Moving towards service accreditation: an update

Suzanne Callander reports on the move towards accreditation of quality and competence of point-of-care testing services to bring them into line with clinical laboratories. Here, she talks to David Ricketts.

In a 2007 review of NHS pathology services in England, Lord Carter of Coles noted that accreditation of laboratories was voluntary and that point-of-care tests in pathology were not covered by the Clinical Pathology Accreditation (CPA) scheme, which is now a subsidiary of the United Kingdom Accreditation Service (UKAS). He called for these issues to be addressed. In a second review, Report of the Second Phase of the Review of NHS Pathology Services in England, published in 2008, Lord Carter found that not much had changed and led him to recommend that the accreditation process should be reviewed. He also recommended that all pathology service providers should be subject to mandatory accreditation, including point-of-care testing (POCT), giving members of the public and other NHS staff the confidence that the quality of the service has been independently verified as meeting objective service standards.

The review recommendations resulted in clinical laboratories increasingly accrediting to the ISO 15189 standard (Medical Laboratories: particular requirements for quality and competence), which specifies requirements for quality and competence in medical laboratories. The scope of the standard was extended with the publication of ISO 15189:2012 to allow laboratory customers and regulatory authorities to confirm and recognise the competence of medical laboratories. It also placed an increased emphasis on the need for continuous improvement. This version of the standard has brought about a greater understanding of the benefits of accreditation and how it can help laboratories to develop their quality management system and assess their own competence.

Benefits of accreditation

“As laboratories become more familiar with the benefits of accreditation, the ISO standard that relates to POCT – ISO 22870:2006 – is now also starting to receive more focus and there is a drive to bring the quality and competence in POCT up to the same standards as laboratory test processes,” said Dr David Ricketts, a member of the Technical Committee ISO/TC TC 212 (Clinical laboratory testing and in vitro diagnostic test systems), representing the IBMS, and who was involved in the creation of the standard. The ISO 22870 standard (Point of Care Testing; particular requirements for quality and competence) forms an adjunct to ISO 15189 and aims to help manage patient risk through the development of a well-designed, fully implemented quality management system which facilitates evaluation of new or alternative POCT instruments and systems; evaluation and approval of end-user proposals and protocols; purchase and installation of equipment; maintenance of consumable supplies and reagents; training; certification and recertification of POCT system operators; and quality control and quality assurance. It can also be used by bodies that recognise the competence of POCT facilities as the basis for their activities. Through accreditation of POC services, it is possible to start to build up a picture of risk.

Point-of-care testing fits in well with the drive to move more services away from secondary care into primary care and also closer to the patient as technology advances allow new clinical pathways to develop. “It is important to bear in mind that if there is intermediate care for a patient, that it is right and this is where the ISO standard for POCT really comes into play,” said Dr Ricketts. There is also a strong economic argument for getting POCT right, because test-for-test it is more expensive than a laboratory test. ISO 22870 covers training and user competence. It highlights the need to ensure that users have an understanding of what is being done and to question the test result if it does not fit the overall patient picture.
test result if it does not fit the overall patient picture and ensuring that machines are looked after properly and that users are aware of the need for quality control, and external quality assessment as well as the need for equipment maintenance.

Laboratory and clinical mindsets are very different so part of the ISO standard aims to help educate people about the benefits of POCT accreditation. “Pathology has always offered a good service and this has resulted in an implicit belief among clinicians regarding the accuracy of test results. This belief can be dangerous in POCT because the test may not have been carried out to the same exacting standards as laboratory tests which have accredited systems and equipment. There is a need to treat the results of POCT with a certain degree of caution if the results do not match the patient picture,” warned Dr Ricketts.

Increasing take up

“ISO 22870 was published in 2006 but has had a very low take up because many were unsure about what to do with it,” said Dr Ricketts. However, this now looks to be changing. “Since the 2012 revision of the ISO 15189 laboratory standards, people have become more comfortable with accreditation of quality and competence. It is also now possible to use the same paperwork for both ISO standards, which makes it easier and simpler to achieve and it is now also possible for a trust to gain accreditation for one POCT test at a time.”

The ISO standard also states that every trust should have a POCT committee to ensure adequate training and to give a system-wide view of POCT using clinicians and the laboratory and those associated with service delivery and risk management. The committee should have a strategic role for POCT detailed in a policy. It should also have ultimate responsibility for defining the scope of POCT, taking into consideration the clinical need, the financial implications, and must ensure that measures are in place to monitor quality and patient safety.

Competence to use the equipment is vital if a clinical decision will be made as a result, so it is important to ensure that the test has been undertaken in a standard, repeatable way and that all the necessary quality controls have been undertaken. The ISO standard outlines acceptability of training, competence and reassessment of competence after a period of time.

Device manufacturers can also benefit from the ISO standard as it can help ensure that new devices are designed to help users comply with the standard. Ideally, POCT equipment should have IT connectivity to allow information to be recorded automatically on the patient’s record. This has been highlighted in the standard, giving device manufacturers a clear indication about what they should be looking to develop in their software as they create new systems.

“Reliance on manually recorded details introduces an opportunity for transcription errors so trusts are gradually upgrading to this latest generation of POCT equipment,” said Dr Ricketts. “Device manufacturers can now also offer some very good training for device users and many clinical laboratories are now happy to pass this task over, once they have been assured that the training meets all the trust requirements. However, it does remain the responsibility of the laboratory to ensure that training happens and, as testing experts, the laboratory also has a duty to ensure that users of the test devices are aware of the implications and impact of getting the test wrong.”

Today there is a stronger economic argument for getting POCT right. Test for test, POCT is more expensive than laboratory testing, but with the drive towards more patient-centred clinical pathways, supported with POCT, it is widely believed to offer overall operational savings. However, a review by St John and Price, which sought to identify economic evidence from the use of POCT, concluded that evidence relating to the cost-effectiveness of POCT is limited, in part due to the limited quality of evidence of clinical effectiveness.

The study identified a need for better understanding of the care pathway and the processes embedded in these pathways, and how they change with the introduction of POCT. It also identified a need for better information on the resource utilisation across all elements of the care pathway, and how that can be leveraged for economic benefit to the stakeholders with the introduction of POCT.

Role of the laboratory

The Medicines and Healthcare products Regulatory Agency (MHRA) states that the hospital pathology laboratory should play a key role in the development and management of a POCT service, in particular in the secondary care environment. The document Management and use of IVD point of care test devices states that “The pathology laboratory can provide advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, quality assessment, and health and safety. There should, therefore, be close liaison between users and the local hospital pathology laboratory on all issues relating to POCT. Wherever possible this liaison should be formally defined by a service level agreement specifying the range of products, services, operational details and the responsibilities of the central laboratory and the POCT user.”

Conclusions

Given the rate of technological advances and the potential benefits to efficiency and quality of care offered by POCT, it seems likely that its prevalence in healthcare will continue to grow and that more commonly performed routine tests will be conducted at or near the point of care. However, it is vital that quality assurance and training protocols be established in every trust. Accreditation to ISO standards for POCT services can provide an important indicator of quality and can help to ensure patient safety as POCT services continue to expand.

References