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CHALLENGES IN POCT

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Abstract: **Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. Although there are many benefits of using POCT devices in terms of their convenience, establishing a POCT indeed is a challenging job. Some of the biggest challenges for the person holding this post are gaining physician and nurse allies and turning non-laboratorians into testing personnel, all while ensuring adherence to best laboratory practices and regulatory agency standards. POCT implementation requires a systematic approach which involves all stakeholders. Most of the healthcare organizations are unfamiliar with the POCT due to which very less efforts are made to establish a complete POCT set up.**

Keywords: **Location, Devices, Quality Control, Data Management, Training, Proficiency.**

I. INTRODUCTION

Challenges in POCT

Point of care testing (POCT) refers to testing that is performed near or at the site of a patient with the result leading to a possible change in the care of the patient. Although there are many benefits of using POCT devices in terms of their convenience, establishing a POCT indeed is a challenging job. Some of the biggest challenges for the person holding this post are gaining physician and nurse allies and turning non-laboratorians into testing personnel, all while ensuring adherence to best laboratory practices and regulatory agency standards. In many hospitals a range of tests are performed in the wards, by staff who are totally uneducated in laboratory sciences and who may not even have the relevant skills in quality assessment to carry out the tests competently. In this article we have review the challenges that needs to be overcome while setting up a POCT.

POCT: Challenges

- Management
- Responsibility
- Location
- Staff training and competency maintenance
- Reliability of POCT results
- Quality Control
- POCT Challenges for End Users:
- Data Management
- Noncompliance with procedures (specimen labeling, QC, proficiency testing etc.)
- Infection Control
- Billing

II. MANAGEMENT OF POINT-OF-CARE IN THE HOSPITAL

Management of POCT is challenging – there can be dozens of sites, hundreds of POCT devices/kits, and thousands of operators to manage to assure quality of testing.

The first challenge in developing a strategy to manage POCT involves building a competent interdisciplinary POC management team including the laboratory, physicians, and nurses. The POC team should hold the ultimate responsibility for determining the test menu, selecting technologies, establishing policies and procedures, ensuring training and regulatory compliance, and providing advisory assistance to the end users of POC technologies. After establishing a POC team a management structure should be build that is responsible to implement new initiatives and to perform corrective action where necessary.

The role of the POCT team includes the following(1):

- 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

The POC management team serves in a consulting role and coordinates the POC program throughout the institution.

- 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.

Managers of POCT should also be aware of their responsibility for clinical governance and of the medico-legal implications of an erroneous result.

Lines of accountability should be clearly written into local policies and procedures and should cover the following areas:

- training
- instructions for use
- standard operating procedures
- health and safety
- quality assurance
- maintenance
- accreditation
- record keeping
- audit
- adverse incident reporting.

III. WHOSE RESPONSIBILITY?

Who holds the responsible for the test results performed outside the laboratory - the operator, the laboratory or the manufacturer? The rational answer to this question would be: all three parties must accept their responsibility toward

assuring the accuracy of every single result. Clinician is the person who is going to take the decision on patients condition whether the test is performed in the laboratory or bedside, whatever the results are obtained expected or unexpected regarding the treatment or repeating test or further work up that may be necessary to arrive at the right diagnosis. The clinician needs to establish his confidence on the reliability of the results obtained out of POCT(2). In reality, the manufacturer cannot monitor a hospital to ensure that all the recommended procedures are being followed and that documentation is adequate. The place where manufacture can contribute is by provideing quality instrument and by performing planned-unplanned maintenance and calibration on routine basis. All these measures do not implies that the laboratory has been relieved of all responsibilities for the quality of these POCT results.(3) The central laboratory, when appropriate, should be responsible for evaluating each new piece of instrument and each new lot of reagent, and maintaining a performance record, carrying out co-relation studies between laboratory instrument and POC instrument. 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).(4) 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.(5)

IV. TRAINING USERS IN POCT

Should cover theory and practice:

– Storage of QC material

– Preparation of QC material

– Appropriate QC frequency for each test

– Principles and practice of QC testing

– Remedial actions for failures

– Recording and documentation of actions

- Once the procedure manual has been created it is necessary that all users have read it and this process should be documented.
- The salient features for each test need to be understood and demonstrated during training.
- This would be followed by a competency assessment which would be the exit examination before the healthcare worker can test patients.

V. CHALLENGES IN TRAINING

Management of Training

- ❖ Number of staff requiring training be in the thousands
- ❖ A high turnover rate
- ❖ Nursing staff can be transferred between different departments
- ❖ Poor communication between nursing administration and POC coordinator.
- ❖ Diverse educational backgrounds

The Designated Trainer

- ❖ Better way to train new hires
- ❖ This designated trainer would aware of all the issues that could occur with the test and would be up-to-date in their competencies

Train the Trainer (6)

- Determine who will conduct the training
- Ensure that this person(s) has the appropriate qualifications, experience and training to be able to train others and that these are documented in their training records
- Conduct the trainer training, and assess their competence to provide training to others
- Document the training and competency assessment.

Peer To Peer Training

- Nurse trainer may not be aware of all the preanalytical, analytical and post-analytical errors that could occur when using the POC test.
- They may also be performing the test in a different way that could be prone to a higher error rate.
- Furthermore, from a regulatory standpoint, the trainer would need to have passed their competencies as well.

Training Methods

- Direct classroom demonstrations and observations
- Supplemented with self-learning , e-learning, lectures via webcam, power point, and a training kit containing manual, laminated posters/aids and CDROM.

Competency Assessment

The aim: To ensure healthcare workers can not only generate quality results consistently from the instrument but can correctly manage them in the decision making process.

- Practical Assessment
- Written Assessment

VI. NON COMPLIANCE WITH PROCEDURES

Majority of the staff involved in the POCT is from non-laboratory side which is unaware of the routine laboratory procedure regarding calibration, maintenance of instruments, quality control processing and analysis of QC data, sample collection procedure and patient preparation before sample collection which posses a threat of non-compliance with standard operating procedure that may contribute to source of errors in POCT. These staff are not aware of the interfering substance, effect of hemolysis and lipemia or compromise samples which results into analytical error or spurious results of the test. Not following the standard operating procedure may contribute to analytical error in addition to pre analytical errors. These are the some of the challenges in case of non-compliance with the procedure which can be eliminated through training and retraining of POC staff and awareness programme.

VII. REALIABILITY OF POCT RESULTS

Questionable quality can occur, given the variety of educational and experience levels and turnover of staff that perform the tests. Greater inter-individual variability in results (compared to central laboratory testing) is common. Waived category does not guarantee reliability. Simplicity is deceptive and there are many ways that staff can inadvertently generate a wrong result with waived or “simple” tests. POCT results are not necessarily comparable to central laboratory results – Standard methods may not be used in POCT and thus it may not be possible to compare results across sites (e.g. when patients travel and are tested at different sites, or when treatment protocols derived from more accurate results are being followed). Differences in specimen types, (e.g. serum, plasma, or whole blood,) may also affect results between traditional central laboratory methods and POCT. Thus, clinical protocols based on central laboratory results may need to be revised when utilizing POCT results. POCT kits and devices may not be FDA approved for all uses that a similar test in the central laboratory can be used for.

VIII. QUALITY CONTROL

Running quality controls (QC) is a mandatory requirement for any point-of-care test because they are designed to detect problems in the test system. They are tested before or alongside a patient test and should always be run according to the manufacturer's instructions in the product insert. Their use monitors test kit and reagent integrity. For example a QC failure could arise from incorrect storage of kits and/or also be due to poor techniques or procedures. Thus QC gives assurance that the device is working and the testing is being performed correctly.

IX. CHALLENGES IN POCT IQC

• Especially, when no enhanced QC design features on the POCT device

• User dependent +++

– Users neglect to perform QC

– Users fail to take corrective action for out of range results.

– Users fail to document or record QC results

- POCT operator most of the type is non-laboratory staff which is not trained in quality control testing and trouble shooting in case of outlier.

• Expensive costs, especially in low volume settings (QC/patient ratio).

- QC material not properly stored - stability problem.

Laboratory professionals are best able to set quality testing recommendations practicable in the field. They should tailor programs without excessive complexity adapted to be performed by non-laboratory operators in a non-laboratory environment. The degree of technological improvement of the PoCT devices, the level of connectivity and the volume of patient testing are major elements to be taken into account.

Non-instrumented qualitative point-of-care tests such as pregnancy tests, HIV tests, rapid strep A or flu tests typically have two types of controls:

Internal controls - built into the test system and are run whenever a patient sample is tested. Confirm that the test system is working, and for lateral flow methods, sufficient specimen has been added to the well to allow the sample to migrate correctly through the strip. The goal of QC testing is to ensure that the PoCT system and the operator are performing correctly (testing reliability and routine work quality) and that results correspond to the expected values of the control material. The QC procedure includes control material testing, immediate results analysis and identification of errors to undertake remedial actions. If QC results fail, patient testing should not be performed until the problem is resolved. Many devices designed for PoCT do not really fit with traditional laboratory QC systems (strip-based devices or cartridge-based) and new-generation devices also have in-built quality controls that automatically check the device. For these instruments, laboratory professionals should have an understanding of what type of instrument has to be checked and what parts of the instrument will be checked to set up the QC program (frequency and nature of control materials).(7)

X. CHALLENGES IN POCT EQA

• Limited period of time to perform testing and to return results on each POCT site

• Low frequency of testing

• Packaging: sealed glass vials…

– How to safely break open the vial

– How to reconstitute the material

– How pipetting the material if necessary

• In case of unsuccessful result:

– identifying the cause

– developing an action plan

• Recording of results

EQA is strongly recommended for all point of care devices. Considering the above challenges mentioned an EQA programme should be selected that offers:

❖ Frequent reporting to minimise the amount of time an error can go unnoticed.

❖ Quality material in a format suitable for use with POCT devices.

❖ Well-designed reports that allow for quick and easy troubleshooting of erroneous results at a glance.

❖ Multiple instrument registrations for each EQA sample provided, helping to save money and monitor performance across all POC instruments.

XI. POCT CHALLENGES OF END USERS

Competencies - Waived vs Non-waived

• Underestimation of risk by the user

– False perception of infallibility

– Pressures of a busy clinical environment

• Training and competency verification

– Large number of users

– Diverse educational backgrounds

• Technical aspects

– Many locations to control (metrology, documents…)

– Adequate storage space to store specimens to repeat the tests between the last successful QC and a failed QC

– Clinical management on receipt of results does not allow the system to be out of control.

XII. INFECTION CONTROL

Standard (universal) infection control precautions

❖ the prevention of occupational exposure to blood-borne viruses, the wearing of gloves and other protective clothing, and the prevention of sharps injuries

❖ prevention of cross infection with blood-borne viruses, including selection of appropriate lancing devices

❖ safe handling and disposal of healthcare waste, including sharps

❖ Hand washing is generally considered the most important measure to prevent the spread of infection. Hands should be washed before patient contact, after patient contact and after contact with body (6)

❖ fluids irrespective of whether gloves are worn or not

❖ safe medical device use, including decontamination of reusable devices.

In an unpublished case study outbreaks of hepatitis B were reported from several environments where blood glucose monitoring was being carried out for multiple patients. Thorough investigations identified that care workers were found to be using lancing devices intended for self-use (by one patient only) to take blood samples from multiple patients. This use of the wrong sort of lancing device was implicated in the transmission of the virus.

XIII. POCT CHALLENGES OF THE DATA MANAGEMENT

POCT data is available at the place of testing but once the patient is shifted form intensive care units or emergency department to general wards or subsequent follow up visit in OPD, the data of POC testing is not available if the devices are not well connected with LIS and HIS. To make this reports of test available at other sites than POC these devices needs to be connected with LIS and HIS. POCT results in the EMR pose additional levels of complexity. Connecting POCT devices to an EMR, for example, requires a computer interface and ongoing maintenance at additional costs. Many POCT devices must pass results through a proprietary data manager (from the specific manufacturer of the device) through a laboratory information system, then into the EMR. Fortunately, universal connectivity options are available that can connect to several POCT devices from different manufacturers and simplifies the transfer of results from multiple devices in an institution. Keep in mind that universal connection creates additional steps in the sequence of passing data from the device to the EMR.

A primary disadvantage of current POCT data management is the requirement to periodically connect or dock a device before the data can pass to the EMR. Data can stay in the device for several hours, days or even weeks if the device has not been docked. Reliance on manual docking delays documentation and billing of patient results.

Although glucose meters, coagulation and blood gas devices have data management and connectivity features, nearly half of the POCT market is visually interpreted dipsticks or kits that require manual data entry to document results in the EMR. Pregnancy, rapid strep, urine dipsticks, HIV and occult blood are all visually interpreted tests that have no connectivity options. Many of the test included are manual dipstick test or card test, in such case it is a tedious job to enter the all data manually which makes the process of data management a challenging task. Manual result entry is an additional step for staff that takes them away from their patient care responsibilities, so institutions cannot expect to achieve 100 percent compliance with documentation of every result.

Location

POCT is conducted at many different locations and can be under different laboratory licenses and medical directors. In a large health system with many testing locations, the display of dozens of glucoses would be extremely confusing in the EMR. A better option is to link this information to each result but suppress the display of the site information such that any clinician or inspector can right-click the mouse to find the analyzing site, address and medical director at the time the test was conducted.

Billing

POC testing are associated with high cost per test due to their rapidity of result generation and consumable cost which is different from that of central laboratory testing. This posses an additional pressure on billing system to assign different code for these test. This again contribute to the source of error in billing in hands of untrained or newly appointed staff resulting into failure to input the data into data management system due to mismatched test code. Also in case serial testing of some parameter that are used for monitoring of patient condition such as ABG, urine ketone, blood glucose testing the tests are carried out frequently. In such cases there are chances of not raising the bills for such frequent test. This will lead to financial losses to institution as well as these unbilled test reports will not be entered into data management system that will lead to incomplete records and subsequent impact on management of patients condition.

XIV. CONCLUSION

POCT implementation requires a systematic approach which involves all stakeholders. Most of the healthcare organization are unfamiliar with the POCT due to which very less efforts are made to establish a complete POCT set up. 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.

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