

Point-of-care testing management – benefits and pitfalls

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ABSTRACT

Point-of-care testing (POCT) or near-patient testing conducted outside of the laboratory by clinical staff is the fastest growing segment of laboratory diagnostics worldwide. This fact is both a consequence of clinical and/or procedural need, but also because of very fast technological developments and aggressive marketing strategies. POCT is used and requested whenever short turnaround times might be of benefit for the patient or clinical pathways. However, mindless implementation of POCT within clinical institutions can bring more harm than benefit, and must therefore be kept under control. This is best achieved through the hospital POCT committee which consists of clinical and laboratory staff and fulfils many functions. Primarily, it should provide professional advice on the quality and implementation of POCT devices. Pre-analytical and analytical issues regarding test results and their interpretation should be thoroughly explained in advance. Also, the POCT committee serves as a gatekeeper against unnecessary POCT device acquisition, since any test done on the POCT device is much more expensive than the same test done within the laboratory. Educating the clinical staff and maintaining their level of competence required for reliable test results, as well as external and internal quality control, remain the cornerstones of a safe and efficient POCT network coordinated by a POCT committee within healthcare institutions.

Key words: point-of-care testing, laboratory management

Point-of-care testing (POCT) or near-patient testing is the fastest growing segment of laboratory diagnostics worldwide. It is most often defined not by what it is, but by what it is not. The term is coined to encompass all laboratory testing performed outside of the clinical laboratory or, in other words, done outside of the laboratory environment or without a laboratory staff. Nowadays it is possible to cover the whole diagnostic spectrum of a small laboratory, such as haematology, urinalysis, basic coagulation and routine chemistry exclusively with POCT devices. POCT brings the whole time-consuming circle of laboratory testing procedure directly to the patient's bedside, home or anywhere else, thus ensuring extremely short turnaround times in comparison with a central laboratory. However, there is a downside to this development which

affects healthcare spending – any single test done on a POCT instrument is invariably more costly in terms of consumables than the same test done within a laboratory. As an example, the costs of a single glucose measurement in a laboratory and that of a POCT glucose meter test strip usually differ approximately by an order of magnitude. Also, assuring the desired level of quality of all steps involved in a testing process might represent a further obstacle in establishing POCT. The question remains: what is the main impetus behind POCT growth within the last decade? Is there a real clinical need, or is it a consequence of clever marketing strategies and technological developments? The first systematic study designed to answer these questions seems to tip this balance toward the latter. (1) This article aspires to summarize all vital points that have to be observed in order to maintain a high quality POCT program within a healthcare institution

in order to ensure patient benefit without introducing unnecessary costs or compromising patient safety. POCT devices are generally intended to be used either in the hospital environment by clinical staff (usually nurses, who predictably might be less than enthusiastic at accepting yet another task, so they may be needed to be motivated accordingly) or at a patient's home by the patients themselves. A typical example of the former category are blood gas analyzers (figure 1) and of the latter example portable glucose meters, widely known as glucometers. All POCT devices should be designed as extremely simple to use with little or no maintenance since they are meant to be handled by people without any training in laboratory skills. The devices intended for home use should be "foolproof" in order to prevent various errors that might occur while patients are using the instrument. The well known examples of faulty devices were glucometers produced by two

big IVD companies. The devices were placed on the market without the option to block the intentional or unintentional change of the units for glucose concentration by the user (mmol/l or mg/dl), the consequence of which was a dramatic change in the displayed glucose value. The glucometers had to be withdrawn from the market until the problem was fixed. Regarding home use of any POCT instrument, it should be kept in mind that devices intended for home use are never meant for diagnostic purposes, but always and only for monitoring purposes.

Within large hospitals today, POCT device installation is commonplace and regarded as an indisputable standard of care. Since POCT is not conducted in the safety, relative tranquillity and focus of a laboratory environment or with the dedication of laboratory staff, there are measures to be taken in order to assure the smooth and reliable functioning of any such testing programme. Also, huge business opportunities that are offered by the POCT segment of the IVD industry, whose annual growth rate is almost double compared to traditional laboratory testing, might turn out to represent an additional financial threat for healthcare resources without any measurable benefit since “faster is not always better”. (2) In theory, there should be an existing case illustrating that any particular clinical procedure or outcome will improve through POCT, but in practice those model studies are rarely done before POCT implementation. Generally speaking, POCT should be introduced after careful consideration and well explained clinical and/or procedural need. After implementation it should remain under constant laboratory surveillance and thus be maintained in a controlled and sensible manner.

Three basic shapes (and sizes) of POCT devices can be found on the market today:

Non-instrumental (disposable) systems – such as drug screens, urine test strips, pregnancy tests

Small, hand-held analysers – such as blood glucose meters, INR monitoring

Desktop analysers – such as those



Figure 1. Blood gas analyser

for blood gases, biochemistry, haematology

No matter what kind of POCT device is considered for implementation, for it to function safely, effectively and economically, one should patiently observe and follow the following three essential steps and perform them one by one.

Step 1. Decision making

Any POCT device may be accepted for daily use in hospitals only if it has been approved by a specific institutional POCT committee. The committee should consist of hospital management representatives, laboratory specialists, clinicians and nurses. A direct vending approach, where IVD industry representatives offer their POCT product immediately to end-users (usually clinicians or nurses within hospitals, and sometimes to hospital management) should be strongly discouraged or, when possible, explicitly forbidden. The fact is that POCT devices are not all of the same quality and a new POCT instrument should never be introduced without prior thorough validation conducted by an expert laboratory staff. Thus, the initial and fundamental role of laboratory specialists within the committee is to explain the advantages and disadvantages, as

well as the crucial differences between certain POCT products or technologies, because there are always limitations that should be known to end-users, such as interferences, pitfalls in methodology or compatibility with routine laboratory results. (3,4,5,6) An example of notorious interferences, and with fatal consequences that have been registered on several occasions, is the susceptibility of certain glucose test strips to react with other similar sugars, thus producing falsely elevated glucose results which led clinicians to administer insulin inappropriately. It is vital that no information on a certain POCT device is withheld from the end-user and sharing this knowledge is the primary role of the laboratory specialists within the committee.

Nurses usually perform POCT testing, which for them represents additional work, so they are normally the ones who need to be mostly motivated to see the benefits of introducing them into daily clinical care. Clinicians are readily allured by the perceived benefit of immediate results, so there is usually no problem to win them over to POCT. Hospital management needs to take the inevitable rising costs into consideration. If the simple cost/test were the basis for POCT approval none of them

would ever be approved, so the benefit must be seen from a broader perspective - such as improved clinical outcome, shorter hospital stay, less blood products or medication used, etc.

An important decision to be made in advance of any POCT implementation within the hospital is the issue of cost coverage – in other words, who pays? The best option is when the costs of POCT are handled by the hospital department where testing is going to be conducted, which helps tremendously in applying common sense regarding the frequency of daily use, or in other words the consumption of reagents. However, a point that is too often neglected is the element of compensation for daily support provided by the laboratory, which is necessary for the smooth and efficient functioning of any POCT system. Medicolegal issues, regarding legal responsibilities for results also need to be cleared in advance. According to the recommendations issued by the Royal College of Pathologists Guidelines for POCT: "whilst there is a need for managerial responsibility of POCT devices... individual users trained and approved for POCT will have legal responsibility for the results they produce." (3)

Step 2. Education

No POCT device within the hospital

should ever be used without the completion of a prior training and without obtaining an official certificate signed by the instructor. Education for both the pre-analytical handling of body fluid specimens and operating POCT devices is always done by laboratory staff at the most convenient location. However, the testing of operators and their techniques should preferably be done not in the classroom or within the laboratory, but under field conditions (i.e. in the same busy clinical environment where daily testing will take place). The system of certification and, equally important, recertification needs to be established within the institution to make sure that the clinical staff always has enough expertise to perform the tests. In other words "...no user should be allowed to perform tests that will alter clinical management without the trainer being satisfied with the competence of the user." (3) Recertification is important in order to maintain the user's knowledge and skill levels needed to ensure the reliability of the obtained results.

Step 3. Maintenance

Standard operating procedures (SOPs) for the handling of POCT devices are obligatory documents produced as a part of the education phase. But they should also be near the device at all

times so that the user can refer to them if needed. (4) They should be written clearly and unambiguously in the local language. Adherence to SOPs should be included in both regular and random check-ups conducted by the laboratory personnel assigned to the POCT team. Analytical quality control (QC) must be put in place and conducted once or several times daily, either automatically or manually, with immediate blocking of the tests where results did not pass the QC. This is not possible on all POCT devices, in which case constant laboratory monitoring becomes even more important. It is of paramount importance that the laboratory staff in charge of POCT makes themselves visible, available and easily approachable for any questions or problems posed by the clinical staff within the previously agreed time period. (4) In this manner all problems, disputes or uncertainties can be solved in the most efficient way possible. Friendly cooperation between laboratory and clinical staff is a very important prerequisite for the smooth flow of the POCT programme within the hospital environment, and it represents the cornerstone for preventing gross mistakes, unnecessary healthcare spending and erroneous results and/or result interpretation with possible dire clinical consequences.

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