AgPlus diagnostics

Challenges to Point-of-Care Testing (POCT)

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CONTENTS

KEY POINTS

Point-of-care tests (POCT) offer rapid diagnostic and/or predictive results in real-time thereby facilitating clinical decision making. However, certain issues relating to Performance, Cost Effectiveness, Quality and Connectivity considerations are perceived as barriers to implementation of these technologies.

The main performance issues of POCT arise as a result of the small sample size used (≤ 5μL), the very fast time-to-result (≤ 15 mins) and the use of Whole Blood with all its cellular and enzymatic constituents

Direct POCT costs are roughly equivalent to their laboratory counterparts. Increasing health economic evidence shows that POCT results in improved patient care and economic savings in both hospitals and in primary care settings

Data handling and quality issues can arise as a consequence of non-laboratory personnel performing POCT and integration of the data with patient medical records

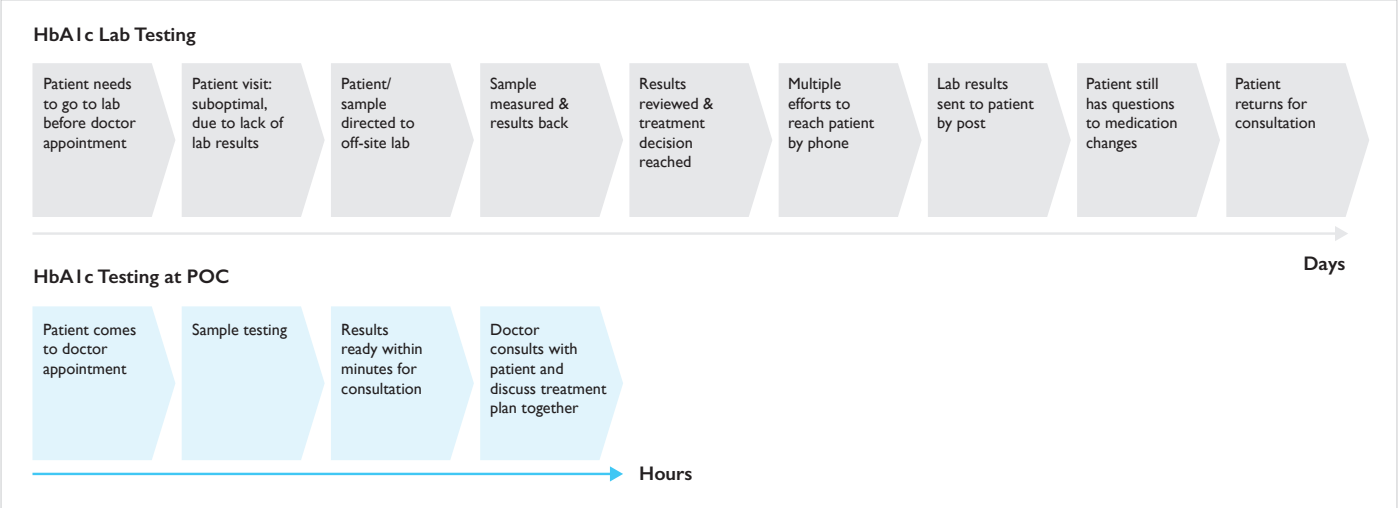
Improvements in POCT with regards to test performance and cost-effectiveness, together with the implementation of effective quality control measures, will support the expansion of POC testing as the method of choice for chronic disease monitoring in daily practice.

INTRODUCTION

POC testing is defined as "testing at or near the site of patient care wherever that medical care is needed." The intention of POC testing is to facilitate immediate medical decisions and therefore, to improve patient outcomes. The rapid availability of test results permits the discussion of the results face-to-face between patient and Health Care Professional (HCP), and has the potential to improve patient-HCP dialogue and patient satisfaction. Most importantly, testing at POC has been shown to improve disease management if undertaken within an adequate comprehensive quality management system

In a hospital or clinic-based setting, the main advantage of POCT is that it provides a faster turnaround time than testing performed in the central laboratory [1].

A further attraction of POCT is that it generally requires less sample volume than tests performed in the central laboratory which obviates the need for a phlebotomist to draw the blood sample. Additionally, many POCT are performed using whole blood thereby obviating the need to prepare serum or plasma samples which is usually performed by centrifugation.



PERFORMANCE

Historical

There are important performance parameters which must be considered when employing POCT. The assays employed can be less analytically sensitive than assays performed in the central laboratory (smaller sample volume, faster time to result) and are more at risk of interferences than traditional laboratory tests. Sample interference can be caused by the use of whole blood due to cellular and coagulation factors not being removed. As an example, POCT glucose measurements have been shown to be affected by hematocrit [2]. Furthermore, POCT methods often employ enzymes or reagents that can perform differently in capillary and venous blood. Environmental interferences can also occur with POC testing not only from performing of tests in environments not controlled for temperature and/or humidity but from electro-magnetic interference which can interfere with the test process [3].

Current & Future Status

In the last 5 years, POC technology has undergone significant development, improving both hardware and software of POC devices, to the extent that a review of an external quality assurance survey in Norwegian general practice offices and hospital laboratories, showed very good results for certain POC testing devices [4]. Over the course of 6 years, about 60%–90% of general practices using POC testing met the quality specifications both for accuracy (≤6.0%) and imprecision (≤0.3%) in diabetes diagnostics. This was comparable and even slightly higher than the 54-84% of the hospital laboratory methods, which met the same quality specifications. There is growing evidence that POCT analytical performance is much improved and in line with laboratory standards [5].

COST EFFECTIVENESS

Historical

POCT benefits have been associated with a monetary cost, as POCT are considered to be more costly than traditional laboratory-based testing. For example, the cost of POCT glucose testing was anywhere from 1.1 to 4.6 times higher than that of glucose testing performed in the central laboratory [6]. There are other costs to POCT that are often not considered including reagents for validating instruments, quality control materials and proficiency testing costs. The costs of medical laboratory technologists required to provide support of the quality assurance system for POCT and information system/information technology staff that are instrumental in supporting POCT connectivity platforms also need to be considered. Creating the interface between POCT software or devices to the laboratory information system and/or electronic medical record is also associated with a cost, which can be quite significant [7].

Current & Future Status

Many of these perceived cost issues have arisen because of a reimbursement approach that primarily reflects direct costs i.e. cost-per-test, rather than outcomes. Indirect costs (related to delayed diagnosis and therapy which in turn impact outcomes with costs for re-admission, emergency departments etc) are significantly higher than the direct costs [8]. Also health authorities are not good at dealing with the challenges of disinvesting in resources made redundant by the adoption of a revised care pathway such as reduced hospital admissions and making the best use of the lower cost of care, for example, at home. One of the largest cost effectiveness studies performed to date relates to comparing costs of Diabetic Patient management through either traditional laboratory testing or via POCT. POCT led to a higher utilisation of tests and to higher costs per clinic visit. However, annual costs were similar for both conventional and POCT strategies, largely because patients using the POCT service had fewer clinic visits per year and patient satisfaction and clinical outcomes were improved [9].

In another study [10], POC testing resulted in increased operational efficiency in a primary care practice due to a decrease in the total number of tests, telephone calls and letters to patients and the number of follow-up visits for an abnormal laboratory result. In agreement with this result, a recent large cost-minimisation analysis using mathematical modelling showed that the total cost of POCT to deliver a health check in primary care is lower than the laboratory–led pathway [11].

QUALITY CONSIDERATIONS

Historical

Many POCT are not performed by laboratory trained individuals but by nurses, physicians, internists and even patients in some cases. Non-laboratory trained individuals often lack an understanding of the importance of quality control and quality assurance. Implementation of POCT to a clinical unit impacts the workflow for staff that have to integrate processes related to POCT such as daily quality control testing, instrument maintenance and troubleshooting issues with POCT devices [12]. Just as with any laboratory test, errors can occur at any point in the testing cycle. A recent study [13] compared the error rates for pre-analytical, analytical and post-analytical factors between testing performed POC and in the central laboratory. A higher rate of pre-analytical errors was found to be associated with POCT compared to central laboratory testing. In particular, the pre-analytical error identified most often was related to positive patient identification.

Current & Future Status

Moderate quality evidence for a positive correlation between HbA1c testing at POC and lab results has been reported by an evidence-based analysis of studies published between January 2003 and June 2013 [14]. High accuracy and precision of HbA1c testing at POC with different devices has been repeatedly reported, making POC a useful aid in diabetes management [15-16].

A further consideration for POC testing success is the implementation of appropriate quality control measures. Participation in external quality control programs or proficiency testing (EQA, external quality assessment) is a possibility and can assist in monitoring quality of results [17]. It is critical to follow the manufacturer's instructions in the use of external quality control materials for regular quality control surveillance. Although CLIA waived tests have been shown to have a significant correlation with lab tests, several reports on the use of waived tests have pointed to the need for proper personnel education to ensure the reliability of the results of POC testing [18]. Therefore, adequate training and continuous personnel education is recommended to ensure POC reliability.

CONNECTIVITY

Historical

Connectivity between POCT data management software and patient information systems is required. When evaluating connectivity of devices, there are a few factors to consider [18]. Some instruments have the capability of communicating wirelessly with the POCT data management software and some require a hard-wired connection. Wireless connectivity is convenient, particularly with hand-held devices such as glucose meters, which are frequently in-use. Even with wireless capability, hard-wired docking stations should be considered if there are concerns about interruptions in the wireless signal. It is important to remember that the time of data transmission from the POCT device to the data management software may not accurately reflect the exact time the patient test was performed. With wireless transmission of results, operators may not be as diligent at returning the device to the docking station required to maintain the charge of the device.

Current & Future Status

There are several POCT management software solutions available on the market which function to facilitate the transmission of POCT results from many different types of POCT devices to the Laboratory Information System (LIS), Hospital Information System (HIS) and EMR. These are web based data management solutions that also allow for management of POCT operators and inventory. The amount of patient information which can be stored on an individual POCT device at any one time is increasing steadily.

CONCLUSION

The very significant increase in the incidence and prevalence of chronic diseases and the serious consequences of this epidemic creates a growing need for innovative diagnostic tools which can be used to monitor patients at the point-of-care. Delayed diagnosis and therapy increase morbidity, mortality and costs; effective implementation of POCT will result in major economic savings in overall healthcare costs.

POCT has been shown to:

- increase compliance with recommendations for testing frequency and treatment adoption
- improve clinical outcomes
- facilitate patient education and motivation
- improve patients' quality of life
- contribute to cost/time savings both for health-care professionals and patients.

In the future, POCT may prove useful for increased early detection of disease and thus the prevention of disease-associated complications.

All these benefits make testing at the POC a highly advantageous technique for chronic disease management and in some conditions eg diabetes POC testing is recommended by the national and international disease authorities. Continued evidence of the analytical improvements of POC systems and cost-effectiveness evaluations, together with the Implementation of effective quality control measures, will support the expansion of these POC testing systems as the methods of choice for disease monitoring in daily practice.

Technology	Examples	Market Ready	Time to Results	Sensitivity	Full Quantitation	IP Position	True PoC/ near patient	Multiplexing
EIA/ELISA	R&D Systems	✓	60-90 mins	ng/ml	✓	No IP	Lab based	✓
	MeMed	✓						
Lateral Flow	Nano Entek BUDDI (LF optical Reader	✓	20 mins	ng/ml	X	Korean Business - patent sold to life technologies	✓	X
	Magnasense (paramagnetic LF)	X/ ✓	15 mins	mg/ml	✓	not known	Research use only in U.S.	X
Conductivity	Nanomix (elab)	X/ ✓	10 mins	ng/ml	X	not known	emergency rooms	✓
SPR	Attomaker	X	10 mins	ng/ml	X/ ✓	5 granted patents	Doctors office research use only	✓
Enhanced LFD	OPKO DX (Claros)	X	10 mins	ng/ml	X	No known	Doctors office pending clearance	X
Electrochemistry	**AgPlus**	X/ ✓	**5-10 mins**	**pg/ml**	✓	**Strong 4 patent families granted (US/Europe/China/Japan)**	Doctors office near patient	✓
Enzyme Kinetic assay	Lumira	✓	20 mins	ng/ml	✓	Patents not listed but stated on website	PoC	✓
Molecular LF DX	Sekisui	✓	30 mins	ng/ml	X	Not known	Must be plugged into a power source bench top	✓
Molecular	Novodiag	✓	80 mins	pg/ml	✓	Not known	q-PCR Lab based	✓
Fluorescent DX	MBio Dx	X/ ✓	30 mins	ng/ml	✓	Strong (4 patents cover US and Japan	Research use in field	✓
	Nano Entek FREND	✓	30 mins	ng/ml	✓	Korean Business-patent sold to life technologies	Requires power supply	X
	Biosensia	X	15 mins	ng/ml	X/ ✓	IP	Research use only	✓
Microarray	MADx (ALEX allergy)	✓	3.5 hours	kU/L	X/ ✓	No Known	Lab based	✓

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