

POINT-OF-CARE TESTING

Nicky Hollowood from Harrogate and District NHS Foundation Trust writes about the importance of software developments in point-of-care testing services.

Point-of-care testing (POCT) services in the UK and worldwide have developed and expanded at a significant pace over the last two decades. This has been driven by technological advancements and the availability of a broad range of POCT devices, which have enabled diagnostic testing to be more accessible across healthcare pathways. As a result, the use of POCT devices by NHS organisations has become more mainstream, but their widespread implementation has not been without challenges.

The use of these devices to support central pathology services has, in the past, divided opinion across the pathology community, with concerns being raised over their suitability, accuracy, quality, cost effectiveness and governance.

However, these concerns have not slowed the development, or growth, of POCT devices in the commercial industry.

Hospital without walls

This growth has led to a more generalised acceptance that pathology professionals need to take a lead in POCT services, to ensure that the devices are used safely, appropriately and effectively.

We have seen the emergence of more POCT departments within NHS pathology departments, which continue to grow at

pace, supporting wider-reaching and sophisticated clinical services. Clinics are being established in community settings, specialist nurses are using POCT devices to support home visits, community hospitals are offering more specialised services and care pathways are being redesigned thanks to accessible tests.

The challenges that we are facing are no longer contained within the four walls of the hospital environment, as we are becoming part of an emerging “hospital without walls” culture. This can be exciting, but also overwhelming when faced with the task of ensuring that these services are supported, led and managed by what is often a small POCT team.

Quality assurance

The introduction of ISO standards as a mark of governance and quality assurance



for pathology, and the growth of the commercial POCT device industry can offer possible solutions. The ISO standards of quality for medical laboratories (ISO 15189) and POCT (ISO 22870) offer a benchmark that can be used as guidance or, if UKAS accreditation is achieved, a mark of quality assurance for POCT services.

Many companies within the commercial industry are developing the functionality of their products, ensuring newer devices coming to market are designed to support POCT services in meeting these rigorous standards.

POCT teams have been vocal about the requirements for user management and lockout, quality control management, use of barcode technology, remote management, electronic results transfer and information needed to audit the service. These elements are now starting to become expected as standard by POCT

teams. Companies are now working on developing more sophisticated functions, such as electronic communication with users, reagent verification, direct EQA transfer and review, to name a few.

Technology

It can be difficult to ensure that a new product meets the service needs for all potential users, as POCT devices are often used by a broad range of staff groups, in different locations and for different clinical purposes, depending on the care pathway. It is important that professionals in pathology work closely with their commercial partners and have input during the development stage, as being involved in the delivery of POCT services we can impart knowledge and experience, which can often lead to improved functionality and suitability when the device comes to be placed in service.

As the NHS moves into a digital era where paper notes are being replaced by electronic records and care is being delivered further from the hospital base, there is a need to ensure that the quality of POCT is upheld and that this service is fully embedded into the clinical care pathways that they support. The use of technology and remote management is essential to ensure that we uphold the quality and effectively govern this diagnostic service.

However, many commercial software solutions and devices may not offer the exact functionality that is needed. We have seen middleware solutions developed by companies that only support their POCT products and, as such, this has led to an IT infrastructure in POCT departments (which use an array of suppliers) being fragmented. Over time, some of these companies have made their

software “open” enabling users to connect POCT devices from other suppliers, but users have often been left frustrated, as the functionality achieved through connecting third party devices in this way is not as sophisticated as the connectivity between the software and the supplier’s own devices.

Connectivity

Middleware solutions have come to market which are vendor-neutral and are limited only by the device functionality. These have been successful in providing an independent solution bringing the remote management of a number of devices onto one platform, but cost has often been a challenge for POCT teams.

As the market widens and more software solutions are becoming available, the cost of achieving this connectivity is slowly becoming more affordable for NHS organisations. The sophistication of the level of connectivity achieved varies widely between organisations, ranging from some having very few connected POCT devices, to some being able to demonstrate full end-to-end connectivity for many of their devices. There does seem to be consensus across POCT teams that some degree of connectivity is essential, with many working hard to electronically connect as many devices as possible so that the results are populated in the electronic patients record.

We need to have open dialogues with our commercial partners and input into future software developments so that new products and services continue to meet the needs of our ever-changing health services. It is by using these POCT products in our care pathways that we are able to highlight opportunities for development and improvements that can’t be identified in a commercial testing environment.



It is increasingly important that we actively engage with our commercial partners

Restructuring

As we look to the future, the shape of the NHS is rapidly changing again, with network groups being formed and the pathology consolidation agenda firmly back on the table, with the NHS improvement team taking a central role.

These regional networks have in many cases been tasked with reshaping a broad scope of health services, pathology being one of the services earmarked for redesign. This restructure will lead to further fragmentation of our health and pathology services before realignment to form more streamlined and effective regional services.

It is difficult to visualise how these new services will look, but there is no doubt that this restructuring could lead to a significant departure from pathology services as we know them.

While POCT services are not a priority in the early stages of this work for many areas, there is no doubt that they will play a pivotal role bridging the gaps that will inevitably form across patient pathways.

Patients will be accessing more clinical services away from the traditional hospital environment and our POCT services will be an essential diagnostic support tool. Being able to remotely manage and govern a POCT service that covers a wide geographical area is a crucial role

that many pathology departments may have to administer. It is increasingly important that we start to actively engage and inform our commercial partners of our regional restructuring plans to ensure that the devices and software are effective for the services that we aspire to deliver.

Collaboration

Many commercial POCT manufacturers recognise the value of these close working relationships and are now actively establishing working and development groups, which seek membership from professionals from varying backgrounds. Participation in these groups is an excellent opportunity to network, learn about new products and feedback difficulties and challenges with existing services. It is through these collaborations that we are able to share experiences, offer solutions and make joint contributions to future developments.

Nicky Hollowood is POCT Manager in Pathology at Harrogate and District NHS Foundation Trust. She is presenting a POCT session at IBMS Congress 2019.



The IBMS is developing an online extended POCT practice course, which will be available shortly. The six-module course aims to provide educational support material to staff who are new to POCT management and service provision.