Connectivity strategies in managing a POCT service

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ARTICLE

Point of Care Testing is increasingly being used for diagnosis and management of various disease states. Management of different Point of Care instruments at multiple sites can be challenging, particularly when such instruments are operated by non technical staff. Connectivity is critical for optimal management of these services which are intimately linked to operator training and competency and are important in minimising harm to the patient by reducing analytical errors. Furthermore, connectivity improves turn around time leading to faster decision making by physicians. Recent advances in technology such as 5G and artificial intelligence are likely to lead to a greater focus on personalized care as a result of big data analysis and development of algorithms.

INTRODUCTION

Point -of-care testing (POCT) is one of the fastest growing aspects of clinical laboratory testing. It is estimated to be increasing by at least 10–12 % per year, with some areas increasing 30 % per year. POCT is defined as patient sample testing at or near the site of patient care whenever medical care is needed. The purpose of POCT is to improve the patient outcomes with higher quality of care by providing immediate information to the physicians about the patient's condition (1). The clinical utilization of POCT should be evidence-based, cost-effective, and focus on improving patient outcomes (2).

WHAT IS CONNECTIVITY

It is a process that enables Point of Care instruments to connect with the Lab or Hospital Information Systems and link with the electronic medical record. An open-access data management system is a key prerequisite as it enables connection to devices from any manufacturer. Such a system automatically validates and transfers patient results obtained from POCT devices to the electronic medical record and helps to monitor and manage data, POCT devices, and operators.

ADVANTAGES AND BENEFITS OF CONNECTIVITY

Laboratorians need to convince hospital administrators that connectivity and its related costs are included when providing and implementing a Point of Care service particularly when it involves multiple sites, multiple tests and multiple instruments. A systematic review identified quality assurance, regulatory issues, and data management as recurrent, significant barriers to clinical implementation of POCT (2).

Faster TAT and error prevention

Since the greatest benefit of a POCT result is a rapid turn around time (TAT), connectivity enables timely reporting of results, with results flowing automatically to patients' electronic medical records. The diversity of point-of-care testing (POCT) locations, devices, and operators makes its management and connectivity challenging. Clinical governance implies that a QC strategy is in place such that POCT improve the clinical outcome, safety, reliability, suitability and efficiency of the POCT testing process (3-5). POCT is usually carried out by non-laboratory personnel, who sometimes may not appreciate the value of quality assurance practices and find them a burden resulting in non compliance of such procedures (6). Most errors in POCT have been reported to be analytical (7) which highlights the importance of QC procedures as well as operator training and competency and how the potential harm to a patient may be greater than laboratory based tests (8). In practice many hurdles are faced when training large numbers of operators and keeping track of their competency, particularly with staff turnover. Connectivity allows these operations to be managed seamlessly and more effectively. Current data systems have the ability to monitor several instruments from multiple manufacturers.

Quality control, instrument maintenance, operator management and competency

ISO 15189 states that "Quality Control (QC) materials shall be periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result" (1). QC connectivity enables co-ordinators to keep central oversight of quality control (QC), device management, user database and competency management. POC connectivity enhances POC staff productivity and helps manage a growing POC program without the need to increase staff (9). It further

reduces the training burden on the POCT team by its ability to streamline IQC reviews and enable test performances review. Device management is critical to maintaining optimal performance of various Point of Care devices that might be used at different sites in the hospital. Connectivity through configuring alerts allows co-ordinators to identify non functioning instruments and resolve instrument issues before they become critical. As part of ISO requirements operator management is necessary whch entails verifying operator certification and competency. Thus, connectivity also supports the issuance of reports that document initial training, 6 monthly and yearly competencies, all of which are needed for accreditation purposes. Data systems are also essential for managing consumables for POCT devices. These tools include reports showing usage and device workload that laboratorians can use to establish the frequency and size of supply orders, potentially reducing costs by eliminating the waste of expired reagents and controls. Reagent and control lot numbers, as well as established QC ranges, can be entered into the data system and uploaded to the POC devices. POC connectivity promotes overall improved documentation which includes pulling out QC and management reports.

Traceability, audits and data monitoring

There is a requirement for traceability for all aspects of the testing procedure in the ISO regulations. POCT results must be labelled clearly to show when and where they were generated, and by whom. Batch numbers of reagents and consumables must also be traceable. Accreditation standards require monitoring of data such as correlation testing, linearity and analytical measurement range verification, proficiency testing, calibration and patient identification. Data systems can automatically capture this data and document it for review. Though this can be entered manually it is prone to transcription errors and

require laborious and time consuming processes. This also allows for audits that ensure that quality assurance procedures are being followed in a timeous manner and ensure adequate risk management and error prevention that are associated with POCT. For example giving insulin based on erroneous glucose results is a significant patient care risk (10) Another study from Canada reported the value of audits in identifying repeat discordant glucose results. (11) Furthermore, POC connectivity makes possible automated billing for all POC tests. Revenue leakage of up to 20% can be caused from tests conducted not being recorded in the Electronic Health Record (EHR).

Connectivity for regulatory compliance and inventory management

Two areas of the testing process are usually scrutinised as part of regulatory requirements. The first is the training and competency of the personnel carrying out the testing and the second is the verification of strict adherence to the procedures specified by the manufacturer. These are labour intensive and time-consuming, especially for large POCT programs that include multiple testing locations, a large number of operators, and an extensive POC test menu. The use of Data Management Systems (DMS) reduces the manual workload and improves efficiency for the POCT coordinator.

Accreditatation

Accreditation is a good way to demonstrate competence and commitment to a high standard of service, with responsibility assigned to the appropriate stakeholders within a healthcare system (12). For point-of-care tests, the use of information systems directly interfaced with the devices or connected through a middleware, serve to ensure that generated results are transmitted without manual interventions, such as transcription, as soon as they

are generated or the devices are docked. This fulfills the requirements of both accuracy and timeliness for optimizing clinical decision support, with accuracy here - meaning freedom from errors associated with manual data entry and not the analytical performance of the POCT instrument.

In the study by Mays and Mathias, 14.2% of the discrepant results (or about 1 in 100) contained risk of *patient harm* in acting on *inaccurate results* (13). Another study found that 24% of reported lab results were inaccurate in critical care patients (14). Accreditation enhances the public confidence in those test results.

THE ROLE OF STANDARDS

In the past, one drawback to POCT connectivity was that since different POCT devices have differing interface capabilities some could only be unidirectionally interfaced, while others were capable of a bi-directional interface. This was challenging and costly when it came to interfacing POC instruments with LIS, EHR or HIS. In 2000, the Connectivity Industry Consortium was formed with the goal of developing POCT connectivity standards. These standards evolved into the Clinical and Laboratory Standards Institute (CLSI) POCT1-A2 connectivity standard (15). The intent of the standard was to work toward a plug-and-play environment for POCT connectivity, where devices are easily interfaced to the LIS, EHR, and HIS. CLSI POCT1-A2, Point-of-Care Connectivity: Approved Standard—Second Edition (15) was developed for those engaged in the manufacture of point-of-care diagnostic devices. These standards have facilitated the development of POCT management systems that can connect multiple devices from various manufacturers, thereby eliminating the need for a computer for each POCT device.

STRATEGIES FOR ENHANCING CONNECTIVITY FOR POCT OPERATIONS

(a) Use of emerging technology such as intelligent connectivity to enhance POCT operations

Intelligent connectivity is the combination of 5G, artificial intelligence (AI), and internet of things (IoT) that forms what we call "intelligent connectivity." Intelligent connectivity largely focuses on the deployment of 5G due to an increase in digital density.This functions as the percentage of connected data used in a unit of activity. This is expected to accelerate technological development from which POCT can benefit.

Artificial Intelligence (AI)

Information collected by devices such as those used for POCT, can now be easily analyzed by AI technology. This will enable personalized patient management and help in decision making. This will allow farmore effective use of data generated by POCT.

This increase of digital density due to increasing collection of data through multiple Point of Care Testing of data via IoT will generate "Big Data " which will help create predicative algorithms by training through machine learning systems. This strategy can therefore be used in POCT to providing personalised solutions for patient management. An increase in digital density due to intelligent connectivity will also create multiple value propositions but this would need security solutions for data privacy and measures to prevent cyber-attacks.

(b) Research and networking as a key strategy to optimise connectivity solutions for POCT

Laboratories that wish to provide better POCT solutions should first research the options available. At the same time they need to contact colleagues on their experience with available data

management systems. In identifying the best option connectivity goals need to be established at the same time. Of course it is also critical to identify and consult with all stakeholders to create an environment for success and buy in. Seeking institutional approval is another ingredient that ensures financial viability and support.

Another important step is to gather key players to discuss POC connectivity goals. This early support and buy-in is an essential ingredient for success.

Use of cellular connectivity as a strategy for Point of Care Testing mangement

The use of cellular networks is also being explored in ambulances and for disaster management.

CONCLUSION

POCT results – irrespective of where they are generated or delivered – must be accurate, precise, relevant and timely to optimize clinical decision support as they have a direct impact on the medical management of patients. Quality Management of POCT in a healthcare facility must involve all stakeholders and assign responsibility appropriately. Connectivity is critical to the successful implementation of a POCT service and should be planned and costed for when such a service is desired. It will have an added benefit of fewer repeats ordered and make the service more efficient and cost effective.

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