Over the past 10 years, the availability and uptake of near-patient testing, known more commonly as point-of-care testing (POCT), has increased exponentially. Opting to manage POCT in an overall framework for diversified testing is an opportunity rather than a threat for progressive laboratories. This transformation is essential to effective clinical care provision. It will also cement the laboratory service as a key stakeholder within an increasingly connected, patient-centred healthcare environment.

Diagnostic laboratory services are no longer solely provided just from one laboratory, but are also delivered across a range of places by many healthcare professionals using various pieces of equipment. The options for patients to test themselves at home are now common. The latest range of smartphone-enabled snap-on devices has transformed testing, so it is affordable and easy to use. However, this introduces data governance issues that separate medical-grade data from patient-generated therapeutic and wellbeing data.

Health and care decisions remain reliant on accurate and timely data provision to the care provider. This diversification of the provision of laboratory test results necessitates an urgent redesign of the service, a rethinking of the ownership and accountability model, and a clear understanding of the relevance of these data in the clinical process. Having data is a by-product of all business; however, transforming data into a three-dimensional information model that enhances patient outcomes requires an integrated approach, one that must span the health, care and patient continuum with an appropriate information architecture to support the new ‘norm’ in the emerging healthcare market.

Available today are pocket-sized devices that can monitor heart rate and the number of steps taken, and simple plug-ins that analyse glucose levels. Having the power to manage our health with handheld devices has never been easier, enabling patient-centred care and providing patient access to results whenever and wherever needed.

Healthcare professionals and patients want the convenience of near-patient testing, so laboratory services must adapt to, and where appropriate make full use of, this evolution. However, laboratories have the responsibility to ensure that the quality and standard of testing performed using such devices are consistent with that undertaken in the highly regulated and controlled environment of traditional laboratories that comply with regulatory standards. This is required to ensure a consistent result on which to base clinical decisions and so reduce risk to patients and minimise service inefficiencies.

**Not a new phenomenon**

Of course, POCT is not a new thing; however, adding to the simple recording of blood pressure or temperature and ‘dip-strip’ urinalysis are more sophisticated tests like blood glucose and international normalised ratio (INR), which increase the scope for immediate decisions that better inform patient care. With the rapid advances in miniaturisation and the use of smart connected devices, the range and ability of such tests is snowballing. The resultant reduction in equipment availability and cost is fuelling an ever-increasing range of testing profiles. Evidence of this change may be seen in the significant regional initiatives to drive adoption, a prime example being the ‘Lab in a Bag’, as implemented by NHS England.1

The attraction to the healthcare provider is obvious. A more rapid turnaround of test results is fundamental to improved patient outcomes. The challenge is to ensure that convenience does not compromise quality. What test information should be kept and how it might form an integral part of the electronic patient record (EPR) dataset are questions that require planning, agreement, and processes for quality control and assurance.

Such processes must accommodate the fact that GPs, nurses, caregivers and other healthcare providers are not trained in laboratory processes and associated regulatory standards. Also, the portability of the devices means that they may be used at dozens of locations with different patients each day. The devices could be used by unsupervised consumers as well.
Issues related to device calibration, accuracy, ranges and use must be considered and addressed.

To deal effectively with these challenges requires a systematic, policy-based approach that engages all stakeholders. This must include adequate training so that equipment is calibrated and used correctly, and sample collection is process standards-compliant. It must also provide failsafe processes to ensure action is taken when the quality control fails, to protect both the patient and the care providers from acting on incorrect results or interpretations of results that could have potential life-threatening consequences.

The laboratory has a pivotal and leading role in each stage of establishing POCT protocols, from managing the training process to a scheduled random review of samples and results to check for any analytical errors. Laboratory teams will need a plan of continuous support to prevent knowledge gaps resulting from new staff and changes, or to manage the technical requirements of upgrades and new equipment or changes in sample collection. Laboratories must embrace and take ownership of the POCT service, and ‘just ignoring it’ until it becomes a clinical problem is inexcusable.

Opting to manage POCT in an overall framework for diversified testing is an opportunity rather than a threat. This transformation is essential to effective clinical care provision. It will also cement the laboratory service as a fundamental stakeholder within a wider, modern patient-centred healthcare model.

Making coordinated care work

Although it comes with many challenges, testing closer to the patient is desirable, yielding major benefits when it is integrated into an EPR. Every UK NHS trust is under increasing pressure to create integrated health records for patients in a bid to support the national Joined-Up Care initiative.²

However, there are often significant disconnects between records in systems used in different departments within a single acute care hospital. There is usually even less integration of records shared between different care settings spanning primary, secondary and community care. Yet this is changing because of a recognised need for chronological pathology results to form part of a patient’s care record. This is particularly important for diversified laboratory testing, where results received from any POCT source can be viewed instantly via the EPR by all medical professionals involved in that patient’s care, allowing rapid decision-making and effective use of the clinical team’s time.

Making this a reality will necessitate a substantial and fundamental update for most of the laboratory information management systems in use today. Data received from POCT devices must simultaneously form part of the patient’s record in the clinical viewer and the sequential records of the traditional laboratory pathology services. Pathology records need to be seamlessly interoperable with other care records, with the authorised shared information accessible to all relevant healthcare professionals through multiple devices. Most laboratory information management systems today do not have these capabilities.

One misunderstanding that sometimes arises from the inclusion of non-laboratory staff in testing is that laboratory staff can be reduced. In fact, pathology staff are the professionals who have the nature and training to detect variances, trends and anomalies in test result data, and to identify information gaps that might impact on the correct diagnosis. So, the next generation of laboratory information systems must empower laboratory staff across the whole continuum of extended testing. The new systems need to enable laboratory staff to review and detect easily the changes that are clinically relevant and assess patient results in the context of a complete patient history. The systems should make it easy for laboratory staff to provide feedback on the results in an efficient and effective manner, to inform the patient, their advocates and their care providers.

It is imperative that the pathology record contains all data generated from the continually evolving and disparate testing modalities. This will reduce any risk associated with the interpretation of a result in isolation, and thus help to ensure the quality of the service.

Financial implications of diversification

Aside from speed, accuracy and record integration, the final hurdle facing near-patient testing is its cost. By its nature, POCT is perceived as being cheaper, but without sufficient control it is commonly found to be more expensive. The discrete cost per test is increased over baseline equivalent costs in laboratory-based bulk testing. If the training and processes are not in place to ensure accuracy, then mismatched data and potential errors will require retests, with the duplication increasing the total cost of ownership.

This is in conflict with the broader realities of pathology services, where laboratories that do testing at scale deliver greater volumes of tests at lower cost.

For laboratories to provide improved cost management, the control systems need to support connected care functionality such as order entry with electronic gate keeping. Alternatively, they must support demand management to allow, for example, clinical directors to institute pre-approval processes for costly near-patient laboratory testing in concordance with their funding policies. At the same time, system workflows can ensure that these orders are submitted automatically for approval to multiple connected parties and that they are released as they are approved, speeding up the process by eliminating the paper-chasing for approval.

Conclusions

Pathology services have a pivotal role to play in the diversification of POCT services that will improve patient care costs and quality of outcomes. The shift of responsibility outside the laboratory setting is not without its challenges, but clinical laboratories that ready their systems and services now and work in collaboration with the broader network of healthcare providers will be able to manage the change process, rather than find themselves at the mercy of the inevitable industry disruption.

References

1. NHS England (www.england.nhs.uk/2015/03/20/lab-in-a-bag/).

More information may be found at InterSystems.co.uk/BeyondLIMS