EDUCATIONAL COMMENTARY –POINT OF CARE TESTING DATA MANAGEMENT

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Learning Outcomes
Upon completion of this exercise, the participant will be able to:

- Explain the advantages and disadvantages of point-of-care testing (POCT).
- Identify standardization of electronic data in POCT devices.
- Use information technology and data management from the POCT device to meet regulatory requirements.

Point of care testing (POCT) provides the clinician timely clinical information that he or she can use for immediate intervention and patient care. Routine laboratory testing requires multiple steps that take precious time before the result is reported. POCT is convenient, efficient, and effective. POCT can also be a daunting management, monitoring, and logistic task for the laboratory. Effective data management alleviates some of the tasks involved with POCT.

Point-of-Care Testing
POCT has evolved from basic analytes of glucose and hemoglobin to highly specific tests that clinicians need for diagnosis and treatment, such as troponin and prothrombin time. POCT devices are used by trained staff at the bedside, physician offices, emergency departments, and in many clinical areas where immediate results for certain tests are essential. The instruments and the analytic methods have improved, having become more stable, accurate, and reliable. Factors that impact the quality of the test result include the operator, instrument maintenance, reagent management, and instrument data.

The majority of POCT devices are used by nonlaboratorians. The users are initially trained on the proper maintenance, quality control (QC), and operation of the device. Their continued competency is monitored by the laboratory where the device was licensed. Many of the devices are manually operated, and results are manually transcribed. To ensure the quality of results, it is important to document the user so that an audit trail can be established, similar to clinical laboratory test results where there is tracking of the clinical laboratory scientist operator who ran the test and released the results.
Once the POCT result is obtained, the confidentiality and security of the result and its timely use by the clinician impacts patient care. Manual entry of data has an inherent risk for error. Improvements in the electronic system and software program in POCT devices have helped minimize this risk.

Quality Data Trail
Every aspect of laboratory testing is monitored and tracked. These requirements are mandated by the College of American Pathologists, Joint Commission, Clinical Laboratory Improvement Amendments of 1988, Commission on Laboratory Accreditation, as well as individual states. POCT is in the same category as laboratory testing and requires the same level of monitoring and scrutiny. The clinical laboratory is centrally located and may have many instruments in operation. However, the laboratory with a POCT setting may have many POCT devices in many areas. These individual devices must be monitored in the same manner. Imagine if the laboratory needs to track several devices manually. The manual record tracking of each device, reagent lot update, calibration, verification, and the like would be very difficult. The need for automated tracking and monitoring methods is crucial for busy laboratory operations.

The device being used, the reagents (e.g., cartridge, strip, chip, module, pad) used for the test, operator proficiency, and a result trail are all required as with the clinical laboratory. The device maintenance, QC, and test verification needs to be tracked. Operator training and continued competency should also be documented and tracked. Reagents used can be traced back to the manufacturer. The final step in the tracking process is tracking that the clinician receives the test results provided by the POCT device.

All of these data trails can be summarized as part of the data management by the device. With advances in information technology (IT), new technologies are being incorporated into the POCT devices. Understanding the data management will help the laboratory perform its monitoring duties. Data management for IT is defined as the development, execution, and supervision of plans, policies, programs, and practices that control, protect, deliver, and enhance the value of data and information assets. Using this definition for laboratory operations, data management is the ability to develop, design, and incorporate data collected from the monitoring of devices and test results, and how to use the information the data provides.

POCT Data Management
Many POCT devices have IT that stores data and information and then monitors the integrity and use of the device. As with laboratory instrumentation, a POC analyzer must be validated (normal range, precision, and method comparison) to a predicate device. Some may not match a laboratory analyzer (in particular PT, APTT) and the laboratory needs to qualify the limitations. With proper design and use of
data, these devices’ IT programs help the laboratory perform its duties to monitor the various aspects of POCT electronically instead of manually recording the information.

The device’s records include information regarding the operators, device maintenance, QC, device malfunction, test data, and other information that can be captured. When established for the needs of the laboratory, the data will enhance and document what is necessary and required. Some information can be stored in the POCT device’s memory. The pieces of information such as the laboratory’s name, laboratory director, device information, and QC information regarding acceptable ranges are stored in its core memory. The information can be programmed to be included in the data stream when uploading the files or printing out a hard copy.

To prevent inappropriate use of the POCT device, there is a “lock-out” feature much like the password that one needs to give when logging into a laboratory computer. It does not allow anyone to operate the device unless she or he has her or his operator code stored in its memory. With the approved operator code, the device can be used. This allows the laboratory to monitor the operator as well as the quality of the test results by tracking every time the device is used and what was resulted. After training and competency assessment, the new operator’s code for the device is activated. Subsequent competency assessment helps maintain the technical quality of the operator. Should the operator not pass a competency assessment in using the device, his or her operator code can be removed until after retraining and retesting for competency.

Reagent lot information and calibration data are also captured with data management. Each time a reagent is put into use, the lot information is recorded. Calibration that is not within the specifications programmed in the device will prevent its use. A helpful monitoring feature is if the expiration date of the reagent is past the current date, the device will not operate and will alert the operator. The lot information can be attached to the result as a permanent record. Any information outside of programmed parameters will prevent use of the device.

Another data management function is monitoring the QC of the test. QC ranges are programmed into the device. Should the QC be out of range, the device will lock out its use until the QC issue is resolved, preventing erroneous results. If the QC is not checked or performed in the proper time interval, the device will lock itself out until the QC is done and within the expected range. All of this information is stored in the device’s memory for later retrieval.

When running patient specimens, most of today’s POCT devices have requirements for patient identification to be entered prior to testing and analysis. It provides a positive link with the test results. Without patient identifiers, the device can lock out and not allow tests to be run. Earlier devices will run the test and provide a result that requires the operator to manually document the test results.
POCT devices are compact. Memory storage capacity is limited; frequent cleaning of the memory files is required. This is done by uploading and transferring the memory files to a host computer like the LIS (Laboratory Information Systems) or to a PC (Personal Computer) that has data storage capabilities. Using a cable connection (such as a USB connector or “fire wire”), the stored data is transferred to the host computer. With advances in wireless technology, transfer of data between the device and the host computer will be instantaneous, saving the additional time of a manual cable hookup. There is no need to wait for an upload from the device. The transferred data is stored in the host LIS or PC for long-term storage and retrieval of information. Information in the host computer will be transferred to the patient’s medical record.

Due to the many POCT devices manufactured and the variety of host computers, the Clinical and Laboratory Standards Institute (CLSI) developed the “POCT 1-A2” (Point of Care Connectivity Standard) to standardize the format for the electronic transfer of data. If there was no standardization every manufacturer could have different software for interfacing with the host computer. It would be a nightmare of software programs for the laboratory to manage and operate. Standardization has alleviated many connectivity issues.

Laboratories and hospitals that have wireless connection between the device and the host computer have the advantage of two-way communication at all times. Information is moved bi-directionally. Test orders can be uploaded to the POCT device with information regarding patient identification. With the patient identification in the device’s memory, when a test is ordered and being run, the identification information needs to be entered. If a discrepancy in the stored memory does not match the patient information being entered by the operator, the device will alert the operator of the discrepancy, and the discrepancy will have to be resolved. The device will lock out to prevent erroneous testing due to incorrect patient identification. After the problem is resolved, the test is then run and resulted. Because the device is wireless and interfaced, the result is recorded in the host computer that ultimately posts the result on the patient’s medical record. The clinician then has the test results she or he needs.

Summary
POCT provides timely laboratory test results to clinicians. These easy-to-operate devices are prone to operator error. With the variety of operator knowledge, experience, and technical skills, ensuring competency of the operator is paramount in quality results. Use of information technology and data management alleviates some of the detailed needs of the laboratory to monitor these devices. Every aspect of the operation of the device is captured and used to monitor operator, reagent, QC, and data transfer to the host computer.
References


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