibilities (6)

1. All POCT devices adopted will: (7)
    - Be used in accordance with manufacturer's or suppliers instructions.
    - Be subject to regular maintenance as specified by the supplying manufacturer.
    - Details of maintenance performed, faults and corrective action taken, will be documented.
    - Only be used for the purpose it has been evaluated and procured for.
    - Be approved for use by the appropriate local management who will be accountable for the integration of the POCT service into the established POCT quality assurance and operational infrastructure.
2. Internal Quality Control will be performed according to the test specific Standard Operating Procedure (SOP) supplied by the laboratory POCT team
3. Electronic rather than visually–read devices will be used whenever possible. (It is recommended that where such visual read devices are in use, the results are checked by at least two trained members of staff).
4. Only trained, certified and competent staff will use POCT equipment. The training and certification of staff will be arranged in conjunction with the laboratory POCT team.
5. All reagent/cartridge/consumable lot numbers will be recorded to facilitate patient tracking in the event of product recall. A direct link must be maintained between patient demographics, test result, and reagent identification numbers.
6. All adverse events relating to POCT will be reported back to Trust Risk Management Team and the POCT committee by local POCT service users using the Trust incident report form. The POCT committee will have the authority to withdraw or suspend service in the event of a safety-related or performance issue or lack of clinical or cost effectiveness.

Responsibilities of POCT users (6):

- All staff must use the equipment in a safe and responsible manner.
- All staff must have a unique operator ID.
- No operator ID must be shared with another staff member.

- An accurate and up-to-date maintenance log for the POCT equipment must be maintained, signed and dated as required.
- All staff members must satisfy the quality control (QC) requirements pertaining to the specific instrument.
- All patient and QC results must be documented. Included with the results should be the operator's initials and the date and time of the test.
- All staff members operating POCT equipment will have up to date competency records.

CONCLUSIONS

To successfully achieve POCT quality in networks, a multidisciplinary organizational approach is required. A clearly defined organizational structure should be put in place for proper functioning and optimum utilization of each POCT unit. POCT unit must include designated authority, responsibility, and accountability. Standard operating procedures and a POCT quality program should be developed and carried out in all areas.

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