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Mini Review

Performing Rapid Laboratory Tests in Outpatient Clinics and Pharmacies to Monitor Drug Treatment

Osredkar Joško[1,2]*

[1]*Institute of Clinical Chemistry and Biochemistry, University Medical Centre Ljubljana, Zaloška, Ljubljana, Slovenia*
[2]*Faculty of Pharmacy, University of Ljubljana, Aškerčeva, Ljubljana, Slovenia*

***Corresponding Author:** Osredkar Joško, Institute of Clinical Chemistry and Biochemistry, University Medical Centre Ljubljana, Zaloška, Ljubljana, Slovenia.

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Abstract

POC testing (POCT) is defined as medical diagnostic testing performed outside the clinical laboratory and in close proximity to where the patient is receiving care. POCT is tipically conducted by clinical personnel whose primary training is not in the laboratory science or by the patients themselves. POCT devices are often small portable analyzers and tests made are often more expensive than lab testing. POCT is defined as "any test that is performed at the time at which the test result enables a decision to be made and an action taken that leads to an improved health outcome". In this article the strengths and weaknesses of analyzers and the general use of this method of testing are presented.

Keywords: *Point-of-Care Testing; Near Patient Testing; Bedside Testing; Home Testing*

Introduction

Point of care testing is laboratory testing performed outside the laboratory. The advantage of such testing prior to classical testing in a laboratory is that the sample does not need to be transported to the laboratory, and full blood is used for analysis, which means gain at a time that is particularly important in the case of emergency treatment of patients when life is at risk. The result of the analysis is thus obtained faster and thus also enables immediate treatment of the patient. Another segment of the use of this technology is ambulances, pharmacies and self-control (diabetes, anticoagulant therapy). POCT technology has advanced considerably in the last decade. POCT circumvents several steps in central laboratory testing including specimen transportation and processing resulting in faster turnaround times. Provider access to rapid test results at the site of patient care allows for prompt medical decision making which can lead to improved patient outcomes, operational efficiencies, patient satisfaction, and even cost savings in some cases [1]. With the integration of micro-and nanotechnology, computer technology, signal processing, biotechnology, andmicroelectronics, medical diagnosis technology is undergoing a transformation as its operational base is gradually shifting from centralized medical centers to individual homes driven by the growing need for a continuous real-time monitoring [2].

Point of care testing (POCT)

Laboratories that investigate biological samples derived from the human body are called medical laboratories. By the ordered investigations, the doctor obtains relevant information to assist in the diagnosis, prognosis or monitoring of the treatment. Laboratory medicine also includes POCT. POCT is part of a laboratory activity run outside the classical laboratory. The most common locations for carrying out

these investigations are listed in table 1. This method of testing is becoming more and more attractive to both medical staff and patients themselves, because it is easy to handle and, of course, also due to rapidly obtained results. Its accessibility is increasing, as the advancement in technology is very fast [3]. POCT thus become one of the fastest growths in medicine, growing annually between 10% - 12% [4]. Laboratory medicine will thus change the novelty of relocating testing of certain laboratory tests to the patient, because the results obtained may have an impact on the immediate treatment of the patient [5].

Patient's home
The workplace of the patient
Location, facilities where we spend free time
Pharmacy
Health center
Diagnostics and treatment center
Clinic
Rescue vehicle/helicopter
Urgency
Reception room
Operating room
Intensive care unit, department

Table 1: *The most common locations for POCT implementation.*

What is POCT?

Point-of-care testing is a laboratory test performed outside the laboratory, usually near the patient, and the results may affect immediate treatment [3]. It is a testing according to the ISO 22870 standard "POCT near-patient testing: testing that is performed near or at the site of a patient with a result leading to possible change in care of the patient" [3,6].

Why choose POCT?

In the past, clinical and chemical tests were carried out only in the laboratory. The development of technology using portable instruments and the introduction of chips ensured that laboratory testing moved closer to the patient. Therefore, POCT testing is being used more frequently in healthcare institutions, in order to obtain results faster than central laboratories. This improves the quality of patient care and the immediate start of treatment, which is very important for the patient, especially in emergency medical units, intensive care units, operating rooms, intervention units, etc. The main reason for the introduction of POCT is that the result of the analysis is accessible in a very short time [3].

Standards and regulations

Because it also involves testing the patient for the analysis of biological material, POCT is subject to the same quality requirements as the medical laboratory, no matter what procedures we use [3,6]. In 2006, the International Organization for Standardization (ISO) issued the ISO 22870 standard; Point-of-care testing (POCT) - requirements for quality and competence. The ISO 22870 standard is used in the implementation of POCT in hospitals, clinics and health facilities offering outpatient care. Testing done by patients alone does not apply to the standard as it is not mandatory for patients. In addition, the requirements of the standard applicable to medical laboratories ISO 15189 must also be taken into account at the same time; Medical laboratories - requirements for quality and competence [3]. Development of a successful POCT program at hospitals and/or health systems requires establishing a quality assurance program or committee with key stakeholders.

Using POCT testing

POCT testing is usually performed on small, simple and portable devices that can be transferred to a variety of locations also outside of health facilities as outlined in table 1. The use of POCT is particularly important in emergency units where the time taken to obtain laboratory results is shortened, thereby reducing the patient's time of treatment and thus faster treatment with appropriate therapy, which at a given moment can be of vital importance. The advantages of using are listed in table 2.

Immediate availability of POCT,
In very short-term results,
Immediate start of treatment,
Help with trials (heart markers, crps),
Shorter treatment time for the patient,
The results are also available in the field [7].

Table 2: *Benefits of using POCT on an emergency.*

Using convenient devices, the patient can analyze glucose, basic urine analyzes, cholesterol, hemoglobin, C-reactive protein (CRP), certain drugs, markers for heart disease, coagulation tests. They also use microbiology to determine group A streptococcus, infectious mononucleosis, *Helicobacter pylori*, influenza virus, and drug [3,8].

Deciding how to use POCT

It is necessary to have an overview of the steps that are important in evaluating the results of diagnostic tests and in carrying out work arising from a decision based on the results obtained. This can help to:

- Understand the needs of the testing clinic,
- Definition of logistics related to the selection of the test, sampling and transport,
- Determine the appropriate analytical method and its performance characteristics,
- To identify the information challenges associated with reporting the test result at a time when it is needed,
- Make a business framework for the appropriate testing method,
- Developing the best working framework for the audit of results,
- Reducing the administrative work related to the requirement to carry out the test.

Avoid or minimize delays in a wide range of testing procedures:

- By collecting samples in accordance with the prescribed requirements,
- Transporting the sample from the place of collection to the place of testing,
- By registering the receipt of a sample,
- By analyzing the sample,
- By recording the results,
- By submitting the results to the client.

These steps represent the risk of using any diagnostic test. On the basis of this, we see that POCT is a very suitable solution because it prevents and/it reduces delays in these processes, while reducing the risks between individual pre-analytic processes, such as:

- Taking a sample from the wrong patient,
- Take the wrong sample,
- Incorrect designation of the sample,
- Loss of sample on the way to the laboratory,

- Incorrect designation of the sample upon receipt in the laboratory,
- Done wrong investigations,
- Reporting incorrect results,
- Failing to deliver the result to the client,
- Time delay from the analysis order to the actual implementation thereof.

On the other hand, there are also risks associated with the use of POCT. The most important among them are the concerns about the technical functioning of the instrument, which is used, both in terms of quality of the instrument, as well as on the professional competence of the user. There are also doubts about the quality of the sample, the manner of reporting the results, their interpretation, and the possibility of archiving the results of the analysis.

The most challenging task in connection with the implementation of POCT is today the introduction of changes in clinical practice in order to maximize the speed at which the result of the investigation can be delivered [9].

Basic requirements for the POCT analyzer

Users of the POCT analyzer are mostly those who were not qualified for analytical work and therefore lack knowledge. For these reasons, POCT devices meet the following requirements:

- The analyzer must be easy to use, which means that we have to get the desired result with as few steps as possible,
- The apparatus and reagents must facilitate the transport, storage and use, including calibration,
- The apparatus must give comparable results to the central laboratory and in accordance with the clinical needs,
- The analyzer must be safe for storage, use and waste.

The best devices are those in which most steps are performed automatically during the performance of the analysis, which means fewer steps required by the person working with the appliance [9].

In addition, it is desirable that POCT analyzers also meet these additional requirements:

- Obtain results in the shortest possible time,
- Transfer of the instrument with reagent disposable cartridges,
- One or two-stage operating protocol,
- Analyzing the sample in full blood or plasma,
- Simple working process,
- Flexibility in the test menu,
- Quantitative results with adequate accuracy and precision compared with the central laboratory,
- Integrated calibration and quality control,
- Storage of reagents at room temperature,
- Storing results on the hard disk,
- Data transfer option,
- Cheap instruments,
- Service that includes service parts [8].

Technological innovation

Modern development is therefore mainly focused on expanding the spectrum of tests and improving small simple analyzers with limited analytical capability do not require a lot of laboratory knowledge, are robust and insensitive to uncontrollable influences and disorders [1].

POCT analyzers can be used to measure an individual analyte or a combination of analytes. Manual analyzers usually measure only one analyte, while analyzers from the other two groups allow measurement of several analytes [9].

Advantages and disadvantages of POCT analyzes

The most important advantage of POCT is certainly that the results are achievable in a very short time, which contributes to faster patient care, faster triage of patients, and the reduction of patient admission in hospitals [9,10]. The time is also obtained by not having to transport the sample to the laboratory and not needing to be pre-treated, as it can be used full of blood. A small sample volume is sufficient for the analysis.

Managing simple devices and more demanding analyzers is mostly easy, so tests can be performed by people who are not professionally trained; they can also be performed at home at the patient‘s home. They are carried out by patients themselves [9].

The advantage is also that the analyzers are usually small, portable, manual and easily transferred from the department to different locations [8].

The disadvantage of POCT results is in the repeatability, correctness and linearity of analytical methods, and in the vastness of the unification of pre-analytical processes.

Different manufacturers of analyzers use different analytical methods for the same analytics, so there can be a big difference between the results obtained. The analyzer producer must provide information on the possible limitation of the apparatus, which the analyst must take into account. The analyst must also be aware of which metabolites, medicines, endogenous substances and other physiological factors affect the results and how to correctly diagnose them. This is particularly important because full blood can be used for analysis [10].

The apparatus that would be needed for certain testing is usually selected and purchased by persons who do not have the relevant know-how in this area and are not familiar with the training and documentation requirements. They do not know for sure whether the choice is appropriate. Thus, in medical institutions, many appliances appear that are similar to each other, but different procedures are used and various results are obtained. Difficulties in comparing the results of the results obtained with POCT with the results obtained in the laboratory are also encountered.

In such cases, the analyst does not know which result to use and thus saving time and money is lost [3].

POCT tests are often carried out by people who do not have a laboratory qualification and therefore also have a lack of knowledge. Training of personnel is required, which must be carried out both by laboratory experts and by the manufacturers of the instrument.

Properly trained personnel are important, as this ensures the quality and reliability of the results [3].

Therefore, it should be pointed out that the patient tests are included in the supplementary tests and in no way among those which would replace the sample analysis in the central laboratory [10].

Quality control

QC is required for all tests. The QC limits and frequency intervals can be configured in the device or managed remotely with the data management system. This prevents an operator from using the instrument once the QC interval has been exceeded or if the result is not

within acceptable limits. The QC results for each device and operator can also bere viewed and evaluated by laboratory personnel, which is a requirement for most laboratory accreditation programs. The data system also captures and stores comments describing corrective action for unacceptable QC results [11].

POCT today and further

POCT is not a replacement for conventional laboratory testing but rather a supplement to it. POCT results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions.The development and adoption of POC systems continues to increase, in part due to expanding test menus, lower costs and advances in data management infrastructure.

The POC market is growing due to advancements in technology and the demand for quick test results. In addition, the increase in the prevalence of infectious disease and lifestyle diseases like cardiac disease and diabetes along with the aging population, is increasing the demand for POC diagnostics. Awareness among people of the easy and convenient way to get faster test results is increasing the demand and physicians also prefer POC for their quick decision making when prescribing a disease-specific drug, which was previously unlikely when doctor started symptomatic treatment as the test procedure could take a long time. There is a tremendous demand for POC in the Americas region, and the increase in awareness in the Asia-Pacific region will lead to tremendous growth in the future as the highest population countries in Asia will drive it tremendously. The traditional method of clinical testing required skilled labour while POC required minimal training, thus reducing the costs of training and the time consumed to perform the test. The major restraint for POCT market is the unwillingness to change traditional treatment practice [12].

Technological advances have made it possible to conduct many laboratory tests at, or near, the POC. These POCT devices give physicians rapid access to test results, allowing greater quality and efficiency in medical care [13]. The increased availability of POCT devices for more commonly performed routine tests would improve efficiency further. In the absence of any immediate health risk, physicians will probably wait to review all the results before reaching any patient management decision. Without universal POCT, prolonged turn arounds for laboratory transit and processing will continue to be the limiting stage in medical decision-making. As technological innovation provides more comprehensive POCT options for CBC, pregnancy testing, infectious disease, cancer screening, and other frequently ordered tests, near patient testing will become increasingly integrated into the traditional healthcare structure. The role and responsibilities of laboratory personnel will likely need reviewing and reworking as testing migrates away from the lab bench and closer to the bedside. Coordination with the central laboratory regarding quality assurance and regulatory matters will be crucial as technology allows the more efficient allocation of testing resources. Outside the hospital setting, POCT provides laboratory quality services to under serviced areas and general practitioners. Near-immediate test results allow patients and doctors to evaluate progress, review results, and establish treatment regimens in a single visit. This simple change can result in improved disease management, treatment adherence, and patient satisfaction. However, without the presence of an in-house laboratory, having measures in place to ensure adequate levels of quality assurance in POCT becomes critically important. As POCT continues to become an integral part of healthcare management, expansive quality assurance and training protocols should be established to ensure maximal benefits to patient care and efficiency in anysetting. The POCT has become an integral part of day to day testing including home healthcare and by healthcare providers. The POCT is essential to provide the patient with quick and accurate treatment, thus avoiding the various side effects caused by prescribed drugs. The POC market is well established in the developed countries, which has the world‘s largest market share. However, developing countries such as those in the Asia-Pacific area have a huge potential due to the high population and increasing awareness of POC. The market is majorly driven by demand and awareness of the quick and easy results.

The success of a potential shift away from curative medicine, to predictive, personalized, and preventive medicine could rely on the development of portable diagnostic and monitoring devices for POCT [11,14,15].

Conclusion

Large central and fully automated laboratories will still cover a significant proportion of laboratory diagnostics and thus spend most of the production of *in vitro* diagnostics. The disruptions will occur due to the availability of new technologies that enter the market unhindered, both for laboratory methods and for POCT. Diagnostics is increasingly focused on the patient rather than on the workflow in the laboratory. The use of modern communication methods for controlling and controlling methods is a stepping stone in an independent process that will come in the future. For this reason, the doctor should also develop to some extent the understanding of the tests and technologies that are available so that the benefit to the patient can be greater. This will be the main task! As the technology continues to evolve, this transition to the POC environment will continue to increase.

Recent advances in emerging technologies (*i.e.* CP-based technologies, PBAs and LOC platforms) are paving the way for next-generation POCT. Advances in novel assay formats and strategies for long-term reagent storage are the prerequisites for emerging POCT technologies.

Current and future analytes for POCT comprise small-molecule metabolites, proteins, cardiac biomarkers and cells. One emerging future trend is centred on miniaturized, fully automated, and network-enabled CP-based POCT technologies integrated with PBAs and/or LOC platforms [11].

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