THE GUIDELINES FOR (POCT)

PRESENTATION
The guidelines for (POCT) represent the national document produced by the TELESAM society of science of the Antel-Assiatel-Aitic confederation. This document reflects a specific line of interest, established by means of a systematic process of literature review, drawing from valid scientific basis; it can be used as a tool to improve on the quality of services, in response to the current ongoing changes, in the method of delivery of health assistance of which the Point of Care Testing Systems are an illustration. The guidelines are an update and training tool that allow a rapid transfer of knowledge on daily clinical activities; it therefore depends on the skills and experience of each individual professional for the application of the recommended mode of conduct to produce qualitatively valid and reliable results helping to follow a common address line for the organization and management of Point of Care Testing.

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Definition

The term Point of Care Testing (POCT) defines the analysis performed before or at the point of patient care and, in general, all the analysis carried out outside of the chemical-clinical laboratory of reference, or decentralized. This decentralization can be maintained within the confines of the hospital, or extended outside of it’s confines and may not only require permanently structured spaces but also kits and instrumentation manually transportable. Conceptually, the POCT is a response to changing modes of delivery of health care. The care is more and more centered on the patient, with a greater emphasis on primary care, with a strengthening of patient triage in the health care system, a reduction in the length of stay in hospital wards, consolidation and reorganization of hospitals, a reduction in the conception of hospital as the only treatment center.

Note: The definition of “Biomedical Laboratory Technologist” may be considered the equivalent of Biomedical Laboratory Scientist as the IFBLS LG define. For this reason you will find a slash to indicate the BLS as the same of BLT: BLT/S

Requirements of a POCT

Requirements of a POCT In any case, the POCT must have two basic requirements: 1) the reduction of the total time of analysis (Turn Around Time, TAT) 2) the demonstrable improvement in the patient's health, that should enable the clinician to quickly make critical decisions about the disease and the consequent treatment to be administered hence improving patient prognosis. The POCT, in fact, is an organizational model, extended to all forms of diagnosis, including instrumental diagnosis, and is then the most appropriate organizational solution in support of those situations in which there are logistical difficulties or problems of response times, or in which it is necessary to obtain a laboratory diagnostic result in deficiency of specific personnel.

Synonyms of POCT

POCT synonyms: The term was originally created to characterize the decentralized analysis within the intensive care and emergency departments of hospitals, but was then extended to all decentralized activities, although for the latter it would be more appropriate the term Near patient testing (next to the patient analysis). According to this definition are many synonyms used, such as examinations at the bedside (bedside test) or close to the patient (near-patient testing) or the analysis performed at the patient's home (home testing), or analysis carried out in the distant setting with respect to the laboratory (remote testing), or ultimately, analysis performed in the outpatient setting by the treating physician (physician’s office laboratories). The Point of Care is in fact by definition performed by anyone professionally or otherwise not formed in the clinical laboratory sectors. It does not fall under this definition the examination carried out autonomously by the patient (selftesting). In the case of analytical activity performed with laboratory instruments by technical personnel configures the satellite laboratory situation, which also responds to same requirements of POCT and hence this will be considered the definition in the presentation of these guidelines.

Areas of application

The POCT is an organizational aspect of the current Laboratory Medicine, which should be considered supplemental and not substitute, and in any case to be activated only if the activities of the Laboratory is not in any way possible or timely in relation to the clinical condition. In particular, in hospital care, the following application areas can be identified: 1) First Aid, Emergency and Admissions Departments, Intensive Care Units, Operating Rooms, Neonatology, Immunology Clinics, Dialysis, Department of isolation, vehicles (ambulance, air ambulance) for transport of critical patients. 2) Territorial Support: primary care (general practice physicians and pediatricians), outpatient specialist care (specialist clinics), emergency assistance (emergency medical service), assistance in geographically remote areas where access to the laboratory is limited, residential care and semi-skilled nursing, home care. 3) Self-testing at home or at pharmacies

NOTE: These guidelines apply in the cases referred to in paragraphs 1 and 2, although the basic principles can also be considered for the cases referred to in paragraph 3.
Types of analytical device

All analytical devices that are used for POCT must satisfy definition of in vitro diagnostic device (IVD) and as such are regulated by the European Directive IVDD 98/79/EC transposed by Italy with Legislative Decree 32/2000. The systems for the decentralized analysis can be classified as: 1) Small-sized analyzers, usually handheld, although of variable size 2) Benchtop Analyzers, larger, include systems designed for use in clinical laboratories or in small satellite laboratories. Manually disposable reactive strips, with visual check of operator, cannot be considered POCT and their use cannot be expected in charitable activities: inadequate analytical performance and impossibility of any form of process traceability increase the risk in an exponential manner of medical errors.

Problems

Drawbacks: POCT should not be a department laboratory, but should serve as a support to Laboratory Medicine Service in specific circumstances. Consequently, the POCT has some problems, of which, those relating to the management and analytical quality control and the need to manage the quality certification of the same, leading to a constant monitoring of the Laboratory Medicine services. The activities of POCT must meet the required quality standards and the results when compared to those of the Department of Laboratory Medicine. The patient must have the same quality of services, wherever the service is delivered. To ensure a better quality of care and possible assistance, the appropriate use of POCT must be considered as a matter of Clinical Governance and must therefore provide feedback in terms of clinical effectiveness, risk management programs, ongoing staff training and processes audit. Mismanagement, the absence of feedback on reliability of POCT, the unsuitable competence of the operators, constitute a risk to patient safety and may pose a legal-medical problems in the event of incorrect results. For patient safety, the Laboratory must have the full responsibility of POCT.

Clinical governance:

Decentralized testing, must produce results completely comparable with those of the laboratory, including the adherence to standards of good laboratory practice, and include: Quality Management (QA), the internal quality control (QCI), and participation in external controls (VEQ) The quality of the analysis must be monitored, by properly documenting the activities that are carried out. To do this we need to build a system that adequately governs the laboratory process. In that perspective, however, the data must be analytically correct and correlated with that of routine activities, there should be a data comparison, verification of analytical precision and accuracy (bias). The documents that best address the aspects mentioned above are: 1) ISO Point of care testing (POCT) - Requirements for Quality and Competence ISO 15189: 2003 Medical Laboratories Particular Requirements for Quality and Competence 2) EN ISO 22870: 2006 Point-of-care testing (POCT) the reference concept is that the management of decentralized instruments must be part of a quality system operated with full involvement of the central Laboratory and all key operators. And of paramount importance is the education and the training of professional to run the POCT analysis, in order to properly perform the analysis, ensuring the quality of the analytical data. POCT is an organizational model of the Clinical Laboratory, aimed at improving the quality of care; since the diagnostic results provided by POCT become an integral part of the clinical history of the patient, the quality guarantees must be consistent with the diagnostic information requested and aligned to the reference laboratory. In this context, the decentralized activities should be integrated with those of the clinical laboratory of reference and therefore are the responsibility of the Director of the Laboratory himself. With Clinical Governance all aspects of the POCT quality can be secured and constantly monitored; it can best be implemented through the establishment of a Corporate Multidisciplinary Commission, or the POCT Commission and an Executive Committee (the Committee or Group POCT)

The POCT Commission.

The local health and university hospitals, should provide and formally regulate the establishment at a corporate level a permanent multidisciplinary POCT Commission normally consisting of: Medical Director (or his delegate), Director of the Department of laboratory (or his delegate), Director of Pharmacy (or his delegate), Manager of Technical Area Health Services, Manager of Nursing Services, Biomedical Laboratory Technologist/Scientist POCT Coordinator (the reference Laboratory), clinical engineering manager (or his delegate), CIO (or his delegate). The Commission may use, if necessary, the advisory opinion of the Technical Services of the Company (Clinical Engineering, Technical Department, SIS, etc. The POCT Commission’s role is to establish the needs of the POCT is not vicarious of organizational deficiencies, and also establish, on the Basis of evidence based medicine, if the POCT is appropriate and if its implementation will lead to an improvement in terms of clinical efficacy (see Annex A). The approval by the
Commission is mandatory and binding for the introduction of any tool of POCT regardless of its acquisition mode. Moreover, the Commission must define, for each POCT site and after consultation with the Director of the facility, the clinical and authorized personnel for the tests, the procedures for the acquisition of technologies (tender specifications and evaluation of tenders) and the procedures for the electronic connection of POCT to the reference laboratory, establish a register of approved POCT, define the criteria for audits and monitoring of POCT, identify a suitable reporting system, evaluating over time the cost / benefit ratio in relation to suitability, define the criteria for the actions against unsatisfactory performance, the misuse and poor practices and for the withdrawal of IVD. All types of POCT must be included in a quality assurance program and risk management, which will be operational before the implementation of each decentralized system. The objectives of the quality management system should be defined in a quality policy statement under the responsibility of the Director of laboratory and inserted in the manual of the laboratory's quality

**Competence and professional responsibilities.**

The responsibility on the correct conditions of use and the quality of the analytical results of any POCT device present in the Settings and / or establishment services is attributed to S.C. Laboratory of P.O. of reference; in particular, will have to be defined organizational models for the planned operation, with regards to the consistency of diagnostic systems with clinical objectives, the formalization of operational procedures and processes, the training levels of the staff concerned, the internal control and external quality assessment. The standards of a quality laboratory system, extended to POCT, must therefore be made dependent on the Reference Laboratory: Choice of diagnostic systems capable of answering specific clinical questions and declared analytical specifications (quantitative methods, semi-quantitative and qualitative). Formalization of operational procedures for the use and maintenance of POCT instruments with specific scheduled maintenance and extraordinary recordings of maintenance and non-compliance of personal definition that can access the POCT and formation / training of staff with programming of periodic verification. Definition of person in charge of the POCT network (Supervisor-Coordinator) within the organization of laboratory. Description and implementation of an internal quality control program (CQI) of the type of product control and an accuracy evaluation program (external evaluation of quality, EQA) or comparison with the central laboratory data, including participation in paths certification according to current ISO norms and standards Maintenance and recording of all process phases (traceability) so that is in accordance with the operational and safety procedures codified definition of the organization's identification, storage and traceability of the data; all POCT results must be kept for at least two years, so that they can be connected with other quality assurance data. POCT committee or group for the purposes listed in the preceding paragraph the Director of the Department of Laboratory, uses an executive committee: Committee or POCT Group

**Committee of POCT Group**

Professional competence on the whole process of laboratory investigations through the use of POCT, as previously identified is attributed to POCT Committee. This group normally consists of at least two Biomedical Laboratory Technologist/ Scientist with at least one having specific function and competencies of POCT coordination (Point of Care Supervisor). To the POCT Committee are recognized the following skills: Use / monitoring / auditing of POCT systems; Coordination of the preparation of operating procedures and instructions ensuring the participation of all interested parties; Verification of alignment of POCT / Reference Laboratory results; Education and training of POCT health personnel not specialized in laboratory analysis; Programming and monitoring maintenance; technical-professional interventions in relation to the verification of the analytical results Reviewing activities and POCT management

**Role of Biomedical Laboratory Technologist/ Scientist (BLT/S)**

The P.O.C.T. technologies must be controlled and managed by the Biomedical Laboratory Technologist/Scientist, by virtue of professionalism established by D.M. 745/1994 and for the qualification possessed, respecting the professional autonomy of Law 42/1999 and Law 251/2000, following the identification of a well-defined system of accountability and the POCT governance model, as listed above, especially in the field of analytical quality control. Providing that the analytical quality of POCT test be the same as that of the clinical laboratory it will necessary to implement all measures aimed at reducing the risk of error in the pre-analytical and post-analytical phase. These principles also apply in cases of POCT for self-testing performed at home or at the pharmacy, from diabetic or on anticoagulant therapy patient. To the BLT staff at the POCT site is in charge of the execution of analysis, (with relative technical validation of results), the quality control tests and the consequent analytical assessment, including the decision
on the correct use of the instrumentation (instrumental performance), as well as the maintenance of the analyzer and the proper handling and storage of the data and the possible forms of maintenance and / or repair. They are also responsible for the technical-professional interventions in relation to emerging issues on site and the control and maintenance of the documentation necessary for the management and quality program. For a good quality of decentralized analysis it is essential the presence of the aforementioned position of the Point of Care Supervisor, BLT that serves the role of supervisor/coordinator and interfaces between the central reference laboratory and POCT. The coordinator must take responsibility for all aspects of POCT in service, including the quality and training. The Supervisor will provide a unique level of coordination and data exchange, globally monitoring the operability of the analyzers and the quality system, and ensure the consistency of procedures in different POCT sites; verify the operability of the analyzers, check the internal quality controls (QCI), and external (VEQ), cooperating with the Director of the Clinical Laboratory (referring physician) to the development of policies and procedures for the Quality System. Also participate in the choice of instruments for analysis performed with POCT technology, design and coordinate the training initiatives, training and mentoring of the BLT personnel and possibly nursing staff (if any), and finally to contribute to the drafting of procedures for analytical activities and for management and control of the asset by the BLT of Laboratory Analysis. In view of what has so far been exposed, it is clear the need for a proper and full use of the BLT in the POCT management and control supplied to both public and private health facilities. It follows that, also through the use of POCT devices depends the result of delivering health services related to specialized expertise related to the actual content of their performance of the BLT, and typified with established procedures. The Nursing staff if present acts in scope of the areas related to operational aspects of the investigation carried out in a decentralized manner and thus the clinical nurses and representatives of their POCT site alongside the Biomedical Laboratory Technologist/Scientist at every stage of the process, so that every decision has highest possible consensus. The nursing staff performing the test must have the authorization, must be adequately trained not only in relation to the analytical phases but also to pre-analytical variables that can affect the accuracy of the result. Only authorized tests can be performed. The staff works in accordance with the procedures codified in relation to maintenance, test execution and QCI. Staff training and connectivity are key to the success of POCT; there must be an accredited program of external evaluation of the quality and internal quality, as a control system.

**Connectivity of the POCT**

The connectivity between informatics systems is an essential component for effective service of POCT inside of an organization; it allows the POCT to be controlled and managed centrally and facilitates the exchange of information from the remote POCT site to laboratory / hospital information system. The key to an effective control by the laboratory on decentralized POCT diagnostic consists in having all the equipment connected to POCT, monitored / supervised and managed by the computerized management system. Among the essential functions that the computerized management system should ensure, include: the ability to verify that the POCT instruments are operating in line with pre-defined analytical quality requirements (by the periodic execution of CQ, etc.), the ability to inhibit, in real time, the use of a parameter and / or the entire analytical / instrument panel when the operating conditions recorded any non-compliance (eg. to causes of drift, micro-clots, interference, etc.), checking the status of activities maintenance preventive / corrective; registering NON conformity and any corrective action taken, the personal data and results of patients, the generation / display and automatic printout of control charts. The traceability of the patient and operators must be guaranteed; it is desirable for the interfacing of POCT to laboratory management system (LIS). In conclusion, it is clear that the introduction of POCT, is related to recent technological and IT developments, which enhance the automation and self-control of all analytical processes, and fits perfectly in the reorganization of the governance systems of the network of laboratories, according the recent State-Regions Agreement and Autonomous provinces of Trento and Bolzano, which implies the need to ensure not only the respect of the organizational and technological standards (DPR 01/14/1997), the analytical standardization and comparability of the results, the homogeneity of reference values and interpretative criteria and the political appropriateness of the request for laboratory tests; only in this way can we combine the efficiency to the effectiveness of the reorganization of laboratory diagnostic processes, such as POCT as an organizational model response to changing modes of delivery of health care.

**Validation of the results and final responsibility**

In such an organization structured, it is possible to perform an automatic validation of the results in real time; the technical validation, required for the storage of analytical data produced by POCT in the LIS repository, can be performed subsequently by laboratory technician. In both cases traceability must be guaranteed. The ultimate responsibility lies with the Director, Department of Laboratory Medicine. Individual operators have operational responsibility in relation to assigned responsibilities. In Annex A to nominate an examination to be transferred to POCT, you must follow a path based on evidence making it possible to fully satisfy the following points:
1. Clinical question to answer complete

   definition of clinical information-gap that has to be bridged performing that particular examination with respect to the clinical presentation.

2. Presumable Clinical Decision based on the result

   The importance of the rapidity of result, appropriate decisions based on the results (ruling in / ruling out)

3. Action actually performed based on the result

   Use of drugs (including blood products) to stabilize the patient in critical situations, invasive diagnostic startup, patient discharge.

4. Expected benefits

   Timing optimization of diagnostic and therapeutic process; reducing dispersion of unnecessary resources, safety and operator confidence, patient satisfaction.

5. TAT required overall response time of the Laboratory Therapeutic response time in relation to actual clinical needs Reduction of therapeutic TAT and improved cost / benefit ratio associated with it

6. Because the Laboratory is unable to provide services

   Number of analytical determinants, time taken for delivery of report. Impracticability / disadvantages of centralized alternative solutions. Need to analyze whether the response times cannot be improved.

7. Appropriate Accuracy and precision

   a) The analytical performance of the method used must be appropriate to answer the clinical question in the most reliable manner, without substantial differences from the clinical outcomes obtained if the same performance was delivered by the central laboratory

   b) The POCT Group is responsible for ensuring the appropriateness of the measures put in place to monitor the overall quality of the decentralized analysis performed inside of the healthcare organization.

   c) The need for an instrument control program and an analytical quality control.

   d) the internal control requirements with procedures which do not deviate from the traditional statistical CQ, even in the presence of alternative CQ, performed on a regular basis, with material acquired and managed in a traceable manner, traceable correction of non-compliance and)

   e) Demonstrated correlation with equivalent performances of central laboratory.

8. Training of operators of the POCT system

   a) The POCT Group is responsible for training of personnel using the equipment, their training, certification and re-certification of the operators of POCT system
b) Besides the information strictly related to the analytical phase, must also be provided elements regarding pre-analytical variables, to quality control with specific statistical rules and post-analytical variables especially regarding the reporting.

c) Uniquely the trained and regularly updated personnel are permitted to access and effectively execute the test.

d) The entire curriculum and the necessary continuous updating should be supervised by the Coordinator of the POCT Group.

Conclusions

These guidelines define a homogeneous path with appropriate scientific basis in order to share a common goal on the organization and management of POCT as a working tool. They also want to contribute to the enhancement and development of skills in the field of Medical Laboratory Technician, similarly to other health professions. These guidelines will be subject to change according to future evolution of organizational and management skills, which will surely result in a wider competency of Biomedical Laboratory Technologist/Scientist also in the prospect of further managerial autonomy.

References


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8. Guidelines of Point-of-Care Testing (Royal College of Pathology)