Contents lists available at ScienceDirect

Practical Laboratory Medicine

journal homepage: www.elsevier.com/locate/plabm

Review Article Communications with lab and POCT users

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ARTICLE INFO

Keywords:

Laboratory

Communication

POC

Lab

POCT

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ABSTRACT

POCT (Point of Care Test) or (Point of Care Testing) has been widely used, as it can provide quick results to be acted upon immediately by the clinician. However, POCT devices do not always have the same accuracy and precision as Lab equipment. Laboratorians need to be much better at communicating what is being done in the "lab" and how that relates to what the clinicians are doing with the results of the tests they order.

1. Introduction to POCT

POCT (Point of Care Test) (sometimes called Near Patient Testing or NPT) has been widely referenced as improving patient care, as it can provide quick results to be acted upon immediately by the clinician. Some position papers now exist, which reference testing done by health care professionals outside of the lab, however some specifically exclude testing done by patients themselves [1]. There is a push by clinicians to have patients engage in their own care. They may treat their own diabetes (for example) at home, but when these patients come into a hospital, the expectation is that they become passive consumers of health care, with their glucose levels measured in the "lab" or measured by hospital POCT glucose meters. This is not consistent with other trends in health care, which see non-medical staff doing testing (and treatment), going back to the original definition of near-patient care. POCT devices are now operated by pharmacists, paramedics, patients, and other non-lab workers. There is a separate, but related, trend to make sure POCT devices are connected to HIS. This is often driven by individuals who look after patients and therefore need access to all their results, not by the lab staff who may operate the quality control (QC) program for this POCT equipment.

The limitations of POCT have been reviewed previously [2], and this paper will not attempt to duplicate nor to update that work. We know that POCT devices rarely have the same accuracy and precision as the lab analysers [2]. Although POCT devices show better accuracy and precision when operated by a lab technologist [3,4], the limitations seem to be inherent in the design, so they do not have the level of precision and accuracy that a "lab" has become known for. Lab tests were not always as accurate and precise as they are now. In fact, years ago, if a lab test result did not match the "clinical" presentation, the physician assumed it was a lab error. Now the inclination is to believe the lab result and reconsider the "clinical" diagnosis in light of the lab results. We have become victims of our own success.

2. Performing POCT

Several organizations have produced documents explaining how to do POCT "properly". The CSCC has produced a position paper on this topic [1], as have several provincial and national organizations [5–7], and there are CLSI guidelines [8]. Some papers (e.g. the CSCC position statement) specifically exclude testing done by patients, while others either include patient self-testing or don't mention the

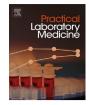
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https://doi.org/10.1016/j.plabm.2021.e00223

Received 18 September 2020; Accepted 9 April 2021

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topic at all. In this paper we will consider all forms of near-patient testing, regardless of who actually performs the test procedure (could be a physician, nurse, health care person, pharmacist, EMT, or the patient themselves). This area has seen dramatic growth in the last few years, and in the era of COVID-19 it is growing even more rapidly, as vendors seek to produce tests that provide prompt results rather than waiting while specimens are sent to a central laboratory, where it may take hours or days for results to come back. POCT technology currently spans a wide range of analytes and will encompass even more in future. It is growing, despite the lack of accuracy and precision, because it offers prompt results and enables clinicians to channel patients to the appropriate care more quickly, for example: a POCT for Troponin (Tn) (a "qualitative test") result can screen for a myocardial infarction (MI) quickly and enable an emergency room physician to discharge the patient quickly if no MI has occurred, whereas a cardiologist cannot use the same result. The cardiologist requires greater accuracy and precision to permit investigation of the cardiac muscle. Collinson identified this problem in his paper using Troponin as an example⁹. Many physicians are not even aware of what methodology is being used – they just assume the lab is using the latest method marketed, but unless the lab states it specifically on the report there is no way of the clinician knowing if the result is from a high-sensitivity Tn or not.

3. Introduction to this paper and its objective

POCT has been widely referenced to improving patient care, as it can provide quick results to be acted upon immediately by the clinician. What may happen afterwards, is that the clinician orders a "lab" test to confirm the POCT result. But what if the "lab" is also using the same device? It could be that the device is operated by lab staff during the day, but by non-lab staff (usually nurses) during the remainder of the 24-h period. In this case, referral to the "lab" would result in the test being done on the same type of instrument (a POCT device).

The general limitations of POCT have been reviewed in a CADTH (Canadian Agency for Drugs and Technologies in Health) Environmental Scan published in 2017 [11]. In a recent paper by Collinson [9] he noted that physicians are likely to assume all Tn results are equivalent, yet all POCT devices which he referenced were using a standard Tn while the guidelines the physicians were using were based on high sensitivity (hs)-Tn, which may have been available through their central lab, but not via the POCT devices upon which they were relying.

We are about to be faced with the introduction of a number of SARS-CoV-2 tests (for the virus that causes Covid-19) in a POCT format, but the tests are not equivalent, and only have emergency approval (in mid-June 2020 there were more than 110 different devices available in the US). A test that is 95% sensitive at detecting the virus and is used on 1 million people would still result in 50,000 people being incorrectly told that they don't have the virus.

If there is no "reference" to which POCT can be compared, the problem is even more serious. Right now a physician who wishes to encourage a patient to monitor their own glucose (for example) may opt to send a blood glucose to the "lab" on the understanding that the "lab" will provide a true result, and thus provide a reference point for the patient's own measurement. But what if a "lab" is not available or is using POCT devices? In such a case the reference result (the "lab" result) is not much better than the result obtained at the bedside by the POCT device, although it may be a bit of an improvement because the testing will be done by lab technologists and hopefully the POCT device used in the lab has been checked against a standardized instrument. It is essential then that clinicians understand, and labs provide, information on the test devices and methodology being used. This is the point Dr. Collinson [9] was making when speaking about Tn. If the user does not get information on the test, or does not understand what is being provided, he/she is likely to make an assumption, which may be incorrect.

4. Comparison of POCT to existing "lab" tests

It has already been established that the pre- and post-analytical phases are the most error-prone steps of any lab test, and that is magnified in POC testing [10]. This severely limits the usefulness of POCT in the real world. Also, "lab" POCT devices, when in use, are likely to be better operated and quality controlled because they are operated by trained technologists to whom quality assurance is a given for all assays [2].

Westgard on his website [12], calculates the Sigma Metric for a Korean study on a POCT device, and finds that it is not acceptable for some analytes (particularly for HbA1c) while others were acceptable or borderline (Cholesterol, Triglycerides, HDL (HDL -Cholesterol), BUN (urea), Creatinine, and Amylase), showing once again that POCT devices don't meet the same standards that we routinely apply to lab instruments.

There may need to be a separate means of indication, perhaps a separate requisition, for tests that need to be sent off-site to a central facility that uses conventional (non-POCT) lab instruments.

5. Discussion of factors to be considered and overall conclusions

We need to consider several factors when implementing POCT:

- 1. What are users doing with the results of the tests they order?
- 2. Clinicians in different roles may have differing needs (as per the Tn example)
- 3. How does the laboratory communicate with users in an effective way?

These questions are not trivial, although they may seem to be outside the normal scope of lab practice. We (laboratorians) need to

understand that clinical training programs in much of the world do not expose clinician trainees to the laboratory. The ideas of precision and accuracy that we take for granted are not universally understood. The users assume that the results are "correct". While this is likely with lab instruments, the same cannot be said of most POCT devices, especially those used outside of the laboratory. IFCC (International Federation for Clinical Chemistry and Lab Medicine) [13], AACC (American Association for Clinical Chemistry) [14] and MLO [15] (Med LAB Observer) have published on this recently. Accreditation agencies have struggled to manage this gap, but they only control the hospital or laboratory, not the pharmacy or patient's home. It is therefore incumbent on the lab (via the printed report or patient care computer system) to identify the source of the test result(s) reported and to provide an option (via the test request form) for referral to a lab that uses non-POCT instruments. This type of reporting is often done for community laboratories, but rarely in hospitals, where results are often trended over multiple days and the clinicians want a "simple" report. The separate referral system is virtually non-existent in health care facilities where there is a lab as there has been no need for it.

In conclusion, we (laboratorians) need to recognize that all tests are not equivalent and those to whom we report results may not appreciate this. We need to find appropriate ways (appropriate to each individual situation) to communicate what is the source of the information being provided and to provide option(s) for referral to a non-POCT lab instrument when the clinician requires confirmation of the result(s).

Declaration of competing interest

None to declare.

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